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LITERATURE REVIEW

HEALTHCARE FAILURE MODE AND EFFECT ANALYSIS DESIGN FOR INDONESIAN HOSPITAL LABORATORIES: A LITERATURE REVIEW

Desain Healthcare Failure Mode and Effect Analysis untuk Laboratorium Rumah Sakit Indonesia: Tinjauan Pustaka

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ABSTRACT

Background: Error rate in medical laboratories is very low. Only one error is identified every 330–1,000 events. The goal of laboratory services should outweigh patient safety in a well-structured manner. Healthcare Failure Mode and Effect Analysis (HFMEA) is a proactive preventive method for identifying and evaluating potential failure.
Aims: This study identified factors affecting patient safety in hospital laboratories and described potential risk identification process using the HFMEA.
Methods: This study was conducted between March-July 2020 and retrieved data from PubMed, Scopus, and Google Scholar. The data were generalized and extracted into Table 1 based on factors dealing with patient safety in hospital laboratories. This study performed a risk identification design based on the steps of HFMEA.
Results: Out of 4,062 articles collected, only 8 articles between 2013–2020 were included for analysis. The highest error rate in laboratories occurred in the pre-analytic phase (49.2%–84.5%). The errors included clotted and inadequate specimen volume, and thus the specimens were rejected. Factors related to patient safety in laboratories were patient condition, laboratory staff performance (including training, negligence, and burnout), facilities, and accreditation.
Conclusion: The HFMEA process used the result of hazard analysis with severity and probability criteria categorized into health sector. Decision tree analysis could determine the next step of the work process. The HFMEA must be adjusted to the equipment and technologies in each hospital laboratory. Leader's commitment in monitoring and evaluation is required to maintain patient safety culture. More comprehensive data from Indonesian hospital laboratories are needed to generate more representative and applicable results.

Keywords: error, HFMEA, laboratory, patient safety

ABSTRAK

Latar Belakang: *Tingkat kesalahan di laboratorium medis sangatlah rendah. Satu kesalahan teridentifikasi pada 330–1.000 kejadian. Keselamatan pasien harus tetap diutamakan sebagai tujuan layanan laboratorium secara terstruktur.* Healthcare Failure Mode and Effect Analysis (HFMEA) *merupakan metode pencegahan proaktif untuk mengidentifikasi dan mengevaluasi potensi kegagalan.*
Tujuan: *Penelitian ini mengidentifikasi faktor-faktor keselamatan pasien di laboratorium rumah sakit serta menunjukan proses identifikasi potensi risiko menggunakan HFMEA.*
Metode: *Penelitian ini dilakukan pada Maret–Juli 2020 menggunakan data dari PubMed, Scopus, dan Google Cendekia. Data digeneralisasi dan ekstraksi dalam Tabel 1 berdasarkan faktor keselamatan pasien di laboratorium rumah sakit. Selanjutnya, proses identifikasi risiko dilakukan menggunakan HFMEA.*
Hasil: *Dari total 4.062 artikel yang didapat, sebanyak 8 artikel keluaran 2013–2020 digunakan dalam penelitian ini. Tingkat kesalahan tertinggi di laboratorium terjadi pada fase pre-analitik (49,2%–84,5%), di antaranya berupa clotting dan volume spesimen yang tidak mencukupi sehingga terjadi penolakan spesimen. Faktor yang berhubungan dengan keselamatan pasien di laboratorium berupa kondisi pasien, kinerja petugas laboratorium (termasuk pelatihan, kelalaian, dan stress kerja), fasilitas dan akreditasi.*
Kesimpulan: *Penerapan HFMEA menggunakan nilai hazard analysis dengan kriteria keparahan dan kemungkinan dikategorikan khusus bidang kesehatan. Decision tree analysis digunakan untuk menentukan langkah berikutnya pada tahap proses pengerjaan. Penerapan HFMEA perlu disesuaikan dengan fasilitas peralatan serta teknologi yang ada pada masing-masing laboratorium rumah sakit. Diperlukan komitmen pimpinan dalam monitoring dan evaluasi untuk menjaga budaya keselamatan pasien. Data lebih lanjut tentang*

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laboratorium rumah sakit Indonesia diperlukan untuk menghasilkan temuan yang lebih representatif dan aplikatif.

***Kata kunci**: eror, HFMEA, laboratorium, keselamatan pasien*

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INTRODUCTION

Patient safety is fundamental to provide essential health services (WHO, 2019). Medical practices have risks that can endanger patient safety and contribute to patient safety incidents due to unsafe health services. According to WHO, adverse events due to unsafe medical services are one of the top 10 causes of deaths and disabilities in the world, where nearly 50% of them can be prevented. Based on the previous study on patient safety in Spanish primary health centres, every 9.6 of 1,000 patient visits would produce adverse effect, although the degree of seriousness was low (Romero *et al.*, 2017).

Hospitals, a complex organization in providing quality services, need to care for the possible risks. The laboratory has an vital role in hospital activities and diagnosis of infectious diseases caused by parasites, fungi, bacteria, and viruses (Megiwati, 2015). According to Plebani (2002), almost 70% of patient's diagnoses and clinical treatment are based on laboratory results. Additionally, Jiang *et al.* (2014) mention 80%–90% of the laboratory test results play an essential role in establishing a patient's diagnosis (Carraro P, 2002; Jiang *et al.*, 2014). Another study has shown despite the low error rate in the medical laboratory compared to other units at the hospital, most of these errors rarely become an adverse event. Patient safety should be the goal of laboratory services, and the principles should be applied systematically in a well-structured manner (Aita *et al.*, 2017).

Research at Cantonal Zenica Hospital Bosnia–Herzegovina from December 2016–March 2017 analyzed 35,343 blood samples that were rejected in the laboratory information system due to pre-analytic errors, including haemolysis at 48.50%, clotting at 39.87%, unsuitable volume samples at 7.81%, wrong tube test at 2.16%, and identification errors at 1.66% (Kadić, Avdagić-Ismić, and Hasić, 2019). Lichenstein (2016) states that 82.8% of the errors in the laboratory were caused by human factors (errors performed by staff (43.5%), nurses (22.6%), and physicians (4.8%)). The majority of the laboratory errors (51.5%) were not associated with harm. As many as 17.4% of the patients were harmed due to the errors, 98.6% of the patients were temporarily harmed, and required treatment, and 0.7% of the patients were hospitalized or had their hospitalization prolonged due to the errors (Lichenstein *et al.*, 2016).

In 2001, the National Center for Safety Patient (NCPS) chose the traditional the Failure Mode and Effect Analysis (FMEA) approach as the basis for developing a risk analysis in the health sector (DeRosier *et al.*, 2002; Widianti, 2015). Based on the investigation results,, the NCPS explains the traditional FMEA was unable to meet the needs of the health sector. The NCPS believes that it is necessary to adjust risk assessment indicators in the traditional FMEA according to the health needs, and thus the concept of Healthcare Failure Mode and Effect Analysis (HFMEA) was born (DeRosier *et al.*, 2002; Widianti, 2015). Risk identification using the HFMEA is a proactive method to identify, evaluate, and record failure modes that cause problems and impacts. These will prevent potential

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risks that can endanger patients and health service staff (Colman *et al.*, 2019).

Some studies have found that the application of HFMEA reduced cases of specimen rejection from 0.92% to 0% in 2010–2013 (Chadwick and Fallon, 2012; Hung *et al.*, 2015). In this article, a literature review was performed to identify risks and factors of patient safety and also design a HFMEA for hospital laboratories.

METHOD

This study was literature review collecting articles from electronic databases such as PubMed, Scopus, and Google Scholar published in English and Indonesian between January 1, 2010-May 31, 2020. The literature search was conducted from March to July 2020 to search for electronic databases and selected journals, as well as cross-checking bibliographies from other published review articles through Mendeley to prevent duplicacy. The last step was all articles were reviewed by the clinical phatologist in an online final project presentation. This current literature review was a qualitative study that focused on identifying patient safety risks in hospital laboratories worldwide. Articles under review were journal articles, clinical trials, systematic reviews, observational studies, and descriptive studies that met the criteria based on Method Adopted for Literature Review by Turrini *et al.*, 2010.

The primary aim of this literature review was to identify risks and factors dealing with patient safety in hospital laboratories using the HFMEA or other methods. After the review process, the Healthcare Failure Mode and Effect Analysis for Indonesia hospital laboratories were designed based on the steps initiated by DeRosier *et al.* (2002). Articles using the HFMEA or FMEA were prioritized for more applicable analysis design in hospital laboratories. The full-text versions of all potentially relevant articles were read independently by the researchers. Eligibility for article inclusion criteria was determined by a structured flow chart and detailed guidelines using PRISMA Flow Diagram (Figure 1). A summary of literature review findings is presented in Table 1. This table outlines the basic characteristics of each article reviewed and briefly summarizes the key findings.

ANALYSIS AND DISCUSSION

A Figure 1 shows 4,062 articles collected were identified, but only 20 articles of them were full text. Finally, 8 relevant articles that met the criteria were included for review. All these included articles identified patient safety risks and factors in laboratories by using the HFMEA and other methods. The eight articles demonstrated the total testing process (TTP) in laboratories was divided into 3 phases, namely pre-analytic, intra-analytic, and post-analytic. The pre-analytical phase is the phase where the laboratory has no direct control on the process (Tournis and Makris, 2018) and occurs first in the laboratory process (Automation and Technology in the Histology Laboratory, 2018). The second phase is the intra-analytic phase, where the "actual" laboratory testing or the diagnostic procedures, processes, and products are conducted to ultimately produce results (Automation and Technology in the Histology Laboratory, 2018). The post-analytic phase is the final examination process which generates laboratory results. The highest error rate in laboratories occurred in the pre-analytic phase from 49.2%–84.5% (Hung *et al.*, 2015; Patel *et al.*, 2018). Errors in this phase were clotted specimens and

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inadequate specimen volume that may cause specimen rejection.

Factors that influenced patient safety in laboratories were patient condition, laboratory staff attributes including training, negligence, and burnout, facility, and accreditation. The review found only one article used the FMEA to identify risk and factors of patient safety in clinical laboratories, and one article integrated the Value Stream Map and HFMEA into Six Sigma method (see Table 1).

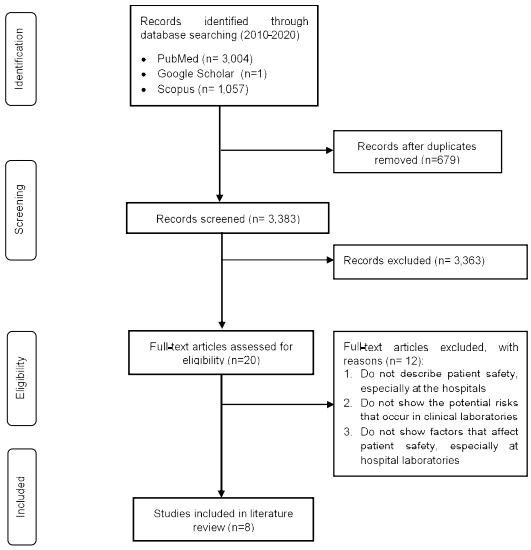

Figure 1. PRISMA Flow Diagram
(Source: Moher *et al.*, 2009)

Potential risks in laboratories

According to the Regulation of Indonesian Ministry of Health No. 411/MENKES/PER/III/2010, clinical health laboratories provide clinical specimen examination services to obtain individual health information, support disease diagnosis, cure the diseases and restore the health (Ministry of Health Republic of Indonesia, 2010). Aproximately 70%–80% of the laboratory results are related to diagnosis and treatment, and thus laboratories are important for health care and patient safety. They may have potential errors such as misdiagnosis, late diagnosis, inappropriate tests, patient safety incidents, cost and time loss (Sinici Lay, Pinar and Akbiyik, 2014; Aita *et al.*, 2017). The error rate in medical laboratories is very low (one error identified every 330–1,000 events) (Kalra, 2004); and the majority of these error rarely become adverse events (Plebani M, 1997), patient safety should be considered the goal of laboratory services and its principles must be systematically applied in a well-structured manner (Aita *et al.*, 2017).

The pre-analytical phase includes test request, patient or sample identification, sample collection, handling and transport, whereas pre-analytical phase involves the steps of samples preparation for analysis such as centrifugation, aliquoting and sorting. It has been demonstrated that most occur in the pre-analytical phase by healthcare personnnel who are not under control of the laboratory, but the majority of these errors are preventable (Gunnur Dikmen, Pinar and Akbiyik, 2015). Pre-analytical phase start following specimen acceptance by the laboratory staff (Lippi and Guidi, 2006).

According to Hung et al, most testing errors occur in the pre-analytical phase accounting for 84.5% of the total errors detected (Hung *et al.*, 2015). Patel et al, collected 172,800 data test performed on 43,200 samples, total number of errors were identified in pre-analytical phase (49.2%), intra-analytical (17.4%), post-analytical (33.4%) (Patel *et al.*, 2018). Jiang et al. who used FMEA in their research explain the highest RPN (Risk Potential Number ≥ 200) in clinical laboratories was in the pre-analytic phase. It occurred due to hemolysis, delay on delivery samples to the laboratory, and inadequate specimen volume (Jiang *et al.*, 2014).

Errors in the pre-analytic phase cause specimen rejection, mostly occurred due to clotting from 43.8%–55.8% (Sinici

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Lay, Pinar and Akbiyik, 2014; Bhat *et al.*, 2012; Guimarães *et al.*, 2012). Clotting was caused by improper blood mixing with anticoagulants (poor mixing method) and the wrong placement of the tube (Sinici Lay, Pinar and Akbiyik, 2014; Gunnur Dikmen, Pinar and Akbiyik, 2015). As much as 54.3% of clotting occurred to adult inpatients, and 26.8% pediatric inpatients (Sinici Lay, Pinar and Akbiyik, 2014). The second reason for specimen rejection is inadequate specimen volume at around 15%–24%, of which 1.8% indicates an excessive specimen volume (Bonini *et al.*, 2002; Plebani *et al.*, 2006, 2014; Guimarães *et al.*, 2012). Excessive specimen volume, particularly in pediatric, neonate, onclogy, and intensive care patients (56% in both adult and pediatric inpatients), occurred largely due to the difficulty in accesing peripheral veins of the patients (Sinici Lay, Pinar and Akbiyik, 2014).

Specimen rejection was caused by inappropriate test requests. As many as 16.97% of the physicians incorrectly determined the test according to patients' needs. Kachalia A, et al (2007) and Wahls and Cram (2007) support this result by stating that 55%-58% of the errors or delays in diagnosis were caused by the failure of the service unit or emergency department to determine appropriate tests according to patients' need (Kachalia *et al.*, 2007; Wahls and Cram, 2007; Patel *et al.*, 2018).

The errors frequency in the intra-analytic phase is around 7%-17.4%. The common errors include delay in reporting laboratory results due to malfunction of the equipment, sample mixing with other samples/ materials, interference (endogenous or exogenous substances), and undetected errors (Sakyi *et al.*, 2015; Patel *et al.*, 2018). This failure occurred in the re-sampling phase (Jiang *et al.*, 2014; Sciacovelli *et al.*, 2017). The final examination process, the post-analytic phase, Patel et al. (2018) stated that the percentage of the errors in the post-analytic phase was 33.4%, of which 12% were failure to report laboratory test results according to the predetermined time (Patel *et al.*, 2018). Jiang et al. (2014) obtain the highest RPN (RPN ≥ 200) due to failure to report test results according to the standard time (RPN = 210) and critical results (RPN = 200) resulting in delayed emergency treatment. The failure occurred due to the carelessness of laboratory staff, such as ignorance about complex work procedures in the laboratory and the inability to operate Laboratory Information System (LIS) or a computer-based technology (Jiang *et al.*, 2014).

Jurnal Administrasi Kesehatan Indonesia Volume 9 No 1 June 2021
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Table 1. Summary of Patient Safety Factors in Laboratories, 2013 to 2020

Factors	Key Findings	Authors	Titles	Results
Patient	Patient Condition	I Sinici Lay et al. (2014) Turki	Classification of reasons for rejection of biological specimens based on pre-preanalytical processes to identify quality indicators at a university hospital clinical laboratory in Turkey	Insufficient sample volume was identified at a clinical laboratory of university hospital in Turkey at a rate of 98.2%. Of the percentage, 1.8% of the samples exhibited the excessive volume, particularly for pediatric, neonate, oncology, and intensive care patients (56% on both adult and pediatric inpatient services), largely due to the difficulty in accessing peripheral veins.
Laboratory Staff	Errors due to laboratory staff	Patel S. (2016) India	Congruity in Quality Indicators and Laboratory Performance	High error rates could occur due to various reasons, such as lack of frequent training for laboratory and extra-laboratory staff, complexity of Total Testing Process (TTP) steps and involvement of different professionals in performing the process, shortage of staff, lack of automation in sample transport, and lack of lab-to-clinics interface through Laboratory Information Systems (LIS)
	Cause of errors in laboratory	Y Jiang et al. (2015) China	Application of failure mode and effect analysis in a clinical chemistry laboratory	The three failure modes with the highest RPNs (≥ 200) showed that the prominent problem existed in the pre-analytic phase, especially during the sample collection. It occurred due to unfamiliarity of technical work to the knowledge of nurses and couriers, increased workload, lack of laboratory knowledge of couriers.
	Staff training	I Sinici Lay et al. (2014) Turki	Classification of reasons for rejection of biological specimens based in pre-preanalytical processes to identify quality indicators at a university hospital clinical laboratory in Turkey	1. Some factors causing the high rates of clotted specimens from inpatient services involved the insufficient number of trained phlebotomy teams, high turnover of staff, particularly physicians. 2. Pediatric hospital staff showed better attention and better knowledge of specimen collection than those at the hospitals for adults.
	Staff negligence	Hung et al. (2015) Taiwan	Integration of Value Stream Map and Healthcare Failure Mode and Effect Analysis into Six Sigma Methodology to Improve Process of Surgical Specimen Handling	Specimen labeling errors and incomplete forms of specimen requisition were the major causes of specimen rejection. Some factors contributed to the errors in the specimen handling process. These include lack of discipline in completing surgical records, late data accuracy checking, lack of inspection mechanism, as well as the insufficient labor force.

Jurnal Administrasi Kesehatan Indonesia Volume 9 No 1 June 2021
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Factors	Key Findings	Authors	Titles	Results
		Y Jiang et al. (2015) China	Application of failure mode and effect analysis in a clinical chemistry laboratory	Errors in the post-analytic occurred due to carelessness of laboratory staff; for instance, the clinical laboratory results were often overlooked or not reported due to its complexity.
Laboratory Staff	Physician burnout	Kroft, S. H (2020) American Society for Clinical Pathology	Well-Being, Burnout, and the Clinical Laboratory	1. As many as 71% of the pathologists experienced burnout at some point. with a full one-third indicating that it was something they were currently experiencing. 2. Pathologists in the ASCP survey reported job-related stress, and 43% of them reported being moderately or very overwhelmed by their workload. 3. Burnout in lab professionals appears to be more prevalent than in pathologists and pathology trainees. About 85% of lab professionals sometimes experienced burnout. A half of them perceived it as a current issue. Over half experienced a lot of stress, and nearly half were moderately or very overwhelmed. Almost 40% were moderately or very anxious. This implies that the results were correlated with burnout.
Facility	Obsolete equipment	Gunnur Z D et al. (2013) Turki	Specimen rejection in laboratory medicine: Necessary for patient safety?	Barcode scanners may misread patient identifiication barcodes due to incompatible size of symbols on patient ID bands or specimen labels and the scanner settings.
		Sakyi A et al. (2015) Ghana	Evaluation of analytical errors in a clinical chemistry laboratory: A 3 year experience	Equipment malfunction and undetected failure in the internal QC were identified mainly as intra-analytical errors. Automation, training of laboratory staff and espousal of internal and external QC programs contributed immensely to the remarkable decline in intra-analytical errors and also the good condition of the Art Analyzer.
Accreditation	Accreditati-on related to error rate	V Tack et al. (2018) European Society of Pathology	Accreditation, setting and experience as indicators to assure quality in oncology biomarker testing laboratories	1. Accredited laboratories had 47% fewer analysis errors compared to non-accredited laboratories (IRR= 0.53, p= 0.030). It indicated that accredited laboratories had better implemetation procedures. 2. University and research settings were associated with less analysis errors than hospitals and (private) laboratories. While an industry setting showed less analysis errors compared to hospitals and (private) laboratories (p= 0.013 and p= 0.012)

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Patient safety factors in laboratory

Based on Table 1, there are 4 factors affecting patient safety in the laboratory.

Patient condition factor

Phlebotomists have difficulties to find peripheral veins of patients, especially in pediatric, neonatal, oncology, and ICU patients, during the blood specimen collection. It may result in the potential risk of inadequate specimen volume for laboratory analysis. Poor condition of patients and uncooperative attitude towards doctor's recommendations become the factors that may cause poor quality specimen (Jiang *et al.*, 2014; Sinici Lay, Pinar and Akbiyik, 2014).

Laboratory staff factor

Patel et al. (2018) assert that high error rates in the laboratory happen due to various reasons such as lack of training for laboratory staff, the complexity of the test procedures, involvement of many professional, lack of human resources, lack of automation in the delivery of samples to the laboratory, weak communication between laboratory staff and department staff (Patel *et al.*, 2018). According to Jiang et al. (2014), the failure in the pre-analytic phase during the sample collection was related to poor knowledge of nurses and couriers about working procedures in the laboratory.

Specimens clotting and hemolysis occur because phlebotomy training is rarely available to nurse or laboratory analysts (Sinici Lay, Pinar and Akbiyik, 2014;Sakyi *et al.*, 2015). Second, the high of turnover staff, especially doctors, also contributed to the errors in the laboratory. As new doctors need to adopt laboratory work procedures, they require training to improve their competence. The tight schedule of doctors and laboratory nurses also hampered their participation in prevention error training (Sinici Lay, Pinar and Akbiyik, 2014).

Research by Hung et al. (2015) has found that negligence of laboratory staff in labeling patient identification forms is another cause of specimen rejection. Negligence occurs due to low discipline in completing the surgical records, low data accuracy, and low inspection mechanism due to insufficient labour (Hung *et al.*, 2015). Jiang et al. (2014) have revealed that due to complex laboratory procedures, laboratory staff were careless in performing their work and thus cause failure in the post-analytic phase (Jiang *et al.*, 2014).

Burnout of laboratory staff also influences the potential risk in the laboratory. As many as 71% of the pathologists in the laboratory experienced burnout. Based on the American Society for Clinical Pathology, work stress is the main cause of burnout, and too much workload is another cause (43%). Most of the laboratory staff (85%) experienced burnout generally because of fatigue in handling the complexity of work in the laboratories. A study has found 40% of the staff experienced moderate to severe anxiety levels (Kroft, 2020).

Facility factor

Another factor contributing to the error is incompatible scanner that fails to read patient barcodes in the pre-analytic phase. Mismatch might occur between the barcode size, the symbol on the patient ID, andspecimen labels (Gunnur Dikmen, Pinar and Akbiyik, 2015). Equipment damage is the main cause of errors in the intra-analytic phase, causing laboratory test results not to be collected in the post-analytic phase. Equipment damage which is not detected in the internal quality control are identified as errors in the intra-analytic phase (Sakyi *et al.*, 2015).

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Accreditation factor

Accredited laboratories (47%) had a lower error rate than non-accredited laboratories (IRR 0.53; p 0.03). Laboratories of university hospitals or research laboratories had a lower error rate than private laboratories (p=0.013). Tack et al. (2018) have hypothesized a positive correlation between laboratory accreditation status and the accuracy of laboratory test results. Accredited laboratories are considered to have a higher level of caution in reporting analysis results to patients. Laboratories of university hospitals had a lower analysis error rate in conducting the analysis than non-university laboratories (Tack *et al.*, 2018).

Discussion

After identify risks and factors in clinical laboratories based on the articles that we have, the author design an Healthcare Failure Mode and Effect Analysis for Indonesia hospital laboratories based on the steps from DeRosier *et al.*, (2002). HFMEA is a traditional FMEA developed specifically for the health sector by NCPS in 2002 (DeRosier *et al.*, 2002). The HFMEA approach was developed to address criticism of using FMEA in healthcare, particularly in respect to the use of a single risk priority number (RPN) to rank vulnerabilities (Arbor, 2014). The process is the same as the traditional FMEA, but there are striking differences in the process, exactly on step 4 of calculating the risk value. In this step, the traditional FMEA assessment is the risk priority obtained from the multiplication of severity, occurrence, and detectability in non-health services. While in the application of HFMEA, the risk value of hazard analysis (see on Formula 1) is a multiplication of severity and probability with four criteria for health services (Table 2).

The use of the conventional FMEA is commonly applied to identify risk in hospital laboratories although the method needs improvements. A report mentioned that the laboratory of PKU Muhammadiyah Yogyakarta Hospital in 2015 employed the Root Cause Analysis (RCA) and Fishbone Analysis rather than the standard FMEA (Hospital Report: RS PKU Muhammadiyah Yogyakarta, 2015). Another study has shown that the laboratory of Wirobrajan Primary Healthcare Center carried out the standard FMEA by determining the cut-off point of the Risk Priority Number (RPN) to ease risk identification according to the error level (Khairani *et al.*, 2015). Research conducted by Sithi and Ani (2018) at Pacitan District General Hospital, East Java province, proved that the FMEA could reduce the RPN value from 250 to 125 for patient identification in inpatient supporting services (laboratory and radiology), pharmacy, and nutrition installations from June to September 2016 (Sithi and Widiastuti, 2018).

The advantage of HFMEA is the hazard scoring matrix process (Table 3). It is a grading method based on the hazard analysis value that determines the severity of the potential risk. After the determination of grading method, corrective action must be immediately planned through step 5 in the action and outcome measures, where the HFMEA team determine preventive steps to avoid potential risks or mitigation steps to minimize the impacts. Then, the team determine whether the failure mode assessed needs to be continued to the next process through the HFMEA Decision Tree Analysis. The decision tree analysis considers not only severity and probability scores, but also assesses the criticality of the failures (i.e, single point weaknesses) and whether there are controls in place to prevent or detect these failures. The use of “yes” or “no” responses in the HFMEA

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decision tree to asses the criticality, presence of control measures, and detectability of the failure mode is less subjective (B, NA and N, 2012) and more easily agreed upon than assigning scores (Chadwick and Fallon, 2012).

Healthcare Failure Mode and Effect Analysis Design

Based on the literature review, the author designed an HFMEA draft to identify potential risks in the laboratories. The laboratory procedures and potential risks in the HFMEA draft are retrieved from various studies that have been reviewed.

Step 1: Define the topic

The HFMEA design specially is applied in the pre-analytical phase because the highest error rate there ranges from 49.2% to 84.5% (Sinici Lay, Pinar and Akbiyik, 2014; Patel *et al.*, 2018).

Step 2: Assemble the team

The HFMEA team consists of multidisciplinary hospital staff who are directly involved in the laboratory risk analysis process. Generally, laboratory personnel consist of clinical pathology specialists, health analysts, nurses, and administrative staff (Ministry of Health Republic of Indonesia, 2010). The head of the clinical laboratory leads the team members during the HFMEA process and ensures them to follow the steps and record HFMEA results. The team members include staff with 5 years experience who fully participate in the implementation of HFMEA to advice based on their respective work experiences. In designing the HFMEA, the author used blood specimen collection process initiated by Jiang et al. (2014). Phlebotomists (nurses or laboratory analysts) would perform the blood specimen collection.

Step 3: Graphically describe the process

To identify potential risks, it is required to analyze all possible failure in each step. Figure 2 shows the flow of blood specimen sampling in a hospital laboratory. The sampling process consists of pre-analytic (5 stages), intra-analytic (2 stages), and post-analytic (2 stages) (Jiang *et al.*, 2014). The researchers took the scope in point 3 for the specimen collection because the error rate there had potential risk of specimen rejection. Then the subprocesses are reconfigured into the flowchart (Figure 3) to allow a list of failure modes in each subprocess. Each failure mode will be transferred to the HFMEA worksheet (Table 4) to analyze potential causes and assess the Hazard Score.

Hazard Analysis= *Severity* x *Probability*

Formula 1. Hazard Analysis

Step 4: Conduct a hazard analysis

The HFMEA team determined the hazard analysis value by multiplying two components of risk severity and probability (Table 2 with the Formula 1). After the hazard analysis values were obtained, the team determined the hazard scoring matrix (Table 3) (DeRosier *et al.*, 2002). The scoring is a simulation number taken by laboratory analysts to provide an overview of the HFMEA process. Table 4, in the decision tree analysis coloumn must be filled by the HFMEA team to make adjustments to the hospital laboratory conditions.

Step 5: Develop actions and outcome measures

At this stage, the team identified actions in accordance with the standard outcome measures, determined people in charge and required leadership commitment in the forms of monitoring and evaluation to develop patient safety culture in a laboratory (DeRosier *et al.*, 2002; Chadwick and Fallon, 2012).

Jurnal Administrasi Kesehatan Indonesia Volume 9 No 1 June 2021
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Table 2. HFMEA Probability–Severity Criteria

Score	1	2	3	4
Probability	**Remote**	**Uncommon**	**Occasional**	**Frequent**
	Unlikely to occur; may happen several times in 5–30 years	Possible to occur; may happen several times in 2–5 years	Probably will occur; may happen several times in 1–2 years	Likely to occur immediately or within a short period; may happen several times a year
Severity	**Minor event**	**Moderate event**	**Major event**	**Catastrophic event**
Patient Outcome	Neither injury nor increased length of stay or increased level of care	Increased length of stay or increased level of care for one or two patients	Permanent lessening of bodily functioning, disfigurement, surgical intervention required, increased length of stay for three or more patients	Death or major permanent loss of function or suicide
Visitor Outcome	Evaluation and treatment refused or not required	Evaluation and treatment for 1 or 2 visitors (less than hospitalization)	Hospitalization of 1 or 2 visitors	Three or more deaths or hospitalization of 3 or more visitors
Staff Outcome	First aid treatment only with no lost time or restricted duty injuries or illness	Medical expenses, lost time or restricted duty injuries or illness for one or two staff	One or more staff being hospitalized, or three or more staff experiencing lost time or restricted duty injuries or illnesses	One death or hospitalisation of three or more staff
Equipment or facilities	Damages of <$10000 without adverse patient outcome	Damages of >$10000 but <$100000	Damages of ≥$100000 but <$250000	Damages of ≥$250000

Source: Adapted VA National Center for Patient Safety (DeRosier et al., 2002; Vries et al., 2018)

Table 3. Hazard Scoring Matrix

		Probability			
	Scores	**Remote 1**	**Uncommon 2**	**Occasional 3**	**Frequent 4**
Severity	**Minor 1**	1	2	3	4
	Moderate 2	2	4	6	8
	Major 3	3	6	9	12
	Catastrophic 4	4	8	12	16

Source: DeRosier et al., 2002

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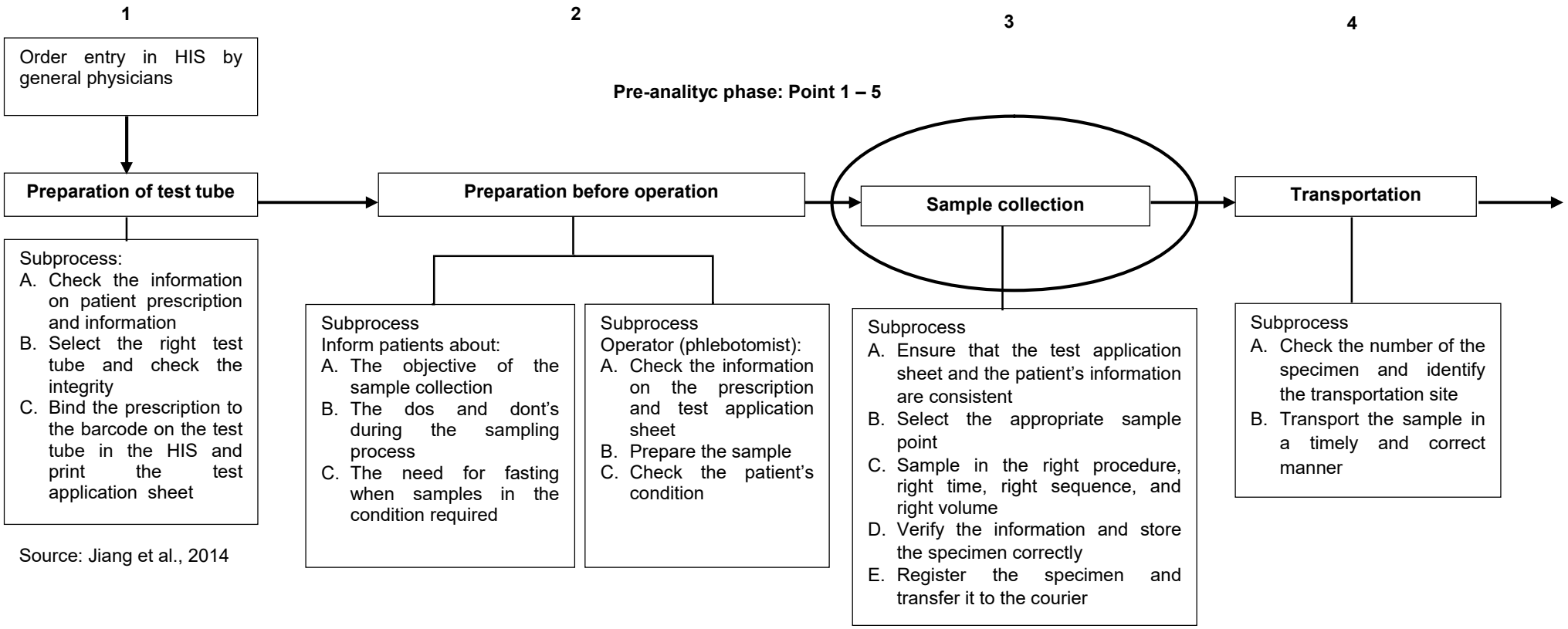

Source: Jiang et al., 2014

Figure 2 (a). Flowchart of blood specimen handling process

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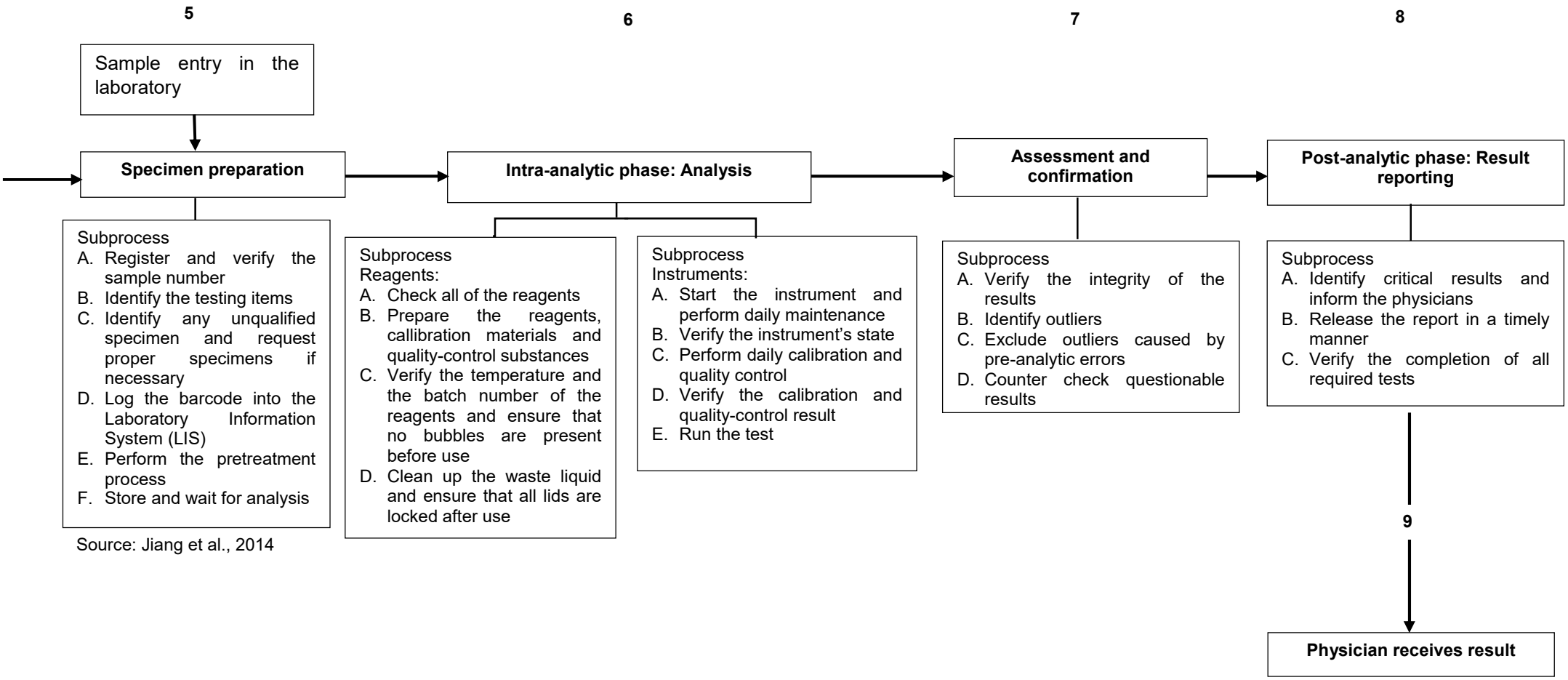

Source: Jiang et al., 2014

Figure 2 (b). Flowchart of blood specimen handling process

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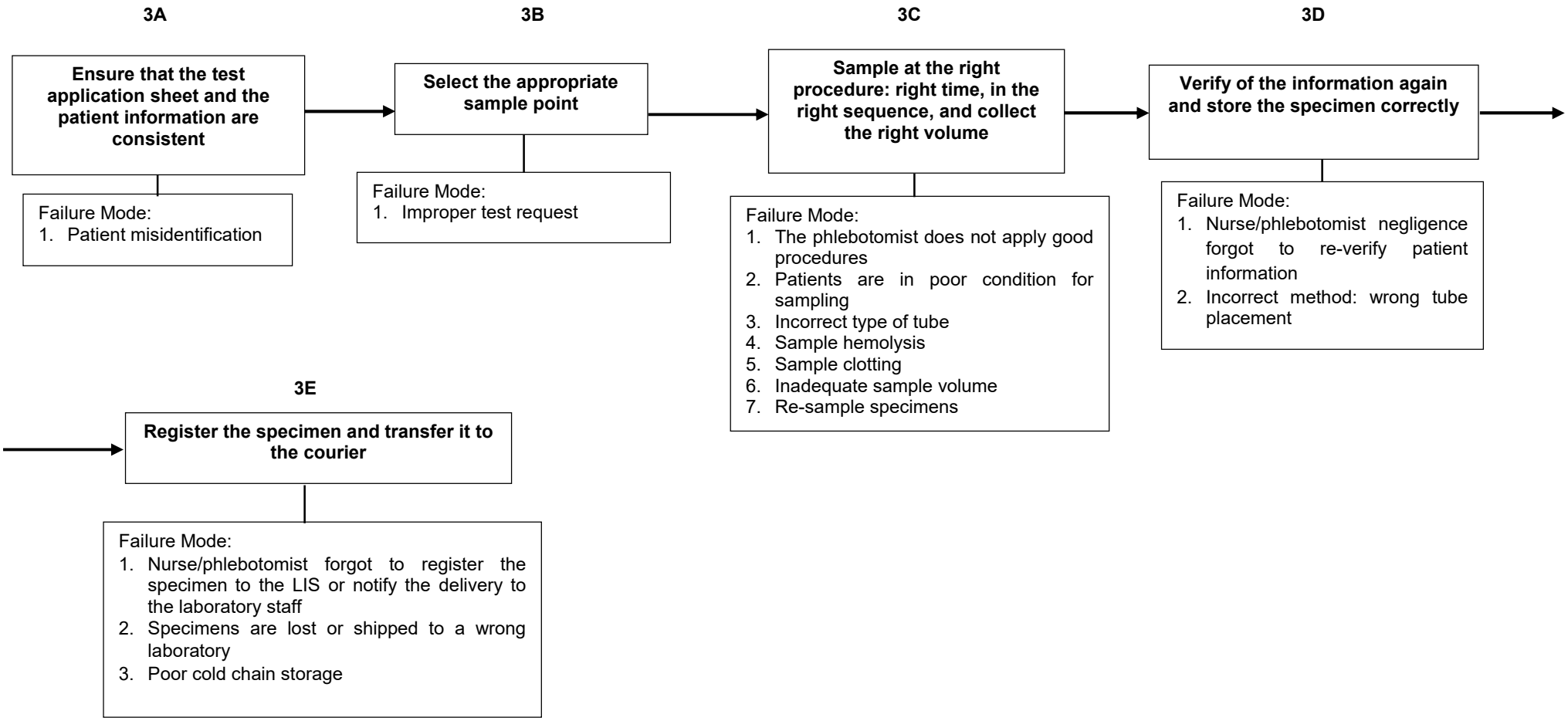

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Figure 3. Failure mode of blood specimen handling

Table 4. HFMEA Worksheet

		HFMEA Step 4: Hazard Analysis*							HFMEA Step 5: Develop Action & Outcome Measures*				
		Scoring**			Decision Tree Analysis								
Failure Mode: First evaluate failure modes before determining potential causes	**Potential cause**	**Severity**	**Probability**	**Hazard Score (S x P)**	**Single Point Weakness? Existing Control Measure**	**Detecable**	**Proceed**	**Action Type (Control, Accept, Eliminate) or Rationale for Stopping**	**Action**	**Outcome Measure**	**PIC**	**Management Concurrence**
3A1 Patient misidentification	Negligence of laboratory staff: Patient information is not checked carefully	2	4	8	N	N	Y	Control	Re-identification	Review patient identity	Lab Supervisor	YES
	Lack of training	1	3	3								
3B1 Improper test request	Laboratory staff burnout	3	3	9								
	Negligence of Laboratory staff	2	3	6								
3C1 Poor application of procedures by the phlebotomists	Poor knowledge of nurses about associated laboratory test	1	2	2								
	Laboratory staff burnout	1	2	2								
3C2 The patient is in poor condition during sampling	Failure to inform about an objection	1	2	2								
	Failure to inform patients about intentions	1	2	2								

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		HFMEA Step 4: Hazard Analysis*						HFMEA Step 5: Develop Action & Outcome Measures*			
		Scoring**			Decision Tree Analysis						
Failure Mode: First evaluate failure modes before determining potential causes	**Potential cause**	**Severity**	**Probability**	**Hazard Score (S x P)**	**Single Point Weakness? Existing Control Measure**	**Detecable**	**Proceed**	**Action Type (Control, Accept, Eliminate) or Rationale for Stopping**	**Action**	**Outcome Measure**	**PIC**	**Management Concurrence**
3C3 Incorrect types of tube	Nurse negligence	2	3	6								
	Lack of training	2	2	4								
	Internal control failure	2	3	6								
3C4 Sample hemolysis	Difficulty in sampling patient's vascular condition	1	4	4								
	Lack of training	1	3	3								
3C5 Sample clotting	Lack of training	1	3	3								
	Improper usage/ storage/ transportation of quality material or other reasons	1	3	3								
3C6 Inadequate sample volume	Lack of training	1	3	3								
3C7 Re-sampling specimens	Patients in poor condition	1	3	3								
	Nurse negligence	2	2	4								
	Lack of training	2	2	4								
	Improper usage/ storage of quality-control material or other reasons	2	2	4								

Jurnal Administrasi Kesehatan Indonesia Volume 9 No 1 June 2021
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		HFMEA Step 4: Hazard Analysis*							HFMEA Step 5: Develop Action & Outcome Measures*				
		Scoring**			Decision Tree Analysis								
Failure Mode: First evaluate failure modes before determining potential causes	**Potential cause**	**Severity**	**Probability**	**Hazard Score (S x P)**	**Single Point Weakness?**	**Existing Control Measure**	**Detectable**	**Proceed**	**Action Type (Control, Accept, Eliminate) or Rationale for Stopping**	**Action**	**Outcome Measure**	**PIC**	**Management Concurrence**
3D1 The nurse/ phlebotomist negligence: forgot to re-verify patient information	Nurse negligence	2	2	4									
	Lack of training	1	2	2									
3D2 Incorrect method: wrong tube placement	Improper usage/ storage of quality-control material or other reasons	2	2	4									
	Lack of training or nurse negligence	1	2	2									
	Internal control failure	2	2	4									
3E1 The nurse/phlebotomist forgot to register the specimen to the LIS or to notify the sample delivery to the laboratory staff	Laboratory staff negligence: operator's failure to input information	2	3	6									
	Laboratory staff burnout	2	2	4									
3E2 Specimens are lost or shipped to a wrong laboratory	Incorrect transportation method, courier negligence	2	3	6									
	Lack of courier training	2	2	4									

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		HFMEA Step 4: Hazard Analysis*							HFMEA Step 5: Develop Action & Outcome Measures*				
		Scoring**			Decision Tree Analysis								
Failure Mode: First evaluate failure modes before determining potential causes	**Potential cause**	**Severity**	**Probability**	**Hazard Score (S x P)**	**Single Point Weakness?**	**Existing Control Measure**	**Detecable**	**Proceed**	**Action Type (Control, Accept, Eliminate) or Rationale for Stopping**	**Action**	**Outcome Measure**	**PIC**	**Management Concurrence**
	Improper usage/ storage/ transportation of quality-control material or other reasons	4	3	12									
	Courier overload	2	3	6									
3E3 Poor cold chain storage	Improper storage/ transportation of quality-control material or other reasons	2	2	4									
	No specimen delivery box	2	2	4									

*HFMEA Steps 4 – 5 filled by the HFMEA team during the Focus Group Discussion
**The scoring is a simulation done by laboratory analysts to provide an overview of the HFMEA process

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CONCLUSION

Laboratories apply the HFMEA by using the hazard analysis, where the severity and probability criteria are categorized for the health sector. Decision tree analysis is a step to determine whether the failure mode is feasible to proceed to the next HFMEA step or not. This can reduce the work process that does not involve the HFMEA team. The use of HFMEA must be adjusted using existing equipment and facilities, that can lead hospital laboratories to different potential risks. Laboratories also need staff leadership commitment by conducting monitoring and evaluation to maintain patient safety culture. In this study, the HFMEA design can be used by hospital laboratories but needs further research analyzed laboratory data in the Indonesia for more representative and applicable references.

To Indonesian health policymakers, the researchers suggest improving the regulations in 411/MENKES/PER/III/2010 about Clinical Laboratories, especially for risk identification to maintain the quality of hospital laboratories. In implementing the HFMEA, it is necessary to point a team and conducy a Focus Group Discussion (FGD) to determine priority measures that can prevent errors in hospital laboratories

CONFLICT OF INTEREST

The authors indicated no potential conflict of interest.

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