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Measuring Compliance Therapy in Type 2 Diabetes Mellitus Patients using Proportion of Days Covered (PDC) Method and Its Effect on Clinical Outcomes

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Abstract: Diabetes Mellitus (DM) is a chronic disease that occurs when the blood glucose level increases more than 200 mg/dl because the body is unable to produce or use insulin effectively. Therapeutic adherence is one of the causes of normal blood glucose levels and the success of patient therapy. Measurement of therapeutic adherence of DM type 2 patients needs to be carried out to monitor the success of their therapy. This study aims to determine adherence to antidiabetic therapy using the Proportion of Days Covered (PDC) method and its effect on the clinical outcomes of type 2 DM patients at Sulawesi Tenggara. The research method used is research with a cross-sectional design. The sample of this study was 186 people obtained using the Slovin formula. Patients are said to be adhering if their PDC value is ≥ 80% and are said to be non-adherent if their PDC value is < 80%. The data were analyzed using the chi-square test. The results showed that patients adhering to treatment amounted to 130 people (69.9%), while patients who did not comply with treatment amounted to 56 people (30,1%) and there was a significant influence between adherence to antidiabetic therapy on the success of therapy (clinical outcome) with p-value = 0.000 in type 2 DM patients at Sulawesi Tenggara. It was concluded that most of the patients in this study were adherent to the treatment and there was a significant influence between the adherence to antidiabetic therapy to the success of the therapy (clinical outcomes)

Keywords: adherence therapy, chi-square, diabetes mellitus success therapy, PDC

Abstrak: Diabetes Melitus (DM) adalah penyakit kronis terjadi ketika kadar glukosa darah meningkat lebih dari 200 mg/dl, karena tubuh tidak dapat memproduksi atau menggunakan insulin secara efektif. Kepatuhan terapi menjadi salah satu penyebab normalnya kadar glukosa darah dan berhasilnya terapi pasien. Pengukuran kepatuhan terapi pasien DM tipe 2 perlu dilakukan untuk memantau keberhasilan terapinya. Penelitian ini bertujuan untuk mengetahui kepatuhan terapi antidiabetika menggunakan metode Proportion of Days Covered (PDC) serta pengaruhnya terhadap outcome klinik pasien DM tipe 2 di Sulawesi Tenggara. Metode penelitian yang digunakan dengan rancangan cross sectional. Sampel penelitian ini sebanyak 186 orang diperoleh menggunakan rumus Slovin. Pasien dikatakan patuh apabila nilai PDCnya ≥ 80% dan dikatakan tidak patuh apabila nilai PDCnya < 80%. Data dianalisis menggunakan uji chi square. Hasil penelitian menunjukkan bahwa pasien patuh terhadap pengobatannya berjumlah 130 orang (69,9%), sedangkan pasien yang tidak patuh terhadap pengobatannya berjumlah 56 orang (30,1%) serta terdapat pengaruh yang signifikan antara kepatuhan terapi antidiabetika terhadap keberhasilan terapi (outcome klinik) dengan nilai p = 0,000 pada pasien DM tipe 2 di Sulawesi Tenggara. Dapat disimpulkan bahwa sebagian besar pasien dalam penelitian ini patuh terhadap pengobatannya serta terdapat pengaruh yang signifikan antara kepatuhan terapi antidiabetika terhadap keberhasilan terapi (outcome klinik).

Kata Kunci: chi square, diabetes mellitus, keberhasilan terapi, kepatuhan terapi, PDC

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1. INTRODUCTION

Diabetes mellitus (DM) is a chronic disease that occurs when blood glucose levels rise above normal limits because the body cannot produce or effectively use insulin. One of the most common types of DM worldwide is Type 2 DM, accounting for over 90%. Data from the International Diabetes Federation (IDF) shows that in 2021, there were 537 million

people with DM globally (IDF, 2021). Indonesia ranks fifth in the world for the highest number of DM patients, totaling 19.5 million in 2021. The prediction for 2045 is that Indonesia will still rank fifth globally, with a total of 28.6 million (Lin *et al.*, 2017).

If patients with type 2 diabetes do not follow their treatment regimen, problems may arise. Therapy

outcomes are positively impacted by treatment compliance (Hamarno *et al.*, 2016). Nonetheless, a number of studies show that Type 2 DM patients still have a low compliance rate. According to a retrospective study by Horii et al. (2019), 36%–93% of Type 2 DM patients who received antidiabetic therapy for a full year of treatment adhered to their treatment plan (Horii *et al.*, 2019). Only 22% of the studies that examined the compliance rate of Type 2 DM therapy revealed that 80% or more of their patients were compliant, according to the findings of a meta-analysis of 27 studies (Swe and Reddy, 2020).

Non-compliance among Type 2 DM patients can be observed through common biological markers used as clinical outcomes, such as HbA1c levels (Soraya *et al.*, 2022). However, the IDF recommends blood glucose levels when HbA1c values are unavailable to monitor therapy non-compliance among Type 2 DM patients (Rasmussen *et al.*, 2014). Therapy non-compliance contributes to abnormal blood glucose levels and the failure of therapy, necessitating the measurement of therapy compliance (Adikusuma and Qiyaam, 2017).

The measurement methods for therapy compliance are divided into direct and indirect methods. However, direct methods have many drawbacks, including the need for healthcare providers, susceptibility to patient refusal, high costs, and ineffectiveness for large populations (Lin *et al.*, 2017). Therefore, indirect methods become an effective way to measure the level of therapy compliance among patients. One of the indirect methods for measuring compliance is the proportion of days covered (PDC). Patients are considered compliant if their PDC value is 80% or higher (Curkendall et al., 2013).

The PDC method has been recommended by the

Pharmacy Quality Alliance (PQA) as a reliable quality indicator for measuring therapy compliance in chronic diseases such as Type 2 DM (Prieto-Merino *et al.*, 2021). However, this method is not widely used in research related to measuring compliance with antidiabetic therapy and its impact on clinical outcomes of Type 2 DM patients in Indonesia, particularly in Southeast Sulawesi. DM is one of the most common diseases in Southeast Sulawesi. DM has been classified 5th with a total of $\pm 7,000$ cases based on disease data.

Therefore, the authors are interested in conducting such research. This study aims to determine compliance therapy using the PDC method and its effect on the clinical outcomes of Type 2 diabetes mellitus patients in Southeast Sulawesi.

2. MATERIAL AND METHODS

This research was conducted at hospitals in Southeast Sulawesi such as RSUD Kota Kendari, RSU Bahteramas Province of Southeast Sulawesi, and RSAD Dr. R. Ismoyo Kendari, by reviewing patient medical records. This study is observational with a cross-sectional design. The sample size was calculated using the Slovin Formula, resulting in 186 patients meeting the inclusion criteria. The inclusion criteria were outpatients with diagnosed Type 2 DM aged 26-65 years who had received oral antidiabetic medication for a minimum of 91 days before the end of the analysis period, with complete medical record data in 2021. The exclusion criteria were Type 2 DM patients with end-stage kidney function impairment, \geq 1 insulin prescription, and a gap between the expiration date of the previous prescription and the redemption date of the next prescription ≥ 30 days.

The research instrument for this study is the medical records of Type 2 DM patients in 2021. The data collected include patient demographics such as

medical record number, age, gender, occupation, education level, diagnosis, prescribed therapy, and laboratory results including blood glucose levels. Data analysis for therapy compliance measurement is calculated using the PDC method). PDC compares the number of days a patient receives medication to the total number of days from the beginning of receiving the medication until the last day of the analysis period. The calculation formula for PDC includes (Horii *et al.*, 2019):

$$PDC = \frac{The number of days receiving medications}{The total number of days receiving prescription until last day of analysis period $\times 100\%$$$

The compliance level in this study is divided into two categories: compliant and non-compliant. Compliance falls into the compliant category if the Proportion of Days Covered (PDC) value obtained is >80%, and non-compliant if the PDC value is <80%. Clinical outcomes in this study, it is observed from the 2-h plasma glucose (2-h PG), which is categorized as controlled and uncontrolled. The controlled clinical outcome category is when the 2-h PG value falls within the range of 70-199 mg/dl, while 2-h PG levels >200 mg/dl are classified as uncontrolled clinical outcomes.

The analysis of the effect of therapy compliance on clinical outcomes is processed using the Chi-Square test, and a p-value <0.05 indicates a significant relationship between the two variables.

3. RESULTS AND DISCUSSION

3.1. Characteristics of Type 2 DM Patients

The Ministry of Health of the Republic of Indonesia (2016) divides the age categories into adults, preelderly, and elderly with ranges of 19-44, 45-59, and ≥60 years. The research data indicate that the highest

number of Type 2 DM patients is in the pre-elderly and elderly age groups, as shown in Table 1.

These findings are supported by Gayatri's research (2019), which indicates that increasing age significantly affects the risk of Type 2 DM incidence, with more than 50% of patients being aged 45-64 years (Gayatri, 2019). This is influenced by the aging process, as individuals aged ≥45 years experience physiological and biochemical changes that lead to insulin resistance. However, Type 2 DM is not exclusively found in individuals over 40 years old, as those over 20 years old can also be affected. This can be influenced by education level, which impacts understanding of Type 2 DM, gender, which affects physiological conditions, and occupation level, which impacts economic status and can influence lifestyle habits such as prolonged, uncontrolled consumption of fast food and sugary foods (Delvechia Agustin, Noor Istiqomah and Aa, 2022).

The results of this study indicate that female patients dominate compared to males. These findings are consistent with data from the Ministry of Health of the Republic of Indonesia (2014), which shows that the number of female Type 2 DM patients is higher than males. Additionally, these results align with Milita et al.'s research (2021), which found that the prevalence of Type 2 DM in males is lower than in females and showed that there is an association between female gender and the risk of Type 2 DM incidence (Milita, Handayani and Setiaji, 2021). This is due to the decline in estrogen and progesterone hormones in women. The decrease in these two hormones leads to increased fat accumulation and changes in lipid profiles, reducing the sensitivity of insulin hormone action, and thereby increasing the risk of insulin resistance.

Table 1: Characteristics of Type 2 DM Patients

Description	Category	Number of Subjects (n=186)	Percentage (%)	
Age	19 - 44 Years	39	20,96%	
	45-59 Years	107	57,52%	
	≥60 Tahun	40	21,50%	
Gender	Male	77	41,39%	
	Female	109	58,60%	
Education Level	Elementary school	1	0,53%	
	Junior high school	20	10,75%	
	Senior high school	93	50%	
	Diploma	1	0,53%	
	Bachelor degree	70	37,63%	
	Magister	1	0,53%	
Work	Housewife	72	38,70%	
	Entrepreneur	33	17,74%	
	Trader	9	4,83%	
	Civil servants	48	25,80%	
	Retired	19	10,21%	
	Farmer	2	1,07%	
	Gardener	1	0,53%	
	TNI	2	1,07%	
Pharmacological Therapy	Monotherapy			
	Glimepiride	89	47,84%	
	Metformin	64	34,40%	
	Glibenklamide	5	2,68%	
	Combination Therapy			
	Metformin and Glimepiride	24	12,90%	
	Metformin and Glibenklamid	4	2,15%	

Type 2 DM patients are predominantly educated at the high school (SMA) and bachelor's (S1) levels. This finding contrasts with previous research indicating that education is closely related to the incidence of Type 2 DM, with individuals with lower education levels being more prone to Type 2 DM. The relatively high level of education in this study is influenced, in part, by environmental factors in urban areas. The phenomenon of urban communities with high education levels, along with the shift in time and

high economy, leads to a shift in lifestyle towards modernity. Modern lifestyles, characterized by reduced physical activity and excessive consumption of high-sugar, low-fiber diets, increase the risk of developing Type 2 DM (Imelda, 2019). The research results also show that the majority of Type 2 DM patients are housewives. This aligns with Atmaja's research (2017), which found that most Type 2 DM patients are housewives (Atmaja, Diani and Rahmayanti, 2017). According to Suyono (2015), housewives require little physical activity, leading to

fat accumulation in the body, resulting in insulin resistance and increased blood sugar levels.

The most commonly used pharmacological therapy for Type 2 DM patients in this study is the monotherapy of glimepiride. This finding is also consistent with Febriyani et al.'s research (2021), which found that the most frequently prescribed antidiabetic drug for Type 2 DM therapy is glimepiride (91.89%). The predominance of glimepiride usage in this study is due to the majority of patients being over 45 years old, which makes it difficult for them to tolerate the gastrointestinal side effects of first-line therapy with metformin due to physiological decline (Febriyani et al., 2021). Additionally, the use of glimepiride offers practical once-daily dosing, minimal occurrence hypoglycemia side effects, long duration of action, rapid onset of action, and affordability (PERKENI, 2021).

The use of combination therapy with glimepiride and metformin is the most common choice because they have complementary and synergistic mechanisms of action. Both drugs have effects on insulin receptor sensitivity. Glimepiride stimulates insulin secretion by pancreatic beta cells, increasing insulin secretion, while metformin decreases hepatic glucose production and increases glucose uptake in peripheral tissues, thereby significantly lowering blood glucose levels more effectively (Meta Srikartika, Akbar and Nautika Lingga, 2019). Based on several studies, combination therapy such as metformin-based reduces HbA1c better than monotherapy (Singh, Singh and Chakraborty, 2021). Compared with monotherapy, all initial combination therapies resulted in significant HbA1c reductions. Compared with metformin monotherapy, initial combination therapies with DPP-4 inhibitors plus metformin, sodium/glucose cotransporter 2 inhibitors and

metformin, respectively, were associated with similar risks of hypoglycemia, but initial combination therapies with sulfonylurea plus metformin, thiazolidinedione and metformin, respectively, were associated with higher risks of hypoglycemia (Cai *et al.*, 2018; Milder *et al.*, 2019).

3.2 Compliance Therapy in Type 2 DM Patient

The measurement of patient compliance levels using the PDC method divides compliance levels into two categories: compliant if the calculated PDC result for the patient is \geq 80% and non-compliant if the calculated PDC result is < 80%.

Table 1.2 Compliance with Type 2 DM Patient Therapy

	Age (Years)							
Compliance	19-44			45-59	≥60			
Level	n	\overline{x} PDC	n	\overline{x} PDC	n	\overline{x} PDC		
Compliant (≥80%)	26	85,99	90	84,87	14	84,39		
Non- Compliant (<80%)	8	61,05	37	59,08	11	62,37		

In line with this study, Soraya et al. (2022) measured compliance with oral antidiabetic therapy in patients with Type 2 diabetes using the PDC method over a one-year analysis period. Of these patients, 98 individuals (77.2%) were compliant with oral antidiabetic therapy, while 29 individuals (22.8%) were non-compliant (Soraya *et al.*, 2022). According to both findings, most assessments of oral antidiabetic medication compliance made using the PDC approach demonstrate compliance.

The measurement of compliance with oral antidiabetic therapy using the PDC method over one year by Carola et al. (2016) yielded results contrary to this study, with fewer compliant patients (42.4%) compared to non-compliant patients (57.6%) (Carola et al., 2016). The difference in results is influenced by differences in patient characteristics, such as aging, which leads to decreased effectiveness of insulin hormone action; higher education levels,

resulting in better knowledge of Type 2 DM therapy; female gender, which poses a higher risk of uncontrolled blood glucose due to hormonal changes in estrogen and progesterone; and light job categories, such as civil servants, housewives, or unemployed individuals, which pose a risk of uncontrolled blood glucose due to lack of physical activity.

3.3 Clinical Outcome in Type 2 DM

The clinical outcome is assessed based on the data of the patient's fasting blood glucose (GDS), whether it is controlled or uncontrolled according to the standard recommendations by Perkeni 2021.

 Table 1.3 The Clinical outcome of Type 2 DM patients

CILL 10		Age							
	Clinical Outcome	1	9-44	4	5-59	:	≥60		
		n	(%)	n	(%)	n	(%)		
_	Controlled	27	14,52	93	50	15	8,07		
	Uncontrolled	7	3,76	36	19,35	8	4,30		

The research results indicate that the majority of patients have controlled clinical outcomes, especially in the adult (19-44 years) and pre-elderly (45-59 years) categories. These findings align with the theory that younger individuals physiologically have better memory and understanding, which makes them more likely to be compliant and have controlled blood glucose compared to the elderly, who experience physiological decline leading to decreased insulin secretion and sensitivity. The results are also influenced by the education and occupation of the patients, with the majority being highly educated (bachelor's degree) and working as civil servants, who have a better understanding of the therapy required. These research findings are supported by Bell et al.'s study (2017), which suggests that better adherence to oral antidiabetic therapy leads to positive treatment outcomes and improved blood glucose control (Bell et al., 2017).

3.4 The impact of compliance level on Clinical Outcomes of Type 2 DM Patients

The analysis results of therapy compliance on clinical outcomes indicate that the majority of patients are compliant with therapy and have controlled clinical outcomes, with a p-value of 0.000 (p<0.05). This result indicates a significant relationship between therapy compliance and clinical outcomes, meaning that patients who are compliant have controlled blood glucose levels, and vice versa.

Table 1.4 The impact of compliance level on Clinical Outcomes of Type 2 DM Patients

	Clinical outcomes						
Therapy Compliance	Cont	rolled		Not ntrolled	P		
	n	%	n	%	-		
Compliant	125	67,21	5	2,69	0,000		
Non-Compliant	9	4,84	47	25,26			

These results are consistent with Bulu et al.'s study (2019), which found a relationship between therapy compliance and blood glucose levels in Type 2 DM patients, where compliant patients have controlled blood glucose levels compared to non-compliant ones. However, there are cases where patients are compliant with their therapy but still have uncontrolled clinical outcomes (Bulu, Wahyuni and Sutriningsih, 2019). This condition may be attributed to the patients' occupations as civil servants or housewives, which fall into the light job category, resulting in insufficient physical activity. Additionally, their high economic status enables them to purchase and consume foods that contribute to uncontrolled blood glucose levels.

The results collected also demonstrate that some patients have regulated clinical outcomes despite not taking their medicine as prescribed. Some of the elements that may contribute to this condition include being an adult, working in government or as an entrepreneur, and having completed high school or a

bachelor's degree. Based on this data, it can be concluded that these patients have controlled blood glucose levels due to their adult age with better physiological conditions. Additionally, their higher education levels contribute to a better understanding of Type 2 DM therapy, even though they may not be compliant with obtaining medication from hospitals; however, they are likely to obtain their medication from other facilities such as pharmacies. Furthermore, patients with high-income levels from their occupations are economically capable of obtaining their medication from other facilities.

3.5 The impact of patient's characteristics on the compliance of type 2 diabetes patients

The impact of patients' characteristics on the compliance of type 2 DM patients can be seen in the following table. The analysis results of the influence

between age and therapy compliance in Type 2 DM patients. As age increases, compliance tends to decrease due to physiological decline, forgetfulness, and the misconception that medication can harm the kidneys.

The analysis results of gender on therapy compliance yielded a p-value of 0.425 (p > 0.05), indicating that there is no significant effect between gender and therapy compliance. This finding is consistent with the study by Almira et al. (2019), which showed no significant effect between gender and therapy compliance because there was no significant difference between compliant male and female respondents (Almira, Arifin and Rosida, 2019).

The analysis results of education on therapy compliance yielded a p-value of 0.000 (p < 0.05),

Table 1.5 The Impact of Characteristics on Therapy Compliance in Type 2 DM Patients

		_			
Characteristics	Complient		Non-complient		p
	n	%	n	%	
Age (Years)					
19-44 (Adult)	28	15,1	8	4,3	0,512
45-59 (Pre elderly)	75	40,3	34	18,3	
> 60 (Elderly)	26	14	15	8	
Gender					
Male	54	23,1	22	11,8	0,425
Female	75	40,3	35	18,8	
Level of education					
Low (SMP-SMA)	60	32,3	45	24,2	0,000
High (S1-S2)	69	37,1	12	6,5	
Work					
Housewife	45	24,2	27	14,5	0,145
Civil servants	57	30,6	10	5,4	
Enterpreneur, etc	27	14,5	20	10,8	
Pharmacological Therapy				-	
Monotherapy					
Combination	91	57,6	67	42,4	0,016
	8	28,6	20	71,4	

of age on therapy compliance yielded a p-value of 0.512 (p > 0.05), indicating that there is no significant effect between age and therapy compliance. This result aligns with the study by Purwanti and Nurhayati (2017), which found no significant effect

indicating that there is a significant effect between education and therapy compliance. This result is consistent with the study, which found a significant effect between education and therapy compliance in Type 2 DM patients. Higher levels of education affect

the learning process, leading to a better understanding of their disease therapy. The analysis results of patient occupation on therapy compliance yielded a p-value of 0.145 (p > 0.05), indicating that there is no significant effect between occupation and therapy compliance. This finding is in line with the study by Diah Kusumaningrum & Khoirunisa (2017), which found no significant effect of occupation on therapy compliance in Type 2 DM patients. However, there is a tendency for working patients to have lower compliance levels because they are busier and may forget to take their medication on time (Ningrum, 2017).

Based on the characteristics of monotherapy and combination drug therapy, p-value of 0.016 (p<0.05) was obtained, which means that there is a relationship between the number of drugs taken and the patient's medication adherence. This is in line with research by Akrom et al. (2019), which states that there is a relationship between the number of medications taken and compliance with taking medication in type 2 DM patients (Akrom *et al.*, 2019). Non-compliance with

taking medication is caused by taking more than two medications in a day, the respondents complained because they have to take >2 medicines a day because they have other illnesses, and sometimes they cause side effects (Ningrum, 2017).

3.6 Analysis of the Effect of Characteristics on Clinical Outcomes of Type 2 DM Patients

The analysis results of the influence of age on clinical outcome yielded a p-value of 0.375 (p > 0.05) (as seen in Table 1.6), indicating that there is no significant effect between age and clinical outcome. This finding contradicts the study by Masruroh (2018), which found a relationship between age and blood glucose levels (clinical outcome). This discrepancy may be due to a physiological decline in individuals over 40 years old, impacting pancreatic function and reducing insulin sensitivity, which can affect blood glucose levels. The analysis results of the influence of gender on clinical outcome yielded a p-value of 0.732 (p > 0.05), indicating that there is no significant effect between gender and clinical

Tabel 1.6 The Impact of Characteristics on Clinical Outcomes of Type 2 DM Patients

Characteristics	Clinical Outcome				
	Controlled		Not o	controlled	P
	n	%	n	%	_
Age (Years)					
19-44 (Adult)	31	16,7	5	2,7	0,375
45-59 (Pre elderly)	74	39,8	35	18,8	
> 60 (Elderly)	29	15,5	12	6,5	
Gender					
Male	55	29,6	21	11,3	0,732
Female	79	42,5	31	16,6	
Level of education					
Low (SMP-SMA)	60	32,2	40	21,5	0,301
High (S1-S2)	74	39,8	12	6,5	
Work					
Housewife	48	25,8	24	12,9	0,253
Civil servants	58	31,2	9	4,8	
Enterpreneur, etc	28	15	19	10,3	
Pharmacological Therapy					
Monotherapy					
Combination	69	43,6	89	56,4	0,803
	11	39,3	17	60,7	

outcome (Masruroh, 2018). This finding is consistent with the study by Yanto & Setyawati (2017), which found no relationship between gender and blood glucose levels in Type 2 DM patients. Despite women having a higher percentage of body fat, their insulin sensitivity is comparable to males (Yanto and Setyawati, 2017).

The analysis results of education on clinical outcome yielded a p-value of 0.301 (p > 0.05), indicating that there is no significant effect between education and clinical outcome. These findings are not consistent with the study by Dewi (2015), which stated a relationship between education and clinical outcome, suggesting that higher education makes it easier to receive information and adhere to therapy (Dewi, 2015). Conversely, individuals with lower levels of education may find it difficult to follow healthcare provider recommendations (Astuti and Purnama, 2018). The analysis results of occupation on clinical outcome yielded a p-value of 0.253 (p > 0.05), indicating that there is no significant effect between occupation and clinical outcome. These results align with the study by Astuti and Purnama (2019), which stated no relationship between occupation and clinical outcome. Working individuals with Type 2 DM may increase their energy expenditure, thereby potentially lowering blood glucose levels. In this study, the use of monotherapy drugs and combination therapy was not related to controlled or uncontrolled patient clinical outcomes with a p-value of 0.803. This is influenced by various factors, including the level of patient compliance.

4. CONCLUSION

Based on the results of this study, therapy compliance with antidiabetic medication among Type 2 DM patients in Southeast Sulawesi is mostly compliant (PDC \geq 80%), and there is a significant influence of

therapy compliance with antidiabetic medication on treatment success.

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