

# BMJ Open Quality Evaluation of a two-sample process for prevention of ABO mistransfusions in a high volume academic hospital

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## ABSTRACT

**Background** Acute haemolytic transfusion reactions due to ABO incompatible blood transfusion remain a leading cause of transfusion-associated morbidity and mortality in the USA. Erroneous patient identification and specimen labelling account for many errors that lead to ABO mistransfusions; these errors are largely preventable.

**Methods** Our hospital requires a two-sample process of ABO/Rh typing prior to transfusion. Both samples must be drawn independently. To prevent simultaneous sample draw, our second sample tube has a unique pink top that is only available from the blood bank and can only be sent to the patient's floor once the first sample arrives in the lab. We performed an audit of this process from 19 March to 30 July 2014 and 19 March to 30 July 2015.

**Results** We reviewed type and crossmatch orders for 2702 new patients during the audit period and 824 patients (30.5%) required transfusion. All patients evaluated received compatible blood, and no mistransfusions were recorded using this method. Three per cent of testing was performed incorrectly, which safely defaulted to giving type O blood.

**Conclusions** The two-sample protocol used by our institution can decrease the risk of mistransfusion. Our protocol was relatively inexpensive, safe, efficient and practical for adaptation by other hospitals.

## INTRODUCTION

For most of the red blood cell (RBC) transfusion era, quality improvement and public focus has been on preventing the transmission of infectious diseases. Over the last several decades, infection from blood transfusion has become increasingly rare; however, the problem of ABO incompatible RBC transfusion remains a major issue.<sup>1-3</sup> The risk of ABO incompatible transfusion is estimated to be about three times the combined risk of HIV, hepatitis B virus and hepatitis C virus transfusion-related infections.<sup>2</sup> ABO incompatible transfusions are preventable and are considered a 'never event' by The Joint Commission, one of the largest healthcare accreditation organisations in the USA.<sup>4</sup>

The major complication of ABO incompatible transfusion is an acute haemolytic transfusion reaction, which remains a leading cause of

transfusion-associated morbidity and mortality today.<sup>5</sup> The estimated incidence of ABO incompatible transfusion ranges between 1:38 000 and 1:100 000.<sup>6,7</sup> Considering that approximately two-thirds of transfused units would be ABO compatible by chance, the actual risk of mistransfusion may be severely underestimated.<sup>8</sup> Some countries report an ABO incompatible transfusion rate as high as 1:400.<sup>9</sup> The estimated mortality from ABO incompatible transfusions ranges from 5.5% to 14% with a risk of death being 1:1.5 million to 1:2 million RBC transfusions.<sup>3,5,7</sup>

The process of blood transfusion requires multiple layers of verification, teamwork and a transparent interface between the laboratory and clinical setting.<sup>10</sup> Human error still exists as a major cause of ABO incompatible transfusion despite advances in technology and electronic medical records.<sup>10</sup> Most of the errors involve patient identification, patient monitoring and specimen labelling.<sup>10</sup> Erroneous patient labelling of blood samples or wrong-blood-in-tube (WBIT), remains one of the leading causes of ABO incompatible transfusion in the USA.<sup>3</sup> According to one multinational study involving 62 hospitals, WBIT accounts for up to 0.09% of samples collected. For several decades, many hospitals have adopted a 'check-type' or 'two-sample' method for decreasing ABO mistransfusion due to WBIT errors. In this protocol, two sample blood types are independently drawn with ABO testing performed on both of them. Multiple studies have confirmed the ability of a two-sample method to prevent ABO mistransfusions and WBIT errors.<sup>8,11-13</sup> In the following sections, we describe our modifications to the two-sample method and the results of our audit to evaluate its safety, efficiency and areas for improvement.

## METHODS

The purpose of this study was to perform an audit of our hospital protocol to assess its



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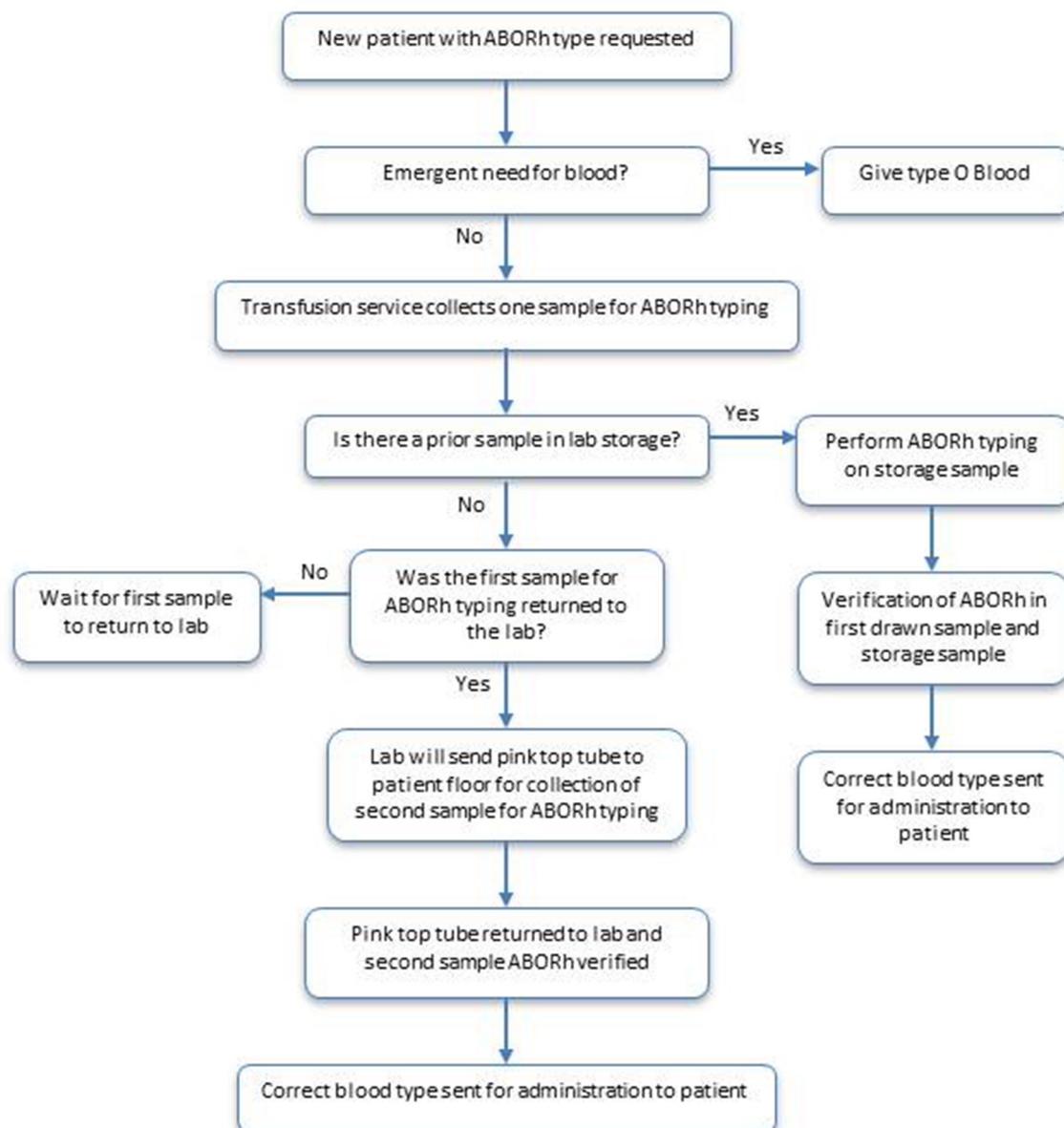
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efficiency and safety over two time periods. In addition to verifying our two-sample method, we aimed to assess our use of non-emergency, uncrossmatched type O blood. By using data from the blood bank that was spaced exactly 1 year apart, we designed our audit to examine if results were reproducible and consistent and to decide if any intervention would be needed to improve our process.

Froedtert Hospital and the Medical College of Wisconsin is an academic tertiary care centre with 784 beds, a level 1 trauma centre, an obstetric and delivery centre and a cancer centre which provides haematopoietic stem cell and solid organ transplant services. Each year, our transfusion medicine service crossmatches over 20 000 RBC units. Six years ago, our institution began using a two-sample protocol, which aimed to prevent ABO mistransfusion and improve the utilisation of our resources. This policy requires that for RBC transfusions, ABO type-specific red cell units would not be issued

until there are two separate and identical blood types on file that are collected from two different phlebotomies. The details of the protocol are shown in [figure 1](#). Until a second ABO type is performed on an independently drawn phlebotomy sample, only type O red cells can be released for the patient. The second sample drawn is of no cost to the patient. If the patient has a prior blood type on file performed by the blood bank, a second sample blood type is not required. The current sample drawn for testing is sufficient to confirm the historical blood type. For patients new to the blood bank, a specimen located in the lab from a prior phlebotomy can substitute as a second sample so long as it is collected in an appropriate preservative (tubes used for complete blood counts are commonly obtained) and is appropriately labelled (date/time of draw and phlebotomist initials are on the tube). We refer to this as a 'storage sample'. If there is no storage sample available, the patient's nurse is notified by the



**Figure 1** Protocol for blood typing new patients.



**Figure 2** Picture of a pink top tube and a normal tube. Once the first, independently drawn blood sample is returned to the lab, a pink top tube is sent to the patient floor for collection of the second confirmatory blood sample. Pink top tubes are only available in the blood bank for distribution.

blood bank that they will be receiving a pink top tube for a second draw for ABO confirmatory testing. These pink top phlebotomy tubes can only be supplied by the blood bank and cannot be found anywhere else in the hospital (figure 2). Moreover, these tubes are a different size than the standard tubes used for blood bank testing, so both colour and volume help distinguish these tubes. Once the second sample in a pink top tube is received in the lab, ABO testing is performed to ensure matching ABO blood types between the first and second sample. On verification, the appropriate ABO type-specific blood is released for that patient, and all future samples from the patient will be compared against these original results.

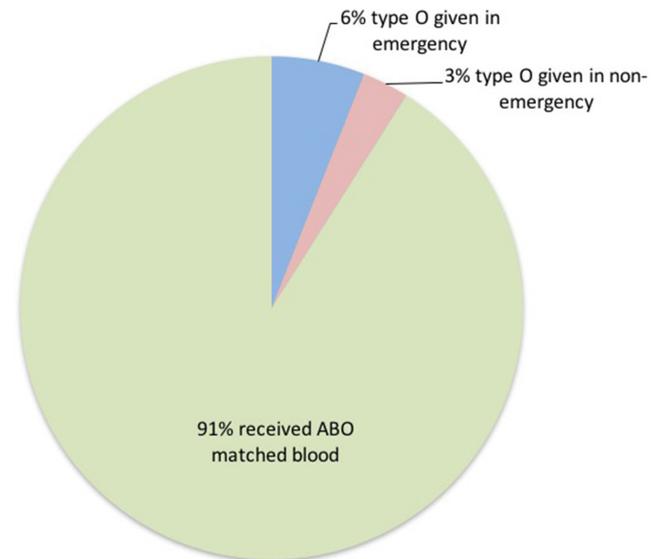
We performed an audit to confirm the safety and efficiency of this process. All new patients requiring a type and screen or a type and crossmatch from 19 March to 30 July 2014 and 19 March to 30 July 2015 were included in the audit. The audit was performed retrospectively as a part of a clinical quality initiative and did not change the way blood samples were collected or processed. Moreover, there were no improvement interventions applied to our two-sample protocol before, during or between audit time periods. Data collected for each sample included the type of second blood type sample used (pink top or other tube), and the subsequent blood ABO-type prepared and sent to the patient if needed. No patient-specific identifiers were collected as a part of this audit.

Descriptive statistics were used to summarise audit characteristics. Audit variables collected between the 2 years were compared using the Fisher's exact test for categorical variables. A statistical significance (alpha) level of 0.05 was used throughout.

## RESULTS

Over those two time periods, a total of 2702 new patients were typed for ABO. A pink top sample was required

## Blood Products Dispensed



**Figure 3** Representation of blood product distribution: type O blood was given to 51 (6%) patients with emergency need for blood and 25 (3%) without emergency need. The remaining 748 (91%) received ABO-matched blood.

for 1782 (66%) of these samples, and 921 (34%) used a storage sample. Of the evaluated patients, 824 (31%) required a RBC transfusion.

All patients were transfused with compatible blood and there were no ABO incompatible mistransfusions. Of those who received transfusions, ABO-matched blood was given to 748 (91%), requested emergency blood (type O blood) was provided to 51 patients (6.2%) and 25 (3%) were given type O red cells without emergency need (figure 3). Overall, the protocol was not performed optimally in 3% of patients ( $n=83/2702$ , 3%), where either an unnecessary second sample was requested when a storage sample was available ( $n=58/2702$ , 2.1%) or a second ABO type was not drawn prior to product request resulting in type O blood being used for a non-emergency transfusion ( $n=25/824$ , 3%). The blood bank required an ABO retype on the current sample if products were needed for transfusion and the second sample pink top was not received. In 1.6% of patient testing, the blood bank failed to perform the ABO retype on the current sample prior to blood product dispense. These patients still received type O blood since a second sample ABO had not been received. There was a small but statistically significant reduction in the release of non-emergency type O units between 2014 and 2015 (19/436, 4.4%, 2014; 6/388, 1.5%, 2015,  $p=0.02$ ).

## DISCUSSION

We described our institution's use of the two-sample protocol with several modifications, including the use of a pink top tube for second samples, to further prevent ABO mistransfusion. The results of our audit confirmed

that the method successfully and reproducibly prevented mistransfusion in our hospital, as no incompatible transfusions were recorded during the two audit periods and maximised the use of limited resources. Our audit further revealed that only 3% of patients received non-emergency type O donor blood which was deemed acceptable, as the protocol was designed to default to giving universally compatible type O blood.

Healthcare systems are mandated to implement systems to reduce medical errors such as mistransfusion.<sup>14</sup> Many solutions have been proposed, some of which included radiofrequency identification tags, staff education, process auditing, automating steps of the transfusion process, checklists, periodic review of protocols, two-sample requirements and documenting previous ABO determinations.<sup>1 8 10 12</sup> The two-sample or 'check-type' method has been shown in multiple studies to decrease WBIT errors and is one of the most significant solutions to be implemented in the transfusion process.<sup>8 12</sup> However, this method is imperfect. Previously published disadvantages to the two-sample method included added cost, inconvenience to the patient or phlebotomist, delays in providing blood and increased type O blood use.<sup>8</sup> The audit of our specific protocol showed that utilising storage samples minimised many of these possible disadvantages, as roughly one-third of patients had a storage sample that could be used for a second ABO type without needing a second blood draw. By using these storage samples, our process reduced the need for a second needle stick in many instances, minimised the time required by phlebotomists and decreased the time interval between the request and release of ABO-matched red cells. In a study of the two specimen requirement by Goodnough *et al*, their inventory of O negative uncrossmatched blood was minimally affected by this protocol.<sup>13</sup> We found our data to be consistent with their findings, as 3% of our transfused blood was non-emergency type O, and we felt this amount to be acceptable.

The use of the pink top tube in our process adds a visual cue to reduce the risk of errors that could lead to mistransfusion. Use of visual cues in the practice of medicine have been extensively studied as a means to reduce errors and have been previously shown to improve hand hygiene compliance, nursing task execution and decrease falls in the elderly.<sup>15-17</sup> A known safety concern regarding the two-sample method is the potential for ancillary staff to draw both blood samples at the same time, increasing the chance for WBIT errors. Our second sample protocol modification required that the second tube could only be released by the blood bank to the blood provider after a first tube was received. Moreover, the colour, size and limited availability of these tubes successfully provided a unique cue for phlebotomists, increasing the chances that the second blood draw would be done correctly.

This audit study did have some limitations. First, our audit sample size was relatively modest, and so undetected weaknesses to our protocol may have been missed. Also, the audit did not specifically require that patient

clinical data was obtained, and thus, reasons for transfusion or the urgency for transfusion could not be ascertained other than that reported to the transfusion service. However, these details were considered beyond the scope of the audit, as the audit was specifically intended to evaluate the protocol itself and not the clinical decisions that lead to a blood order. Lastly, we could not determine with certainty the reason for the reduction in number of non-emergency type O units between audit year 2014 and 2015. While we speculate that the change may have been due to increased technologist awareness that an audit was being done, the data collected by this audit was not sufficient to identify the cause.

Despite advances in technology, ABO incompatible transfusion still exists as a major cause of transfusion-related morbidity and mortality.<sup>18</sup> High demands for blood transfusion persist, as there are over 15 million units of blood transfused each year in the USA and 85 million units of blood transfused worldwide.<sup>19</sup> The use of a pink top tube as a part of a two-sample protocol for prevention of mistransfusion is safe and effective despite the high transfusion demand at our institution.

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