The Differences of Patient Safety Incident by Health Workers in Accredited and Non-Accredited Primary Health Care

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Abstract The study aims to identify the differences of patient safety incident (PSI) by health workers in accredited and non-accredited Primary health care (PHC) by its frequency and severity of harm. This research used analytic crossectional method. A well-structured questionairre of 15 patients' safety indicators was administered to collect response of Nurse and midwife in 3 accredited PHC and 3 non-accredited PHC about patients' safety incident in last month. In the result, overall the incident happened more frequent in non-accredited PHC than in acrredited PHC which is statistically significant (CI 95%, p=0.002). Specifically, what the nurses handle is about medication (CI 95% $p=0.018$) and therapeutic treatment (CI 95% p=0.036). Also, it is about the education (CI 95% p=0.025) and documentation (CI 95% p=0.013). Still, two indicators of midwife's treatment while transferring and about the education involved minor harm.

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Introduction

In recent years, the number of patients' safety incident (PSI) increases in international area and in Indonesia. In 1980-2014, in average there were 2-3 PCI in 100 visits in Primary Health Care (PHC) (Panesar et al., 2016). Moreover, there is minimum 1 PCI which happens daily in Primary Health Care (PHC) in Swiss (Gehring et al., 2012). In UK, there are 2191 PCI in pediatric which make minor harm to death in PHC in 2005-2013 (Rees et al., 2017). In Indonesia, the data of PSI on PHC are still rare and unclear, and those are still most available in hospital not in PHC. Besides, the example is taken from PSI report by Komite Keselamatan Rumah Sakit (KKPRS) in 2007 by province. Jakarta ranks highest (37.9%) among 8 other provinces. They are Central Java (15.9%), Yogyakarta (13.8%), East Java (11,7%), South Sumatera (6.9%), West Java (2.8%), Bali (1.4%), Aceh (10.7%), and South Sulawesi (0.7%) (Keles, 2015). In Yogyakarta itself, the data mostly get from hospital too. For example, in a hospital of Yogyakarta, there are 2 PSI about fall risk and near miss from January until June 2013 (Fatimah & Rosa, 2016).

WHO responds this PSI issues by making a modul of "The Technical Series on Safer Primary Care". It has happened because PHC becomes a soul of continuing care in society. Also, it can realize the aim of Sustainable Development Goals (SDG) which gives priority of health life and well-being life promotion (Simmonds & Alexander, 2015; WHO, 2017). Indonesia starts paying attention to patients' safety in PHC by applying BPJS system which utilizes the PHC more. In this case, it makes the PHC get more attention in patients' safety aspect too. Patients' safety in Indonesia is regulated in Permenkes number 11 year 2017

regarding the patients' safety and in Permenkes number 75 year 2014 about PHC. Then, this rule is inserted in PHC accreditation standard as an assesment standard of PHC (Kemenkes RI, 2015b, 2015a, 2017).

Indonesia implemented PHC accreditation in last 2015. The purpose of this accreditation is to increase the facility and quality of PHC service in human resources, equipment, infrastructure, and the legal aspect. In Yogyakarta, most of PHC have been accredited, and most of them are passed and certified as basic (dasar), middle (madya), primary (utama), or plenary (paripurna) level.

Then patient safety is mentioned in article 7, 11, 15, 17, and 16 of PHC accerditation standard. Moreover, patients' safety is specially regulated in chapter IX that is chapter of quality service and patients' safety. But, this standard refers to Hospital Patient Safety guidelines, so the PHC is required to have their own indicators about the patients' safety based on each PHC. This indicators should be evaluated, monitored, and followed-up based on the result. And regarding the fulfillment of the elements of PHC accreditation assessment, PHC will strive to maintain and continue the patients' safety event in PNC so the incident of patients' safety at the accredited PHC can decrease. But no research has indicated any influence of PHC accreditation in patient safety aspect, especially in PSI. Therefore, we sought to identify the differences of PSI in accredited and non-accredited PHC.

Literature Review and Hypothesis Development

According to Permenkes RI Number 11 year 2017 about Patient safety, patient safety is a system in hospital which make the patients feel safe. The system includes the risk assesment, identification, report, incident analysis, lerning ability, follow-up the plans, and the solution implementation (Kemenkes RI, 2017).

Patients' safety was started in 1999 when the Institute of Medicine (IOM) broadcasts the report about "To Err is Human". Also, it influences international to reduce harm in patient which is caused by health workers (Kohn, Corrigan, & Donaldson, 2000).

Patients' safety target In Indonesia is based on WHO standard and Joint Comission International (JCI). Then it is applied as a rule in patients' safety and in PHC accreditation assesment standard. There are 6 targets, namely right patient identification, effective communication, high alert drug supervision, right location, right procedure, and right patient in the surgery. The following target is to reduce the risk of nasocomial infection, and reducing patient fall risk comes up as the last target.

Patient safety incident (PSI) in Indonesia is regulated in Permenkes RI number 11 year 2017. PSI is an incident or the conditions that result or potential result in a preventable injury to the patient consists of harmful incident/adverse event (KTD), near miss (KNC), no harm (KTC), reportable circumstance (KPC), and sentinel. Harmful incident or adverse event is an incident which results dangerous threatment to a patient. Nearmiss is an incident which does not reach the patient. Not giving dangerous threatment to the patient is one of the ways which an event reached a patient without giving discernable harm resulted. Reportable circumstance is a situation which significant potential for harm is, but there is no incident occurred. Hence, sentinel is a harmful incident or adverse event which causes the death or serious harm.

PSI is caused by so many factors. According to Carayon et al. (2006) who used work system model, a person can be a care provider, another employee of a healthcare institution such as a biomedical engineer, a unit clerk, or the patient performs a range of tasks using various tools and technologies. The performance of these tasks occurs within a certain physical environment

and under specific organizational conditions. The five components of work system (person, tasks, tools and technologies, physical environment, organizational conditions) interact and influence one another. The interactions among the various components produce different outcomes such as performance, safety and health, and quality of working life. Besides, a study conducted by Rees et al. (2017) and Singh et al. (2013) contributes in Primary care in UK, and the factors contributed to PSI are staff factor, organization factor, patient factor, equipment and drug factor, and environment factor.

PHC accreditation in Indonesia is regulated by Permenkes RI number 46 year 2015 which mentioned that accreditation is the acknowledgment given by the independent accreditation organizers stipulated by the Minister after meeting the Accreditation standards (Kemenkes RI, 2015b)

This accreditation program was prepared since 2014, but it was just started in 2015. This program will be held gradually, and in 2019, all health centers in the region of Indonesia have been accredited. Puskesmas will be categorized into accredited plenary (paripurna), accredited primarily (utama), accredited medium (madya), accredited basis (dasar), or not accredited based on accreditation assessment. The aims of the accreditaion are to improve the service of quality and patients' safety. Also, it is to improve the protection of human resources health, society and environment, and Puskesmas, and to improve the performance of PHC during giving health service. In accreditation assesment standard, patients' safety is regulated in chapter IX which assesses the responsibility of health workers, comprehension of quality service, assesment of quality service and patient safety target, and improvement of quality service and patient safety.

The relation between accreditation and patient safety has been discuss but in hospital not PHC. According to (Lee, 2016) and (Wijaya & Dewi, 2015), hospital accreditation influences the patients' safety culture and nurse's report. After processing of accreditation, nurse can identify about the patients' safety and is aware to report PSI. However, (Gehring et al., 2012) has been asses the PSI indicator in PHC in Germany. Still, he did not mind about the accreditation status.

Research Method
This research has been conducted in 3 primarily (*utama*) accredited PHC and 3 non-accredited PHC in a district of Yogyakarta for two months from September 2017 until November 2017. The method is analytical crossectional quantitative design. The population in this study is nurse and midwife in those PHC.
Total sampling method got 89 nurses and midwives, specifically 45 nurses and midwives in accredited PHC while in non-accredited PHC was 44 nurses and midwives who met the inclusion and exclusion criteria. The inclusion criteria was the nurse and the midwife who agreed to be the respondents and submitted the questionairre on time. Accordingly, the exclusion criteria were the nurse and midwife who had in periods of leave, sick, or undertaking further studies when the research was ongoing.
Tools and materials used in this research are the informed consent form and a questionairre about patient safety incident. The questionairre consists of 15 PSI indicators and was taken and modified from previous research by Gehring et al. (2012) and Rees et al. (2015, 2017). This questionaire asked the respondents to recall the PSI frequencies which they had done in last month. Also, it recalled the memory of respondent about severity of harm which arised from PSI by "no harm", "minor (minimal) harm", "moderate", "severe", or "death".
The questionairre was directly given to the respondent and the researcher gave the respondent one week to fill the questionairre. It was intended to make the respondent have more time in recall and filling the questionairre. But, the respondent was guided and accompanied by the

researcher before fill the questionairre. Then, non parametric independent-t-test was used to identify the differences of PSI in accredited PHC and non-accredited PHC. After the test got result, it could be identified the differences of patient safety incident between accredited and non-accredited PHC based on it's frequency and it's severity of harm.

Result and Discussion

Characteristic

This research used 89 nurses and midwifes as the repondents from 3 accredited PHC and 3 non-accredited PHC. The table 1 shows that most of respondents are midwives (60%) both in accredited and non-accredited PHC. Based on the gender, most of them are woman calculated in 91% in non-accredited PHC and 95% in accredited PHC. In non-accrdited PHC, most of them are 31-50 y.o. (78%), have worked more than 10 years (50%), and 5-10 years have worked in the last place (49%). In accredited PHC, most of them are 31-50 years old who worked as long as 5-10 years (52%) and have been in the last place in 5-10 years (61%). Both of PHC do not have the workers in the age of more than 58 years old. This is appropriate with the provisions of retirement age, which is 58 years old. Based on participation in patient safety training, most of respondents never follow the training both in non-accredited PHC (67%) and in accredited PHC (98%).

Table 1. Responden Characteristics by Profession, Age, Gender, Year of proffesional experience, Years of work in this office, and Participation in patient safety training

No	Characteristic	Number (%)	
		Accredited PHC	**Non-Accredited PHC**
1	**Profession**		
	Nurse	18 (40)	18 (20)
	Midwife	27 (60)	26 (60)
2	**Gender**		
	Male	4 (9)	6 (5)
	Female	41 (91)	57 (95)
3	**Age**		
	<31 y.o.	7 (16)	4 (9)
	31-50 y.o.	35 (78)	28 (63)
	51-58 y.o.	3 (6)	12 (27)
	>58 y.o.	0 (0)	0 (0)
4	**Year of proffesial experience**		
	1-5 years	4 (9)	1 (2)
	5-10 years	18 (40)	23 (52)
	>10 years	23 (50)	20 (46)
5	**Years of work in this office**		
	1-5 years	4 (9)	4 (9)
	5-10 years	22 (49)	27 (61)
	>10 years	19 (42)	13 (30)
6	**Participation in patient safety training**		
	Yes	15 (33)	1 (2)
	No	30 (67)	43 (98)
Total		45 (100)	44 (100)

PSI Frequency

This study aims to identify the differences of PSI in accredited PHC and non-accredited PHC by identified the frequency and its severity of harm in nurse and midwife in the last month. This discussion focused on the patients' safety indicator which had more frequency or only happened in accredited PHC and indicator which effect severity of harm in patient.

Table 2 shows that overall PSI in both nurse and midwife is more frequent in non-accredited than accredited PHC. It is supported by the different aspect which is statistically significant (p=0.002).

Table 2. Frequency of PSI in Accredited and non-Accredited PHC in August 2017 by Nurse and Midwife

No	Profession	PSI		
		Frequency		CI 95%
		Accredited PHC	Non-Accredited PHC	
1	Nurse	47	35	0.335
2	Midwife	49	19	0.002
	Total	96	55	0.002

This differences were caused by the accredited PHC had assesed during proccess of accreditation especially in Chapter Quality Service and Patients' Safety which consists of clinical staff's responsibilities, understanding, measurement, and quality improvement on clinical services and patient safety. Those made health workers, nurse and midwife in accredited PHC knew more about quality service and patient safety. Besides, the result was in line with Elnour et al. (2014) who said that in Australia, the accreditation program had improved the quality service and patient safety, especially in PSI reporting and regular meeting to discuss about PSI prevention. Mohebbifar, Rafiei, Asl, Ranjbar, & Khodayvandi (2017) also explained that hospital accreditation status in Bangladesh statistically significant wtih patient satisfaction on hospital infrastructure, equipment, information, education, and communication because accreditation had reached both in clinical and non clinical proccess and outcome. It can be concluded that in development country, accreditation becomes one improvement factor in quality of service.

Specifically, figure 1 and table 3 show the PSI in nurse and midwife. Three top rank indicators in non-accredited PHC by nurse is Q14 (Information from external provider is missing, incomplete, or errant when required), Q13 (Relevant message or notice relayed, left, or passed incomplete, wrong, incorrect, or unclear), and Q3 (Required medication not prescribed, administered, or dispensed). Besides, midwifes are Q13 (Relevant message or notice relayed, left, or passed incomplete, wrong, incorrect, or unclear), Q14 (Information from external provider is missing, incomplete, or errant when required), and Q8 (Failure to perform a properly ordered therapeutic intervention while transferring the patient).

In Acredited PHC, three top rank indicators through nurse are Q13 (Relevant message or notice relayed, left, or passed incomplete, wrong, incorrect, or unclear), Q14 (Information from external provider is missing, incomplete, or errant when required), and Q12 (Failure to educate

Frequency of Patient Safety Incident (PSI) in Accredited and Non-Accredited Primary Health Care (PHC) by Nurse and Midwife in Last Month

	Q1	Q2a	Q2b	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14
Non-Accredited (Nurse)	3	0	0	5	4	3	3	3	1	1	2	4	4	6	8
Accredited (Nurse)	0	1	0	0	0	0	1	2	1	2	1	2	6	10	9
Non-Accredited (Midwife)	5	4	0	5	0	1	0	3	5	4	0	4	1	9	8
Accredited (Midwife)	2	4	1	1	1	1	1	1	1	1	1	1	1	1	1
CI 95% (Nurse)	0,74	0,317	1	0,018	0,036	0,074	0,296	0,338	1	0,968	0,552	0,188	0,313	0,435	0,884
CI 95% (Midwife)	0,4	0,694	0,308	0,095	0,308	0,979	0,308	0,321	0,095	0,312	0,308	0,176	0,979	0,025	0,013

Indicator

Legend: Non-Accredited (Nurse), Accredited (Nurse), Non-Accredited (Midwife), Accredited (Midwife)
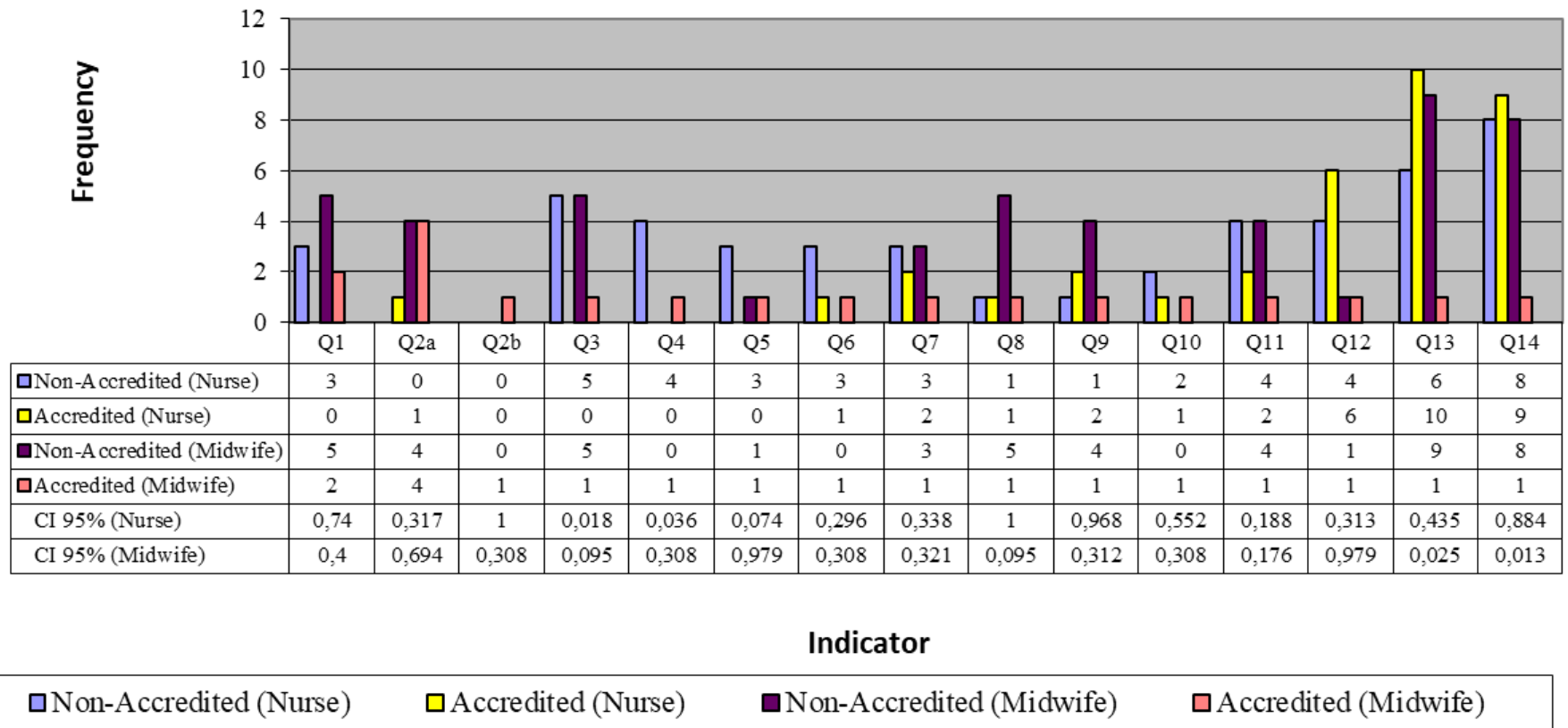
Figure 1. Frequency of PSI in Accredited PHC and Non-Accredited PHC by Nurse and Midwife in last month

patient about use of medication when administering or dispensing drugs). While by midwife are Q2a (Errant or incorrect prescription, administration, or dispensing of medication: wrong agent or wrong route or wrong dose/amount or wrong timing) and Q1 (Indicated test or examination not performed or performed at the wrong time).

Table 3. Indicators of PSI by nurse and midwife

Q1	Wrong or unnecessary test or examination performed
Q2	Errant or incorrect prescription, administration, or dispensing of medication:
	a. agent or wrong route or wrong dose/amount or wrong timing
	b. known interaction or contraindication, or intolerance or allergy not considered
Q3	Required medication not prescribed, administered, or dispensed
Q4	Wrong or inappropriate therapeutic intervention ordered or performed
Q5	Indicated therapeutic intervention not performed, or delayed
Q6	Failure to accurately perform a properly ordered therapeutic intervention
Q7	Failure to adequately monitor patient subsequently after therapeutic procedure in the office
Q8	Failure to perform a properly ordered therapeutic intervention while transferring the patient
Q9	Urgency of patient need not recognized at contact
Q10	Tests or treatments performed without patient consent
Q11	Failure to communicate correct test results or diagnosis to patient
Q12	Failure to educate patient about use of medication when administering or dispensing drugs
Q13	Relevant message or notice relayed, left, or passed incomplete, wrong, incorrect, or unclear
Q14	Information from external provider is missing, incomplete, or errant when required

The figure 1 also shows that most of the indicator have the higher frequency in non-accredited PHC than accredited PHC. However figure 1 also shows about the indicator which has higher frequency in acrredited PHC, but it is not statistically significant. Those indicators are Q2a (Errant or incorrect prescription, administration, or dispensing of medication: wrong agent or wrong route or wrong dose/amount or wrong timing), Q9 (Urgency of patient need not recognize at contact), Q12 (Failure to educate patient about use of medication when administering or dispensing drugs), and Q14 (Information from external provider is missing, incomplete, or errant when required) by nurse. Thus, midwife is Q2b (Errant or incorrect prescription, administration, or dispensing of medication known as interaction or contraindication, or intolerance or allergy not considered) and Q6 (Failure to accurately perform a properly ordered therapeutic intervention).

Those summarization is about diagnosis, medication/treatment, communication, and documentation. Even though, it was contardictory with PHC accreditation assesment in chapter 9.3.1 about Measurement which had to use effective instruments to assess quality of service and patient safety target. On that chapter, in number 3, there was criteria of quality service assesment including patient's assesment aspect, diagnosis support service, use of antibiotic, and nasocomial infection control (Kemenkes RI, 2015a). Those criteria should be a standard to prevent PSI on PHC. But, that criteria as the government policy factor is not the only one factor which influences PSI. According on Rees et al. (2017) and Singh et al. (2013), the factors that influence PSI in UK PHC come from staff factor, organization factor, patient factor, drug and equipment factor, and environment factor. Moreover, Carayon et al. (2006) explained that most of errors and inaccuracies appear not form individues, but it comes from conflict, incomplete system, or less optimal system in work place. Lawton et al. (2012) also mentioned that there are 18 factors which influence PSI in hospital, and those are communication, equipment availibility,

government policies, design of equipment, individu factor, management, patient factor, workplace environment, patient safety culture, schedule, work time, supervision, support form government, work characteristic, team factor, and the last is education and training factor.

One factor about government policies was explained by Mohebbifar et al. (2017) who stated that in Bangladesh there was no consistency between accreditation standard and patient medical needs, so it needs evaluation which can fulfill the patient's need. In this case, it occurs about communication. Health worker knowledge as another factor was explained by Bawelle, Sinolungan, & Hamel (2013) that in one of Hospital in North Sulawesi healthworker knowledge was statistically significant with patient safety implementation. Higher knowledge health worker made more active in patient safety implementation. In this research, the respondents in accredited PHC had more frequency on those indicators because they had more knowledge about patient safety from pra and pasca accreditation training. Pra accreditation training is one of accreditation process series to make the PHC ready for the accreditation assesment. Besides, pasca accreditation accompaniment is an event to maintain and improve the standard accreditation achievement until the next accreditation assesment. Those apects mentioned previously, could make health worker in accredited PHC more understandable to the patient safety, so they could identify potential incident before the real PSI.

Severity of Harm
Severity of harm in this study is divided into no harm, minor, moderate, severe, and death. However, the data result in table 4 shows that the severity harm which happened is only no harm and minor harm. There is no indicator which shows moderate, severe, or death. Also, the minor harm only happened by midwife in non-accreditation PHC. Those indicators are Q8 (Failure to perform a properly ordered therapeutic intervention while transferring the patient)) and Q13 (Relevant message or notice relayed, left, or passed incomplete, wrong, incorrect, or unclear).

In this study, there were 2 indicators of midwife in non-accredited PHC which influence minor harm in patient. Thos indicators were about educating the patient and giving treatment while transfering the patient. Those factors did contribute to harm even death in patient, and in this midwifery, it was neonatal and maternal death.

According to Handriani & Melaniani (2015), transferral procces in Sidoharjo district of East Java affected the maternal death. Besides, the midwife should educate the productive woman age, improve the family role, people, and health cares to detect the complication during pregnancy, labour, post partum, improve the quality of Ante Natal Care (ANC), and improve the transferral quality by using closed tranferral system in the maternal area who has high risk can be followed-up.

In addition, according to Trisnantoro & Komala (2015), in Bantul district there was fact that human resources availibility, equipment, and drug were not appropriate with Basic Emergency Neonatal Obstetric Services (PONED) and Comprehensive Emergency Neonatal Obstetric Services (PONEK). Moreover, referral communicatin levels was not ideal. The implementation of health insurance did make the late medical claimed service while the government supervision is not optimal.

Table 4. PSI Severity of Harm by Nurse and Midwife in Accredited and Non-Accredited PHC in August 2017

No	Indicator	Nurse		Midwife	
		Non-accredited	Accredited	Non-accredited	Accredited
Q1	Wrong or unnecessary test or examination performed	100% No Harm	-	100% No Harm	100% No Harm
Q2	Errant or incorrect prescription, administration, or dispensing of medication:		100% No Harm	100% No Harm	100% No Harm
	a. agent or wrong route or wrong dose/amount or wrong timing	-	-	-	-
	b. known interaction or contraindication, or intolerance or allergy not considered	-			
Q3	Required medication not prescribed, administered, or dispensed	100% No Harm	-	100% No Harm	100% No Harm
Q4	Wrong or inappropriate therapeutic intervention ordered or performed	100% No Harm	-	-	100% No Harm
Q5	Indicated therapeutic intervention not performed, or delayed	100% No Harm	-	100% Minor	100% No Harm
Q6	Failure to accurately perform a properly ordered therapeutic intervention	100% No Harm	100% No Harm	-	100% No Harm
Q7	Failure to adequately monitor patient subsequently after therapeutic procedure in the office	100% No Harm	100% No Harm	100% No Harm	100% No Harm
Q8	Failure to perform a properly ordered therapeutic intervention while transferring the patient	100% No Harm	100% No Harm	50% No Harm 50% Minor	100% No Harm
Q9	Urgency of patient need not recognized at contact	100% No Harm	100% No Harm	100% No Harm	100% No Harm
Q10	Tests or treatments performed without patient consent	100% No Harm	100% No Harm	-	100% No Harm
Q11	Failure to communicate correct test results or diagnosis to patient	100% No Harm	100% No Harm	100% No Harm	100% No Harm
Q12	Failure to educate patient about use of medication when administering or dispensing drugs	100% No Harm	100% No Harm	100% No Harm	100% No Harm
Q13	Relevant message or notice relayed, left, or passed incomplete, wrong, incorrect, or unclear	100% No Harm	100% No Harm	67% No Harm 33% Minor	100% No Harm
Q14	Information from external provider is missing, incomplete, or errant when required	100% No Harm	100% No Harm	100% No Harm	100% No Harm

Educating the patient or communication aspect still becomes one of reported medical error, near miss, or potential factor (Smith, Baker, & Wesley, 2017). This is also in line with Haskard Zolnierek & DiMatteo (2009) in 1949-2008 who stated that health worker communication is statistically significant wtih patient adherence. Additionally, Haskard Zolnierek & DiMatteo, (2009) explained that there was 19% higher risk of patient nonadherence in health worker who had less communication with their patient. It is also supported by Firdaus & Dewi (2015) that communication becomes one determinant factor of patient satisfaction as a service user, and it is also communication as one of the indicators in the assessment of service quality in health service. Satisfied patients will deal with the advice, loyal and adherence the treatment plan. Moreover Marie & Sinsky (2015) showed that adherence patients give bigger influence in patient's health. Consequently, those studies showed that communication aspect between health worker and patient become one important factor in making better or worse the patient condition.

Besides in minor harm, another no harm indicator should be aware too. This causes no harm indicators that may be potential to be another PSI, as near miss, accordance with the definiton in Permenkes RI number 11 year 2017 about Patient safety (Kemenkes RI, 2017). Therefore, it needs attention from health worker, PHC managerial, and even from government in controling and reducing PSI in PHC.

Conclusion

This study showed that accreditation process can reduce the PSI frequency and severity of harm in PHC which is proved by the higher frequency of PSI in non-accredited PHC than in accredited PHC. Besides of that, PSI indicator in non-accredited PHC involved minor harm. That's because of the accredited PHC had assesed during proccess of accreditation especially in Chapter Quality Service and Patients' Safety which consists of clinical staff's responsibilities, understanding, measurement, and quality improvement on clinical services and patient safety. Those made health workers, nurse and midwife in accredited PHC knew more about quality service and patient safety. But, regular meeting should be routinely performed to evaluate the PSI and also refreshing training about patient safety in diagnosys, therapy, communication, documentation, and proffesional ethics should be conducted, too. However this study can not identify the specific incident form and the right factor which influences the PSI. That way, in the further study, it should not only do the quantitative study, but also qualitative study by doing deep interview to the respondents.

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