### **Review Article**

# The protocol for diabetic foot care services by community pharmacists in Thailand

Jadesada Lertsirimunkong<sup>1\*</sup>, Wiwat Thavornwattanayong<sup>2</sup>, Khwanruetai Yongrat<sup>2</sup>, Natapon Huengraksa<sup>2</sup>, Pairote Chakranon<sup>2</sup>, Panjapon Nimnuan<sup>2</sup>

<sup>1</sup>Department of Pharmacy Practice, College of Pharmacy, Rangsit University, Pathum Thani, Thailand <sup>2</sup>Department of Community Pharmacy, Faculty of Pharmacy, Silpakorn University, Nakhon Pathom, Thailand

\***Corresponding author:** Jadesada Lertsirimunkong Jadesada.l@rsu.ac.th

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### ABSTRACT

Most of diabetic patients are risk for developing diabetic foot ulcers (DFU) which lead to lifelong disability and diminish the quality of life. Comparative with the patients who have no history of foot complications, the patients who have a history of foot complications have a mortality rate of 3.5 times. There are many international articles showing the important roles and abilities of pharmacists, including and how they can provide services for diabetic foot patients. Despite there are no services available for diabetic foot care in pharmacies in Thailand, this article attempts to encourage community pharmacists with the aim of providing a better care for diabetic patients by developing a protocol for diabetic foot care services in community pharmacy. The protocol was adopted from Standard management of Diabetes Mellitus, Clinical Practice Guideline for Diabetes in Thailand and Clinical Practice Guideline: Prevention and Management of Diabetic Foot Complications. Key component services: Screening, Inspection, Treatment of bacterial infection, Education and Referral established in the protocol. This protocol is an opportunity and extended challenging services for community pharmacists in Thailand to help the diabetic patients to reduce their risk factors and have a better quality of life.

### **1. INTRODUCTION**

In Thailand, about 1-20% of diabetic patients have foot ulcers<sup>1</sup>, in this case, 20-70% of these patients suffer from peripheral neuropathy<sup>1</sup> and 4-30% from reduced pedis pulse<sup>1</sup>, resulting in 0.5-32% of potential lower extremity amputation<sup>1</sup>. According to the statistics, there appears that most of diabetic patients are risk for developing diabetic foot ulcers (DFU) which lead to lifelong disability and diminish the quality of life<sup>2,3</sup>. In this regard, comparative with the patients who have no history of foot complications, the patients who have a history of foot complications have a mortality rate of 3.5 times<sup>1</sup>.

Focusing on diabetic foot care services, international articles, such as "Diabetic Foot – what a pharmacist can do", showed that a pharmacist who is responsible for a diabetic foot care services could deal with different types of wound, educate patients, and also refer the high risk patients to the specialists<sup>4</sup>. "Diabetic Foot Ulcer Assessment and Treatment: A Pharmacist's Guideline", illustrated the roles of pharmacists in a health care team which include screening for risk factors, evaluating treatment for sufficient

care and also drug counseling<sup>5</sup>. "Diabetic Feet: Addressing Problems Seen in the Pharmacy Clinic" insisted that pharmacists' services including screening and primary management of diabetic feet problems could be given by a pharmacist<sup>6</sup>. "Current Advice To Pharmacists on Diabetic Feet and their Management" confirmed that the roles of pharmacists in diabetes mellitus were prevention of diabetes and its complications such as neuropathy, peripheral arterial disease or diabetic foot, and encouragement of the compliance for taking medication<sup>7</sup>. All these examples of international articles showed the important roles and abilities of pharmacists and how they can provide services for diabetic foot patients.

Nowadays, in Thailand, community pharmacy is the healthcare channel where the patients can get primary care services easily<sup>8-10</sup>. In addition, the primary care services that community pharmacists also participate are selection of an appropriate drug for individualized patients<sup>8</sup>, dispensing<sup>8</sup>, preventing adverse drug reaction<sup>8</sup>, health education<sup>8</sup>, health promotions<sup>8</sup> and referral the clinical case to the specialists<sup>8</sup>. Some articles showed that the community pharmacists also provide screening for some metabolic syndromes<sup>9,11</sup> and educate on various subjects such as immunization for children<sup>9, 11</sup>, prevention of asthma<sup>9</sup>, the accurately use of birth control pills and emergency contraceptive pills<sup>9, 11</sup>, unwilling pregnancy<sup>11</sup> and sexual transmitted infections<sup>11, 12</sup>. While some professionals (doctor and nurse) have developed protocol<sup>1, 13</sup>, there are no protocol for pharmacist. Moreover, the role of pharmacists in diabetes only was mentioned in the Clinical Practice Guideline for Diabetes in Thailand 2017 but it is not specific for diabetic foot care services. Despite no activities fulfill this gap, the new protocol for diabetic foot care services by community pharmacists in Thailand which could provide services by screening, education, assessment, and referral may decrease the risks and complications of diabetic patients and also provide a better of quality of life for Thai people in the future<sup>14</sup>.

In addition to the new services, this article attempts to encourage community pharmacists with the aim of providing a better care for diabetic patients by developing a protocol for diabetic foot care services in community pharmacy.

### **1.1. Etiology and clinical presentations**

Neuropathy, infection and peripheral arterial disease (PAD) are three causative

components that lead to diabetic foot complications<sup>2, 15</sup>. Diabetic neuropathy is related to poor glycemic control and characterized by the involvement of sensory, motor and autonomic fibers<sup>5, 15-17</sup>. The possible pathogenesis of diabetic neuropathy are based on theories of alteration in the vesa nervorum or abnormalities in metabolism. Sensory neuropathy affects the small-diameter pain and temperature fibers, then the injury will be increased since the sensation of these patients against pressure-related trauma or minor injury on the skin has been dropped<sup>15</sup>. These sensory dysfunctions lead to loss of protective sensation (LOPS)<sup>16</sup> (assessed by Semmes-Weinstein monofilament<sup>18</sup> as shown in Table 1) and increase the risk of ulceration<sup>16</sup>. Motor neuropathy affect the long fibers that innervate the foot, which impact to both intrinsic foot muscles and leg muscles. In this regard, it causes the muscle weakness, intrinsic muscle imbalance and results in joint rigidity with consequent abnormal walking pattern and foot deformities<sup>15, 16, 18</sup>. Autonomic neuropathy is the result of changing in microvascular blood flow and arteriolar-venous shunting<sup>18</sup>. It causes dry skin through the loss of sweat and oil gland function resulting in high possibility of breakdown, fissure, and the bacterial entrance.<sup>15,</sup> <sup>18</sup>. Foot infection, the most common reason for hospitalization and lower extremity amputation in diabetic patients<sup>16, 19</sup>, the diabetic patients are easily get a foot infection because of declinable efficiency of neutrophil function, including the insufficiency of neuropathy and vascular<sup>16</sup>. Recently, there are some evidences revealed that diabetic foot infection is caused by more organisms, multidrug-resistant such as methicillin resistant Staphylococcus aureus (MRSA) and extended-spectrum beta-lactamases (ESBLs), but the most common pathogen is Gram-negative rods which commonly found in the tropical climate region<sup>19</sup>. The International Working Group on the Diabetic Foot (IWGD) 2011 has classified the foot infections in level 1 to 4 as PEDIS grade (PEDIS: perfusion, extension/size, depth/tissue loss, infection, and sensation) corresponding to Guidelines for Diabetic Foot Infections which have classified the foot infections in uninfected, mild, moderate, and severe<sup>20</sup>. The patients with a severe infection level or PEDIS grade 4 should be admitted for possible surgical intervention, while most patients are in uninfected level or PEDIS grade 1 (wound lacking purulence or any manifestations of inflammation<sup>20</sup>) and mild level or PEDIS

Table 1 The technique for assessment of neuropathy<sup>a 1</sup>

- 1. Screen in a quiet room at room temperature
- 2. Show and explain the step of assessment to the patients
- 3. Advise the patients to sit before screening by using a monofilament
- 4. Before starting, tell the patients to close both eyes
- 5. Touch the skin in perpendicular posture with the sole of the foot by monofilament at 4 points as the below figure, one point at the big toe and three points on the sole of the foot. Press the monofilament slowly until it bends and holds for 1 to 1.5 seconds then release it. Ask the patients about what he/she feels or senses. Repeat this step 3 times for each point.



6. Evaluate another 3 points on the sole for both feet

- After the completion of assessment, interpret each point as follows:
  - 1. If the patients can detect feeling correctly 2 out of 3 times or more for each checking point, it means normal sensation at this point.
  - 2. If the patients can detect his/her feeling correctly either only 1 time or none at each checking point, the evaluator has to re-evaluate this position again. If the result is the same, it means abnormal sensation at this point.
  - 3. Overall, if one of the positions on the foot has abnormal sensation, this means the patients has an insensate foot.

<sup>a</sup>specificity and sensitivity of the assessment are between 34 to 86 percent and 66 to 91 percent respectively <sup>14</sup>

grade 2<sup>5</sup> (no other local complications/systemic illness and presence of  $\geq 2$  manifestations of inflammation; purulence, erythema, pain, tenderness, warmth, induration<sup>20</sup>) can be treated cautiously on an outpatient basis<sup>21</sup>. PAD is caused by atherosclerotic plaque occlusion of the arterial lumen<sup>22</sup> result from the atherosclerotic process progressively complete occlusion then impact to inadequate blood flow to the lower extremities<sup>22</sup>. Intermittent claudication and pain at rest in the lower extremities are the most common symptoms of PAD<sup>22</sup> which contribute to ischemia, gangrene and finally reach the lower extremity amputation<sup>23</sup>. The coexistence of neuropathy and PAD cause the development of severe and extensive infections in the lower extremities provided that it is not adequately treated, it may lead to amputation and death<sup>24</sup>.

### **1.2. Roles of community pharmacists in diabetic foot care services**

The management of the diabetic foot patients should be seen as a partnership between the patients and health care professionals, in which the professionals will support the patients in the aspect of self-managing. Taking care of every patient should commence with a detailed assessment at the initial assessment including an appraisal of diabetes complications and risk factors for complications. This is the basis of continuing care that includes a treatment plan, treatment administration, monitoring, and review.

With the development of the concept of pharmaceutical care in which the pharmacists are engaged more widely in patient care and professional care team, the opportunity exists for pharmacists to have a power role in delivering improvements in the care of diabetic foot patients<sup>2,25-29</sup> which are as the example lists below.

1. Reminding, reinforcement and extending the education to the diabetic patients, evaluate individual knowledge of the condition and ensure treatment concordance<sup>26-29</sup>.

2. Counseling the diabetic patients for selfmanagement and providing information to help them handle with their diabetes<sup>5, 25-29</sup>.

3. Health screening for diabetes and DFU, and encouraging yearly foot exams to assess for abnormal foot sensation<sup>2, 25, 28</sup>.

4. Conduct health promotion, education programs for smoking cessation, obesity control and help the patients to archive metabolic control. Thus, diet and exercise should coincide with possible escalation of medication therapy <sup>2, 5, 25-29</sup>.

5. Monitoring drug regimen and advising on how to take medication safely for maximum effectiveness<sup>25, 26, 28, 29</sup>.

6. Referral of the patients whose the ulcer severity has been increased, or lack of progression of healing, for further assessment and evaluation by the specialists<sup>25, 27, 28</sup>.

The results of all reviews make an evident support for the role of pharmacist in diabetic foot care services. Likewise, the roles of pharmacists in diabetic health care units in Thailand has been presented by The Diabetes Association of Thailand, including drug counseling, medical reconciliation, medication therapy management<sup>30</sup>. Furthermore, the role of community pharmacists which is indicated in the Clinical Practice Guideline for Diabetes in Thailand 2017<sup>31</sup> also states that the community pharmacists should screen and prevent disease, support a healthcare team, handling drug related problems and referral of the patients to the specialists. Apart from the role of community pharmacists on diabetic foot care as mentioned above, the protocol for diabetic foot care services for community pharmacists in Thailand was adopted. This challenging protocol may contribute positively to the clinical outcomes of the diabetic patients.

## **1.3.** The protocol for diabetic foot care services by community pharmacists in Thailand: The challenging protocol

There are 2 phases stated in this developed the protocol i.e. firstly, literature review phase, it was focused on the roles of pharmacists in diabetic foot care services as prescribed in the Standard Management of Diabetes Mellitus<sup>30</sup>, Clinical Practice Guideline for Diabetes in Thailand 2017<sup>31</sup> and Clinical Practice Guideline: Prevention and Management of Diabetic Foot Complications<sup>1</sup>. Lastly, this developed protocol was approved by 3 experts that consist of the specialist in diabetic clinic, pharmacist specialized in diabetes and community pharmacists. The protocol is presented in Figure1.

The protocol in figure 1 demonstrates 4 dimensions as follows:

1. Diabetic foot patients screening. According to the recommendation of Clinical Practice Guideline for Diabetes in Thailand 2017 <sup>31</sup> for pharmacists, if there appears the following problem in the patients, they should be referred to the specialists immediately.

A. The capillary blood glucose CBG less than 70 mg/dl, or CBG more than 200 mg/dl consecutively over 2 times in different day, or CBG more than 300 mg/dl)

- B. Resting pulse more than 100 beats per minute and/or orthostatic hypotension, or blood pressure more than 180/110 mmHg, or for the treated patient, there appears systolic blood pressure more than 140 mmHg and/or diastolic blood pressure more than 90 mmHg consecutively over 3 months
- C. There is other special conditions such as leg pain in resting stage, acute blurred vision, etc.
- D. There is history of lower extremity amputation or foot ulcers.

2. Foot complications evaluation such as foot deformities (abnormal foot skin or foot shape), peripheral arterial disease (abnormal pedis pulse) and neuropathy (loss of protective sensation). If any abnormal condition is found, referral also should be done;

3. Foot ulcers and infection evaluation for mild level i.e. swelling, inflame, pain, warm, purulent discharge, size of ulcers and lymphangitis as the detail of evaluation stated in figure 1.

4. Management (treatment of infection, dressing and education in mild level) or refer to specialists.

The key points of the diabetic foot care services by community pharmacists in Thailand mainly concern in the step of screening, inspection (foot deformities, PAD, neuropathy, and infection), treatment of bacterial infection, education and referral. According to the protocol, treatment with bacterial infections should be treated by topical and oral antibiotic. This means rational selection of antibiotics such as clindamycin, amoxicillin-clavulanate and gram-positive erythromycin for bacterial infections, ciprofloxacin or oral cephalosporins for gram-negative bacterial infections and also combined it with metronidazole for anaerobe bacterial infection (if it is necessary). The recommendations for ulcers management<sup>1</sup> are cleaning the ulcers with sterile water or 0.9% normal saline solution, once or twice daily and monitoring the ulcers within 24 to 48 hours. If it shows improvement, pharmacists should follow up for 3-7 days but if not, pharmacists should refer the patients to the specialists. For the following step, the education of the medicine and self-foot care in diabetic patients is demonstrated in the Table 2. In the case of that, the patients are unable or unwilling conform to the proper ulcer care or



Figure 1. The protocol for diabetic foot care services by community pharmacists in Thailand

<sup>a</sup> Evaluations of
1. Abnormalities of the skin and nails, including dry skin, calluses, abnormal nails and fungal infections
2. Abnormalities of foot shape including charcot foot, pes cavus, claw toes, flat feet, hallux valgus and restricted motion of foot joints

<sup>b</sup> Evaluations of abnormalities of pedis pulse (dorsalis pedis pulse and posterior pedis pulse)

<sup>c</sup> Evaluations of Loss of protective sensation (LOPS), evaluated by the use of a Semmes-Weinstein monofilament as shown in Table 1

Table 2 Education for self-foot care in diabetic patients

1.	Inform the patients of updating and reviewing medication list every time, if the medications are changed.
2.	Explain the patients on how to take medicine for the maximum benefit and safety.
3.	Discussing about vitamins and herbal supplements that diabetic patients can take.
Educati	on for self-foot care <sup>1</sup>
1.	Inspection: Check the abnormality on skin, nails or corns. If they are detected, ask the pharmacists for help
2.	Washing: always keep clean and dry feet after washing.
3.	Lotioning: after washing, the patients should always use an emollient on their skin to prevent dry skin.
4.	Nail care: cut the nails properly
5.	Checking: corns and calluses which are causes of foot ulcers from peripheral neuropathy.
6.	Wear socks: since it can reduce sheering forces which is one of the causes of foot ulcers.
7.	Wear proper footwear: it can reduce the risks of foot ulcers.

should be hospitalized, pharmacists should consider to refer the patients to the specialists.

### 2. CONCLUSION

Where opportunity and time are available, efforts of the community pharmacists as a resource for diabetic foot care services. Many evidences support the role of pharmacists in providing a wide range of extended diabetic foot care services<sup>2,25-28</sup>, from screening to ongoing disease state management. The diabetic foot care services by community pharmacists in Thailand as recommended in the protocol is an opportunity and extended challenging services that may help the diabetic patients to reduce their risk factors.

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