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Effectiveness of CTCAE-Based Remote Patient Monitoring Using Hermina Caretrack in Chemotherapy-Related Adverse Events: A Quasi-Experimental Study

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Abstract

Chemotherapy is a primary modality in cancer treatment but is commonly associated with various adverse effects that may lead to serious complications if not detected early. Conventional monitoring after chemotherapy often relies on scheduled visits and passive reporting, which can delay clinical intervention and increase the risk of complications and hospital readmission. This study aimed to evaluate the effectiveness of the Hermina CareTrack Remote Patient Monitoring (RPM) system, based on the Common Terminology Criteria for Adverse Events (CTCAE), in improving early detection of chemotherapy-related side effects, accelerating clinical response time, and reducing complication severity and readmission rates. A Quasi Experimental Study was conducted involving 50 chemotherapy patients at Hermina General Hospital Sukabumi. Participants were divided into an intervention group (RPM-based monitoring) and a control group (conventional care), each consisting of 25 patients. Patients in the intervention group reported daily symptoms through a web-based system integrated with CTCAE version 5.0, while healthcare providers monitored patient conditions via a dashboard. Outcomes measured included severity of side effects, response time, incidence of complications, and readmission rates. Statistical analysis was performed with a significance level of $p < 0.05$. The intervention group demonstrated a lower proportion of severe side effects (grade ≥3) compared to the control group (20% vs. 36%, $p = 0.041$). The average response time was significantly faster in the intervention group (38 ± 15 minutes) than in the control group (240 ± 45 minutes; $p = 0.001$). CTCAE based RPM using the Hermina CareTrack system improves early detection of chemotherapy side effects and accelerates clinical response, with potential to reduce complication severity and readmission rates.

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Introduction

Cancer remains one of the major global health challenges, with morbidity and mortality rates continuing to rise. The Global Cancer Observatory (GLOBOCAN) report indicates a significant increase in the global incidence of cancer, with the greatest burden occurring in developing countries, including Indonesia [1]. In Indonesia, cancer is among the leading causes of non-communicable disease-related mortality, with the number of cases showing an increasing trend each year [2]. This situation necessitates a healthcare system that is adaptive, responsive, and patient-safety oriented.

Chemotherapy is one of the principal modalities in cancer management. Although effective in inhibiting cancer cell proliferation, chemotherapy frequently causes adverse effects such as nausea, vomiting, diarrhea, neutropenia, fever, and fatigue, which may reduce patients' quality of life and increase the risk of clinical complications [3]. Adverse effects that are not detected at an early stage may contribute to increased emergency department visits and hospital readmissions [4].

In conventional healthcare practice, post chemotherapy patient monitoring still relies primarily on scheduled follow-up visits and passive reporting by patients. This model may result in delayed healthcare provider responses (*response time*) to symptoms occurring at home. Delayed clinical responses are associated with an increased risk of severe complications and 30-day post-treatment readmissions [4,5]. Therefore, a monitoring system capable of bridging the gap between patients and healthcare providers in real time is needed. The digital transformation of healthcare has driven the development of technology-based innovations to improve the quality of care. Remote Patient Monitoring (RPM) is one *digital health* approach that enables patients' health conditions to be monitored remotely through an online system. The implementation of RPM in oncology patients has been shown to improve the early detection of adverse effects, accelerate clinical interventions, and reduce emergency department visits and readmission Rates [6,7].

To ensure that chemotherapy-related adverse effects are assessed objectively and systematically, a valid and standardized assessment instrument is required. The *Common Terminology Criteria for Adverse Events* (CTCAE) version 5.0, developed by the National Cancer Institute, remains an international standard for the classification and grading of adverse events associated with cancer therapy [3].

Based on these needs, the Hermina CareTrack Remote Patient Monitoring (RPM) system was developed as a web-based platform integrating CTCAE v5.0 assessment into post chemotherapy patient monitoring. The system enables patients to independently report their daily health conditions, while healthcare providers can monitor the severity of adverse effects through an integrated dashboard equipped with a standardized SBAR (*Situation, Background, Assessment, Recommendation*) communication format.

This study aimed to analyze the effectiveness of implementing Hermina CareTrack RPM for monitoring chemotherapy-related adverse effects by assessing the following variables: (1) severity of adverse effects based on CTCAE, (2) healthcare provider *response time* to patient reports, and (3) post-chemotherapy readmission rates. This system is expected to improve the early detection of treatment-related toxicities, accelerate clinical responses, reduce complications and readmissions, and strengthen the safety and continuity of care for oncology
patients

Literature Review

Chemotherapy

Chemotherapy is a systemic treatment that uses cytotoxic agents to inhibit proliferation and induce cancer cell death through various molecular mechanisms, including DNA damage and cell-cycle inhibition. However, because its mechanism of action is not entirely selective for malignant cells, chemotherapy also affects normal cells with high rates of proliferation, such as gastrointestinal mucosal cells, hematopoietic cells in the bone marrow, and hair follicles, thereby resulting in various systemic adverse effects [8].

Chemotherapy-related adverse effects may occur across a wide range of severity, from mild to severe and potentially life-threatening. This variation in severity requires systematic and continuous assessment to prevent clinical deterioration [8,9]. Commonly reported clinical manifestations include *chemotherapy-induced nausea and vomiting* (CINV), diarrhea, mucositis, neutropenia, fever, and *cancer related fatigue*, all of which can directly affect patients' quality of life.[9,10] When not identified at an early stage, these adverse effects may progress to serious complications, including systemic infection, severe dehydration, metabolic disturbances, and the need for hospital readmission within 30 days after treatment [10].

Continuous monitoring of patients following chemotherapy is an essential component of modern oncology nursing practice. A proactive monitoring approach enables early detection of changes in clinical condition, shortens healthcare providers' *response time*, and helps prevent complications that may increase emergency department visits and readmission rates [11,12].

Nurses play a central role in conducting standardized symptom assessments, providing comprehensive education, and coordinating interprofessional follow-up care. An active monitoring-based nursing care model has been shown to improve patient safety, reduce post chemotherapy complications, and enhance continuity of care between the inpatient setting and home-based care [12,13]. Therefore, integrating structured, technology-based monitoring systems represents an important strategy for improving the quality of oncology care and enhancing patient safety.

CTCAE

Common Terminology Criteria for Adverse Events (CTCAE) is a classification and grading system for adverse events associated with cancer therapy, developed by the National Cancer Institute (NCI) as a standard for toxicity reporting in clinical research and oncology practice. CTCAE is widely used internationally to identify the type, frequency, and severity of adverse events experienced by patients during cancer treatment [14]. CTCAE version 5.0 categorizes adverse events according to organ systems and types of clinical manifestations and establishes a severity grading system ranging from Grade 1 to Grade 5 [14,15]. The severity grades are defined as follows:

- **Grade 1 (mild):** Minimal or asymptomatic symptoms; generally requiring no specific intervention.
- **Grade 2 (moderate):** Requiring further monitoring or minimal intervention; limiting instrumental activities of daily living.
- **Grade 3 (severe):** Clinically significant and requiring prompt medical intervention or hospitalization; limiting self-care activities.
- **Grade 4 (life-threatening):** A critical condition requiring immediate intervention to prevent death.
- **Grade 5:** Death related to the adverse event.

In the context of post-chemotherapy patient monitoring, the use of CTCAE version 5.0 provides an objective and standardized framework for nurses to conduct consistent symptom assessments [15]. A CTCAE-based approach improves the reliability of clinical assessments, facilitates interprofessional communication, and supports evidence-based decision-making in determining the need for intervention and the urgency of clinical responses [16].

In this study, CTCAE version 5.0 was used as the basis for assessing adverse events reported by patients through the Remote Patient Monitoring system. The assessed parameters included nausea, vomiting, fever, diarrhea, fatigue, and conditions at the intravenous infusion site. Integrating CTCAE into a digital system enables automated classification of adverse-event severity, thereby potentially shortening response time, improving the accuracy of clinical triage, and supporting the prevention of complications and post chemotherapy readmissions

Remote Patient Monitoring

Remote Patient Monitoring (RPM) is an implementation of information technology in healthcare that enables patients' conditions to be monitored remotely through an integrated digital system. RPM facilitates the collection, transmission, and evaluation of patients' clinical data in real time or at predetermined intervals without requiring direct face-to-face visits [17]. This approach has become an important component of the digital health transformation, focusing on improving access, efficiency, and the quality of healthcare services. In clinical practice, RPM enables patients to independently report health parameters and symptoms from home,

while healthcare professionals monitor, analyze, and provide follow-up care based on the data received [18]. This model is particularly relevant for conditions requiring continuous monitoring, including chronic diseases and oncology care. In post-chemotherapy patients, RPM plays an important role in the early detection of changes in clinical condition, allowing interventions to be initiated promptly before significant deterioration occurs [19].

The implementation of RPM in cancer patients has been shown to improve the early detection of treatment-related toxicities, shorten healthcare providers' response time, and reduce emergency department visits and preventable hospital readmissions [20]. Furthermore, symptom-based monitoring systems contribute to improvements in quality of life and patient safety through a more proactive and patient entered care approach [21]. The main benefits of RPM in healthcare include:

1. Improving continuity of care after patients are discharged from the hospital.
2. Supporting early detection of clinical deterioration.
3. Reducing delays in symptom reporting and accelerating clinical decision making.
4. Increasing patient engagement in self-monitoring and management of their health.

In nursing practice, RPM serves as a strategic tool for improving nursing efficiency through a digital triage system based on symptom severity [21]. This approach supports patient safety-focused care, strengthens inter professional coordination, and optimizes continuity of care during the transition from hospital-based treatment to home-based care [22].

Framework

Patients undergoing chemotherapy are at risk of experiencing various adverse effects with varying degrees of severity. Failure to detect symptoms at an early stage and delayed healthcare provider response time may lead to clinical deterioration, increase the risk of complications, and contribute to higher rates of emergency department visits and post chemotherapy readmissions. In conventional practice, patient monitoring remains largely passive and dependent on scheduled follow-up visits, potentially creating a gap between symptom onset and clinical intervention.

The implementation of *Remote Patient Monitoring* (RPM) through the Hermina CareTrack system, integrated with assessment based on the *Common Terminology Criteria for Adverse Events* (CTCAE) version 5.0, provides a more proactive and standardized monitoring approach. Patients independently report their symptoms, after which the system classifies their severity according to CTCAE grading. This information enables healthcare providers to perform digital triage and determine the priority of follow-up care more rapidly and appropriately.

Conceptually, the implementation of CTCAE based RPM is expected to reduce *response time*, improve the early detection of adverse effects, and prevent symptom progression into severe complications. Faster clinical responses are expected to contribute to a reduction in post chemotherapy complications and readmission rates during the specified monitoring period. Thus, there is a relationship between the implementation of RPM (independent variable) and the severity of adverse effects, *response time*, complication rates, and readmission rates (dependent variables), collectively contributing to improved patient safety and quality of oncology care.

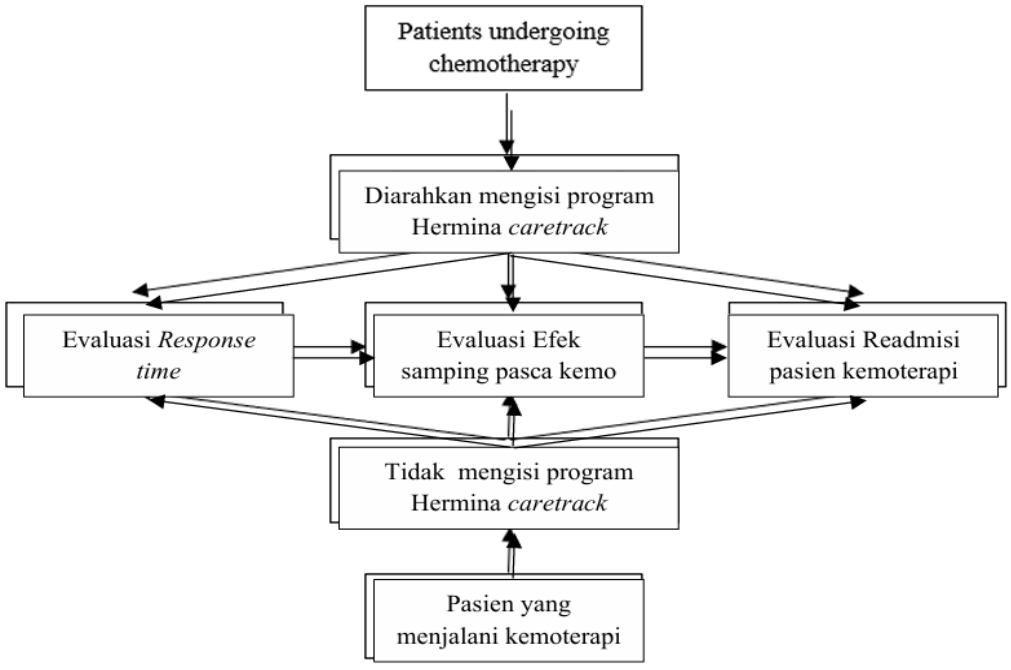

Figure 1. Framework

Alternative Hypothesis (H_1): The implementation of CTCAE-based *Remote Patient Monitoring* (RPM) through Hermina CareTrack has a statistically significant effect on reducing *response time*, post-chemotherapy complication rates, and readmission rates among patients undergoing chemotherapy.
Null Hypothesis (H_0): The implementation of CTCAE-based *Remote Patient Monitoring* (RPM) through Hermina CareTrack has no statistically significant effect on *response time*, post-chemotherapy complication rates, or readmission rates among patients undergoing chemotherapy.

Research Method

This study involved all cancer patients undergoing chemotherapy at Hermina Sukabumi General Hospital who met the predefined inclusion and exclusion criteria. Eligible patients were aged ≥18 years, had a confirmed malignancy diagnosis based on histopathological or cytological examination, were undergoing chemotherapy with curative, adjuvant, neoadjuvant, or palliative intent, and had completed at least one cycle of chemotherapy. All participants were also required to have access to and be capable of using the Hermina CareTrack application to independently report adverse effects or with assistance from a family member, and to provide written informed consent to participate in the study. Patients with severe neurological disorders, cognitive impairment, or severe psychiatric disorders that interfered with self reporting were excluded from the study. Patients with terminal conditions requiring continuous intensive care or those unable to use digital devices without assistance were also excluded. Participants were additionally excluded if they experienced an emergency condition during the observation period, failed to provide complete data through the system, or withdrew from the study.

This study was a quantitative study using a prospective analytical observational design. Chemotherapy-related adverse effects were monitored through the Hermina CareTrack application-based *Remote Patient Monitoring* system, using the *Common Terminology Criteria for Adverse Events* (CTCAE) as the standard for grading treatment-related toxicity. Adverse effects were classified according to severity, from Grade 1 to Grade 5, in accordance with CTCAE guidelines. The primary variables analyzed included the severity of chemotherapy-related adverse effects as the independent variable, while healthcare provider *response time* to patient reports, 30-day post-chemotherapy readmission rates, and post-chemotherapy complication rates were considered dependent

variables. Data were collected in real time through the system and analyzed to assess the relationship between adverse-effect severity and the speed of clinical response, as well as clinical outcomes including readmission and complications. Statistical analyses were performed using correlation or regression tests according to the characteristics and distribution of the data, with statistical significance set at $p < 0.05$.

The aim of this study was to evaluate the effectiveness of CTCAE-based *Remote Patient Monitoring* in improving the early detection of adverse effects, accelerating clinical responses, and reducing readmission and complication rates among patients undergoing chemotherapy.

Research Variables

The variables in this study consisted of independent and dependent variables. The independent variable was the severity of chemotherapy-related adverse effects reported by patients through the Hermina *CareTrack Remote Patient Monitoring* system and assessed using the *Common Terminology Criteria for Adverse Events* (CTCAE). Toxicity severity was classified according to the CTCAE grading scale (Grade 1–5), in which Grade 1 indicates a mild adverse effect and Grade 5 indicates death related to toxicity.

The dependent variables included healthcare provider *response time* to patients' adverse effect reports, measured in minutes or hours from the time the report was submitted through the system; the 30-day readmission rate following a chemotherapy cycle; and the rate of post-chemotherapy complications, such as febrile neutropenia, severe infection, severe dehydration, or other conditions requiring medical intervention or hospitalization.

Results and Discussion

A total of 50 patients undergoing chemotherapy at Hermina Sukabumi General Hospital were included in this study, comprising 25 patients in the intervention group (*CTCAE*-based *Remote Patient Monitoring* through Hermina CareTrack) and 25 patients in the control group receiving conventional care. The baseline characteristics of the participants in both groups were relatively homogeneous in terms of age, sex, and disease stage ($p > 0.05$).

Table 1: Data Demographic

Variables	Intervension Group (n=25)	Control Group (n=25)	P Value
Age	51,8 ± 9,6	53,1 ± 10,4	0,62
Gender			0,74
Male	9 (36%)	10 (40%)	
Female	16 (74%)	15 (60%)	
Stage of cancer			0,71
Stage 1-2	12 (48%)	11 (44%)	
Stage 3-4	13 (52%)	14 (56%)	

Tabel 2: Frequency Distribution of Post Chemotherapy Adverse Events Based on CTCAE

Sign and symptoms	Grade	Intervension Group (n=25)	Control group (n-25)
Nausea	Grade 1-2	8 (32%)	11 (44%)
	Grade 3-4	2 (8%)	5 (20%)
Vomit	Grade 1-2	5 (20%)	8 (32%)
	Grade 3-4	1 (4%)	4(20%)
Fever	Grade 1-2	2 (8%)	5 (20%)
	Grade 3-4	1 (4%)	3 (12%)
Diarrhea	Grade 1-2	3 (12%)	6 (24%)

	Grade 3-4	1 (4%)	3 (12%)
Fatigue	Grade 1-2	12 (48%)	14 (56%)
	Grade 3-4	2 (8%)	4 (16%)
Allergic reaction	Grade 1-2	0 (0%)	1 (4%)
	Grade 3-4	0 (0%)	0 (0%)

Tabel 3: Research Results

Variable	Intervension Group (n=25)	Control group (n-25)	P Value
Readmission	2 (8%)	5 (20%)	0,058
CTCAE Grade			0,041
Grade 1-2	20 (80%)	16 (64%)	
Grade ≥3	5 (20%)	9 (36%)	
Response time	38±15 meni	240± 45 menit	0,001

The results of this study demonstrated that the implementation of CTCAE-based *Remote Patient Monitoring* (RPM) through Hermina CareTrack significantly improved the early detection of chemotherapy-related adverse effects and accelerated the clinical response of healthcare providers. The intervention group had a lower proportion of severe adverse effects (Grade ≥3) compared with the control group.

This finding suggests that real-time reporting enables early intervention before treatment related toxicities progress to more severe grades.

The most notable difference was observed in *response time*, with the intervention group demonstrating a substantially shorter response time than the control group. Prompt clinical responses play an important role in preventing the progression of adverse effects and reducing the need for hospitalization. The lower readmission rate observed in the intervention group further supports the hypothesis that remote monitoring can facilitate proactive management of chemotherapy-related toxicities [11,12].

The RPM system enables healthcare providers to receive real-time notifications when patients report symptoms through the application, allowing clinical responses to be initiated within minutes. In contrast, in the control group, responses generally occurred during the next scheduled follow-up visit or when patients presented to a healthcare facility after their condition had already deteriorated [10,11].

Faster clinical responses are important in preventing the progression of chemotherapyrelated toxicities. Early interventions, such as dose adjustment, administration of supportive therapy, or immediate patient education, may prevent adverse effects from progressing to more severe grades. Clinically, this accelerated response represents one of the key mechanisms explaining the reduction in complications observed in the intervention group [11,13]. The lower proportion of severe adverse effects (Grade ≥3) in the intervention group suggests that a monitoring system based on the *Common Terminology Criteria for Adverse Events* (**CTCAE**) may facilitate early detection of treatment-related toxicities. Systematic and structured self-reporting by patients enables mild symptoms to be identified promptly before they progress to conditions requiring intensive medical management.

This approach also enhances *patient engagement* in the care process, which may contribute to improved patient safety. Early identification of symptoms such as severe nausea, diarrhea, or fever enables timely preventive measures, thereby reducing the risk of subsequent complications such as severe dehydration or febrile neutropenia [8,11]. Although the reduction in the readmission rate in the intervention group did not reach statistical significance,

a clinically meaningful difference was observed. The lower risk of readmission in the intervention group suggests that remote monitoring may help prevent clinical deterioration that would otherwise result in hospitalization.

Conceptually, the digital monitoring system serves as a bridge between patients and healthcare providers outside routine follow-up schedules. Through rapid two-way communication, symptoms can be addressed before progressing to acute conditions requiring hospital-based care. From a healthcare service perspective, reducing readmissions may also have implications for cost efficiency and reducing the burden on inpatient services [11].

This study has several limitations. First, the relatively small sample size may have reduced statistical power, resulting in some outcomes not reaching statistical significance despite clinically meaningful differences. Second, the observational analytical design without randomization may have introduced selection bias and potential confounding factors that could not be fully controlled. Third, the effectiveness of RPM depends on patient adherence and digital literacy, creating the potential for *reporting bias*. Fourth, the study was conducted at a single healthcare center, Hermina Sukabumi General Hospital, limiting the generalizability of the findings. In addition, assessment of adverse effects using CTCAE based on patient self-reporting may introduce variability and subjectivity in symptom assessment.

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