Research article

Designing Tailor-made Interventions for Patients with Diabetes at Setthathirat Hospital, Lao People's Democratic Republic

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Abstract

Objectives: To design tailor-made interventions (TMIs) for patients with diabetes at Setthathirat hospital in Lao People's Democratic Republic (Laos PDR) **Methods:** This study was undertaken at Diabetes clinic, Setthathirat Hospital in Lao PDR, using mixed research methods. There were 2 main phases. Phase 1 was the cross-sectional descriptive study in patients with at least 45 years old, having type 2 diabetes with or without hypertension, having hemoglobin A1c (HbA1c) $\geq$7% and fasting blood sugar > 130mg/dL. Patients' knowledge about diabetes and its management was measured using the 24-item Diabetes Knowledge Questionnaires (DKQ). Brief Medication Questionnaires (BMQ) were used to measure patient's compliance. Drug-related problems (DRPs) were identified and classification using the criteria of the Pharmaceutical Care Network Europe working group (PCNE Version 9.1, 2020). Phase 2 involved focus group interviews with all health care professionals working at the Diabetes Clinic in Setthathirach Hospital based on the information from phase I. The interviews were conducted to brainstorm and design TMIs suitable for the practice. **Results:** One hundred and ten participants were recruited. The majority was female (59.1%), with the mean age of 56.00±9.20 years. The average fasting blood sugar was 185±65.31 mg/dL and HbA1c was 9.26±1.94%. The majority of subjects (86 or 78.18%) had the score on the DKQ ranging from 9 to 18 from the full score of 24. Forty percent of the subjects were considered non-compliant as measured by the BMQ. The most common DRP was "P1.1 no effect of drug treatment" (85.5% of the subjects). Phase II study identified three major themes related to establishing TMIs including views of services, views of organizational barriers, and roles of health care professionals for providing TMIs. Recommendations for utilizing assessment and educational tools as well as pharmacist's roles in providing TMIs with doctors and nurses for patients with DRPs and poor outcomes were proposed. **Conclusion:** The health care team agreed on the importance of providing TMIs for diabetic patients with poor compliance and health outcomes. This approach may help not only to improve standards of patient care but also patients' health outcomes.

Keywords: diabetes care, drug-related problems, tailor-made interventions, pharmaceutical care

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บทความวิจัย

การออกแบบวิธีการรักษาแบบเฉพาะสำหรับผู้ป่วยโรคเบาหวานที่
โรงพยาบาลเศรษฐาธิราช สาธารณรัฐประชาธิปไตยประชาชนลาว

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บทคัดย่อ

วัตถุประสงค์: เพื่อออกแบบวิธีการรักษาแบบเฉพาะราย (tailor-made interventions: TMIs) ในผู้ป่วยโรคเบาหวาน
ของโรงพยาบาลเศรษฐาธิราชในประเทศสาธารณรัฐประชาธิปไตยประชาชนลาว (สปป. ลาว) **วิธีการ:** การศึกษานี้ดำเนินการที่
คลินิกเบาหวาน โรงพยาบาลเศรษฐาธิราช สปป.ลาว การศึกษาแบ่งเป็น 2 ระยะ ระยะที่ 1 เป็นการศึกษาเชิงพรรณนา
ภาคตัดขวางในผู้ป่วยอายุ 45 ปี ขึ้นไปที่เป็นโรคเบาหวานประเภท 2 โดยอาจมีโรคความดันโลหิตสูงร่วมด้วยหรือไม่ก็ได้ มีค่า
HbA1c ตั้งแต่ 7% ขึ้นไปและระดับน้ำตาลในเลือดมากกว่า 130 mg/dL ความรู้เรื่องโรคเบาหวานและวิธีการจัดการของผู้ป่วยวัด
ด้วยแบบวัด Diabetes Knowledge Questionnaires (DKQ) จำนวน 24 ข้อ แบบวัด Brief Medication Questionnaires (BMQ)
ใช้เพื่อประเมินความร่วมมือในการใช้ยาของผู้ป่วย การค้นหาและการจัดประเภทปัญหาการใช้ยา (drug-related problems:
DRPs) ใช้เกณฑ์ของ Pharmaceutical Care Network Europe working group (PCNE Version 9.1, 2020) การศึกษาระยะที่ 2
เป็นการสัมภาษณ์แบบกลุ่มระหว่างทีมบุคลากรทางการแพทย์ที่ทำงานในคลินิกเบาหวาน โรงพยาบาลเศรษฐาธิราช โดยอาศัย
ข้อมูลจากวิจัยระยะที่ 1 การสัมภาษณ์เป็นการระดมสมองและออกแบบ TMIs ที่เหมาะสมกับการปฏิบัติงาน **ผลการวิจัย:** ผู้ป่วย
เข้าร่วมการศึกษา 110 คน ส่วนใหญ่เป็นผู้หญิง (ร้อยละ 59.1) อายุเฉลี่ย 56.00±9.20 ปี ระดับน้ำตาลในเลือดขณะอดอาหาร
เฉลี่ยอยู่ที่ 185 ± 65.31 mg/dLและ HbA1c เฉลี่ย คือ ร้อยละ 9.26±1.94 ตัวอย่างส่วนใหญ่ (86 รายหรือร้อยละ 78.18) มีคะแนน
เมื่อประเมินด้วยแบบวัด DKQ อยู่ระหว่าง 9 to 18 จากคะแนนเต็ม 24 ผู้ป่วยร้อยละ 40 ไม่ร่วมมือในการใช้ยาเมื่อประเมินด้วย
BMQ ประเภทของ DRP ที่พบบ่อยที่สุด คือ "P1.1 ไม่มีผลของการรักษาด้วยยา" (ร้อยละ 85 ของผู้ป่วย) การศึกษาในระยะที่ 2
พบ 3 ประเด็นที่เกี่ยวข้องกับการพัฒนา TMIs คือ มุมมองด้านการให้บริการปัจจุบัน มุมมองเกี่ยวกับอุปสรรคภายในองค์กรต่อ
การให้บริการผู้ป่วย และบทบาทของบุคลากรทางการแพทย์ใน TMIs ทั้งนี้ มีข้อเสนอแนะให้ใช้เครื่องมือในการประเมินและให้
ความรู้ ตลอดจนข้อเสนอต่อบทบาทของเภสัชกรใน TMIs ร่วมกับแพทย์และพยาบาลในการดูแลผู้ป่วยที่พบ DRPs และมี
ผลการรักษาที่ไม่ดี **สรุป:** ทีมบุคลากรทางการแพทย์เห็นพ้องกันถึงความสำคัญของ TMIs ในการดูแลผู้ป่วยเบาหวานที่มีปัญหา
การไม่ใช้ยาตามสั่งและมีผลลัพธ์การรักษาไม่ดี รูปแบบการให้บริการนี้น่าจะช่วยเพิ่มมาตรฐานการดูแลผู้ป่วย และยังช่วยให้
ผลลัพธ์ด้านสุขภาพของผู้ป่วยดียิ่งขึ้น

คำสำคัญ: การดูแลผู้ป่วยเบาหวาน ปัญหาการใช้ยา การให้บริการสำหรับผู้ป่วยเฉพาะราย การบริบาลทางเภสัชกรรม

Introduction

Diabetes mellitus, an important cause of morbidity and a risk factor for other diseases in developed countries, is increasing rapidly in developing countries. Global diabetes prevalence will increase to approximately 10.2%, affecting around 578 million people by 2030 and then 10.9% or around 700 million people by 2045 (1). The prevalence is higher in urban than rural areas as well as higher in high-income countries than low-income countries. The rising prevalence results in significant socioeconomic challenges in developed as well as developing nations. Setthathirat Hospital, located in the Lao People's Democratic Republic (Laos PDR), serves as a 259-bed central hospital. Its diabetes clinic has provided services for 2,659 diabetic patients, with 1496 patients unable to control their blood sugar (55.24% of total diabetic patients). Unfortunately, the staff in the clinic includes internal medicine doctors and nurses, but with no pharmacists to provide pharmaceutical care services. The researcher (as a pharmacist) as well as the health care team were highly interested in any effective approach including tailor-made interventions (TMIs) to be developed and provided for uncontrolled diabetic patients.

Tailored intervention strategies (2-7) are frequently recommended for improving health outcomes and health care services. They are designed for individual patients based on their unique characteristics, related to the outcomes of interest, and derived from an individual assessment. Recognizing the differences between individuals, delivering tailored interventions for individuals could help to improve sustained self-management for patients with chronic diseases. This intervention necessitates robust collaborations within a multidisciplinary team to enhance the facilitation of care processes and the monitoring of health outcomes in individuals (5). However, there have been limited studies on TMIs in patients with diabetes. Previous studies (3-7) have used different methods to identify determinants of practice and to select interventions to address individual needs. There has been a lack of evidence on the development of TMIs for patients with diabetes particularly. Therefore, the aim of this study was to design TMIs provided by a pharmacist working in collaborations with the health care team at Diabetes Clinic at Setthathirat hospital in Laos PDR.

Methods

This study was mixed-method research including quantitative and qualitative studies. This research had two major phases consisting of cross-sectional descriptive study in phase I, and focus group interviews in phase II. This study was undertaken at the Diabetes Clinic at Setthathirat Hospital in Laos PDR. This research was approved by the Human Research Ethics Committee of Mahasarakham University, Thailand (370-293/2021). We also received the ethical approval from the National Ethic Committee for Health Sciences Research of the Minister of Health, Vientiane, Laos PDR (036/NECHR).

Phase I: Cross-sectional study

Subjects

Inclusion criteria for the participants were patients aged 45 years and older, having type 2 diabetes with and/or without hypertension, having glycated hemoglobin (HbA1c) $\geq$7% and fasting blood sugar > 130 mg/dL and being ambulatory patients without walking aids and being cognitively competent in understanding. Exclusion criteria were those with visual impairments, a history of neurological disorders, cognitive disorders, severe mental disorders, or pregnancy.

The sample size calculation was based on Cochran's formula for descriptive study with qualitative data (13). The study by Wang et al reported that around 37.6% (47/125) of non-complaint patients had poor glycemic control (14). The type I error was set at 0.05 and acceptable margin of error was at 0.10. The

calculated sample size was approximately 90. The number of subjects was increased for 20% because loss of subjects was anticipated during data collection. The final sample size was 110.

Data collection

The study assessed the patients' knowledge on diabetes and its management using the 24 item Diabetes Knowledge Questionnaires (DKQ) (11). Higher score indicates higher knowledge on diabetes and its management. Scores on the DKQ were divided into 3 groups, i.e., 0-8, 9-18 and 19-24. Translation and back translation method was applied by translating the DKQ from English to Laos and then from Laos to English. Three experts in English (two pharmacy lecturers and researchers from Mahasarakham University) and one pharmacy lecturer from University of Health Sciences, Laos PDR were the translators. After the revision for appropriate translation, content validity of the translated measure was examined by 3 pharmacy lecturers from University of Health Sciences, Laos PDR. Reliability test of the DKQ was examined in 30 diabetic patients. Cronbach's alpha calculated was 0.74.

The Brief Medication Questionnaires (BMQ) (15) were used to measure patient's compliance to prescribed medications. The BMQ consists of 4 subscales on regimen screen, belief screen, recall screen and access screen. The regimen screen (7 items) assesses how patients took the medication in the past 7 days. The belief screen, the recall screen, and the access screen, each consists of 2 questions to detect each types of barriers to medication compliance. If patients answered yes to at least one item of the BMQ, they would regard as non-compliant. Identification and classification of drug-related problems (DRPs) was conducted using the criteria of the Pharmaceutical Care Network Europe working group (PCNE DRP Registration Form Version 9.1 in 2020. Assessment of DRPs was conducted by the first author (SS) and subsequently reviewed by the research team (PK and WA).

Data analysis

Patient characteristics were analyzed by using descriptive statistics. Associations among patient's characteristics and diabetes knowledge, compliance and DRPs were analyzed by using Chi-Square tests, Spearman Rho correlations and Mann-Whitney U test

Focus group interviews

The focus group interviews were conducted among health care professionals working in the Diabetes Clinic at Setthathirat Hospital. The purposive sampled participants included all four doctors, four nurses, and three pharmacists. Key results from phase 1 study including patients' knowledge on diabetes, diabetic medications and self-management, medication compliance and DRPs and their causes were briefly presented to the participants. These patients' problems were discussed and brainstormed by the team to design TMIs suitable for the context of the Diabetes Clinic at Setthathirat Hospital.

The researchers conducted focus group interviews according to the interview guides including 1) What do you think about information on DRPs and patients' knowledge and attitudes towards diabetes and its management identified from phase I study? 2) What do you think about providing TMIs and what could be barriers of setting up this service?, and 3) What should be the roles of health care team to facilitate the service provision of TMIs?. After the completion of the focus group interviews, the research team (SS, PK and WA) conducted content analysis of the data to summarize the key components of the agreed TMIs and the preparation for provision of TMIs in patients having poor clinical outcomes. The process and tools used for providing TMIs were proposed to the head of internal medicine doctor and the rest of health care team. The process and tools were then revised based on their comments and suggestions. They were revised for three times before being finally approved and then implemented into practice.

Results

Phase I: cross-sectional study

Patient characteristics

Table 1 shows characteristics of 110 patients participating in the cross-sectional survey. The average age was 56±9.20. The majority were female (59.1%). The average fasting blood sugar was 185±65.31 mg/dL and average hemoglobin A1C (HbA1c) at 9.26±1.94%. Average systolic and diastolic blood pressures were 149±15.69 and 84±6.134 mmHg, respectively. Average duration of being diagnosed with diabetes mellitus was 7.15±3.14 years. Average body mass index was 24±3.75 (Table 1).

Table 1. Characteristics of patients participating in the cross-sectional survey (N=110)

demographic data	
age (year), number (%)	
40-49	27 (24.5)
50-59	38 (34.5)
>60	45 (40.9)
mean±SD (year)	56.00±9.20
gender, number (%)	
male	45 (40.9)
female	65 (59.1)
family history of diabetes, number (%)	
father	53 (48.2)
mother	46 (41.8)
other direct relatives	11 (10.0)
fasting blood sugar (mg/dL) (mean±SD)	185±65.31
hemoglobin A1C (%) (mean±SD)	9.26±1.94
blood pressure (mmHg) (mean ±SD)	
systolic	149±15.69
diastolic	84±6.134
duration of diabetes (year), number (%)	
1-5	53 (48.2)
5.1-10	38 (34.5)
10.1-20	19 (17.3)
mean±SD	7.15±3.14

Table 1. Characteristics of patients participating in the cross-sectional survey (N=110) (continued)

demographic data	
number of co-morbidities, number (%)	
2	13 (11.7)
3	72 (64.9)
4	25 (22.5)
mean±SD	3.11±0.58
body mass index (kg/m^2), number (%)	
18-23	42 (38.2)
23.1-29	59 (53.6)
>29	9 (8.2)
mean ±SD	24±3.75
education status, number (%)	
primary school	19 (17.3)
secondary school	63 (57.3)
bachelor	24 (21.8)
master	2 (1.8)
no formal education	2 (1.8)

Diabetic knowledge and medication compliance

Most participants gained the score on DKQ ranging from 9-18 out of 24, indicating moderate level of knowledge. (86 out of 110, 78.2%). The assessment with the BMQ showed that 40% of participants were not compliant to prescribed medication, mostly (36.4% of subjects) because of their respond to the questions *"difficulties in getting medicines on the scheduled date due to the house being far away and not being able to stop working",* and *''forgetting to take this drug on some days or some meals''.* Respondents discontinued diabetic medications or temporarily missed some doses due to the following reasons; negative beliefs in taking medications, not appreciating medication effectiveness, and experiencing disturbing side effects.

Classification of drug-related problems

DRPs were identified in all 110 participants. However, causes of DRPs differed from patients to patients. P1.1 (no effect of drug treatment) was the

most common DRPs, accounting for 85.5% of the subjects (table 2). Its most common causes of DRPs were C7.10 (patient unable to understand instructions properly) in 56.4% of subjects, and C7.1 (patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason) in 38.7% of subjects. The second most common DRP was P1.2 (effect of drug treatment not optimal) accounting for 38.8% of patients. Its most common causes were C9.2 (other cause) in 50.9% of patients and C7.5 (patient takes food or herbal medicines that interacts with their regular medicines) in 49.1% of subjects (table 2).

Knowledge, attitudes and DRPs

There were no significant relationships between knowledge and attitudes about diabetes and DRPs (P>0.05). However, there were significant relationships between the number of medicines and having P1.2 "effect of drug treatment not optimal" as DRPs (P< 0.01)

Phase II: Focus group interviews

There were three major themes identified from the focus group interviews.

Views of current services

Doctors, nurses, and pharmacists had the same views that current services for diabetics needed to be improved. Most diabetic patients had inadequate knowledge on proper use of diabetic medications. They were not aware of the importance of taking medicaitons regularly in order to prevent and/or delay the progrssion of diseases. These problems then led to poor clinical outcomes, resulting in major or minor complications as well as poor health outcomes.

Views of organizational barriers

All doctors, nurses, and pharmacists realized the importance of provision of proper counseling to patients in practice, but such counseling was not undertaken due to many barriers. Major barriers were lack of human resources, hospital policy support, and financial support. Doctors said that if the hospital had adequate budgets,

Table 2. Classification of drug-related problems identified by clinical pharmacists

classification of drug related problems	number (%)
P1.1 No effect of drug treatment: there is no improvement in the treatment effect even though the patient has already taken medicines.	94 (85.5)
Cause: C7.10 Patient unable to understand instructions properly	62 (56.4%)
C7.1- Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason (The patient does not take the medicine as prescribed by the doctor, the patient deliberately stops taking the medicine and forgets to take the medicine from time to time.)	43 (38.7%)
C7.2- Patient uses/takes more drug than prescribed (The patient said that sometimes they retook some medicines because they had forgotten that medicines were already taken.)	38 (34.2%)
P1.2 Effect of drug treatment not optimal: patient takes medicines less than prescribed and some of them also used traditional medicines.	35 (31.8)
Cause: C9.2- Other cause (The patient likes to have desserts and /or sticky rice on a regular basis)	56 (50.9%)
C7.5 Patient takes food or herbal medicines that interacts with their regular medicines.	54 (49.1%)

Note: Numbers in P1.1 and P 1.2 represent the number of subjects with DRPs. The numbers in causes are the numbers of DRPs. Some DRPs may have more than one causes.

then the system would have been established and all health care teams could have worked more effectively and monitored the pateints more closely. It was also quite a workload or burden for medical doctors to be in charge of many things at the same time.

Roles of health professionals in TMIs

At Setthathirat hospital, doctors and nurses currently worked together as a team. Doctors gave general counseling to diabetic patients and provided regular monitoring for individual patients. Nurses measured blood pressure and recorded important laboratory values including FBS and HbA1c. However, pharmacists were not able to provide counseling for individual diabetic patients at all due to exiating heavy workloads, time constraints and pharmacy staff shortage.

Doctors said that their roles included prescribing medicines, giving some important information to patients and monitoring patients as necessary. Doctors and nurses had the same suggestions about pharmacists' roles; for instance, providing key information on how to take medicine safely, its side effect, interactions between food and drugs, interactions between drugs, interactions between herbs and drugss, important things to be aware of, and not buying medicine at the drug stores. A private area for pharmacy counselling was also suggested. Doctors agreed that the importance and benefits of having pharmacy counselling were not just directly for the patients but also help save time for doctors.

Recommendations for providing TMIs

A few drafts of TMIs were reviewed and revised by the head of internal medicine doctor and the rest of health care team. The plan for TMIs was finally approved for implementation in practice for diabetic patients with poor clinical outcomes. The roles and functions of pharmacists were clearly specified in the process of delivering TMIs to teh patients as described below.

Assessment and educational tools

Before providing TMIs for individual patients, the patient will be assessed by three tools. The first one is the DKQ consisting of 3 main components, i.e., knowledge about diabetes (types, symptoms, complications), diabetic medications and proper lifestyle medications. The second tool is the BMQ for assessing medication compliance. There are 2 domains in the BMQ including necessity of taking medicines and concern about taking medicines. The third tool is the PCNE Drug-related problems classifications (version 9.1) used to assess DRPs and their causes. Educational tools contain knowledge on diabetes, targeted blood sugar, drug treatments, appropriate diets and lifestyle modifications.

TMIs for individual patients by pharmacist

Pharmacist is tasked with providing tailored information and interventions for individual diabetics with non-compliance or any other DRPs or both problems by using aforementioned three assessment tools and educational recources. Providing education to individual diabetic patients encompasses a comprehensive understanding of diabetes and its management. This includes insights on drug therapies, dietary requirements, lifestyle adjustments, safe and proper medication administration, potential side effects of diabetes medications, food and drug interactions, as well as cautionary awareness of risks associated with the consumption of unauthorized herbal remedies and non-prescriptive medications available in retail environments. The following tools are also provided--the medication tracking schedule on calendar, a medication dosing device (a bag filling pills for each dose), and phone reminder on drug taking and appointment on next visit. In case of having any difficulties for hospital visit or receiving medicines at Setthathirat hospital, nurses could coordinate with community hospitals nearby patients' home. The patients could pick up their medicines at that community hospitals and be followed

Discussion

This study is the original study in Laos health care system, initiating the concept of TMIs for diabetic patients with poor health outcomes. It also indicated the importance of pharmacy workforce and competency of pharmacists for providing effective pharmaceutical care tailored for individual patients with chronic disease having either socioeconomic problems or DRPs or both. Of 110 participants, most had moderate level of diabetes knowledge and its management particularly proper lifestyle modification and were not compliant to diabetic medications. This was consistent with the results from other studies (3, 7, 9) reporting that patients did not have adequate knowledge about proper self-care for their chronic diseases. Patient education and proper diabetes management are recommended in order to reduce and delay diabetic or hypertensive complications (9).

Previous study indicated that diabetes knowledge and perceived health status are the most important factors associated with glycemic control (9-10, 12). In addition, studies from Europe, Asia, and the United States (2-5) showed that older age had significant relationships with poor compliance and clinical outcomes as well as inappropriate drug treatments. However, the results of this study were not consistent with these results. This study did not find significant relationships between age, knowledge about diabetes and its management and DRPs. This might be due to smaller number of participants in the study. Only number of medicines were found to be related with DRPs (P1.2 effect of drug is not optimal). This was consistent with results from the previous studies (9-10) indicating that polypharmacy and use of herbal medicines as alternative treatments were strongly associated with non-compliance.

Focus group interviews revealed that health care providers agreed with the need to improve current services for diabetic patients as well as to have appropriate educational tools for patients. This was consistent with the findings from previous research (8-12) on views of either healthcare providers or patients on the improvement of diabetes care and services by using the concept of TMIs. Nevertheless, challenges arise in achieving health outcomes for individuals with chronic disease, depending on various factors unique to each country including health policy, health environment, system and service and accessibility, attitudes of health care providers and patient engagement.

The strength of this research was the use of mixed research methodology. Quantitative study enabled healthcare team within the Diabetes Clinic to gain comprehensive insights into DRPs, as well as patients' knowledge and attitudes concerning diabetes and its management. Subsequently, a qualitative research methodology facilitated the discussion and conceptualization of TMIs aimed at addressing individual patient concerns and DRPs. This intervention was determined to be mainly conducted by a clinical pharmacist working alongside with the health care team.

The study had some limitations. First, the study did not use pill counts to confirm participants' medication compliance. Second, patient might have recall bias for some questions used to assess patient's compliance and DRPs, leading to underestimate or overestimate these problems. Filling gaps of this study is recommended for future research. An experimental research to evaluate health outcomes of diabetic patients receiving TMIs is further recommended.

Conclusion

TMIs for individual diabetic patients is crucial and could be implemented in the process of care and

up by a clinical pharmacist via telephone. Follow-up phone call after receiving pharmacist intervention to check patient's compliance and resolutions of DRPs as well as clinical outcomes are monitored by a clinical pharmacist and the health care team.

services based in the hospital. It should also be incorporated into the quality improvement program for improving patient communications, self-reflection, self-awareness, and health outcomes for individuals.

Acknowledgements

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