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Laboratory Specimen Rejection in Affecting **Quality of Patient Care in Healthcare Services:** A Retrospective Cohort Study in Hospital **Bentong**

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ABSTRACT

Background: Pre-Analytical errors during blood specimen taking & specimen handling may cause specimen rejection at laboratory. A specimen that is judged by the pathology department as not fit for Laboratory analysis should be rejected & resampling should be taken. Rejection of specimen may affect the overall quality of healthcare services as the rejection will delay patient treatment, increase in cost & increase workload of healthcare workers of both laboratory & non laboratory personnel.

Aim & Objectives: This study was conducted to analyze the various factors contributing to sample rejection & the impact in patient care in Hospital Bentong.

Materials & Methods: The data & cause of the rejected samples from January – December 2022 were extracted from Laboratory Information System (LIS, Chemolims) which is integrated to Hospital Information System (HIS, Sistem Pengurusan Pesakit).

Conclusion: Rate of laboratory rejection sample was increasing in trend in year 2022. Rejection due to clots & hemolysis were the major causes identified where 44.81 % & 36.24 % respectively among the total rejected sample in Hospital Bentong.

Keywords: Specimen rejection, Pre analytical & Patient Care

1.0 **INTRODUCTION**

Quality of care in clinical laboratory is essential in providing results with optimum accuracy for patient management by clinicians & physicians. The laboratory contributes 80% of the objective data in the clinical record and influences 60% - 70% of critical decision-making in-patient management such as admission, therapy & discharge.¹ Thus, it is crucial to have a Standard Operating Procedure on Specimen Acceptance Criteria in Laboratory to ensure only quality specimens accepted for analysis as a Patient Safety necessity. According to Core Procedure Laboratory of Hospital Bentong, there are six Rejection Criteria & all these six criteria are updated in Laboratory Information System as the reason for rejection to be chose by Medical Laboratory Technologist upon rejection in system. The standard Rejection Rate according to Malaysian Standards for Quality in Hospitals (MSQH) is less than 1 %.

Sample Lysis, Specimen clots, Lipemic, Wrong Barcode, Wrong Vacutainer & Insufficient sample are the six listed rejection criteria in LIS of Hospital Bentong. Hemolysis is conventionally defined as rupturing of red blood cell which may cause the release of hemoglobin and other intracellular components of



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erythrocytes into the extracellular space of blood.² In vitro hemolysis contributes biological interferences such as elevated potassium in serum.³ Potassium concentrations due to in vitro hemolysis are clinically inaccurate while the magnitude of which depends on the degree of hemolysis.⁴ In vivo hemolysis is due to patient factor where the reported serum potassium is accurate & rejecting this sample is malpractice.⁵ Errors associated from clinical laboratory have a great impact on patient safety where the errors may mislead clinicians in patients monitoring & care. The medical laboratory is known as growing further where laboratory increasingly integrated with patient care, facilitating patient diagnosis assisting diagnosis and predicting clinical outcomes.⁶ Specimen rejections result in longer laboratory turnaround times (LTAT) due to repeating the whole process of blood taking. Longer LTAT may lead to delay in providing optimal treatment to patient as Clinicians depends on some of the laboratory investigations to reach to a diagnosis. Delay in Critical investigation such as patients underlying hypokalaemia/hyponatraemia may cause increase in rate of mortality if not address immediately. Rejection of specimen cause delay in blood test result which is important to detect any abnormalities which requires correction or escalation of therapy especially in ill patients. Timely laboratory investigation aid in making right decision in ruling in & ruling out concept as the most specific aid in rule in diagnosis while the most sensitive test aid in rule out in diagnosis.⁷

Rejection of sample increases costs due to repeating of the samples causes repeated use of consumables⁷. The cost of consumables inclusive of vacutainers, syringe, needle, alcohol swab, cotton, plaster, & barcode. Retesting of Laboratory sample increases the cost. In five years from 2018 - 2022, 10 952 samples were rejected in entire Hospital Bentong which is equivalent to wastage of RM 54 760.00.

Specimen Rejection causes an unpleasant situation between laboratory & medical staffs where the medical staffs need to redo the whole process of blood taking from registering of the laboratory request, venepuncture & sending the sample again to Laboratory while Laboratory staff need to record all the process of rejection in LIS.⁸ The proses of rejection is includes notifying respective departments regarding the reason for rejection, record to whom the rejection being notified & who notify the rejection in LIS for audit trail purposes. Not forgetting the patients' side of annoying where re-drawing of blood from a patient is uncomfortable, and complications such as hematoma and iatrogenic anaemia are potential risks.⁹

2.0 METHODOLOGY

This study was conducted at the Hospital Bentong, Malaysia which caters for patients from the local community and referral cases from public healthcare centres in Bentong Districts. Hospital Bentong has the capacity of a 152-bedded hospital, offering services in mainly General Medicine & Emergency services. Other services include general surgery, respiratory, primary care, paediatric, obstetrics and gynaecology & orthopaedic. Hospital Bentong provides diagnostic laboratories & blood banks services under one roof, which is known as Unit of Pathology & Transfusion Medicine. The laboratory operates 24 hours a day.

The inclusion criteria are all patients who required laboratory diagnosis while the exclusion criteria are patients' physiological factors & medical condition which may contribute to sample rejection. Every rejection will be notified to respective departments for recollecting of sample. The rejection details such as reason for rejection, time of rejection, to who rejection notified & who notified the rejection will be recorded in Laboratory Information System (LIS)

The sample rejection data was extracted from Laboratory Information System (LIS). The rejected samples were classified according six Rejection Criteria by departments. The extracted data was analysed by



Laboratory Quality Manager using Rejection rate calculation formula while the sigma values were calculated using online calculators. Descriptive statistics were done using Microsoft Excel. Rejection rate calculation formula as below:

Rejection Rate:

Total Sample received in Laboratory

X 100

Total Sample of Rejected

3.0 **RESULTS**

During the period of 1 year from January 2022 to December 2022, a total of 130 800 samples were received in laboratory. Out of these, 2227 samples were rejected. The monthly sample number, samples rejected, and the rejection rates are shown in Figure 2. The average percentage of rejection for the year 2022 was 1.70% (Table 1).

Table 1: Percentage Laboratory Specimen Rejection for the year 2022 in Hospital Bentong				
MONTH	NO OF SAMPLE	SAMPLE REJECTED	PERCENTAGE OF	
			REJECTION	
JAN	10597	151	1.42	
FEB	9444	132	1.40	
MAR	12113	179	1.48	
APR	10139	156	1.54	
MAY	10196	129	1.27	
JUNE	11504	169	1.47	
JUL	10963	205	1.87	
AUG	11111	206	1.85	
SEP	11463	213	1.86	
OCT	9954	206	2.07	
NOV	11248	258	2.29	
DIS	12068	223	1.84	
TOTAL	130800	2227	1.70	







The process of care which includes steps from blood taking until reporting of results is shown in Figure 2. According to process of care, there are two rejection phases where first phase of rejection occurs during screening of specimen upon receiving. Any defeats such as wrong barcode, wrong container, underfilled/overfilled samples, haemolysis & lipemic (after centrifugation), will get rejected during first phase of rejection. Second phase of rejection may occur during results verification prior to reporting. Any non-reliable results caused by contamination will be rejected in second phase of rejection. Sample registered as Short Turn Around Time (STAT) will be reported within 45 - 60 minutes upon receiving while for routine samples will take less than 4 hours for results reporting. Delayed in results reporting may occur if the sample get rejected in any phase of rejection



Figure 2: Process of Care of steps from blood taking until reporting of results

The major cause of sample rejection was found to be clotted samples (998) followed by hemolysis (807). Two hundred nineteen undefiled samples were sent to lab for analysis. One hundred twenty-five samples were wrongly labelled. For 78 samples were send in wrong vacutainers & no lipemic samples found in year 2022.



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Figure 3: Frequency of causes of sample rejection

Routine samples are the most rejected sample in Hospital Bentong. Total of 1453 routine sample & 142 urgent samples were rejected in year 2022 while 655 sample category was not stated by Hospital Information System.



Figure 4: Rate of sample rejection according to urgent & routine sample



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4.0 **DISUSSION**

Accurate & timely laboratory results are the main clinical laboratory quality objectives where Hospital Bentong fixed the standard of 80 % of Laboratory Turn Around Time (LTAT) for all the internally analysed routine test while 90% for urgently requested tests. LTAT measures from the time laboratory receives the specimen to the time the test result is reported. Monitoring of work process in all three phases in Total Testing Process (TTP) such as pre analytical, analytical & post analytical may control the errors & eventually could reduce the rejection rate.

Rejection of laboratory specimen been the area of concern as it could double up the cost due to repeating of the whole process as mentioned in Figure 2. Besides cost, rejection tremendously affects patient care due to delay in getting laboratory results. Delayed laboratory results eventually causing delay in reviewing results by medical practitioners which may further contribute longer hospital stay.¹⁰ Untimely laboratory results tremendously affect patients in critical condition due to delay critical value notification from laboratory.

Rejection also increases the workload of the healthcare workers. At the same time causes inconvenience to patients where need to prick for second time or even more in some cases. This may lead to hematoma in certain patients.⁹ Multiple venipunctures on a patient due to sample rejection may cause distrust of patient on healthcare services.

The maximum number of rejections in Hospital Bentong is caused by clots presence in the sample. Specimen clots are due to improper mixing of the sample according vacutainer manufacturer's claim. Rejection of sample due to blood clots is preventable if the collected blood immediately inverted following manufacturer's claim to ensure the anticoagulant presence in the vacutainer dissolves fully in the blood.¹¹ Visible clots in blood sample may get rejected while presence of micro clots is very difficult to identified. The micro clots presence in the sample may affect the integrity of the sample as the accuracy of the results is questionable.¹¹ Besides that, micro clots also will cause damage to analyser as it blocks the pathway & probe in the analyser.¹¹ Malfunction of the analyser or unplanned analyser downtime may cause service interruption which eventually affects patient care.

In vitro hemolysis of the sample was the second leading cause of rejection in Hospital Bentong. Hemolysis mainly caused by improper techniques in blood taking & also associates with skill of the phlebotomist. Thus, the rejection caused by in vitro hemolysis is remediable. Excessive shaking of the sample after the blood collection process, improper techniques in handling syringe such as pulling or pushing of the plunger during blood taking may cause rupturing of red blood cell.¹² The other causes of sample rejection in Hospital Bentong are insufficient sample, wrong barcode & wrong use of vacutainers. These cause of rejections due to negligence of healthcare worker at workplace.

Limitation

This study was based on a single district healthcare centre from government sector in Pahang State of Malaysia. A multi district healthcare centre study will provide a wide range of judgement in improving rejection rates in district hospital settings.

5.0 CONCLUSION

The average rejection rate of Hospital Bentong is 1.70%. The laboratory samples were rejected on fixed rejection criteria where clotted sample & hemolysis were the main contributing factor of rejection.



Analysis of the rejection data indicates that the rate of rejection could be reduced by adherence to pre analytical procedures, a strong remedial interventions & a team of committed operators.

6.0 ACKNOWLEDGEMENT

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TABLES & FIGURES

Table 1: Percentage Laboratory Specimen Rejection for the year 2022 in Hospital Bentong

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SEP	11463	213	1.86
OCT	9954	206	2.07
NOV	11248	258	2.29
DIS	12068	223	1.84
TOTAL	130800	2227	1.70



Figure 1: Total number of monthly samples received, samples rejected, and the percentage of monthly sample rejection for the year 2020



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Figure 2: Process of Care of steps from blood taking until reporting of results







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Figure 4: Rate of sample rejection according to urgent & routine sample