



The Development and Validation of The Indonesian Insulin Adherence Influence Factor Questionnaire (IIAIFQ)

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Abstract

Background: Type 2 diabetes mellitus (DMT2) is a metabolic disease due to abnormalities in insulin secretion. Insulin is one of DMT2 therapy. **Objective:** This study aimed to validate a modified the insulin adherence influence factor questionnaire based on the health belief model (HBM) among Indonesian patients with DMT2. **Methods:** The Indonesian insulin adherence influence factor questionnaire (IIAIFQ) was developed based on modified some literature reviews and internal expert discussions. The study included 30 participants aged ≥ 17 y.o years old who had been taking insulin in the previous two months. The questionnaire consists of seven dimensions to measure HBM : perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, cues to action and insulin adherence. **Results:** The construct validity test showed that of the 34 question items in the questionnaire, 10 items were invalid, 24 others were demonstrated valid based on the Pearson Correlation ($>$ table 0.361; $p < 0.05$; loading factor > 0.5). Furthermore, 24 valid items were tested for reliability at a significance level of 0.05, and the results showed that each size had a Cronbach's Alpha > 0.6 with an overall score was 0.858, indicating that all domains in the questionnaire were reliable. **Conclusion:** IIAIFQ based The HBM theory is a valid and reliable instrument for assessing insulin adherence in diabetes mellitus patients.

Keywords: adherence, health belief model, insulin, reliability, validity

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INTRODUCTION

Diabetes mellitus (DM) is a non-communicable disease that is a top 10 (ten) cause of death globally. In 2021, DM disease in Indonesia ranked fifth highest globally after China, India, Pakistan, and the United States (International Diabetes Federation, 2021). The results of Basic Health Research show that the prevalence of people aged ≥ 15 years with DM has increased from 6.9% in 2013 to 8.5% in 2018 (Kemenkes RI, 2018).

The International Diabetes Federation estimates that more than 537 million people worldwide suffer from DM, and around 150-200 million are treated with insulin (Masieriek *et al.*, 2022). Insulin therapy is needed when oral antidiabetics in optimal doses cannot improve blood glucose levels and HbA1C values $> 9\%$ with metabolic decompensation conditions (Perkumpulan Endokrinologi Indonesia, 2021a).

In Indonesia, several types of insulin are categorized based on their origin, namely insulin analogues and human insulin. The use of insulin analogues is higher than human insulin (Kehlenbrink *et al.*, 2018). Based on its duration of action, insulin therapy consists of fast-acting, short-acting, intermediate-acting, long-acting, and fixed insulin mix (premixed insulin) (Perkumpulan Endokrinologi Indonesia, 2021b). Adherence to oral drug therapy and insulin therapy influences therapeutic outcomes in diabetic patients. According to the treatment recommendation, good insulin adherence is critical in managing DM therapy. Adherence to insulin therapy is linked to better glycemic control, which lowers the risk of developing microvascular and macrovascular complications and all-cause mortality (Stolpe *et al.*, 2016).

Patients' beliefs about using drugs and their health conditions influence adherence to medication therapy. Individual beliefs include perceptions of susceptibility, severity, benefits, barriers, and self-efficacy. Cues to action also have an impact on compliance (Pakpahan *et al.*, 2021). Adherence to medical regimens extends the health belief model (HBM) implementation (Irwan, 2017).

Based on the literature review, numerous questionnaires assess diabetes mellitus treatment adherence in general and the factors that influence it. The questionnaire about the adherence to insulin used was adapted from the Morisky Medication Adherence Scale (MMAS) (MIAS) (Osborn & Gonzalez, 2016). There was a questionnaire about factors determining insulin adherence like diabetes knowledge, such as the

patient diabetes knowledge questionnaire (PDKQ) and diabetes knowledge questionnaire (DKQ) in the Taiwanese population; a questionnaire about quality of life, such as the Asian diabetes quality of life questionnaire and Indonesian version of the A the audit of diabetes dependent quality of life questionnaire (ADDQoL); and the questionnaire about diabetes mellitus patient behaviour in primary health care service (Hsieh *et al.*, 2022; Lim *et al.*, 2023; Oliveira *et al.*, 2022; Permana *et al.*, 2021; Rooswita *et al.*, 2021; Saputri *et al.*, 2019).

There are only a few questionnaires specific to Indonesian patients with DMT2 with insulin treatment therapy. Fitriani *et al.* (2019) developed an insulin adherence questionnaire based on the health belief model (HBM) only on individual belief or only 5 (five) dimensions. A study was done by compiling personal beliefs and cues to action became 6 (six) dimensions for measuring insulin adherence, and factors determining insulin adherence in Indonesian patients with DMT2 is still limited. This study aimed to develop and validate the insulin adherence influence factor questionnaire based on the health belief model (HBM) among Indonesian patients with DMT2.

MATERIALS AND METHODS

Tools

The Indonesian insulin adherence influence factor questionnaire (IIAIFQ) was developed in the Indonesia language based on literature reviews (Cipolle *et al.*, 2012; Hepler & Strand, 1990; Perkumpulan Edukator Diabetes Indonesia, 2017; Rusmadi *et al.*, 2021; Strachan & Frier, 2013; van der Ven *et al.*, 2003) and expert discussion. This questionnaire consisted of seven dimensions (34 statement items), namely 3 statement items on perceived susceptibility (PSu), 3 statement items on perceived severity (PSv), 5 statement items on perceived benefits (PBe), 6 statement items on perceived barriers (PBa), 4 statement items on perceived self-efficacy (PSE), 3 statement items on cues to action (CA), and 10 statement items on insulin adherence (IA). Assessment of the six dimensions of individual belief used a Likert scale with a score of 5 for the answer "strongly agree", 4 for the answer "agree", 3 for the answer "neutral", 2 for the answer "disagree" and 1 for the answer "strongly disagree". While one dimension of insulin adherence used a Likert scale with ratings of 5 for the answer "always", 4 "often", 3 for the answer "sometimes", 2 for the answer rarely, and 1 for the answer "never."

Method

Study design

This cross-sectional survey was conducted in Banjarbaru City, South Borneo, Indonesia, from March to April 2023. Convenient sampling was employed to select respondents for construct validity and reliability. Ethical approval for this research was received from the Health Research Ethics Committee of Idaman Hospital Banjarbaru City with reference No.RS00122/KEPK-RSDI/02/2023.

The face and content validity test of IIAIFQ was established by an internal research team consisting of pharmacists based on their expertise and credibility in pharmaceutical care. The construct validity test of IIAIFQ was conducted on 30 respondents who visited Nirwana Hospital and Syifa Medika Hospital, Banjarbaru City (Yurdugül, 2008; Yusoff *et al.*, 2021).

Those hospitals were selected by considering the highest number of DMT2 patients who use insulin. The population of the construct validity test in this study were DMT patients who use insulin. The sample were all type 2 diabetes mellitus patients who met the following criteria: aged ≥ 17 years, taking insulin at least in the last 2 months, able to read and hear, and willing to contribute to the study by approving and signing informed consent.

Data collection

Data were collected directly from the respondents via questionnaires when the patients took the medication in the outpatient department at the pharmacy. Data collection techniques include asking respondents a series of questions or writing them down after they were informed about the purpose of the study and consented to participate by signing an informed consent form.

Data analysis

Analysis of the construct validity and reliability results used Jeffrey's Amazing Statistics Program (JASP) application. The construct validity of each statement item can be seen from the Pearson Correlation value using the distribution (table r) at a significance level of 0.05 for a two-way test with r table = 0.361 because of degrees of freedom ($df=N-2=30-2=28$). If the correlation coefficient value equals or exceeds the r table value, then the statement item is considered valid. Then, it was continued with convergent validity; if the loading factor > 0.5 , then the statement is considered valid (Hair *et al.*, 2010). Furthermore, reliability tested each dimension at a significance level of 0.05 by looking at Cronbach's alpha value. The statement is deemed reliable if Cronbach's alpha value is ≥ 0.6 (Sani, 2018).

RESULTS AND DISCUSSION

The demographic characteristics of the respondents can be seen in Table 1. The majority of respondents, or 23 people (76.7%), were patients aged 45-65 years. This aligns with research conducted by Gamayanti *et al.* (2018) at the Internal Medicine Polyclinic of the State General Hospital and Vonna *et al.* (2021) at Dr Zainoel Abidin Hospital in Banda Aceh, who stated that diabetes mellitus patients who use insulin at the most are aged 46-65 years (Gamayanti *et al.*, 2018; Vonna *et al.*, 2021). Another study on people with DMT2 at the Outpatient Pharmacy Installation at ST Elisabeth Hospital in Semarang found that most patients who use insulin were over 45 years (Rukminingsih & Nova, 2021). Based on gender, it can be seen that the majority of respondents in this study (17 people) were male (56.7 %). According to a review, women have a higher prevalence of DMT2 in their youth than men, while men have a higher prevalence in their middle years (Huebschmann *et al.*, 2019). Women patients with DM aged 56-65 years are more susceptible to depression than women patients with DM aged 46-55 years (Fatmawati *et al.*, 2023).

According to Table 1, all respondents used insulin analogue, and the majority of respondents used rapid-acting insulin in the form of Novorapid 100U/mL; as many as 7 seven people (23.3 %) and a combination of long-acting and rapid-acting insulin with the trade name Levemir 100U/ mL + Novorapid 100U/ mL; as many as 7 seven people (23.3 %). This aligns with the findings of Anggraini *et al.* (2020) and Zaim *et al.* (2021), who discovered that the use of insulin analogues is greater than that of human insulin (Anggriani, Rianti, Pratiwi, & Puspitasari, 2020). This is because the risk of hypoglycemia of insulin analogues is lower than human insulin and can be given immediately without paying attention to mealtimes (Fibriani, 2014). The use of a rapid-acting and long-acting insulin combination is in line with research conducted by Adinda *et al.* (2023), which stated that a long-acting and rapid-acting combination is also the most extensively used insulin in Dr Soetomo Hospital, Surabaya (Ayu *et al.*, 2023). The combination of insulin glargine (long-acting insulin) with insulin aspart (rapid-acting insulin) resembles the human body's normal insulin profile because it provides a faster onset of action with a longer duration of action (Kartika *et al.*, 2013).

Table 1. Demographic characteristics of the participants (n = 30)

Demographic	Category	n (%)
Age	< 45 years	4 (13.3)
	45-65 years	23 (76.7)
	> 65 years	3 (10.0)
Sex	Men	17 (56.7)
	Women	13 (43.3)
Education	None	0 (0.0)
	Primary school	1 (3.3)
	Junior high school	4 (13.3)
	Senior high school	13 (43.3)
	D3	2 (6.7)
	D4	0 (0.0)
	Bachelor degree	8 (26.7)
	Master degree	2 (6.7)
	Doctoral	0 (0.0)
Occupation	Unemployment	6 (20.0)
	Retired	4 (13.3)
	Government employees	11 (36.7)
	Self-employed	9 (30.0)
Monthly family income	< IDR 1000000	2 (6.7)
	> IDR 1000000- IDR 2000000	3 (10.0)
	> IDR 2000000- IDR 3000000	6 (20.0)
	> IDR 3000000- IDR 4000000	6 (20.0)
	> IDR 4000000- IDR 5000000	6 (20.0)
Sources of funding for treatment	> IDR 5000000	7 (23.3)
	BPJS/JKN KIS	27 (90.0)
	Private insurance	1 (3.3)
Duration of diabetes mellitus (years, mean ± sd)	Self-pay	2 (6.7)
		4.23 ± 4.5
Comorbidity	None	6 (20.0)
	Allergy	1 (3.3)
	CHF	2 (6.7)
	Dyslipidemia	6 (20.0)
	Hypertension	2 (6.7)
	Maag	1 (3.3)
	CHF + Osteoporosis	1 (3.3)
	Dyslipidaemia + CHF	1 (3.3)
	Dyslipidaemia + Maag	1 (3.3)
	Hypertension + CHF	1 (3.3)
	Hypertension + Dyslipidaemia	1 (3.3)
	Hypertension + Gout	2 (6.7)
	Hypertension + Maag	1 (3.3)
	Hypertension + Sirosis hati	1 (3.3)
	Hypertension + Stroke	1 (3.3)
Maag + Asthma	1 (3.3)	
Hypertension + Dyslipidemia + Gout	1 (3.3)	
Duration of use insulin (months, mean ± sd)		12.5 ± 22.1
Other diabetes medications currently in use	None	17 (56.7)
	Acarbose 100 mg	1 (3.3)
	Glimepiride 2 mg	1 (3.3)
	Glimepiride 3 mg	1 (3.3)
	Metformin 500 mg	5 (16.7)
	Metformin 850 mg	1 (3.3)
	<i>Gliclazide 80 mg</i>	1 (3.3)
	Metformin 500 mg + Glimepiride 2 mg	1 (3.3)
	Metformin 500 mg + Glibenclamide 2.5 mg	1 (3.3)
	Metformin 500 mg + Acarbose 100 mg	1 (3.3)

Table 2. Construct validity for the 34 statements of the IIAIFQ

No	Dimension	Statements	Pearson correlation	r table	Explanation
1	Perceived susceptibility (PSu)	1. I am vulnerable to the risk of blood sugar deficiency when using excessive doses of insulin	0.789	0.361	Valid
2		2. I am vulnerable to infection when using insulin with a syringe that is not replaced	0.853	0.361	Valid
3		3. I am vulnerable to experiencing the risk of swelling of the skin that is injected at the same place continuously	0.790	0.361	Valid
4	Perceived severity (PSe)	1. I feel worried about the condition of my sugar level if I don't adhere to using insulin properly	0.860	0.361	Valid
5		2. I am worried that my health condition will get worse if I don't adhere to using insulin properly	0.922	0.361	Valid
6		3. I am worried about the dangerous condition of the complications of diabetes mellitus	0.831	0.361	Valid
7	Perceived benefits (PBe)	1. I feel the benefit of being obedient to using the correct insulin is that my blood sugar levels are controlled	0.769	0.361	Valid
8		2. I feel that the benefit of adhering to using the correct insulin is that it can prevent complications of blindness	0.946	0.361	Valid
9		3. I feel the benefit of sticking to using the correct insulin is that it can prevent complications of kidney failure	0.915	0.361	Valid
10		4. I feel that the benefit of adhering to using the correct insulin is that it can prevent complications of heart disease	0.938	0.361	Valid
11		5. I feel the benefit of sticking to using the correct insulin is that it can prevent complications of paralysis	0.869	0.361	Valid
12	Perceived barrier (PBa)	1. I feel the fear that insulin will cause pain when injected is an obstacle in sticking to using insulin properly	0.562	0.361	Valid
13		2. I have trouble remembering the schedule for injecting insulin	0.509	0.361	Valid
14		3. I need someone else's help to be able to inject insulin properly	0.488	0.361	Valid
15		4. I find it challenging to buy a refrigerator to store insulin	0.523	0.361	Valid
16		5. I find it challenging to buy insulin because it's expensive	0.789	0.361	Valid
17	Perceived self-efficacy (PSv)	6. I feel uncomfortable with the side effects of insulin	0.605	0.361	Valid
18		1. I feel able to inject insulin properly	0.876	0.361	Valid
19		2. I feel able to inject insulin according to the recommended dose every day	0.895	0.361	Valid
20		3. I feel able to inject insulin when I'm at home even though I'm sick	0.713	0.361	Valid
21		4. I feel able to inject insulin even when I'm outside the house/travelling	0.578	0.361	Valid
22	Cues to action (CA)	1. Information and education from the doctor will be critical to help me take insulin treatment properly	0.319	0.361	Invalid
23		2. Information and education from the pharmacist will be critical to help me take insulin medication correctly	0.940	0.361	Valid
24		3. The support from my family encouraged me to adhere to insulin treatment properly	0.851	0.361	Valid
25	Insulin adherence (IA)	1. I inject insulin according to the dosage recommended by a doctor or health worker	0.361	0.361	Valid
26		2. I inject insulin before eating as directed by a doctor or health worker	0.621	0.361	Valid
27		3. I checked the expiration date of the insulin	0.542	0.361	Valid
28		4. I clean my hands before using insulin	0.744	0.361	Valid
29		5. I removed the protective seal on the needle without touching the needle	-0.044	0.361	Invalid
30		6. I do priming (gas bubble removal) before taking insulin	0.606	0.361	Valid
31		7. I did a cleanup on the location to be injected	0.775	0.361	Valid
32	8. I poked the needle into the skin quickly at a 90-degree angle	0.214	0.361	Invalid	
33	9. I store used insulin at room temperature	0.417	0.361	Valid	
34	10. I store unused insulin in the refrigerator	0.161	0.361	Invalid	

Table 3. Loading factor of convergent validity for IIAIFQ

Dimension	Indicator	Loading Factor
Perceived Susceptibility	PSu1	0,822
	PSu2	0,883
	PSu3	0,729
Perceived Severity	PSv1	0,852
	PSv2	0,922
	PSv3	0,838
Perceived Benefit	PBe1	0,796
	PBe2	0,944
	PBe3	0,910
	PBe4	0,935
	PBe5	0,859
Perceived Barrier	PBa4	0,748
	PBa5	0,798
	PBa6	0,852
Perceived Self Efficacy	PSE1	0,918
	PSE2	0,937
	PSE3	0,665
	PSE4	0,526
Cues to Action	CA2	0,931
	CA3	0,931
Insulin Adherence	IA1	0,870
	IA2	0,901
	IA4	0,553
	IA9	0,797

The construct validity test of the IIAIFQ listed in Table 2 showed that four of the 34 statement items were invalid because the correlation value was less than 0.361, resulting in only 30 statement items being declared valid. The four invalid items were 1) Information and education from a doctor would be critical to help me take insulin medication properly, 2) I removed the protective seal of the needle without touching the needle, 3) I inserted the needle rapidly into the skin at an angle of 90 degrees, and 4) I store unused insulin in the refrigerator.

Providing information to DMT2 patients about the benefits and importance of compliance and the risks of non-adherence is one way to improve adherence to insulin use (Mathew et al., 2022). Item statement no.1 comes from the dimension of cues to action. Item 1 was invalid, which may be due to the results where the majority of 21 people (70%) gave agreed answers. While item statements number 2-4 come from the dimensions of adherence to insulin use. Statements 2-4 are invalid perhaps because the majority of respondents, as many as 29 people (96.7%), answered "always" on item 2, the majority of as many as 27 people (90.0%) answered "always" on statement item 3, and most as many as 13 people (43.3%) answered "always" on the 5th statement item.

There were 30 items of valid statements in IIAIFQ by Pearson's validity analysis, it was then tested for convergent validity, as shown in Table 3. For 24 items of valid statements in IIAIFQ by convergent validity analysis, each dimension was tested for reliability, as shown in Table 4. The reliability test showed that each dimension had a Cronbach's Alpha value greater than 0.6 with an overall score of 0.858 with details for perceived susceptibility of 0.729, perceived severity of 0.841, perceived benefits of 0.927, perceived barriers of 0.711, perceived confidence of 0.757, cues to action by 0.844, and adherence to insulin use by 0.645. This means that all dimensions in the questionnaire are declared reliable.

Several studies on medication therapy adherence have been carried out using the Health Belief Model (HBM) theoretical approach. Fitriani (2019) conducted insulin treatment adherence research using a questionnaire that measures adherence to insulin treatment therapy from the five dimensions of HBM theory: perceived vulnerability, perceived severity, perceived benefits, perceived barriers, and perceived self-efficacy (Fitriani, 2019). This aligns with research conducted by Hidayati *et al.* (2020), which only included these five dimensions to analyze behavioural factors that affect adherence to medication therapy in gout patients (Hidayati *et al.*, 2020).

Table 4. Reliability for IIAIFQ

Dimension	Cronbach's alpha coefficient	Standard coefficient	Explanation
Perceived susceptibility (PSu)	0.729	0.60	Reliable
Perceived severity (PSv)	0.841	0.60	Reliable
Perceived benefits (PBe)	0.927	0.60	Reliable
Perceived barrier (PBa)	0.711	0.60	Reliable
Perceived self-efficacy (PSE)	0.757	0.60	Reliable
Cues to action (CA)	0.844	0.60	Reliable
Insulin adherence (IA)	0.645	0.60	Reliable
All dimension	0.858	0.60	Reliable

Research conducted by Fithri *et al.* (2021) also included these five dimensions with an additional dimension, namely perceived threat, in a questionnaire to assess factors that affect medication adherence in elderly patients with hypertension (Fithri *et al.*, 2021). In this study, the questionnaire was made to measure six dimensions of the HBM theory: perceived vulnerability, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy, and cues to action. This aligns with previous research conducted by Rusmadi *et al.* (2021), which also included the six dimensions of the HBM theory in the medication adherence questionnaire in elderly patients with hypertension (Rusmadi *et al.*, 2021). The six dimensions of the HBM theory also measure self-care practices and associated factors among diabetic patients in Gondar City (Melkamu *et al.*, 2021).

Another perspective studies on diabetes mellitus medication adherence have been carried out using the Theory of Planned Behavior (TPB) approach. Oliveira *et al.* (2022) verified the content validity of questions of an insulin adherence questionnaire in outpatients DMT2 from the four dimensions of TPB: intention, attitude, perceived norm, and perceived control (Oliveira *et al.*, 2022). This aligns with previous research that included these four dimensions that affect antidiabetic medication adherence (Wu & Liu, 2016; Zomahoun *et al.*, 2016).

The instrument or questionnaire designed for Indonesian DMT2 patients and specific to analyzing diabetes treatment by insulin pen based on health behaviour theory distinguishes this study from others. This questionnaire measures the six dimensions of the HBM theory: perceived vulnerability, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy and cues to action. Previous research did not include cues to action dimensions (Fitriani, 2019). The limitations of this study were due to the distribution of questionnaires carried out in two private hospitals in Banjarbaru City, so each respondent had different health service experiences. It affected the respondent's experience regarding cues to action related

to the role of health workers in the treatment of DM, especially the use of insulin. This questionnaire is less suitable when applied to research conducted at only one health facility. More research may be needed to test this questionnaire in a larger, more representative sample and only at one health facility to appropriately depict insulin adherence behaviour in that area. In order to create a comprehensive questionnaire, other approaches such as factor analysis for concept validity, known group validity, split half or test-retest reliability must be incorporated into the validity and reliability study.

CONCLUSION

IIAIFQ is a valid and reliable tool for assessing the factors that influence insulin adherence in Indonesian patients with DMT2 based on the HBM.

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AUTHOR CONTRIBUTIONS

Conceptualization, Y. S., U. A., E. Z., A. M.A.; Methodology, Y. S., U. A., E. Z., A. M. A.; Software, Y. S.; Validation, Y. S., U. A., E. Z., A. M. A.; Formal Analysis, Y. S., U. A., E. Z.; Investigation, U. A., E. Z., A. M. A.; Resources, Y. S.; Data Curation, Y. S.; Writing - Original Draft, Y. S.; Writing - Review & Editing, Y. S., U. A., E. Z., A. M. A.; Visualization, Y. S., E. Z.; Supervision, U. A., E. Z., A. M. A.; Project Administration, Y. S.; Funding Acquisition, Y. S.

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CONFLICT OF INTEREST

The authors declared no conflict of interest.

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