JOURNAL of dr. ALOEI SABOE (J IAS)

Vol. 5 No. 2 (2025) | E ISSN: 2985-4059

ANALYSIS OF ADVERSE DRUG REACTIONS AMONG DIABETES MELLITUS PATIENTS PARTICIPATING IN THE PROLANIS PROGRAM AT THE COMMUNITY HEALTH CENTER OF KOTA UTARA DISTRICT, GORONTALO CITY

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ABSTRACT

Diabetes mellitus is a chronic metabolic disease requiring long-term pharmacological therapy, thereby increasing the risk of adverse drug reactions (ADRs). Patients enrolled in the Indonesian Chronic Disease Management Program (PROLANIS) commonly receive continuous antidiabetic treatment, making pharmacovigilance an essential component of patient safety. This study aimed to analyze the risk of adverse drug reactions among diabetes mellitus patients participating in the PROLANIS program at the North Kota Community Health Center, Gorontalo City. A quantitative descriptive study with a cross-sectional design was conducted using secondary data obtained from patients' medical records. Total sampling was employed, resulting in 53 eligible participants. ADR risk was evaluated using the GerontoNet ADR Risk Score, while demographic characteristics, medication use, and clinical profiles were analyzed descriptively using frequencies and percentages. The findings showed that most participants were female and aged between 51 and 60 years. Metformin was the most frequently prescribed antidiabetic medication, followed by sulfonylureas and combination therapy. Most patients had fewer than four comorbidities and no documented liver disease, renal impairment, or previous ADR history. However, approximately one-third of the participants received eight or more medications, indicating the presence of polypharmacy as a potential contributor to ADR risk. These findings suggest that although the overall clinical risk profile was relatively low, medication burden remains an important concern. Routine pharmacovigilance, regular medication review, and individualized treatment monitoring should be incorporated into the PROLANIS program to improve medication safety and optimize diabetes management in primary healthcare settings.

Keywords: diabetes mellitus; adverse drug reactions; pharmacovigilance; PROLANIS; GerontoNet ADR Risk Score

INTRODUCTION

Diabetes mellitus (DM) is one of the fastest-growing chronic non-communicable diseases worldwide and represents a major challenge to global health systems. According to epidemiological estimates, approximately 537 million adults were living with diabetes in 2021, and this number is expected to increase substantially over the coming decades due to population aging, urbanization, obesity, and unhealthy lifestyles [1]. The burden of diabetes is particularly pronounced in low- and middle-income countries, where the majority of patients reside and healthcare resources remain limited [2]. In Indonesia, diabetes continues to increase in

Submit: Nov 01st, 2023 Accepted: June 16th, 2025 Published: August 30th, 2025

prevalence and has become one of the leading causes of morbidity, placing the country among those with the highest numbers of people living with diabetes globally. Regional epidemiological reports have also demonstrated a continuous increase in diabetes prevalence in Gorontalo Province, with Gorontalo City consistently reporting one of the highest numbers of diabetes cases within the province.

The progressive increase in diabetes prevalence has been accompanied by a corresponding rise in the utilization of antidiabetic medications. Although pharmacological therapy is essential for achieving optimal glycemic control and preventing diabetes-related complications, prolonged treatment frequently exposes patients to adverse drug reactions (ADRs). Patients with diabetes are particularly susceptible to ADRs because treatment often requires long-term medication use, combination therapy, and management of multiple comorbidities. Polypharmacy further increases the likelihood of drug interactions and medication-related complications, potentially resulting in hypoglycemia, gastrointestinal disorders, renal impairment, and other clinically significant adverse events [3][4]. Previous studies have also demonstrated that diabetes significantly increases the risk of ADRs among hospitalized patients, especially older adults, thereby contributing to increased morbidity, prolonged hospitalization, and healthcare costs [5].

The World Health Organization defines an adverse drug reaction as a harmful and unintended response occurring at doses normally used for prophylaxis, diagnosis, or treatment. ADRs may reduce therapeutic effectiveness, decrease medication adherence, and ultimately compromise disease control. Consequently, pharmacovigilance has become an essential component of patient safety by systematically detecting, assessing, understanding, and preventing adverse effects associated with medication use [6]. Continuous monitoring of ADRs is particularly important in patients with diabetes because early identification of medication-related problems enables healthcare professionals to optimize treatment, minimize preventable harm, and improve clinical outcomes.

To improve chronic disease management, the Indonesian government introduced the Program Pengelolaan Penyakit Kronis (PROLANIS) through the National Health Insurance administered by BPJS Kesehatan. PROLANIS is an integrated healthcare program designed to optimize the management of chronic diseases, including diabetes mellitus, through regular medical consultations, health education, laboratory monitoring, medication evaluation, and physical activity programs. The program aims to maintain optimal health status while improving healthcare efficiency and reducing long-term complications. Evidence suggests that PROLANIS contributes to better metabolic control, improved self-management, and enhanced quality of life among patients with diabetes [7][8][9]. Nevertheless, variations in program implementation, participation rates, and healthcare service quality across primary healthcare facilities remain important challenges [10].

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Despite considerable evidence regarding the effectiveness of PROLANIS in improving clinical outcomes, studies specifically evaluating the occurrence of ADRs among patients participating in the program remain limited. Most previous studies have primarily focused on glycemic control, patient adherence, service quality, or metabolic outcomes, while medication safety has received relatively little attention. Considering that patients enrolled in PROLANIS generally receive long-term pharmacotherapy and frequently experience polypharmacy, evaluating ADRs represents an important aspect of ensuring treatment safety and optimizing therapeutic outcomes.

At the North Kota Community Health Center, preliminary observations identified 68 patients with type 2 diabetes mellitus enrolled in the PROLANIS program, consisting of 18 males and 50 females. Although healthcare providers have recognized the occurrence of medication-related adverse events among these patients, the magnitude and characteristics of ADRs have not been systematically evaluated. This lack of local evidence limits the ability of healthcare professionals to implement targeted pharmacovigilance strategies and optimize medication safety within primary healthcare settings.

Therefore, this study aims to analyze adverse drug reactions among diabetes mellitus patients participating in the PROLANIS program at the North Kota Community Health Center. By identifying the occurrence and characteristics of ADRs in routine clinical practice, this study is expected to provide evidence supporting pharmacovigilance activities, improve medication safety, and strengthen the quality of chronic disease management in Indonesian primary healthcare facilities.

RESEARCH METHODS

Study Design

This study employed a quantitative descriptive research design using a cross-sectional approach. According to John W. Creswell and J. David Creswell [11], quantitative research is a systematic approach that examines objective theories by collecting numerical data and analyzing them using statistical procedures. A cross-sectional design was adopted because data were collected from each participant at a single point in time to describe the characteristics of the study population and assess the potential risk of adverse drug reactions (ADRs) among diabetes mellitus patients participating in the PROLANIS program.

Study Setting and Population

The study was conducted at the North Kota Community Health Center, Gorontalo City, Indonesia. The study population comprised all patients diagnosed with type 2 diabetes mellitus who were registered as participants in the Chronic Disease Management Program (PROLANIS) and received treatment at the health center during the study period.

Sample and Sampling Technique

A total sampling technique was employed, whereby all eligible patients meeting the inclusion criteria were included in the study. Based on the available medical records, a total of 53 patients were included in the final analysis.

The inclusion criteria were as follows:

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1. Patients diagnosed with type 2 diabetes mellitus;
2. Registered as PROLANIS participants at the North Kota Community Health Center;
3. Had complete medical records containing demographic, clinical, and medication-related information required for the study.

Patients with incomplete medical records were excluded from the analysis.

Data Collection

This study used secondary data obtained from patients' medical records. The collected variables included demographic characteristics (age and sex), comorbidities, antidiabetic medications, number of medications prescribed, and other clinical information required for assessing the risk of adverse drug reactions.

Assessment of Adverse Drug Reaction Risk

The potential risk of adverse drug reactions was evaluated using the GerontoNet ADR Risk Score, a validated clinical assessment tool developed to estimate the likelihood of ADR occurrence. The assessment considered several risk factors, including the number of comorbidities, presence of heart failure, liver disease, renal impairment, number of prescribed medications, and previous history of adverse drug reactions. Each patient's GerontoNet score was determined based on information extracted from their medical records.

Data Analysis

The collected data were analyzed using descriptive statistics. Categorical variables were summarized using frequencies and percentages to describe patients' demographic characteristics, patterns of antidiabetic medication use, and the distribution of GerontoNet ADR Risk Score components. The findings were presented in tables and interpreted descriptively to provide an overview of the potential risk of adverse drug reactions among diabetes mellitus patients participating in the PROLANIS program.

RESEARCH RESULTS

Characteristics of Diabetes Mellitus Patients

Sex Distribution

The distribution of diabetes mellitus patients participating in the PROLANIS program according to sex is presented in Table 1.

Table 1. Distribution of Diabetes Mellitus Patients by Sex

Sex	Frequency (n)	Percentage (%)
Male	12	22.6
Female	41	77.4
Total	53	100.0

Source: Processed medical record data (2023).

As shown in Table 1, a total of 53 diabetes mellitus patients were included in this study. Female patients accounted for the majority of participants, with 41 patients (77.4%), whereas male patients represented 12 patients (22.6%). These findings indicate that most PROLANIS participants at the North Kota Community Health Center were female.

Age Distribution

The distribution of participants according to age group is presented in Table 2.

Table 2. Distribution of Diabetes Mellitus Patients by Age Group

Age Group (years)	Frequency (n)	Percentage (%)

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20–30	3	5.7
31–40	9	17.0
41–50	15	28.3
51–60	26	49.1
Total	53	100.0

Source: Processed medical record data (2023).

Table 2 shows that patients aged 51–60 years constituted the largest age group, comprising 26 patients (49.1%). This was followed by patients aged 41–50 years, with 15 individuals (28.3%). Meanwhile, only three patients (5.7%) were between 20 and 30 years of age. Overall, the majority of participants were over 40 years old.

Pattern of Antidiabetic Drug Use

The pattern of antidiabetic drug use among diabetes mellitus patients participating in the PROLANIS program is presented in Table 3.

Table 3. Pattern of Antidiabetic Drug Use

Drug Class	Medication	Frequency (n)	Percentage (%)
Biguanide	Metformin	38	71.7
Sulfonylurea	Glibenclamide, Glimepiride, Gliclazide	31	58.5
Biguanide + Sulfonylurea	Metformin combinations	27	50.9
Rapid-acting insulin + Biguanide	Novorapid + Metformin	4	4.8
Long-acting insulin + Biguanide	Levemir/Ryzodeg + Metformin	4	4.8
Rapid-acting insulin	Novorapid	15	28.3
Long-acting insulin	Levemir/Ryzodeg	20	37.7
Rapid-acting + Long-acting insulin	Novorapid + Levemir/Ryzodeg	13	24.5

Source: Processed medical record data (2023).

Table 3 demonstrates that metformin, belonging to the biguanide class, was the most frequently prescribed antidiabetic medication, used by 38 patients (71.7%). Sulfonylureas were prescribed to 31 patients (58.5%), while combination therapy consisting of biguanides and sulfonylureas was used by 27 patients (50.9%). Insulin therapy was also common, with long-acting insulin prescribed to 20 patients (37.7%) and rapid-acting insulin to 15 patients (28.3%). Combination insulin therapy and insulin–metformin regimens were prescribed less frequently.

Analysis of Adverse Drug Reaction Risk Based on the GerontoNet ADR Risk Score

The distribution of GerontoNet ADR Risk Score components among diabetes mellitus patients participating in the PROLANIS program is presented in Table 4.

Table 4. Distribution of GerontoNet ADR Risk Score Components

Variable	Category	Frequency (n)	Percentage (%)
Number of comorbidities	≥4	2	3.8
	<4	51	96.2
Heart failure	No	52	98.1
	Yes	1	1.9
Liver disease	Yes	0	0.0
Number of medications	≤5	28	52.8
	6–7	7	13.2
	≥8	18	34.0
Previous ADR history	Yes	0	0.0
Renal	Yes	0	0.0

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impairment	

Source: Processed medical record data (2023).

As presented in Table 4, most patients had fewer than four comorbidities (96.2%), whereas only two patients (3.8%) had four or more comorbid conditions. Heart failure was identified in one patient (1.9%), while no cases of liver disease were documented. Regarding medication use, 28 patients (52.8%) received five or fewer medications, seven patients (13.2%) received six to seven medications, and 18 patients (34.0%) were prescribed eight or more medications. Furthermore, no documented history of previous adverse drug reactions or renal impairment was identified among the participants based on the reviewed medical records.

DISCUSSION

The present study analyzed the characteristics of diabetes mellitus patients participating in the PROLANIS program, patterns of antidiabetic medication use, and factors associated with the risk of adverse drug reactions (ADRs) using the GerontoNet ADR Risk Score. The findings provide an overview of patient demographics and clinical characteristics that may influence medication safety in primary healthcare settings.

Sex Distribution

The study found that female patients constituted the majority of PROLANIS participants with diabetes mellitus. This finding is consistent with previous studies reporting a higher prevalence of type 2 diabetes among women, particularly in middle-aged and older populations. Hormonal changes associated with menopause, differences in body fat distribution, and reduced insulin sensitivity have been suggested as contributing factors that increase women's susceptibility to diabetes mellitus. Moreover, women generally demonstrate greater utilization of primary healthcare services, which may explain their higher participation in chronic disease management programs such as PROLANIS.

From a pharmacovigilance perspective, sex differences are also clinically important because females have been reported to experience ADRs more frequently than males. Biological differences in drug absorption, distribution, metabolism, and elimination, together with hormonal influences, may alter drug responses and increase the likelihood of ADRs. Xiang et al. [12] identified female sex as one of the factors associated with medication safety issues among patients with type 2 diabetes, while Nyamagoud et al. [13] also reported a higher prevalence of ADRs among female diabetic patients receiving antidiabetic therapy. These findings suggest that female patients enrolled in PROLANIS may require closer therapeutic monitoring to optimize treatment safety and effectiveness.

Age Distribution

Most participants in this study were between 51 and 60 years of age, indicating that diabetes mellitus predominantly affected middle-aged and older adults. This observation is consistent with the natural progression of type 2 diabetes, where advancing age is accompanied by reduced pancreatic β-cell function, increased insulin resistance, and declining metabolic capacity.

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Age is also an important determinant of ADR risk because physiological changes occurring during aging affect drug pharmacokinetics and pharmacodynamics. Declining renal and hepatic function, together with the presence of multiple chronic diseases, may increase drug exposure and susceptibility to adverse reactions. Monteiro et al. [14] reported that elderly patients with diabetes frequently experienced serious ADRs, including hypoglycemia and lactic acidosis. Similarly, the SENATOR trial demonstrated that older adults with diabetes have a significantly higher risk of ADRs and mortality than non-diabetic patients because of multimorbidity and age-related physiological decline [5]. Therefore, routine medication review and age-specific monitoring remain essential components of diabetes management within the PROLANIS program.

Pattern of Antidiabetic Drug Use

Metformin was the most frequently prescribed antidiabetic medication in this study, followed by sulfonylureas and combination therapy consisting of metformin and sulfonylureas. This prescribing pattern is consistent with current diabetes management guidelines, which recommend metformin as the first-line pharmacological treatment for type 2 diabetes because of its proven efficacy, favorable safety profile, and relatively low risk of hypoglycemia.

The frequent use of sulfonylureas and insulin observed in this study may reflect the need for intensified glycemic control among patients whose blood glucose levels cannot be adequately controlled with metformin alone. Combination therapy is commonly prescribed to achieve better glycemic outcomes through complementary mechanisms of action. However, increasing the number of medications may also increase the risk of ADRs and drug interactions.

Previous studies have shown that metformin is commonly associated with gastrointestinal adverse effects, whereas sulfonylureas and insulin are frequently implicated in hypoglycemic events. Singh and Dwivedi [15] and Shareef et al. [3] reported that hypoglycemia and gastrointestinal disturbances were among the most frequently observed ADRs in diabetic patients receiving antidiabetic medications. Likewise, Nyamagoud et al. [13] emphasized that careful monitoring of antidiabetic therapy, particularly among patients receiving combination treatment, is essential to minimize preventable ADRs. These findings reinforce the importance of individualized medication selection and continuous evaluation of treatment response in primary healthcare settings.

GerontoNet ADR Risk Assessment

Assessment using the GerontoNet ADR Risk Score demonstrated that most participants had fewer than four comorbidities, no documented liver disease or renal impairment, and no previous history of ADRs. Nevertheless, approximately one-third of the participants were prescribed eight or more medications, indicating the presence of polypharmacy among a considerable proportion of patients.

Polypharmacy is a well-recognized predictor of ADRs because increasing medication burden raises the likelihood of drug-drug interactions, medication errors,

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and reduced treatment adherence. Although most patients in this study exhibited relatively few clinical risk factors included in the GerontoNet score, the high proportion of patients receiving multiple medications suggests that medication safety should remain an important concern. The SENATOR trial demonstrated that older diabetic patients receiving multiple medications had significantly higher risks of ADRs and adverse clinical outcomes [5]. Similarly, Xiang et al. [12] reported that prescribing five or more medications substantially increased medication-related safety problems among patients with type 2 diabetes.

These findings indicate that implementation of structured pharmacovigilance activities, including periodic medication review, assessment of polypharmacy, and early identification of ADRs, should be integrated into the PROLANIS program. Such strategies may improve medication safety while maintaining optimal glycemic control among patients with diabetes mellitus.

Clinical Implications

The findings of this study highlight several important implications for diabetes management in primary healthcare. First, demographic characteristics such as female sex and older age should be considered during routine clinical assessment because both factors are associated with increased vulnerability to ADRs. Second, patients receiving combination antidiabetic therapy or multiple medications require regular medication reviews to reduce unnecessary polypharmacy and prevent avoidable ADRs. Finally, incorporating pharmacovigilance tools such as the GerontoNet ADR Risk Score into routine PROLANIS services may assist healthcare professionals in identifying high-risk patients and implementing individualized monitoring strategies to enhance medication safety.

Strengths and Limitations

This study provides real-world evidence regarding ADR risk factors among diabetes mellitus patients participating in the PROLANIS program in a primary healthcare setting. The use of the GerontoNet ADR Risk Score offers a structured approach for evaluating medication-related risk using routinely available clinical information.

However, several limitations should be acknowledged. The study was conducted at a single community health center with a relatively small sample size, limiting the generalizability of the findings. In addition, ADR assessment relied on medical record documentation rather than prospective monitoring; therefore, undocumented ADRs may not have been captured. Future multicenter studies involving larger populations and prospective pharmacovigilance monitoring are recommended to provide more comprehensive evidence regarding ADR occurrence among patients with diabetes mellitus.

CONCLUSION

This study demonstrates that diabetes mellitus patients participating in the PROLANIS program at the North Kota Community Health Center were predominantly middle-aged or older women, with metformin representing the most commonly prescribed antidiabetic

medication. Assessment using the GerontoNet ADR Risk Score indicated that most patients exhibited relatively low clinical risk factors for adverse drug reactions, as evidenced by the low prevalence of multiple comorbidities, heart failure, liver disease, renal impairment, and documented previous ADRs. Nevertheless, a considerable proportion of patients experienced polypharmacy, highlighting medication burden as an important factor that may increase the likelihood of adverse drug reactions despite an otherwise favorable clinical profile. These findings emphasize the importance of integrating routine pharmacovigilance activities, periodic medication reviews, and individualized risk assessments into the PROLANIS program to enhance medication safety and optimize therapeutic outcomes. Future studies should involve larger multicenter populations and prospective monitoring of adverse drug reactions to provide more comprehensive evidence and strengthen pharmacovigilance practices in primary healthcare settings.

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Submit: Nov 01st, 2023 Accepted: June 16th, 2025 Published: August 30th, 2025