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Analysis of Readiness Factors in Implementing the Clinical Research Unit Concept at Yarsi Hospital

Listiyani[1], Sri Wuryanti[1]; Dicky Budiman[1,2]; Chandra Yusuf[1]; Danial Rasyid[1]; Soroy Lardo[3,4]

[1] Master of Hospital Administration, Postgraduate Program, YARSI University, Jakarta, Indonesia
[2] Center of Environmental and Population Health, Griffith University, Australia
[3] Medical Doctor, Internist, Infectious Disease Consultant, Jakarta, Indonesia.
[4] Pertahanan University, Jakarta, Indonesia

Corresponding author: Listiyaniismail@gmail.com

ABSTRACT This study explores the readiness factors required to implement a Clinical Research Unit (CRU) at YARSI Hospital. The research was driven by the necessity to enhance clinical research in Islamic hospitals that currently lack an integrated CRU. Utilizing a qualitative exploratory approach with a case study design, the study involved interviews, observations, and document analysis. The findings identified five key dimensions influencing CRU readiness: human resources, regulations, funding, infrastructure, and the organizational culture rooted in Islamic values. This study integrates organizational capability theory, institutional theory, and maqashid shariah principles, recommending the establishment of Indonesia's first Sharia-compliant CRU.

INDEX TERMS Clinical Research Unit, organizational readiness, Islamic hospital, clinical research, maqashid sharia.

I. INTRODUCTION

Clinical research plays a vital role in advancing evidence-based medical therapies. Countries like the United States and European nations have incorporated Clinical Research Units (CRUs) as a mandatory infrastructure in clinical research to ensure quality, patient safety, and ethical standards. In contrast, Southeast Asia, particularly Indonesia, contributes only 4% of global clinical trials, with significant gaps compared to countries like Thailand and Singapore [1].

For Islamic hospitals, CRUs hold strategic value, particularly by integrating maqashid shariah principles, such as the protection of life, intellect, and property, into research governance. These principles emphasize halal practices, fairness in subject selection, and strict adherence to Islamic ethics, which are essential in the clinical trial process at YARSI Hospital. However, despite national policies advocating for CRUs, the implementation of these units in hospitals, including YARSI Hospital, remains hindered by various challenges [2]. YARSI Hospital, as a Sharia-compliant teaching hospital, holds considerable potential to pioneer a Sharia-based CRU [3]. However, the absence of a structured CRU underscores the need for a comprehensive assessment of organizational readiness.

II. METHOD

This research uses a descriptive-exploratory qualitative approach with a case study strategy. This approach aims to deeply understand the dynamics of organizational readiness in implementing CRU at YARSI Hospital from the perspective of internal stakeholders. The selection of this approach refers to Creswell (2018), who stated that qualitative research is suitable for exploring the meaning behind complex and contextual social processes. Furthermore, exploratory research is intended to explore unstructured data to find patterns and relationships between variables in a specific context. The qualitative approach was conducted through interviews with stakeholders, such as healthcare workers, researchers, and hospital management, to explore factors influencing readiness for CRU implementation [4]. Informants were selected using purposive sampling techniques with theoretical criteria, namely informants who have a strategic role in the planning, implementation, and development of clinical research at YARSI Hospital. This selection was based on active involvement, experience in research, and policy-making authority or operational support for the establishment of the CRU. This study used an exploratory qualitative approach with primary data collection techniques through interviews and observations. Interviews were conducted semi-structured using interview guidelines developed based on the research focus. This technique was chosen to allow researchers to delve deeper into the understanding, experiences, and views of key informants regarding the readiness of CRU implementation at YARSI Hospital [5]. This research adopts a descriptive-exploratory qualitative approach using a case study strategy to understand the dynamics of organizational readiness for CRU implementation at YARSI Hospital from the perspective of internal stakeholders. The study involves semi-structured interviews, observations, and document analysis. The purposive sampling method was used to select informants

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based on their strategic roles, involvement in clinical research, and policymaking authority, which are critical for establishing the CRU [7]. Data were analyzed using thematic analysis, which involved identifying recurring themes from interview transcripts and categorizing them according to the dimensions of readiness. Triangulation between different data sources (interviews, observations, and documents) was employed to ensure data validity, alongside member checking with key informants. A SWOT analysis was conducted to identify the strengths, weaknesses, opportunities, and threats associated with the CRU implementation process [8].

III. RESULTS

The findings indicate that human resource readiness is a crucial factor that still needs strengthening. The study identified five key themes for human resource readiness:

1. Education and Training: Continuous training in Good Clinical Practice (GCP) is essential to meet international standards.
2. Experience and Human Resource Selection: Success in implementing the CRU relies on recruiting personnel with relevant experience in clinical research.
3. Technology Mastery: Mastery of technological tools for research documentation and data management is crucial.
4. Communication and Collaboration: The involvement of hospital management and effective communication between departments are vital for successful implementation.
5. Mentality and Motivation: Offering incentives and facilitating training programs are essential for motivating healthcare workers to engage in clinical research.

The analysis revealed that YARSI Hospital has some supportive governance frameworks, but it lacks comprehensive policies and standard operating procedures (SOPs) for clinical research. This gap in regulatory support is an obstacle to the establishment of a well-integrated CRU. Funding plays a critical role in the sustainability of CRUs. While internal budgets have been allocated, a more structured approach to funding—both internal and external is necessary to support the CRU's operations. The hospital's infrastructure and information systems are not yet fully integrated for supporting clinical research activities. While existing facilities, such as laboratories, show potential, there is a lack of dedicated research space and technological integration for research purposes. Five main themes emerged from the interviews:

TABLE 1
Results of Thematic Analysis of Human Resource Readiness Factors.

No	Confirmation	
	Thematic	Quotes
1	Education and Training (Diklat)	1) "The training provided must be continuous according to competency" (P10) 2) "Can be started by getting involved in journal writing or GCP research and training" (P11)
2	Experience (HR Selection)	"Recruitment through selection of candidates who meet the Clinical Research Unit criteria" (P4)
3	Technology Mastery	"Training strategies as well as periodic monitoring and evaluation to ensure continuous improvement of HR competencies" (P4)
4	Communication and Collaboration	1) "The strategic role of hospital management in supporting the implementation and sustainability of the Clinical Research Unit" (P1) 2) "Providing an understanding to health workers of the importance of being involved in clinical research" (P10)
5	Mentality and Motivation	"Management needs to be proactive in facilitating training and incentives to motivate health workers to be involved in research" – (P11)

According to the information inTABLE 1, most students are Thematic analysis of interview data shows that human resource readiness to support CRU implementation in hospitals covers five main themes, namely: ongoing training, HR experience and selection, technology mastery, communication and collaboration, and internal motivation and support. Each theme is reinforced by quotes from the interviewees.

1. Education and Training The importance of ongoing training was emphasized by informants as a prerequisite for developing competent human resources in clinical research. One informant stated: "The training provided must be ongoing according to competency" (P10), "It can be started by involving in journal writing or research and GCP training" (P11). Continuous Good Clinical Practice (GCP) training is an international standard that must be met by clinical research teams so that studies run according to ethics and scientific quality [8].

2. Experience and Human Resource Selection: Experience-based human resource selection is a key factor in readiness. A source stated, "Recruitment is carried out through the selection of candidates who meet the Clinical Research Unit criteria" (P4). This indicates that the success of CRU implementation depends on the selection of individuals with relevant experience and background. According to Gagliardi et al. (2020), experienced research teams significantly improve the efficiency and integrity of clinical studies, especially in the early stages of CRU formation.

3. Technology Mastery The ability to master information technology and research documentation systems is a crucial requirement. This is reflected in the speaker's statement: "Training strategies, as well as periodic monitoring and evaluation, are needed to ensure continuous improvement of human resource competencies" (P4). The Indonesian Ministry of Health (Director General Decree HK.02.02/D/1782/2025) emphasizes the importance of utilizing technology in data recording, clinical trial monitoring, and research information management as part of the readiness of CRU human resources.

4. Communication and Collaboration HR readiness is also influenced by the support of hospital management in building communication and collaboration between divisions. The informant said: "The strategic role of hospital management in supporting the implementation and sustainability of the Clinical Research Unit" (P1), "Providing an understanding to health workers of the importance of being involved in clinical research" (P10). According to [9] in the CFIR Framework, leadership involvement and cross-unit communication greatly influence the successful adoption of organizational innovation, including the formation of the CRU.

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5. Mentality and Motivation Support in the form of incentives and training facilitation is an important factor in building the motivation of health workers to engage in clinical research. This is reflected in the quote: "Management needs to be proactive in facilitating training and incentives so that health workers are motivated to engage in research" (P11). [10] emphasizes that the involvement of health workers in clinical research needs to be supported by a clear incentive and recognition system so that the sustainability of the program can be maintained.

Through data triangulation from interviews, observations, and document reviews, it can be concluded that human resource readiness at YARSI Hospital is still potential but has not been systematically facilitated. While human resource potential is evident in their academic background and interest in research, there is a lack of structural support and policies that enable medical personnel to actively participate in research activities. The lack of supporting facilities, dedicated time, and operational policies are major obstacles to mobilizing existing human resource capacity.

The findings show that most healthcare workers at YARSI Hospital do not have GCP certification and are not yet accustomed to conducting systematic research. This is due to two main factors: first, the absence of a structured training system that requires GCP training for all medical personnel; The findings show that most healthcare workers at YARSI Hospital do not have GCP certification and are not yet accustomed to conducting systematic research. This is due to two main factors: first, the absence of a structured training system that requires GCP training for all medical personnel [11].

Internal policies and regulations are fundamental components in supporting clinical research governance in a hospital environment. Clear regulations, an efficient licensing system, and the availability of operational guidelines are essential prerequisites for the establishment of an integrated and sustainable research unit. This sub-chapter will explore the extent to which YARSI Hospital has established an adequate regulatory framework to support the clinical research process, from the ethical review stage and inter-unit coordination to the reporting and evaluation system. Through thematic analysis of interviews, this section will outline informants' perceptions regarding the hospital's policy readiness, challenges faced in its implementation, and recommendations for strengthening the regulatory system that supports the establishment of a credible and competitive CRU [12].

TABLE 2
Results of the Thematic Analysis of Regulatory and Policy Readiness Factors.

No	Confirmation	
	Thematic	Quotes
1	Governance	"The hospital issues a policy that stipulates that clinical research is permitted and facilitated within the hospital environment" (P1) "The legal umbrella for everything is based on the applicable laws, under which there are SOPs and general provisions made by the department" (P2)
2	Ethical Review	"In clinical research regulations, permission from the Ethics Committee is required" (P1)
3	Monitoring and Evaluation	"Training strategies as well as periodic monitoring and evaluation to ensure continuous improvement of HR competencies" (P4)
4	Results and Publications	"So that hospitals can become institutions that not only serve, but also produce knowledge and innovation" (P1) "CRU can be a source of income for hospitals" (P2) "Can provide research-based health services" (P3)
5	Data / Sample	"Building a secure and regulatory-compliant data management system" (P1)

Thematic analysis of key informant interviews revealed five main themes reflecting hospital regulations and policies in facilitating clinical research. These themes include: governance, ethical review, monitoring and evaluation, results and publication, and data/samples. Funding availability is a strategic aspect in achieving the successful establishment and operation of a CRU. Without adequate financial support, clinical research activities risk being hampered, from planning and implementation to dissemination of results. This subchapter will examine in depth how hospital funding structures have or have not been directed to support research functions, including potential internal budget allocations, access to external grants, and incentives for healthcare workers involved in research.

TABLE 3
Results of Thematic Analysis of Funding Factors.

Funding	Confirmation	
	Existing	Ideal
1	"Allocate a special budget for initial operations" (P1) "There is a budget allocation, because it is hoped that this research will become one of the hospital's revenue sources" (P3) "There is an internal proposal submission process" (P6) "What costs must be accounted for in terms of reporting, including for official procurement" (P6)	"CRU can be initiated with the internal budgets of hospitals and universities, including training, human resources, and basic infrastructure budgets," Director General Decree HK.02.02/D/1782/2025 "Stipulating that hospitals can allocate funds from the education, research, and training budgets to finance CRU as part of developing service quality" Minister of Health Decree No. 1458/2023
External	• "There is an external proposal submission process" (P6) • "Increase grants in research" (P12)	"CRU can be funded through external sources such as national grants, industry sponsorships, and CSR" Director General Decree HK.02.02/D/1782/2025 "Emphasizes that hospitals can establish research funding partnerships with external sectors, including industrial clinical trials" Minister of Health Decree No. 1458/2023

Based on the interview results, funding and financial resources have a strategic role in supporting the formation of CRU. Thematic analysis groups these aspects into two main sources, namely internal and external, each reflecting the existing and ideal conditions expected for the sustainability of CRU [13].

The findings indicate that despite the initiation of internal fund allocation and proposal submission mechanisms, the

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funding structure remains unintegrated and lacks dedicated management. Potential external funding, such as grants and industry collaborations, has also not been optimally utilized due to the lack of a dedicated research management unit. This is despite national regulations, such as Minister of Health Decree No. 1458/2023, opening up opportunities for research funding from various sources. Therefore, the establishment of a CRU requires a planned and accountable funding strategy and strong institutional support for sustainable clinical research.

TABLE 4
Results of Thematic Analysis of Infrastructure and Information System Readiness Factors.

No	Confirmation	
	Thematic	Quotes
1	Availability	"The facilities available are sufficient to support sample collection and storage, but are not yet specific for clinical research" (P2) "The challenge is to provide tools, BHP and medical equipment needs" (P6)
2	Quality	"The laboratory has basic capabilities, but to support the CRU, more consistent validation and calibration instruments are needed" (P1)
3	Adaptation	"The role of laboratories and pharmacies already exists, but the flow of communication and coordination must be clarified" (P6)
4	Integration	"Inter-unit systems are not ready to support CRU data and process integration" (P8)
5	Sustainability	"It is important to create a system that does not depend on people, but is systematic and supported by hospital regulations" (P11)

Based on the triangulation results between interviews, observations, and documents, it can be concluded that the readiness of infrastructure and information systems at YARSI Hospital to support CRU operations is still in the early stages and is inadequate. There is potential to develop facilities from existing space and technology assets, but there are no policies or investments that lead to the development of integrated clinical research facilities [14].

TABLE 5
SWOT Analysis Results.

No	Strength	Weakness	Opportunities	Threats
	Internal		External	
1	The hospital's mission supports research, with a solid ethical Islamic culture.	Lack of formal SOPs and CRU structures.	Opportunities for collaboration with medical faculties and the halal industry.	Competition for grants
2	Strong and ethical Islamic culture	Overburdened human resources without adequate training.	Regulatory support from the Ministry of Health and BPOM regulations.	Unprepared IT infrastructure and systems for handling research data

IV. DISCUSSION

This study aims to analyze the readiness factors in implementing CRU at YARSI Hospital, a sharia-based teaching hospital. Based on the results of thematic analysis of in-depth interviews, observations, and document reviews, this study concludes that the readiness for implementing CRU at YARSI Hospital is determined by five main dimensions [15], namely: (1) human resources that are not yet optimal in terms of training and research time; (2) hospital regulations and policies that are still administrative in nature without long-term strategic direction; (3) funding that has not been specifically allocated to support clinical research; (4) infrastructure and information systems that are not yet fully integrated with research activities; and (5) a strong sharia organizational culture in terms of values, but has not been formalized in research procedures [16].

The study concludes that the readiness of YARSI Hospital to implement a CRU is contingent on addressing several key factors. Human resource readiness is crucial, but insufficient training and the lack of structured policies remain major barriers [17]. Furthermore, the regulatory and policy frameworks need strengthening to ensure long-term support for clinical research. Although funding has been partially allocated, the absence of a comprehensive strategy and dedicated research management unit hampers the sustainability of the CRU [18]. Infrastructure and information systems are still in the early stages of development, and while some facilities have potential, integration is lacking [19].

The hospital's strong Islamic values provide a unique advantage in shaping a research unit that complies with Islamic ethical standards. The integration of maqashid shariah principles will offer distinct guidance for research operations but requires formalization in policy and SOPs [20].

V. CONCLUSION

YARSI Hospital is positioned to be a pioneer in establishing the first Sharia-compliant CRU in Indonesia. However, successful implementation will require systemic changes, including enhanced human resource readiness, the establishment of comprehensive regulatory frameworks, better funding strategies, and the development of integrated infrastructure. The hospital's strong commitment to Islamic values provides a solid foundation for creating a CRU that aligns with both scientific rigor and Sharia principles.

ETHICAL APPROVAL

Based on the description presented in this chapter, it can be concluded that the implementation of the CRU at YARSI Hospital is a strategic step in increasing clinical research capacity based on quality, ethics, and Sharia values. However, the success of this implementation is highly dependent on the hospital's internal readiness, particularly in terms of human resources, regulations and policies, funding, and supporting infrastructure. Therefore, this study is crucial to produce a comprehensive readiness mapping and recommendations for YARSI Hospital in establishing and managing the CRU effectively, sustainably, and in accordance with the principles of a Sharia hospital.

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