The Impact of Open Vs. Closed Blood Collection on Specimen Quality, Health Care Worker Safety, & Work Efficiencies, at a Tertiary Care Centre in South India

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ABSTRACT

BACKGROUND

In the present era of automation, the quality of laboratory specimens is critical towards the delivery of accurate and useful results. The mode of collection of the sample is one such variable. Proper collection and handling of blood samples prevent erroneous results, reduce turnaround time and ensure safety of healthcare workers and patients. The study purpose is to compare open and closed systems of blood collection and the impact of closed collection system in the reduction of pre analytical errors and promoting health care worker safety.

METHODS

This is a prospective comparative study and it was conducted on blood samples collected in the Outpatient Department of Government Medical College, Kottayam and preanalytical study variables were assessed at Departments of Haematology and Biochemistry. At the beginning of the study, the quality and the quantity of specimen, result accuracies and healthcare safety parameters were assessed for 4778 samples using open blood collection system. This was followed by training of the phlebotomists for closed system of blood collection. The same parameters were studied for another 2508 blood samples collected via closed collection system by the same phlebotomists. The open blood collection system was carried out using non vacuum tubes (Plain and K3 EDTA), 5 ml syringe and 23G needles and closed blood collection system used BD vacutainer (K2 EDTA and serum gel tubes), Eclipse™ safety 22G needles and pronto™ reusable safety holders. The study was conducted from 01-01-2021 to 31-03-2021.

RESULTS

The specimen quality errors namely fibrin mass, strands, haemolysis, re-centrifugation, and insufficient volume in biochemistry lab were significantly reduced with introduction of closed collection system. In haematology lab, closed collection system reduced incidence of clotted sample, insufficient volume accompanied by significant reduction in platelet and WBC differential flags. Closed collection system also reduced occurrence of blood smeared containers and blood spillage on test requisition forms, hence improving safety of health care personnel.

CONCLUSIONS

The study establishes a significant reduction in pre-analytical errors with closed blood collection system, prevents test cancellation and improved workflow efficiency.

KEY WORDS

Accuracy, Blood Collection Systems, Errors, Phlebotomist, Preanalytical, Spillage, Variables.

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BACKGROUND

Advances in medical technology have led to an increased reliance of medical decision making on lab results. In a paper published by Mayo clinic in 1996, the author states "We know that, although the laboratory represents a small percentage of medical centre costs, it leverages 60–70 percent of all critical decisions for example admission, discharge and therapy."¹ The aim of every lab today is to provide timely and accurate results. Lab Automation has played a critical part in improving turnaround time (TAT) and standardizing analytical processes. However, every machine is still dependent on the quantity and quality of the specimen presented. It is a well-established fact that preanalytical errors are influenced by a variety of reasons including specimen collection techniques, transportation, interfering substances, and patient factors.²⁻⁵ Further, type of collection and collection containers are known to impact the specimen quality and result outcomes.⁶ Several studies conducted in the past have demonstrated improvement of specimen quantity and quality after shifting from open to closed collection system. Open collection systems are known to cause high incidence of haemolysis, blood spillages and exposure of potentially infectious materials to the patients and health care workers (HCW). Incidence of under filled specimen containers are known to be more than 10 times higher in open collection system, leading to significant preanalytical errors, like cell shrinkage especially in EDTA specimens.⁶ On the other hand, closed collection system practices are associated with reduced specimen rejections, improved overall workflow efficiencies, cost benefits due to minimal repeat testing & re-draws, lesser instrument maintenance and enhanced HCW (healthcare worker safety).⁶⁻⁷ While a lot of studies have demonstrated improvement of specimen quality with the use of closed collection, its direct impact on result accuracies is often missed in most of the studies.

The purpose of this study is to monitor error/rejection rates & HCW safety indices with open and closed blood collection devices in the outpatient department (OPD) of a busy government hospital to understand the quantum of impact of practice change from open to closed systems on specimen quality, result accuracy, work efficiencies and HCW safety.

METHODS

This is a prospective comparative study and it was designed to compare the impact of open collection system, Group A: Open collection by 5ml syringe, 23G needles and non-vacuum tubes (Plain serum 2 ml tubes & K3 EDTA 2 ml tubes) vs closed collection system, Group B: BD Vacutainer® K2 EDTA 2 ml, serum gel tubes 5 ml, Eclipse™ safety needles 22G, and Pronto™ reusable safety holders on the specimens collected in the OPD of Govt Medical College, Kottayam. At the beginning of the study, the quality and the quantity of specimen, result accuracies and healthcare safety parameters were assessed for 4778 samples using open blood collection system. This was followed by training of the phlebotomists for closed system of blood collection. The same parameters

were studied for another 2508 blood samples collected via closed collection system by the same phlebotomists. The study was approved by the Institutional Ethics and Scientific Review Committee and it was conducted from 01-01-2021 to 31-03-2021. The study was designed for sequential enrolment of patients with baseline assessments in open collection phase followed by staff trainings on closed collection phase (8 phlebotomists) and end line assessment on closed collection with no change in the specimen collection staff.

Study Setting

The specimens collected between 8 am to 2 pm were transported manually to haematology and biochemistry departments where they were assessed for quantity & quality of specimen, result accuracies and HCW safety parameters. All specimens were inspected visually to record number of blood-stained requisition forms and containers & spillage in lab. Data thus collected was transcribed into data register at the end of each day.

Haematology

Specimens were visually inspected for clot and volume insufficiency for the impact i.e., sample rejected or tested but report released with a comment

- Platelets - All specimens flagged by the instrument were reflexed to manual smear and discrepancies from machine results were recorded and analysed.
- WBC differential count – Approximately 15 specimens flagged as high/low for differential counts were selected randomly on a daily basis and reflexed to manual slides. The data was recorded and analysed for discrepancy between manual and machine results.

Biochemistry

Specimens were inspected visually for fibrin strands, fibrin mass, haemolysis, volume insufficiency. Haemolysis grading was done using haemolysis chart.

Inclusion Criteria

All venous blood samples collected between 08:00 am to 02:00 pm at the OPD of biochemistry and haematology departments.

Exclusion Criteria

All samples collected from IPD, OPD samples collected between 2 pm to 8 am, specimens other than venous and specimens collected by any other method except study methodology (syringe or closed system) were excluded from study analysis.

Statistical Analysis

Data collected in the study was presented as number of errors, % of errors and % change in errors. The statistical significance was analysed using unpaired t test (two tailed).

RESULTS

On comparison with open collection in the Department of Biochemistry, specimen quality errors (Table 1) like fibrin mass, fibrin strands, haemolysis, re-centrifugation and insufficient volume to perform test were significantly reduced with p value < 0.01 in closed blood collection system along with the reduction in "report released with comments".

On comparison with open collection (Table 1), the percentage of blood smeared containers and blood spillage on requisition slips in laboratory (p value < 0.01) were reduced to zero (0.0 %) in the closed blood collection system, thereby improving the HCW safety by reducing the exposure to blood.

In the Department of Haematology, specimen collection by closed collection methodology resulted in significant improvement in specimen quality, (reduction in incidence of clotted samples & insufficient blood volume (p value < 0.01) result accuracy and workflow efficiency (significant reduction in platelet and WBC differential flags (p value < 0.01). Specimen collection by closed collection also reduced the risk of contamination by reducing the incidence of blood smeared containers and blood spillage on requisition slips (p value < 0.01) (Table 2).

Biochemistry		Open Collection - n = 3427		Closed Blood Collection - n = 1474		% Reduction in Error	p
		No. of Errors	%	No. of Errors	%		
Specimen quality	Fibrin mass	258	7.5%	11	0.7%	6.8 %	< 0.01
	Fibrin strands	272	7.9%	111	7.5%	0.4 %	< 0.01
	Moderate haemolysis	151	4.4%	0	0.0%	4.4 %	< 0.01
	Gross haemolysis	97	2.8%	0	0.0%	2.8 %	< 0.01
	Re-centrifugation	230	6.7%	0	0.0%	6.7 %	< 0.01
Report released with comment	Insufficient volume to perform test	204	5.9%	0	0.0%	5.9 %	< 0.01
	Fibrin thread/mass	530	15.4%	122	8.20%	7.2 %	< 0.01
	Haemolysis	248	7.2%	0	0.0%	7.2 %	< 0.01
HCW safety	Insufficient volume	204	5.9%	0	0.0%	5.9 %	< 0.01
	Blood smeared containers	218	6.3%	0	0.0%	6.3 %	< 0.01
	Blood spilled on requisition slips	255	7.4%	0	0.0%	7.4 %	< 0.01
	Blood spillage in laboratory	15	0.4%	0	0.0%	0.4 %	< 0.01

Table 1. Impact of Specimen Collection Methodology on Preanalytical Errors in Biochemistry Department

Haematology		Open Collection - n = 1351		Closed Blood Collection - n = 1034		% Reduction in Error	p
		No of Errors	%	No of Errors	%		
Specimen quality	Clotted Samples	27	2.0%	0	0.0%	2.0 %	< 0.01
	Insufficient volume	05	0.4%	0	0.0%	0.4 %	< 0.05
WBC differential flags	Total specimens reflexed to slide	390	29.0%	110	10.7%	18.3 %	< 0.01
	False high	158	12.0%	61	6.0%	6.0 %	< 0.01
	False low	232	17.0%	49	4.7%	12.3 %	< 0.01
	Total specimens Reflexed to slide	301	22.0%	87	8.4%	13.6 %	< 0.01
Platelet Flags	False high	176	13.0%	41	4.0%	9.0 %	< 0.01
	False Low	125	9.0%	46	4.4%	4.6 %	< 0.01
	Blood Smeared Containers	40	3.0%	0	0.0%	3.0 %	< 0.01
HCW Safety	Blood spilled on requisition slips	86	6.0%	1	0.1%	5.9 %	< 0.01
	Blood spillage in laboratory	0	0.0%	0	0.0%	NA	NA

Table 2. Impact of Specimen Collection Methodology on Preanalytical Errors in Haematology Department

Parameters	Ashavaid et al. ⁷		Ashavaid et al. ⁶		Present Study	
	Open Collection	Closed Collection	Open Collection	Closed Collection	Open Collection	Closed Collection
Fibrin mass/ strands	0.36 %	0 %	---	---	15.4 %	8.2 %
Haemolysis	16.4%	0.06%	---	---	7.2 %	0 %
Insufficient volume to perform test	6.64 %	0.0 %	---	---	6.4%	0 %
Clotted samples	---	---	1.52 %	0.0 %	2.0 %	0.0 %

Table 3. Specimen Quality Errors with Open vs Closed Blood Collection - Literature Review

Parameters	Ashavaid et al. ⁷		Ashavaid et al. ⁶		Present Study	
	Open Collection	Closed Collection	Open Collection	Closed Collection	Open Collection	Closed Collection
Blood smeared containers	---	---	0.19%	0.0%	9.3 %	0.0 %
Blood spilled on requisition slips	---	---	---	---	13.4 %	0.1 %
Blood spillage in laboratory	1.01 %	0.02 %	---	---	0.4 %	0.0 %

Table 4. Risk of Contamination with Open vs Closed Blood Collection - Literature Review

DISCUSSION

As shown in the above tables, all specimen quality and HCW safety indicators in haematology and biochemistry improved significantly with closed collection system.

Fibrin Strands/Mass

In the present study, we observed an incidence of post-centrifugation fibrin in 15.4 % specimens (fibrin mass 7.5%, strand 7.9 %) collected in open collection system and the same was reduced to 8.2 % (p value < 0.01) in closed blood collection system. This was consistent with the study conducted by Ashavaid et al.⁷ (Table 3). Residual fibrin, long recognized as a possible interferent in the clinical laboratory, may be present because of improper mixing with clot activator or inadequate clotting time before centrifugation. It can be present either as a visible clot, which may physically occlude the instrument sampling probe or, more insidiously, as an invisible microfiber or as strand. Fibrin strands may directly affect some assays, especially immunoassays.⁸⁻¹¹ Presence of latent fibrin in serum poses a risk of blocking analyser probe resulting in probe maintenance/replacement, and system breakdown, all of which were estimated to carry significant economic cost for the laboratory.¹² It is thus important to mix the serum samples well and allow adequate clotting time. On the other hand, most of the hospital labs are faced with a challenge to provide results faster and often analytical quality gets sacrificed for a faster TAT. Despite installing high end automation and tracks, clotting time becomes the rate limiting step for most of the serum-based tests. While gel-based serum separator tubes offer faster clotting time, STAT or emergency tests may require an even faster TAT. In such situations, plasma specimen or a thrombin based rapid serum tubes (RST), may offer a better solution by reducing sample processing time.¹³

Haemolysis

The incidence of haemolysis was 7.2 % in open collection system and the same was reduced to 0.0 % ($p < 0.01$) in closed blood collection system. This was consistent with the study done by Ashavaid et al.⁶ (Table 3). Haemolysis could arise, whenever there is trauma to relatively fragile red blood cells, either during collection or after phlebotomy is completed. The common procedural errors that can cause haemolysis are forceful aspiration of the blood during syringe draw, injecting blood into the container using pressure, use of too small or too large bore needle, application of tourniquet for more than a minute, mixing additive tubes vigorously, rough handling during transport and frothing of blood caused by improper fit of the needle on a syringe.¹⁴ Furthermore, haemolysis also affects various chemical parameters such as potassium, creatine kinase due to the efflux of intracellular constituents and affects the test results.⁷ Since, haemolysis is the major risk factor for the inaccurate test results and the incidence is higher in open collection system, it is advisable to go for closed blood collection system.

Volume Related Issues

It was observed that 5.9% of biochemistry samples and 0.4 % of haematology samples had insufficient volume to perform one or more analysis in case of open collection method. In such instances, either specimen was redrawn, or the report was released with comment. As compared to the open collection system, the incidence of insufficient volume was reduced to 0.0 % (p value < 0.01) in closed blood collection system. This was consistent with other study done by Ashavaid et al.⁷ (Table 3). Underfilling or overfilling of tubes during open collection system can be an outcome of low volume draw because of selecting a wrong/difficult vein or a smaller syringe as well as due to the prejudices of the phlebotomist who believes certain tests can be performed with a very low volume of blood. It is important to point that adequacy of blood to additive ratio is important not just for sample quality but also for result accuracy. As an example, samples collected in overfilled EDTA tubes may clot faster whereas underfilled EDTA tubes may impact cell morphology and shrink RBCs which leads to decrease of mean corpuscular volume (MCV) and haematocrit values.^{15,16,17} This important factor is taken care by closed collection system by virtue of predetermined vacuum in the tubes which ensures adequate blood to additive ratio is maintained in each specimen.

Clotted Samples

The incidence of clotted specimens was 2.0 % in open collection system and the same was reduced to 0.0 % (p value < 0.01) in closed blood collection system. This was consistent with the other study done by Ashavaid et al.⁶ (Table 3). The presence of clots in EDTA samples can be explained primarily due to overfilling or improper mixing of the sample after syringe transfer. This could pose a major risk of erroneous results and analyser breakdown.⁶

Report Released with Comment

Under ideal circumstances, a specimen with a known preanalytical error should not be processed. However, in our

lab with high sample volume and limited resources, it has proven to be difficult to reject the samples and request for repeat collection. Hence, the sample with concerns are tested but reported with riders mentioned in the comment. With the improvement in specimen quality, the incidence of "reports released with comments" was reduced significantly (p value < 0.01) in closed collection which is reassuring to the lab as well as the clinician.

WBC Differential Flags

In general, the change in cell morphology could impact the ability of the cell counter to report/separate different populations of cells and hence raise a flag that indicates the same. This requires the laboratory to either report differential count using microscopy which increases the TAT. We observed that 29 % of samples collected using an open method raised a differential flag, whereas the incidence of differential flag generation in case of closed collection was 10.7 %. The data clearly demonstrated that closed collection resulted in lower incidence of differential flagging. As described in the literature, decrease in WBC count not related to agglutination has been reported in samples containing excess of K3-EDTA (but not K2-EDTA) anticoagulant, resulting from insufficient blood drawn after venepuncture.¹⁸ This was consistent with our study results since 17.0 % specimens showed false low WBC count in open collection system (k3 EDTA) when compared with closed collection system (4.7 %). Also, the analyser can give pseudoleukocytosis secondary to large platelet aggregates as these can mimic the size of WBC which could be the reason of the flags with closed collection system.¹⁹

Platelet Flags

Our study showed a high incidence of platelet flagging by analyser with open collection system (22 %) which was reflexed to slide for manual verification. The incidence of platelet flagging was reduced significantly (8.4 %, p value < 0.01) with closed collection system. As described in the literature, K3 EDTA alters the platelet shape from discoid to spherical there by increasing the mean platelet volume (giant platelets). These giant platelets tend to be counted as either RBC or WBC by the analyser.²⁰ This results in false low platelet count by the analyser which have to be verified manually there by increasing the TAT despite installing a high end five-part analyser. This was consistent with the present study, where we observed a high incidence of false low platelet count (9.0 %) because of platelet clumps in open collection and the same was reduced significantly with closed collection system (p value < 0.01).

Health Care Worker Safety

According to world health organisation, approximately two million HCW are exposed to blood borne pathogens per year.²¹ Laboratory workers are exposed to a wide range of hazards during collection and analysis of patient specimens. Procedures such as phlebotomy are considered as high-risk procedures due to a high probability of needle stick injury (NSI) which increase the likelihood of infection with human immunodeficiency virus (HIV) and hepatitis C virus (HCV).²²

Syringe collections pose a great risk of NSI as well as contamination of requisitions and tube exteriors during the transfer of specimen from syringe to tube and during transportation. Blood-stained requisitions and tubes can be cause of transfer of infections when pathogens are shed in blood and contact transfer is an important route of transmission example of Covid-19.²³

In present study, the incidence of blood exposure (blood smeared containers, blood spilled on request slips, blood spillage in laboratory) to HCW was 23.1 % in open collection system and the same was reduced to 0.1 % ($p < 0.01$) with closed blood collection system. This was consistent with the study done by Ashavaid et al.^{6,7} (Table 4). Closed collection systems, by virtue of direct transfer of blood from vein to tube, protect the HCWs against risk of NSI and contact transfer of infections.

CONCLUSIONS

This study once again establishes that open collection systems are associated with a high incidence of preanalytical errors leading to probe blockage, inaccurate results, repeat samples, test cancellations and impaired workflow efficiencies despite a high level of automation. Such limitations can impact the adequacy and timeliness of treatment especially during situations of health care overload like infectious outbreaks (e.g.: Dengue, Covid-19) where the benefits of automation i.e., improved TAT and accuracy are most essential. Based on the observations in this study, it is evident that the use of an evacuated closed collection system for venous blood collection improved the sample quality, workflow efficiency and decreased the potential exposure of HCW to blood and blood borne pathogens. It also reinforces the need and urgency to shift to closed collection system in the face of the ongoing pandemic to ensure HCWs are protected enough to provide health care to others.

Conflict of Interest

The study was designed and conducted by the faculty of Government Medical College, Kottayam. The materials for the closed collection procedures were provided by Becton Dickinson India Pvt. Ltd.

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