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Original Research Article

From Failure Modes to Modifiable Factors: Root Cause Analysis of Whole Blood Collection Failure

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Abstract:

Background: Whole blood collection can occasionally fail even after phlebotomy has been started. Such events result in loss of consumables, staff time and donor effort, and may also affect the donor's willingness to return. Because these failures often arise from a combination of donor, technical, procedural and environmental factors, we analyzed them using a root cause analysis approach.

Methods: We retrospectively reviewed all whole blood donation attempts recorded over a three-year period in the Department of Transfusion Medicine. Collection failures were classified using the Ishikawa framework under the domains of People, Process, Equipment, Material and Environment. Two investigators reviewed the records independently, and differences were resolved by discussion. Failure rates were compared according to donor sex, collection setting and staff experience. Chi-square or Fisher's exact test was used as appropriate, and relative risks and odds ratios were calculated with 95% confidence intervals. Pareto analysis was used to identify the main failure modes.

Results: Among 6,021 donation attempts, 85 ended in collection failure, giving an overall failure rate of 1.41%. Failure was more frequent among female donors than male donors, 2.98% versus 1.02%, with a relative risk of 2.92, 95% CI 1.91–4.48. Outdoor camps also had a substantially higher failure rate than in-house collections, 6.87% versus 0.83%, RR 8.31, 95% CI 5.47–12.61. Although outdoor camps accounted for only 9.7% of donation attempts, they contributed 47.1% of all failures. Staff experience was another important factor. Less-experienced personnel had a higher failure rate than trained personnel, 3.54% versus 0.33%, RR 10.87, 95% CI 6.04–19.58. Among failed collections, phlebotomy-related failures were also more common when less-experienced staff were involved, 80.6% versus 38.5%, OR 6.63, 95% CI 1.88–23.38. The three most frequent failure modes were hematoma, vasovagal reaction and clot formation, which together accounted for 83.5% of all failures.

Conclusion: Collection failure was uncommon, but it showed a consistent pattern. Most failures were related to the phlebotomy process and were associated with staff experience and outdoor camp conditions. The findings support a CAPA plan focused on competency-based training, closer supervision, better management of difficult venous access, early correction of slow flow, and prevention of vasovagal reactions and standardization of outdoor camp practices. These measures should be evaluated prospectively.

Keywords: Blood Donors; Phlebotomy; Root Cause Analysis; Hematoma; Vasovagal Syncope; Quality Improvement.

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Introduction

Safe transfusion practice begins with safe and successful blood collection. This step has a direct impact on the quality, safety and adequacy of a transfusion service. It is also the point at which donors come into close contact with the blood centre, so the standard of practice during collection is especially important [1]. Errors are common during the collection stage. In an eight-year review of errors at a national blood establishment, 54.4% of all errors occurred during blood collection. The authors related this to the number of staff involved, the manual nature of many steps, dependence on the skill and experience of technicians, and the need to reorganize work repeatedly at changing collection sites [2]. Blood collection failure refers to a situation in which phlebotomy is started but no usable

blood unit is obtained. It has been reported to account for 47.3% of errors at the collection facility [3]. Each failed collection results in loss of a blood bag, consumables and staff time. More importantly, it may leave the donor with an unpleasant experience, which can reduce the likelihood of future donation [3].

Most published studies have focused on individual donor-related causes of failure, such as vasovagal reactions or difficult venous access [4]. Phlebotomist competency and technical skill are also important for successful collection and donor safety [5]. In actual practice, however, collection failure usually does not have a single cause. Procedural issues, equipment problems, environmental conditions, donor factors and staff experience may all contribute.

The Ishikawa, or fishbone, diagram is a useful tool for root cause analysis. It groups possible causes into domains such as People, Process, Equipment, Material and Environment. This allows each failure to be examined in relation to the whole collection process rather than only by its final outcome.

We therefore carried out a retrospective RCA of blood collection failures at our centre. The aim was to identify the root causes of these failures using the Ishikawa framework and to develop targeted corrective and preventive actions.

Materials and Methods

Study Design and Setting: This retrospective, observational, analytical study was conducted in the Department of Transfusion Medicine over a period of three years.

Study Population: All blood donation attempts made during the study period were screened for inclusion, and 6,021 attempts were included in the analysis.

Inclusion Criteria

- All whole blood donation attempts started during the study period
- Donations at both in-house and outdoor camp sessions
- Donations in which phlebotomy had begun

Exclusion Criteria

- Donors deferred before venipuncture
- Incomplete records with missing procedural details
- Therapeutic phlebotomy procedures

Definition of Blood Collection Failure: Blood collection failure was defined as any donation attempt in which phlebotomy was performed but no usable blood unit was obtained, so that the unit had to be discarded.

Data Collection: Data were retrieved retrospectively from the following records:

- Blood donor registers
- Adverse donor reaction registers
- Blood donation camp records
- Incident reporting registers

Categorization of Causes: The possible causes of each failure were grouped into five predefined Ishikawa domains: People, Process, Equipment, Material and Environment. Operational definitions for each domain were agreed before data extraction so that all events would be classified in the same way.

After review of the donor records, adverse event registers and incident reports, each failure was assigned to the domain that best represented its primary contributing factor.

Two investigators classified the events independently, and disagreements were resolved by consensus.

Classification of Staff Experience: Staff who performed blood collection were classified by their blood bank experience and procedural training.

Trained Personnel: This group included personnel with at least one year of experience in blood collection:

1. Trained blood bank nurses
2. Trained blood bank technicians

Less-experienced Personnel: This group included personnel with less than one year of experience in blood collection:

1. Junior residents
2. Nursing trainees
3. Students undergoing procedural training

Classification of Phlebotomy-related Failures: Failures were classed as phlebotomy-related when they resulted mainly from technical difficulty during venipuncture or collection. These were:

- Hematoma formation
- Clot formation
- Failed repeat venipuncture

Statistical Analysis: Data were entered in Microsoft Excel and analyzed with IBM SPSS Statistics.

Appropriate statistical tests were used.

Ethical Considerations: The study was conducted in accordance with the principles of the Declaration of Helsinki.

Because the study used existing records only, all extracted data were anonymized, and no donor identifiers were used in the analysis.

Results

Of the 6,021 donation attempts evaluated, 85 ended in collection failure, giving an overall failure rate of 1.41%.

Collection Failure by Donor Sex: Male donors accounted for 4,812 attempts and female donors for 1,209. Failure occurred in 49 male donors (1.02%) and 36 female donors (2.98%).

The failure rate was significantly higher in female donors ($\chi^2 = 26.65$, $p < 0.001$), with a relative risk of 2.92 (95% CI 1.91–4.48) compared with male donors (Table 1).

Table 1: Collection failure by donor sex

Variable	Donation attempts	Collection failures	Failure rate (%)	Relative risk (95% CI)	p-value
Male donors	4,812	49	1.02	Reference	—
Female donors	1,209	36	2.98	2.92 (1.91–4.48)	<0.001

Collection Failure by Collection Setting: Of all attempts, 5,439 were made in-house and 582 at outdoor blood donation camps. Failure occurred in 45 in-house donations (0.83%) and 40 camp donations (6.87%). Failure was significantly more frequent at outdoor camps ($\chi^2 = 138.06$, $p < 0.001$), with a relative risk of 8.31 (95% CI 5.47–12.61) (Table 2). Outdoor camps made up only 9.7% of all donation attempts but contributed 47.1% of all collection failures.

Table 2: Collection failure by collection setting

Variable	Donation attempts	Collection failures	Failure rate (%)	Relative risk (95% CI)	p-value
In-house donations	5,439	45	0.83	Reference	—
Outdoor camps	582	40	6.87	8.31 (5.47–12.61)	<0.001

Root Cause Analysis Using the Ishikawa Framework: All 85 failure events were reviewed for their documented contributing factors, which were then mapped to the predefined Ishikawa domains of People, Process, Equipment, Material and Environment. For each event, three components were distinguished: the failure mode, the contributing factors recorded at the time, and any system-level root cause that could be addressed by corrective action. A system-level factor was classified as a root cause only when the records supported a plausible and actionable condition underlying the failure. Where the records did not support a deeper causal inference, the finding was kept as a contributing factor. The results are summarized in Table 3.

Table 3: Ishikawa-based root cause analysis of blood collection failures

Failure mode	n (%)	Documented contributing factors	Ishikawa domain	Likely root cause / system issue
Hematoma	43 (50.6)	Wrong technique, wrong vein selection, difficult or thin veins, unsupervised procedures, needle or arm movement	People, Process	Inadequate venipuncture experience and supervision, particularly during difficult venous access
Vasovagal reaction	15 (17.6)	Donor anxiety; hot and humid conditions; prolonged waiting; pain during venipuncture	People, Environment, Process	Donor susceptibility compounded by discomfort, waiting and environmental conditions
Clot formation	13 (15.3)	Slow flow from improper needle placement or thin vein, tight tourniquet, kinked tubing, failure to open tubing	Process, People	Inadequate recognition and correction of slow blood flow during collection
Failed repeat venipuncture	7 (8.2)	Wrong technique; difficult venous access	People, Process	Limited success in managing difficult venous access and repeat attempts
Inadequate donor screening	2 (2.4)	Missed examination, undisclosed risk history	Process, People	Gaps in pre-donation screening and history elicitation
Donor-requested termination	2 (2.4)	Anxiety, dizziness and pain	People	Donor discomfort or intolerance during collection
Other isolated failures	3 (3.5)	Antiseptic reaction, blood collection monitor failure, couch malfunction	Material, Equipment	Isolated material- and equipment-related events; insufficient evidence for a broader system-level cause

Pareto Analysis: Hematoma was the most frequent failure mode, accounting for 43 of 85 events (50.6%), followed by vasovagal reactions (15/85, 17.6%) and clot formation (13/85, 15.3%). These three modes made up 83.5% of all failures, above the 80% cumulative threshold, and were therefore set as the main targets for corrective and preventive action (Figure 1).

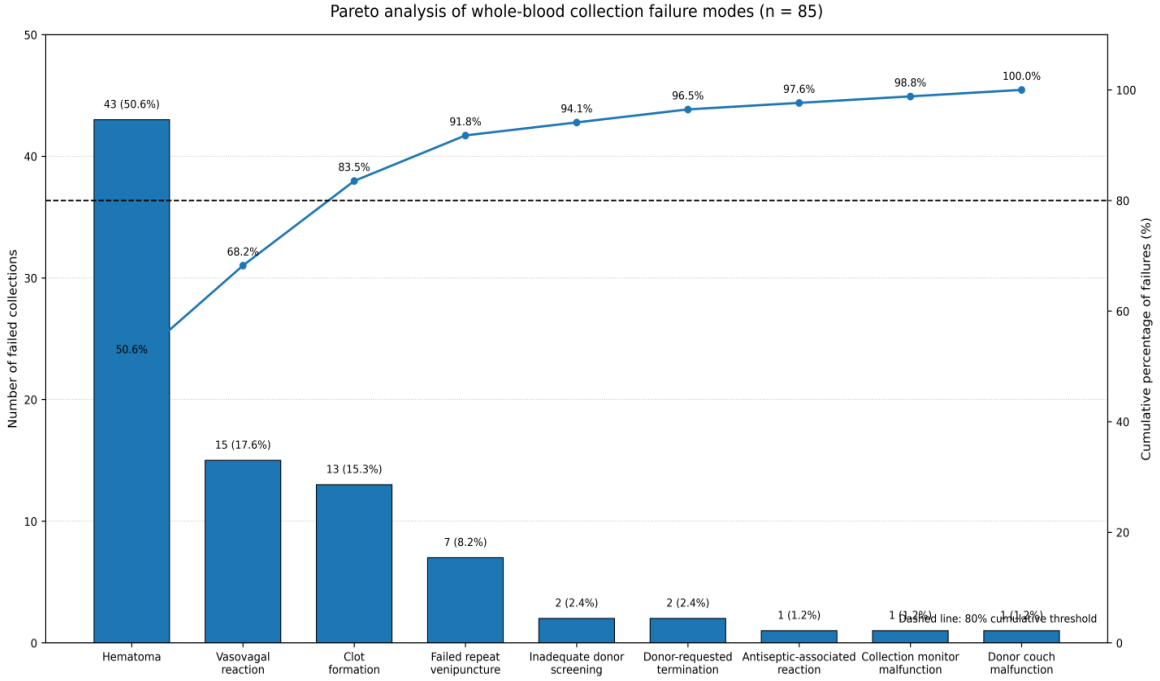


Figure 1: Pareto analysis of blood collection failure modes (n = 85).

Bars show the frequency of each failure mode, and the line shows the cumulative percentage of failures. The horizontal line marks the 80% threshold.

Staff Experience and Collection Failure: Failure was strongly associated with staff experience. Trained personnel handled 3,989 attempts, of which 13 (0.33%) failed. Less-experienced personnel handled 2,032 attempts, of which 72 (3.54%) failed. The risk of failure was therefore about 11 times higher with less-experienced personnel (RR 10.87, 95% CI 6.04–19.58; χ^2 = 100.13, $p < 0.001$) (Table 4). The type of failure also differed between the two groups. Of the 72 failures with less-experienced personnel, 58 (80.6%) were phlebotomy-related, compared with 5 of 13 (38.5%) with trained personnel. Among failed collections, less-experienced personnel had higher odds of a phlebotomy-related than a non-phlebotomy-related failure (OR 6.63, 95% CI 1.88–23.38; χ^2 = 10.17, p = 0.001; Fisher's exact p = 0.003) (Table 5). This agrees with the event-level RCA, in which technical and venous-access factors dominated the main failure modes.

Table 4: Association of staff experience with blood collection failure

Staff experience	Donation attempts	Collection failures, n (%)	Relative risk (95% CI)	p-value
Trained	3,989	13 (0.33)		—
Less experienced	2,032	72 (3.54)	10.87 (6.04–19.58)	<0.001

Percentages are the proportion of donation attempts that ended in collection failure within each group. Pearson's χ^2 = 100.13. RR compares less-experienced with trained personnel. Trained personnel had at least one year of relevant experience.

Table 5: Association between staff experience and type of failure among failed donations (n = 85)

Staff experience	Phlebotomy-related, n (%)	Non-phlebotomy-related, n (%)	Total failures	Odds ratio (95% CI)	p-value
Trained	5 (38.5)	8 (61.5)	13		—
Less experienced	58 (80.6)	14 (19.4)	72	6.63 (1.88–23.38)	0.001

The OR compares the odds of a phlebotomy-related versus a non-phlebotomy-related failure in less-experienced and trained personnel. Pearson's $\chi^2 = 10.17$; Fisher's exact $p = 0.001$

Discussion

This study treated blood collection failure as a quality-system outcome and used an Ishikawa-based RCA to examine its causes. Of 6,021 donation attempts, 85 (1.41%) failed to yield a usable unit. Although the number of failures was small, their distribution was non-uniform. They were significantly associated with donor sex, collection setting and staff experience, and most were related to phlebotomy. Collection failure is therefore worth tracking as a quality indicator, because it points to specific areas where practice can be improved.

Our failure rate of 1.41% was higher than the 0.84% reported by Radovčić et al. in a six-year analysis of 618,251 donations [6]. Comparisons between centers need care, however, because definitions of collection failure, donor profiles, and collection practices, reporting systems and operating conditions vary. Of more practical use is that our data give a center-specific baseline against which future improvement can be measured. This matters because failed collections and donation-related complications cost more than a single lost unit. A poor donation experience can also affect whether a donor returns [7].

Female donors had a higher failure rate than male donors (2.98% vs 1.02%), with almost three times the risk (RR 2.92, 95% CI 1.91–4.48). Radovčić et al. also found more collection failures among women [6], and Indian donor-vigilance data show a higher overall rate of adverse donor reactions in female donors [8]. A recent systematic review and meta-analysis of 71 studies, covering about 19 million donations, found that female sex, younger age, first-time donation, lower estimated blood volume and lower blood pressure were all linked to a higher risk of VVR [9]. These findings offer a plausible explanation for our result, but they do not show why failure was more common among women in our cohort. We did not analyze body weight, estimated blood volume, donation history or blood pressure, so female sex should be read as an associated characteristic and not an independent cause. The practical implication is closer donor-specific risk assessment, not any restriction on eligible female donors.

The largest difference we found was by collection setting. Failure occurred in 6.87% of outdoor camp donations and 0.83% of in-house donations (RR 8.31, 95% CI 5.47–12.61). Camps accounted for only 9.7% of donation attempts but for 47.1% of failures, which makes them a clear priority for quality review. Conditions at outdoor sessions tend to be less predictable than at a fixed blood center, including donor flow, available space, comfort, equipment layout and staffing. An Indian review of 424 voluntary blood donation camps found that 73% did not meet one or more predefined quality and safety parameters, and that regular monitoring with targeted intervention reduced these deviations [10]. A multicenter study of 30,928 donations from 181 camps also stressed the need for standard donor selection, preparation, monitoring and management of donation-related complications in the camp setting [11].

Even so, the higher risk at our camps does not prove that the outdoor setting itself caused the failures. We did not adjust for staffing, donor characteristics, workload or environmental conditions together. Recent evidence on vasovagal reactions has also not shown a consistent independent difference between mobile and fixed sites [9]. The camp finding is better seen as a marker of a higher-risk working environment in which several factors may act at once. Our event records fit this view, since heat, humidity and long waits were noted in some vasovagal events. The response should be better standardization of how camps are organized, not fewer outdoor collections. The Ishikawa analysis characterized the distribution of failure modes. Hematoma was the most common failure mode (43 of 85; 50.6%), followed by vasovagal reaction (17.6%), clot formation (15.3%) and failed repeat venipuncture (8.2%). Hematoma was also the leading cause of collection failure in a large blood establishment study, though at a lower proportion of 32.4% [6]. Again, the difference in size should be interpreted with caution, given differences in case definitions, reporting practices and settings.

When hematoma, clot formation and failed repeat venipuncture were grouped as defined in the methods, 63 of 85 failures (74.1%) were phlebotomy-related. These findings identify the collection procedure as a primary target for quality improvement. Radovčić et al. likewise found that 91% of failures in their setting were mainly due to venipuncture technique or vein selection [6]. In our data, these failures did not come down to a single technical problem. The records described poor technique or vein selection, difficult or thin veins, lack of supervision, needle or arm movement, slow flow, poor needle position, an over-tight tourniquet and tubing problems. This is where RCA is useful. It looks past the final label of "hematoma" or "clot" to the conditions in the process that led up to it.

Staff experience was the strongest modifiable factor we identified. Failure occurred in 13 of 3,989 attempts by trained personnel (0.33%) and in 72 of 2,032 attempts by less-experienced personnel (3.54%), an approximately 11-fold higher risk (RR 10.87, 95% CI 6.04–19.58; $p < 0.001$). The type of

failure differed as well. In the less-experienced group, 58 of 72 failures (80.6%) were phlebotomy-related, against 5 of 13 (38.5%) in the trained group. A failure was therefore significantly more likely to be phlebotomy-related when less-experienced staff were involved (OR 6.63, 95% CI 1.88–23.38).

We found few studies that directly measure the risk of failed collection by staff experience, indicating that this is an important operational finding. Audits of blood bank phlebotomy do support the wider point that technical competence needs ongoing monitoring. In a prospective audit of 11,260 donors, Pandey et al. found both technical and clerical errors in the phlebotomy area and recommended regular competency assessment and active detection of procedural deviations [12]. In that study, errors were not limited to newly recruited staff. This supports how we read our own results: staff experience should not be used as a proxy for individual blame. The problems that can be fixed lie at system level, namely training, supervision, competency assessment, assignment of donors with difficult veins to suitable staff, and timely escalation when problems arise.

This distinction is relevant to quality improvement. Our data do not show that inexperience on its own caused the failures, since difficult donors or difficult collections may not have been spread evenly between the two staff groups. Still, the size of the association, the excess of phlebotomy-related failures among less-experienced staff and the observations recorded in the RCA make a strong case for structured, competency-based training and supervision.

Vasovagal reactions caused 15 of 85 failures (17.6%), making them the second most common failure mode. The records for these events noted donor anxiety, long waits, hot or humid conditions and pain at venipuncture. This is in line with the wider donor-safety literature. Wu et al. identified female sex, younger age, first-time donation, lower estimated blood volume and lower blood pressure as consistent risk factors for VVR, and their narrative synthesis also linked fear and anxiety about donation to higher risk [9]. Indian donor-vigilance data similarly show that generalized reactions make up most reported adverse donor reactions [8].

Because VVR usually has several causes, it is consistent with an Ishikawa approach. In a given donor, underlying susceptibility may combine with anxiety, pain, waiting time and the collection environment. Our retrospective data cannot measure the separate contribution of each factor, so these should be treated as documented contributors and not as proven causes. Some of them can be changed, however, and randomized trials support simple preventive measures. A systematic review and meta-analysis found that drinking water before donation reduced the risk of VVR (RR 0.79, 95% CI 0.70–0.89), and applied muscle tension has also shown benefit [13,14]. These measures could be combined with better donor counseling, shorter waits, improved comfort and early recognition of symptoms, especially for donors at higher risk.

The remaining failures were uncommon. They included inadequate donor screening, donor-requested termination, an antiseptic-associated reaction and equipment or couch malfunction. Their small numbers do not support broad conclusions about cause, but they should not be ignored either. In a quality system, a single event can expose a weakness that needs fixing, particularly when it involves equipment, screening or procedural safety. On the other hand, assigning a deeper root cause without enough evidence risks over-interpretation. We therefore kept isolated events as contributing factors when the records did not support a defensible system-level cause. This cautious approach is important in retrospective RCA, which can only be as good as the records made at the time. The Pareto analysis identified the principal priorities for intervention. Hematoma, vasovagal reactions and clot formation accounted for 83.5% of all failures. This finding has operational relevance because most failures were concentrated within a small number of failure modes. Read together with the staff analysis and the Ishikawa findings, the results point to a short list of priorities: venipuncture competency and supervision, management of difficult veins, early detection and correction of slow flow, and prevention and early management of vasovagal reactions. Less frequent failures should still be monitored, but addressing these main categories first is likely to reduce the overall failure burden the most.

Implications for Quality Improvement: Our findings indicate the need for a system-level CAPA plan rather than measures directed at individual staff members. The first priority is competency-based assessment of venipuncture skills, especially for less-experienced personnel, with supervised practice until competence is shown. Training should cover vein assessment and selection, needle placement and securing, management of difficult venous access, recognition and correction of slow flow, and clear rules on when to escalate before a repeat venipuncture. Experienced staff should also be reassessed periodically, since competence has to be checked and cannot be assumed from length of service alone [12]. For clot-related failures, the event analysis supports closer monitoring of flow throughout collection, early correction of needle or tubing position, correct tourniquet use and prompt action when flow drops. For VVR-related failures,

attention should go to donor anxiety, avoidable waiting, hydration, comfort and early recognition of symptoms. Where practical, pre-donation water and applied muscle tension can be offered to susceptible donors [13,14].

The much higher failure rate at outdoor camps also supports a structured readiness check before each camp. This should cover staffing and supervision, equipment function, donor flow, waiting arrangements, ventilation and temperature, privacy and a suitable collection area. These are risk-based measures drawn from the RCA, and their effectiveness has not yet been tested. The CAPA plan needs to be followed by prospective measurement. Overall and cause-specific failure rates, failure by staff experience and by collection setting, and process indicators such as completion of competency assessment and supervision of less-experienced staff can be tracked over time. The next improvement cycle can then show whether the measures actually reduce failures, instead of assuming that they work once they are in place.

Strengths and Limitations: A strength of this study is that it combined event-level review with statistical analysis. Each failure was examined using a predefined Ishikawa framework, and the findings were then supported by risk estimates and Pareto analysis. Because denominators were available for donor sex, collection setting and staff experience, we could estimate failure rates rather than only describe the number of events.

Another strength is that the failure mode, contributing factors and likely system-level issue were kept separate. This reduced the risk of treating the final event itself as the root cause.

The study also has limitations. First, it was retrospective and depended on the quality of existing documentation. Contributing factors that were not recorded at the time could not be reconstructed later. Second, collection failures often involve several interacting causes, and assigning a primary domain may simplify a more complex process.

Third, the associations with donor sex, outdoor collection and staff experience were not adjusted for one another or for other possible confounders. Therefore, they should not be interpreted as proof of causation. Fourth, some failure categories had very small numbers, limiting further statistical analysis. Finally, the proposed CAPA plan has not yet been evaluated prospectively. Follow-up measurement will be needed to determine whether these actions reduce failures in practice.

Conclusion

Blood collection failure was uncommon in this study, but it was not evenly distributed across donors, settings and staff groups. Failures were more frequent among female donors, at outdoor camps and when less-experienced staff performed the collection. Most failures were related to the phlebotomy process, and hematoma alone accounted for about half of all events. Hematoma, vasovagal reaction and clot formation together made up more than four-fifths of all failures.

The findings suggest that improvement should focus on strengthening the collection system rather than assigning blame to individual staff members. Key areas include competency-based training, supervision, difficult-vein management, early recognition of slow flow, donor comfort and standardization of outdoor camp practices. Prospective monitoring after implementation will be necessary to confirm whether these measures lead to a sustained reduction in collection failures.

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