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THE DEVELOPMENT OF CLINICAL RISK MANAGEMENT IMPLEMENTATION MODEL IN IMPROVING QUALITY AND PATIENT SAFETY

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Clinical risk management plays an important role for hospitals in promoting patient safety and improving service quality in order to reduce or prevent risk related to patient care. The purpose of this study was to develop a model for implementing clinical risk management in improving quality and patient safety in class C private hospital in West Jakarta. This research using Participatory Action Research method. Participants in this study amounted to 20 people divide into 8 clinical units in the hospital. Data were collected using focus group discussions (FGD), using observation sheets, and quantitative assessment using questionnaires. Qualitative data analysis was performed by content analysis and quantitative data analysis using Wilcoxon test. The results of this study are clinical risk register model as a form of clinical risk management implementation, 8 clinical units in the hospital had clinical risk registers and the result of Wilcoxon test showed that there were significant differences in the level of participant knowledge about clinical risk management before and after the implementation (Asymp. Sig. value of 0.000 < α 0.05).

INTRODUCTION

The World Health Organization (WHO) states that the occurrence of adverse events due to unsafe treatment is one of the ten main causes of death and disability in the world (WHO, 2021). In the period from April to June 2017, the National Patient Safety Agency (2017) stated that there were 496.683 patient safety incidents reported from the UK, where this number had increased by 0.6% compared to the time span from April to June 2016 (493.930). Based on patient safety incident data in 2019 in Indonesia, there were 171 cases of death, 80 cases of serious injury, 372 cases of moderate injury, 1183 cases of minor injury, and 5.659 cases of non-injury (Larasati & Dhamanti, 2021)

The existence of patient safety incidents that occur in hospitals can cause major losses to hospitals, including decreased levels of patient, family and community satisfaction, increased risk of lawsuits, extended length of stay, injury to patients, and even death. Patient safety issues can

also lead to blaming behavior, even can cause conflict in the community, which can ultimately reduce the image of the hospital in society (Larasati & Dhamanti, 2021). Most of the injuries and deaths that occur as a result of patient safety incidents can be prevented by designing and planning procedurs to support patient safety. To be able to handle this challenge and improve the quality of service and patient safety, health service providers are faced with efforts to foster an effective safety culture (Hassanzadeh, Abazari, & Farokhzadian, 2021)

The risks associated with patient care cannot be completely eliminated, so that clinical risk management is needed which plays an important role for hospitals in promoting patient safety (Guttman-Yassky et al., 2020). Risk management needs to be implemented to minimize or prevent these risks. Organizations that actively carry out risk management are one step ahead compared to organizations that do not implement risk management in terms of security and service quality (Faraone et al., 2021).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines risk management as proactively identifying, assessing, and prioritizing risks with the aim of eliminating or minimizing their impact. The purpose of implementing risk management by hospital accreditation agencies such as Komisi Akreditasi Rumah Sakit (KARS) and also the Joint Commission International (JCI) is set forth in an accreditation standard which states that risk management programs are used to identify risks in order to reduce adverse events and other risks threaten the safety of patients and staff (Djatnika, Arso, & Jati, 2019).

A systematic review study conducted by (Shambe, Embu, Envuladu, & Ozoilo, 2017) showed that clinical risk management is an important effort in improving health services to provide quality health services. (Ito, Ueno, & Homma, 2020) at a university hospital in Tyrol, Austria, concluded that compared to previous years where clinical risk management had not been implemented, there was 52.9% reduction in the incidence of injury or loss due to treatment and an average incidence rate of patient safety decreased from 7.04 to 3.45 ($p<0.001$) after implementation of clinical risk management.

Class C private hospitals in West Jakarta have outpatient services, inpatient care, emergency departments, delivery rooms, operating rooms, perinatology, supporting examinations such as laboratory and radiology, as well as pharmacy and have participated in SNARS Accreditation 1.1 Edition in 2019 held by KARS and the result is "tingkat dasar". In implementing risk management, the hospital has carried out several activities such as incident reporting activities, Failure Mode and Effect Analysis (FMEA), and attended training to make Root Cause Analysis (RCA). In 2019, this hospital already has regulations and programs regarding hospital risk management and also has a list of risks in the hospital with the scope of patients, medical staff, health workers and other staff working in hospitals, hospital facilities, hospital environment, and hospital business. However, in 2021, researchers found that there were still some problems in its implementation.

According to the results of a brief interview with hospital management, the organizational structure of the hospital Quality Committee has been formed, but in practice, researchers see that the role of the Quality Committee has not been effective because the head of the Quality Committee is currently holding another position. The head of the Quality Committee has also not received Quality Improvement and Patient Safety training. Regarding the hospital quality program, in 2021, the hospital didn't have a written quality program, including no clinical risk management program. The list of risks in the hospital has also not been fully implemented in all units, so that the hospital cannot carry out a risk evaluation, whether there is an increase in risk status or a decrease in risk status in several units that do not have a risk list.

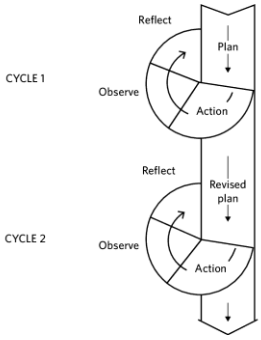
As of December 2021, this hospital has also never conducted risk management training for its staff. Exposure on new risk management is only done once, which is during the orientation

of new employees. Specialist doctors as clinical care providers also have not received risk management training. Efforts made by the Quality Committee to provide risk management knowledge are only socialization, such as during morning reports or coordination meetings, but there is no formal internal training specifically for risk management training itself. Therefore, as an effort to improve patient quality and safety in order to reduce the occurrence of patient safety incidents, a clinical risk management implementation model is needed.

RESEARCH METHODS

Study design

This study used a research method with the Participatory Action Research (PAR) approach, which consisted of the reconnaissance, planning, acting and observing, and reflecting stages (Kemmis et al, 2014). This research will be conducted in 2 cycles of action research.



Picture 1. Action Research Cycle

Meanwhile, to find out whether there were significant differences in the level of knowledge of participants before and after the implementation of clinical risk management, a comparative descriptive quantitative study was used.

Participant

The study participants were selected by purposive sampling of 20 people consisting of the Quality Committee, the head of the medical service department, general practitioners, the head of nursing, head and staff of inpatient department, head and staff of outpatient department, head and staff of emergency department, head and staff of the operating room department, head and staff of pharmacy department, head and staff laboratory department, head and staff of radiology department, and head and staff of nutrition department. This research also involved a team of experts to validate research instruments and also a team of experts to formulate an implementation model and observe the implementation process.

Instruments

In this study, focus group discussion (FGD) guides were used, observation sheets, and knowledge questionnaires which had been tested for validity by 3 experts with a Content Validity Index (CVI) of 0.89. The knowledge questionnaire was used to determine the difference in the level of knowledge of the participants before and after the implementation of clinical risk management.

Data collection

The research was conducted from June to July 2022 by conducting FGD two times for approximately 45-60 minutes for each FGD session. FGD and distribution of knowledge questionnaires were carried out in the reconnaissance and reflecting stages of the second cycle. The process of implementing clinical risk management was observed using observation sheets at the observing stage of each cycle.

Data analysis

Qualitative data were analyzed using content analysis and quantitative data for measuring the level of knowledge were analyzed using a difference test with SPSS Statistics 20 software.

Ethical consideration

This research has received approval from the Esa Unggul University Research Ethics Commission with Number 0923-01.002/DPKE-KEP/FINAL-EA/UEU/I/2023. The ethical consideration in this research is to ensure the confidentiality of the data collected.

Trustworthiness

The validity of the data in this study was evaluated using trust criteria consisting of credibility, transferability, dependability, and confirmability.

RESULTS AND DISCUSSION

The demographic characteristics of the 20 participants show that most of participants (18 or 90%) are 25-30 years old, were female (16 or 80%), have worked for 1-2 years (15 or 75%), and have a bachelor's degree (11 or 55%). The frequency distribution of participant demographic characteristics can be seen in table 1.

Table 1. Characteristics of Participants (n=20)

Characteristics	f	(%)
Age (years old)		
25-30	18	90
31-35	1	5
>35	1	5
Sex		
Male	4	20
Female	16	80
Working period (years)		
1-2	15	75
≥ 3	5	25
Level of education		
Postgraduate	1	5
Bachelor	11	55
Diploma III	7	35
Vocational high school	1	5

Reconnaissance stage

The results of data collection from this stage through FGD found 5 themes, including 1) participant knowledge about clinical risk management, 2) implementation of clinical risk management, 3) challenges faced in implementing clinical risk management, 4) supporting factors in implementing risk management clinical, and 5) the greatest need to improve the implementation of clinical risk management.

The results of measuring the level of knowledge of the participants using a knowledge questionnaire showed that most of the participants had a good level of knowledge (16 or 80%), while the other 4 participants were included in the category

of sufficient level of knowledge (20%) with an average score of 12.5. The distribution of participants' knowledge levels can be seen in table 2.

Table 2. Knowledge of Participants in Reconnaissance Stage (n=20)

Knowledge	f	%	*Mean*
Good	16	8	
Enough	4	20	12.5
Less	0	0	

Based on data collection at the reconnaissance stage, two findings were found consisting of: 1) there was participant which is in the sufficient level of knowledge (20%), and 2) there was no model for implementing clinical risk management to improve quality and patient safety.

Cycle 1

Planning stage

Researchers together with a team of experts formulated a clinical risk management implementation model as the form of a risk register that refers to the Institute for Clinical Risk Management (IMRK/Institut Manajemen Risiko Klinis) and accreditation standards from the Joint Commission International. This clinical risk register consists of 7 sections of: 1) activities and objectives, 2) risk register, 3) risk assessment heat map, 4) risk profile, 5) risk management plan, 6) risk control monitoring, and 7) monitoring report. However, in this study the risk control monitoring section and monitoring report cannot be implemented because this section is a follow-up to the risk management plan that will be carried out. The model of the clinical risk register can be seen in the following tables.

Tabel 3. Activities and Objectives Model

NO	NAMA KEGIATAN	TUJUAN KEGIATAN	PEMILIK RISIKO	KATEGORI RISIKO
1				
2				
3				
4				
5				

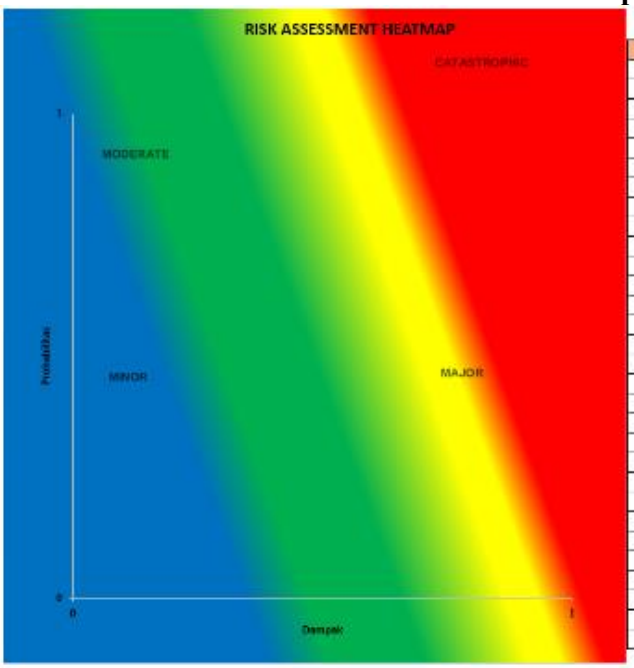
Table 4. Risk Register Model

No	NAMA KEGIATAN (PROSES BISNIS)	TUJUAN KEGIATAN	AREA / LOKASI	SEBAB	KODE RISI-KO	RISIKO	DAMPAK	PERNYATAAN RISIKO	PENGENDALIAN YANG SUDAH ADA SAAT INI
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)

ANALISA RISIKO INHERENT					EVALUASI RIISIKO	ALTERNATIF TEKNIK PENANGANAN RISIKO		
DAMPAK	PROBA-BILITAS	CONCAT (D & P)	SKOR	PERINGKAT RISIKO	APAKAH PERLU PENANGANAN RISIKO ?	OPSI TEKNIK PENGEN-DALIAN RISIKO	URAIAN PENANGAN-AN RISIKO	PEMBIAYAAN RISIKO
(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)

RISIKO RESIDUAL				PEMILIK RISIKO/ PENANGGUNG JAWAB	TARGET WAKTU
DAMPAK	PROBABILITAS	SKOR	PERINGKAT RISIKO		
(20)	(21)	(22)	(23)	(24)	(25)

Table 5. Risk Assessment Heatmap Model



No Risiko	Dampak	Probabilitas
R1		
R2		
R3		
R4		
R5		
R6		
R7		
R8		
R9		
R10		
R11		
R12		
R13		
R14		
R15		
R16		
R17		
R18		
R19		
R20		
R21		
R22		
R23		
R24		
R25		
R26		
R27		
R28		
R29		
R30		

Table 6. Risk Profile Model

NO	KATEGORI RISIKO	PERNYATAAN RISIKO	AKAR MASALAH (PENYEBAB UTAMA RISIKO)	DAMPAK (D)	PROBABILITAS (P)	CONTROLL-ABILITY (Pengendalian)	SCORING	RANGKING
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8) (5x6x7)	(9)

Table 7. Risk Management Plan Model

No	KEGIATAN	SASARAN	Risiko	ALTERNATIF TEKNIK PENANGANAN RISIKO		Pengendalian yang sudah ada			Rencana pengendalian			Pemilik Risiko	Penang-gung Jawab TL Pengenda-lian
				Opsi Teknik Penanganan Risiko	Uraian Penanganan Risiko	Pengendalian yang sudah ada	Efektif/ Kurang efektif	Pengendalian yang harus ada	Kegiatan	Waktu	Jenis (Detektif (D), Prevantif (P), Korektif (K))		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)

Table 8. Risk Control Monitoring Model

No	Kegiatan	Sasaran	Risiko	Penanganan			Usulan perbaikan	Waktu Pemantauan		Penanggung Jawab Pemantauan
				Rencana (Pengendalian yg harus ada)	Realisasi (Kegiatan Rencana Pengendalian)	Yang Belum Tertangani		Rencana	Realisasi	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)

Table 9. Monitoring Report Model

Prioritas Risiko	Penanganan Risiko						Status Risiko	
	Aksi/ Pengendalian	Output	Target	Realisasi	Waktu Implementasi	Penanggung Jawab	Trend (naik/turun)	Peringkat/ Level Risiko
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Acting and observing stage

At this stage socialization of the clinical risk register model and how to fill it out was carried out. Twenty participants involved in this study were divided into 8 units that would make a risk register. Those 8 units were the emergency department, inpatient department, outpatient department, operating room department, pharmacy department, laboratory department, radiology department, and nutrition department. All the units were given 2 weeks to make clinical risk register. Researchers together with a team of experts made observations in the implementation of making clinical risk register by 8 units using observation sheets.

Reflecting stage

The results of reflection from the implementation process of making a risk register in the previous stage found that there were 3 units (emergency, inpatient and outpatient department) that were not suitable for describing a risk statement and there were 5 units (emergency, inpatient, outpatient, pharmacy, and laboratory department) that are not suitable for conducting residual risk analysis.

Cycle 2

Revised plan stage

Based on the results of reflection in the first cycle, the clinical risk register that had been formed still found discrepancies in filling it out. Re-socialization on how to fill in the clinical risk register will be carried out in the second cycle of acting and at the end of this cycle an FGD will be carried out and also a measurement of the level of knowledge of the participants after implementation.

Acting and observing stage

The participants who were divided into 8 clinical units reviewed the clinical risk register that had been made and the researchers re-socialized the method of research. Participants made improvements of the clinical risk register that has been made and researchers observe the process of improving the clinical risk register by participants.

At this stage, a total of 55 risks have been identified in the clinical risk register that has been made and from the observations made by the researchers and the expert team, the clinical risk register that has been made is appropriate.

Reflecting stage

The results of the second cycle of observation were that the 8 units that involved in this research had made a clinical risk register up to risk treatment plans and had made them according to the technical instructions given. The results of the FGD at this stage produced 5 themes: 1) experience in making a clinical risk register, 2) challenges in making a clinical risk register, 3) supporting factors in making a clinical risk register, 4) improvements that must be made in making a clinical risk register, and 5) expectations from making a clinical risk register as a model for implementing clinical risk management in efforts to improve quality and patient safety.

Outputs of action research

The output of this study is the model of clinical risk register as implementation of clinical risk management and the formation of a clinical risk register in 8 clinical

units with a total of 55 risks identified from 8 units. The format for this clinical risk list has been established through a Hospital Director's policy.

Outcomes of action research

The results of the FGD at the reflecting stage of the second cycle showed an increase in participants' knowledge about clinical risk management as evidenced by statements from participants. Prior to the implementation of the clinical risk management implementation model, 80% of the participants had a good level of knowledge and 20% of the participants had a sufficient level of knowledge. After implementing the clinical risk management implementation model, it was found that all participants (100%) had a good level of knowledge. The average scores before and after implementation are 12.5 and 14.9. Comparison of the level of knowledge before and after the implementation of clinical risk management can be seen in table 11.

Table 11. Participants' knowledge improvement (n=20)

Knowledge	Before imple-mentation		After imple-mentation		Mean	
	f	%	f	%	Pre	Post
Good	16	80	20	100		
Enough	4	20	0	0	12.5	14.9
Less	0	0	0	0	-	

To find out whether there were significant differences in the level of knowledge of the participants before and after implementation, data analysis was carried out using a hypothesis test. The normality test is carried out first to see whether the data is normally distributed.

Table 12. Normality Test

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Sebelum	.217	20	.014	.859	20	.008
Sesudah	.527	20	.000	.351	20	.000

a. Lilliefors Significance Correction

The Shapiro-Wilk test in table 12 obtained the value of Sig. before implementation is 0.008 and after implementation is 0.000, where this number shows less than 0.05 so it can be concluded that the data is not normally distributed.

Because the data is not normally distributed, the researcher transforms the data. From the results of graphical analysis it was found that the shape of the histogram graph is moderate negative skewness so that the data is transformed using SQRT (k-x), where 'k' is the highest value of the raw data and 'x' is the raw data to be transformed. The normality test with Shapiro-Wilk after data transformation can be seen in the following table.

Table 13. Normality Test after Data Transformation

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.

Trans_sblm	.197	20	.040	.896	20	.035
Trans_ssdh	.527	20	.000	.351	20	.000

The results of the normality test after transforming the data in the table above show that the data is still not normally distributed because the Sig. smaller than 0.05, so that the researchers then used non-parametric analysis with the Wilcoxon Sign Rank Test. Non-parametric test results can be seen in table 14.

Table 14. Non Parametric *Wilcoxon Sign Rank Test*

Ranks

		N	Mean Rank	Sum of Ranks
Sesudah – Sebelum	Negative Ranks	0[a]	.00	.00
	Positive Ranks	18[b]	9.50	171.00
	Ties	2[c]		
	Total	20		

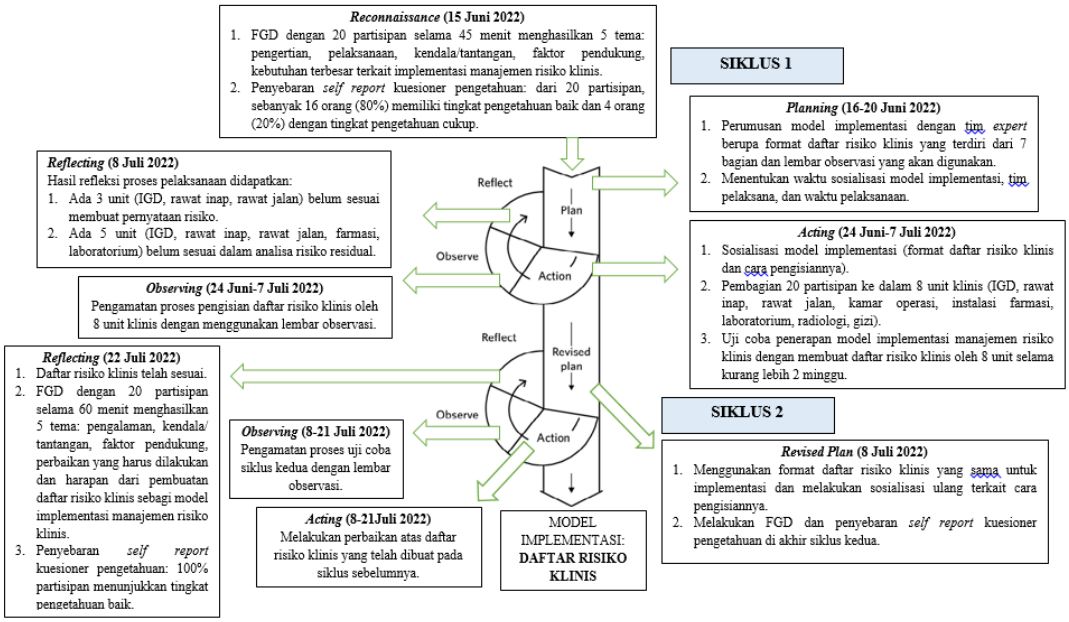
a. After < Before
b. After > Before
c. After = Before

Test Statistics[a]

	After - Before
Z	-3.757[b]
Asymp. Sig. (2-tailed)	.000

a. Wilcoxon Signed Ranks Test
b. Based on negative ranks.

From the results of the hypothesis test with the non-parametric Wilcoxon Sign Rank Test, the Asymp value was obtained. Sig. (2-tailed) is worth 0.000 (<0.05) so it can be concluded that there is a significant difference in the level of knowledge of the participants before and after the implementation of clinical risk management.



Picture 2. Scheme of Action Research Results

The process of developing a clinical risk management implementation model begins with the reconnaissance stage. (Dillon, 2008) stated that reconnaissance is included in the action research phase. This stage is the stage where the researcher determines 'where I am, what achievements are expected, and how to get these achievements' so that the existing problems can be formulated. Researchers collected initial data as material for formulation through data collection methods, which is focus group discussions and distributing questionnaires.

Focus Group Discussion (FGD) is a data collection technique in which a group of selected people discuss a particular topic or problem in depth facilitated by a moderator. This method aims to capture participants' complex personal experiences, beliefs, perceptions, and attitudes through moderated interactions (Cornwall & Jewkes, 1995). While the questionnaire is data collection that is done by giving a set of questions or written statements to respondents to answer (Noeraini & Sugiyono, 2016). (Galdas, 2017) state that in collecting data, trust is needed in the relationship between researchers and participants. The problems in this study can be identified because of the mutual trust between researchers and participants. The researcher established trust with the participants for quite a long time since the researcher worked at the research hospital (approximately 5 years before the research was conducted), so that researchers and participants were open to each other in discussions about this study. Based on the reconnaissance stage that has been carried out through FGDs and also distributing questionnaires, there are problems formulated by researchers related to the clinical risk management implementation model. The problem is that there is no clinical risk register for each unit as part of clinical risk management as an effort to improve quality and patient safety.

The results of research conducted by (Har-Noy et al., 2017) stated that the risk register helps to facilitate the implementation of good risk management and also risk management governance within the organization along with organizational

commitment, availability of resources, and staff capabilities to support risk management activities are needed so that the implementation of risk management can run well.

Cycle 1

At the planning stage, the researchers formulated a model of clinical risk management implementation together with a team of experts. (Kemmis, McTaggart, & Nixon, 2014) explained that the planning stage means oriented researchers with others to be able to make improvements and changes to be achieved. Researchers and participants together are in a position to unify the ideas in a detailed action plan. This plan must be perfected through a discussion (communicative action) as a basis for agreement about what the researcher will do. This statement is also in accordance with Costello (2003) which requires the role of active participants in action research research.

Researchers and the expert team discussed and agreed to use the model of clinical risk register from the Institute for Clinical Risk Management (IMRK/Institut Manajemen Risiko Klinis) in 2022. The researchers and expert team agreed to use the model from IMRK because this clinical risk register model already refers to hospital accreditation standards from Joint Commission International (JCI). Hopkin (2010) states that there is no fixed model for a risk register, but a risk register must contain at least a description of the risk, the level of risk (probability, impact, and risk score), and risk management measures. The existing risk register model from IMRK is a modification of the standard risk register according to Hopkin (2010). The risk register model that must be filled in consists of 7 sections, such as: activities and objectives, risk register, risk assessment heatmap, risk profile, risk management plan, risk control monitoring, and monitoring report. Before the researchers and the expert team agreed on the model of this clinical risk register, the researchers and the expert team conducted a trial by filling out the clinical risk register.

At the acting and observing stage, the researcher socialized the risk register model and how to fill it out to the participants. The activity of implementing clinical risk management in the form of compiling a clinical risk register by the participants was carried out in approximately 2 weeks. To see the progress of the implementation of clinical risk management in each unit, the researcher made an observation sheet as a reference in observing this implementation. This is in accordance with the opinion of Kemmis, McTaggart, and Nixon (2014) where at this stage the researcher collects various evidence or findings about what happened. The researcher begins to piece together the results of the observations made, collate the findings, and filter them to see if everything is going as the researcher planned. The results of these findings will be analyzed at a later stage. Observations were carried out by researchers together with the expert team, where clinical risk management is the scope of work that is carried out daily by researchers and also researchers have obtained risk management training certification from the Komisi Akreditasi Rumah Sakit (which is one of the accreditation institutions in Indonesia) while the assessment team are also the team who formulate the clinical risk register model used in this study are two experts in clinical risk management. The results of

observations from the researchers and the expert team were documented so as to generate feedback that the researchers would carry out in the reflecting stage in the first cycle, so that the reflection results obtained from the implementation of clinical risk management in the first cycle could be corrected in the second action research cycle.

The advantages of the acting and observing stage in this first cycle are the involvement of hospital management as participants in this study so that hospital management can obtain an overview of the importance of implementing clinical risk management that must be carried out by a hospital in order to minimize clinical risks that may occur. The participants have a commitment to improve the implementation of clinical risk management so that it can run even better. While the weakness in this stage is that the participants involved in this study are only representatives of their units so that participants who take part in the socialization and receive directions regarding making this clinical risk register must really understand so they can apply it in their units.

The reflecting stage was carried out by the researcher at the end of the first action research cycle. At this stage the researcher reflected on the process of implementing clinical risk management in the form of making a clinical risk register by each unit using the model which is has been agreed before. Kemmis, McTaggart, and Nixon (2014) stated that the reflecting stage is used as a stage for analyzing, synthesizing, interpreting, explaining, and drawing conclusions so that researchers can discover what happened, review what happened, including the achievements and limitations of implementation that has been done so it can be a reference for further actions and entered into planning in the next cycle. This statement is also in accordance with that stated by Costello (2003). At this stage it was found that there were still several units that were not suitable in filling out the clinical risk register, especially in the risk statement and residual risk analysis sections. This was because some participants were still confused and did not fully understand filling out the clinical risk register because some participants had never been exposed to clinical risk management before, so filling out this clinical risk register was something new for some participants. From the results obtained by the researchers at this reflecting stage, this research will then enter the second cycle, where improvements will be made in the second cycle so that the clinical risk register made by each unit can be appropriate.

Cycle 2

In the early stages of the second cycle, re-planning was carried out based on the reflection results obtained on the implementation of the first cycle. This stage is in accordance with the statement of Costello (2003) where action research is described as a cycle, where the cycle has critical actions and reflections that occur sequentially or alternately. Reflection is used to review previous actions and plan the next steps. Based on the reflection results obtained at the reflecting stage in the first cycle, the researchers and the expert team still found that there were several parameters that were not filled in according to the way they were filled out. The researcher plans to re-socialize the method of filling out the clinical risk register.

The acting stage of the second cycle is carried out for 2 weeks where participants do the re-check of clinical risk register that has been made for each unit in the previous cycle based on the clinical risk register model and make improvements if there are parameters that are not filled according to the recommendation from the expert team. The observation results showed that the participants had been able to make a clinical risk register by identifying clinical risks and planning to manage these risks. The results obtained at the acting and observing stages of the second cycle are in line with research conducted by (Qammaz, AlNasser, AlHamed, & Al-Khaldi, 2020) which states that education and training are important factors for the application of risk management to be effective and lack of knowledge can be a barrier not only in successful risk management but also the beginning of the implementation of risk management itself. Through the research process which was carried out in two cycles, in the second cycle of observation, there was an improvement in each participant in making a clinical risk register.

In the reflecting stage of the second cycle which is the final stage of these 2 action research cycles, FGDs are conducted and the measurement of the level of knowledge after implementation. (Kilanowski, 2017) explained that the end result of action research is not only related to increasing knowledge but also related to increasing awareness. The action research research process regarding the development of clinical risk management implementation models has an impact on increasing the knowledge of the participants involved. This impact is known through data collection conducted by researchers through the observations of researchers and expert teams, focus group discussions, and self-report knowledge questionnaires where the results of the hypothesis test conducted using the Wilcoxon Sign Rank Test show the Asymp value. Sig. (2-tailed) is 0.000 where the value obtained is less than the level of confidence (<0.05) so that it can be concluded that there is a significant difference in the level of knowledge of the participants before and after the implementation of clinical risk management. The results of this study are in line with research conducted by De França, et al. (2019) where there is an intervention in a process and also the provision of information that is carried out continuously can increase knowledge effectively. This is also supported by (Amiri, Sharifian, & Soltanizadeh, 2018) which states that someone who is given the same information continuously tends to have good knowledge, where knowledge will affect competence which can produce changes for the better.

Talet (2018) states that knowledge has an important role in implementing risk management through risk assessment. This statement is also in line with (Carroll, 2015) where one of the important components in the risk management framework is the existence of human resources who have competence, experience and ability to manage risk. We hope that the participants' knowledge about the clinical risk management implementation model in this study will increase the implementation of clinical risk management in class C private hospitals in West Jakarta to be more effective and optimal to ensure quality of service and patient safety.

Limitations of the study

In the process of this research, there were several limitations: 1) limited information from existing literature or journals, because during the search by researchers, researchers found there was still a lack of similar studies or journals that use of action research in reviewing the implementation of clinical risk management; 2) this study was only conducted in two cycles so that researchers could not see significant changes related to the application of clinical risk management in improving the quality and patient safety in hospitals by evaluation and monitoring of the clinical risk register that had been made through the clinical risk register model in the monitoring risk control section and monitoring reports section that have not been implemented and also the formation of the work culture of hospital staff; and 3) limitation of time on each action research cycle, where each cycle is only carried out in approximately two weeks time due to the limitation of time of researchers and participants.

CONCLUSION

This research was conducted to develop a model for implementing clinical risk management to improve quality and patient safety in class C private hospitals in West Jakarta with an action research approach conducted in 2 cycles. At the reconnaissance stage a focus group discussion (FGD) was carried out and a self-reported knowledge questionnaire was also distributed to determine the participants' level of knowledge about clinical risk management prior to implementation. In the first cycle planning stage, the formulation of a clinical risk management implementation model that will be applied in this study is clinical risk register model based on references from the Institute for Clinical Risk Management (IMRK/Institut Manajemen Risiko Klinis) and JCI accreditation standards, which will be made by 8 units in the hospital containing emergency department, inpatient department, outpatient department, operating room department, pharmacy department, laboratory department, radiology department, and nutrition department.

The preparation of the clinical risk register was carried out in the acting stage after socialization of the clinical risk register model and how to fill it in, then the implementation process was observed in the observing stage using observation sheets by the researchers and the expert team. The results of the reflection of the first cycle at the reflecting stage found that there were 3 units (emergency, inpatient and outpatient department) most of which were not appropriate in describing the 'cause', 'risk' and 'impact' statements that made a risk statement which are described are also not appropriate and there are 5 units (emergency, inpatient and outpatient, pharmacy, and laboratory department) most of which are not appropriate in providing scoring in the residual risk analysis. Based on the reflection results obtained from the first cycle, a plan was made re-socialize on how to fill out the clinical risk

register and the participants returned to improve the clinical risk register that had been made in the second cycle acting stage and were observed again.

From the implementation of the second cycle, it was found that the clinical risk register made was appropriate from the 8 existing units. The second stage of FGD was conducted at the end of the second cycle in the reflecting stage and at the self-report at the end of the cycle, it was found that 100% of the participants had good knowledge where this result indicated an increase in participant knowledge and a hypothesis test was carried out using the non-parametric test with the Wilcoxon Sign Rank Test with an Asymp value. Sig. (2-tailed) is 0.000 (<0.05) so that it can be concluded that there is a significant difference in the level of knowledge of the participants before and after the implementation of clinical risk management.

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