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Pharmacovigilance and Adverse Drug Reaction Reporting by Nurses to Improve Patient Safety Goals at Hospital in Bekasi - West Java

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Abstract

Nurses are frontline healthcare providers who spend much time with patients and can help avoid, mitigate, promote public health, and determine and maintain medicine safety. To ensure patient and medication safety, nurses need knowledge and experience in pharmacovigilance. This study aims to assess nurses' pharmacovigilance and adverse drug reaction reporting to implement patient safety goals with patient safety culture as intervening variables at X Hospital in Bekasi. This research is a quantitative causality study with a cross-sectional design to see the effect of pharmacovigilance knowledge on implementing patient safety goals mediated by patient safety culture. The study was conducted on 130 nurses at X Bekasi Hospital who met the inclusion and exclusion criteria. Sampling was carried out using the purposive sampling technique. The data collection process uses a closed questionnaire instrument; the answers to the questionnaire questions have been determined. Data were analyzed using the Smart PLS program's Structural Equation Modeling technique. The study's results found that knowledge of Pharmacovigilance and adverse drug reactions significantly affected the implementation of patient safety goals (F count is greater than F table / 64.5> 2.67; (R^2) = 0.667). Pharmacovigilance knowledge significantly influences improving patient safety culture (p-value = 0.000). The estimated value of the influence of pharmacovigilance knowledge on patient safety culture is 60.9%. Knowledge, attitude, and pharmacovigilance practice are the dominant variables in influencing patient safety culture and positively influence the implementation of patient safety goals. However, knowledge, attitude, and practice significantly impact patient safety culture, so efforts to implement consistent and continuous Pharmacovigilance can improve patient safety culture, which will continue with implementing patient safety goals.

INTRODUCTION

Patient safety means that a patient does not get hurt in a way that could have been avoided during health care and that the risk of harm from health care is acceptable. Patient safety is a pillar of health care. Every step in the process of providing care contains a degree of inherent risks. Problems with practices, procedures, or systems may result in adverse events (Xuanyue et al., 2013). The Institute of Medicine (IOM) states that if adverse events can be reported without blame, people can learn from their mistakes and improve to prevent future human and system errors, promoting patient safety. Thus, hospitals must understand patient safety culture to improve patient safety (Donaldson et al., 2017). Patient safety culture is a product of values, attitudes, and competencies of individual and group

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behavior patterns that determine commitment, style, and a healthcare organization's ability to program patient safety (World Health Organisation, 2019). This belief extends to all levels of the organization (e.g., system, department, unit) and influences the actions and behavior of staff throughout the organization. Patient safety culture is a product of values, attitudes, and competencies of individual and group behavior patterns that determine commitment, style, and a healthcare organization's ability to program patient safety (Lawati et al., 2018).

Implementing patient safety in hospitals can detect risks that will occur and minimize their impact on patients and health workers. By creating a patient safety culture in the hospital, risks can be identified, and negative impacts on patients can be reduced (Brittain & Carrington, 2021). All health workers, especially nurses, must avoid mistakes when providing hospital medical services (Xuanyue et al., 2013). The first step of the safety program for patients in the hospital is building a culture of patient safety or raising awareness among all employees of the importance of the values of hospital safety. So, to improve the quality of patient safety services at the unit level, efforts must be made to change the patient safety culture throughout Hospital units (Kementrian Kesehatan, 2017).

Knowledge and attitudes regarding pharmacovigilance in Indonesia are still essential for health workers in health service facilities to prevent Adverse Drug Reactions (ADRs) and improve patient safety and quality of life. Unreported ADRs can be a significant problem, making it urgently necessary to improve the quality and quantity of reporting (Bethasari, 2023). Healthcare professionals' involvement and reporting of adverse drug reactions are essential for the success of a pharmacovigilance program (Khan et al., 2023). Nurses play an essential role in patient safety programs in providing health services because they are around patients and their families every day. Nurses are employees who have a strategic role in the health care system. Nurses interact more directly with patients than other medical workers. Services are essential to health services and significantly affect patient safety programs (Salehi et al., 2021). Nurses are critical in reporting unwanted incidents, especially those related to pharmacovigilance. Therefore, hospital nurses' knowledge, perspectives, and practices regarding reporting, followed by follow-up actions in resolving incidents, are essential for implementing patient safety programs (Griffith, 2013; Afaya et al., 2021).

Hospital X in Bekasi is a class B hospital with 281 beds and complete facilities. Patient safety is essential for hospital management. This hospital's quality and patient safety committee consistently supervises implementing and evaluating patient safety programs according to applicable regulations.. Data on implementing quality and patient safety programs in the early quarter of 2023 shows that several quality indicators still need to reach targets. Based on data from monthly reports, which are evaluated every three months, nine patient safety incidents were recorded, namely, work negligence related to examinations (4 incidents), patient falls (2 incidents), support errors (1 incident), and damage to medical equipment (2). Indicators of compliance in patient identification (97.2%), hand hygiene (78.63%), clinical pathways (66.1%), and errors in handing over pharmaceutical supplies (0.01%).

Nurses at X Hospital in Bekasi showed that only about 70% of them knew about the existence of pharmacovigilance and the actions and activities related to it. Furthermore, there are also issues with communication across hospital units (48%), resulting in reports or responses that must be sent quickly if treatment is delayed or experiencing delays. Only 70% of nurses already know about the unwanted side effects of drugs, and 9% know about the incidence of unwanted drug reactions. Based on the background, this study aims to assess nurses' pharmacovigilance and adverse drug reaction reporting to implement patient safety goals with patient safety culture as intervening variables at X Hospital in Bekasi.

METHODS

This research is a quantitative causality study with a cross-sectional design to see the effect of pharmacovigilance knowledge on implementing patient safety goals mediated by patient safety culture. The population in this study were all nurses at X Hospital in Bekasi, totaling 195 people, who met the inclusion and exclusion criteria. The inclusion criteria were nurses who already had a license to practice and serve patients directly, had worked as nurses at RS X Bekasi for more than one year, and were willing to participate in this study by signing informed consent. The exclusion criteria were Nurses who were inactive or absent during this study, were not willing to participate, or resigned before the study was completed were exclusion criteria.

The sampling was carried out using the method of purposive sampling. One hundred thirty (130) nurses who fulfilled the inclusion and exclusion criteria participated in the research

and completed the questionnaire. Questionnaires were designed and evaluated for their validity and reliability to assess several aspects of pharmacovigilance, such as patient safety knowledge, implementation of patient safety goals, and organizational culture. The compilation of questions in the list was based on a Likert scale, which utilizes a range of responses from highly positive to highly negative. Specific words represent these responses, notably "Strongly Agree" (SA) with a value of 4, "Agree" (A) with a value of 3, "Disagree" (DA) with a value of 2, and "Strongly Disagree" (SD) with a value of 1. The research instruments consist of 3 variables: Pharmacovigilance, denoted as X1, encompasses various dimensions, including knowledge, attitude, and practice. X2, representing knowledge, is further characterized by correctly identifying patients, incident reporting, and reducing the risk of infection related to health services. Patient safety culture (Z) encompasses various dimensions, including management commitment to safety, safety systems, work pressure, communication, teamwork, non-judgmental response to mistakes, and leadership. Implementing patient safety goals (Y), such as accurately identifying patients and reducing the risk of healthcare-associated infections.

Data Analysis

Descriptive Analysis

Descriptive statistical tests can explain the object under study by showing each dependent variable's minimum, maximum, average (mean), and standard deviation values. In this study, the dependent variable was implementing patient safety goals. In contrast, the independent variables in this study were pharmacovigilance and knowledge, while patient safety culture was an intervening variable. Descriptive statistical testing in this study was carried out using the SPSS version 25 (Kaliyadan & Kulkarni, 2019).

Outer Model Analysis

In this study, the data analysis method used was Structural Equation Modeling-Partial Least Squares (SEM-PLS) using SmartPLS software. In the analysis of the outer model, there is a reliability and validity test for the reflective variable using an indicator, namely the Loading factor. There are two criteria for assessing the outer model that meets the convergent validity requirements for the reflective construct: outer loading must be above 0.50, a significant p-value is less than 0.01 ($p<0.01$), and composite reliability Cronbach's alpha should be >0.6. After testing the reliability of the reflective variable and then testing its validity using the Average Variance Extracted (AVE), the AVE value must be above 0.5 (AVE > 0.5.) (Ghozali, 2014).

Inner Model Analysis

The purpose of inner model evaluation is to calculate the R square value of determination, which measures the strength of the link between the study's variables. According to Ghozali (2014), a solid exogenous variable (X) affects endogenous variables (Y) if the IR Square value is 0.67, moderate if it is 0.33, and weak if it is 0.19 (Ghozali, 2014).

Description of the Respondent's Answer

Respondents' descriptions were analyzed using index analysis. Respondents' answers to each variable will be based on the average score (index), which is categorized into a range of scores based on the calculation of the three-box method.

Upper limit of score range: (%F*10)/10
(100*10)/10= 100

Lower bound of the score range: (%F*1)
/10 = (100*1)/10 = 10

The cumulative index value amounts to 100. According to the criteria outlined in the Three-box Method, a range of 100 (30-100) will yield a range of 30, which will serve as the foundation for interpreting the index result. The scoring technique used in this study is with a maximum score of 4 and a minimum score of 1, then the calculation of the respondent's answer indexes are calculated using the following formula Index Value = [(%F1*1)+(%F2*1)+ (%F3*1)+ (%F4*1)] / 4

Information:

F1 = Frequency of respondents who answered 1 of the scores used in the list of questionnaire questions

F2 = Frequency of respondents who answered 2 of the scores used in the list of questionnaire questions

F3 = Frequency of respondents who answered 3 of the scores used in the list of questionnaire questions

F4 = Frequency of respondents who answered 4 of the scores used in the list of questionnaire questions

Testing of Hypotheses

The multicollinearity test was performed in two steps. The multicollinear test looks at the Inner VIF value; if it is less than 5, there is no multicollinearity between the variables (Hair et al., 2017). The second stage is hypothesis tes-

ting, which includes both direct effect testing and mediation testing (indirect effect). To assess the simultaneous effect of the Pharmacovigilance (PV), Knowledge (P), and Patient Safety Culture (BD) factors on the Implementation of Patient Safety Goals (IM), use the formula:

$$F = \frac{(n-k-1)R^2}{k(1-R^2)}$$

When interpreting the value of f square to determine the direct effect, it can be observed that a value of 0.02 indicates a modest effect, a value of 0.15 suggests a moderate influence and a value of 0.35 signifies a significant effect (Sarstedt et al., 2020).

RESULT AND DISCUSSION`

Hospital X in Bekasi is a Class B hospital that has a bed capacity of 281 with a Bed Occupancy Rate (BOR) of 61.15%, an Average Length of Stay (ALOS) of 5.70, and over Interval (TOI) of 3.62 days. This hospital provides specialist and subspecialist services. This hospital provides specialist and subspecialist services. Health services are divided into three places: the Emergency Room, which provides 24-hour service (including inpatients and referrals). The integrated polyclinic, the executive polyclinic, provides routine hospital services specifically for outpatients. The characteristics of the respondents can be seen in Table 1 and Table 2, which show descriptive statistical test results.

Table 1. Characteristics of Respondents

Characteristics	Number of Respondents (%)
Gender	
Men	21 (16)
Women	109 (84)
Age (Year)	
20-30	58 (44)
30-40	49 (38)
40-50	22 (17)
>51	1 (1)
Length Of Work (Year)	
1-5	59
6-10	19
10-15	52
Work Unit	
Polyclinic	15
VVIP And VIP Rooms	8
Inpatient Regular Room	30
Emergency Departments	12
Surgery Room	16
Hemodialysis Room	10
ICU/HCU	30
Perina	9
Education	
Diploma	110
Bachelor	20
Masters	0

Table 2. Descriptive statistical test results (N=130)

Variable	Minimum	Maximum	Mean	Std. Deviation
Pharmacovigilance (X)	2	4	3.1452	0.43191
Knowledge (Y)	2.67	4	3.3274	0.38273
Patient Safety Culture (Z)	2.19	4	3.1762	0.3928
Implementation of Patient Safety Goals (Y)	2.5	4	3.3295	0.39943

Result of Outer Model Analysis

The result of the outer model analysis is presented in Figure 1. The pharmacovigilance knowledge dimension comprised five measurement items, and an outer loading between 0.783 and 0.865 proved valid. The item with the highest outer loading (0.865) is at PV1.4; the respondent knows that reporting adverse drug reactions is

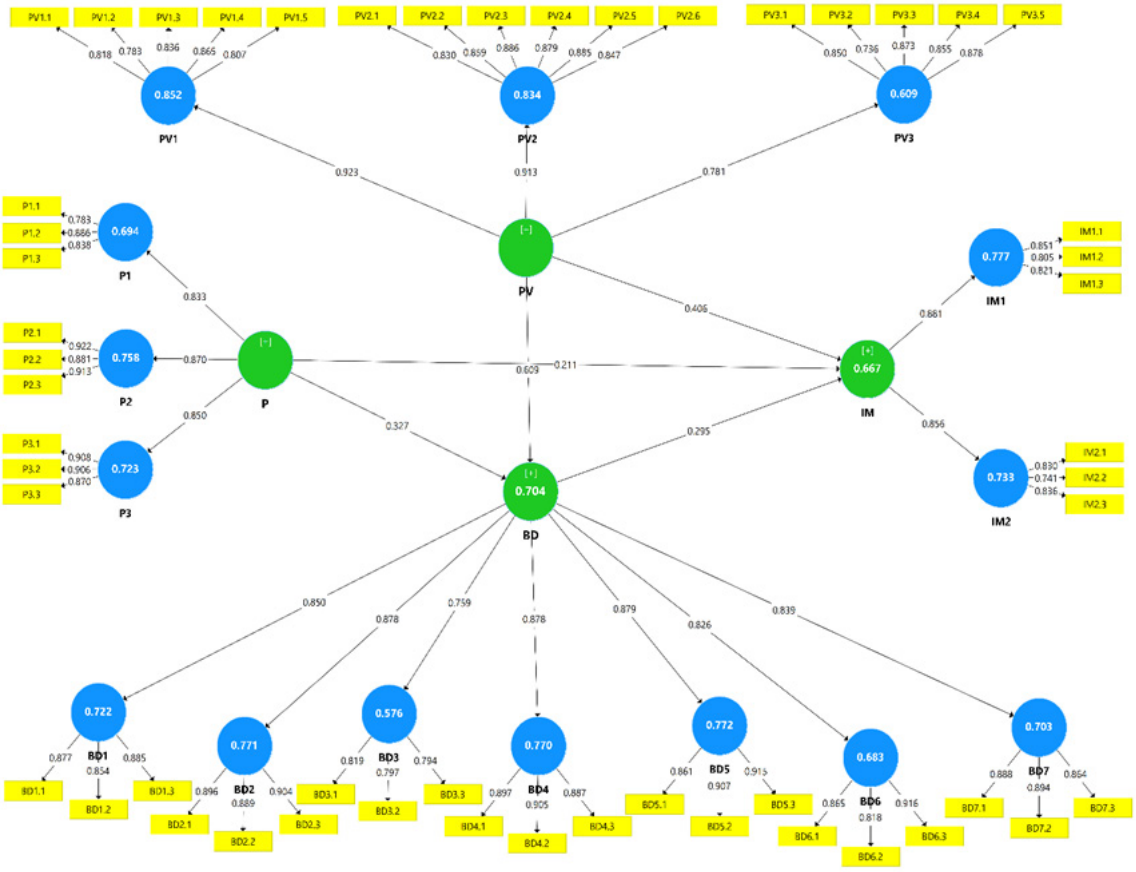

Figure 1. Outer Loading Value

not restricted to hospitalized patients. In the meantime, the outer loading value for item PV1.3, which measures respondents' agreement that ADR reporting is an obligation for all health employees, is 0.836%. The PV1.2 measurement item (Adverse Drug Reactions can occur with prescription and over-the-counter medications) has the lowest outer loading, at 0.783. This item requires improvement by informing nurses that adverse drug reactions are possible with all medications. The dimensions of pharmacovigilance attitude were measured using 6 question items with outer loading values between 0.830 and 0.886 and declared valid. The measurement items with the highest outer loading were PV2.3 and PV2.5, with outer loading values of 0.886 and 0.885, respectively. Respondents stated that ADR reporting would improve patient safety and pharmacovigilance training, i.e., essential in-patient safety programs, detecting, monitoring, and treating unwanted drug reactions. Pharmacovigilance practice dimensions were measured using 5 question items and were declared valid with an outer loading between 0.736 – 0.878. The measurement item with the highest outer loading, i.e., 0.878, is PV3.5, meaning that most respondents stated that they had attended a pharmacovigilance training session, namely training on detecting ADR events/unwanted drug reactions and handling them. In item PV3.3, the respondent has seen the ADR/unwanted drug reaction reporting form; the outer loading value is 0.873. The lowest outer loading value, i.e., 0.736 in item PV3.2, where only a few respondents who, during their work, had encountered ADR events / unwanted drug reactions in patients and then the nurse reported the ADR incident to doctors and hospital management.

In the knowledge variable, the outer loading value for the dimension of correctly identified patients is valid, with an outer loading between 0.783 – 0.886. The question item with the highest outer loading, 0.886, is PI.2, where the respondent agrees that patient identification must be carried out with at least two identities. In item PI.3, the identity of newborns in the hospital must use the biological mother's name, which has an outer loading of 0.838. Incident reporting dimensions were measured using three question items with outer loading between 0.881 and 0.922, which states that the three items are valid. The measurement items with the highest outer loading are at P2.1 (I understand how to report patient safety incidents) and P2.3 (I understand that

unexpected events that result in death or disability to patients (sentinel events) must be reported within 24 hours, with outer loading values of 0.922 and 0.913, respectively. The dimension of minimizing the risk of infection associated with health services was measured with three questions and deemed valid with an outer loading between 0.87 and 0.90. The measurement item with the highest outer loading is P3.1, which is a statement that the respondent can explain five moments of hand hygiene, with an outer loading of 0.908, and item P3.2, which is a statement that "I must check the condition of the puncture site every day and replace it every three days in patients who are infused," with an outer loading of 0.906.

The patient safety culture variable on the dimension of working pressure with 3 question items has an outer loading between 0.794 – 0.819. The item with the highest outer loading is in BD3.1, namely, sharing the workload with fellow health workers. The other two items, BD3.2 (I can always handle work pressure at the hospital) and BD3.3 (I can always finish work on time), still need improvement. The communication dimension, which consists of 3 questions, has an outer loading between 0.887 – 0.905. The measurement item with the highest outer loading is BD4.2 (communication between units in the hospital is going well). The teamwork dimension with three questions has an outer loading between 0.861 – 0.915. The measurement item with the highest outer loading is BD5.3, which is related to cooperation between units in the hospital in preventing patient safety incidents, which is quite good. The dimensions of a nonjudgmental response to errors are measured using 3 question items with an outer loading between 0.818 – 0.916. The question item with the highest outer loading is BD6.3 (supervisors will coordinate well if the nurse makes a mistake that endangers patient safety. The leadership dimension is measured using 3 question items with an outer loading between 0.864 – 0.894. The measurement item with the highest outer loading is BD7.2, which is related to the hospital manager's commitment to implementing patient safety.

In in-patient safety implementation variables, the dimension of correctly identifying patients is measured using 3 question items, declared valid with an outer loading between 0.805 – and 0.851. The measurement item with the highest outer loading is at IM3.3, consistently identifying inpatients according to standard operating procedures by asking the patient to state two identities, namely name, and date of birth if the patient is conscious, and matching the identity with a bracelet if the patient is unconscious. The dimension of reducing the risk of infection associated with health services is assessed by three items and declared valid with an outer loading between 0.741% and 0.836%. Item IM2.3, which always utilizes new consumables (e.g., syringes) for different patients, has the highest outer loading value. In contrast, the outer loading value of IM2.2 items (constant use of personal protective equipment during aseptic activities) is the lowest.

Table 3. Reliability variable and Average Variance Extracted (AVE}

Variable	Cronbach's Alpha	Composite Reliability	Average Variance Extracted (AVE)
Pharmacovigilance (PV)	0.944	0,907	0,765
Knowledge (P)	0.901	0,887	0,724
Patient Safety Culture (BD)	0.958	0,946	0,714
Implementation of patient safety goals (IM)	0.799	0,860	0,754

Table 3. shows the reliability variables and Average Variance Extracted (AVE). The level of reliability at the dimension level demonstrates satisfactory results, with all dimensions exhibiting a level of reliability with Cronbach's Alpha and Composite Reliability values greater than 0.70. This value indicates that the dimension's reliability is very high. The internal reliability or consistency of dimension-measuring instruments is exceptionally high. The measure of convergent validity for each dimension is also acceptable if the AVE is more significant than 0.50.

Results of the Inner Model

The adjusted R square and R square values for each variable, namely patient safety culture (BD), are 0.704 and 0.700, respectively. Meanwhile, the variable implementation of patient safety goals (IM) adjusted R square and R square values are 0.667 and 0.659. Based on the R-square value, it can be concluded that there is a substantial influence of pharmacovigilance (PV) and knowledge (P) on patient safety culture (BD), accounting for 77.6% of the observed variance (indicating a high effect). The impact of pharmacovigilance (PV), knowledge (P), and pa-

tient safety culture (BD) on the implementation of patient safety goals (IM) is significant, with an effect size of 66.7%.

Description of the Respondent's Answer Results

According to the calculation, the index number is derived from 130 to 32.5. The continuum of values is partitioned into three segments with the three-box technique, yielding an index value of 32.5 for each segment. The subsequent value will be employed for category interpretation. Table 6 displays the range values and criteria utilized in the Three-box Method (Ferdinand, 2014).

Descriptive analysis of the pharmacovigilance variable (X1) consists of three indicators: knowledge, attitudes, and practices. The calculation results show that the average index value is 115.428, which is in the high category. This value means that nurses at Hospital X Bekasi have good knowledge, attitudes, and pharmacovigilance practices. The highest index value is found in the questionnaire items PV2.2 and PV2.4, which reflect the dimensions of pharmacovigilance attitudes, namely, "At work, you are responsible for reporting adverse drug reaction (ADR) events, and every nurse must understand pharmacovigilance" (score: 108.25). This score indicates that most nurses recognize the significance of pharmacovigilance in hospitals as part of their duties. The lowest index value is PV3.4 for the pharmacovigilance practice indicator, "you have attended a pharmacovigilance training session (training on detecting ADR events - unwanted drug reactions and handling them)," with a score of 89. This value indicates that nurses still need to receive full pharmacovigilance training. The practice dimension has a lower average index than the knowledge and attitude dimensions. This index indicates that the implementation of pharmacovigilance practices must be enhanced so that the three dimensions can operate effectively.

The calculation results of the descriptive analysis of the knowledge variable (X2) obtained an average index value of 132.2778, which is in the high category. This value indicates that nurses know incident reporting, identifying patients, and reducing health-related risks. The highest index value is found in the questionnaire item P3.2, which reflects an attitude indicator in reducing the risk of infection, namely, "I know that patients who are infused must be checked for the condition of the puncture site every day and must be replaced every 3 days" with a score of 112. This score reflects that most Nurses can take actions that can reduce the risk of infection related to health services. Meanwhile, the lowest index value is P1.1 (incident reporting indicator, expressly "I understand how to report patient safety incidents," with a score of 102.25. This rating suggests that extra training is required for incidents and all aspects of patient safety. The index values from the average of the three aspects in the knowledge variable indicate a high value, implying that nurses' understanding of patient safety is adequate.

A descriptive analysis of the variable patient safety culture (Z) reveals a mean index value of 133,278 that falls within the high category. This criterion indicates that nurses have a strong safety culture. The highest index value in item BD1.1 of the questionnaire indicates management's dedication to safety: "I feel that hospital management consistently emphasizes the implementation of safety" (score 107.25). The majority of nurses hold the belief that hospital administration consistently prioritizes the execution of patient safety measures. The elements BD 3.1 and BD 3.2 exhibit the lowest index value, scoring 99, about the questionnaire item "I can consistently distribute my workload among my colleagues, and I can effectively manage work pressure within this healthcare facility." That implies that nurses need help from the people in charge of the hospital to divide up their work and do routine jobs. Some individuals cannot handle work stress, so their coworkers and managers must help them. All parties involved must communicate well to plan and implement quality programs to ensure patient safety in the hospital.

The results of the descriptive study implementing patient safety goals (Y) were an average index of 126.22, which is in the high category. This index indicates that nurses have effectively implemented patient safety objectives. The IM2.3 questionnaire item with the highest index value (19.75) reflects the indicator for reducing the risk of infection related to patient care: "I always use new consumables (e.g., syringes) for different patients." This value indicates that most nurses believe hospital administration consistently prioritizes patient safety. The IM2.1 questionnaire item "I always use personal protective equipment every time I carry out aseptic activities," with a score of 99, has the lowest index value. Even though this value is still included in the high criterion, some nurses still need to grasp the importance of wearing personal protection equipment whenever they perform tasks. Aseptic is critical in improving patient safety, mainly when infected with an infectious condition. The average score for both

aspects, namely identifying patients with and minimizing the risk of infection associated with health services, is in the high range, with nearly identical values of 108.083 and 108.33. It is plausible to assume that executing patient safety goals is feasible.

The findings from the descriptive analysis utilizing the three-box technique indicate that the participants, who were employed as functional nurses at Hospital X Bekasi, had favorable pharmacovigilance behavior, possessed adequate knowledge, and exhibited a positive patient safety culture in implementing patient safety goals.

The Findings of the Hypothesis Test

The inner Variance Inflated Factor (VIF) value of the PLS model (Table 4) shows that all variables are worth less than 5, so the multicollinearity between variables is low (can be ignored). These results indicate that the resulting PLS model parameter estimates are acceptable/unbiased.

The results of the simultaneous effect test

Table 4. Inner Variance Inflated Factor (VIF) value

Variable	Culture (BD)	Implementation of Patient Safety Goals (IM)
Patient culture (BD)		3.383
Knowledge (P)	1.471	1.834
Pharmacovigilance (PV)	1.471	2.728

obtained the results of the F statistic was 64.50, while the F table was 2.674 (p-value = 0.05; F count > F table). As a result, Pharmacovigilance (PV), Knowledge (P), and Patient Safety Culture (BD) all have an impact on the implementation of patient safety goals (IM).

Simultaneous effect test results for hypothesis H1: Pharmacovigilance (PV), Knowledge (P), and Patient Safety Culture (BD) simultaneously influence the Implementation of Patient Safety Goals (IM) demonstrates that the pharmacovigilance, knowledge, and culture of patient safety at Hospital X Bekasi substantially affect the success of patient safety initiatives. The F-statistic or F-model calculation demonstrates this conclusion as 64.50 > 2.67. Coefficient of determination (R2) test findings show an estimated value of 0.667 for the impact of pharmacovigilance, patient safety knowledge, and patient safety culture on achieving patient safety objectives. This percentage indicates that pharmacovigilance, patient safety knowledge, and patient safety culture have a 66.7% impact on achieving patient safety objectives. Other variables outside this study, such as work experience, nursing attitude, work tiredness, and others, influence the remaining 33.3%. Three box method analysis on practice indicators in pharmacovigilance against is the lowest average indicator where the lowest score is found in item PV 3.4, "You have attended a pharmacovigilance training session (training on detecting ADR events - unwanted drug reactions and their treatment)" which means that training on detecting ADR events/unwanted drug reactions is still required in order to increase patient safety culture and implement patient safety goals. This finding supports the hypothesis that knowledge, attitudes, and pharmacovigilance practices influence the success of patient safety implementation and are critical to achieving patient safety goals. This result follows a study by Sing et al., 2021 which concluded that formal training is necessary for producing consistent and meaningful safety reports (Singh et al., 2021). Best practice also entails a certain amount of follow-up and diligence to ensure the information reported is comprehensive, indicating the data's quality. The function reporting severe adverse effects is the primary method for monitoring drug safety during drug development. Nurses utilize their knowledge and experience to identify and evaluate events for safety reporting, thereby improving the consistency and quality of the safety data reported (Griffith, 2013). Because of their education and experience, nurses are in a unique situation to know how important it is to report bad things that happen. Managers and nurses with much experience in drug safety often guide and teach nurses and other healthcare workers who are new to the drug safety field so they can understand how vital pharmacovigilance is for patient safety (Salehi et al., 2021). The patient's safety is the most essential part of pharmacovigilance, so it is a reasonable step for nurses to make. Drug safety nurses can use their education and experience to keep the circle of safety going by watching for things that could be related to drugs and should be reported (Hamid et al., 2022).

Based on the three-box method analysis on the indicator of reporting incidents in knowledge, it has the lowest average indicator with the lowest score found in item P1.1, "I understand how to report patient safety incidents," where this can affect the results of implementing patient safety

goals. Therefore, increasing nurses' knowledge through seminars and discussion forums is necessary to implement pharmacovigilance. The role of nurses in pharmacovigilance is vital. Nurses are health workers who interact the most with patients compared to others. Nurses are responsible for accompanying patients 24 hours a day in their care, and it is only natural that nurses are the first to know about patient complaints and vital signs in patients. This condition requires nurses to know about pharmacovigilance and adverse drug reactions to recognize, monitor, and report ADRs that occur in patients (Singh et al., 2021; Gunawan & Tutik Sri Hariyati, 2019). The indicator of work pressure in patient safety culture also obtained a low average value; the lowest score was found in items BD 3.1 and BD 3.2: "I can always share my workload with my fellow health workers, and I can always overcome work pressure at work." This value indicates that management needs support to increase a sense of togetherness to improve patient safety. Thus, implementing a patient safety culture properly will positively impact the implementation of patient safety goals (Lawati et al., 2018). Implementation of safety management requires support from the organization and service personnel (Donaldson et al., 2017). Leadership, safety culture, fulfillment of suitable structures and systems, and management are supports for fulfilling patient safety (Alanazi & Falqi, 2023). Patient safety programs prioritizing strengthening leadership and management functions, implementing a safety culture in services, and increasing knowledge about patient safety will improve the quality and safety of patients in hospitals (Shenoy, 2021).

Table 5. Results of hypothesis testing directly (direct effect)

Hypothesis Statement	Estimation	T Statistics	P Values	F square
PV -> IM	0.406	3.982	0.000	0,181
P -> IM	0.211	2.552	0.011	0,073
PV -> BD	0.609	10.183	0.000	0,854
P -> BD	0.327	5.182	0.000	0,246
BD -> IM	0.295	2.739	0.006	0,077

Table 5. displays the outcomes of the direct hypothesis testing. The analysis of the test findings indicates a statistically significant relationship between the variables of pharmacovigilance (PV)/X1 and knowledge (P)/X2 and the variable of Patient Safety Culture. This result implies that any alteration in the PV/X1 and P/X2 variables will substantially impact changes observed in the Patient Safety Culture variable. The relationship between implementing patient safety goals (Y) and using (BD)/Z. The impact of pharmacovigilance (PV) factors on the implementation of patient safety goals (IM) is more significant compared to the influence of knowledge (P). The impact of PV on IM is determined to be 0.406, indicating a moderate level of influence. Similarly, the effect of P on IM is estimated to be 0.211, signifying a low level of impact. In comparison, the effect of PV on BD is higher (0.609 / high level) than the effect of P on BD (0.327 / moderate level). Even so, the cultural variable (BD) also plays a significant role as a mediating variable, but its mediating role is still considered low. PV and P have a significant effect with high and moderate effects on BD, but the transformation of BD's effect on IM is still considered low.

Pharmacovigilance (PV) has a significant effect on improving patient safety implementation goals (IM) with a path coefficient (0.406) and t statistic (3.982 > 1.96) or p-value (0.000 <0.05). The effect of Pharmacovigilance (PV) on the implementation of patient safety goals (IM) at the structural level includes a moderate effect (f square = 0.181). Any changes to pharmacovigilance (PV) fully support improving the Patient Safety Implementation goals (IM) at a moderate/moderate level.

Knowledge (P) has a significant effect on increasing the implementation of patient safety goals (IM) with a path coefficient (0.211) and t statistic (2.552 > 1.96) or p-value (0.011 <0.05). The influence of knowledge (P) on the Implementation of Patient Safety goals (IM) at the structural level includes a low to moderate effect (f square = 0.073). Any change to Knowledge (P) fully supports improving the Patient Safety Implementation goal (IM) but is still at a low to moderate level.

Pharmacovigilance (PV) has a significant effect on improving patient safety culture (BD) with a path coefficient (0.609) and t statistic (10.183 > 1.96) or p-value (0.000 <0.05). The effect of pharmacovigilance (PV) on patient safety culture (BD) is at a high level (f square = 0.854). Any changes to Pharmacovigilance (PV) fully support the promotion of patient safety culture

(BD) at a high level.

Knowledge (P) has a significant effect on improving patient safety culture (BD) with a path coefficient (0.327) and t statistic (5.182 > 1.96) or p-value (0.000 <0.05). The effect of Knowledge (P) on Patient Safety Culture (BD) was at a moderate level (f square = 0.246). Any change to Knowledge (P) fully supports enhancing Patient Safety Culture (BD) at a moderate level.

Patient Safety Culture (BD) has a significant effect on increasing the Implementation of Patient Safety (IM) with a path coefficient (0.295) and t statistic (2.739 > 1.96) or p-value (0.006 <0.05). The influence of Patient Safety Culture (BD) on the Implementation of Patient Safety goals (IM) (f square = 0.077) is at a low to moderate level. Any changes to the Patient Safety Culture (BD) support an increase in the Implementation of Patient Safety goals (IM), but in this case, it is still low to moderate.

Implementation of high patient safety goals is determined by pharmacovigilance, the knowledge possessed by hospital employees, and a well-established patient safety culture. Pharmacovigilance significantly affects the implementation of patient safety goals (Jacob et al., 2013). Employees with a high level of pharmacovigilance understanding can improve the implementation of patient safety goals. Knowledge has a significant effect on the implementation of patient safety goals. Employees with good knowledge about patient safety will increase the implementation of patient safety goals, and vice versa; if employees need more knowledge about patient safety, the implementation of patient safety goals will also decrease. Pharmacovigilance significantly affects patient safety culture (Hamid et al., 2022). Employees with a good understanding of pharmacovigilance will improve patient safety culture and vice versa; if an understanding of pharmacovigilance is lacking, then patient safety culture will also decrease (Varallo et al., 2017). Knowledge has a significant effect on patient safety culture. Employees with good patient safety knowledge will improve patient safety culture, and vice versa; if employees need more knowledge, then patient safety culture will decrease. Patient safety culture significantly affects the implementation of patient safety goals (Xuanyue et al., 2013). Employees with a good safety culture are committed to their work to maintain patient safety; Implementing patient safety goals will be even better (Lawati et al., 2018).

Based on the results of the research that has been done, the following are some suggestions that researchers can give; namely, hospital management should create a system to increase understanding of pharmacovigilance and knowledge about patient safety for each new team member and provide learning opportunities for nurses who have worked for a long time at the hospital. Paying attention to and reinforcing the existing patient safety culture so that it can influence the implementing nurse in improving patient safety behavior and being able to behave and be able to create a work environment that supports patient safety efforts. This research is still minimal because it was only carried out on a limited number of practicing nurses; therefore, the researchers suggest that further research can be carried out with more diverse respondents and that data collection with interview data with management can be complemented. Future research can further expand in measuring the impact of each variable by adding other statements to the questionnaire or adding other variables such as motivation, training, organizational commitment, job satisfaction, work pressure, workload, patient-centered care, organizational culture behavior in nurses, and other variables.

CONCLUSION

Pharmacovigilance and knowledge considerably impact the implementation of patient safety goals, demonstrating a strong link between pharmacovigilance and the implementation of patient safety goals. Pharmacovigilance, patient safety knowledge, and culture substantially impact the implementation of patient safety goals. Pharmacovigilance, hospital staff knowledge, and a well-developed patient safety culture all play a role in achieving high patient safety goals.

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