

# Insulin Refill Adherence among Type 2 Diabetes Mellitus Patients Attending Public Health Clinics in Perlis, Malaysia

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## ABSTRAK

Pematuhan pengambilan ubat diabetes yang rendah, terutamanya insulin, masih menjadi kebimbangan. Kajian ini bertujuan untuk menilai pematuhan pengisian semula insulin dalam kalangan pesakit diabetes yang menghadiri klinik kesihatan awam di Perlis sebelum dan semasa pandemik COVID-19. Faktor-faktor yang berkaitan dengan pematuhan pengisian semula insulin juga disiasat. Kajian keratan rentas ini telah dijalankan dalam kalangan pesakit diabetes melitus jenis 2 dengan rawatan insulin dari lima klinik kesihatan awam di Perlis. Kaedah persampelan rawak digunakan untuk memilih peserta daripada pangkalan data Sistem Maklumat Farmasi (PhIS). Pematuhan kepada pengisian semula insulin diukur dengan nisbah pemilikan ubat sebelum dan semasa wabak COVID-19. Model linear am digunakan untuk mengenal pasti faktor yang berkaitan dengan pematuhan kepada pengisian semula insulin. Seramai 426 pesakit telah dimasukkan dalam kajian ini. Kebanyakan pesakit dalam kajian ini berbangsa Melayu (94.3%) dan perempuan (63.1%). Pematuhan pengisian semula insulin adalah jauh lebih lemah semasa wabak COVID-19 ( $\text{min}=59.24$ ,  $\text{SD}=28.97$ ) berbanding sebelum wabak ( $\text{min}=68.31$ ,  $\text{SD}=31.27$ ) ( $p<0.001$ ). Hanya jumlah dos insulin harian ( $\beta = -0.129$ ;  $p=0.012$ ) dan tidak mempunyai hipertensi ( $\beta = -7.359$ ;  $p=0.043$ ) dikaitkan secara signifikan dengan pematuhan pengisian semula insulin. Kajian ini menekankan bahawa pematuhan pengisian semula insulin secara keseluruhan dalam kalangan pesakit di klinik kesihatan awam di Perlis masih rendah, terutamanya semasa pandemik COVID-19. Perhatian khusus harus diberikan kepada pesakit yang menggunakan jumlah dos insulin harian yang tinggi dan tidak mempunyai hipertensi untuk meningkatkan pematuhan.

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**Kata kunci:** COVID-19, diabetes melitus jenis 2, insulin, Malaysia, pematuhan ubat

## ABSTRACT

Poor adherence to diabetes medications, particularly insulin, is still a concern. This study aimed to assess insulin refill adherence among diabetes patients attending public health clinics in Perlis before and during the COVID-19 pandemic. The underlying factors associated with insulin refill adherence were also investigated. This cross-sectional study was conducted among type 2 diabetes mellitus patients with insulin therapy from five primary health clinics in Perlis. Simple random sampling method was used to select participants from the Pharmacy Information System (PHIS) database. Adherence to insulin refill was measured by medication possession ratio before and during the COVID-19 pandemic. A general linear model was used to identify factors associated with adherence to insulin refills. A total of 426 patients were included in this study. Patients in this study were mostly Malay (94.3%) and female (63.1%). The insulin refill adherence was significantly poorer during the COVID-19 pandemic (mean=59.24, SD=28.97) than before the pandemic (mean=68.31, SD=31.27) ( $p < 0.001$ ). Only total daily insulin dose (adjusted  $\beta = -0.129$ ;  $p = 0.012$ ) and not having hypertension (adjusted  $\beta = -7.359$ ;  $p = 0.043$ ) were significantly associated with insulin refill adherence. This study highlighted that overall insulin refill adherence among patients in public health clinics in Perlis was still low, especially during the COVID-19 pandemic. Special attention should be given to patients using high total daily insulin doses and having no hypertension to improve adherence.

**Keywords:** COVID-19, insulin, medication adherence, Malaysia, type 2 diabetes mellitus

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## INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterised by insulin resistance and insufficient pancreatic insulin production resulting in abnormally high blood glucose levels that persists over time (Ministry of Health Malaysia 2020). The T2DM is commonly recognised as the world's fastest-growing chronic disease. Globally, diabetes is estimated to impact approximately 463 million

individuals, with a projected increase to 700 million by 2045 (Saeedi et al. 2019). In Malaysia, according to the 2019 National Health and Morbidity Survey, the prevalence of diabetes among Malaysian adults aged 18 and above have increased from 11.2% in 2011 to 18.3% in 2019 (Institute for Public Health 2020).

Over time, diabetic patients may develop long-term macrovascular and microvascular complications such as retinopathy, nephropathy, sexual

dysfunction, and diabetic neuropathy (Fowler 2008; Gregg & Bracco 2019). Additionally, uncontrolled T2DM increases the risk of developing conditions predisposing patients to hospitalisation, such as cardiovascular diseases, stroke, nephropathy, infections, and lower-extremity amputations (Khalid et al. 2014). Diabetes was reported to directly result in 1.6 million deaths worldwide in 2016. In Malaysia, approximately 35% of the total mortality was related to diabetes (World Health Organisation 2018). The rising number of diabetic patients places a significant strain on the healthcare system and society.

The mainstay of T2DM management involves multifactorial strategies, including diet control, exercise, glucose monitoring, weight control, and pharmacological intervention (Glasgow & Strycker 2000). In the most newly diagnosed T2DM cases, the patients are advised for lifestyle modification. If the blood glucose level remains suboptimal, the patients will be prescribed with oral anti-diabetic agents in order to achieve normoglycemia and delay the progression of long-term diabetes complications (Ministry of Health Malaysia 2020). However, as T2DM is a progressive disease, many diabetic patients may eventually require insulin to ensure adequate glycemic control (American Diabetes Association 2018).

Insulin is a glucose-lowering hormone produced by the pancreas. It is responsible for regulating the body's carbohydrate, fat, and protein metabolism (American Diabetes Association 2004). As there is

presently no cure for diabetes, certain T2DM patients may require insulin in conjunction with oral hypoglycemic medications if the previous treatment did not effectively control the glycemic level. There is a range of insulin injections available. They vary in terms of the onset and the duration of its effects in the body (Ministry of Health Malaysia 2020). In Malaysia, the most often used forms of insulin are short-acting, intermediate-acting, and premixed insulin. Additionally, analogue insulin is available in rapid-acting, long-acting, and premixed forms. At present, most insulin supplied to patients is available to be used with insulin pens.

Long-term use of pharmacotherapy is common in the treatment of chronic conditions. While these medications are efficient at combating disease, their full benefits are often not achieved if patients do not take the drugs as prescribed. Unfortunately, poor adherence to diabetes medications, particularly insulin, is still a concern. Furthermore, a systematic review revealed glycemic control was deteriorated among T2DM patients during lockdown period of COVID-19 pandemic (Eberle & Stichling 2021).

Identifying the level of insulin adherence is crucial for improving glycemic control. There are various methods for determining drug adherence including patients' self-reports, pill counts, electronic medicine monitoring, therapeutic effect measuring, and pharmacy refill data (Farley et al. 2003). As there is no gold standard to measure drug adherence, reviewing medication

refills from pharmacy claims data can be beneficial. Refill adherence can be determined based on the concept that patients cannot comply if they do not have enough drugs (Hawkshead & Krousel-Wood 2007).

In Malaysia, after consultations from public health clinics, most of the chronic illness patients will receive a prescription that will last between one and six months, depending on their condition. Since 2011, the Quality Use of Medicine (QUM) Pharmacy Practice Guideline has mandated drugs for prescriptions that last longer than one month to be given monthly (Bahri & Ibrahim 2014). As a result, patients will be required to get their medications, including insulin, at the health facility once a month. The Pharmacy Information System (PhIS) is a comprehensive and integrated system managing pharmacy-related services in most public healthcare settings in Malaysia. Prescription refill records from this centralised system can be a valuable data source to measure patient adherence to chronic medications (Steiner et al. 1988).

Additionally, following to the implementation of the first phase of the movement control order in Malaysia on 18 March 2020 in response to the COVID-19 pandemic, patients' access to healthcare facilities for routine care and medication management may have been limited during the lockdown period due to rigorous border control and quarantine efforts (Desvars-Larrive et al. 2020). Despite its evident importance, the literature on patients' insulin refill adherence during the COVID-19 pandemic is relatively

scarce. Therefore, the current study aimed to assess insulin refill adherence among diabetes patients in health clinics in Perlis before and during the COVID-19 pandemic and explore factors related to nonadherence.

## MATERIALS AND METHODS

This cross-sectional study was conducted from 1<sup>st</sup> January 2022 to 30<sup>th</sup> June 2022. This study was registered with the National Medical Research Register (NMRR ID-22-00227-KJZ) with the Medical Research and Ethics Committee approval. Permission to carry out this study and access to the PhIS data was also obtained from the Kangar District Health Officer before conducting this study.

Five health clinics were selected based on different geographical areas in Perlis, i.e. Padang Besar Health Clinic in the north, Kuala Perlis Health Clinic in the west, Arau Health Clinic in the east, Kuala Sanglang Health Clinic in the south, and UTC Health Clinic in the central area of Perlis. The current study involved T2DM patients who had been prescribed with insulin therapy from primary health care centres in Perlis. The inclusion criteria were T2DM patients aged 18 years old and above using insulin therapy during the period from 1<sup>st</sup> September 2019 to 30<sup>th</sup> September 2020. Pregnant patients with gestational diabetes mellitus were excluded from this study.

The sample size estimation for the first specific objective was calculated using population proportion formulae (Lemeshow et al. 1990). According to a previous study, the prevalence of

insulin adherence was 57.0% (Chew et al. 2015). If Type 1 error probability was set at 5% with a statistical power of 95%, a total of 318 samples was needed. The final sample size was 398 after considering the 20% dropout rate. A list of eligible patients was generated from the electronic system (PHIS). Then, simple random sampling method was used for participant selection in this study. Random numbers were generated from Microsoft Excel to create a sampling frame for participant selection.

A standardised data collection form was formulated to assess patients' demographic data (age, gender, and ethnic), comorbidities, insulin-related information (types of insulin used, insulin regimen, total daily insulin dose, and the number of daily injections), and insulin refill records before (September 2019 to February 2020) and during (April to September 2022) the COVID-19 pandemic. Adherence to insulin refill were measured by medication possession ratio (MPR) (Stolpe et al. 2016) based on prescription data obtained from the PHIS. Patients were considered adherent at an MPR 80% (Stolpe et al. 2016).

$$MPR = \frac{\text{Total number of days of insulin supplied in all fills within a valid prescribed period}}{\text{Total number of days insulin prescribed}} \times 100\%$$

The distribution of continuous variables (MPR score, age, and total daily insulin dose) were assessed by using skewness and kurtosis (Kim 2013). Then, student's t-test, Pearson's

Correlation, and One-way ANOVA were performed in univariable analysis. All variables with  $p < 0.25$  from the univariable analysis were included for downstream analysis (Zhang 2016). A general linear model (multiple linear regression) was used to identify factors associated with adherence to insulin refills by adjusting the confounding variables. A p-value of less than 0.05 was considered statistically significant. All analyses were performed in SPSS software version 21.0 (IBM Corp, Armonk, NY).

## RESULTS

A total of 426 patients were included in the final analysis. About two-thirds of the patients were between the ages of 51 and 70. The majority of this study's patients were female (63.1%) and Malay (94.3%). Premixed (41.8%) and basal-bolus (44.1%) insulin were prescribed for most patients. Half of the patients had a total daily insulin dose of less than 50 units, while 41.5% of patients used insulin doses between 51 and 100 units. Analogue insulin was utilised by only six patients. A considerable proportion of patients were also diagnosed with hypertension (83.6%) and dyslipidemia (92.5%). The sociodemographic characteristics and insulin-related information of patients were shown in Table 1.

Insulin refill adherence was also found to be significantly poorer during the COVID-19 pandemic (mean=59.24, SD=28.97) than before the pandemic (mean=68.31, SD=31.27) ( $p < 0.001$ ) (Table 2). About 40% (n=170) of participants had good adherence to

Table 1: Patients’ demographic data and diabetic characteristics, n=426

Variable	Category	n (%)
Age (years)	≤30	5 (1.2)
	31-50	60 (14.6)
	51-70	287 (67.4)
	>70	72 (16.9)
Gender	Male	157 (36.9)
	Female	269 (63.1)
Ethnicity	Malay	359 (94.3)
	Chinese	41 (9.6)
	Indian	11 (2.6)
	Others	15 (3.5)
Insulin regimen used	Bolus only	60 (14.1)
	Basal-bolus	188 (44.1)
	Premixed	178 (41.8)
Total daily insulin dose (unit)	<50	211 (49.5)
	51-100	177 (41.5)
	>100	38 (8.9)
Analogue insulin used	Yes	6 (1.4)
	No	420 (98.6)
Comorbidities	Hypertension	356 (83.6)
	Dyslipidemia	394 (92.5)

their insulin refills (MPR 80%) prior to the COVID-19 pandemic. However, only 122 individuals (28.6%) adhered well to their insulin refill schedule during the COVID-19 pandemic (Table 3).

Table 4 showed the association between sociodemographic data, comorbidities, and insulin-related information towards insulin refill adherence. Univariate analysis revealed three factors (insulin regimen used, total daily insulin, and hypertension) were significantly associated with

Table 3: Percentage of patients’ adherence to insulin refill

Variable	Before COVID-19 Pandemic n (%)	During COVID-19 Pandemic n (%)
Adherent to insulin refills		
Yes	170 (39.9)	122 (28.6)
No	256 (60.1)	304 (71.4)

Notes: Patients are considered adherent at an MPR ≥80%.

insulin refill adherence. Only total daily insulin dose (adjusted  $\beta=-0.129$ ,  $p=0.012$ ) and not having hypertension (adjusted  $\beta=-7.359$ ,  $p=0.043$ ) were significantly associated with insulin refill adherence in the general linear model after adjusting for confounding variables (Table 5).

## DISCUSSION

Globally, poor adherence to insulin regimens is common among diabetic patients (Chew et al. 2015). Nonadherence to insulin was found in most countries, including Japan (44%), the United States (42%), the United Kingdom (41%), Germany (40%), China (33%), Turkey (24%), Spain (23%) and France (19%) (Doggrell & Chan 2015). Several studies conducted in Malaysia among diabetic patients

Table 2: Patients’ adherence to insulin refill before and during COVID-19 pandemic, n=426

Variable	Before COVID-19 Pandemic Mean (SD)	During COVID-19 Pandemic Mean (SD)	t	p-value
Medication possession ratio (MPR)	68.31 (31.27)	59.24 (28.97)	6.20	<0.001*

Notes: t = t-statistic; \* =  $p<0.05$

Table 4: Univariable analysis on insulin refill adherence, n=426

Variable	Category	Patients' insulin refill adherence Mean (SD)	Test-statistics	p-value
Age			r = 0.076	0.119
Gender	Male	68.38 (25.05)	t (424) = 0.042	0.966
	Female	68.27 (26.95)		
Ethnicity	Malay	67.78 (26.66)	t (424) = -0.976	0.330
	Non-Malay	71.18 (23.81)		
Insulin regimen used	Bolus only	76.15 (24.72)	F (2,423) = 3.607	0.028*
	Basal-bolus	65.76 (27.82)		
	Premixed	68.36 (24.57)		
Total daily insulin dose (unit)		68.31 (26.24)	r = -0.169	<0.001*
Analogue insulin used	Yes	56.47 (33.18)	t (424) = 0.906	0.365
	No	68.42 (26.19)		
Hypertension	Yes	69.45 (25.73)	t (424) = -2.028	0.043*
	No	62.52 (28.16)		
Dyslipidemia	Yes	68.56 (25.78)	t (424) = -0.694	0.488
	No	65.21 (31.60)		

Notes: SD=standard deviation; t=t-statistic; r=Pearson's coefficient; F=F-statistic; \*=p<0.05; All variables of p<0.25 were included for multivariable analysis

found about 41% to 53% of patients were nonadherent (Ahmad et al. 2013; Chew et al. 2015; Chua & Chan 2011). The current study examining patients' refill records revealed that 60.1% of patients had a suboptimal level of insulin refills during the study period.

Furthermore, their insulin refill

adherence rate was much lower during the initial period of the COVID-19 pandemic in Malaysia. Several episodes of lockdowns and movement restrictions during the initial phase of the pandemic were major problems for patients with chronic diseases requiring follow-ups and prescription refills

Table 5: Multivariable analysis on factors associated with insulin refill adherence using General Linear Model, n=426

Variable	Adjusted β (95% CI)	t	p-value	
Age	0.046 (-0.200, 0.291)	0.367	0.714	
Total daily insulin dose (unit)	-0.129 (-0.230, -0.028)	-2.513	0.012*	
Insulin regimen used	Basal	2.878 (-6.868, 12.623)	0.580	0.562
	Basal-bolus	Ref.		
	Premixed	-0.623 (-6.615, 5.369)	-0.204	0.838
Hypertension	Yes	Ref.		
	No	-7.359 (-14.494, -0.224)	-2.027	0.043*

Notes: β = Regression coefficient; adjusted R<sup>2</sup>=0.043; t=t-statistic; Ref.=reference group; \*=p<0.05

(Kretchy et al. 2021). Nonadherence to prescribed regimens is associated with suboptimal treatment outcome, higher risk of hypo- or hyperglycemia, and significantly increased mortality rates (Polonsky & Henry 2016). The pandemic has highlighted the urgent need for medical compliance to be reconceptualised.

Consistent with earlier research findings, gender and race have not been seen to be associated with the level of medication adherence (Ahmad et al. 2013; Mariye et al. 2019; Peyrot et al. 2010). Most studies found that younger adults were more likely to be nonadherent to their medication (Ahmad et al. 2013; Chew et al. 2015). Some patients intentionally skipped taking their insulin doses for weight control (Peyrot et al. 2010). Interestingly, this study found no significant difference in patients' age.

Insulin nonadherence normally occurs when the treatment regimen is complicated, whether in terms of administration method, scheduling, or storage (Jimmy & Jose 2011). Those with complex insulin regimes, particularly with a greater number of insulin injections per day, had a higher rate of insulin injection omission (Peyrot et al. 2010). Nevertheless, this study did not discover that the types of insulin regimens significantly affected the degree of patient adherence. On the other hand, this study found that patients with greater daily insulin doses had poor refill adherence levels. A larger daily insulin dose may result in a higher rate of minor hypoglycemia and, therefore, a higher likelihood of skipping an insulin dose (Yavuz et al.

2015). Consequently, these patients may have excess insulin supply, resulting in a lower rate of insulin refills.

Previous literature conducted among T2DM patients attending public health clinics in Malaysia found that patients' medication adherence was lower if they had concurrent comorbidities such as hypertension and dyslipidemia due to complex medication regimens (Ahmad et al. 2013). Interestingly, this study found that T2DM patients with hypertension had higher adherence to insulin refills. These patients could be more health conscious of adhering to therapeutic recommendations and follow-up appointments closely after being diagnosed with additional comorbidities (Chew et al. 2015).

In most countries where diabetes treatment is often from out-of-pocket expense, and treatment involving insulin is costly, financial factors are often associated with nonadherence to insulin (Bermeo-Cabrera et al. 2018; Sharma et al. 2020). However, the financial factor was not examined in this study. In Malaysia, the vision of health is to provide a healthcare system that is equitable and affordable to the population (World Health Organisation 2012). The Ministry of Health is the key healthcare provider in Malaysia, with an extensive network of primary care clinics and large public hospitals in every state. Every citizen of Malaysia is eligible for public healthcare services that are heavily subsidised by the government (Tumin et al. 2016).

There were a few limitations in the study. This study only obtained data from the pharmacy database (PHIS). The authors may lose information that

was unavailable in the system, such as marital status, education levels, monthly household incomes, and duration of diabetes, which could influence their insulin refill adherence. However, the data was more reliable compared to patients' self-reporting adherence measurement, as the latter may be subjected to reporting bias. Some patients may overreport their adherence for various reasons.

In early 2022, the Pharmaceutical Services Divisions of Perlis State Health Department introduced a new Pharmacy Value-Added Services (VAS), namely UM3 (Pembekalan Ubat Susulan Melalui Pihak Ketiga). This new service was introduced through the concept of delighting the customer, ensuring continual access to follow-up medication supplies, and preventing congestion in the pharmacy waiting areas. Refill medications, including insulin, can be delivered to a location of the patient's choice via collaboration with a chosen delivery company to ensure continuity of medicine for all patients with the new norm.

The current study contributed to the existing literature on patients' insulin refill adherence, allowing future research to expand based on the findings, including insulin-taking behaviour and the underlying factors contributing to nonadherence. Further studies investigating the true factors associated with insulin nonadherence should be explored either through qualitative in-depth interviews or a case-control study.

## CONCLUSION

In conclusion, this study highlighted that overall insulin refill adherence among patients in public health clinics in Perlis was low, particularly during the COVID-19 pandemic. Poor insulin adherence is a significant issue that can lead to suboptimal glucose control and increased utilisation of healthcare resources. Interventions should focus on T2DM patients in health clinics, particularly those who require high total daily insulin doses and those without hypertension, to improve medication adherence and treatment outcomes.

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