Data Mining to Improve Safety of Blood Donation Process

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Abstract

Blood donation is a voluntary activity in the United States and provides critical blood units for transfusions. Blood is collected, processed and transported by blood centers to hospitals, though some hospitals also collect blood directly from donors. Blood donation is very safe, but a small percentage of donors can have reactions and some of these reactions can lead to serious injury. Donor hemovigilance is the surveillance and analysis of donor reactions with the goal of understanding the factors influencing reactions and indentifying steps to improve donor safety [9]. Historically in the U.S., donor hemovigilance is managed by individual collection centers to improve their specific organization's donation processes. The Department of Health and Human Services (HHS) has developed a software tool (called DonorHART™) to collect, organize and analyze reactions that occur at different participating blood centers and hospitals [6, 8]. Data mining is used to analyze factors influencing the donor reactions, and the insights are shared with the community to help blood center and hospital managers and quality improvement administrators undertake interventions to improve donor safety [10]. The paper presents the history of the donor hemovigilance development and two data mining efforts performed on the data collected to improve the safety of blood donation processes.

1. Background

Donor hemovigilance involves the collection and analysis of information related to reactions associated with blood donation [6, 9, 13]. The goals of donor hemovigilance are to analyze the factors influencing blood donation and to facilitate the ability of organizations to implement interventions that improve blood donors' safety. Donor hemovigilance involves collecting and organizing data related to reactions that occur during the blood donation and information about donor, donation and reaction attributes that potentially influence the reactions. Donor hemovigilance also involves providing baseline reaction metrics and analyses of reaction trends. It serves as the cornerstone for improving donor safety.

Recognizing the importance of donor hemovigilance, the Department of Health and Human Services (HHS) and the U.S. blood bank community, under the leadership of the American Association of Blood Banks (AABB), undertook efforts to establish a national level donor hemovigilance system [6, 8]. These efforts are coordinated through the AABB donor hemovigilance working group (DHWG). Participating members of DHWG are AABB, American Red Cross (ARC), Blood Systems Inc. (BSI), Canadian Blood Services, Coffee Memorial Blood Center, the Mayo Clinic, and the Plasma Protein Therapeutic Association (PPTA) as well as the U.S. Department of Defense (DOD). HHS contracted Knowledge Based Systems, Inc. (KBSI) to design and develop the software tool (DonorHART™) in coordination with DHWG [8]. This paper presents the current status of the DonorHART™ system and how data mining is used on data collected to improve the safety of the blood donation process.

In this paper we use multivariate logistic regression (LR) as the primary analytical technique for analyzing the factors influencing donor reactions. While machine learning techniques like trees, support vector machines, and Bayesian models have provided good results in certain situations [3, 4, 14, 15, 16, 17. 18], LR is extensively used in the medical profession [1, 5, 10]. The adjusted odds ratios that are derived from LR model coefficients are used in the medical profession to interpret and rank factors influencing the dependent variables after accounting for the confounding and correlating factors [12, 13]. Such insights are used to hypothesize and design interventions to improve the focus metric [6, 9]. To

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facilitate comparison with the previous work of the authors and other published literature in this area, LR was used as the analysis technique in this work [1, 5, 6, 9, 10, 12, 13]. We plan to research the results of other advanced machine learning techniques and compare results obtained in our future work.

1.1. DonorHART™ Tool

One of the important contributions of the DHWG was the standardization of reaction types, categories and data that should be collected for donor hemovigilance. DHWG designed the data elements to facilitate analysis of factors influencing reactions rather than pure surveillance of the numbers of reactions. The DonorHART™ tool is designed to be a gold standard system that allows for the capture of comprehensive donor hemovigilance data elements. Many blood centers in the U.S. currently do not capture and report all of the data elements that can be tracked in the DonorHART™ tool. The intent of the DonorHART™ tool design was to provide a menu of key data elements that blood centers can plan to eventually capture and report. Participating organizations must adopt the DHWG standardized categorizations for reaction type, category, signs, and symptoms. Many are modifying the data captured and managed in their donor management systems based on the template provided by the DHWG.

Table 1 shows the reaction types and categories captured and managed within the DonorHART™ system.

Reaction Type	Reaction Category
Vasovagal	• Prefaint, no LOC (uncomplicated or minor) • LOC, any duration (uncomplicated) • LOC, any duration (complicated) • Injury
Local injury related to needle	• Nerve Irritation • Hematoma / Bruise • Arterial Puncture
Apheresis	• Citrate • Hemolysis • Air Embolus • Infiltration
Allergic	• Local • Systemic • Anaphylaxis
Other	• Other

Table 1. Reaction Types and Categories in the DonorHART™ Tool

Table 2 shows a sample of signs and symptoms available in the DonorHART™ tool that can be assigned to a particular reaction or category.

Reaction Type	Category	Signs and Symptoms
Vasovagal	Prefaint, no LOC (uncomplicated or minor)	1. Cold extremities, chills 2. Feeling of warmth 3. Hypotension 4. Lightheaded / Dizziness 5. Nausea / vomiting 6. Normal pulse 7. Pallor, pale skin or lips 8. Rapid pulse 9. Slow pulse 10. Sweating 11. Twitching 12. Weakness

Table 2. Sample Signs and Symptoms Associated with Reactions

The DonorHART™ tool also captures details on adverse events that happened during the blood donation process (Table 3).

Adverse Event Category	Events in the Adverse Events Category
Major Blood Vessel Injury	1. Arteriovenous fistula 2. Axillary vein thrombosis 3. Brachial artery pseudoaneurysm 4. Compartment syndrome 5. Deep vein thrombosis 6. Thrombophlebitis
Major Cardiovascular Events	1. Angina pectoris within 24 hours 2. Cardiac arrest 3. Cerebrovascular accident 4. Myocardial infarction within 24 hours 5. Transient ischemic attack within 24 hours (TIA)

Table 3. Sample Adverse Events during Blood Donation

The DonorHART™ tool is implemented as a web application and is available at https://www.donorhemovigilance.org/Default.aspx. Key features of the DonorHART™ tool are presented below.

1) Support for both manual and file based data entry. Blood collection centers that do not have an internal hemovigilance tool can enter data manually into the DonorHART™ tool. In fact, these blood centers can use the DonorHART™ system as their enterprise hemovigilance software tool. Blood collection centers already using donor management systems that track donor reactions can upload hemovigilance data using files in a specified format. Each participating organization is able to download their data in a variety of formats.

2) Robust representation framework. Standardization of reaction definitions and categories must be addressed in any hemovigilance system. Unless participating organizations adopt the uniform definitions, analysis of hemovigilance data across organizations may not be useful. One of the conscious decisions taken by the DHWG was to capture the diagnosis of the reaction (e.g., vasovagal) as well as the associated signs and symptoms (e.g., loss of consciousness, loss of bladder and bowel

control) rather than to collect data using subjective and potentially evolving criterion (e.g., mild, moderate, or severe). This contrasts with the approach adopted by other international efforts that use hard coded definitions such as injury to nerve with symptoms persisting for less than two weeks as moderate. Capture of such pre-classified data will make the previously collected data obsolete if the criterion of classification is changed. Since the data reported to the DonorHART™ tool are captured at a fundamentally factual level, it can be easily translated to more abstracted systems to facilitate international collaboration.

3) Comprehensive denominator. Some hemovigilance systems capture only information about reactions and their frequency. For comparison both internally to an organization and externally to other organizations, the capture of aggregate denominator data such as "Number of Donations" allows reaction rates to be calculated. In addition to collecting aggregate denominators, the DonorHART™ tool captures denominator categories including age, weight, estimated blood volume, gender, blood pressure, first time vs. repeat, procedure type, etc. and donation specific attributes (e.g., donation type, device, manufacturer, and collection container). This allows the tool not only to calculate the different reaction rates (e.g., vasovagal reactions without any complications), but also to analyze how the reaction rates vary across different groups (male vs. female, young vs. old, across different device types, etc.). Organizations can even compile detailed information for each donation and not only for donations associated with reactions. This allows multivariate analyses such as Logistic Regression (LR) to calculate adjusted odds ratios of multiple variables on reactions.

4) Role Based Access Control (RBAC). The DonorHART™ tool supports role based access control to facilitate access privileges to different user roles (e.g., data reporters, analysts, and administrators) at individual organizations as well as at the nation and system levels.

5) Data validation. The DonorHART™ tool includes a wide suite of data validation procedures to ensure the completeness and consistency of data. The data validation ranges in complexity from validation based on a single element (e.g., valid ranges for height and weight) to consistency checking based on multiple elements (e.g., reaction type consistent with procedure type, donation date consistent with reaction date).

6) Assembly of donor history profile. Should comprehensive data be entered into the tool, the DonorHART™ system can assemble the complete donation and reaction history of a donor. This feature is useful for analyzing the long term effects of multiple donations on donor health (e.g., the long-term effects of donations on RBC, platelet and plasma counts). This feature was also used in the multiple reaction analysis presented in this paper.

the DonorHART™ tool supports a number of standardized reports covering key performance metrics, reaction rate trends over time, and comparison reports between individual organizations and nation level benchmarks. The following sections describe two data mining studies performed on the DonorHART™ tool data. The focus of these studies was to identify factors affecting certain types of reactions, so that organizations can develop and deploy interventions to improve the safety of the blood donation process. The two studies are (1) multiple vasovagal reaction characterization and (2) delayed vasovagal reaction characterization.

2. Multiple Vasovagal Reaction Analysis

2.1. Problem Statement

Vasovagal reactions are the most common type of reaction that occurs during the blood donation process and symptoms range from feelings of lightheadedness (pre-faint) to reactions involving loss of consciousness (LOC), falls, and injuries. Symptoms of vasovagal reactions include chest pain, cold extremities, chills, hypotension, lightheaded/dizziness, loss of bladder or bowel control, LOC, nausea/vomiting, rapid pulse, sweating, twitching, and weakness. Vasovagal reactions typically occur at the rate of 0.1-0.3% [12] for whole blood donations. For the health and safety of the donor, it is important to reduce the occurrence of vasovagal reactions.

Repeat donors are critical to an adequate blood supply [2]. When a repeat donor has a vasovagal reaction, it has an impact on the donor's likelihood of returning to donate again and the timing of such a donation. Table 4 shows the effect of vasovagal reactions on frequent Whole Blood (WB) donors who donate at least twice a year based on the data reported by a blood collecting organization to the DonorHART™ tool. For those donors who do not experience any vasovagal reaction, the percentage of those who come for a subsequent donation (return rate) is high: 92%. However, if they encounter more than two vasovagal reactions, the return rate drops to 75%.

	No Reactions	Single Vasovagal Reaction	Multiple Vasovagal Reactions
Not Returning	25293	180	47
Returning	285354	1243	144
Return Rate	0.92	0.87	0.75

Table 4. Effect of Vasovagal Reactions on Return Rate of Frequent Donors

Occurrence of vasovagal reactions also affects the inter-donation interval (Figure 1) based on the analysis performed on data reported by a blood collecting organization to the DonorHART™ tool.

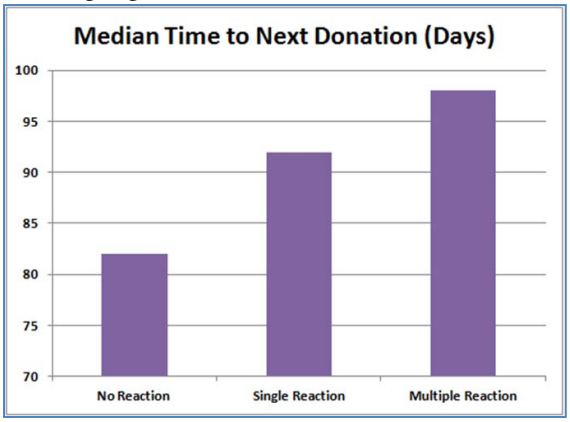

Figure 1. Effect of Vasovagal Reactions on Time to Next Donation for Frequent Donors

Identifying the factors in repeat donors associated with the likelihood of multiple reactions will lead to interventions helpful in reducing repeat reactions and maintaining the safety of blood donors. Several studies have described donor characteristics associated with high reaction rates [1, 2, 10, 12, 13]. Eder et al. evaluated the risk of recurrent syncope among returning donors and found that a prior reaction after whole blood donation does not reliably predict recurrent syncope among returning donors [2]. The focus of this study is to determine if there are factors predicting repeat vasovagal reactions (VVR) and whether these factors are the same or different from factors that can predict single vasovagal reactions. The goal of the study is to identify the characteristics that differentiate donors who have had multiple reactions compared to those characteristics associated with donors who had only a single reaction across different donations.

2.2. Approach and Results

Data consisting of 1,026,386 allogeneic whole blood donations and 8,528 VVR from a blood collecting organization in the United States were collected from January 2010 to October 2011. Donors with more than one VVR (across different donations) were classified as the target class and donors who had a single reaction were classified as the reference class. Donors who donated only once during the study were excluded. The unadjusted odds ratios were calculated to characterize donors who had multiple vasovagal reactions. Age, body mass index (BMI), collection center, collection site (fixed, mobile set-up, mobile bus), days since last visit, donation history, estimated blood volume (EBV), ethnicity, race, gender, whether accompanied by needle injury, diastolic and systolic blood pressures, pulse, number of previous donations, reaction time zone (during, after, off-site), severity, and collection event sponsor group (high school, college, military and other) were included in the unadjusted OR analysis. EBV was calculated using Nadler's formulae [11]:

$$(0.006012 * H^3) + (14.6 * W) + 604 \; for \; Males$$

$$(0.005835 * H^3) + (15 * W) + 183 \; for \; Females$$

Where Height (H) is in inches and Weight (W) is in pounds.

Variables that were significant ($p<.05$) in the unadjusted model were used to develop a logistic regression model. The coefficients of the logistic regression model were used to calculate the adjusted odds ratio (OR) [Table 5]. A 95% Confidence Interval (CI) was used to evaluate whether a variable significantly influenced the occurrence of VVR.

Variable	Odds Ratio	Lower Limit of 95% Odds CI	Upper Limit of 95% CI
GENDER			
Female	1.00		
Male	0.98	0.80	1.20
ETHNICITY			
Not Hispanic	1.00		
Hispanic	0.83	0.69	0.99
SPONSOR GROUP			
Other	1.00		
College	1.10	0.81	1.49
High School	1.08	0.88	1.33
Military	1.43	0.80	2.54
Work Place	0.82	0.62	1.08
COLLECTION SITE			
Mobile Set-up	1.00		
Fixed Clinic	1.40	1.18	1.67
Mobile Bus	0.93	0.73	1.18
REACTION TIME ZONE			
Unavailable	1.00		
After-Donation	0.87	0.43	1.76
During	1.35	0.67	2.72
Off-site	0.46	0.19	1.11
AGE			
25-65	1.00		
17-18	1.49	1.24	1.79
19-24	1.10	0.90	1.34
=16	1.71	1.28	2.28
>65	0.94	0.69	1.29
PULSE			
65-90	1.00		
<65	1.12	0.93	1.36
>90	1.20	1.01	1.43
EBV			
>4775	1.00		
3500-4000	1.56	1.24	1.96
4001-4775	1.37	1.11	1.68
<3500	1.59	1.11	2.28
DAYS SINCE LAST VISIT			
91-180	1.00		
181-360	0.77	0.64	0.93
30-90	1.02	0.85	1.22
<30	0.32	0.04	2.47
>360	0.26	0.20	0.34
SEVERITY			
MILD	1.00		
LOC	0.58	0.29	1.17
LOCWithInjury	0.26	0.07	0.98
PreFaint	0.84	0.42	1.68

Table 5. Adjusted Odds Ratios for Multiple Vasovagal Reactions Based on Logistic Regression

Ethnicity (0.69-0.99 for Hispanics), collection site (1.18-1.67 for fixed clinic), young age (1.28-2.28 for =16 and 1.24-1.79 for 17-18 years), EBV (1.11-2.28 for <3500, 1.24-1.96 for 3500-4000, 1.11-1.68 for 4001-4775), time since last visit (0.64-0.93 for 180-360 days and 0.20-0.34 for >= 360 days), and severity (0.07-0.98 for LOC with injury) were found to be significantly associated with multiple VVR reactions based on the 95% confidence interval.

2.3. Analysis

Developing interventions to reduce reactions in younger age donors (<=18 yrs), a preference to high EBV, and having a gap of 180 days or more between donations appear to be good strategies for reducing multiple reactions across different visits. Ethnicity (Hispanic) and collection site (mobile bus) are other variables significantly associated with multiple VVR, but these may be more difficult to control. Gender (male) and race (black) have been identified as having a significant effect on single reaction rates in previous studies [1, 5, 13]. They were not significantly associated with multiple VVRs in this analysis. A prolonged inter-donation interval was associated with a lower risk of multiple reactions. One might consider a prolonged deferral period for donors who suffer a reaction, especially for younger donors and those with low EBV.

3. Delayed Vasovagal Reaction Analysis

3.1. Problem Statement

Based on the time of the VVR reaction relative to the completion of the donation process (i.e., needle removal), reactions can be classified as immediate or delayed [1, 5]. Typically, immediate reactions occur before the donor completes the donation and walks away from the bed. It covers the registration process, the donor screening process, and the blood collection. Donors can experience vasovagal reactions after completion of the donation, and these delayed reactions can occur on the way to the canteen, in the canteen, and at other locations within the blood center and off-site. Delayed VVR can lead to serious injuries including accidents while driving making it important to understand the factors contributing to delayed VVRs and to develop interventions to reduce them [1, 5].

3.2. Approach and Results

We chose to study VVRs with LOC, which can occur at different stages of the donation process. In this study, reactions that occurred at greater than or equal to five minutes after needle removal were classified as delayed and reactions that occurred up to five minutes following the blood donation were classified as immediate reactions. Delayed VVR with LOC was classified as the target class and immediate VVR with LOC was classified as the reference class. When interpreting the results of this study, it is important to consider that the odds ratios and analysis are based on having immediate VVR with LOC as the reference class.

The unadjusted odds ratios were calculated to characterize donors who had delayed VVR with LOC (Table 6). Age, BMI, collection center, collection site (fixed, mobile set-up, mobile bus), donation history, estimated blood volume (EBV), ethnicity, race, gender, diastolic and systolic pressures, pulse, and sponsor group (high school, college, military and other) were included in the unadjusted OR analysis. Variables that were significant ($p<.05$) in the unadjusted model were used to develop a logistic regression model. The coefficients of the logistic regression model were used to calculate the adjusted odds ratio (OR) (Table 6). 95% CI of OR was used to determine the significant variables. Collection center was one of the variables influencing delayed

reactions. It was included in the LR model, but is not reported in Table 6.

Variable	Odds Ratio	Lower Limit of 95% CI	Upper Limit of 95% CI
GENDER			
Male	1.00		
Female	1.68	1.38	2.04
AGE			
25 - 65	1.00		
17 - 18	1.03	0.84	1.25
19 - 24	0.86	0.71	1.03
= 16	1.30	1.02	1.67
> 65	2.08	1.53	2.83
SYSTOLIC PRESSURE			
100 - 140	1.00		
< 100	0.76	0.57	1.01
> 140	0.91	0.70	1.19
EBV			
> 4775	1.00		
3500-4000	1.39	1.11	1.74
4001-4775	1.23	1.01	1.50
< 3500	1.26	0.90	1.77
COLLECTION SITE			
Mobile Inside Set-up	1.00		
Fixed site	1.41	1.16	1.70
Mobile donor coach	1.43	1.21	1.68
DONATION HISTORY			
Repeat	1.00		
First	0.85	0.74	0.96
ETHNICITY			
Not Hispanic or latino	1.00		
Hispanic or Latino	1.27	1.03	1.56
PULSE			
65 - 90	1.00		
< 65	0.85	0.72	1.01
> 90	1.13	0.94	1.35
RACE			
White	1.00		
African American or Black	2.61	1.36	5.02
American Indian/Alaska Native	1.07	0.68	1.69
Asian	1.85	1.18	2.91
SPONSOR GROUP			
Other	1.00		
College	1.08	0.83	1.41
High school	1.15	0.92	1.44
Military	0.60	0.33	1.08
Work Place	1.01	0.82	1.24

Table 6. Adjusted Odds Ratios for Delayed VVR with LOC with Immediate VVR with LOC as Reference

3.3. Analysis

Young donors (= 16 years) (95% CI of 1.02 – 1.67) as well as older donors (>= 65 years) (1.53-2.83) are more likely to experience delayed VVR with LOC reactions (in comparison to immediate reactions). Donors with low EBV are also more likely to have delayed reactions (1.11-1.74 for EBV of 3500-4000; 1.01-1.50 for EBV of 4001-4775). The primary mechanisms of VVR are thought to include (1) fear, anxiety and nervousness experienced during the donation, (2) hypovolemic state due to removal of 500 ml of whole blood, and (3) the orthostatic effects superimposed on a hypovolemic state after the donation [12]. The second and third factors explain the high occurrence of delayed VVR in donors with low EBV when they stand up after completing the donation.

First time donors have a low occurrence of delayed reactions in comparison to immediate reactions (0.74-0.96). This might be because first time donors are more prone to fear, anxiety and nervousness during the donation and are more likely to experience immediate VVRs.

Females have a higher occurrence of delayed VVR with LOC (1.38-2.04). Asians (1.18-2.91) and African Americans (1.36-5.02) also have a higher occurrence of delayed reactions. Fixed sites (1.16-1.70) and mobile donor coaches (1.21-1.68) have higher delayed reactions compared to mobile inside set-ups.

Organizations might consider introducing interventions that provide a more relaxing environment for first time and female donors through supplemental education and by providing them with additional time. Organizations might also consider interventions which increase the blood volume (e.g., salty snacks, water) [10] to reduce delayed reactions in donors with low EBV.

4. Summary

Blood donation is very safe in the U.S., but a small percentage of donors can have reactions and some of these reactions can lead to serious injury. Donor hemovigilance is the surveillance and analysis of donor reactions with the goal of understanding the factors influencing reactions and taking steps to improve donor safety. HHS has developed the DonorHART™ tool that collects, organizes and assists with the analysis of donor reaction data reported from participating blood centers and hospitals. Data mining is used to analyze factors influencing donor reactions and insights are shared with the community to help blood center and hospital managers and quality improvement administrators undertake interventions to improve donor safety. This paper presents two studies performed on data reported to the DonorHART™ tool: (1) multiple vasovagal reactions, and (2) delayed vasovagal reactions with loss of consciousness. Insights gained by performing multivariate Logistics Regression (LR) modeling and Odds Ratio (OR) calculations in terms of characteristics associated with multiple vasovagal reactions and delayed vasovagal reactions are presented. The systematic collection of donor hemovigilance data on a national level using data mining and analysis can lead to interventions to improve donor safety.

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