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Validation of the Blood Product Transportation Process with a Stable Temperature of 2-10ºC

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ABSTRACT

Introduction: Blood and blood products play an essential role in health care. Availability, security, and easy access to blood and blood products must be guaranteed. The quality of blood and blood components depends on the starting materials, packaging materials, processing, quality control systems, premises, equipment, and facilities used, and personnel involved, including the cool box's internal temperature. This study aimed to evaluate the validation of the blood product transport process with a stable temperature of 2-10ºC.

Methods: This semi-experimental descriptive study was conducted from 12 October to 28 December 2021 at the Blood Donation Unit, Indonesian Red Cross, Bandung City, and affiliated hospitals. Blood products were transported using cold boxes with ice packs, tested under varying distances and capacities, each repeated three times. Temperatures were recorded and compared against the 2–10°C regulatory standard. Validation included documentation, measurement, and reporting, with data analyzed descriptively.

Results: Based on data collection and analysis, all sample temperature measurements remained within the acceptable range of 2–10°C across all test configurations. The lowest recorded temperature was 3.8°C, and the highest was 6.3°C. These values were obtained across both minimum and maximum capacity settings, and during transport to both near and far destinations. Ambient room temperatures during testing ranged from 22.8°C to 28.0°C.

Conclusion: The temperature remained within the acceptable standard. Therefore, the validation of the blood product transportation process with a stable temperature of 2–10ºC was deemed valid.

Keywords: blood, validation, transportation
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INTRODUCTION

Blood transfusions in clinical practice are administered based on specific indications. They may involve various components, including whole blood, packed red cells (PRC), washed erythrocytes (WE), platelets, fresh frozen plasma (FFP), and cryoprecipitate. To ensure optimal therapeutic benefit for recipients, the storage, handling, and compatibility testing of blood products must be performed in strict accordance with established guidelines. The primary objectives of blood transfusion are to restore and maintain adequate circulating blood volume, correct deficiencies in cellular components, enhance tissue oxygenation, and support homeostatic functions.[1]

Blood transfusion is a medical procedure involving the transfer of blood or blood components from a donor to a recipient, often providing critical or even life-saving benefits. Blood and its derivatives play a vital role in healthcare delivery, making their availability, safety, and accessibility essential. In line with the resolution of the World Health Assembly on May 21, 2010, concerning the availability, safety, and quality of blood products, achieving self-sufficiency in the national supply and ensuring product safety are key objectives of health systems.[2] Therefore, this study aimed to evaluate the validation of the blood product transportation process, specifically assessing whether temperatures remained stable within the recommended 2–10ºC range.

METHODS

This semi-experimental study employed a descriptive design and was conducted by transporting blood products to various hospitals, followed by the collection and analysis of temperature data. The recorded transport temperatures were subsequently evaluated in accordance with the reference thresholds specified by the Indonesian Minister of Health Regulation No. 91 of 2015 on Blood Transfusion Service Standards.

The study took place at the Indonesian Red Cross (Palang Merah Indonesia, PMI) Blood Donation Unit in Bandung City, as well as in selected hospitals across Bandung and West Java, from 12 October to 28 December 2021. The samples included blood transport cold boxes and ice packs used for maintaining the required temperature. Cold boxes were categorized based on destination distance (nearest and furthest) and capacity (minimum and maximum load). Each configuration was tested in triplicate, and results were considered valid if the internal temperature during transport remained consistently between 2–10ºC.

The validation process comprised six key steps: (1) developing the validation flow,

(2) preparing supporting documentation, (3) establishing validation protocols, (4) scheduling the testing, (5) conducting data analysis, and (6) compiling a final validation report. All data were processed and analyzed using Microsoft Excel and presented in tabular and narrative formats. The temperature measurement design is illustrated in **Figure 1**.

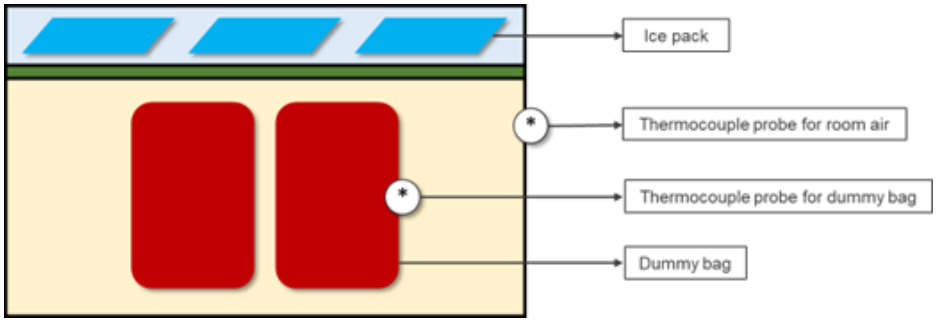

Figure 1. Temperature measurement design in the cool box

RESULTS

Based on data collection and analysis, all recorded transportation temperatures, whether for the nearest or furthest destinations, remained within the acceptable range of 2–10°C, as stipulated by the Indonesian Minister of Health Regulation No. 91 of 2015 on Blood Transfusion Service Standards. The lowest recorded temperature was 3.8°C, while the highest was 6.3°C. These findings indicate that the transportation process consistently met regulatory temperature requirements across all test conditions. Detailed temperature measurements are presented in **Table 1.**

Table 1. Cool box temperature measurement results

Sample code	Destination Distance	Cool box capacity	Highest average temperature	Average room temperature
A	Nearest	Minimum	4.3	27.2
		Maximum	4.4	27.2
	Furthest	Minimum	4.8	26.3
		Maximum	4.4	26.3
B	Nearest	Minimum	3.8	22.8
		Maximum	3.8	25.7
	Furthest	Minimum	6.2	22.8
		Maximum	6.2	25.7
C	Nearest	Minimum	6.1	24.5
		Maximum	5.5	23.6
	Furthest	Minimum	6.3	26.6
		Maximum	5.8	25.9
D	Nearest	Minimum	5.3	28.0
		Maximum	5.3	28.0
	Furthest	Minimum	4.6	25.2
		Maximum	4.7	25.2

DISCUSSION

This study reported that all transported blood samples remained within the optimal temperature range of 2–10°C, consistent with current international guidelines for the preservation of blood product viability. This finding aligned with previous studies demonstrating that rigorous cold chain maintenance, supported by validated containers and temperature monitoring, ensures the stability and clinical safety of blood components during transit.[3–5] Notably, Tiwari et al. (2015) emphasized the importance of irreversible temperature indicators in confirming uninterrupted cold chain integrity, while Aalaei et al. (2014) highlighted that up to 12% of transports without real-time monitoring exhibited temperature deviations.[6,7]

In contrast, a cross-sectional study by Aalaei et al. (2019), which continuously monitored 100 red blood cell (RBC) units using embedded temperature sensors during real-world transport and storage, revealed that 10% of the 121,262 recorded temperature data points exceeded the acceptable temperature thresholds of 1–6°C for storage and 1–10°C for transport. Notably, 65% of these temperature deviations occurred during storage in the blood bank itself, highlighting that breaches in the cold chain are not limited to transit, but may originate at the point of dispatch. Additional violations were observed in the operating room (17.3%), during transportation (12.6%), and in the intensive care unit (5.3%). Recorded temperatures ranged from as low as 0°C to as high as 19.5°C, surpassing safety limits and placing blood product integrity at risk. These findings underscore systemic vulnerabilities in temperature regulation across multiple stages of the transfusion chain. The study also emphasized that conventional visual assessments by personnel often fail to detect thermal excursions, advocating for continuous temperature monitoring devices to mitigate unnoticed degradation and potential clinical harm.[8]

Validating blood transportation processes is crucial because temperature instability can lead to a cascade of adverse effects, including biochemical degradation and severe clinical complications. Elevated temperatures accelerate hemolysis, ATP depletion, and denaturation of coagulation factors such as Factor V and VIII, while sub-thermic exposures increase the risk of cryohemolysis.[9,10] These alterations compromise the functional integrity and therapeutic efficacy of blood products, often resulting in increased transfusion demands and elevated healthcare costs.[11–13] Moreover, temperature excursions can facilitate bacterial proliferation

(*Escherichia coli* and *Staphylococcus aureus*), significantly heightening the risk of transfusion-transmitted infections and potentially life-threatening sepsis, especially in platelet concentrates stored at room temperature.[14]

Several contemporary methods and technologies have been proposed to strengthen validation processes. For example, closed insulation systems and portable containers like the Golden Hour Box (GHB) have demonstrated efficacy in maintaining target temperatures for up to 100 hours, even in extreme environmental conditions.[5] Similarly, temperature-sensitive indicators also provide visual confirmation of cumulative thermal exposure. Advancements in sensor technology, such as dual-mode resonant labels and microfluidic temperature-triggered frequency shifts, have further increased the precision and sensitivity of transport validation. More recently, predictive analytics using machine learning algorithms have been developed to anticipate temperature excursions based on route data and environmental inputs, enabling preemptive mitigation through early-warning systems.[4,13,15]

Despite technological advances, challenges persist in implementing universal standards across diverse settings, especially in remote or resource-limited regions, which often rely on iceless containers and extended-duration insulation strategies to compensate for harsh or unpredictable environmental exposures.[8]

CONCLUSION

The validation of the blood product transportation process at the Indonesian Red Cross of Bandung City was found to be valid and in full compliance with the requirements set forth in the Minister of Health Regulation No. 91 of 2015 concerning Blood Transfusion Service Standards. As all temperature measurements remained within the acceptable range, no revalidation is required. Therefore, the existing standard operating procedures for blood transportation may continue to be applied effectively within the Bandung City healthcare system.

DISCLOSURES

FUNDING

The author is responsible for all of the study funding by ultimately using personal funding without a grant or any external funding sources.

CONFLICT OF INTEREST

The author has no conflict of interest.

AUTHOR CONTRIBUTION

The author was responsible for the conceptualization of the study, data acquisition, data analysis, statistical interpretation, manuscript drafting, critical revision, and preparation of the final version for publication.

ETHICAL CONSIDERATIONS

Ethical approval was obtained from the Health Research Ethics Committee.

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REFERENCES

1. Wahidiyat PA, Adnani NB. Transfusi Rasional pada Anak. Sari Pediatr. 2017;18(4):325. doi: 10.14238/sp18.4.2016.325-31
2. The National Institute for Health and Care Excellence (NICE). Blood Transfusion Guideline. Natl Inst Heal Care Excell Guidel 2015. Available from: www.nice.org.uk/guidance/NG24
3. Harris JC, Crookston KP. Blood Product Safety. In Treasure Island (FL), 2025. PMID: 30969648
4. Youn DY, Jung U, Naqi M, Choi SJ, Lee MG, Lee S, et al. Wireless Real-Time Temperature Monitoring of Blood Packages: Silver Nanowire-Embedded Flexible Temperature Sensors. ACS Appl Mater Interfaces. 2018 Dec;10(51):44678–85. doi: 10.1021/acsami.8b11928
5. Vuong A, Derkenne C, Travers S, Javaudin O, Clavier B, Martinaud C, et al. Performance of far forward iceless blood storage containers in controlled cold environments. Transfusion. 2024 May;64 Suppl 2:S50–7. doi: 10.1111/trf.17745
6. Aalaei S, Amini S, Keramati MR, Shahraki H, Abu-Hanna A, Eslami S. Blood bag temperature monitoring system. Stud Health Technol Inform. 2014;205:730–4. PMID: 25160283
7. Tiwari AK, Sharma P, Pandey PK, Rawat GS, Dixit S, Raina V, et al. A cost effective model for appropriate administration of red cell units and salvaging un-transfused red cell units by using temperature sensitive indicators for blood component transportation in a hospital setting. Asian J Transfus Sci. 2015;9(1):36–40. doi: 10.4103/0973-6247.150948
8. Aalaei S, Amini S, Keramati MR, Shahraki H, Eslami S. Monitoring of Storage and Transportation Temperature Conditions in Red Blood Cell Units: A Cross-Sectional Study. Indian J Hematol Blood Transfus [Internet]. 2019;35(2):304–12. doi: 10.1007/s12288-018-1038-6
9. Nakanishi R, Sakayori T, Matsui D, Kono M, Maki M, Dunois C, et al. Effects of storage time and temperature on coagulation factor and natural anticoagulant activities in healthy individuals. Sci Rep. 2025;15(1):1–7. doi: 10.1038/s41598-025-95389-w
10. Blaine KP, Cortés-Puch I, Sun J, Wang D, Solomon SB, Feng J, et al. Impact of different standard red blood cell storage temperatures on human and canine RBC hemolysis and chromium survival. Transfusion. 2019 Jan;59(1):347–58. doi: 10.1111/trf.14997
11. Poder TG, Nonkani WG, Tsakeu Leponkouo É. Blood Warming and Hemolysis: A Systematic Review With Meta-Analysis. Transfus Med Rev. 2015 Jul;29(3):172–80. doi: 10.1016/j.tmrv.2015.03.002
12. Kalsi KK, González-Alonso J. Temperature-dependent release of ATP from human erythrocytes: mechanism for the control of local tissue perfusion. Exp Physiol. 2012 Mar;97(3):419–32. doi: 10.1113/expphysiol..2011.064238
13. Palela M, Giol ED, Amzuta A, Ologu OG, Stan RC. Fever temperatures impair hemolysis caused by strains of Escherichia coli and Staphylococcus aureus. Heliyon. 2022 Feb;8(2):e08958. doi: 10.1016/j.heliyon.2022.e08958
14. Haesebaert J, Bénet T, Michallet M, Vanhems P. Septic shock during platelet transfusion in a patient with acute myeloid leukaemia. BMJ Case Rep. 2013 Oct;2013. doi: 10.1136/bcr-2013-010412
15. Chan YJ, Anwar N, Reuel NF. Cold and ultra-cold chain integrity monitoring via embedded resonant sensor indicators. Sensors Actuators A Phys [Internet]. 2024;372:115346. Available from: https://www.sciencedirect.com/science/article/pii/S092442472400339X