ORGANIZATION AND QUALITY SYSTEMS IN TRANSFUSION MEDICINE

Original article

Assessing operational readiness for plasma fractionation within Indonesia's National Transfusion Medicine System: a cross-sectional mixed-methods study

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Background - Plasma-derived medicinal products (PDMPs) such as albumin, immunoglobulins, and clotting factors are essential in treating life-threatening conditions. Indonesia lacks local plasma fractionation capacity and relies heavily on imports, leading to high costs and financial strain on the National Health Insurance. Developing national plasma production capacity is vital for pharmaceutical independence and health system resilience.
This study assessed the readiness of regional blood centers and hospital blood center in Indonesia as potential suppliers of plasma raw material for domestic PDMP production and identified logistical and governance challenges in the existing system.

Materials and methods - A cross-sectional mixed-methods study was conducted in five institutions –four regional blood centers and one hospital blood center– across Java. Readiness was evaluated across three domains: preparation, inventory, and transportation. Instruments were adapted from WHO, LIAT, and LSAT guidelines, with expert-validated content. Content validity was ensured through expert panel review involving WHO and national regulatory representatives, and reliability was measured using the Kuder-Richardson Formula 20 (KR-20). Quantitative data were analyzed descriptively using Kruskal-Wallis and Dunn's tests, while qualitative data were thematically analyzed.

Results - The overall KR-20 was 0.821, indicating strong reliability (Preparation=0.801; Inventory=1.00; Transportation=0.856). No significant inter-institutional differences were observed (p=0.406), suggesting uniformly high readiness. Bias testing confirmed consistent scoring patterns.

Discussion - This study provides a structured baseline assessment of Indonesia's readiness to support domestic PDMP production, revealing strong preparedness across key operational domains. While readiness does not yet translate to full production capacity, these findings establish an evidence-based foundation for future implementation, investment planning, and governance reforms toward a sustainable and transparent plasma supply chain.

Keywords: *plasma-derived medicinal products, blood centers, supply chain readiness, plasma fractionation, Indonesia.*

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INTRODUCTION

Plasma fractionation is a fundamental biopharmaceutical process that enables the production of plasma-derived medicinal products (PDMPs), such as albumin, immunoglobulins, and coagulation factors[1]. Many PDMPs are included in the World Health Organization (WHO) Model List of Essential Medicines, and PDMPs are widely regarded as critical for treating life-threatening conditions[2-4]. Establishing domestic fractionation capacity ensures that donated plasma can be transformed into high-value therapeutic products, thereby strengthening national health security and ensuring continuous access to critical biologics[5].

Globally, many countries have advanced toward PDMP strategic autonomy as part of broader health security and pharmaceutical independence strategies. Successful models in the USA, Europe, and Asia demonstrate that developing local fractionation capability not only stabilizes supply chains but also reduces long-term healthcare expenditure[6]. However, low- and middle-income countries (LMICs) still face significant challenges related to the supply and ability to produce PDMP, particularly Indonesia. Building on these experiences, Indonesia faces both an urgent need and a strategic opportunity to develop its own plasma fractionation capacity, aligning with the global movement toward sustainable access to essential biologics[7,8].

In Indonesia, the demand for PDMPs has increased sharply alongside the expansion of the National Health Insurance program, which now covers over 200 million citizens[9]. The growing number of patients requiring chronic and high-cost therapies –particularly immunoglobulins and albumin– has increased the national need for plasma-based treatments[9,10]. In response, substantial efforts have been undertaken in recent years to strengthen regulatory frameworks and harmonize plasma collection, storage, and quality assurance procedures, led by the Ministry of Health in collaboration with the Indonesian Red Cross (PMI) –an organization that manages the national and regional blood center– and the Indonesian Food and Drugs Administration (BPOM)[11-14]. As part of these initiatives, Indonesia has also initiated international collaboration to support interim plasma processing capacity. Under this program, plasma collected in Indonesia has been exported to a fractionation facility in Andong, Republic of Korea, for processing into PDMPs. Launched in 2023, this initiative represents the first instance in which plasma donated by Indonesian citizens has been processed overseas to support a more stable national supply of plasma-derived therapeutics while domestic production capacity is being developed[15]. Nevertheless, despite these advances, Indonesia remains fully dependent on imported PDMPs due to the absence of local plasma fractionation facilities, ongoing limitations in cold-chain scalability, and persistent challenges in cross-sectoral governance integration.

Before establishing a national plasma fractionation facility, it is crucial to evaluate the readiness of upstream plasma suppliers –the regional and hospital blood centers– that underpin Indonesia's transfusion medicine system. Despite a well-established blood network, no standardized instrument currently exists to assess institutional preparedness for PDMP production. To address this gap, this study introduces a structured readiness assessment tool covering three operational domains: preparation, inventory management, and transportation. The findings are expected to reveal logistical, governance, and technical challenges, providing evidence to guide national policy and strategic investment toward a sustainable and integrated PDMP supply chain.

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MATERIALS AND METHODS

Study design

This study represents a baseline cross-sectional mixed-methods assessment designed to evaluate institutional readiness prior to any implementation or pilot-scale plasma fractionation activities. The approach integrates quantitative survey data and qualitative interviews to capture both measurable indicators and contextual insights. The study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional research, ensuring methodological transparency and reproducibility[16]. Rather than measuring the outcomes of a fractionation program, this research focuses on the upstream readiness of institutions, providing the foundational evidence necessary for future implementation planning.

Setting

The study was conducted in five health institutions across Java, Indonesia, comprising four regional blood centers

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and one hospital blood center (this facility has similar role as plasma collector). These sites were purposively selected to represent operational heterogeneity across different service capacities, catchment areas, and institutional types. This design aimed to capture readiness diversity within existing infrastructure rather than to generalize findings to all national facilities. The selected sites thus serve as a representative microcosm of Indonesia's broader blood system, informing upstream readiness for PDMP production.

Data source and data collection

Primary data were collected to capture current operational practices and institutional conditions related to plasma handling within Indonesia's transfusion medicine system. The data were collected through structured surveys and in-depth interviews (*Online Supplementary* **Table SI**). Secondary data were collected to contextualize primary findings within existing regulatory, technical, and governance frameworks. The data were obtained from government regulations[17], WHO technical documents of human plasma for fractionation[18-19], and pharmaceutical industry reports on plasma fractionation and blood system governance[20].

The survey instrument was structured around three readiness domains: 1) Preparation domain (Pre): infrastructure readiness, documentation, and staff competence; 2) Inventory domain (Inv): storage, temperature conditions –20 or –30°C, monitoring, and inventory control; and 3) Transportation domain (Trans): cold chain logistics, traceability, and transport validation. Survey items were adapted from WHO guidelines[18,21-23], the Logistics Indicators Assessment Tool (LIAT)[24], and the Logistics System Assessment Tool (LSAT)[25], ensuring conceptual alignment with international benchmarks. The instrument's content validity was evaluated through an expert panel comprising representatives from WHO, the Indonesian FDA, and the National Blood Center. Their review ensured that each item was contextually appropriate, comprehensive, and relevant to Indonesia's regulatory environment.

Participants

Purposive sampling was applied to identify institutions actively engaged in plasma collection, storage, and distribution, all of which had established quality management systems. A total of seven operational managers participated, with one to two respondents from each institution, representing supervisory roles in plasma processing and logistics.

Variables

The independent variables consisted of readiness indicators categorized under the three operational domains (Preparation, Inventory, and Transportation). The dependent variable was the institutional readiness score, calculated as the total sum of affirmative ("Yes"=1, "No"=0) responses across all items within a given domain.

Bias control

To minimize potential sources of bias, several methodological safeguards were applied throughout the study. Instrument bias was mitigated through expert validation, involving representatives from the WHO, the Indonesian FDA, and the national blood center, who reviewed each survey item for clarity, relevance, and comprehensiveness. Information bias was reduced through triangulation between survey responses, institutional documentation, and interview data, ensuring internal consistency and data accuracy. Selection bias was minimized by purposively including only institutions with established plasma collection and quality management systems, thereby maintaining contextual comparability across sites. Analytical bias was further addressed by performing Kruskal-Wallis tests across domains to identify potential inter-institutional variations that might indicate scoring inconsistency. Additionally, interpretive bias was minimized by implementing inter-rater reliability checks during qualitative coding to ensure objectivity in data interpretation. Although no pilot fractionation was performed, this baseline assessment provides the necessary methodological foundation for future implementation studies by identifying structural and logistical constraints that could influence operational feasibility.

Data analysis

Quantitative data were analyzed using descriptive statistics. Reliability was evaluated with the Kuder-Richardson Formula 20 (KR-20)[26-28], and construct validity was assessed through expert review involving representatives from WHO, Indonesian FDA, and the national blood center, ensuring that each survey item was conceptually relevant, clear, and representative of its

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Table I - *Study characteristics*

No.	Location/ Institution	Facility type	Type of Blood Center[17]	Storage facility	Quality management system	Research activities related to PDMP	Participant (No.)	Note
1	Organization 1	Regional Blood Center	B	Freezer ≤ –30°C, data logger	ISO 9001, MoH accreditation	Supply chain research, operational cost	2	Regional distribution center
2	Organization 2	Regional Blood Center	B	Freezer ≤ –20°C	Blood center internal procedure	Cold chain evaluation	1	Human resources challenges
3	Organization 3	Regional Blood Center	B	Freezer ≤ –20°C	Blood center internal procedure	Logistic mapping	1	Solid transportation access
4	Organization 4	National Blood Center	A	Freezer ≤ –30°C, temperature alarm	ISO 9001	Plasma processing research	2	Near airport
5	Organization 5	Hospital Blood Center	A	Freezer ≤ –30°C, limited capacity	Hospital accreditation	Internal supply clinical trials	1	Focuses on clinical services

A: National scale; B: Regional scale

domain. The KR-20 score ranges between 0 and 1, with the highest score being more reliable.

Comparative analysis among institutions was performed using the Kruskal-Wallis test, followed by Dunn's *post-hoc* test with Benjamini-Hochberg correction to adjust for multiple comparisons. A domain-level bias analysis was conducted using Kruskal-Wallis tests to examine inter-institutional consistency across readiness domains. Qualitative data were thematically coded and integrated with quantitative results to provide contextual interpretation of operational and policy implications. As this study serves as a pre-implementation diagnostic, no predictive or intervention modeling was performed, emphasizing descriptive readiness patterns rather than causal inference. All the statistical analyses were performed using RStudio.

RESULTS

Study characteristic

Five institutions have facilities that maintain plasma storage conditions consistent with WHO standards. Institutional details are summarized in **Table I**, showing capacity, accreditation, and infrastructure readiness. **Table II** summarizes the proportion of "Yes" responses for each institution across the three readiness domains. All institutions demonstrated full compliance in the preparation domain (100%), while minor variations were observed in the inventory and transportation domains.

Reliability and validity tests

The analysis showed that the KR-20 value for all items combined was 0.821 (**Table III**). At the domain level, the inventory (Inv) domain yielded a perfect KR-20 score

Table II - *Institutional compliance by domain*

Domain	Organization	Proportion (Yes)	Score	No.
Pre	bdrs1	100.0%	18	18
Pre	utd1	100.0%	18	18
Pre	utd2	100.0%	18	18
Pre	utd3	100.0%	18	18
Pre	utd4	100.0%	18	18
Inv	utd3	93.8%	15	16
Inv	utd4	87.5%	14	16
Inv	bdrs1	100.0%	16	16
Inv	utd1	100.0%	16	16
Inv	utd2	100.0%	16	16
Trans	bdrs1	93.8%	15	16
Trans	utd3	93.8%	15	16
Trans	utd1	62.5%	10	16
Trans	utd4	62.5%	10	16
Trans	utd2	56.2%	9	16

Bdrs: Hospital blood center; Inv: Inventory: Pre: Preparation; Trans: Transportation; utd: Regional blood center

Table III - *Reliability summary (KR-20)*

Threshold	Items_Kept	KR20_ALL
1.00	12	0.821
0.95	12	0.821

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of 1.00, although interpretation should be cautious as this domain consisted of only two items, limiting variability.

The transportation (Trans) domain demonstrated a KR-20 value of 0.856, reflecting good consistency across items (*Online Supplementary* **Table SII**).

Parallel analysis and Bartlett's test indicated that the dataset was not suitable for factor analysis, consistent with highly uniform dichotomous responses. As a result, construct validity was not estimated statistically. Instead, content validity established by an expert panel confirmed the adequacy of item formulation and domain coverage.

Readiness performance by domain

Across all domains, the majority of responses were affirmative ("Yes"), suggesting high institutional readiness for supplying plasma raw materials for fractionation. The *Preparation* domain emphasized compliance with standard operating procedures and staff competency. The *Inventory* domain showed full compliance in plasma storage monitoring and data logging. The *Transportation* domain reflected consistent implementation of cold-chain tracking and emergency protocols. Sample findings are detailed in **Table IV**.

Statistical analysis

The *Kruskal-Wallis test* indicated no statistically significant difference in total readiness scores across institutions (p=0.406) as presented in **Table V**.

Table V - *Significant and bias analysis per domain*

Domain	p-value	Statistic	Conclusion
Pre	-	-	-
Inv	0.406	4	No significant bias detected
Trans	0.406	4	No significant bias detected

Post-hoc Dunn's test with *Benjamini-Hochberg correction* confirmed that all pairwise comparisons yielded p>0.05 (*Online Supplementary* **Table SIII**).

These results indicate homogeneous readiness levels among facilities, suggesting that standardized operational practices have been effectively implemented across the national blood service network.

Bias testing per domain similarly revealed no significant inter-institutional variation, confirming consistent scoring patterns and minimal analytical bias in the dataset. This uniformity reinforces the conclusion that the observed readiness levels reflect true operational conditions rather than measurement items.

DISCUSSION

This study represents an initial, evidence-based effort to evaluate institutional readiness for plasma fractionation within Indonesia's blood supply network, applying a due diligence perspective across the domains of preparation, inventory, and transportation. The results show that regional and hospital blood centers exhibit uniformly high operational compliance with WHO standards on plasma storage, documentation, and staff competency.

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Table IV - *Interview results*

No.	Questions	Respondent answers	Domain LIAT/WHO	Verification proof	Notes
1	*Does the facility have a dedicated ≤ –20°C freezer for plasma storage?*	Yes	Storage conditions (LIAT); WHO TRS 941 Chapter 5	Direct observation; take pictures of the freezer and temperature label	Need to verify thermometer calibration and daily temperature records
2	*Is storage temperature monitored and recorded daily?*	Yes	Logistics management information systems; WHO PDMP Supply Guide Chapter 6	Temperature record sheet; data logger	Check the consistency of recording and the presence of temperature deviation alarms
3	*Is FIFO/FEFO system implemented in plasma management?*	Yes	Inventory management (LIAT); WHO TRS 941 Chapter 7	Stock rotation document	Confirmation by physical audit of inventory
4	*Are there procedures in place for handling cold chain failures?*	Yes	Distribution & storage (LIAT); WHO PDMP Transport Guide Chapter 4	Written SOP; incident report	Verification of emergency procedure simulation exercises
5	*Are there regular trainings for staffs regarding plasma storage and distribution?*	Yes	Human resources & training (LIAT); WHO Design Blood Centre	Training absence; certificate	Ensure the last training is <12 months

These findings indicate that Indonesia possesses a foundational infrastructure capable of supporting future domestic plasma fractionation, provided that governance integration, regulatory alignment, and targeted investment are pursued.

The reliability analysis exceeded the accepted threshold between 0.4-0.8 and indicating good internal consistency of the survey instrument[26-28]. However, exploratory factor analysis (EFA) could not be performed successfully due to the data structure violating statistical assumptions, specifically, the binary nature of items, limited sample size, and low variance across institutions, which resulted in a non-positive-definite correlation matrix[29,30]. Consequently, construct validity was primarily supported through content validity, evaluated by an expert panel. This process ensured that the instrument captured all relevant operational dimensions of plasma supply-chain readiness within the Indonesian context.

The statistical analysis further showed no significant differences in total readiness scores among institutions suggesting a homogeneous level of preparedness[31]. The non-significant Kruskal-Wallis and Dunn results indicate comparable readiness levels across institutions, reflecting systemic uniformity rather than data insensitivity. However, this homogeneity also limits discriminative power, suggesting the need for graded scales in future assessments. This homogeneity may reflect successful standardization of blood service operations under national regulations and WHO guidance. According to Davis (2010), homogeneity of variance assumes that populations being compared exhibit relatively similar variances rather than identical ones. Therefore, the absence of statistically significant differences ($p>0.05$) in readiness scores across institutions suggests relative homogeneity in preparedness levels. Moreover, the bias analysis per domain also revealed no significant inter-institutional variation, indicating consistent scoring patterns and minimal analytical bias in the dataset[32]. The absence of significant inter-institutional variation also implies that scoring consistency was maintained across sites, suggesting minimal analytical bias in the dataset. This aligns with Ioannidis' assertion that diminishing bias through rigorous methodological standards and consistent research practices can enhance the reliability of study findings. These findings strengthen confidence in the reliability and fairness of the assessment tool, implying that institutional performance differences are not driven by measurement bias but by genuinely comparable operational systems. Nonetheless, such homogeneity may also limit the discriminative power of the instrument, suggesting that future evaluations should incorporate graded or scaled response formats to detect subtler variations in readiness[33].

Compared with global experiences, countries such as Thailand and Egypt have shown that building a domestic plasma fractionation industry requires a phased approach, beginning with centralized plasma collection, toll fractionation agreements, and subsequent technology transfer[34]. Indonesia's context aligns with this model: a robust donor base and a functioning national blood centres offer strategic advantages. However, fragmented governance –distributed among local blood centers, Indonesian FDA, and the Ministry of Health– remains a key institutional challenge[35,36]. Strengthening interagency coordination, particularly in plasma standardization, donor qualification, and logistics regulation, is essential to enable a sustainable PDMP program integrated into the national transfusion system.

Economically, reducing dependency on imported PDMPs could significantly relieve the financial burden on the national health insurance system, which faces recurrent deficits due to the high cost of biologics used in chronic disease management[20]. Developing local plasma fractionation capacity would not only improve affordability and access but also enhance national health resilience by securing essential medicines during emergencies[37]. Nonetheless, the establishment of domestic production requires substantial investment, long-term regulatory planning, and partnerships between government, industry, and international stakeholders. A pilot validation program embedded within the transfusion service network –starting from regional plasma pooling and quality testing– would provide the practical evidence needed to transition from readiness to operational implementation.

This study has several limitations. First, the number of institutions and respondents was limited to four regional and one hospital blood centers, which may restrict generalizability to the national context. Second, the binary ("Yes/No") format, while practical for readiness

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assessment, constrained the variability of responses and contributed to the observed ceiling effect. Third, laboratory validation of plasma quality was not performed; thus, the findings primarily reflect structural and procedural readiness rather than biochemical assurance. Finally, self-reported and observational data may introduce response bias. Future research should expand the sample size, employ scaled response instruments, integrate laboratory-based quality verification, and assess the cost-effectiveness of establishing local PDMP production.

CONCLUSIONS

This study provides a structured baseline assessment of Indonesia's institutional readiness to support local PDMP production. The assessment reveals that blood centers have achieved a strong foundational level of preparedness across key domains of preparation, inventory management, and transportation, reflecting a standardized operational culture shaped by national and WHO guidelines.

From a broader perspective, these findings contribute to the growing discourse on supply chain due diligence in the health sector, particularly within emerging economies seeking to enhance the sustainability and resilience of biologics production. By introducing and validating a readiness assessment framework, this study establishes an evidence-based approach that can inform future implementation research, investment prioritization, and governance reform in plasma supply systems.

While readiness does not yet guarantee operational capacity for fractionation, it offers a crucial first step toward designing an integrated and ethically governed plasma ecosystem. Strengthening interagency coordination, expanding donor base planning, and fostering public-private partnerships will be essential to transition from readiness to production capability. In doing so, Indonesia can not only reduce dependence on imported biologics but also advance regional leadership in responsible and transparent plasma supply chain development.

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Ethics declaration

The Ethical Approval number for the research is 528/UN6.KEP/EC/2025.

The Authors declare no conflicts of interest.

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