

Development of Warfarin Safety Monitoring System at Primary Health Care grounded on Chronic Care Model

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ABSTRACT

Warfarin, an anticoagulant with a high risk of fatal adverse effects, requires a safety monitoring system in primary health care. This study aimed to investigate the problems of warfarin use, discover factors related to blood clotting and develop a safety monitoring system for warfarin. A mixed method was conducted in two phases. Phase one consisted of home visits for 104 patients using warfarin and aimed to investigate the occurrence of warfarin problems and the percentage of patients who could control their International Normalised Ratio (INR). In phase two, focus groups including all stakeholders were conducted, which aimed to develop a community-based system grounded on the Chronic Care Model (CCM). The system was implemented for a month and evaluated using the qualitative data of the stakeholders' satisfaction. The results revealed that in phase one, 38.5% patients with warfarin at home had missed their treatment appointments. Their warfarin compliance was $91.1 \pm 21.3\%$. 53.5% of patients had unused warfarin at home; 37.4% had inappropriate warfarin storage; 13.1% suffered the side effect of minor bleeding; 17.3% had potential warfarin-herb interactions; and 61.3% experienced drug-warfarin interactions. Two factors significantly affecting the INR and %Time in Therapeutic Range (%TTR) were inappropriate warfarin dosages and taking other medications. %TTR was influenced by warfarin compliance. In phase two, the safety monitoring system and protocol were created using CCM. The developed system comprises six elements that were the joint effort of primary health care personnel and the inter-professional team of the hospital. This promoted the continuity of services from the hospital to the community. After one month of implementation by the health team, all three groups of stakeholders were satisfied with the results. We concluded that the main problems afflicting warfarin patients were missed treatment appointments, receiving extra medicines from other services, inappropriate dosages and non-compliance. The developed system covered patients in primary health care, and all stakeholders were satisfied with its outcomes.

Keywords: Warfarin, International Normalised Ratio (INR), Primary Health Care, System Development, Chronic Care Model

INTRODUCTION

Warfarin is an oral anticoagulant medication that is used to treat and prevent blood clots. It has a narrow therapeutic index and complicated pharmacokinetics and pharmacodynamics. There are many different factors that affect patients'

responsiveness to warfarin, such as warfarin-drug interactions, smoking, drinking alcohol, vitamin K-rich food intake, not following doctor's medication instructions and having comorbid diseases (The Heart Association of Thailand under the Royal Patronage, 2011). An important issue for warfarin

use is patient compliance (Levine *et al.*, 2016; Katemateegaroon and Jarensiripornkul., 2002). 39.5% of problematic incidents are related to the interaction between warfarin and other drugs (Peerapattanapokin *et al.*, 2018). 54.0% of patients suffer from warfarin-related side effects (Jittsue *et al.*, 2015). In one study, 51.6% of participants overdosed on warfarin, resulting in major organ bleeding (Wittayachanyapong *et al.*, 2003). Studies of warfarin use problems in communities showed that 24–28.7% of patients experienced warfarin–drug interactions (Stafford *et al.*, 2012; Aphisitsak, 2016), 3.2% had warfarin non-compliance, 13.7% missed treatment appointments (Wangsook *et al.*, 2014) 8.96% experienced minor bleeding, 1.5% consumed energy drinks or alcoholic beverages (Grunau *et al.*, 2011), 2% misused warfarin and 8% experienced adverse side effects (Aphisitsak, 2016). Such examinations showed that there are still many warfarin-related problems in the community, even though the Ministry of Public Health of Thailand has paid particular attention to warfarin use, allowing its prescription only in secondary and tertiary healthcare. The Service Plan of 2013–2017 stated that the development of warfarin clinics for heart disease patients on anticoagulant drug treatment is needed. Community hospitals should provide anticoagulant drug treatment by interprofessional care, as well as by the monitoring of International Normalised Ratios (INR) – a clinical outcome for warfarin control. They also need to have a patient referral system in case of complications, which allows information to be shared between the main site and its networks. Patients using warfarin can then be referred from general hospitals to community hospitals (Wangsook *et al.*, 2014; Witt *et al.*, 2016).

The warfarin clinic of Wang Hin hospital, a 30-bed community hospital in Si Sa Ket Province, Northeast Thailand, was established in 2016. During 2017, there were 38 registered patients, and in 2018, 60 patients. The clinic performance in 2018 reported that (1) 4.5% of patients with warfarin missed appointments; (2) 47.5% of patients had an unacceptable INR target; (3) 0.4% of patients had suffered strokes; and (4) no patients had major bleeding. A monitoring system at the patient's home, coupled with care provided by an interprofessional team, would help to identify problems with warfarin use. With information gained from the clinic, drug treatment plans could be individually designed to suit each patient at their home. Therefore, in order to systematically and

continuously supervise patients' warfarin use, the researcher – a hospital pharmacist at this warfarin clinic – is interested to learn more about warfarin-related problems in the primary health care of the community, the factors that affect the control of INRs and the stakeholders' idea for the development of a monitoring system to ensure the safety of warfarin use – a system that will be adapted from the Chronic Care Model (CCM) (Davy *et al.*, 2015). Moreover, during the COVID-19 pandemic, the continuation of warfarin monitoring for patients in the community is more important and needed (McClay, 2020). This is the first move of a community-based care system for patients using warfarin in the Northeast region of Thailand. This research was initiated by the hospital pharmacist and the warfarin clinic interprofessional team. The findings will be used as evidence for health professionals and people in the community to ensure that implementation of the warfarin monitoring system in other communities will benefit patients at the primary health care level. This study aimed to investigate warfarin-associated problems, identify factors related to INRs and develop a monitoring system for safe warfarin use at the primary health care level.

MATERIALS AND METHODS

This investigation was conducted through a mixed methods approach, using both quantitative and qualitative research. It was divided into two phases.

The first phase was the quantitative study using a community-based approach through home visits for all patients using warfarin in the Wang Hin District. The home visits allowed for an examination of patients' warfarin-related problems using the developed tool and enabled exploration of the relationship between the relevant issues and the control of INRs. INR is measured for the purpose of monitoring adverse events every month by the warfarin clinic team of Wang Hin hospital; the target INR is 2.0–3.0. The time in the therapeutic range or INR in the range of 2.0–3.0 (TTR) indicates the warfarin therapy quality. This phase was initiated by a pharmacist and an interprofessional team of the warfarin clinic at Wang Hin hospital and facilitated by the co-operation of primary health care providers. The main outputs from this phase were the determination of the occurrence of warfarin use problems, the percentage of patients using warfarin who could control their INR and the significant factors relating to INR control.

The second phase was a qualitative study using focus groups that were organised by a warfarin clinic team consisting of people who were part of the caring process of warfarin use in the community. To ensure the quality of the discussion, pharmacist, a key investigator has been trained for and pre-testing by the team was completed before launching the discussion. These focus group discussions were performed in order to design and develop a community-based monitoring system. The system implementation was collaboratively managed by stakeholders in the community and the warfarin clinic team, and stakeholders' satisfaction with the system and its outcomes was evaluated using focus group discussions.

Research tools

After a review of warfarin-related problems and influential factors, a questionnaire and group discussion guidelines were drafted by the researchers. Three experts considered the validity of the questionnaire with a content validity index (CVI) > 0.8, and the questions for group discussion were found to be in accordance with the study objectives. The questionnaire was tested for reliability using ten patients in the warfarin clinic.

Data collection

This research was approved by the Ethics Committee for Human Research, Mahasarakham University, with the approval number 142/2562. For the first phase, data for 104 patients who had been prescribed warfarin were primarily collected by home-based care teams of Wang Hin Hospital between July and November 2019. Hospital pharmacists retrieved patients' data from the Wang Hin Hospital information system, prepared the research tools and led the team to follow a five-month schedule for home visits for patients using warfarin.

For the second phase, data were collected between December 2019 and March 2020. The process involved (1) a group discussion in order to develop a monitoring system for safe warfarin use at a primary health care level, using CCM as a framework. Participants consisted of inter-professional personnel who were involved in caring for patients, including one doctor, one pharmacist, three nurses, one Village Health Volunteer (VHV), two patients on warfarin and one caregiver. They created a protocol of warfarin safety monitoring in primary health care (Figure 1); (2) application of the system was developed for one month (Table V and Figure 2-3), a second group

discussion amongst the care team with the aim of assessing the system, involving one doctor, one pharmacist, three nurses and three VHVs. Patients and their relatives were in a separate group consisting of five patients and four caregivers.

Data analysis

Fisher's exact tests were applied to differentiate two groups of independent variables. Student's t-test was employed to compare means between two groups. These statistical methods were analysed using a STATA programme. Focus group dialogues to develop and assess the system in the second stage were examined using a content analysis method. A directed approach using CCM theory as guidance for coding was applied for content analysis.

RESULT AND DISCUSSIONS

First phase: Home visit

The characteristics of the patients, their medication use and their warfarin-related problems were collected during the home visits. The clinical data such as INR and %TTR were retrieved from the hospital information system (HIS) and (Table I). 63.5% of the patients received their warfarin from Wang Hin Hospital, and 70.2% managed warfarin use by themselves. 37.5% had an INR that was not within the target, and the average of their most recent INR from HIS was 2.47 ± 0.94 . The average %TTR range was 48.48 ± 24.34 . 64.6% of the patients did not have their %TTR within their treatment target. 9.62% had been hospitalised from warfarin use in the past six months. For warfarin-related problems, 33.6% of the patients missed appointments that impacted their medical prescriptions, and 26.0% arrived earlier and 7.7% arrived later than the time of their appointment. It was found that five people, or 4.8%, did not turn up for their appointment at all. Patient warfarin compliance was also calculated by counting the remaining pills that they possessed and interviewing them or their carers about their warfarin administration. It was found that $91.14 \pm 21.18\%$ of the patients adhered to taking warfarin and $86.19 \pm 21.24\%$ of them were compliant with taking other medicines for chronic illnesses. Regarding the problem of leftover warfarin at home, 53 participants (53.5%) fell into this category. The three most common reasons for having leftover warfarin were over-prescription (43.4%), patient forgetting to take the medication (30.2%) and failure to return drugs after doctors changed prescriptions.

Table I Characteristics and warfarin use of patients using warfarin from home visits (n = 104)

Patient's characteristics	Number (%)
General characteristics	
1. Gender: Male	53 (51.0)
2. Age: Mean \pm SD	66.82 \pm 12.30
3. Highest educational level: Primary school	94 (90.4)
4. Occupation: Farming	48 (46.2)
5. No carer for medicine intake at home	7 (6.7)
Social history : - Alcohol drink	6 (5.8)
- Cigarette smoke	10 (9.6)
Personal illnesses	
1. Illnesses indication of warfarin use: - Atrial fibrillation	80 (75.9)
- Stroke	18 (17.3)
- Valvular heart disease	16 (15.4)
- Mechanical prosthetic valves	13 (12.5)
2. Have comorbidity diseases/Illnesses	55 (52.9)
3. Comorbidity found: Hypertension	32 (58.2)
4. Have \geq 5 drugs (polypharmacy)	59 (54.8)
Warfarin use	
1. Patients do not know about warfarin	53 (51.0)
2. Period of time since starting warfarin (year): Mean \pm SD	4.04 \pm 3.70
3. Prescribed warfarin outside Wang Hin Hospital	38 (36.6)
4. Preparation of warfarin for taking: Patients themselves	73 (70.2)
5. Targeted INR for treatment: at 2–3%	97 (93.3)
6. Latest INR within target: %INR outside of target	39 (37.5)
7. %TTR outside of target <60%	67 (64.6)
8. Warfarin-related use hospitalisation (within the past six months)	10 (9.6)
Problems relating to the use of warfarin	
1. Past one year did not attend the treatment appointments	5 (4.8)
2. Missed appointments: Arriving late	27 (25.9)
3. % compliance on warfarin use (Mean \pm SD = 91.14 (0–100))	22 (21.3)
4. Warfarin leftover problem at home	53 (51.0)
5. Main cause for leftover warfarin (n = 53): - Receiving too much warfarin	23 (43.4)
- Forgetting to take warfarin	16 (30.2)
6. Patients' warfarin storage: Unsuitable	37 (35.6)
7. Found undesirable side effects from warfarin (n = 99)	13 (13.1)
8. Co-taking herbal medicine and diet supplement	18 (17.3)
9. Receiving medications from other institution	17 (16.3)
10. Chances of interaction: - Warfarin and other drugs	65 (62.5)
- Warfarin and food	16 (15.1)
- Warfarin and herbal medicines	14 (13.5)
11. Suitability of dosage (n = 99): - Too low dose	3 (3.0)
- Too high dose	2 (2.0)
Factors relating to the control of INR	
1.Receiving extra medicines from other services ^{a*} (<i>p</i> = 0.047)	%Patient Controlled INR
•Not received (n = 85)	58 (68.2)
•Received (n = 17)	7 (41.2)
2.Having inappropriate dosage ^{a*} (<i>p</i> = 0.046) : - Yes (n = 94)	64 (68.1)
- No (n = 5)	1 (20.0)
% Patients' compliance on warfarin (0–100) ^{b*} (<i>p</i> < 0.001):	Mean \pm SD
•Patient with %TTR \geq 60	97.66 \pm 3.47
•Patient with %TTR < 60	87.72 \pm 25.60

a = Fisher's exact test, b = Student's t-test, *statistical significance at *p* < 0.05

Unsuitable storage conditions for warfarin at home was also a problem; the most common three poor storage conditions were removal of pills from the packets and storing them without packaging (27.0%), removal of tablet packets from their labelled sleeves (27.0%) and storage of pills in wrongly labelled sleeves (13.5%). 13.1% of the sample had suffered undesirable side effects; all of them experienced minor bleeding. Regarding the use of herbal supplements, 18.3% had done so and 17.31% were still doing so. 61.33% were receiving medicines that may interact with warfarin; 62.5% had received warfarin and other medicines, and 15.2% took herbal medicines that may interact with warfarin. 13.5% received warfarin with foods that may interact with it.

Factors relating to the control of INR and %TTR

The patients' receipt of different medicines from institutions other than their usual ones, and the prescription of an appropriate dosage of medicine, were significantly related to the control of INR, with $p = 0.047$ and 0.046 , respectively. The patients' compliance on warfarin; for who had $\%TTR \geq 60$ was 97.66 ± 3.47 and the patients with $\%TTR < 60$ was 87.72 ± 25.60 were statistically different, $p < 0.001$.

Second phase: System development, implementation and evaluation

The development of a monitoring system for safe warfarin use in the community

A group discussion was conducted in order to design a monitoring system for safe warfarin use in the community. Questions were designed and adapted from the original ideas of the CCM model. Participants in the group discussion were those involved in supervising safe warfarin use in the community. There were nine participants in this study – one doctor, one pharmacist, three nurses (with one nurse from a hospital and two nurses from sub-district hospitals), one VHV, two patients and one patient caregiver. The analytical result from the group discussion was the idea to develop a monitoring system for safe warfarin use at the primary health care level. The operational protocol of the monitoring system was developed by an inter-professional team in the community, including doctors, pharmacists, VHVs, primary health care providers, local authorities, patients and caregivers (Figure 1).

The roles and responsibilities of each member in the team (Table II).

The assessment of the monitoring system for safe use of warfarin in the community after one month of implementation.

A group discussion was conducted in order to assess the system after a one-month implementation period (Figure 2). The participants in the group dialogue were those involved in supervising safe warfarin use in the community. They were divided into two groups: the health providers group and a group of patients and their caregivers. The former group consisted of one doctor, one pharmacist, three nurses (one nurse from a hospital and two nurses from primary care unit) and three VHVs. The latter group consisted of five patients and four caregivers.

Regarding satisfaction with the system on the part of the patients and their relatives, it was found that all patients and their caregivers were satisfied with the monitoring system. This was because such a structure continuously provided care for patients from hospitals to the community. The purpose of such a service was to ensure the safety of the patients. Home visits were conducted. When problems occurred, a system was in place for village health volunteers and Primary Care Unit (PCU) to be contacted and for them to provide care for people at home. Moreover, it also had positive mental effects on the patients as they could see that the medical personnel truly cared for their safety. Regarding the satisfaction of health providers with the monitoring system, everyone was satisfied with the patient supervision structure since it allowed continuous care for the patients at the community level and opened further means of opportunity for all sides, namely medical staff, patients and caregivers, to care for patients and truly benefit them. The participants in the group discussions were of the collective view that more effort needed to be made to further the level of awareness of individuals about their conditions and that increased knowledge of health and self-care should be delivered in such a way as to permit patients to apply it to their situations. Assessment of the amount of know-how of the patients and their caregivers should also be conducted. The qualitative data for all stakeholders' satisfaction that were collected from the focus group discussion (Table III).

Table II-1. Six elements CCM-based operational guidelines of the monitoring system for safe warfarin use in the community.

Elements of the system based on CCM	Operational guidelines of the system with inter-professional roles and responsibilities
1. Information sharing and patient transfer system (hospital to community)	<ul style="list-style-type: none"> • Wang Hin Hospital is the centre of the network for the collection and sharing of information. • Information is shared in document form, through the Line programme or email. • For patients who received medicines from other hospitals, the VHV considered their information and passed them on to Wang Hin Hospital or a sub-district hospital. • Patients are transferred as follows: for non-urgent matters, patients may travel by themselves with their relatives or carers; if no transport is available, then the sub-district hospital shall assist the patients in their transfer; in case of emergency, an ambulance should be called. • Patients, their relatives or carers shall be given information to assess the levels of severity of the illnesses.
2. Information sharing on health, hygiene and self-care by hospital pharmacists and inter-professional team	<ul style="list-style-type: none"> • Provide information and training for the patients and their relatives, providing them with information leaflets. • Transferred patients from other hospitals, together with their relatives, shall be given a revision of information. • Small discussion groups shall be arranged for information, experiences, problems and knowledge to be shared and discussed. • Community broadcasting centre shall be used to impart knowledge to the community. • Patient assessments shall be done to determine the level of care that they need and to assess their potential for self-care. • Build patients' capacity by allowing them to plan their own care for their illnesses with the health personnel team. • Learn more about the patients through home visits in order to understand their problems as well as their strengths and be able to better support the patients.
3. Clinical Information Technology and Policy by hospital pharmacists and inter-professional team	<ul style="list-style-type: none"> • Setting a notification system in the programme that the patients are on warfarin and cannot use some medicines. • Use programmes to provide services for patients and record problems found during their home visits to find solutions and plan for the next visit. • The executives need to be aware of the importance of warfarin and should provide support and allocate resources as needed. • The executives need to be clear in their policies and set development goals and guidelines towards them. Incentives should be created in their communications and exchange of information both within their own agencies and others.
4. Design the monitoring system to care for and monitor undesirable side-effects and missed appointments by inter-professional home-based care	<ul style="list-style-type: none"> • Determine roles and responsibilities for the team providing care to the patients and ensure clear orders for the working groups. • Develop a diagram for patient care to be used as a guideline for the care and transfer of patients. • Apply Long Term Care procedure for patients on warfarin. • For patients who cannot travel to hospital, such as the elderly and the disabled, home visits should be conducted and treatments provided at home. • Nurses or pharmacists at a hospital shall be responsible for checking whether the patients have missed their appointments. • Patients shall be monitored by telephone, or the sub-district hospital or VHV shall be notified to monitor the patients. • The VHV shall assist in finding out the reasons for patients' missed appointments and monitor patients who received their medications from other hospitals who missed their appointment. • Incentives should be created for patients to come to their appointments and receive their medications. The appointment cards should be clear to prevent the appointment from being forgotten.

Table II-2. Six elements CCM-based operational guidelines of the monitoring system for safe warfarin use in the community.

Elements of the system based on CCM	Operational guidelines of the system with inter-professional roles and responsibilities
5. Training and capacity-building in patient care for officers and the support of clinical decision-making by home-based care team	<ul style="list-style-type: none"> • Training and capacity-building sessions shall be held for the management and care of the patients. These were done by health professionals from the hospital. • Lessons learned and field trips shall be taken from and in model areas where patient care has successfully been achieved. • In-home patient care shall be explored to gain a true understanding of patients. • A handbook shall be developed to provide care guidelines for sub-district hospitals and a diagram shall be created on the care and transfer of patients. Information shall be acquired from reliable sources.
6. System for giving advice and liaising with agencies	<ul style="list-style-type: none"> • Advice about warfarin treatment may be given through the Line programme, Facebook messenger or by telephone from the pharmacist. • Doctors or pharmacists may be consulted during work hours on days when chronic disease clinics at sub-district hospitals are in operation. • The VHV shall assist as a liaison when advice is needed or when officers need to be contacted. • Patients may consult doctors or pharmacists when receiving services at hospitals. • Channels of communication between the community hospitals, sub-district hospitals and the community itself may be through the following: emails, VDO call, Line programme, using the transfer document or telephone.

Table III-1 Satisfaction with the warfarin monitoring system in primary health care – focus group

Stakeholders	Their satisfaction with the warfarin monitoring system in primary health care
Health care providers	<p>Medical Doctor 1 in Hospital ‘...As for satisfaction, I am satisfied. This is because if the syst can really be done properly throughout, it would be useful and would decrease my worklo From what I have seen, I think it has reached an appropriate point now since the patients : informed in advance. I do not have to spend time explaining the same thing over and over ag to each patient. If I have to keep on doing that, it would have taken up too much of my tir When outpatients come for their examination, there is no need for such explanation. I just ne to inform them the results of their blood test, adjust their medication and warn them about : side effects from the adjustment that they need to be aware of...’</p> <p>Nurse 1 in Primary Care ‘...Regarding satisfaction, I think the system that we initiated me: we are a model of primary health care. That is to say we can see a drastic change in the syst when a patient on warfarin comes to our Primary Health Care. As our community hospital, wh is a network centre hospital, has established a pop-up system for us, we can see that suc patient is on warfarin. This is so even if the patient does not inform us. We just need to en the patient’s information into the system and the information pops up. We can also acc information on the patient’s medicine and herbal use. For example, if a patient comes complaining of aches and pains, we can see what medication of pain relief we can give in addit to what the patient already has. The satisfaction I meant is that we have a good network wh has created a pop-up information for us. Our system of primary care service can be bet provided to this group of patients....’</p>
Patients	<p>PT1 ‘...Yes, I am satisfied. It is more convenient, and the doctor can follow up on the patie throughout the process, from hospital to home care...’</p> <p>PT2 ‘...The care is provided even at home. If anything were to happen, then we can cont someone quickly. The village health volunteer can also better liaise with the primary hea care. As I live near a VHV, I feel that if anything happens then I can call on them. This is especia true if I am seriously ill and my partner or children are not home. I feel more relieved now t the system is in place...’</p> <p>PT3 ‘...The strong point here is its benefit. We are not afraid to consult with the primary hea care personnel in our area. The personnel can also see the living conditions that a patient warfarin is in. So, they know our problems and we can work together to solve them...’</p>

Table III-2. Satisfaction with the warfarin monitoring system in primary health care – focus group

Stakeholders	Their satisfaction with the warfarin monitoring system in primary health care
Community Representative (VHV)	<p>VHV1 ‘...As for the system, I am satisfied that all sides can participate and co-operate through it. This is especially the case between the community and the hospitals. The system helps us work better with other agencies. What is clear is that where there is community-based care, the VHVs can link their work with the hospital to care for the group of patients too...’</p> <p>VHV2 ‘I used to be on this medication. Most VHVs really do not know what warfarin used for and why it needs to be taken. They only know that the doctor prescribed from the hospital. However, now that the information all linked up through the system all the way down to community level, it is beneficial to our VHVs, the village and the community. We are beginning to understand the benefits and the danger of the medicine. When a patient experiences side effects, we know the basics of what to do. The system is beneficial to all VHVs, doctors and nurses, as well as all of our patients in the community too.’</p>

The research identified problems relating to patients keeping their appointments and found that missed appointments were a problem, with 38.5% of the sample falling into this category, a higher proportion than what was shown in the research conducted by Wangsook *et al.* (2014), with 23.9% of their sample experiencing the same issue. There were various causes: patients finding alternative treatment methods such as cannabis oil, patients misunderstanding instructions and therefore believing that doctors had told them to stop taking their medication and patients deciding to stop the treatment themselves since they felt fine and decided to stop the appointments altogether. Awareness and understanding are needed in terms of this group of patients, and they should be persuaded to continue their treatments and come to their appointments. The research found that 91.1% of the participating patients were compliant in taking their medication.

The lack of cooperation in some patients was the result of forgetfulness and then stopping their medicine when they suffered from other illnesses. Thus, in order for the medication to successfully treat patients, compliance needs to be maximised. The problem of leftover medicine was mostly a result of receiving too much of it. The most common problem regarding storage was pills being taken out of their packets, with 27.0% of the sample doing so. Other medicine storage problems included storing pills in damp places or places with high temperatures. Problems with drug interactions between warfarin and other medications were also found, with simvastatin being the most common

medication to interact with warfarin (36.6% of the sample). However, since this is the type of medicine that most patients need to use continuously, the dosages of warfarin were adjusted so as to be suitable for the patients.

This was consistent with the study of Jittsue *et al.* (2015) that found simvastatin to be the medicine most likely to interact with warfarin: 52% of their sample fell into this category. The investigation also found many patients that used herbal medicine or dietary supplements (16.4%). Patients wishing to use these medicines and supplements should always consult a medical doctor prior to taking them. The research examined the relationship between the warfarin use problem and the control of INR; receiving other medications for different illnesses from a health care centre other than their usual one was related to the control of INR with statistical significance. Such patients sometimes received medicine that may interact with warfarin, leading to difficulty with controlling their INR. With respect to the suitability of dosages for patients, those whose INR was too high or too low and who had not had their warfarin intake adjusted were found to have difficulties controlling their INR. This was different from the results of research conducted by Saengsuwan *et al.* (2019) that found the factors relating to the control of INR were marital status, educational level and whether the patient was an existing patient of the relevant health institution. The research presented here demonstrates the relationship between the control of INR and %TTR. The compliance of patients in using warfarin related to %TTR \geq 60 with statistical significance.

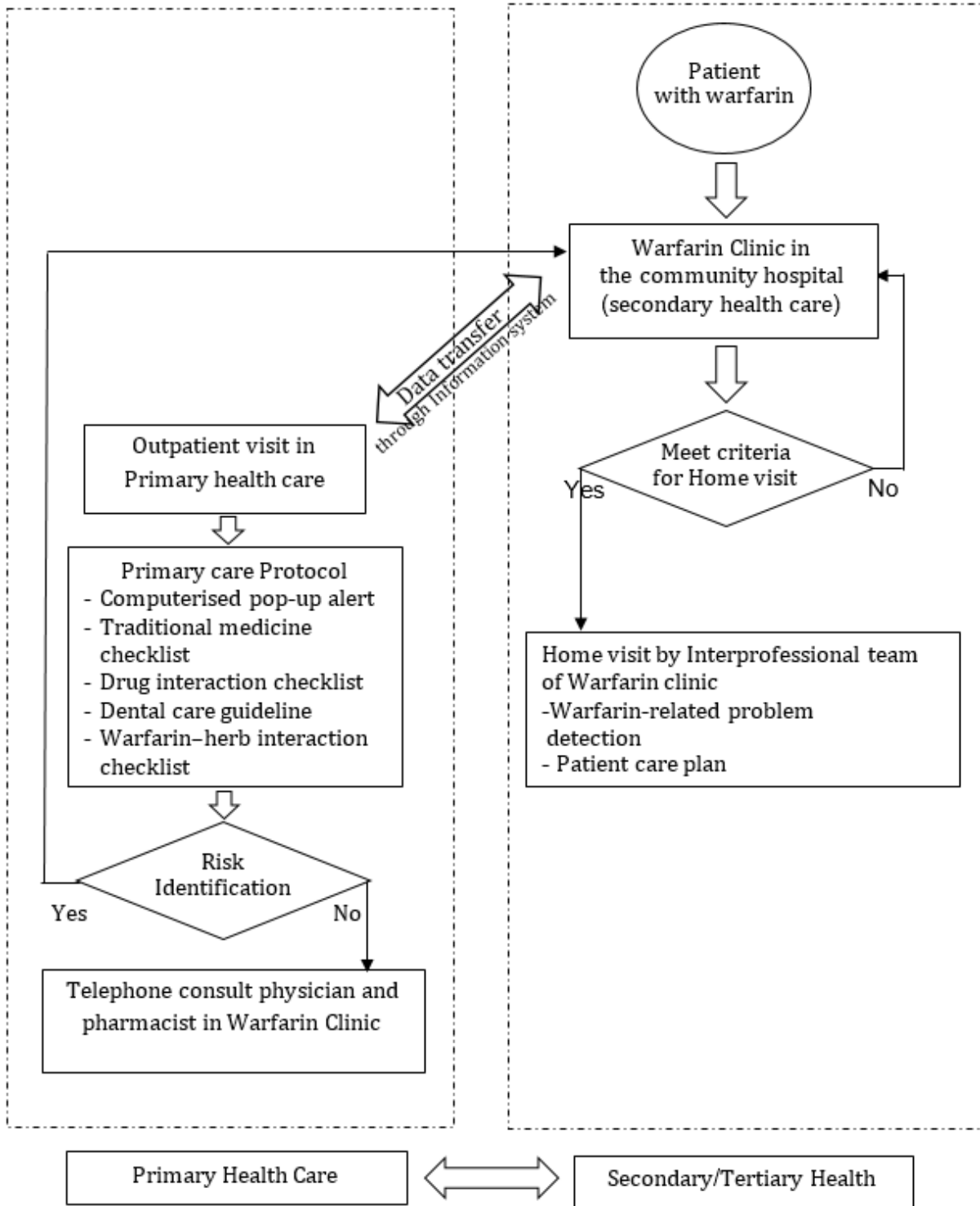


Figure 1. Developed protocol of warfarin safety monitoring in primary health care

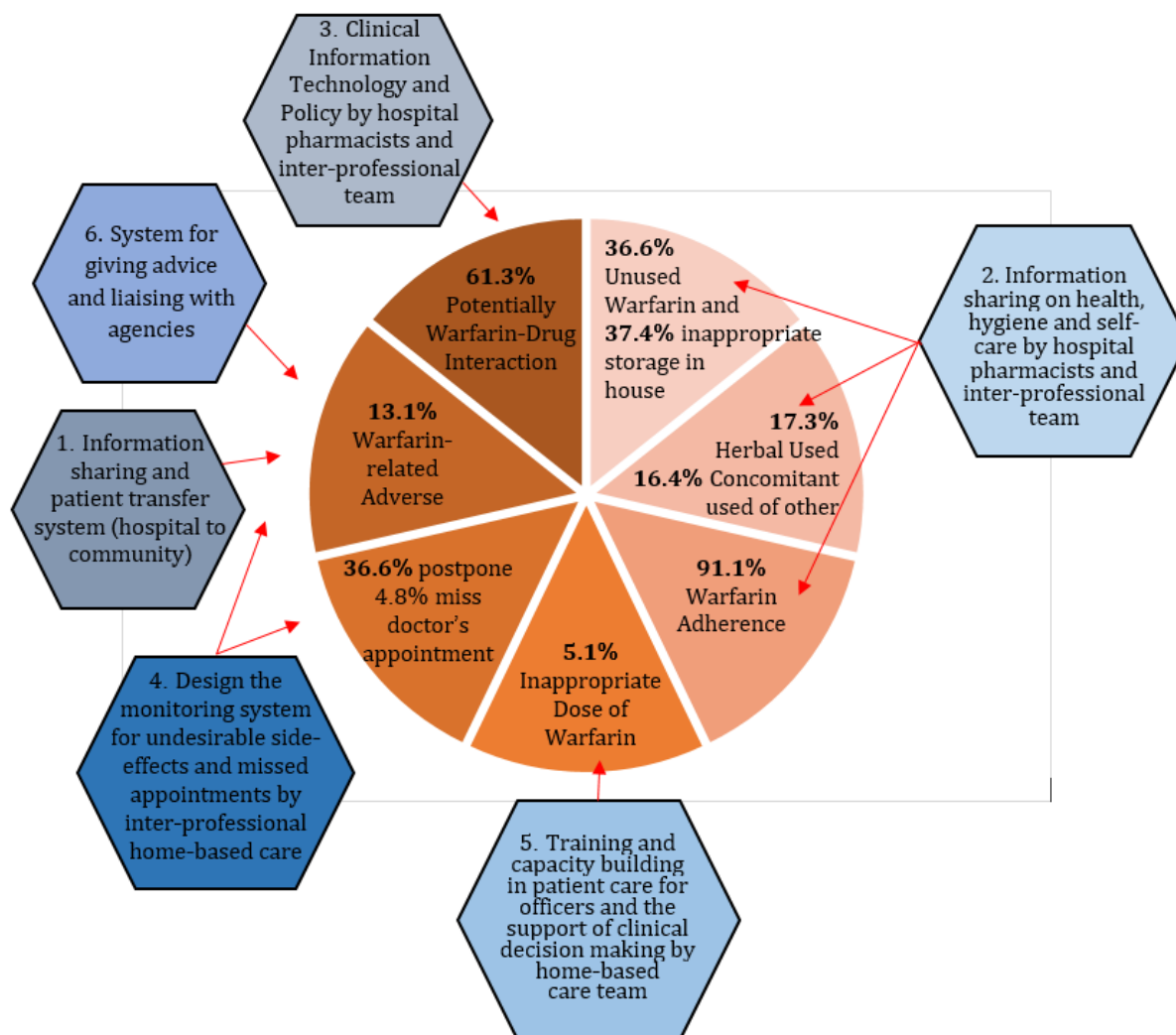


Figure 2. Warfarin-related problems and six elements CCM-based warfarin monitoring system

The examination that was carried out by Yomsrikhen *et al.* (2017) found that the variable relating to the INR control to the most significant extent was the use of more than three other medications. However, this research did not find the use of more than three other kinds of medication to be statistically related to %TTR \geq 60. When the problems relating to warfarin usage were identified during the first phase of the investigation, the researcher, as a pharmacist, initially gave advice to the patients. For problems relating to leftover medicine, they took the medicine back to the hospital. With regard to unsuitable storage conditions, they advised the patients on the proper storage of medication. In terms of issues relating to the taking of herbal

medicines or dietary supplements, they advised the patients to stop using them. In cases where the patients received medications from other health care institutes, the researcher advised the patients to stop taking the medications that interact with warfarin. When patients lacked knowledge or understanding of warfarin, they gave the correct explanation and information to the patients.

The development of a monitoring system for safe warfarin use at a primary health care level was examined. Comparisons were made with the research results of a study on patient care in diabetes type 2 cases at a PCU of Naresuan University Hospital. It was found that the Chronic Care Model for primary health care of patients was also used, but in a different manner. In research

conducted by Cherngyooth *et al.* (2012), the results included measurements of decreased blood sugar levels. The supervisory system was compared to the development of care systems for diabetic patients at Chaiyaphum Hospital (Cherngyooth *et al.*, 2012), which also applies a Chronic Care Model to all six factors at a community level but in an alternative way. An investigation performed by Luecha *et al.* (2013) assessed the operational results by the level of HbA1C and the decreased number of complications. The present examination did not gauge the operational results of the system since it had only been used for a short period of time (one month). The research was compared to the development of care networks for patients on warfarin at the sub-district hospital of Ratchawongsa district, Amnat Charoen province (Aphisitsak, 2016). The network's method of operation was similar to the system that was implemented in this study in that it involved the systematic transfer of patients receiving treatments from community hospitals to PCU. Primary care units played a role in home visits in their area of responsibilities, in the treatment and care of patients in accordance with guidelines of care for patients on warfarin at PCU, and shared information from PCU with community hospitals. It also recommended (Akor, 2021) that pharmacists in both secondary health care and primary health care settings should provide integrated warfarin care between the two levels.

The focus group discussions provided operational guidelines of the monitoring system for safe warfarin use in the community covering six elements of CCM. The plan, resources and management were initiated by all stakeholders. They developed and designed a monitoring system for safe warfarin use and tested it. The medical personnel, patients and their caregivers were satisfied with the system. This is similar to the study and assessment of projects connected with creating care networks for patients on warfarin at PCU (Grunau *et al.*, 2011). The difference is that this present study found that the issues and hindrances faced by the system were the lack of information possessed by new patients who received medications from other hospitals and the lack of advertisement of, or publicity for, the structures. The suggestions made as part of this examination indicated that a network of patients and their caregivers is needed in order to exchange data and knowledge. Interdisciplinary medication management with clear assignment of inter-professional roles and responsibilities will

facilitate good collaborative practice and improved patient outcomes (Eickhoff *et al.*, 2021). Technology or computer programmes may also be used to care for patients. Further cooperation with other agencies is also needed in order to facilitate care for patients in the community.

CONCLUSION

The conclusion of this research is that there were warfarin-associated problems at patients' homes that were identified during home visits. Some of these problems could not have been identified at hospitals. The significant difficulties that were experienced by patients on warfarin were missed appointments, drug-drug interactions, improper storage of medicine and use of herbal products or dietary supplements. Factors that affected the control of INR included patients receiving other medicines from different health care providers, inappropriate dose of medicines and the patients' adherence to medical advice for taking their medicine. The most concerning warfarin-associated problem is warfarin nonadherence because it affected TTR and INR control. Another concern is the potential for warfarin-drug interactions, which is a major cause of life-threatening events or permanent damage. In this study, a Chronic Care Model was adapted to care for patients on warfarin, creating a monitoring system for safe warfarin use by focusing on dealing with warfarin use problems and the prevention of undesirable side effects that may occur.

Recommendations for further research on the effectiveness of the monitoring system for safe warfarin use in the community should be examined. The system needs to be followed continuously and the long-term assessment of the system may be achieved by: (1) repeated home visits to patients in order to examine warfarin-related complications and compare the results before and after the system is put in place in primary health care; (2) assessing the system performance by using the Ministry of Public Health's KPI; and (3) examining the levels of satisfaction that are felt by the relevant people who are involved with the system in order to assess the system and seek further recommendations for its improvement.

What do we already know about this topic?

Warfarin, a high-risk medication, has been found to have a high incidence of use problems, including warfarin-drug or herb interactions, non-compliance, missed treatment appointments and serious adverse side effects, especially when

patients using warfarin are in communities during the COVID-19 pandemic. The crucial reason is that there is no compulsory warfarin safety monitoring system at the primary care level of Thai healthcare; it is implemented only in secondary care and tertiary care. Moreover, the community has no opportunity to participate in taking care of patients using warfarin for system sustainability. The warfarin safety monitoring system at the primary healthcare level is needed for community implementation.

How does your research contribute to the field?

From home visits for all patients with warfarin in communities that were in the catchment area of a secondary care hospital, we determined the main warfarin use problems that the warfarin clinic in the hospital could not easily investigate from outpatient hospital visits. These problems included unused warfarin at home, inappropriate warfarin storage, patients suffering from the side effect of minor bleeding, potential warfarin-herb interactions and patients experiencing drug-warfarin interactions.

All stakeholders in the community, including doctors, pharmacists, nurses, village health volunteers (VHVs), patients and their caregivers, were given the opportunity to participate in creating a protocol of warfarin safety monitoring in primary health care using the chronic care model (CCM) as the grounded theory. The warfarin monitoring system that was developed consisted of six elements and was the joint effort of primary health care personnel and the inter-professional team of the hospital. The system promoted the continuity of services from the hospital to the community. After a one-month implementation by an inter-professional team, all three groups of stakeholders were satisfied with the results.

What are the implications of your research towards theory, practice or policy?

The warfarin safety monitoring system has been created and implemented by the stakeholders in the community. They used CCM as the grounded theory for a holistic approach in the system development. The intermediate outcome and the satisfaction of stakeholders were evaluated. This is the first move of a community-based monitoring system for patients using warfarin. These findings will be used as evidence for health policy makers, health professionals and people in the community to participate in the planning and implementation of the warfarin monitoring system. The system could also be generalised to other communities or

other high-risk medications to benefit patients at the primary health care level.

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