Study of the Pharmacovigilance Reporting System Based on Hospital Reporting in North Sumatra from 2019-2024

Kajian Sistem Pelaporan Farmakovigilans Berdasarkan Pelaporan Rumah Sakit Di Sumatera Utara Pada Rentang 2019-2024

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Abstract

Pharmacovigilance safeguards patient safety, yet hospital ADR reporting in North Sumatra remains limited. This research to assess compliance with BPOM's 10 completeness criteria and identify determinants that support or hinder implementation. Methods: A mixed methods approach with a sequential explanatory design was applied. descriptive analysis of 2019-2024 e-MESO reports and in-depth interviews with hospitals categorized as Complete, Incomplete, and Non-reporting. Results: Out of 210 hospitals, only 11 (5%) actively reported through e-MESO, producing 50 reports, 98% complete and 2% incomplete. About 74% were spontaneous reports, mostly skin reactions, with 40% serious cases in elderly patients. Qualitative analysis revealed seven main themes: understanding, reporting process, barriers, management support, e-MESO system, expectations, and interprofessional collaboration. Conclusion: While individual report completeness is high, system-level participation is low, so full compliance with the 10 criteria is not yet achieved. Reporting quality is largely shaped by managerial support, organizational readiness, and interprofessional collaboration. Recommended actions include expanding SOP-based reporting on the 10 criteria, appointing a clinical pharmacist as the person-in-charge, conducting cross-profession training, and coordinating e-MESO technical issues with BPOM particularly strengthening type-C hospitals.

Keywords: *Pharmacovigilance, Adverse Drug Reaction, e-MESO, Hospital, Patient Safety.*

Abstrak

Farmakovigilans penting untuk keselamatan pasien, namun pelaporan efek samping obat (ESO) di rumah sakit Sumatera Utara masih rendah. Tujuan: Menilai kepatuhan pelaporan terhadap 10 kriteria BPOM serta mengidentifikasi faktor pendukung/penghambat implementasinya. Metode: Penelitian ini menggunakan pendekatan mixed methods dengan desain sequential explanatory. ata kuantitatif laporan e-MESO 2019-2024 dianalisis deskriptif, data kualitatif diperoleh melalui wawancara pada RS kategori Complete, Incomplete, dan Tidak Lapor. Hasil: Dari 210 rumah sakit, hanya 11 (5%) yang aktif melapor melalui e-MESO, menghasilkan 50 laporan, dengan 98% lengkap dan 2% tidak lengkap. Sebanyak 74% laporan bersifat spontan, didominasi reaksi kulit, dan 40% kasus serius terjadi pada pasien lansia. Analisis kualitatif menghasilkan tujuh tema utama: pemahaman, proses pelaporan, kendala, dukungan manajemen, sistem e-MESO, harapan, dan kolaborasi antarprofesi. Kesimpulan: Secara berkas, kelengkapan hampir memenuhi 10 kriteria; namun pada tingkat sistem, partisipasi RS masih rendah sehingga target belum terpenuhi. Kualitas pelaporan terutama dipengaruhi dukungan manajemen, kesiapan organisasi, dan kolaborasi antarprofesi. Rekomendasi operasional: perluasan pelaporan berbasis SOP 10 kriteria, penunjukan apoteker klinis sebagai PIC, pelatihan lintas profesi, serta koordinasi teknis e-MESO dengan BPOM dengan penekanan pada RS tipe C.

Kata Kunci: Farmakovigilans, Efek Samping Obat, E – MESO, Rumah Sakit, Keselamatan Pasien.

https://doi.org/10.36490/journal-jps.com.v9i1.1212

Introduction

Pharmacovigilance is a crucial part of the healthcare system that guarantees the public's access to safe, helpful, and effective pharmaceuticals. Due to limitations in sample size, study duration, population variation, and clinical conditions that do not reflect real-world practice, pre-marketing trials can offer a preliminary overview of a drug's efficacy and safety, but they are never enough to predict the full risk profile [1]. Because of this, many new adverse drug responses (ADRs) and drug side effects (DSEs) are discovered only after the drug has been widely used in the population. In this regard, the pharmacovigilance system especially reports from medical facilities is essential as a means of detecting drug safety problems early on [2].

Because they are the point of service with the most medication exposure, particularly for patients with acute disorders, chronic diseases, comorbidities, polypharmacy, and complex therapy, hospitals are the most significant source of pharmacovigilance data. The majority of reported significant adverse drug reactions (ADRs) come from hospital settings rather than pharmacies or primary care clinics. Consequently, a region's efficacy in medication safety monitoring can be directly determined by the caliber and volume of hospital pharmacovigilance reports [3]. The BPOM Regulations in Indonesia mandate that all healthcare facilities, including hospitals, notify BPOM, the National Pharmacovigilance Center, of suspected adverse drug reactions, medication errors, and post-immunization adverse events [4,5]. However, a number of assessments indicate that hospitals' reporting rates remain much below expectations. Despite the growing clinical load on patients and the increasing complexity of pharmaceutical use, the underreporting problem still exists. This low reporting rate makes it more difficult for BPOM to quickly identify safety flags. A real-world example is the cough syrup ethylene glycol disaster of 2022, when just a small percentage of hospitals reported drug adverse effects prior to the product's recall. This situation demonstrates that Indonesia's hospital pharmacovigilance reporting system is still subpar and has to be assessed using actual data [5].

North Sumatra is one of Indonesia's biggest provinces, and because of its extremely varied topography from densely populated cities like Medan to island and mountainous areas with no access to medical care it struggles with an inequitable healthcare system. There are notable disparities in the quality of clinical services and the capacity to identify adverse drug reactions (ADRs) early among areas as a result of the unequal distribution of healthcare facilities and staff among districts. According to national research, the frequency of polypharmacy in secondary care institutions, the burden of chronic diseases, and the use of high-risk pharmaceuticals (such as antibiotics, antidiabetics, and cardiovascular therapies) all raise the risk of adverse drug reactions (ADRs) in places with limited clinical capability. Given this, the national pharmacovigilance system may have a blind spot due to the low reporting participation from primary and secondary referral hospitals, which make up the majority of hospitals in North Sumatra. This could delay the detection of drug safety signals from that area [6].

The 2019–2024 timeframe is very pertinent to research since it captures the changes in the national reporting system. BPOM introduced e-MESO 2.0 in 2019 to replace manual forms and streamline hospital reporting. The COVID-19 pandemic of 2020–2022 prompted the introduction of novel drugs with unknown safety profiles [7]. The stress on the healthcare system is really one of the reasons for irregular reporting, even though this should have reinforced reporting frequency and raised monitoring. The BPOM Regulation No. 7 of 2024, which was released in 2024, tightens the pharmacovigilance system's performance indicators. This includes the requirement that hospitals report serious adverse drug reactions within a maximum of 15 days (T+15) and the minimum standard requirements for pharmacovigilance activities [8]. The years 2019–2024 are

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perfect for analysis to find trends, strengths, and weaknesses in the hospital-level reporting system due to regulatory changes, the digitization of reporting, and clinical dynamics during those six years ([9].

In addition to systemic and regulatory factors, human resource challenges are important. Indonesian hospitals, including those in North Sumatra, continue to struggle with a lack of qualified pharmacovigilance staff, inadequate training for medical staff, and a lack of awareness of the significance of reporting adverse drug reactions (ADRs) even when the causative relationship is not yet established. Reporting is a low priority due to a lackluster reporting culture, a heavy clinical burden, and worries about possible legal repercussions. These obstacles align with global research, which indicates that underreporting is a widespread issue even in nations with well developed healthcare systems. Therefore, to fully comprehend how the pharmacovigilance system actually operates at the service level, an assessment based on real hospital data is essential [10,11].

One of the biggest provinces with a rapidly expanding hospital network is North Sumatra, which contributes significantly to the national pharmacovigilance system. Nevertheless, there aren't many studies that explicitly outline the pattern of ADR reporting from hospitals in this area as of yet. There is currently no systematic analysis of the quantity of reports, report kinds, annual trends, adherence to BPOM standards, and variables impacting the rise or fall in reporting. Without this information, it is challenging to assess whether North Sumatra hospitals have appropriately complied with regulatory requirements and whether the current system has been effective in shielding patients from drug hazards [12].

To evaluate the efficacy of the reporting system, pinpoint implementation shortcomings, and develop the required strengthening measures, a pharmacovigilance reporting study based on hospital data from 2019–2024 is essential. It is anticipated that this assessment will give a thorough picture of how North Sumatra hospitals support the national pharmacovigilance system, what obstacles they face, and how to enhance report quality to aid in the early identification of drug safety concerns. As a result, this study is strategically valuable for enhancing patient safety, fortifying the healthcare system, and promoting data-driven and responsive pharmacovigilance regulations.

Research Design

This research is a non-experimental study with a mixed-method sequential explanatory non-identical design to evaluate the quality of drug side effect reporting by hospitals in North Sumatra. The quantitative approach was conducted by analyzing ADR reporting data extracted from the database based on e-MESO BPOM for the period 2019–2024, using 10 quality evaluation criteria for reporting according to BPOM. These quantitative results were then explored in depth thru a qualitative approach by conducting interviews with pharmacovigilance reporting managers at selected hospitals to identify supporting and hindering factors in reporting. The combination of these two approaches allows for a comprehensive understanding of the pharmacovigilance reporting system's performance and its implementation context in healthcare facilities [13]. The sequential explanatory non-identical design used in this study is a mixed methods strategy in which a quantitative phase is carried out first, and then a qualitative phase is conducted with the express purpose of elucidating, interpreting, or deepening the quantitative findings.

Populations and Sample
Populations
The study population consists of all hospitals in North Sumatra that have an e-MESO account.

Sample
The quantitative sample consists of hospitals in North Sumatra that reported adverse events (AEs) sent to the National Agency of Drug and Food Control (BPOM) thru e-MESO 2019-2024. The inclusion criteria for hospitals were those that already had a BPOM e-MESO account and reported drug side effects to BPOM during the period 2019-2024. The exclusion criteria for this study were hospitals that already had a BPOM e-MESO account but never reported drug side effects to BPOM during the period 2019-2024. The sample for the qualitative interviews in this study consists of individuals who report adverse events (AEs) or those responsible for pharmacovigilance reporting at hospitals that serve as the source of AE reports, including those who report AEs completely or incompletely.

Sample Size

For complete and incomplete reports, total sampling was used. For hospitals with e-MESO accounts but never reporting, sampling was done by matching (1:1) according to hospital type with complete and incomplete reports.

Data Collection Methods

Secondary data from reports of adverse drug reactions received and managed by BPOM. Primary data from interviews with those responsible for monitoring adverse drug reactions or those designated by hospitals to report adverse drug events to BPOM during the period 2019-2024.

Data Analysis

To determine the relationship between enabling and impeding factors and reporting quality, quantitative data will be evaluated descriptively and qualitative data will be analyzed thematically.

Results and Discussion

Distribution of Hospitals in North Sumatra

This study analyzed a total of 210 hospitals in North Sumatra. The distribution list of hospitals by location can be seen in Table 1.

Table 1. Distribution of Hospitals in North Sumatra by Location.

Type of Hospital	Medan City Outside	Medan City Other		Total
		Medan City	District	
A	3	0	0	3
B	14	6	8	28
C	43	22	53	118
D	7	7	43	57
Primary D	0	35	108	210
Total	67	35	108	210

It is consistent with international study findings that while only a small number of hospitals in North Sumatra engage in ADR reporting, the reports that are received are quite comprehensive. Underreporting is a common occurrence, particularly in healthcare facilities with few staff members, heavy workloads, and no pharmacovigilance training, according to systematic investigations [14]. The conclusion that hospitals reporting adverse drug reactions (ADRs) typically have more robust organisational structures, active clinical pharmacists, and sufficient management support is corroborated by additional research. This explains why there aren't many reporters, but the reports that are received are of extremely high quality. This is because only hospitals that have a well-developed patient safety culture, competent staff, and a system that is ready to go can report on a regular basis.

There are only 67 hospitals in Medan City, but 143 hospitals (±68.10%) are spread over other districts (108 hospitals) and other municipalities (35 hospitals). The difficulties in implementing decentralized pharmacovigilance are reflected in the predominance of secondary and primary referral hospitals (Type C and D) in non-urban locations. Drug safety monitoring procedures must be modified in light of this condition, especially with regard to logistical limits, healthcare staff shortages, and regional reporting infrastructure. The increased number of type C and D facilities, especially in districts, can be explained by their status as secondary healthcare providers in the national referral system [7].

Distribution of e-MESO Accounts and Active Reporting Status

Just 61 (29.05%) of North Sumatra's 210 hospitals have an e-MESO account with BPOM. With only 11 hospitals (5.24% of the total) regularly reporting pharmacological side effects between 2019 and 2024, this disparity grows even more when taking Active Reporters into account. The existence of widespread underreporting practices at the regional level is typically confirmed by this extremely low active participation rate. The reporting preparedness gaps by hospital type are shown in Table 4.2. Table 2 shows North Sumatra's hospital distribution, e-MESO account ownership, and medicine side effect reporting.

Table 2. Distribution of Hospitals, Ownership of e-MESO Accounts, and Reporting of Adverse Drug Reactions in North Sumatra.

Type of Hospital	Hospitals in North Sumatra	Hospitals with an e-MESO Account	e-MESO Active Reporting Hospital	Hospital Not Reporting e-MESO
A	3	3	2	1
B	27	19	4	4
C	122	33	5	18
D	55	4	0	4
Primary D	3	0	0	0
Unknown		1	0	1
Total	210	61	11	50

The most obvious gaps are in C and D type hospitals, especially in the districts. This indicates the need for more intensive e-MESO technical assistance for secondary/primary health facilities, including the socialization of reporting procedures and the strengthening of content quality assurance [15].

Drug Adverse Event Reporting Profile Based on Hospital Reporting
Relationship between Drug Type and Gender with Drug Side Effect Type

According to the research findings, the majority of the drug side effect profile reported by North Sumatra hospitals during the study period was made up of reactions that were categorized as expected. These reactions are consistent with type A reactions, which are predictable and associated with the pharmacological mechanism of the drug. With 80–90% of pharmacological side effects falling into the category of dose-related reactions, such as gastrointestinal discomfort from the use of nonsteroidal anti-inflammatory drugs (NSAIDs) or constipation from opioid agonists, type A reactions are prevalent worldwide [16]. These results validate that the majority of adverse drug effects that occur are caused by the drug's known pharmacodynamic effects and are included in the safety profile specified in the product information [17]. However, there are still a few unexpected reactions that are quite significant from a clinical standpoint. The main immunological or idiosyncratic processes causing this reaction include Stevens-Johnson syndrome and anaphylaxis, both of which have the potential to be lethal. Given that BPOM's pharmacovigilance rules mandate rapid reporting for responses not specified in the medication safety information, the occurrence of this unexpected reaction highlights the significance of timely and thorough reporting. This level of sensitivity to safety signals is uncommon in hospital settings, which is crucial for bolstering the pharmacovigilance system [18].

Relationship between Age Group and Severity Level

Age groupings of patients are compared to the severity level categories of reactions in this investigation. According to WHO and ICH criteria, serious ADRs are categorized into seriousness categories. These include reactions that are life-threatening, cause death, necessitate hospitalization, cause disability or sequelae, or are deemed medically significant (even if they do not meet the aforementioned criteria). Table 3 shows the correlation between seriousness category and age group.

Table 3. Relationship between Age Group and Severity Level

Age Group	Non-Serious	Hospitalization	Life-Threatening	Other Medically Important	Total Reports
Neonates (<1 month)	1	0	0	0	1
Infants (1–23 months)	2	0	0	0	2
Children (2–12 years)	4	1	0	0	5
Adolescents (13–17 years)	4	0	0	0	4
Adults (18–59 years)	26	5	1	1	33
Elderly (>60 years)	3	2	0	0	5

According to this study, 40% of pharmacological side effects in older adults were deemed serious, demonstrating how susceptible the elderly are to severe side effects. However, young people are also responsible for certain severe drug side effects; this may be because they are exposed to a wider variety of drugs or because they take bigger dosages within the productive age range. On the other hand, the lack of major drug adverse effects in pediatric patients may indicate that children use drugs more cautiously, that

dosages have been changed, or that serious drug side effects in children have not been reported (perhaps due to under-reporting) [19].

Relationship between the Number of Drugs Used and the Type of Adverse Drug Reaction

Clinical pharmacy staff in hospitals play a crucial role in reviewing patients' multi-drug regimens, allowing potential drug side effects to be prevented or detected early. The distribution of the type of adverse drug reaction in the report with 1 and ≥2 suspected drugs can be seen in Table 4.

Table 4. Distribution of Adverse Drug Reaction Types in Reports with 1 and ≥2 Suspected Drugs

Type of Reaction	Reports with 1 drug	Reports with ≥2 drugs
Pruritus	9 case	3 cases (involving 2 drugs)
Rash	3 case	1 case (involving 2 drugs)
Angioedema	1 case	1 case (involving 2 drugs)
Other allergic reactions	14 case	0
Non-allergic reactions	17 case	0
Total reports	44	4

The majority of complaints (96%) involved only one suspected medication, making the identification of the cause rather simple, according to an analysis of the association between the number of pharmaceuticals used and the kind of adverse drug reactions. Two suspicious medications were mentioned in just four cases; these were all skin hypersensitivity reactions, including rash, angioedema, and pruritus. Although the number of instances is still small, this pattern suggests that drug combinations are more likely to cause allergic reactions than non-allergic reactions [20] Because pharmacodynamic or pharmacokinetic interactions might intensify the immune response to medication allergens, this occurrence is consistent with the literature that indicates polypharmacy as a risk factor for enhanced drug side effects. The association between age, therapeutic complexity, and drug side effect risk was further supported by the fact that patients with ≥2 suspected drugs were slightly older than the study population average. The possibility of additive effects in causing allergic reactions is demonstrated by a case study such as the combination of ranitidine and vancomycin, which was reported to induce severe pruritus [21]. The results from multi-drug instances emphasize the significance of exercising caution when it comes to combination therapy, even if the bulk of drug side effects in this study still resulted from single-drug use. Strategic measures to reduce the risk of pharmacological side effects include the deprescribing concept and clinical pharmacists' assessment of drug interactions. From the standpoint of pharmacovigilance, reports should be more comprehensive, particularly when many drugs are suspected of being the cause. This will allow for more accurate and evidence-based examination of drug combination risk patterns [22].

Relationship between Hospital Type and Reaction Outcome

This section analyzes the relationship between hospital type and the reported outcomes of adverse drug reactions. Outcome refers to the patient's final condition as a result of the reaction, for example: cured, improving, not cured, cured voluntarily, or unknown. The relationship between the outcome of the reaction and the type of hospital can be seen in Table 5.

The majority of patients in all service facility types demonstrated good clinical improvement, according to an analysis of the association between hospital type and drug side effect reaction outcomes. Twenty percent of patients were in the process of recovering, and sixty-six percent of patients had recovered out of fifty reports. This pattern holds true for hospitals of the A, B, and C types and indicates that pharmacological side effects-especially common ones like skin hypersensitivity are managed rather effectively. This discovery is significant because it shows the existence of long-lasting pharmacological side effects, such as hepatotoxic reactions that necessitate a prolonged recovery period, even if the percentage of cases that did not recover was quite low (8%). Moreover, instances that recovered with sequelae (4%) demonstrate that certain pharmacological side effects can have long-term repercussions, including issues with the skin or organs as a result of severe reactions like Stevens-Johnson syndrome. The need for enhancements to the reporting follow-up system was highlighted by a report with an uncertain outcome. All hospital types reported no drug-related deaths, suggesting that the supportive care, drug withdrawal, and early detection procedures are working effectively. Nonetheless, the disparity in results among hospital types continues to indicate that the quality of managing pharmacological side effects can be influenced by facility preparedness, clinical team expertise, and

completeness of reporting. Therefore, to lower the risk of severe adverse drug reactions and avoid incidents with sequelae, pharmacovigilance capacity must be strengthened. This includes training healthcare personnel, more thorough reporting, and more systematic risk analysis [23].

Table 5. Relationship between Hospital Type and Reaction Outcome

Outcome of Adverse Drug Reaction	Type A Hospital	Type B Hospital	Type C Hospital	Total
Recovered	14 (64%)	8 (62%)	11 (73%)	33
In recovery	7 (32%)	2 (15%)	1 (7%)	10
Not yet recovered	1 (4%)	2 (15%)	1 (7%)	4
Recovered with sequelae	0 (0%)	1 (8%)	1 (7%)	2
Outcome unknown	0 (0%)	0 (0%)	1 (7%)	1
Total ADR reports	22	13	15	50

Qualitative Analysis

Qualitative analysis in this study was conducted thru a thematic approach by gathering insights from informants representing complete, incomplete, and non-reporting hospitals.

Theme 1: Understanding Pharmacovigilance

In general, all informants understood that pharmacovigilance is an activity encompassing the detection, assessment, understanding, and prevention of drug side effects, but the depth of their understanding varied across groups. The "Complete" category indicates a comprehensive understanding and views pharmacovigilance as an integral part of patient safety, including seeing the reporting of adverse drug reactions as a professional responsibility in ensuring safe and rational drug use. The informant's statement is revealed as follows: "*Pharmacovigilance is the science and activity related to the detection, assessment, understanding, and prevention of adverse drug reactions or other drug-related problems. The goal is to ensure drug safety after it is on the market by continuously monitoring its benefit-risk profile." "With the side effects of medication reports, we can be more cautious in using certain antibiotics, especially those that require a skin test first."*

Conversely, the Incomplete group only understands pharmacovigilance from a practical and administrative perspective without internalizing the scientific basis behind the activity. One informant stated: *"Pharmacovigilance is the activity of monitoring, assessing, and preventing drug side effects to ensure the safety of drug use."*

However, in the non-reporting category, there was still a significant lack of knowledge or understanding, both about the importance of reporting and who should report. "*Pharmacovigilance is an activity related to drug side effects, but we have never encountered serious side effects." "We don't fully understand, but we know the importance of reporting drug side effects."*

This difference indicates a gap in understanding, where only the Complete group positions pharmacovigilance as a patient safety-based clinical practice, while the other two groups still view it as an additional administrative task. This finding confirms the need for continuous education to align perceptions and improve the competency of all healthcare professionals in the implementation of pharmacovigilance. [24].

Theme 2: The Process of Reporting Adverse Drug Reactions in Hospitals

Hospitals in the Complete category have a structured reporting process for drug side effects, starting with identification by doctors or nurses, verification by clinical pharmacists and the Pharmacy and Therapeutics Committee using the Naranjo algorithm, and finally reporting to e-MESO BPOM. The informant's statement is as follows: "*side effects of medication identification is done by doctors, nurses, then confirmed by pharmacists in the Pharmacy Department, filled out on the ESO form, verified by the Pharmacy and Therapeutics Committee using the Naranjo algorithm, and then reported to e-MESO BPOM." (Complete Informant) "The process is, the nurse reports to the head of the room, then it is forwarded to the doctor and clinical pharmacy. We record it on the yellow form, label it as an allergy, and then report it to e-MESO." (Complete Informant)*

In the Incomplete group, reporting has been done but does not meet all completeness requirements because some information, such as drug batch numbers or diagnoses, is often unavailable at the time of reporting. The informant's statement revealed, "*Drug production codes are often not filled in because records are only filled out by the pharmaceutical industry. Sometimes the diagnosis is not yet confirmed when the report is made." (Incomplete Informant)*

Meanwhile, hospitals in the "Not Reported" category lack clear SOPs or reporting pathways, leading to non-reporting due to ignorance of the mechanism or the belief that they have never encountered drug side effects. The statements made by the informants are: *"We have never reported, there is no clear SOP, and we don't know where to report." (Informant Did Not Report) "We have never reported because we haven't experienced any serious side effects." (Informant Did Not Report)*.

These findings indicate that in some healthcare facilities, early detection systems and interprofessional coordination are not yet optimal, which impacts the low reporting response and the lack of a strong reporting trigger within the national pharmacovigilance chain [25].

Theme 3: Challenges in Reporting Adverse Drug Reactions

The challenges in reporting drug side effects differ among informant groups. In the Complete category, the obstacles encountered are primarily technical, such as difficulty determining the causative drug when patients are taking multiple medications simultaneously and limited information regarding drug brands and batch numbers. The informant's statement is revealed as follows: *"Sometimes it's difficult to assess the suspected causative drug because the patient is taking several medications, or the drug packaging is no longer available." (Complete Informant)*.

The Incomplete group faces more complex constraints, particularly the lack of coordination among healthcare workers and the limitations of the e-MESO system's features, which do not allow for temporary storage. The informant's statement was revealed as follows: *"Lack of coordination with nurses, sometimes nurses are unwilling to report if there are side effects of medication in the inpatient room." (Informant Incomplete)*.

Meanwhile, the Non-Reporting group faces fundamental obstacles such as lack of training, the absence of clear internal policies, and concerns about legal liability, leading to frequent disregard for reporting. The statements provided by the informants are:

"Lack of training for our human resources to report side effects of medication."

"Often, side effects are considered mild or common, so they are not reported."

"We are not yet accustomed to reporting procedures, and we have never participated in training on side effects of medication."

This finding indicates that reporting barriers are not only technical, but also structural and cultural. Referring to the concept of Organizational Readiness for Change, low organizational readiness can trigger resistance to reporting behavior, making human resource capacity building, policy support, and strengthening inter-professional communication important steps to improve the pharmacovigilance system. [26].

Theme 4: Management support

Management support has proven to be a key factor in the successful implementation of pharmacovigilance in hospitals. In the Complete group, managerial support was tangibly present thru direction, the provision of reporting facilities, the appointment of dedicated staff, and active supervision by the Pharmacy and Therapeutics Committee. This form of support reflects strong organizational support, thereby strengthening healthcare professionals' adherence to reporting drug side effects. The informant's statement was revealed as follows:

"Hospital management strongly supports complete reporting as a corrective and preventive measure for patient safety."

"Management provides direction and support for reporting, and sometimes even helps with socialization."

In the Incomplete group, management support was acknowledged but not yet consistent, as it remained more at the policy level without monitoring or operational follow-up. This condition results in a gap between commitment and implementation. The informant's statement was revealed as follows:

"Management provides direction and support for reporting, but there has been no routine follow-up or monitoring."

Meanwhile, the No Report group reported a lack of managerial support, characterized by the absence of clear socialization, reporting instructions, or internal policies. The informant's statement was revealed as follows:

"If there are no specific instructions from management yet, then side effects of medication reporting hasn't started."

"So far, I think it's still lacking. It should start with managerial policies so that reporting can be optimal.

These findings indicate that weak leadership support significantly contributes to low reporting rates, aligning with BPOM guidelines that leadership commitment is a key determinant of the success of the pharmacovigilance system in healthcare facilities. [27].

Theme 5: Reporting System (e-MESO)

The utilization of e-MESO as a drug side effect reporting system shows variation across hospital groups. In the Complete group, e-MESO was considered helpful for the reporting process, although occasional technical difficulties such as network disruptions, upload errors, or forgotten passwords were experienced, these obstacles were generally overcome. The informant's statements are revealed as follows:

"Sometimes there are network disruptions or system errors when uploading files, but these can be resolved by re-reporting after the connection is stable."

"The e-MESO system is convenient because you just fill it out, but sometimes you forget your password or there are errors."

The Incomplete group also uses e-MESO, but technical constraints such as the lack of a temporary storage feature often lead to data loss and reduce the completeness of reports. As stated by the informant:

"Filling out MESO cannot be paused. If the system errors, the data that has already been entered is lost and must be repeated."

Meanwhile, the Non-Reporting group has not used e-MESO because they do not have an active account, lack training, or are unaware of the reporting mechanism. The informant's statement was revealed as follows:

"I don't yet know or understand how to report it."

"Up until now, reporting has still been done thru other systems like SITB."

"Experiencing technical difficulties, such as forgetting login accounts, slow internet connections, and unclear reporting formats.

This sometimes hinders the reporting process." The reported obstacles include difficulties accessing accounts, slow internet connections, and unclear reporting formats.

These findings confirm the importance of continuous training and strengthening information technology infrastructure to support the optimal use of e-MESO, in line with the WHO recommendation that electronic reporting systems can only be effective if supported by user competency and organizational readiness. [26].

Theme 6: Expectations of the Reporting System

Most informants expressed the hope that reporting drug side effects would become part of an organizational culture involving all healthcare professionals, not just pharmacists. They want an e-MESO system that is easier to use, has a temporary storage feature, and provides quick feedback from BPOM. The informant's statements are as follows:

"Hopefully, the reporting system will become easier to use and there will be faster feedback from BPOM." (Complete Informant)

"Hopefully, training will be conducted again and involve doctors and nurses, not just pharmacists." (Incomplete Informant)

"If possible, the e-MESO system should be more user-friendly, have a temporary save feature, and reports should also receive feedback." (Incomplete Informant)

"My hope is to be more cooperative with fellow healthcare workers and to have pharmacovigilance training conducted regularly." (Incomplete Informant)

"BPOM should write to hospital management to establish a structured side effects of medication reporting policy." (Non-reporting Informant)

"To have side effects of medication training conducted for hospitals and monitoring done at least every three months." (Non-reporting Informant)

[28,29].

Theme 7: Interprofessional Collaboration

Interprofessional collaboration has emerged as a crucial component in the effectiveness of pharmacovigilance reporting. In the Complete group, coordination between doctors, nurses, and pharmacists has been good, allowing for the systematic identification and follow-up of drug side effect cases. The informant's statement is revealed as follows:

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"The findings of drug side effects are reported to the pharmacist, the pharmacist conducts an assessment and prepares both internal and external reports to the BPOM

Conversely, the Incomplete and Not Reported groups indicate that limitations in interprofessional communication often hinder the flow of information, leading to delays or failure in reporting drug side effects. This condition indicates that multidisciplinary communication culture has not yet developed optimally in many healthcare facilities, even tho the WHO emphasizes that the success of pharmacovigilance is highly dependent on cross-professional collaboration. The informant's statement was revealed as follows:

"Lack of coordination with nurses, sometimes they are unwilling to report ESO events in the ward." (Information Incomplete)

Overall, the research findings indicate that the success of pharmacovigilance reporting is determined by three main factors: the level of understanding and awareness among healthcare professionals, structural support from management and technology systems, and the effectiveness of interprofessional collaboration. Hospitals in the Complete category have demonstrated more mature reporting implementation, while the Incomplete group is still constrained by technical and coordination aspects, and the No Report group faces fundamental obstacles such as a lack of training and policy support. This finding confirms the need for integration between education, organizational policies, and strengthening digital reporting systems to sustainably strengthen the national pharmacovigilance system [28].

Mixed Methods Study

The results of this study indicate that the reporting of drug side effects in hospitals in North Sumatra is still at a low level, both in terms of participation and the sustainability of the reporting system. Out of 210 hospitals, only 29% have electronic accounts for monitoring drug side effects, and only 11 hospitals (5%) actively reported during the period 2019–2024. Nevertheless, the quality of the reports received was good, with a completeness rate of 98% based on 10 BPOM criteria. The imbalance between the high quality of the reports and the low number of reports indicates the presence of structural and operational barriers that cannot be explained by technical factors alone [30].

Qualitative analysis provides in-depth context for this phenomenon. A complete category hospital indicates that successful reporting is highly influenced by management support, the presence of SOPs, interprofessional coordination, and a good understanding of pharmacovigilance. Reporting is considered part of service quality. Conversely, hospitals in the incomplete and not reported categories face more fundamental obstacles, such as the absence of SOPs, lack of training, high workloads, and a shortage of pharmacists. Permenkes No. 72 of 2016 explicitly states that pharmacists are required to provide clinical pharmacy services, including monitoring drug side effects. However, in practice, the shortage of personnel leads to pharmacists being more absorbed in managerial and dispensing tasks, resulting in suboptimal clinical services—including the investigation of drug side effects. Individual barriers such as doubt in assessing the cause-and-effect relationship of the drug, high workload, and lack of time also worsen the low reporting frequency. Beside human and organizational factors, technical barriers to e-MESO for drugs also contribute. The system is not yet equipped with an auto-save feature, data is easily lost when the connection is interrupted, and the lack of temporary drafts makes officers reluctant to refill lost reports. Dependence on the internet network and lack of technical training are also among the reasons why reporting is not sustained. Nevertheless, these technical barriers do not fully explain the low participation; non-technical barriers such as organizational culture, leadership, and interprofessional coordination are actually more dominant in influencing reporting success [31].

From a pharmacovigilance theory perspective, this condition reflects the common pattern of under-reporting in spontaneous reporting systems. WHO recommends a combination of spontaneous reporting and active surveillance to improve the detection of drug side effects. In Indonesia, Permenkes No. 72 of 2016 has included monitoring active drug side effects as part of the clinical pharmacy service functions, but the findings of this study indicate an implementation gap in the field. The low participation of hospitals despite clear regulations indicates the need to strengthen internal policies thru Director's Orders, SOPs, quality indicators, and human resource capacity building [11] Interprofessional collaboration is a key component that is not yet optimal. The ideal process—doctor/nurse identifies suspected drug side effects, pharmacist analyzes and reports, then management follows up—doesn't work uniformly. In some hospitals, reliance on specific individuals leads to unsustainable reporting. Information from interviews confirms the need for regular interprofessional forums, audits of adverse drug reactions, and a feedback loop to clinicians so that reporting has a real impact on clinical decision-making [28].

Based on the synthesis of quantitative and qualitative data, there are several priority recommendations: (1) regular pharmacovigilance training for all healthcare professionals; (2) strengthening internal policies by appointing a pharmacovigilance PIC and establishing standard operating procedures; (3) improving the technical reliability of e-MESO thru automatic storage features, integration with electronic medical records, and IT system improvements; and (4) strengthening interprofessional collaboration thru structured communication and unit performance indicators. For BPOM, important feedback includes the need for faster feedback, continuous socialization, and periodic monitoring and evaluation involving all hospitals. This study has several limitations. First, the number of available drug side effect reports was only 50 over five years, making strong statistical generalizations impossible. The report profile, which is dominated by skin reactions, is likely influenced by the small sample size. Second, the qualitative data comes from hospitals willing to be interviewed, so the potential for response bias is unavoidable. Hospitals that do not participate may have different barriers. Third, this study only uses passive reporting thru e-MESO without conducting active surveillance. In fact, comparing it with monitoring the side effects of active drugs can provide a more accurate picture of the actual level of under-reporting [32].

Conclusions

This study shows that pharmacovigilance reporting by hospitals in North Sumatra for the period 2019–2024 is still not optimal. The completeness of adverse drug reaction reports is quite high, but it has not yet reached 100%, and the participation rate of hospitals in reporting thru e-MESO is still low. Supporting factors for reporting primarily include staff understanding, management support, the availability of SOPs, training, and the ease of using e-MESO. Conversely, emerging barriers include a lack of cross-professional training, limited human resources, workload, irregular coordination between units, the absence of standard SOPs, and technical constraints of the e-MESO system. The electronic reporting system plays an important role but still needs improvement. Based on these findings, it is necessary to strengthen training, increase human resource capacity, improve SOPs, enhance coordination, and optimize e-MESO to improve the quality and coverage of drug adverse event monitoring reporting in North Sumatra.

Conflict of Interest

The authors state that there are no conflicts of interest regarding the design, implementation, analysis, or reporting of this research. All authors confirm that there are no personal, financial, academic, or institutional relationships that could influence the objectivity and integrity of the research findings in this manuscript.

Acknowledgment

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