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Research Article

Follow-Up Evaluation on Oral Antidiabetic Drug Use: A Study of Effectiveness, Safety and Patient Adherence in Surabaya Primary Health Care

Lisa Aditama[1*], Umi Athiyah[2], Wahyu Utami[3], Abdul Rahem[3]

Faculty of Pharmacy University of Airlangga Surabaya

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ABSTRACT

Medication non-adherence is one of the biggest causes of leftover medicines. Up to 50% of patients worldwide do not take their prescribed medicines as recommended. Optimising the use of medication is beneficial to improving clinical outcomes for patients with chronic disease. Purpose: The aim of this study was to determine the effectiveness and safety of drug therapy, evaluate patient adherence, and identify of the patient's non-adherence behavior for oral antidiabetic drugs (OADs). Methods: This study using non-experimental design, with mixed-methods (explanatory sequential design). A total of 32 patients with type 2 diabetes mellitus in referral program of national health care security system (BPJS Kesehatan) were included in this study from Primary Health Care in the north region of Surabaya. There are 6 domains of adherence behavior developed in this study. Results: The effectiveness of drug therapy in this study was 56,25%. About 68,75% of patients experienced to hypoglycemia and 6,25% had gastrointestinal problems caused by drug therapy. The adherence assessment found that 43,75% patients non adherence to medication. Leftover medicines found in the patient's home comes from multiple visits to health care facilities (53,12%) and patient non-adherence (37,5%). Conclusion: Follow-up evaluation as the continuous process in medication management services, led pharmacist in the strategic position to evaluates the patient's response to drug therapies in terms of effectiveness, safety, adherence and also avoiding unnecessary leftover medicines.

Keywords: follow-up evaluation, oral antidiabetic drugs, primary health care.

INTRODUCTION

Diabetes prevalence in Indonesia was increased rapidly, multi-risk factor, prolonged progression, and if not managed properly, consequently becoming incurable and developing complications[1]. The Indonesian Endocrinology Association states that currently Indonesia has entered an epidemic of type 2 Diabetes Mellitus (DM). There are about 50% of diabetics were undiagnosed and only two-thirds of those diagnosed underwent pharmacological or non-pharmacological treatment and only one-third were properly controlled[2]. DM is the first target of four Non-communicable Diseases (NCDs) to be managed and prevented. The incidence and impact of DM including other NCDs can be prevented or reduced by approaches that include evidence-based interventions, affordable and cost-effective[3]. DM management is very important to emphasize optimal blood sugar levels through adherence behavior to medication. Preventing or resolve drug related problems may improve the achievement of clinical outcomes. Research conducted by Wertheimer and Santella in Cipolle et al. (2014) found that 60% of patients were unable to identify or recognize their own drug, 30-50% of patients ignored instructions for using the medication, 12-20% of patients used other people's drugs, and treatment rates in hospitals increases every year with causes of non-adherence[4]. Patients with chronic diseases tend to consume more than 2 types of drugs, that will affect the level of adherence. Patients with complex drug therapy had low level of adherence, factors that could influence are the frequency of drug administration, the identity or brand name and number of drugs taken in a day[5]. Good adherence was important to determine the health outcomes of patients with chronic diseases. In Japan, all residents are protected by public health insurance and make payments at relatively low prices. Most patients with chronic diseases consult with their doctors regularly, and prescription drugs depend on the consultation schedule so that if treatment compliance was high enough, patients with chronic diseases should not have residual medication. However, from the results of non-compliance tests, it was found that leftover drugs, stored at home by patients, did not only occur in Japan but also in other countries[6]. The causes of drug leftover vary from inefficient prescription to drug stockpiles due to patient recovery and non-compliance[7]. Some factors that can impaired patient compliance are patients do not understand the instructions, cognitive factors, large medical costs, patients tend to have a poor understanding of the goals of therapy and patient beliefs[4]. A patient-centered communication style that uses person-

*Author for Correspondence: lisa_aditama@yahoo.com

Table 1: The Domain of Adherence Behavior and Definitions.

No.	Domain (Item of Questionnaire)	Definition
1.	The patient does not understand the instructions (Q. 1-4)	Patients do not understand how to consume or use their medications appropriately
2.	The patient cannot afford the product (Q. 5-8)	The inability of the patient to buy prescription drugs because the price of the drug product is too expensive
3.	The patient prefers not to take the medication (Q. 9-13)	Patients understand the instructions to take medicine but prefer not to use drug therapy as intended
4.	The patient forgets to take the medication (Q. 14-17)	The patient does not remember to take sufficient doses of the drug
5.	The drug product is not available for the patient (Q. 18-20)	Drug products are not available to patients, because of insufficient supplies
6.	The patient cannot swallow or self-administer the drug product appropriately (Q. 21)	The patient cannot swallow or administer drug therapy as intended

Table 2: Patient's Demographic Data.

Demographic	Characteristics	∑Subjects (n)	Proportion (%)
Gender	Female	22	68,75 %
	Male	10	31,25 %
Age	20 – 29 years	0	0%
	30 – 49 years	2	6,25 %
	50 – 69 years	18	56,25 %
	70 – 79 years	12	37,5 %
	>80 years	0	0%
Level of Education	Primary School	12	37,50
	Junior High School	15	46,88
	Senior High School	5	15,62
Ocupation	Employee	4	12,5%
	Unemployment	28	87,5%
Period of Diabetes	1-5 years	6	18,75%
	6-10 years	14	43,75%
	>10 years	12	37,5%

Table 3: Characteristic of Patient's Diabetes Treatment.

Type of Therapy	∑Subjects (n)	Proportion (%)
Mono therapy	7	21,87
Dual therapy	22	68,75
Triple therapy	3	9,38

Table 4: The Effectiveness Profile of OAD.

Effectiveness	∑Subjects (n)	%
Blood glucose in the range	18	56.25
Blood glucose outside the range	14	43.75

centered and strength-based language, active listening, elicits patient preferences and beliefs, and assesses literacy, numeracy, and potential barriers to care should be used to optimize patient health outcomes and health-related quality of life[8]. The pharmacist role in pharmaceutical care is to take a patient-oriented approach aimed to optimizing the patient's health outcomes and treatment. The most important thing that must be done is to establish the relationship between the patient and their pharmacist so that effective communication is established with the patient, family and nurse throughout the process. Pharmacists must be able to continue to collaborate, document, and communicate with doctors, other pharmacists, and other health care in the provision of safe, effective and coordinated care[9]. Medicines optimisation is an integral part of the health care system. Preventing medicines treat or manage many illnesses or conditions are the most common intervention in health services. Optimising the use of medicines is crucial to improving clinical outcomes for patients and providing financial benefits. It is becoming increasingly important to maximize the use of medicines. One vital area that needs extensive improvement is ensuring patients obtain optimal benefit from their prescribed medicines. This can be done by improving adherence and avoiding unnecessary wastage of medicines[10]. Pharmacists have unique training and expertise in the appropriate use of medications and provide a wide array of patient care services in many different practice settings. The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed[9]. The evaluation step is where clinical experience and new knowledge are gained. In fact, most learning occurs during follow-up evaluations[4].

The follow-up evaluation is the step in the process when the practitioner sees which medications and doses were most effective or caused the most harm. In a well conducted follow-up evaluation, the practitioner evaluates the patient's response to drug therapies in terms of effectiveness, safety, and adherence and also determines if any new problems have developed. The outcomes of drug therapies, drug therapy decisions, drug information, referrals, and other interventions are unknown until the practitioner conducts a follow-up evaluation with the patient[4].

Novelty of the work

Developing a follow-up evaluation as the initiation of medication therapy management of chronic illness in

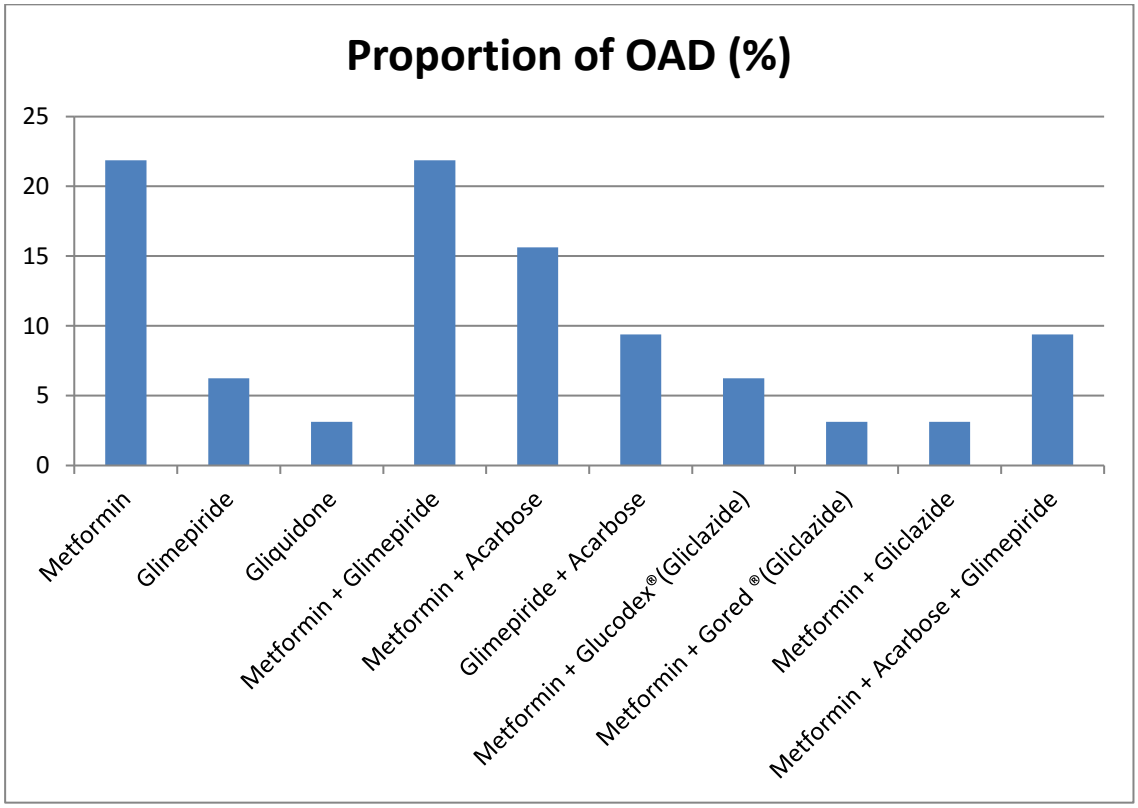

Figure 1: Profile of Oral Anti Diabetic Medication Used.

Table 5: The Safety Profile of OAD.

Adverse Drug Reactions	∑Subjects (n)	%
Hypoglycemia	22	68.75
GI problems	2	6.25
None	8	25

Table 6: Patient's Adherence Characteristics All Domain.

Adherence Characteristics	∑Subjects (n)	Proportion (%)
Adherence	18	56.25%
Non Adherence	14	43.75%

primary health care facilities to assess the effectiveness, safety and patient adherence of oral antidiabetes drugs. The quantitative adherence assessment was developed in this study.

METHODS

This study was designed using non-experimental design, with mixed methods (explanatory sequential design). The specific activities performed at a follow-up evaluation are described as follows:

Observe the positive results the patient has experienced from drug therapies (*effectiveness*). Effectiveness is evaluated using secondary data of glucose rapid test results owned by the patient or by asking the person directly

Observe any undesirable effects the patient has experienced that were caused by a drug therapy (*safety*). Safety data evaluated using interview of unintended pharmacological effects (side effects) of the patient's drug therapy.

Determine the actual dosage of medication the patient is taking that is producing the results observed (*adherence*). Data collection developed as questionnaires to identify patient adherence behavior and follow up with interview. Adherence is defined as the patient's ability and willingness to carry out a therapeutic regimen that have been clinically assessed by practitioners that all drug therapy is appropriate, effective enough, and can produce the desired outcomes without any harmful effects based on all available evidence Adherence behavior domain adopted from the Pharmaceutical Care Practice: The Patient Centered Approach to Medication Management Services reference[7]. Following are the adherence behavior domain which to be the research variables and the definitions of each variable (Table 1).

There are 21 item questions of adherence behavior with yes or no answer. The scoring of adherence behavior is calculated by dividing total score with total item of questions answer. Score 1 for "yes" and 0 for "no". If the mean score is 1 typically classified as adherence and if the mean score is < 1 typically classified as non adherence. The 21 item question of adherence behavior questionnaire can be seen on appendix 1.

The target population in this study were all type 2 diabetes mellitus patients who used Oral Anti Diabetic agents (OAD) in Primary Health Care (Puskesmas) in the east and south district area of Surabaya who met the inclusion and exclusion criteria.

Inclusion Criteria:

Have used OAD for at least 3 months

Patients refered back to primary health care (GP) from ambulatory chronic care

Table 7: Characteristic of Leftover Drugs.

Drug Source	∑Subjects (n)	Proportion (%)
Derived from the drug currently in use (the patient is not compliant)		
1. The drug is not used (because concern of drug safety)	12	37,5
2. Change the therapeutic regimen		
Prescribing excess (the amount of drug administered exceeds the total amount to use)	1	3.13
Multi doctor / health center (outside BPJS)*	17	53.12
Double drug delivery (health facilities I and II)**	2	6.25
TOTAL	32	100

* Patients get the same medicine (sometimes a different brand) from a doctor outside the BPJS, refill their own medication to the pharmacy because the medicine runs out or buy at the pharmacy when the medicine is not available at the puskesmas.

** Patients get double drugs when referred to secondary health facility and referred back to primary health facility.

Exclusion Criteria:
Unable to read and/or write
Multi medical conditions
The research sample size was determined based on the Slovin formula.

$$\boldsymbol{n = \frac{N}{1 + Ne^2}}$$

Where are:
n = the minimum number of samples
N = total population (patients refered back to Puskesmas on OAD treatment in district area)
e = error tolerance limit

$$\boldsymbol{n = \frac{80}{1 + 80(0{,}15)^2}}$$

n= 28,57 ~ 30

Based on the validity test, the developed adherence behavior questionnaire has a calculated r value > r table of each item, and in the reliability test this questionnaire shows reliable results with Cronbach's alpha ≥ 0.959.

RESULTS

A total of 32 patients with type 2 diabetes mellitus in referral program of national health care security system (BPJS Kesehatan), were observed in this study with purposive sampling from Primary Health Care in the north region of Surabaya. Patient's demographic shown in Table 2 and characteristic of patient's diabetes treatment shown in Table 3.

Quantitative Analysis

Effectiveness

In this study, the effectiveness of the patient's treatment will be seen using secondary data of glucose rapid test results owned by the patient or by asking the person directly. Blood glucose level target based on Glycemic Targets (Standards of Medical Care in Diabetes 2018): preprandial capillary plasma glucose 80–130 mg/dL, peak postprandial capillary plasma glucose <180 mg/dL.

Safety

Safety data include the evaluation of unintended pharmacological effects (side effects) of the patient's drug therapy. Evaluation of safety data also includes whether laboratory tests/ glucose rapid test results/ symptoms have become dangerously abnormal due to the drug therapy.

Adherence Behavior

Adherence assessment are carried out using adherence behavior questionnaire developed in this study. The following is a description of the results of the adherence assessment (Table 6), characteristic of leftover drugs (Table 7) and proportion of adherence behavior of each domain (Table 8). The most highly non adherence behavior which score <1 is the patient does not understand the instructions, followed with the other non adherence behavior as the patient forgets to take the medication, patient cannot afford the product and prefers not to take the medication.

Qualitative Analysis

After a quantitative survey, patients followed with structured interview at patient's home. Some observations were made to see drugs being used, instructions on labeling and drug monitoring records to see the suitability of all drugs received and used by the patients. The results of interviews using recording devices were then transcribed manually and coded then analyzed into themes to find out the root of patient's nonadherence behavior, as seen on Table 8.

Structured interview results displayed in quotes on the highest non-compliance domain

The domain patient does not understand the instructions.

Patients need help from others to understand the instructions to use the medication and the limitation of vision because of the disease or age. Lack of patient knowledge regarding the purpose of drug therapy encourages patients to use their own rules.

Theme 1: Need help from other people to read the instruction to use

" yeahh... my lack of understanding, often forgetting, afraid of something to forget, afraid of missed understanding " (Subject 6)

" yeahh... the problem is that I can't read as well, sometimes I wrong.. which are used during the day are sometimes used at night, so... if there is my doughter in the house I'll use my medication, and don't if there are no help " (Subject 20)

Theme 2: Using own instruction

"it feels like I'm not sure, because sometimes it feels uncomfortable. Sometimes I feel that if I had taken medicine five times, it feels more painful, more uncomfortable, if it feels like that, then I try to stop ... and after that it feels better, later if I'm sick again I used again" (Subject 20)

Table 8: Patient's Adhrerence Behavior Each Domain.

No	Adherence Behavior Domain	Adherence (mean score =1)		Non Adherence (mean score <1)	
		∑Subjects (n)	Proportion (%)	∑Subjects (n)	Proportion (%)
1	The patient does not understand the instructions	21	65.6	11	34.38
2	The patient cannot afford the product	27	84.3	5	15.63
3	The patient prefers not to take the medication	27	84.38	5	15.63
4	The patient forgets to take the medication	23	71.88	9	28.13
5	The drug product is not available for the patient	29	90.63	3	9.38
6	The patient cannot swallow or self-administer the drug product appropriately	32	100.00	0	0.00

"Yes, I use the rules myself, because the rules are not written ... so basically I don't know if I take it after eating or before eating, morning or night, so I make my own rules, sometimes taking at night or morning. So the principle is that there are no rules, so all I take is what I like ... ha ... ha ... usually it should have a rule before eating, after " (Subject 17)

"*Yes, I was wrong because I did not fulfill the rules ... Well, sometimes it was.. if I feel bad, then I stop first*" (Subject 18)

Theme 3: Not timely to take medication

" Yes, yeah, just like that three times, sometimes I miss it once or twice" (Subject 9)

The domain patient forgets to take the medication

In this domain, patients were nonadhrerence because of intentions for classically reasons.

Theme 1: Unintentional because it has become a habit

" yes sometimes forget Miss he..he.., but I don't double it, still one"(Subject 9)

"if there is a drug taken after a meal, I don't take it immediately ... usually I wait a few minutes, sometimes it is missed so I don't take the drug" (Subject 25)

The domain patient prefers not to take the medication

The patient feels that the drug is causing negative changes so decides not to use it.

Theme 1: Reducing the frequency of taking medication because of worry

"Look ... I was once given this drug (metformin) and aborte (acarbose)... Which is used when eating (acarbose), it causes nausea, so I don't use it. I told the doctor... doc ... every time I took this medicine, I felt sick... so.. I was told to stop it. And if I use this (metformin), I take 3 times, if I take on Saturday and Sunday, I feel on here..(holding the kidney area) it hurts.." (Subject 18)

"Here I am ...not only 1 or 2 times experiencing too high drug dosing .. If the dose is high I only taking half of it, sometimes it becomes cold sweat. I felt the dosage was too much, then I told the doctor, said the doctor ... yes, just reduced ... the metformin was reduced by 1 tablet if cold sweat appearing" (Subject 9)

Theme 2: Affected by family and other people's opinions

"Yes, my mother said, if most people take the medicine, they can be addicted, they'll resistance to the drugs, so I follow the advice of my mother, don't take too much medicine because then be resistance to the drugs. So if you get sick later... there will be no reaction, so if I feel better so I stopped the medication, don't focus too much on the medicine, better to manage the food consumption ... Now my mother has died so no one has advised me anymore" (Subject 20)

"Yes, I was given gliclazide for just 3 days. For the next, I bought it myself" (Subject 20)

The patient cannot afford the product

Reconciliation is needed when the patient cannot afford the medication because of the drug is not available.

Theme 1: Cannot access the drug product because it is not available at the health center

"I decide to stop the medicine. If I take the medicine from my GP and my specialist .. I think there are any interaction or contraindication. I feel bad like dizzy, shaking, weak.. If I can, I'll take medicine on my GP (PKM), but the drug often doesn't exist, then the doctor look anger, so I ask to a reference" (Subject 20)

DISCUSSION

The majority of patients in this study are female (68,75%) and classified as elderly, not at work at all, the level of education was secondary school, and taking dual therapy OAD (68,75%). The average subject has diabetes more than 5 years (81,25%). If the monotherapy cannot reach the HbA1C target (<7%) within 3 months then the therapy can be increased to dual therapy, consisting of drugs given in the first line plus other drugs that have different working mechanisms[11]. There are two branded of gliclazide, potentially not as easy to access and impact to patient adherence and finally impaired the therapeutic outcome.

Table 9: Themes of Patient's Nonadherence Behavior.

Domain	The Nonadherence Behavior Themes
The patient does not understand the instructions	Need help from other people to read the instruction to use Using own instruction Not timely to take medication
The patient cannot afford the product	Cannot access the drug product because it is not available at the health center
The patient prefers not to take the medication	Reducing the frequency of taking medication because of worry Affected by family and other people's opinions
The patient forgets to take the medication	1. Unintentional because it has become a habit
The drug product is not available for the patient	The medicine not available so the patient does not use prescription drug Patients have leftover medication due to non adherence
The patient cannot swallow or self-administer the drug product appropriately	-

The effectiveness of the patient's treatment will be evaluate using secondary data of glucose rapid test results owned by the patient or by asking the patient directly. There is only 56,25% of patients in this study on the target level based on Glycemic Targets on ADA 2018[12]. Clinical parameters often used to determine the effectiveness of drug therapy. Changes in these parameters was determined by asking the patient at the follow-up evaluation as presenting complaint/ subjective finding, then comparing the patient's response to what observed and documented during the initial follow-up as objective finding[4].

Several factors can contribute to the effectiveness of drug therapy, there are pharmaceutical and clinical factors. Pharmaceutical factors was the intervention factors given to the patients. Patient knowledge of indications, dosage forms and regiment of drug use may relate to patient perceptions and beliefs when using the drug. The clinical factor was the patient's medication experience. Confirmation of both factors can be measured through assessment of symptoms and results of clinical/ laboratory values[4]. From follow-up interview in this study, found that patient factors contribute for the effectiveness of drug therapy. Patients tend to reduce the regiment therapy that are used even decide to stop it when experiencing symptoms that raise concerns about health and organ disorders. As seen on the domain the patient prefers not to take the medication on the theme reducing the frequency of taking medication because of worry.

Beside of that reason, about 43,75% of patients in this study non-adherence with medication given. The most highly non-adherence behavior is the patient does not understand the instructions, followed with the other non adherence behavior as the patient forgets to take the medication, patient cannot afford the product and prefers not to take the medication. Patient with long term disease such as diabetes with poor control and non-adherence which use high risk medication are classified as patient at-risk and need to comprehensive medication management[13]. Promoting Medication Therapy Management (MTM) for at-risk populations recognized that clinicians in ambulatory care settings face challenges in providing care to patients with low socioeconomic status who have chronic conditions. These patients often face challenges in understanding how to take their medications appropriately and being actively engaged in self-managing their health conditions. The MTM focused on addressing these challenges by incorporating pharmacists within the primary care team to provide comprehensive medication therapy management to patients[14,15].

The domain patient forgets to take the medication, frequently express what they want in terms of concerns about the medication or how it must be taken. Common concerns include risks of taking certain medication, confusion over how to take a medication and lack of support from the patient's relatives to remind them to take. These unintentional nonadherence is a passive process whereby patients fail to adhere to prescribing instructions through forgetfulness, carelessness, or circumstances out of their control (e.g., health literacy)[16]. Medication adherence is an important part of improving clinical outcomes for patients with diabetes. Barriers to medication adherence are complex and individualized, reflecting the fact that each patient manages his or her medications in the context of is or her own life[17].

The domain patient cannot afford the product, reconciliation is needed when the patient cannot afford the medication because of the drug is not available. Patient cannot access the drug product because it is not available at the health center and decide to stop the medicine. State reasons why taking the medication or improving their health will help them feel better in the short term, become better able to handle stresses associated with current situations. Help the patient with some objective measures, home monitoring to allow her to see the numbers[18]. Pharmacist may the strategic position to collaborate with patients to manage medications, health care professionals must acknowledge patients' unique experiences to be authentically patient-centered medication experience as a part of patients' lifeworlds with chronic conditions and medications[19].

Based on this study, there are found that patients tend to non-adherence which modify the regiment of medications and have considerable reluctance to take medications because of do not have a good understanding of the medicine and impacted to the effectiveness and safety of drug therapy in referral program of national health care security system (BPJS Kesehatan). MTM services have been an integral part of bridging the gap between the old and the new approach to patient care. Interestingly, a recent perspective article discussed factors for why

patients were not receiving optimal care. Patient adherence and health outcomes could be improved by focusing on optimizing and reconciling medications, coordinating care and sharing electronic data, and engaging and supporting patients on an individual level[20].

CONCLUSION

This study found that , the effectiveness of the patient's treatment based on secondary data of blood glucose level with rapid test are not the optimum target. While the safety of drug therapy must be take a highly pharmacist responsibility to determine if drug therapies are safe for the patients, and the best way to ensure safety is to determine whether the patient is experiencing any negative effects. Furthermore, the most highly non-adherence behavior are the patient does not understand the instructions, followed with the other non adherence behavior as the patient forgets to take the medication, patient cannot afford the product and prefers not to take the medication. Patients have the ultimate choice in their health and utilization of medication. Discuss with patient to achieve health goals, set follow-up and hold them accountable are valuable.

The follow-up evaluation requires proactive practitioner involvement. It is the best method available to determine patient outcomes, what the patient experiences as a result of specific drug therapies and related drug information, advice, and other interventions. Follow-up evaluations are the critical points at which the effectiveness and safety of the patient's care plan and associated drug therapies are determined and balanced against one another, and where decisions concerning further adjustments in drug therapy are made.

Implementation to Pharmacy Practice

This adherence assessment tool might be use as an follow up instrument of MTM, to determine patient's adherence and re-assess as needed.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, gifts, or honoraria.

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