DEVELOPING AND EVALUATING STRATEGIES TO IMPLEMENT AN INSULIN PATIENT DECISION AID IN AN ACADEMIC PRIMARY CARE CLINIC IN MALAYSIA

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FACULTY OF MEDICINE
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ABSTRACT

Patient decision aids (PDAs) are decision-making tools to facilitate shared decision-making; however, their routine use in clinical consultations is still lacking. This study aims to develop and evaluate strategies to effectively implement a locally developed insulin PDA in an academic primary care clinic in Malaysia. This implementation study began with a qualitative exploration to identify PDA implementation barriers in Malaysian public healthcare settings (Phase 1). In Phase 2, an implementation intervention was systematically developed for the insulin PDA in an academic primary care clinic. This involved stakeholders using a multi-voting technique to prioritise Phase 1 barriers. Next, strategies were identified to overcome the prioritised barriers based on evidence, pragmatic suggestions from clinic stakeholders, and implementation taxonomies. The intervention was finalised through a clinic stakeholders meeting. In Phase 3, a mixed-methods evaluation was conducted to assess implementation outcomes guided by the 'Reach', 'Adoption', 'Implementation', and 'Maintenance' dimensions of the RE-AIM framework. In Phase 1, unique and prominent barriers to the insulin PDA implementation were found in the Malaysian healthcare settings such as role boundary, the lack of continuity of care, the lack of SDM culture, language barrier, and patient literacy level. In Phase 2, 13 barriers were prioritised and they were related to healthcare providers' (HCP) roles, patient's characteristics and attitudes, and follow-up difficulties. Eleven strategies including training, feedback, PDA availability, and systematic documentation were integrated into an implementation intervention to address the barriers. The outcomes showed that for 'Reach', 88.9% of the doctors received PDA training and this was attributed to their self-motivation, mandated changes, and timing of the PDA workshop. The PDA reached 387 patients and was facilitated by the doctors who delivered the PDA to them and their own desire to know more about insulin. Barriers to reaching patients were their attitudes towards their health, and lack of interest to initiate insulin. Doctors' adoption of the PDA was high (83.3%) and was attributed to their positive experience with the PDA use, its usefulness, and the training workshop effectiveness. Barriers to adoption were patients' non-use of the PDA, availability of doctors in the clinic, and the lack of effectiveness of the strategy 'Provide feedback'. Patients' adoption was moderate where only 65.7% read the given PDA. Among the reasons for not reading the PDA were a lackadaisical attitude towards their health, and perceived adequate knowledge about diabetes and insulin. The degree of 'Implementation' of the PDA varied for different tasks and was challenging for reasons such as the perception of unnecessary steps, the clinic's appointment system, and nurses' attitudes. Finally, for 'Maintenance', 80% of the doctors were willing to continue using the PDA due to its benefits. In conclusion, this study outlines a systematic process of developing PDA implementation intervention. When implementing PDAs, it is crucial to consider the healthcare culture and system. Focusing on implementation efforts such as training to improve providers' knowledge and skills, organisational leaders' support and utilising a documentation system to facilitate follow-ups can lead to a higher reach and adoption of PDAs.

Keywords: Implementation, Implementation research, Patient decision aids, Shared decision making, Type 2 diabetes mellitus

ABSTRAK

Alat bantuan membuat keputusan (PDA) adalah alat untuk membantu pesakit untuk membuat keputusan bersama; walaubagaimanapun, penggunaan PDA semasa konsultasi masih ditahap yang rendah. Tujuan kajian ini ialah untuk membangun dan menilai strategi implementasi penggunaan PDA untuk permulaan rawatan insulin untuk penyakit kencing manis jenis 2 (insulin PDA) di salah satu klinik rawatan akademik di Malaysia. Fasa 1 kajian ini dimulakan dengan kaedah kualitatif untuk mengenal pasti halangan yang akan dihadapi sekiranya pengunaan PDA dilaksanakan di klinik kesihatan awam di Malaysia. Di Fasa 2, satu intervensi penggunaan insulin PDA di satu klinik rawatan akademik telah dibangunkan. Pembangunan intervensi ini dilakukan secara sistematik dengan melibatkan pihak berkepentingan klinik dalam satu sesi multivoting untuk mengenal pasti halangan-halangan utama daripada hasil kajian kualitatif di Fasa 1. Seterusnya, strategi pelaksanaan telah dikenalpasti daripada penilaian literatur, taksonomi strategi pelaksanaan dan juga cadangan-cadangan pragmatik dari pihak berkepentingan di Fasa 1 untuk mengatasi halangan-halangan utama ini. Strategi pelaksanaan intervensi telah dimuktamadkan setelah mencapai persetujuan/konsensus bersama dengan pihak berkepentingan klinik. Dalam Fasa 3, kaedah gabungan digunakan untuk menilai hasil implementasi dipandu oleh dimensi *'Reach', 'Adoption', 'Implementation', and 'Maintenance'* dalam rangka kerja RE-AIM. Dalam Fasa 1, antara halangan utama yang telah dikenalpasti untuk pelaksanaan implementasi insulin PDA di klinik kesihatan awan Malaysia adalah batasan peranan pengamal perubatan, kekurangnya rawatan susulan, kekurangan budaya membuat keputusan bersama, masalah pertuturan bahasa dan tahap literasi kesihatan pesakit. Dalam Fasa 2, 13 halangan utama telah dikenalpasti dan ianya berkaitan dengan peranan pengamal perubatan, ciri-ciri dan sikap pesakit, dan kesukaran untuk rawatan susulan. Sebelas strategi pelaksanaan telah dibangunkan untuk mengatasi halangan tersebut. Antara strategi intervensi pelaksanaan yang dibangunkan adalah dengan menyediakan latihan penggunaan PDA kepada pengamal perubatan, pemberian maklum balas, ketersediaan insulin PDA di klinik dan juga proses dokumentasi sistematik secara menyeluruh. Hasil kajian menunjukkan seramai 88.9% doktor (*Reach*) telah menyertai bengkel latihan pelaksanaan PDA di klinik disebabkan oleh motivasi diri, mandat yang telah diberikan, dan kesesuaian waktu bengkel/latihan. Seramai 387 pesakit telah menerima insulin PDA daripada doktor dan faktor lain seperti keinginan pesakit sendiri untuk mengetahui tentang insulin dengan lebih lanjut. Antara faktor halangan untuk pesakit menerima insulin PDA adalah sikap pesakit terhadap isu kesihatan dan kekurangan minat untuk menerima rawatan insulin. ‘*Adoption*’ insulin PDA oleh doktor adalah tinggi (83.3%) dan dikaitkan dengan pengalaman positif dengan penggunaan PDA, kebergunaan insulin PDA dalam proses konsultasi dan keberkesanan bengkel latihan PDA. Halangan untuk penggunaan PDA adalah disebabkan oleh pesakit yang tidak menggunakan PDA yang diberi, kekurangan doktor yang bertugas di klinik dan kekurangan keberkesanan strategi ‘pemberian maklumbalas’. Manakala untuk ‘Adoption’ insulin PDA antara pesakit, hanya seramai 65.7% pesakit yang membaca PDA yang diberi. Antara alasan tidak membaca PDA adalah sikap kurang endah terhadap kesihatan mereka, dan pesakit merasakan mereka telah mempunyai pengetahuan yang cukup mengenai diabetes dan insulin. Bagi ‘*Implementation*’, tahap perlaksanaan PDA berbeza bagi langkah-langkah yang berlainan. Antara cabaran untuk implementasi PDA ialah persepsi terhadap langkah-langkah perlaksanaan yang tidak diperlukan, halangan sistem janji temu klinik, dan sikap jururawat. Akhirnya, bagi '*Maintenance*', seramai 80% doktor menyatakan kesudian untuk terus menggunakan PDA didalam konsultasi kerana manfaatnya. Kesimpulannya, kajian ini menggariskan satu proses untuk membangunkan strategi pelaksanaan PDA di klinik kesihatan awam. Budaya dan sistem penjagaan kesihatan adalah salah satu faktor yang penting untuk dipertimbangkan dalam proses pelaksanaan PDA di klinik kesihatan awam. Hasil kajian ini juga menunjukkan bahawa pelaksanaan yang berfokus kepada latihan pengetahuan dan kemahiran pengamal perubatan, sokongan pemimpin organisasi dan penggunaan sistem dokumentasi untuk memudahkan susulan dapat membawa kepada ‘*Reach’* dan ‘*Adoption’ PDA* yang tinggi.

Kata kunci: Implementatsi, kajian implementasi, alat bantuan membuat keputusan, membuat keputusan bersama, Diabetes mellitus jenis 2

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LIST OF SYMBOLS AND ABBREVIATIONS

BCT	Behaviour change technique
CJN	Chirk Jenn Ng (the researcher’s supervisor)
DVD	Digital versatile disc
EMR	Electronic medical record
EPOC	Effective Practice and Organization of Care
ERIC	Expert Recommendations for Implementing Change
HCP	Healthcare provider
MAGIC	Making Good Decisions in Collaboration
NHS	National Health System
PDA	Patient decision aid
PYL	Ping Yein Lee (research collaborator)
RCT	Randomised controlled trial
RE-AIM	‘Reach’ ‘Effectiveness’ ‘Adoption’ ‘Implementation’ ‘Maintenance’
SD	Standard deviation
SDM	Shared decision making
TICD	Tailored Implementation in Chronic Diseases
UMMC	Universiti Malaya Medical Centre
UK	United Kingdom
US	United States
USD	United States dollar
YKL	Yew Kong Lee (the researcher’s supervisor)

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

1.1 Introduction

This chapter provides the background and rationale for conducting this study. It begins by introducing shared decision making (SDM) and patient decision aids (PDAs). Then, it describes the issues surrounding their implementation. This chapter also highlights gaps identified when developing implementation interventions for PDA. Then, an insulin PDA, which was developed in Malaysia is introduced and the study rationale is described. This chapter ends with the study's overall aim and objectives, followed by a summary.

1.2 Shared decision making (SDM) and patient decision aid (PDA)

Before, patients accepted treatments and advice from healthcare providers (HCPs) willingly without questioning due to the fact that they were grateful for the free medical treatment that they could not afford and the belief that doctors know best. However, with the growing amount of health information, patients are more knowledgeable and have expectations towards the health care they received (Coulter & Oldham, 2016). Now, many patients want to be involved in their healthcare. By supporting them to do so can help to provide the care they need and at the same time reduce the burden on health services (The Health Foundation, 2016). Many healthcare organisations have also begun to move from clinician-centered to patient-centered care (Coulter & Oldham, 2016; Gaudet, 2011; Institute of Medicine Committee on Quality of Health Care in America, 2001). In patient-centered care, patients are players in their own healthcare as their health needs drive their clinical decisions. Their desired outcomes take into consideration their emotional well-being, preferences, needs, and values (NEJM Catalyst, 2017).

SDM is an integral part of patient-centered care. Patients collaborate with clinicians on a treatment consensus considering evidence-based information about treatment options, risks, benefits, and outcomes (Coulter & Collins, 2011). It is particularly relevant when the decision is preference-sensitive; decisions that have no single best option, or, when there is a balance between benefits and harm of a treatment (Keirns & Goold, 2009). Patients often faced decisional conflict and have unrealistic expectations when they are given preference-sensitive decisions (Hoffmann & Del Mar, 2015). This can lead to decision delays, discontinuance with the chosen treatment, regret, dissatisfaction, and even blaming HCPs for negative outcomes (Gattellari & Ward, 2005). The goal of SDM is to provide patients with quality information to support them in making an informed decision about their treatment options. Several decision support innovations can facilitate the SDM process, such as, training clinicians to support patients in decision-making, decision coaching, and use of PDAs. Among these innovations, PDAs are the most well-studied and effective (Stacey et al., 2017).

PDAs are evidence-based tools that HCPs can use with patients to help them make informed decisions about health treatment options (Coulter & Collins, 2011). PDAs provide explicit information about the treatment decision, the available treatment options based on scientific evidence, and the pros and cons of each option (Drug and Therapeutics Bulletin, 2013). PDAs are distinct from general health educational materials in that, apart from containing educational information about treatment options, they also include values clarification. Values clarification enables patients to deliberate the risks and benefits of treatment options against their values and preferences when making treatment decisions (Koon, 2020). The Decision Aid Library Inventory Canada hosts the most comprehensive collection of PDAs to date with more than 300 PDAs of varying topics and formats, such as printed and web-based materials, and digital versatile discs (DVDs) (The Ottawa Hospital Research Institute, 2020).

In 2017, a Cochrane systematic review (Stacey et al., 2017) of 105 randomised controlled trials (RCT) showed that PDAs improve decision-making processes, improve patient value alignment, and influence some health decisions. For decision-making, PDAs increase a patient's knowledge, the accuracy of risk perceptions, involvement in decision-making, and improve patient-doctor communication (Stacey et al., 2017). PDAs help patients reduce decisional conflict and make informed decisions that align with their values. Some studies showed that patients who used PDAs favour conservative options compared to surgeries (e.g. in prostate cancer) or were more likely to initiate new medications (e.g. for diabetes). Adverse events from PDA use were not reported in any of the studies (Stacey et al., 2017).

1.3 Poor implementation of PDAs in routine clinical practice

Despite the abundance of PDAs and the level of evidence on their effectiveness, the implementation of PDAs in clinical practice remains poor (Elwyn et al., 2013; Herrmann, Mansfield, Hall, Sanson-Fisher, & Zdenkowski, 2016). One study showed that PDAs were not used even when they were freely available (Hill et al., 2009). A systematic review of 17 studies on the integration of PDAs into routine clinical practice found that no studies achieved the "maintenance" level (new practice integrated into routine use); most of the studies (n=10) only achieved the level of "insights" (understanding and insights into implications for routines) while four achieved the level of "change" (actual adoption, try out change in practice) (Elwyn et al., 2013).

The barriers to implementing PDAs in routine settings include time constraints, HCPs' attitudes, the perceived legitimacy of the PDA, lack of applicability due to patient characteristics, clinic capacity, processes of care, and the health care environment (Elwyn et al., 2013; Gravel, Legare, & Graham, 2006; Shultz & Jimbo, 2015). Facilitators to PDA implementation were provider's motivation, provision of training and skills development for providers and, identification of a clinical champion. Additionally, the introduction of a system whereby eligible patients were systematically identified and supported the use of PDAs ahead of relevant clinical consultations, and the positive impact on the clinical process and patient outcomes also were facilitators (Elwyn et al., 2013; Gravel, Legare & Graham, 2006).

1.4 Gaps in the process of development of implementation intervention for PDA implementation

It has been reported that interventions are often haphazardly designed and poorly specified (Flodgren et al., 2011; Michie & Johnston, 2012). Gaps in intervention development were also found among PDA implementations. Implementation of health innovation is a large endeavor involving many steps (barrier identification, selection of strategies, evaluation), variables (innovation, settings, determinants, strategies, types of outcomes), stakeholders (researchers, providers, consumers), and methods (observation, interviews, survey, literature review). Therefore a systematic approach is crucial to disentangle the complexity of intervention development by ensuring relevant steps, variables, stakeholders and methods are included. However, there lacks a systematic approach to intervention development among PDA implementation studies (Holmes-Rovner et al., 2000; Silvia & Sepucha, 2006). Eventhough the use of theories, models, and frameworks were recommended to guide translating research innovations to practice (Nilsen, 2015; Proctor, Powell, & McMillen, 2013), few PDA implementation studies have reported using them (Elwyn, et al., 2013). Implementation that did not use a guiding framework can hamper efforts due to the lack of understanding of key variables, the relationships to be tested and understanding of mechanisms by which implementation strategies exert their effects (Proctor, Powell, Baumann, Hamilton, & Santens, 2012). This can result in flawed understanding about the implementation context, development of inappropriate interventions, erroneous conclusions and, wasted resources (Moullin et al., 2020).

In some PDA implementation studies, the intervention development process was found to be too simplistic as the strategies selected seemed to be based on intuition or familiarity with a specific strategy instead of an explicit rationale (O'Cathain, Walters, Nicholl, Thomas, & Kirkham, 2002; Uy, May, Tietbohl, & Frosch, 2014). Some PDA implementers simply let implementation sites or HCPs decide how to implement the PDAs in their practice (Holmes-Rovner et al., 2000; Silvia & Sepucha, 2006; Wirrmann & Askahm, 2006). Thus, the lack of guidance and support was reported to hamper effective implementation (Frosch, Singer, & Timmermans, 2011).

In addition, there is also a lack of partnership between implementers, and HCPs and patients in the design of the intervention. Intervention that did not consider key stakeholders are less likely to achieve effective implementation as the priorities and preferences of the stakeholders don’t fit with the purpose of the PDA (Hsu, Liss, Westbrook, & Arterburn, 2013).

1.5 Malaysia and the burden of diabetes

Malaysia is a Southeast Asian country with a population of 32.7 million. Its population comprises of three main ethnic groups; Malay and Bumiputera (69.6%), Chinese (22.6%), Indian (6.9%), and others (1.0%) (Department of Statistics Malaysia, 2020). In 2018, the Malaysia’s gross domestic product per capita was United States Dollar (USD) 10,747.33 (Department of Statistics Malaysia, 2018) and the World Bank classified the country as an upper, middle-income nation (The World Bank, 2018).

Type 2 diabetes is a major health problem in Malaysia and its prevalence continue to rise (Institute for Public Health, 2019). It is a significant factor for cardiovascular disease that is the leading cause of death in Malaysia (Department of Statistics Malaysia, 2019). As nearly three-fourths of Malaysian diabetic patients are unable to achieve glycaemic targets (Feisul & Azmi, 2013), insulin is now recommended for early treatment (Ministry of Health Malaysia, 2009). However, there are a number of factors and misconceptions that make Malaysian patients reluctant to initiate insulin therapy such as fear of pain and injections, risks for kidney failure, and the perception that insulin therapy indicates end stage diabetes (Nur Azmiah, Zulkarnain & Tahir, 2011; Lee, Lee, & Ng, 2012; Ng, Lai, Lee, Azmi, & Teo, 2015; Tan, Asahar, & Harun, 2015; Wong et al., 2011). There is a need to support decision making for insulin use to control blood sugar and one way to do this is the use of PDA.

1.6 The insulin PDA in Malaysia

In 2012, an insulin PDA booklet (Lee et al., 2012) was developed in Malaysia to promote SDM practices and to help people living with type 2 diabetes make informed decisions about their treatment (Lee, 2014). The development of the insulin PDA began in 2010 and was based on evidence from a systematic review, decision support theories and frameworks, and the needs of local healthcare managers, clinicians, and patients (Lee, 2014). The PDA was first developed in the English language and subsequently translated to the Malay, Chinese and Tamil language to cater to the multiethnic and multilingual population in Malaysia. The translations were conducted by professional translators and checked by HCPs to ensure accuracy. The insulin PDA aims to help people living with type 2 diabetes make informed decisions about starting insulin but also recognises the value of offering patients other treatment options.

The booklet has 12 pages divided into five sections (Appendix A: The insulin patient decision aid). The first and second sections provide information about diabetes and insulin, and the pros and cons of available treatment options. The third section entails the value clarification exercise where patients share what is important to them about insulin initiation and their concerns with insulin. Subsequently, patients are asked explicitly if they needed more support before finally making a decision. It is emphasised in the insulin PDA that it is not meant to replace a medical consultation and the patient should discuss treatment options with a HCP. According to the International Patient Decision Aids Standards Collaboration, which assesses the quality and standards of a PDA, the insulin PDA scored 7/7 for decision aid criteria (to be defined as a PDA) and 5/8 criteria that the PDA can lower the risk of making a bias decision (The Ottawa Hospital Research Institute, 2020). Following development, the insulin PDA has not been formally implemented.

1.7 Rationale of the study

PDA implementation studies show that PDAs are still underutilised in routine clinical practice despite their availability and proven effectiveness. This gap in the translation of evidence-based innovations into practice is exacerbated by the lack of clarity in literature on how interventions can be systematically developed to increase the success of PDA implementation in different health settings.

In the local context, findings on PDA implementation are mainly from developed and western countries and they may not apply to Asia, where socio-cultural barriers such as language (Ng et al., 2013), physician paternalism (Claramita, Nugraheni, van Dalen, & van der Vleuten, 2013; Ng et al., 2013) and the lack of infrastructure or technology development are more significant (WHO, 2012). While an increasing number of PDAs are being developed in the region such as in Hong Kong and Malaysia, few studies have reported the implementation of these PDAs (Huang et al., 2015).

Therefore, a study that systematically develops and utilises strategies for PDA implementation in the Asian context is needed. To date, the insulin PDA has not been formally implemented in the Malaysian healthcare setting. This forms the implementation context for this study.

1.8 Study overall aim and specific objectives

This study is a pilot implementation aimed to explore barriers and facilitators to the insulin PDA implementation, and systematically develop and evaluate an intervention that could effectively implement the PDA in an academic primary care clinic in Malaysia. The findings of this study aim to inform future PDA implementations.

The specific objectives of this study were to:

1. identify the barriers and facilitators influencing the insulin PDA implementation in the Malaysian public healthcare settings,
2. prioritise barriers to implementing the insulin PDA,
3. develop an effective implementation intervention,
4. evaluate implementation outcomes, and
5. understand the reasons that contributed to the implementation outcomes in an academic primary care clinic in Malaysia.

1.9 Study operational definitions

Below are the clarifications of the operational terminologies used in this study.

Clinic staff

All the workers in a clinic including doctors, diabetes educators, nurses, medical assistants and appointment clerks.

Clinic stakeholders

Individual who has a role to play in the clinic and this include the HCPs, clinic staff other than HCPs such as appointment clerks, and patients.

Determinants

Factors or barriers and facilitators that can affect implementation.

HCPs

Clinic staff who provide clinical care to patients and this include doctors, diabetes educators and nurses.

HCP-mediated strategies

Strategies provided to HCPs but aimed at mediating patients' attitudes, knowledge, skills, behaviours and/or health outcomes.

Innovation

Object that is being implemented such as health practice guideline, policy, product, practice, service, system, or programme.

Patient-directed strategies

Strategies provided to patients to directly influence their attitudes, knowledge, skills, behavior and/or health outcomes.

Strategy

Strategy is a "*method or technique used to enhance the adoption, implementation, and sustainability of a clinical program or practice"* (Proctor, Powell & McMillen, 2013, p. 2).

Tailored intervention

Tailored interventions refer to strategies that are designed to address identified barriers to effect change in healthcare practice (Wensing, Bosch, & Grol, 2010).

Intervention

An integrated set, bundle, or package of discreet strategy ideally selected to address specific identified barriers to implementation success.

Patient decision aid (PDA)

PDAs are evidence-based tools that can be used by HCPs with patients to help them make informed decision about health treatment options. PDA provides explicit information about the treatment decision that needs to be made, the available treatment options based on the available scientific evidence and pros and cons about each treatment options (Drug and Therapeutics Bulletin, 2013).

Shared decision making (SDM)

A process whereby patients are engaged in playing collaborative role with clinicians to arrive at a treatment consensus after considering evidence-based information about treatment options, risks and benefits and outcomes (Coulter & Collins, 2011).

1.10 Chapter summary

Despite proven effectiveness, PDA implementation in clinical practice remains poor. There is a lack of a systematic process for PDA implementation. An insulin PDA was developed in the Malaysia to help patients make an informed decision about insulin initiation and to foster SDM and patient-centered care in the healthcare practice. This current study will help uncover barriers and facilitators to PDA implementation and develop a systematic approach to implement PDAs in routine clinical practice, using the insulin PDA as an exemplar. The next chapter will look into past literature on the approaches that have been adopted for PDA implementation.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter explores existing knowledge related to this study. First, factors influencing PDA implementation found in the literature were described. The factors were categorised by HCP, patient, organisational, system and innovation. The next section explores intervention development processes to implement PDAs in routine clinical settings. Due to a scarcity of literature that reported on the development of an intervention to implement PDAs, studies that detailed intervention development for implementation of other health innovations were also described. The next section details strategies that have been utilised for PDA implementation and their effectiveness. Subsequently, approaches to evaluating PDA implementation outcomes were looked into such as utilised frameworks, study designs, and the types of outcome measures. Figure 2.1 below illustrates the topics of the literature review that are covered. A synthesis of the literature is then provided which informed the development of the study conceptual framework. This chapter concludes with the chapter summary.

FACTORS INFLUENCING PDA IMPLEMENTATION

HCP factor

- Awareness of SDM and PDA
- Remembering to use PDA
- Knowledge and skills of SDM and PDA
- Belief that SDM is already being practised
- Belief that their knowledge is superior to that of PDA
- Disagreement with the content of the PDA
- Perception that SDM and PDA are not applicable to clinical situation
- Perception on the benefits of SDM and PDA

Patient factor

- Patients' characteristics
- Awareness and knowledge of SDM and PDA
- Literacy, knowledge and skills
- Preference for SDM and PDA use
- Reliance on clinicians to make health decisions
- Trust in HCPs
- Resources to access PDAs

Organisational factor

- Time
- Competing materials or other quality improvement initiatives
- Integration of PDA into existing patient care pathway or HCPs' workflow
- Having dedicated clinic staff member or team to implement the PDA
- Organisational leadership
- Organisational culture
- Organisational teamwork
- Presence of opinion leaders
- PDA use as part of staff performance standards or duties
- Access to PDA
- Organisational resources and infrastructures
- Cost to develop and support PDA implementation

System factor

- Clinical practice guideline or standard of care
- Policies, regulation and legal
- Payment model
- Reimbursement and incentives

Innovation factor

- Design and format of the PDA

DEVELOPMENT OF INTERVENTION

Development of intervention for PDA implementation

Development of intervention for implementation of other health innovations

PDA implementation strategies and their effectiveness

- Conduct educational meetings
- Audit and provide feedback
- Educational outreach visits
- Identify and prepare champion
- Mandate change
- Pre-visit PDA delivery approach
- Involvement of other staff in the implementation
- Provider incentives

EVALUATION OF PDA IMPLEMENTATION

Figure 2.1: Literature review topics

The literature review of this study was initiated by identifying studies related to PDA implementation. Table 2.1 lists the search terms used.

Table 2.1: Terms used in literature search

	Terms
PDA	“decision aid [MESH]”; “decision support intervention”, “decision tool”, “decision support programme”
SDM	“decision making, shared [MESH]”; “decision support”, “informed decision”, “informed choice”
Implementation	“implementation science [MESH]”; “integration”; “adoption”

These terms were applied to the database PubMed. Relevant articles were also searched within the ‘Implementation Science’ journal website. Further online hand searching was also conducted to identify gray literature such as published reports. One systematic review found looked into PDA implementation strategies and outcomes in routine practice (Elwyn et al., 2013) involving 17 studies published between July 2011 and January 2012. All the articles in the paper were included for review in this study.

Due to the dearth of PDA implementation studies that reported on the processes of intervention development, literature review was also conducted to identify studies that described their implementation intervention development processes. Search terms used were: “intervention development”, “strategy development”, “intervention design”, “strategy design”, “implementation”, “tailored implementation”, and “tailored strategy”. Random online search was conducted to identify more literature that reported implementation intervention development process. The review conducted helped to identify what are the current gaps in literature surrounding PDA implementation and informs the conceptual framework of this study. The search process and study inclusion and exclusion criteria are provided in Figure 2.2.

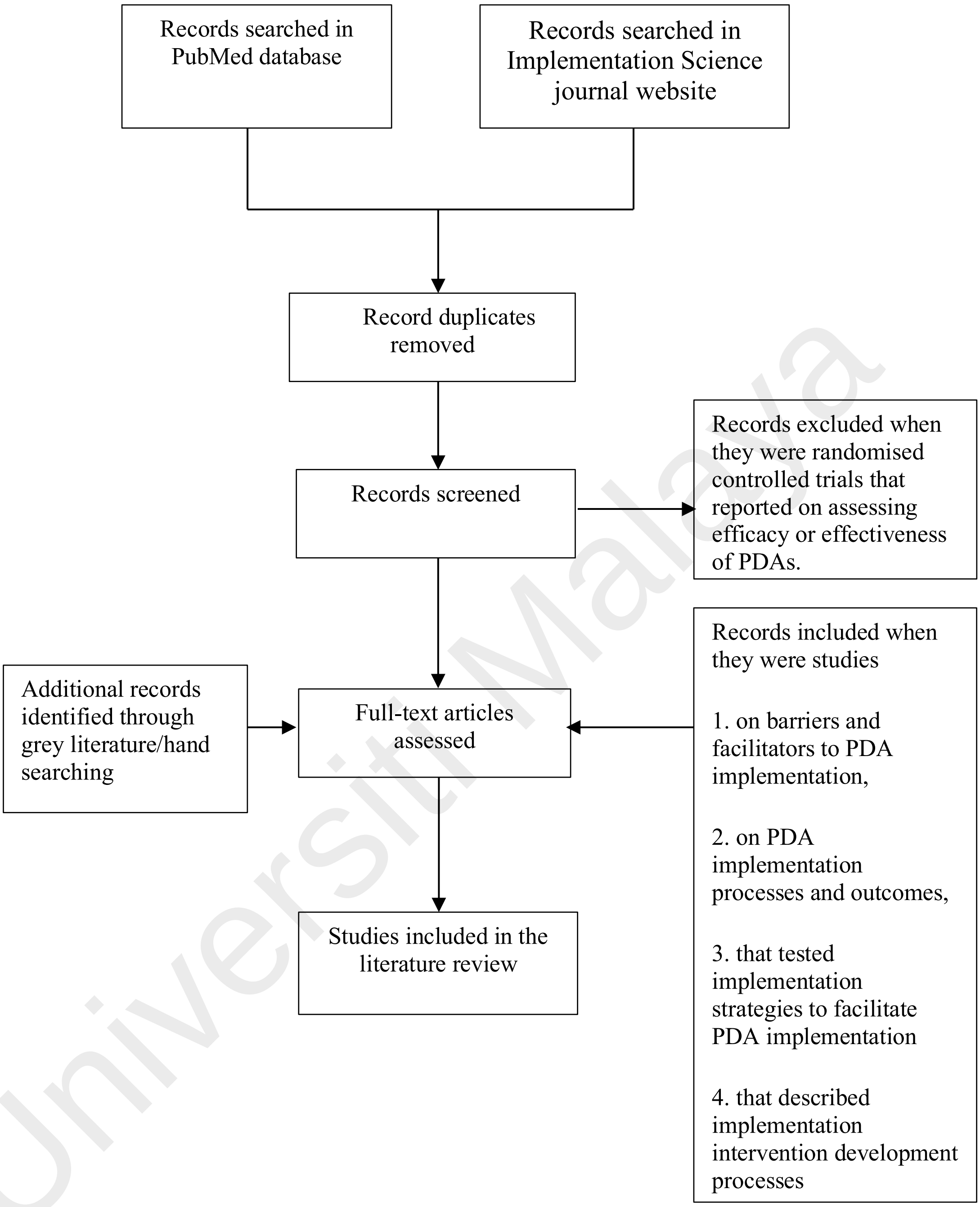


Figure 2.2: Literature search process and study inclusion and exclusion criteria

2.2 Factors influencing PDA implementation

2.2.1 Healthcare provider (HCP) factors

Awareness of PDA

One of the challenges to PDA implementation is the lack of awareness of PDAs among HCPs. When HCPs are not aware of the existence of PDAs, understandably, its adoption would be low. In a baseline survey study of 174 physicians throughout the state of Hawai'I, which measured knowledge, attitudes, and practice of PDAs, the lack of awareness of PDAs was one of the leading barriers to its adoption and only 14.3% of the physicians reported its use (Alden, Friend, & Chun, 2013).

Remembering to use PDA

Even when some clinicians were aware of the availability of PDAs in their clinic settings, forgetting to use had also been reported as the main barrier to implementation. In a study, which profiled 10 years of SDM and PDA implementation at Massachusetts General Hospital, clinicians forgetting to order PDAs for patients during a visit was reported to be the main barrier to implementation (Sepucha et al., 2016).

Additionally, some clinicians also reported that they did not remember to ask patients about their PDA use during their follow-up visits, citing there were no existing mechanism reminding them to do so (Newsome, Sieber, Smith, & Lillie, 2012).

Knowledge and skills of SDM and PDA

Knowledge of SDM and PDA such as what it constitutes, its purpose, and the skills needed to operate them can affect HCPs' decision to adopt PDAs and follow their intended use. In a qualitative study exploring general practitioners' and men's perception to use an early detection of prostate cancer PDA, the participants expressed that their lack of experience in using the PDA might hinder its use (Engelen, Vanderhaegen, Van Poppel, & Van Audenhove, 2017).

In a study among rural primary care clinicians in the Unites States (US), a discrepancy was found between the knowledge of SDM and the practice of PDA. Despite 65% of the clinicians being unfamiliar with the term SDM, 91% claimed they were using PDAs in their practice. This reflects clinicians' lack of knowledge of PDA functions and may have used them for other purposes (King, Davis, Gorman, Rugge, & Fagnan, 2012).

In Taiwan, SDM and PDA was implemented nationwide supported by the Ministry of Health and Welfare since 2016 through a multiprong approach that included development of PDAs, establishing a SDM platform and, implementing SDM in clinical practice. However, the lack of knowledge and skills on SDM and PDA was one of the main challenges to implementation in addition to time constraint, limited resources and financial support, uncertainty about the legal status of SDM and, the complex patient-family relations (Liao et al., 2017).

Belief that SDM is already being practised

Clinicians who perceived that they were already engaging in SDM with patients formed another barrier to PDA implementation. This was found in the United Kingdom (UK) National health System (NHS) Direct implementation effort to introduce web-based PDAs into NHS clinics in England. HCPs felt that they were already involving patients in decisions about their care and did not see the need to refer patients to the web-based PDAs (Elwyn, Rix, Holt, & Jones, 2012). Similarly, another study conducted among breast cancer surgeons from both community and academic hospitals in Ontario, Canada found that the surgeons did not feel the need to use PDAs because they believed that their patients were sufficiently informed and understood about the choices that they had conveyed (O'Brien et al., 2014).

Belief that their knowledge is superior to that of PDAs

PDA implementation was also affected by HCPs who did not agree with the concept of SDM and felt that their knowledge is superior to that of PDAs. In a national survey conducted among 1422 radiation oncologists and urologists in the US, some of them perceived their ability to estimate the risk of prostate cancer recurrence to be more superior to that of prostate cancer treatment PDAs. Only 35.5% of them reported to use a PDA in their practice (Wang et al., 2015). When HCPs felt their knowledge was better than a PDA, they thought they were making the ‘best’ decision for their patients and did not advocate PDA use (Rees, Shaw, Bennert, Emmett, & Montgomery, 2009).

Disagreement with the content of the PDA

HCPs have also refused to participate in PDA implementation studies when they disagree with the PDA content. In one study, a surgeon felt that the descriptions in the surgical treatment choice for a breast cancer PDA were too explicit and refused to participate in the SDM programme (Holmes-Rovner et al., 2000). Similarly, in the Picker Institute Europe study on implementation of prostate cancer and benign prostatic hyperplasia PDAs in urology departments at four NHS Hospital Trusts in England, one hospital chose not to participate in the programme as the clinicians felt that the content of the PDA was overly biased against surgery (Wirrmann & Askahm, 2006).

Perception that SDM and PDA are not applicable to clinical situation

The lack of applicability of PDAs to clinical situations has also been reported to be a barrier for PDA implementation in conditions perceived to be life-threatening or time-sensitive. For conditions such as breast cancer, patients identified to have surgery were quickly scheduled to minimise the time they would spend at home feeling anxious about having cancer (Holmes-Rovner et al., 2000). For conditions such as chronic stable angina, insertion of the stent is usually performed when the condition is diagnosed through an angiogram. If SDM discussion were to be conducted, this would subject the patients to undergo a second round of sedation and cardiac catheterisation (Hsu, Liss, Frosch, Westbrook, & Arterburn, 2017). Patients also expressed concerns that PDA use might delay definitive treatment (Bhavnani & Fisher, 2010).

Perception of the benefits of SDM and PDA

In a study to explore HCPs' views on two computer-based PDAs for women choosing a mode of delivery after previous caesarean sections, the belief that PDAs can help to empower and provide greater satisfaction to women on the decision that is made was found to be a facilitator for PDA implementation among midwives and clinicians (Rees, Shaw, Bennert, Emmett & Montgomery, 2009). HCPS who favoured a patient-centered approach and SDM were more likely to talk positively about using PDAs even when facing difficulties compared to HCPs who were more practitioner-centered. None of the practitioner-centered HCPs reported adopting PDAs in their routine practice and they tended to use the difficulties rhetorically to justify their lack of use of PDAs (Watson, Thomson, & Murtagh, 2008). Some surgeons did not adopt PDAs as they felt that the PDA outcomes were not compelling enough to change their practice, compared to more interesting innovations such as surgical techniques that could affect surgical outcomes (O'Brien et al., 2014).

2.2.2 Patient factors

Patients' characteristics

Many HCPs raise that patients' characteristics such as age, physical health (Graham et al., 2003), ethnicity, culture (Uy, May, Tietbohl & Frosch, 2014) and language (Rees, Shaw, Bennert, Emmett & Montgomery, 2009) are factors that can influence their PDA use with patients (Stacey, Graham, O'Connor, & Pomey, 2005). There were concerns HCPs may have their preferences on which patients would be *easier* to engage in SDM and use the PDA with, thereby leading to inequitable access to PDAs especially among the vulnerable populations (Légaré & Witteman, 2013; Lewis & Pignone, 2009; Rees, Shaw, Bennert, Emmett & Montgomery, 2009). This concern is not unfounded as HCPs in some studies have reported that they are likely to use PDAs with patients who have adequate literacy levels, have the motivation to use the PDA, do not have health issues such as vision problems, have concentration abilities, and do not have language discordance with them (Graham et al., 2003; Scalia, Elwyn, & Durand, 2017).

People in the older age group who easily accept the authority of a doctor (Bastiaens, Van Royen, Pavlic, Raposo, & Baker, 2007) may be difficult to engage in SDM with while the same goes for people in the younger age group as communication about health care usually occurs between parents and doctors. Some younger age patients reported that they were unable to speak for themselves as doctors often addressed their parents rather than them (van Staa, 2011).

Patients who are too ill or have cognitive impairments (e.g.: dementia) may not have the strength or may face difficulties to receive information, thus they are unable to communicate with HCPs to engage in SDM and PDA use (Caress, Beaver, Luker, Campbell, & Woodcock, 2005; Doherty & Doherty, 2005; Ekdahl, Andersson, Wirehn,

& Friedrichsen, 2011; Larsson, Sahlsten, Segesten, & Plos, 2011; Sainio, Lauri, & Eriksson, 2001).

Awareness and knowledge of SDM and PDAs

The lack of awareness can result in patients not knowing that they can engage in SDM with HCPs (Hajizadeh, Uhler, & Pérez Figueroa, 2015) and that there are tools such as PDAs to assist them to make informed decisions. In a nurse call center, low public awareness on the availability of a decision support service for people facing values-sensitive decisions had been reported as a barrier to its implementation that led to a low call volume (Stacey, Graham, O'Connor, Pomey, 2005). Some patients were not aware that they had options or felt they had little or no say in treatment decisions (Caress, Beaver, Luker, Campbell & Woodcock 2005). Coupled with the perception that doctors 'know best' (Bastiaens, Van Royen, Pavlic, Raposo, & Baker, 2007) and they are the best persons to make healthcare decisions (Belcher, Fried, Agostini, & Tinetti, 2006), patients often undervalue their own contribution to decision-making (Fraenkel & McGraw, 2007; Lewis & Pignone, 2009) and this can hamper a patient's engagement in SDM and PDA use.

Furthermore, the lack of clarity of the purpose and advantages of PDAs can cause patients to be ambivalent about using them (Newsome, Sieber, Smith & Lillie, 2012). In a study exploring perceived barriers and facilitators of implementing SDM and decision support in a tertiary paediatric hospital, patients had difficulty articulating their preferred role in decision-making. One of them was uncertain why a patient would not simply accept the physician's preferred treatment option. Some did not consider the decision support program to be necessary and were unsure if they would use or recommend it (Boland, McIsaac, & Lawson, 2016).

Literacy, knowledge and skills

HCPs often brought up patients' literacy level, knowledge and skills to engage in SDM and PDA as one of the main barriers to PDA use (Feibelmann, Yang, Uzogara, & Sepucha, 2011; King, Davis, Gorman, Rugge & Fagnan, 2012; Scalia, Elwyn & Durand, 2017). Clinicians reported that patients' difficulty in understanding everything needed to know to make decisions was another main barrier to PDA use (King, Davis, Gorman, Rugge & Fagnan, 2012), such as comprehension of medical data (Hajizadeh, Uhler & Perez Pigueroa, 2015).

In a qualitative study among general practitioners' and men's views on a PDA for early detection of prostate cancer, both parties agreed that the topic was difficult for men and thus there was a need for patient-centered information. Men reported they needed support from doctors when discussing the topic (Engelen, Vanderhaegen, Van Poppel & Van Audenhove, 2017). Some patients also reported being uncomfortable using computers and needed assistance to navigate a computer or web-based PDA (Crothers et al., 2016).

Preference for SDM and PDA use

Patients' preference and willingness to participate in SDM can affect PDA adoption. The US Breast Cancer Initiative that disseminates breast cancer PDAs to almost 200 sites in New England reported that 12% of the providers heard from patients that they did not want the PDAs (Feibelmann, Yang, Uzogara, & Sepucha, 2011). Some patients were unaccustomed to making medical decisions and were unwilling to learn about treatment options, and preferred to rely on clinicians' judgment for decisions rather than using PDAs (Uy, May, Tietbohl & Frosch, 2014). This is especially among those who are fearful, anxious or overwhelmed with their illnesses (Belcher, Fried, Agostini, & Tinetti, 2006; Elwyn, Rix, Holt, & Jones, 2012; Silvia, Ozanne, & Sepucha, 2008).

Patients also expressed concerns that PDA use meant that they were left to make decisions alone. They were concerned that HCPs may rely PDAs to address sensitive treatment options and reduce the emotional support provided (Bhavnani & Fisher, 2010). Patients who already have a strong preference for a treatment decision may be less likely to use PDAs given their lack of interests in knowing about other treatment options (Rees, Shaw, Bennert, Emmett & Montgomery, 2009).

Patients' lack of interest in SDM can also affect HCPs' use of the PDA. HCPs have been found to use PDAs with patients based on their assumptions on the patient's willingness to participate in SDM. HCPs did not offer PDAs to patients who did not seem interested to participate in decision-making (Stapleton, Kirkham, & Thomas, 2002), and patients who preferred not to know their options and instead rely on doctors to help them make the decision (Silvia, Ozanne, & Sepucha, 2008).

Reliance on clinicians to make health decisions

Patients who tended to rely on HCPs to make healthcare decisions was another barrier to SDM and PDA use (Elwyn Rix, Holt, & Jones, 2012; Holmes-Rovner et al., 2000; Silvia, Ozanne, & Sepucha, 2008). Often, patients believed that HCPs are experts in the medical field (Henderson, 2002; Peek et al., 2010) and that their knowledge is inferior to HCPs (Bastiaens, Van Royen, Pavlic, Raposo, & Baker, 2007). Therefore, patients defer the decision-making to clinicians for fear of making the wrong decisions (Henderson, 2002). Some patients believed that they should not question clinicians for fear that the clinicians would think that they do not trust them, that they are undermining the clinicians' capabilities, or do not respect them as professionals. They fear the repercussions of offending HCPs would lead to poor quality care and attention (Frosch, May, Rendle, Tietbohl, & Elwyn, 2012; Henderson, 2002). Even when they are encouraged to participate in their health decision-making, some patients were reluctant.

They try to be a ‘good’ patient, one who is obedient and does not voice opinions (Henderson, 2002).

In contrary, patients who were aware of the importance of their preferences and that it was acceptable to ask questions was a facilitator for SDM (Claramita, Nugraheni, van Dalen, & van der Vleuten, 2013; Peek et al., 2010). Clinicians’ attitude towards engaging patients in SDM and using PDAs can influence patient participation (Legare et al., 2011). HCPs explicit encouragement to patients to be involved in treatment discussions was a facilitator for SDM (Entwistle, Prior, Skea, & Francis, 2008; Peek et al., 2013).

Trust in HCPs

Another reported factor influencing SDM and PDA use was the level of trust patients have for their clinicians as this can influence their decision-making role preferences (passive, shared, and autonomous) (Peek et al., 2013). When patients do not trust the clinician, they may not want to share their feelings or concerns and this impedes effective communication, which is crucial in SDM and PDA discussions (Belcher, Fried, Agostini, & Tinetti, 2006).

Patients who trust their physicians are more comfortable to share information and ask questions and this can facilitate SDM (Lown, Clark, & Hanson, 2009; Peek et al., 2013). However, when there is too high level of trust and confidence in a clinician’s knowledge, patients may become passive in their health care involvement as they have faith that the clinician will do what is best for them. Hence, this precluded SDM and PDA use (Belcher, Fried, Agostini, & Tinetti, 2006; Peek et al., 2013).

Resources to access PDAs

In the UK NHS implementation of web-based PDAs whereby patients were directed by HCPs to PDAs hosted in the NHS Direct website, patients' inability to access the Internet had been reported (Elwyn, Rix, Holt, & Jones, 2012).

2.2.3 Organisational factors

Time

Time constraint was a commonly cited barrier to PDA implementation. Even though HCPs were in favour of using PDAs, there was a concern about the amount of time needed to use PDAs with patients during consultations. One clinician was unsure how to incorporate the use of a computerised PDA into a 10-minute consultation (Watson, Thomson & Murtagh, 2008), especially if they have to guide patients through the PDA (Rees, Shaw, Bennert, Emmett & Montgomery, 2009). Some healthcare settings noted they were already overloaded, hence could not find the time to develop an organised system to disseminate the PDAs to patients (Silvia, Ozanne, & Sepucha, 2008).

When HCPs had a high workload, PDA implementation was considered as extra work and was neglected by HCPs as they prioritised their clinical tasks. As evidenced in a study, clinicians wanted to prescribe PDAs to patients prior to their scheduled consultation but staff member who were tasked with contacting eligible patients postponed doing so as they focused on performing clinical tasks. As a result, these patients were not contacted. Extra appointments for PDA discussions alone were not possible in view that some physicians were already practising at their maximum patient visit capacity (Uy, May, Tietbohl & Frosch, 2014).

Besides HCPs, patients also noted time constraint as a challenge to use the PDA during clinical consultations. They noted that there was limited time to ask questions, voice their concerns, and seek guidance on medical decisions during consultations. Some patients felt guilty taking up their clinician's time (Frosch, May, Rendle, Tietbohl & Elwyn, 2012) and reported to limit their questions during PDA discussion in consultations (Stapleton, Kirkham & Thomas, 2002).

On the contrary, the belief that PDAs can help reduce the time needed to provide information to patients during consultations is a facilitator for PDA implementation (Lin et al., 2013; Rees, Shaw, Bennert, Emmett & Montgomery, 2009; Stapleton, Kirkham & Thomas, 2002). It was suggested that to promote SDM and PDA use, there is a need to "sell" the idea that PDA use would not increase much consultation time to HCPs, in addition to other benefits such as health outcomes. Some clinicians viewed SDM as a process involving several consultations and PDAs can be used to facilitate informed decision-making that can *save time in the future* (Watson, Thomson & Murtagh, 2008).

Competing materials or other quality improvement initiatives

Besides time constraints, PDA implementation can also be further hampered by other available resources for patients. In the US Breast Cancer Initiative PDA implementation study, 15% of the 59 implementation sites reported too many education materials as one of the barriers to PDA implementation (Feibelmann, Yang, Uzogara, & Sepucha, 2011). Some clinics chose to use other videos instead of PDAs while another clinic noted that it already had a decision coaching service established that was working well for patients (Silvia & Sepucha, 2006).

Integration of PDA into existing patient care pathway or HCPs' workflow

Some SDM and PDA implementation processes may involve additional appointments or increased wait times, which may further stress clinical processes and resource utilisation (Bhavnani & Fisher, 2010; Boland, McIsaac & Lawson, 2016). PDA use in the clinic's waiting area prior to consultation may interrupt the clinics' workflow; if patients arrived late or if the clinic was running ahead then patients could be stuck using the PDA when it was their time to meet the clinician (Jimbo et al., 2013).

The challenge to fit PDA implementation into clinical processes was found in the implementation of PDAs in urology departments of four NHS Hospital Trusts. Eventhough the implementation sites were given the flexibility to implement the programme within their settings, however, some sites chose a much simpler and fairly straightforward way; PDAs were delivered to patients by post which circumvented the need to reorganise patient care pathway to incorporate the PDAs. This resulted in the PDAs not being utilised to their full advantage (Wirrmann & Askahm, 2006).

PDAs are most likely to be adopted if they are integrated into the existing patient care delivery pathway and do not require additional appointments to be made (Rees, Shaw, Bennert, Emmett & Montgomery, 2009). In Silvia & Sepucha's (2006) study of PDA implementation at nine sites, sites that had the highest utilisation rate made PDAs part of their patient care routine. In one of the academic centers, patients was automatically scheduled to view the video when they made an appointment with the surgeon; nurse practitioners also called patients to come earlier for their appointment to view the video-based PDAs (Silvia & Sepucha, 2006).

Having dedicated clinic staff member or team to implement the PDA

Implementation of the PDAs appeared to be higher in settings that had a designated staff person, such as a nurse, social worker, patient educator, or clinic coordinator, responsible for eligible patients outreach compared to those which did not have these dedicated resources (Silvia, Ozanne, & Sepucha, 2008). One study reported that more patients viewed at least a portion of the target PDA when a dedicated staff member was available to identify and approach patients (Miller, Brenner, Griffith, Pignone, & Lewis, 2012).

Organisational leadership

The importance of organisational leadership in PDA implementation was demonstrated at the Palo Alto Medical Foundation SDM programme, which involved implementation of PDAs at five primary care clinics. In clinics with low PDA implementation performance, there was a lack of leadership to champion PDA implementation and caused low distribution. Clinic staff were unaware of the efforts made to integrate PDA use and no solutions were made to resolve disagreements between clinicians on the distribution of the PDAs. Whereas in the highest performing clinic, a high level of leadership support was found to be the main facilitator for successful implementation as clinic staff received strong and consistent messages about the importance of project from their clinic supervisor (Tietbohl et al., 2015).

Organisational culture

Organisational culture is influenced by the degree of shared views, values and goals among leaders, staff, and even patients. When people in an organisation do not share the same views on the practice of SDM, this can hamper PDA implementation. This was found in the Making Good Decisions in Collaboration (MAGIC) SDM programme, an initiative by a group of frontline staff, managers and academics in NHS sites to implement and embed SDM across sites at Newcastle and Cardiff, commissioned by the UK Health Foundation. From their programme evaluation, it was found that HCPs in the same clinical team had different views and approaches to decision-making with patients. Some HCPs thought they were already practising SDM, some thought SDM was inappropriate, some felt HCPs should spare patients from the ‘agony’ of making choices, and some who thought they could do SDM better. These different views among HCPs was found to be a challenge for SDM implementation (Lloyd, Joseph-Williams, Edwards, Rix, & Elwyn, 2013).

Compatibility between SDM and decision support concepts with a hospital’s organisational culture, values, and practice ideals among all the clinic stakeholders was a facilitator to implementation of a decision support programme in a paediatric hospital. The senior administrators endorsed the decision support program by including the program implementation in the hospital’s corporate objectives. They also agreed on ongoing collaboration for decision support implementation into clinical pathways. Parents in the study also unanimously agreed that patients and families should be involved in health decisions. They supported the decision support program, and expressed willingness to use and recommend the service (Boland, McIsaac & Lawson, 2016).

Organisational teamwork

Teamwork among HCPs is a crucial factor that can affect PDA implementation. A lack of teamwork can affect the collaborative approach needed for effective PDA implementation. One study reported that a nurse supervisor at one clinic wanted all medical assistants to screen patients for eligibility for a colorectal cancer screening PDA but this was deterred by clinicians who did not want PDAs to be given to patients to prevent getting questions from them (Lin et al., 2013).

In a study on PDA implementation at five primary care clinics, it was found that clinics that were successful in implementing the PDAs were characterised by having clinic staff that had a positive working relationship with one another. The staff were aware of their own roles and other's roles in the PDA distribution process. In some clinics, clinic staff worked with one another to coordinate the process of distributing the PDAs to patients. The shared responsibility also led some staff to independently solve implementation issues that helped to faciliate PDA distribution by other staff (Tietbohl et al., 2015).

Presence of opinion leaders

The HealthPartners organisation which had successfully embedded the use of PDAs in existing workflows attributed the success to an opinion leader; a hand surgeon, who encouraged and demonstrated the benefits of the tools and successfully influenced other clinic staff to implement them (Scalia, Elwyn & Durand, 2017).

PDA use as part of staff performance standards or duties

The incorporation of SDM and PDA use as part of staff performance standards or duties can influence implementation. In a Canadian province-wide health call center, the lack of performance standards has been reported to be a barrier for implementation of the decision support programme through PDA use (Stacey, Graham, O'Connor, Pomey, 2005).

A study on the distribution of PDAs at five Northern California primary care clinics showed that two clinics had a higher PDA distribution compared to the other three clinics. This might be attributed to the clinical supervisors who made PDA use part of the staff performance standards when preparing exam rooms and promoted PDA distribution as part of the clinic staff's normal duties (Lin et al., 2013).

Access to PDA

HCPs would not distribute PDAs if they were placed at an area where retrieval is difficult especially when they are already busy with other work (Uy, May, Tietbohl & Frosch, 2014). In a study, one of the implementation sites placed its SDM programme in a separate building and this might have deterred the clinicians from referring patients to the programme due to logistic issues (Holmes-Rovner et al., 2000).

Timely access to the PDA was also highlighted as an important factor that could affect its implementation. Many HCPs prefer patients to read PDAs ahead of consultations (Jimbo et al., 2013; Newsome, Sieber, Smith & Lillie, 2012; Schroy, Mylvaganam, & Davidson, 2014). In the implementation of PDAs for breast cancer patients at the UCSF Breast Care Center, one of the implementation goals was to ensure the PDA reached the right patient at the right time, which was before an upcoming specialist appointment. However, due to the short time frame between patients making and attending a decision-making appointment, PDAs that were mailed to patients only reached them after their appointments and this was a barrier for implementation (Belkora et al., 2012).

Print-based PDAs that are placed within the reach of HCPs are more likely to result in higher distribution and adoption. Physicians reported they distributed PDAs to patients more when it was placed in the consultation rooms as compared to ordering one from medical assistants (Lin et al., 2013). Making PDAs available online was also favoured to improve patient access given the numerous barriers of accessing the PDAs within clinic settings (Feibelmann, Yang, Uzogara, & Sepucha, 2011; Rees, Shaw, Bennert, Emmett & Montgomery, 2009).

Organisational resources and infrastructures

HCPs have raised that lack of space in the clinic settings was an issue to store leaflet PDAs (Watson, Thomson & Murtagh, 2008) and to allow patients to view computer-based PDAs (Rees, Shaw, Bennert, Emmett & Montgomery, 2009). In the implementation of an early stage breast cancer surgical choice video/DVD and booklet, implementation sites that adopted the scheduling delivery model (i.e. patients being 'scheduled' to view the programme at the clinic), the lack of space for PDA viewing was reported to be a barrier as the two rooms that were equipped with videocassette recorder for PDA viewing was sometimes occupied by HCPs for patient consultations (Silvia & Sepucha, 2006).

Environmental issues such as noise, uncomfortable room temperatures, poorly lit rooms (Park & Song, 2005), and lack of privacy (Doherty & Doherty, 2005) were also reported by patients and HCPs as communication barriers to SDM engagement and PDA use (King, Taylor, Williams, & Vanson, 2013).

Settings that were able to accommodate the resources that were needed to integrate PDA use in routine clinical practice were more successful than clinics that were less able. In one of the clinics that was able to maintain PDA distribution over time, a dedicated space for PDA was assigned for easy retrieval and distribution by HCPs (Uy, May, Tietbohl & Frosch,, 2014). In another study, clinics that provided a space for video viewing facilitated the logistics of having patients review a PDA before their consultation (Frosch et al., 2011).

Infrastructures and communication technologies were raise as factors that can facilitate PDA implementation (Lewis & Pignone, 2009; O'Connor et al., 2007). However, the availability and development of these resources in some of the implementation sites has yet to allow support of PDA implementation. In the Informed Medical Decision Making Foundation SDM demonstration study, the clinical information systems in many of the primary care practices could not help flag eligible patients, notify providers on patients who have received the PDAs, serve as a mechanism for communicating patient-reported values and preferences to providers, and provide longitudinal functions to track patients through the SDM process. In all the practices, patients' decision-relevant values and preferences were captured in a questionnaire that was not incorporated in the clinical information system, which limits post-PDA conversations (Friedberg, Van Busum, Wexler, Bowen, & Schneider, 2013).

The University of California, San Diego Family Medicine Division integrated eight PDAs into its electronic medical record (EMR) that clinicians could prescribe electronically to patients. However, HCPs reported that various technological changes were still needed to improve the system to facilitate ordering more than one PDA, indication to other HCPs about which PDAs had been ordered, and having a trigger system for clinicians to remember to conduct a PDA follow-up at the subsequent patient appointment (Newsome, Sieber, Smith & Lillie, 2012).

Implementation sites that utilised their clinics' EMR to facilitate implementation showed better PDA distribution and use. In settings where the EMR was well established and patient health portals were available, providers were able to order PDAs to patients who viewed the tool online through the patient portal (Hsu, Liss, Westbrook, & Arterburn, 2013; Sepucha et al., 2016). Some EMRs could also generate a note in the patient's chart to document that the PDAs were sent (Sepucha et al., 2016).

The availability of billing records and an EMR allowed queries to be conducted to generate the list of potentially eligible patients for PDAs (Holmes-Rovner et al., 2011). This can lead to better efficiency in reaching patients with the PDAs compared to a manual review of patient medical records by clinic staff (Miller, Brenner, Griffith, Pignone & Lewis, 2012).

Cost to develop and support PDA implementation

Implementation of PDAs may require active dissemination and multifaceted interventions to change HCPs' behaviours and this would incur high costs (Grimshaw et al., 2001; Lewis & Pignone, 2009). HCPs raised the issue of the cost of purchasing, setting up, maintaining, and updating PDAs (Graham et al., 2003; Rees, Shaw, Bennert, Emmett & Montgomery, 2009).

2.2.4 System factors

Clinical practice guideline or standard of care

Another barrier to PDA implementation is the perception that SDM and PDA use would contradict practice guidelines. HCPs fear the liability risk that SDM might impose as there is a possibility that patients might not adopt the treatment option that is most appropriate according to standard of care (Lindor et al., 2016). Hence, HCPs may not use the PDA at all or use them incorrectly. This was found in a study on the use of informed choice leaflets in 13 maternity care units in Wales, where the leaflets were used by obstetricians to promote "right" choices that were clinically secure to protect them against litigation rather than promoting informed decisions. Eventhough women had their own preferred choices, their preference was not met as they did not follow established clinical practices (Stapleton, Kirkham & Thomas, 2002).

Policies, regulation and legal

The use of PDAs has been promoted through policies, legislation and regulation. In the US, the practice of PDA use to facilitate SDM was promoted in the 2010 Affordable Care Act (Senate and House of Representatives, 2010). SDM practice was tied with reimbursement and increased protection from litigation to encourage PDA use. The Washington state legislation had three provisions to facilitate PDA use and they were: 1) the state is required to develop a process to certify the accuracy and neutral status of any PDA used as part of the SDM process, 2) incentivisation of PDA use by providing greater legal protection for HCPs who are exposed to failure-to-inform malpractice liability and 3) the need for the Washington State Health Care Authority to examine feasibility and financial implications of integrating SDM into medical care for a variety of conditions (Moulton & King, 2010). Under the US Centers for Medicare & Medicaid Services, HCPs would not be reimbursed for performing lung cancer screening with low-dose computed tomography unless SDM or PDA use occurred with patients (Centers for Medicare & Medicaid Services, 2015).

In countries such as Chile, Spain, Iran, and Italy, patient involvement and rights, and patient-centered care have been established in laws and policies but specific policies on SDM are absent. SDM is clearly defined at the policy and legislation levels in countries such the UK, Australia, and Germany. However, the execution of these policies and legislations are still slow (Harter, van der Weijden, & Elwyn, 2011). In the UK, SDM is mentioned in key policy documents such as the NHS Constitution 2015 (Department of Health, 2009) but it has no incentives and is not promoted systematically at national, regional, or organisational levels (Joseph-Williams et al., 2017).

Payment model

Organisations that use the fee-for-service and pay-for-performance payment formulas may be at odds with practising SDM. In a fee-for-service system, clincians are paid according to the number of services they provide to patients. Hence, to maximise their revenues, they may offer as many services as they can to patients. In a pay-for-performance programme, clinicians are paid based on how they perform across process and efficiency measures to reach healthcare quality targets. However, in SDM, patients may decline recommended treatments by clinicians and this can result in a decrease in revenues or poor statistics on the organisations' performance or quality outcomes (Keirns & Goold, 2009). Hence, the organisation may not advocate SDM practice and implement PDAs.

HCPs expressed that they were unsure of the benefits of the PDAs as they felt that its adoption was mainly due to pressure from insurance companies rather than its clinical benefits (Jimbo et al., 2013). Furthermore, the need to meet efficiency targets (such as in cancer management) deterred them from engaging patients in SDM as there was a pressure to get to a decision (Elwyn, Rix, Holt, & Jones, 2012).

Reimbursement and incentives

Many HCPs have called for incentives for engaging in SDM and PDA use (Lin et al., 2013). In a survey among a large sample of 174 US rural primary care clinicians, more than 90% reported that they are more likely to use PDAs if they were reimbursed for their time (King, Davis, Gorman, Rugge & Fagnan, 2012).

However, in many other places and settings, current payment schemes fail to reward providers for taking extra time to fully inform patients and engage them in the decision-making process (Belcher, Fried, Agostini, & Tinetti et al., 2006) compared to taking or performing certain clinical procedures.

2.2.5 Innovation factors

Design and format of the PDA

The design and format of a PDA can influence clinicians on whether they would use it or not (Graham et al., 2003). One of the key barriers for the continued use of PDAs among surgeons in an RCT was difficulty in obtaining information using the computer-based PDA whereas PDAs in the format of a decision board was felt to be too big and awkward to use in a small consultation room (O'Brien et al., 2014). Video PDAs that were too lengthy (35-55 minutes) was also found to be challenging to incorporate into routine consultation (Hsu, Liss, Westbrook, & Arterburn, 2013).

Clinicians are more likely to use PDAs that are perceived to be easy to use (Graham et al., 2003). In a survey among clinicians in the state of Hawai‘i, the most commonly reported PDA format used was paper-based PDAs such as brochures or options matrix sheets. Majority of the clinicians felt that the most appropriate format for clinic use was paper-based brochure PDAs (75%) while for outside clinic use, the format was interactive online website program (73.5%) (Alden, Friend & Chun, 2013). Similarly, findings from clinicians in rural practices also showed that paper-based PDAs were preferred, where a majority used brochures (85%) followed by handouts (45%) web-based PDAs (33%), and DVD or video home system (2%) formats (King, Davis, Gorman, Rugge & Fagnan, 2012). While electronic PDAs were lauded for its interactive format, paper-based PDAs were felt to be beneficial in terms of saving time during clinic visits and were perceived to be especially useful for getting information to patients outside of the context of the clinical encounter (Jimbo et al., 2013).

Brief PDAs were also raised to facilitate PDA implementation. The availability of having information in one page was a facilitator for using the PDAs. Furthermore, they could also easily photocopy the PDA for their patients and for office records (O'Brien et al., 2014). In Scalia, Elwyn & Durand’s (2017) study, the brief nature of the one-page Option Grid PDA fits into the need of HCPs at the CapitalCare organisation to satisfy financial incentives for practising SDM without burdening the clinical workflow (Scalia, Elwyn & Durand, 2017).

2.3 Development of intervention

2.3.1 Development of intervention for PDA implementation

In some studies where large organisations aimed to implement SDM and PDA implementation involving multi-sites, the research team worked with practices to determine the most efficient ways to integrate the use of PDAs into their clinical workflow rather than tailoring strategies to identified barriers. The Group Health is an integrated health care organisation at Washington State and Northern Idaho and in 2009, efforts were initiated to implement video-based PDA into routine practice at six service line specialties within Group Health’s Western Washington Group Practice Division. In their PDA implementation, the Group Health project management consultants engaged with service line leaders to develop implementation agreements and process flow diagrams for each service line. Then, the Group Health consultants presented the intervention to frontline HCPs and staff to introduce the PDAs and the distribution process. Revisions to the implementation plan was made based on suggestions that were raised and finalised once consensus was reached (Hsu, Liss, Westbrook, & Arterburn, 2013).

Similarly, when the Palo Alto Medical Foundation aimed to implement PDAs at five primary care clinics in Northern California, the project team worked with the clinics to tailor PDA distribution methods to individual clinic workflows. The development of the implementation processes were not explicitly described, however, a physician and staff champion were assigned to promote the PDA programme. The clinics were told the objective was to provide PDAs to patients in-clinic but before consultations with the physician (Frosch et al., 2011). Similarly, in the implementation of PDAs at four urology departments at four hospitals in England, the implementation team worked with established working groups from the sites and a national steering group on the implementation tools and plan. The plan was then adapted to each of the departments (Wirrmann & Askahm, 2006).

2.3.2 Development of intervention for implementation of other health innovations

In an earlier study that reported on intervention development, psychological theories were used to develop the intervention for implementation of guidelines for depression at 34 general practices. The research team used psychological theories to explain barriers and selected appropriate strategies to address specific barriers. The findings revealed that the intervention did not increase adherence to all of the guideline recommendations. The researchers highlighted that eventhough the use of theories could help in explaining the reason a strategy was selected, it did not guide in selecting which particular strategy would have been more effective and how to execute the strategy. For example in terms of dosage required (Baker, Reddish, Robertson, Hearnshaw, & Jones, 2001).

Another study considered suggested strategies proposed by general practitioners and medical assistants as well as reviewed evidence of effectiveness of strategies to develop an intervention to implement evidence-based guidelines for urinary tract infection and sore throat in general practices in Norway. The strategies selected were written into a table mapped to the identified barriers, with rationale provided. However, the implementation findings revealed that not all barriers were adequately overcome by the selected strategies which was attributed to a few reasons. First, many different barriers emerged across practices and no major barriers were identified for either of the guidelines use. The researchers noted that it was not feasible to assess which strategy might be most effective for a particular practice or practitioner in this study. Second, they were also limited in the choice of strategies such as using more active interventions like outreach visits due to a lack of resources (Flottorp & Oxman, 2003).

In another study, rather than the researchers identify and select strategies by themselves, clinic stakeholders were engaged to select strategies to increase rates of delivery of a broad range of evidence-based preventive services at 38 primary care practices. All physicians and clinic staff at each practice were called for a meeting by nurse facilitators. During the meeting, the nurse facilitators discussed with the clinic stakeholders on their current approach to identify existing gaps. Then a list of tools and approaches to help enhance preventive service delivery was presented. The nurse facilitators helped practices choose from the presented options and created a plan for change, taking into consideration the practices' office structures, practice size and personnel available, existing procedures to preventive service deliver and practice values based on their available resources and capabilities. Follow-up visits were also conducted to individualise and implement the chosen tools and approaches. The intervention was carried out at 38 practices and was effective in increasing preventive service delivery rates. However, the researchers also reported that this approach required time and, monetary investments to hire two nurse facilitators to carry out the intervention (Goodwin et al., 2001).

In a study to develop an intervention for the implementation of insurance medicine guidelines for depression, a more systematic approach was utilised to highlight approaches previously described in this chapter such as the use of psychological theories, review of evidence in the literature, and involvement of clinic stakeholders in proposing and selection of strategies (Zwerver, Schellart, Anema, Rammeloo, & van der Beek, 2011). This approach known as the intervention mapping (Bartholomew, Parcel, & Kok, 1998), originated from the field of health promotion and is a six-step protocol for development of intervention. The steps outlined in the protocol are: (a) assessment of needs or problem analysis, (b) creation of matrices of change objectives, (c) selection of theory-based intervention methods that match the determinants into which the identified beliefs aggregate, and translate these into practical applications that satisfy the parameters for effectiveness of the selected methods, (d) integration of the practical applications into an organised programme, (e) planning for adoption, implementation, and sustainability of the intervention, and (f) evaluation of the intervention effectiveness (Bartholomew, Parcel & Kok, 1998). In the study by Zwerver, Schellart, Anema, Rammeloo & van der Beek (2011), following the conduct of needs assessment with insurance physicians, the behavioural and environmental determinants of the program were defined and performance and change objectives were developed. Subsequently, theory-based methods and practical strategies were mapped in a matrix to the performance and change objectives. Once the conceptual plan of the intervention was developed, semi-structured interviews and consultation rounds were conducted with stakeholders to obtain input for the program development process. At this step, programme implementation strategy was developed. The intervention was then tailored to meet local needs and interests and this was done through consultation with users (who participated in the needs assessment) and stakeholders regarding the content of the program and the implementation strategy. Next, the developed intervention was evaluated. This study shows that the intervention mapping approach was feasible and useful as it provides concrete steps and integrates theories and stakeholders input in implementation intervention development (Zwerver, Schellart, Anema, Rammeloo & van der Beek, 2011). The multifaceted intervention was also found to increase guideline adherence as compared to implementation in a RCT (Zwerver, Schellart, Knol, Anema, & van der Beek, 2011). The strength of the intervention mapping approach is that it provides concrete steps for development of implementation intervention. However, the intervention mapping approach has been reported to be a laborious and time-consuming process (Looijmans-van den Akker et al., 2011; McEachan, Lawton, Jackson, Conner, & Lunt, 2008).

Another systematic approach is the use of the Tailored Implementation in Chronic Diseases (TICD) checklist (Flottorp et al., 2013). The TICD checklist was developed based on a systematic review of frameworks of determinants of practice and consensus among implementation researchers. The development of this checklist was part of the TICD project, which aimed to assess the effectiveness of tailored programmes to improve healthcare for patients with chronic diseases in five countries and at the same time advancing knowledge on the concepts and methods of tailoring interventions to identified determinants (Wensing et al., 2011). The TICD checklist comprised of five worksheets arranged in a way that follows a systematic process to develop interventions based on prioritised determinants; (a) worksheet 1: prioritisation of recommendation, (b) worksheet 2: initial assessment of determinants, (c) worksheet 3: prioritisation of determinants, (d) worksheet 4: development of an implementation strategy, and (e) worksheet 5: reporting the identified determinants. In the worksheets, specific instructions and information were provided to users such as aspects to consider when selecting recommendations, how many people should be involved in the decision process, proposed methods for investigations when there is a disagreement or a need for clarification, the need to obtain evidence of the presence of the factor and its likely impact on adherence, and methods to score determinants' and potential strategies' impact on adherence (Flottorp et al., 2013). In one of the countries studied, the TICD worksheets were utilised to implement recommendations for the treatment of elderly patients with depression. Following the identification and prioritisation of 99 determinants in a previous barrier identification process (Aakhus, Oxman, & Flottorp, 2014), the TICD worksheet 3 was used to further prioritise the determinants from 99 to 22 through a scoring process and discussions among researchers. The potential strategies to address the 22 determinants, their likely impact, and whether the strategy should be targeted or adjusted were discussed. A total of 55 strategies that could address the 22 determinants were grouped together with the six recommendations in a drafted implementation plan. In separate activities, brainstorming sessions followed by structured group interviews were conducted with relevant key stakeholders (including patients) to identify strategies that could address each determinant. Current evidence regarding effectiveness of strategies to implementation of depression guidelines were presented to the participants. The participants were asked to discuss and prioritise the strategies they had suggested based on considerations on perceived importance of the targeted determinant, perceived impact of the implementation intervention, research evidence underlying the effect of the intervention, feasibility and cost of the intervention and other considerations. The findings from the group sessions were later compared with the initial implementation plan drafted by the researchers. New interventions and modifications were added or made to the researchers' drafted plan based on suggestions from the group sessions. The researchers then reviewed the revised intervention plan and scored the strategies according to feasibility and usefulness. The scores were later used to guide decisions on whether the strategy should be prioritised for implementation and if they should be adjusted to each municipality or practice. Disagreements were resolved by discussions (Aakhus, Granlund, Oxman, & Flottorp, 2015). This study demonstrated a comprehensive approach in using the TICD worksheets to systematically identify and prioritise determinants of practice, and to identify interventions that could address them through a scoring process that provides objective means to prioritise determinants and strategies and takes account of key stakeholders' perspectives. Nevertheless, one of the issues with the use of the TICD worksheet is that it led to a large number of suggested determinants and strategies that were not feasible to be addressed systematically in focus group discussions (FGDs) and this may have resulted in superficial assessments for some determinants or strategies (Aakhus, Granlund, Oxman, & Flottorp, 2015).

2.3.3 PDA implementation strategies and their effectiveness

This section describes strategies that have been utilised for PDA implementation and their effectiveness. Experimental studies that test the effectiveness of strategies in PDA implementation were scarce (Herrmann, Mansfield, Hall, Sanson-Fisher & Zdenkowski, 2016). Nevertheless, there are PDA implementation studies that have reported utilisation of strategies in real-world conditions. The following section describes some strategies and their effectiveness reported qualitatively in PDA implementation studies in routine clinical settings.

Conduct educational meeting

The strategy 'conduct educational meetings' was utilised in many PDA implementation efforts and showed various benefits. In the SDM implementation programme at the Massachusetts General Hospital, SDM training sessions were conducted at 15 of the hospital's 18 adult primary care practices involving 165 clinicians and other staff members. The trainings were incorporated into a regularly scheduled practice meeting attended by clinicians and other staff members. During the training, the participants watched a video PDA, reviewed provider and practice-level data on the PDA use, discussed challenges and concerns with their practice leaders and colleagues, and learnt about the EMR-enabled ordering program. A majority of the participants evaluated the training as useful (86%) or very useful (88%) and stated that they would make changes in their practices based on the session. Through the training, clinicians were more aware of the PDA content and understood the processes of delivering a PDA to patients. They were also motivated to use the PDA after seeing the provider and practice-level data. The training sessions resulted in more than doubling of the PDA use (Sepucha et al., 2016).

In Stacey et al.’s (2015) study on the implementation of the cystic fibrosis lung transplant referral PDA, a 5-hour educational workshop with role-play was conducted to increase HCPs’ knowledge, skills, and confidence in using the PDA. The workshop was similar to the one tested in a RCT conducted by the researchers previously, which showed improvements in HCPs’ knowledge and skills in providing better quality decision support compared to a control group (Stacey, O'Connor, Graham, & Pomey, 2006). The training workshop was attended by 15 nurses and one pharmacist from 18 clinics. The workshop taught the HCPs to identify patients who were ready for transplant discussions, getting them to use the PDA and to consider patient values. HCPs who participated reported that their confidence in providing decision support for patients increased after the training workshop (Stacey et al., 2015).

The Health Foundation’s MAGIC SDM programme as alluded above developed two training workshops as part of its multifaceted intervention. First was an introductory training to SDM aimed at all participating staff and the second was a 2-hour advanced training SDM workshops aimed at clinicians who were implementing SDM through the use of Option Grids PDAs (Elwyn, Llyod, Joseph-Williams et al., 2013). The advanced training workshop was reported to be one of the most successful strategies in facilitating the implementation. The trainings were effective in helping build coherence, improved skills, and promoted positive attitudes among clinicians about SDM practice. Practical skills were taught through role-play and was effective for showing that PDAs may support the process but do not replace communication skills. Furthermore, role-play with emphasised practical skills was shown to be better than theory-heavy presentations. The training helped clinicians understand how SDM differed from their current working ways. More than 75% of the clinical team members attended the training workshop, out of which 93% agreed that the training helped them explain to others what SDM is and 90% agreed that the training influenced them in their day-to-day practice. The training shifted the clinicians' minds from believing that they are already practising SDM to something they can do better (Joseph-Williams et al., 2017; Lloyd & Joseph-Williams, 2016).

Audit and provide feedback

In several PDA implementation studies, provision of feedback on HCPs' performance data, and patients' feedback and outcomes to HCPs had positive effects on PDA adoption. HCPs are more motivated to use PDAs when they see patient positive feedback (Silvia & Sepucha, 2006) and data on improvements of patient satisfaction, knowledge or other outcome measures (Feibelmann, Yang, Uzogara, & Sepucha, 2011). Ongoing provision of feedback was also crucial in getting HCPs to adopt PDAs (Tietbohl et al., 2015).

In the Group Health's SDM demonstration study, project management consultants provided twice-monthly reports to specialty service line providers. The reports contained information on the number of PDAs orders or viewed online, the volume of elective surgical procedures related to each PDA topic, and the 'defect rates' which was the proportion and number of patients who underwent a preference-sensitive procedure without having an opportunity to view a PDA. These regular data updates allowed the service lines and individual providers to assess their implementation progress by comparing their PDA distribution rate to other providers, and allowed the service line leaders to determine the source of process gaps, which helped support ongoing process improvement efforts. Feedback from one of the Group Health researchers stated that the monthly reports played a role in motivating some of the service lines to participate in the PDA implementation. Furthermore, clinicians received feedback about high patient satisfaction results with SDM and PDAs thus increased their commitment to using the PDAs, which led to continued sustainability (Arterburn, Westbrook, & Hsu, 2016; Hsu, Liss, Westbrook, & Arterburn, 2013; King & Moulton, 2013).

HCPs' performance and patient feedback were utilised in the MAGIC programme. Patient feedback was provided to clinicians in terms of the extent of patients involvement in making choices and decisions about their care and treatment during their appointment utilising the SDM patient experience questionnaire and patient's understanding of treatment options; their preferences (what is important to them); their readiness to decide; and their preferred choice of treatment using the decision quality measures. The SDM patient experience questionnaire was perceived to be helpful, however, the clinicians felt that the uniformly high scores in the results generated were not critical enough to stimulate them to reflect on and improve their practice. Patients may have answered the SDM patient experience questionnaire as a satisfaction survey, out of deference or due to their lack of confidence. Nevertheless, feedback from the decision quality measures were felt to be more effective as it provided real time data. It was administered during consultation and clinicians could assess patients' information needs or preferences and actively respond to them. The decision quality measures helped clinicians ensure alignment of patient preferences and treatment, reach better quality decisions, and demonstrate to clinicians that patients benefited from SDM. Besides the SDM patient experience questionnaire and decision quality measures, data from patient record systems on SDM activities entered by clinicians were also feedback to clinical teams. The data presented were the amount of SDM activities conducted by individual clinicians and such feedback created light-hearted competition between clinicians and served as an ongoing reminder to the clinicians to practise SDM. In addition, clinical teams were involved in appraising information from the quality improvement Plan-Do-Study-Act cycle reports and this contributed to the implementation process as providers could see changes in their practice which brought them together on the common goal of improving their practice (King, Taylor, Williams & Vanson, 2013; Lloyd, Joseph-Williams, Edwards, Rix & Elwyn, 2013).

Educational outreach visit

A few PDA implementation efforts included educational outreach visits as part of its implementation intervention but its effect appeared to be limited. In Lin et al.'s (2013) study, despite research team members engaged in academic detailing visits every other week, clinicians demonstrated a lack of understanding of the purpose and content of PDAs as they tended to use PDAs to replace consultations (Lin et al., 2013; Tietbohl et al., 2015).

In Uy, May, Tietbohl & Frosch's (2014) study on implementation of PDAs at four community-based solo practitioner primary care practices, research team members conducted weekly academic detailing. During visits at the clinics, a research team member familiarised the clinicians and staff with the PDA inventory and reviewed different PDA content. Furthermore, barriers to implementation were identified and solutions were developed. While this strategy led clinicians to prescribe various types of PDAs, it did not lead to an increase in prescribing volume (Uy, May, Tietbohl & Frosch, 2014).

Identify and prepare champion

In the MAGIC programme, clinical champions were chosen by including clinicians who were known to have experience or commitment with SDM such as those who had taken part in SDM projects (including development of PDAs), those who had studied SDM as part of their formal education, and those who were known to advocate to the ethos and principles associated with SDM. Some of the clinician champions were identified based on existing professional relationships and networks with the MAGIC core team members. The clinical champions were reported to be critical to the success of the programme. They played a key role in encouraging clinicians to take part in the programme, provided support and, sustaining their engagement over time (King, Taylor, Williams & Vanson, 2013).

In Silvia & Sepucha's (2006) study involving implementation of breast cancer surgical PDAs at nine sites, those that had champions were able to increase PDA adoption compared to sites without champions. The physician champions played a facilitating role by encouraging and arranging surgeons to view the video PDAs, making them understand the importance of the PDA, and having the patients view them. These made the clinicians more comfortable in recommending the PDA to patients. One of the champions was also the director of the center and encouraged their colleagues to adopt the PDA. In one of the sites where there was no physician champion to encourage PDA use, only a small proportion of patients viewed the PDA. However, this study also highlighted that having a champion alone was not sufficient for effective implementation when other implementation barriers are present. Three sites which had champions did not use the PDA at all due to the lack of clinical support, lack of system support, competing priorities for patient education and support, and scheduling problems (Silvia & Sepucha, 2006).

Mandate change

In the Group Health PDA implementation study alluded above, one of the effective strategies was having senior clinical leaders support the project and mandate to frontline staff on PDA implementation. The senior clinical leaders promoted PDA implementation in verbal and written communications to HCPs, highlighting the advantages of PDAs in terms of better-informed patients, greater liability protection under the new legislation, and improved quality of care. They engaged service line leaders in selecting a preference-sensitive condition for PDA use in the demonstration project and to design an integration plan. Then, the service line leaders mandated the PDA implementation to frontline providers and staff by consistently highlighting the importance and benefits of PDAs and made changes in organisational systems and procedures to enable distribution of PDAs and allowed providers to engage patients in SDM conversations. Project leaders also approached other service lines leaders that were less receptive to discuss distribution goals and showed implementation models used by other service lines for adoption or adaptation. This strong leadership and consistent messages led HCPs to believe the importance of the project and reinforced the expectation that the PDAs would be distributed and that providers would engage patients in SDM (Hsu, Liss, Westbrook, & Arterburn, 2013).

Similarly in the MAGIC programme, organisational leadership was effective to facilitate SDM and PDA implementation. Organisational leaders showed clinicians that SDM was an important organisational priority through internal board reports, conducting clinic visits, senior clinicians presentations in grand rounds, and when an executive board member worked with the implementation team. As a result, in clinicians saw SDM as something the organisation participated in rather than as another initiative being imposed on them that competed with other demands, hence driving higher engagement (Joseph-Williams et al., 2017; Lloyd, Joseph-Williams, Edwards, Rix & Elwyn, 2013).

Pre-visit PDA delivery approach

In a study that tested four strategies for distributing cancer screening PDAs in primary care, one of the strategies utilised was the the pre-visit model whereby patients watched the video PDA that was mailed to them before the clinic appointment. Clinicians reported a higher satisfaction rate compared to those who were exposed to a post-visit model (patients receiving a PDA after their appointment and having a follow-up during a second appointment or through other follow-up channels). The pre-visit model enabled clinicians to save time from communicating facts and instead discuss patient values, preference, and implementing choice as patients were already prepared to make a cancer screening decision (Brackett, Kearing, Cochran, Tosteson, & Blair Brooks, 2010).

In another study, a majority of the clinicians who participated in a RCT on the use of a computer-based colorectal cancer screening PDA felt that patients who used the PDA pre-visit was an appropriate use of their time and prepared them for discussions about choices which enhanced the quality of doctor-patient interactions and allowed patients to make an informed decision (Schroy, Mylvaganam & Davidson, 2014).

The Health Partners practice integrated the use of the Option Grid PDA in routine clinical practice and attributed its success to the pre-visit planning by nurses. In the pre-visit planning, nurses identified and familiarised patients with the PDA content before their discussions with the hand surgeons. This helped alleviate the burden on doctors to operationalise the Option Grid PDA during consultations. Furthermore, since patients had gone through the PDA beforehand, consultation time was shortened and patients could focus on the areas they wanted to discuss. This also contributed to patients being better informed and better prepared to make decisions (Scalia, Elwyn & Durand, 2017).

Involvement of other staff in the implementation

Engagement of staff other than clinicians can help facilitate and results in a more effective implementation. Other staff such as nurses were also more supportive of PDAs or decision support programmes compared to clinicians (Holmes-Rovner et al., 2000; Silvia, Ozanne, & Sepucha, 2008) and contributed to high rates and better quality of PDA distribution. They also had more time introducing and explaining the PDAs to patients (Friedberg, Van Busum, Wexler, Bowen & Schneider, 2013).

Two healthcare organisations, which had successfully integrated the use of Option Grid PDAs in routine practice, involved nurses in their implementation. In CapitalCare, nurses identified eligible patients to use the PDAs and attached the relevant PDA to the patient encounter form to alert the clinicians to use them during consultations. In the HealthPartners practice, nurses identified and facilitated a discussion to familiarise patients with the PDA content before they met with clinicians. These collective actions by nurses facilitated the integration of the Option Grid™ use into the clinical workflow and promoted PDA adoption (Scalia, Elwyn & Durand, 2017).

Provider incentive

Provision of a financial incentive was tested on PDA adoption at four community-based solo practitioner primary care practices. Clinicians or the clinical staff received a USD 15 incentive per PDA prescription. An incentive cap of 75 programs (USD 1125) per implementation was established. It was found that at implementation sites that prioritised PDAs as an educational tool for patients, financial incentive was not the key driver for clinicians to prescribe the PDAs to patients. However, at another site, financial incentive accelerated PDA prescription to the point that the inventory was restocked each week. This might have also led some clinicians to wrongly prescribe PDAs to patients as some were unsure why they were given a PDA. However, prescribing stopped when the incentive cap was reached (Uy, May, Tietbohl & Frosch, 2014).

The Centers for Medicare and Medicaid Services implemented the Comprehensive Primary Care Initiative, which focused on promoting patient engagement and practices that meet stipulated milestones each year would receive financial incentives. The CapitalCare organisation, which participated in the Comprehensive Primary Care Initiative, implemented SDM and introduced the use of Option Grid PDAs to its HCPs. While some HCPs were motivated to use the PDAs to meet the financial incentives, there were some who were not and this resulted in four out of the ten CapitalCare sites in Albany to fail to routinely implement the PDAs (Scalia, Elwyn & Durand, 2017).

2.4 Evaluation of PDA implementation

In Stacey et al.'s (2008) study of implementation of decision support and PDA at an Australian nationwide cancer call center, a quantitative approach was employed. A survey among HCPs was used to measure implementation outcomes such as HCPs' perceived barriers and facilitators to providing decision support, knowledge of decision support, and service outcome that included call length and quality of decision support provided to standardised callers (Stacey, Chambers, Jacobsen, & Dunn, 2008).

Miller, Brenner, Griffith, Pignone & Lewis (2012) was guided by the RE-AIM framework and assessed 'reach' and 'efficacy' of an in-clinic PDA distribution method using a designated clinical staff member to identify and distribute PDAs to eligible patients. The primary measures were the proportion of PDAs distributed to eligible patients (reach), and the proportion of decision aids viewed (efficacy) (Miller, Brenner, Griffith, Pignone & Lewis, 2012).

Another study adopted a three-part logic model to evaluate the implementation of SDM and PDA for stable coronary artery disease in a clinical practice. A questionnaire was administered to patients and clinicians to assess self-reported change in knowledge, skills, attitudes, and behaviors. Among the measures were implementation outcomes such as proportion of clinicians contacted, proportion of providers trained, proportion of patients seen, length of group visits, understanding of tasks and intention to use PDAs/guides, patient satisfaction, relevance to patients, patient intent to use SDM and perceived efficacy with SDM model (Holmes-Rovner et al., 2011).

Some studies adopted the qualitative study design and conducted interviews with HCPs and patients. The study examined the use of evidence-based leaflets at 13 maternity care units in Wales in a RCT, where the researchers conducted an independent qualitative study to examine how PDAs were used and how informed choice and decision-making occurred in the maternity care units. Non-participant observation and in-depth interviews (IDIs) were carried out involving HCPs and patients (Stapleton, Kirkham & Thomas, 2002).

Similarly, at the University of California, San Diego family medicine clinics, qualitative interviews utilising FGDs were conducted to examine PDA use and uncover barriers to utilisation at three primary care clinics among HCPs, clinic staff, and patients who were involved in the PDA distribution. However, one limitation noted in this study was that there was a lack of recruitment of HCPs who rarely used the PDAs hence input on why the PDAs were not utilised were not sufficiently explored (Newsome, Sieber, Smith & Lillie, 2012).

Some studies adopted the mixed-methods approach whereby both quantitative and qualitative data were collected. In a study to examine the implementation of a range of PDAs using a lending system at four solo primary care community clinics and the impact of a financial incentive on PDA prescribing, quantitative data was collected to assess the practices' average PDAs prescribed per month and patient PDA viewing rates whereas qualitative data involved collecting ethnographic field notes and performing interviews with the clinicians and staff to assess the clinics' receptivity towards the PDAs and perspectives on the implementation (Uy, May, Tietbohl & Frosch, 2014).

The US Breast Cancer Initiative used the Roger's theory of diffusion to guide the evaluation of implementation of breast cancer PDAs to almost 200 sites in New England. Quantitative measures were collected based on the adoption process outlined in the theory namely 'knowledge of PDAs' (number of sites that received the information about the PDAs ⁄Number sites contacted), 'interest in PDAs' (Number of sample set requests ⁄Number sites contacted), 'decision to adopt' (Number of signed participant agreement forms ⁄Number of sites contacted), 'implementation of PDAs' (Number of sites that reported using the PDAs with at least one patient ⁄number of sites contacted), 'sustained use' (Number of sites using the programmes regularly with patients at least 6 months after signing the participant agreement form ⁄ number of sites contacted). Semi-structured telephone interviews were also conducted but only one HCP from each implementation site was recruited to uncover their experiences and the resources and barriers that facilitated in hindering them from using PDAs. Hence, the feedback given was not truly representative of all HCPs involved in the PDA implementation in the settings. Furthermore, survey data was not collected from sites that were not interested to participate (Feibelmann, Yang, Uzogara, & Sepucha, 2011).

Belkora, Teng, Volz, Loth & Esserman (2011) also utilised the logic model for evaluation of their quality improvement study, which aimed to expand the use of breast cancer PDAs at the University of California's Breast Care Center. Evaluation of 'reach' of the PDAs to patients and process evaluation were conducted utilising quantitative and qualitative approaches respectively. The former assessed of the number of new patients who received the PDAs while the latter enabled tracking of when, how, and why the programme changes. The number of PDAs sent to patients was obtained from the study research records while notes from programme design meetings were analysed to track process changes (Belkora, Teng, Volz, Loth, & Esserman, 2011).

2.5 Synthesis of the literature review

Barriers and facilitators to PDA implementation

The literature review highlighted that there is a myriad of barriers and facilitators to PDA implementation and they were related to HCP, patient, organisational, system and innovation factors. The HCP and patient factors highlighted that PDA implementation can be affected by their ignorance (lack of awareness of PDAs, forgot to use), poor practice (lack of knowledge and skills, belief that they are already practising SDM, treating as educational material) and active resistance (belief that their knowledge is superior to PDA, disagreement with the PDA content, prefer to rely on clinicians to make health decisions). While active resistance to PDA implementation may be the hardest to overcome, barriers due to ignorance and poor practice were more widespread.

In terms of organisational factors, time constraint was the most commonly reported barrier to PDA implementation and this may be further exacerbated by competing materials for patients and PDA implementation would disrupt an organisational workflow. Organisational factors to PDA implementation can be affected by soft approaches that focus on positive encouragement and fostering a positive working culture, while a hard approach can be making PDA use as part of staff performance standards or duties. Having adequate resources such as computers, space (i.e. rooms) or the Internet is crucial for effective implementation and the use of EMR could facilitate PDA distribution to patients.

Development of implementation intervention

Among literature surrounding PDA implementation, there is a lack of reporting on how interventions were developed to implement PDA in routine practice. Only a few studies reported the use of implementation frameworks to guide their PDA implementation endeavours. Despite the presence of various barriers to PDA implementation in the literature, only a few studies reported the use of tailored intervention (Wensing, Bosch & Grol, 2010). Tailored intervention refers to strategies designed to overcome identified barriers to affect change in healthcare practice (Wensing, Bosch & Grol, 2010). Among studies that used tailored intervention, there is a lack of explicit details on how the strategies were selected such as the processes and who were the stakeholders involved.

One of the gaps identified in the literature of intervention development is the prioritisation of barriers which was infrequently reported in tailored implementation studies. As barrier assessment is the first step of developing a tailored implementation intervention, usually many barriers would be identified. However, there is a scarcity of details on how barriers were prioritised from an unwieldy list of barriers identified from an initial needs assessment exercise in studies, which used tailored intervention (Foy et al., 2005; Schouten et al., 2007). For example, in the paper by Foy et al., (2004), barriers selected to be addressed was briefly stated as *"The intervention content subsequently focused on factors considered most amenable to change"* without detailing the processes on how the considered factors most amenable to change were selected (Foy et al., 2004, p. 727). In implementation research, using a standardised prioritisation methods to identify key implementation barriers to select strategies is an understudied area (Craig et al., 2017). Prioritisation of barriers is a crucial step as not all barriers identified from needs assessment can be overcome given limited resources.

The literature review on implementation of health innovations in general found that the most common approach to selection of strategies for intervention development was engagement of clinic stakeholders by implementation researchers. Stakeholders who are engaged in the intervention development can provide contextual input on whether a strategy is likely to be effective or feasible in the implementation context.

Intervention mapping and the use of the TICD worksheets provide a more comprehensive and systematic approach to developing interventions that incorporate theories, evidence, and engagement of stakeholders. However, the processes were reported to be laborious and time-consuming. There is a need for a simpler approach for intervention development for implementation.

A lack of patient engagement in the process of intervention development was also found. Patients' perspectives were often not included to identify prospective barriers to selection of strategies even though it has been shown that patients' beliefs, motivation, and personality traits can have a significant impact on implementation outcomes (Feldstein & Glasgow, 2008).

The literature review also revealed that RCTs on testing strategies specifically to implement SDM and PDA are scarce (Herrmann, Mansfield, Hall, Sanson-Fisher & Zdenkowski, 2016) and there is a lack of evidence that could guide which strategies to be adopted. Nevertheless, effectiveness of strategies for PDA implementation in routine clinical settings was reported albeit qualitatively. Strategies such as conducting educational meetings, auditing and providing feedback, identifying and preparing champion, mandating changes, pre-visit PDA delivery, and involvement of other staff in the implementation were reported to facilitate PDA implementation in many studies. Provider incentives did not have a lasting impact and did not play a big role in influencing

HCPs to implement PDAs. Limited effectiveness was reported for the strategy educational outreach visit.

Evaluation of PDA implementation

In PDA implementation studies, only a few studies reported adopting implementation frameworks to guide evaluation. Various studies used different number and types of outcomes to measure success of their implementation endeavors. Feasibility was most often assessed with barriers and facilitators commonly reported, while fidelity was least assessed.

There were many studies that adopted the mixed-methods approach for evaluation. However, among PDA implementation studies that adopted RE-AIM as the evaluation framework, the studies either used the qualitative (Jones, Nowels, Kutner, & Matlock, 2015) or the quantitative approach (Belkora et al., 2015; Miller, Brenner, Griffith, Pignone & Lewis, 2012).

Furthermore, there was also a lack of recruitment of participants who rejected or did not participate in the implementation. Recruitment of this study population is important to provide a comprehensive understanding on the success or failure of an implementation. A lack of patient's feedback on the implementation was also found among PDA implementation studies.

2.6 Study conceptual framework

The study conceptual framework was developed based on the literature review. The literature review pointed that there was a lack of use of implementation framework to guide PDA implementation endeavours. The use of frameworks can help to provide systematic guidance on how to transfer research innovations to practice, helps to suggest barriers and facilitators that influence implementation outcomes, and provides directions in selecting and tailoring strategies that could predict the likelihood of an implementation success (Nilsen, 2015). In this study, the Knowledge to Action framework (Graham, Tetroe, & The Knowledge Translation Theories Research Group, 2007) was chosen and adapted to guide the implementation of the insulin PDA.

The Knowledge to Action framework

As the field of implementation science advances, various terms (e.g.: knowledge translation, knowledge transfer, knowledge exchange, research utilisation, implementation, dissemination, and diffusion) have been used and this has caused confusion. The Knowledge to Action framework was developed in 2006 to provide clarity on concepts and components involved in the process of translating research to practice (Graham et al., 2006). It is derived from 31 planned action theories from nursing and interdisciplinary fields (Graham et al., 2007).

The framework has two components; the Knowledge Creation (represented by the funnel) and the Action Cycle (surrounding the funnel). Knowledge creation comprised of three phases: knowledge inquiry, knowledge synthesis, and knowledge tools and products. Knowledge inquiry refers to generation of primary data from empirical research. Knowledge synthesis involves synthesis of primary data that leads to identification of a knowledge pattern such as results from systematic reviews and meta-analysis. Knowledge tools and products is the creation of third generation knowledge, i.e. evidence-based innovations utilising synthesized knowledge and presenting them in user-friendly formats. It can be understood that as knowledge moves down the funnel, it becomes more distilled and practical for stakeholders to use (Graham et al., 2006). Once the knowledge tools or products are created, it should go through the Action Cycle to translate into practice through the following steps: (a) identify problem or identify, review and select knowledge, (b) adapt knowledge to local context, (c) assess barriers to knowledge use, (d) select, tailor and implement intervention, (e) monitor knowledge use, (f) evaluate outcomes and (g) sustain knowledge use (Graham et al., 2006). Figure 2.3 illustrates the Knowledge to Action Framework.

The Knowledge to Action framework was chosen for this study for a number of reasons. First, a Cochrane systematic review found that implementation is more likely to be effective in changing professional practice and healthcare outcomes if the strategies are tailored based on identified barriers and facilitators (Baker et al., 2015). The literature review on factors influencing PDA implementation highlighted numerous implementation barriers; hence the tailored implementation approach is an appropriate method. The Action Cycle in the Knowledge to Action Framework depicts the translation of knowledge to practice using tailored implementation intervention.

Second, the framework provides a clear and broad practical step-by-step guidance on how to move evidence-based innovation to practice as compared to other frameworks such as the Promoting Action on Research Implementation in Health Services Framework (Kitson, Harvey, & McCormack, 1998; Kitson et al., 2008), which only considers elements and sub-elements. The seven steps in the Action Cycle are also not too many and simple to understand for execution as compared to the Quality Implementation Framework, which detailed 14 defined steps (Meyers, Durlak, & Wandersman, 2012).

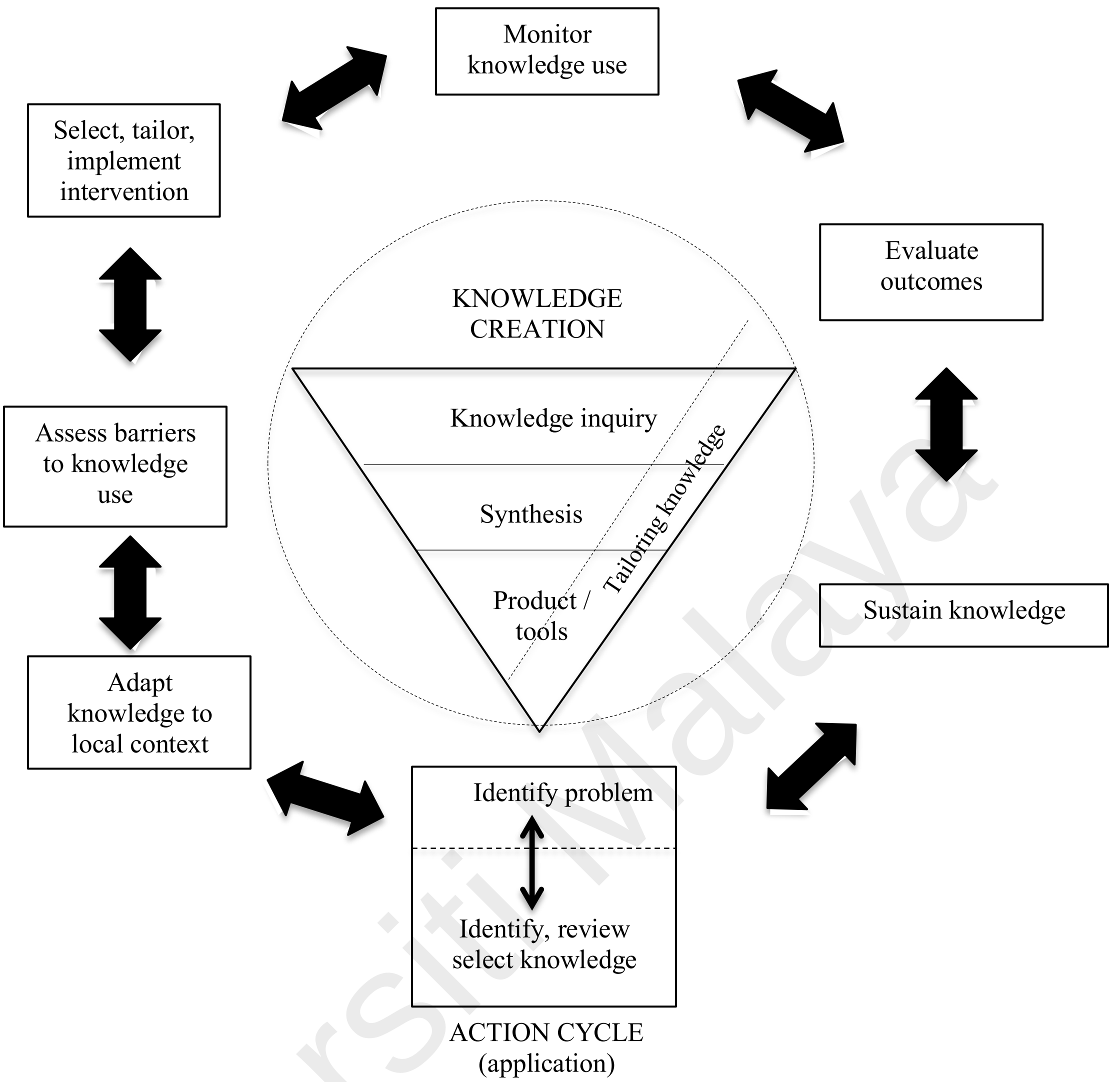


Figure 2.3: The Knowledge to Action Framework

Thirdly, the Knowledge to Action framework provides flexibility in terms of how each of the steps in the Action Cycle can be operated. The framework can be adapted or combined with other theories and frameworks to enhance findings (Field, Booth, Ilott, & Gerrish, 2014).

Lastly, the Knowledge to Action framework is one of the most frequently cited conceptual frameworks for knowledge translation. A total of 146 research papers have cited the use of this framework from various fields (Field, Booth, Ilott & Gerrish, 2014) including implementation of PDAs (Stacey et al., 2015).

Operationalisation of the Knowledge to Action Framework in this study

In this study, the implementation of the insulin PDA was guided by the steps ‘Barriers to knowledge to use’, ‘Select, tailor, implement interventions’, ‘Monitor knowledge use’, ‘Evaluate outcomes’ and ‘Sustain knowledge use’ of the Action Cycle in the Knowledge to Action Framework. This study comprised of three phases:

Phase 1: Assess barriers to knowledge to use,

Phase 2: Select, tailor, implement interventions, and

Phase 3: Monitor, evaluate and sustain knowledge use.

In phase 3, the last three steps of the Action Cycle were combined to a single phase known as ‘Monitor, evaluate and sustain knowledge use’ as it involved measuring implementation outcomes.

The ‘Knowledge Creation’ domain and step 1 ‘Identify, review, select knowledge’ and step 2 ‘Adapt knowledge to local context’ were not included in this study as they were completed. As alluded in the Introduction, an evidence-based insulin PDA was already developed (knowledge creation) specifically for the Malaysian context (adapt knowledge to local context) to address the issue of poor glycaemic control among patients with type 2 diabetes (identify, review, select knowledge).

In this study, Phase 1 corresponded to step 2 of the Action Cycle (assess barriers to knowledge use) in the Knowledge to Action framework and involved exploring potential barriers to the insulin PDA implementation. In this phase, the Theoretical Domains Framework (Cane, O’Connor, & Michie, 2012) was chosen as the determinant framework (Nilsen, 2015) to identify the barriers to implementation of the insulin PDA at the UMMC primary care clinic.

Phase 2 corresponded to step 3 (select, tailor, implement intervention) in the Action Cycle and involved selecting, tailoring and implementation of strategies to overcome the identified barriers in phase 1. However, based on the literature review, it was found that prioritisation of barriers was infrequently reported in the development of intervention in implementation studies nor explicitly stated as a concrete step in many implementation frameworks. Prioritisation of barriers for tailoring intervention is a crucial step as barrier assessment often leads to an unwieldly list of barriers where not all can be overcome (Powell et al., 2017). In the area of quality improvement efforts, decision makers and clinicians had difficulties in selecting their area of focus when quality issues were given. Furthermore, staff may only be able to focus on one or two quality improvement areas at a time (Rantz et al., 2001). To address all the barriers would require a large amount of resources hence the implementation may not be feasible. Therefore, there is a need for a systematic and an objective approach to prioritise the barriers and fine-tune the strategies to have effective implementation. Therefore, step 3 of the Action Cycle was expanded to include the barrier prioritisation step in addition to select, tailor and implementation of the strategies. Once the intervention was developed, the insulin PDA was then implemented.

Phase 3 corresponded to step 5 and 7 of the Action Cycle, which focused on implementation evaluation. The RE-AIM framework (Glasgow, Vogt, & Boles, 1999) was selected as the evaluation framework (Nilsen, 2015) for this study as the literature review pointed that many studies selected only a few implementation outcomes for their evaluation endeavor. The RE-AIM framework provides comprehensive and relevant dimensions to measure within the monitor, evaluate, and sustain knowledge use steps of the Knowledge to Action framework. The RE-AIM ‘Reach’, ‘Adoption’ and ‘Implementation’ dimensions correspond to the ‘Monitoring knowledge use’ step of the Action Cycle, which was to measure instrumental knowledge use (i.e. changes in behavior or practice related to knowledge use) whereas the ‘Effectiveness’ dimension corresponds to the ‘Evaluate outcomes’ step of the Knowledge to Action framework, which aims to measure the ultimate impact of the implementation, that is the efficacy of the PDA when implemented. The ‘Maintenance’ dimension refers to evaluation of the sustainability of the implementation and this corresponds to the ‘Sustain knowledge use’ step of the Knowledge to Action framework. In the RE-AIM framework, each of the dimensions are clearly defined hence it provided explicit guidance on what to assess.

In this study, step 6 ‘Evaluate outcomes’ of the Action Cycle was not undertaken given that the effectiveness of PDAs such as patient decisional conflict, patient involvement in SDM, and doctors’ satisfaction with the SDM and PDA discussion have been well established in many trials (Stacey et al., 2017) including trials conducted in the Asian settings (Gao et al., 2021; Jalil et al., 2020; Lin et al., 2020;). A few studies on PDA implementation in routine settings have also shown PDA to be effective when they were actually used (Belkora et al., 2012; Newsome, Sieber, Smith & Lillie, 2012). It has been highlighted that there is a need for distinction between implementation, service system and clinical treatment/patient outcomes (Proctor et al., 2011). Implementation outcomes are proximal indicators of implementation processes and serve as intermediate outcomes to achieve effective health services and clinical outcomes. When an innovation is implemented well and according to plan, it can lead to its desired outcomes hence implementation outcomes are indicators of implementation success (Proctor et al., 2011). This study aimed to focus on implementation outcomes to understand the translatability of PDAs in the real world as this is the main issue that is plaguing the field of SDM and PDA. Furthermore, for ‘Effectiveness’ to be assessed in a real-world implementation, it would first require that the innovation be adopted, implemented, and reached its target users. Only when success levels of adoption, implementation and reach are attained can effectiveness then be assessed. Figure 2.4 illustrates the study conceptual framework and the shaded boxes indicate the three phases of this study.

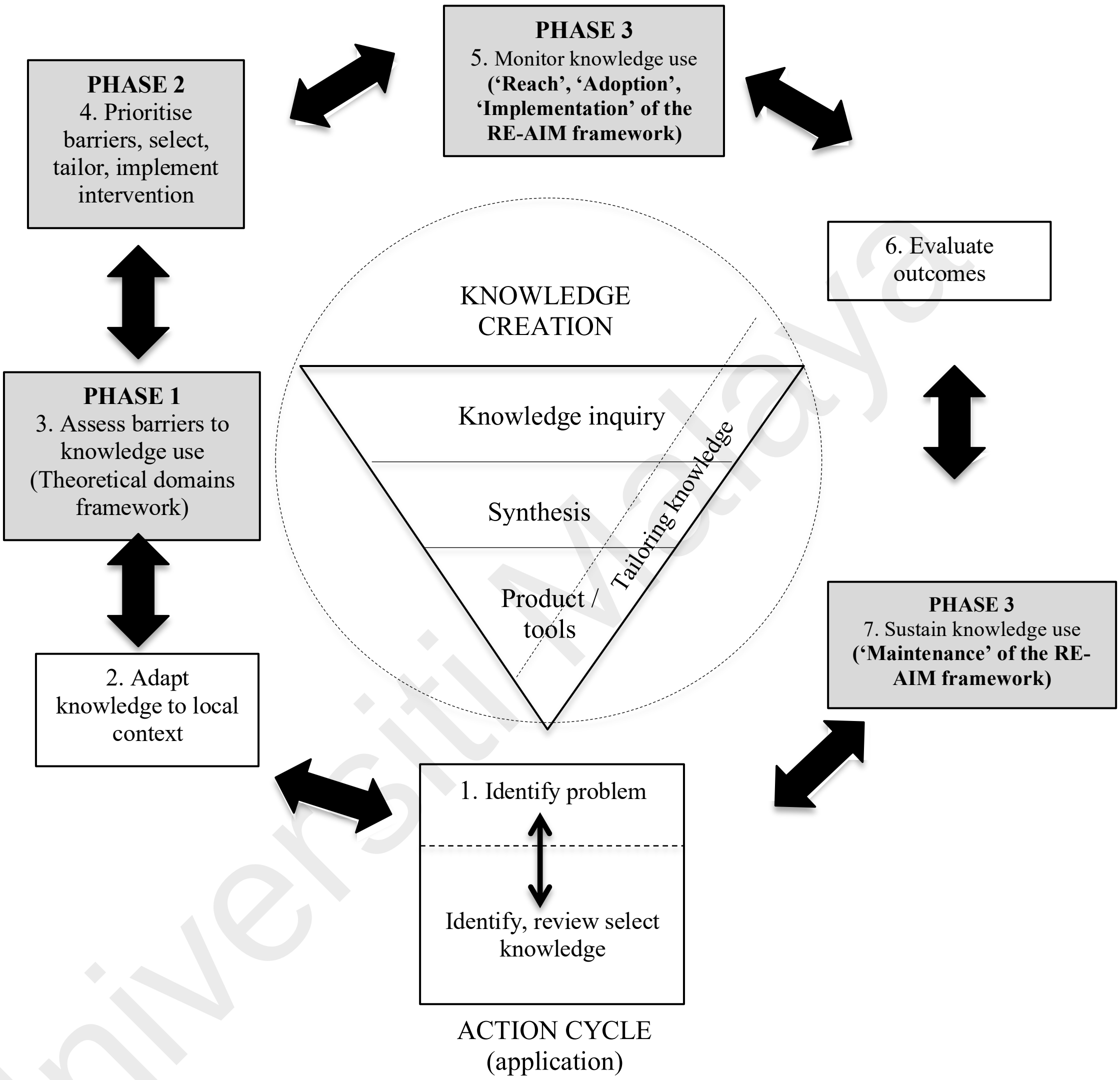


Figure 2.4: Study conceptual framework

2.7 Chapter summary

The extensive review of literature conducted on factors that could influence PDA implementation showed that PDA implementation can be affected by HCP, patient, organisational, system and innovation factors. It was also found that a majority of the studies were conducted in the Western countries.

Reporting on the development of interventions to implement PDAs are scarce and often do not include explicit details. Some studies used the tailored intervention approach while others developed their intervention by working with clinic stakeholders. Studies of implementation of other health innovations offered more insights on steps that can be utilised for intervention development such as the use of theories, identification of strategies, and the use of the intervention mapping approach or the TICD checklist. Gaps in the process of intervention development were identified which included the lack of use of implementation framework, the lack of focus on the prioritisation of barriers, and a lack of studies that adopted the tailored implementation approach. There was also a lack of involvement of patients in intervention development.

In terms of evaluating implementation outcomes, there was also a lack of utilising an evaluation framework to guide the process. Different types of implementation outcomes were measured in various studies and a lack assessment of fidelity was found.

The conceptual framework of this current study was developed based on the literature review conducted. The conceptual framework follows the Knowledge to Action framework and the rationale was explained. The framework was also complemented with additional frameworks such as the TDF to explore barriers and facilitators, and the RE-AIM framework for assessment of implementation outcomes. Prioritisation of barriers was also included in the 'Select, tailor and implement intervention' step. The reason for not undertaking the 'Identify problem', Identify, review, select knowledge', 'Adapt knowledge to local context' and 'Evaluate outcomes' steps of the Action Cycle was explained. The conceptual framework was developed to set the direction for this study. The next chapter discusses the study methodology and results.

CHAPTER 3: METHODS AND RESULTS

3.1 Introduction

This chapter presents the study's methods and results according to three phases. The study conceptual framework is reshown below to indicate the three phases of this study.

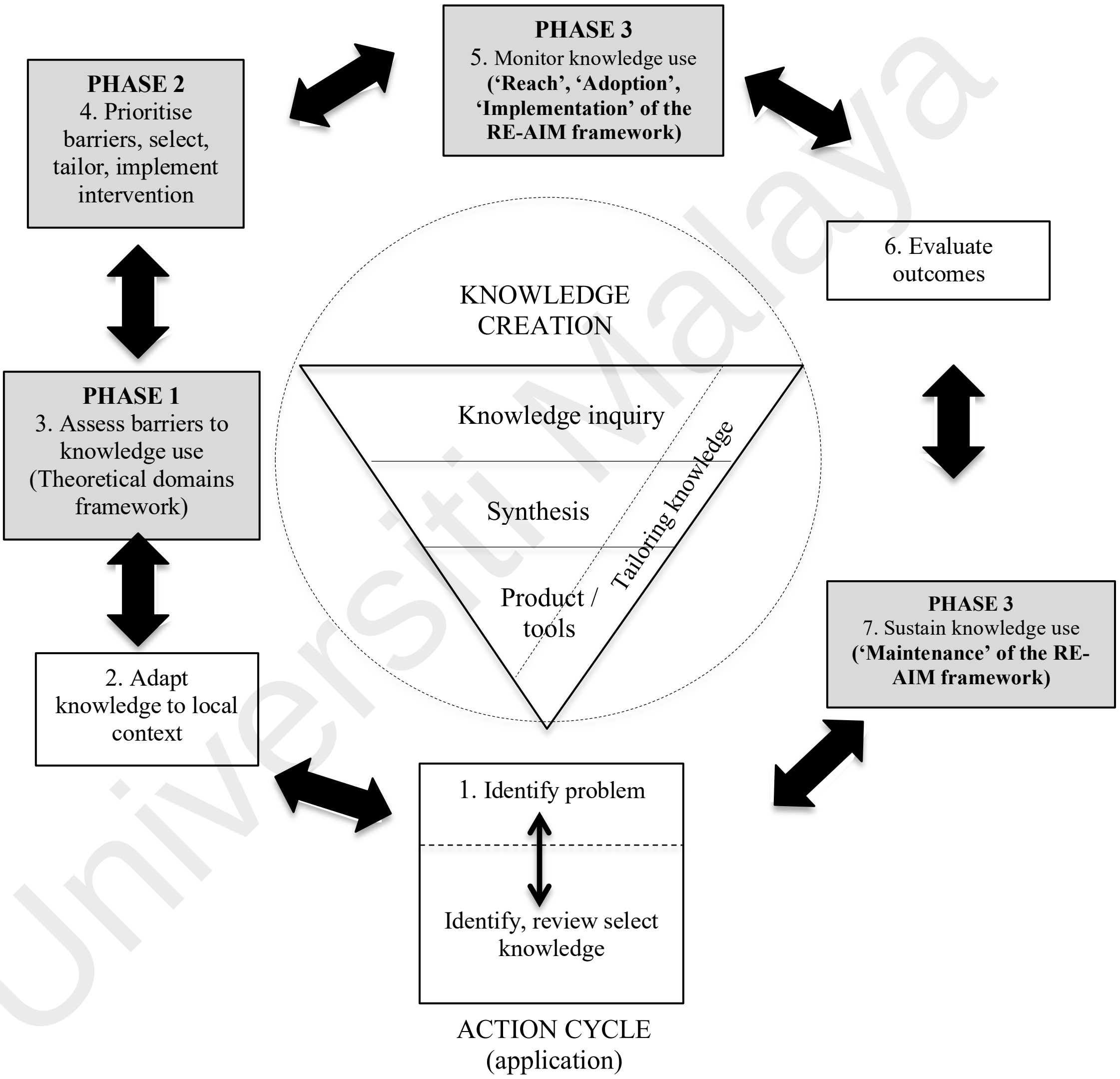


Figure 2.4: Study conceptual framework

This chapter is split into 3 sections, to detail the methods and results of each Phase and the corresponding step in the Action Cycle.

The first section details how in Phase 1, the qualitative study design was adopted and how findings on the barriers and facilitators influenced the implementation of the insulin PDA in the Malaysian public healthcare settings. This corresponds with Step 3 of the Action Cycle.

The second section describes how Phase 2 aimed to develop and implement a pragmatic intervention to overcome the barriers identified in Phase 1. This corresponds with Step 4 of the Action Cycle with an additional step on the prioritisation of barriers. The steps involved in Phase 2 were:

Step 1: Prioritising barriers to implementation of the insulin PDA,

Step 2: Select and tailor strategies to overcome the prioritised barriers,

Step 3: Operationalisation of the strategies, and

Step 4: Finalisation of intervention and pathway through a clinic stakeholders meeting.

The methods involved in carrying out each of the step were explicitly described and subsequently, the results resulted from each of the step were presented. Then, detailed descriptions of the implementation of the intervention at the UMMC primary care clinic were reported.

This chapter also details the methods and results for Phase 3, which aimed to evaluate the implementation outcomes of the insulin PDA implementation and to explore the reasons for the outcomes. This phase corresponded to Step 5 and 7 of the Action Cycle.

The approaches to the mixed-methods evaluation were reported in detail and the findings were subsequently presented.

3.2 Phase 1: Exploring barriers and facilitators to implementation of the insulin PDA

This phase describes the study design, data collection approach for the first phase of this study, which was to explore the barriers and facilitators to implementation of the insulin PDA in the Malaysian public healthcare settings followed by presentation of the findings. The shaded box at Figure 3.1 illustrates Phase 1 of this study in the study conceptual framework.

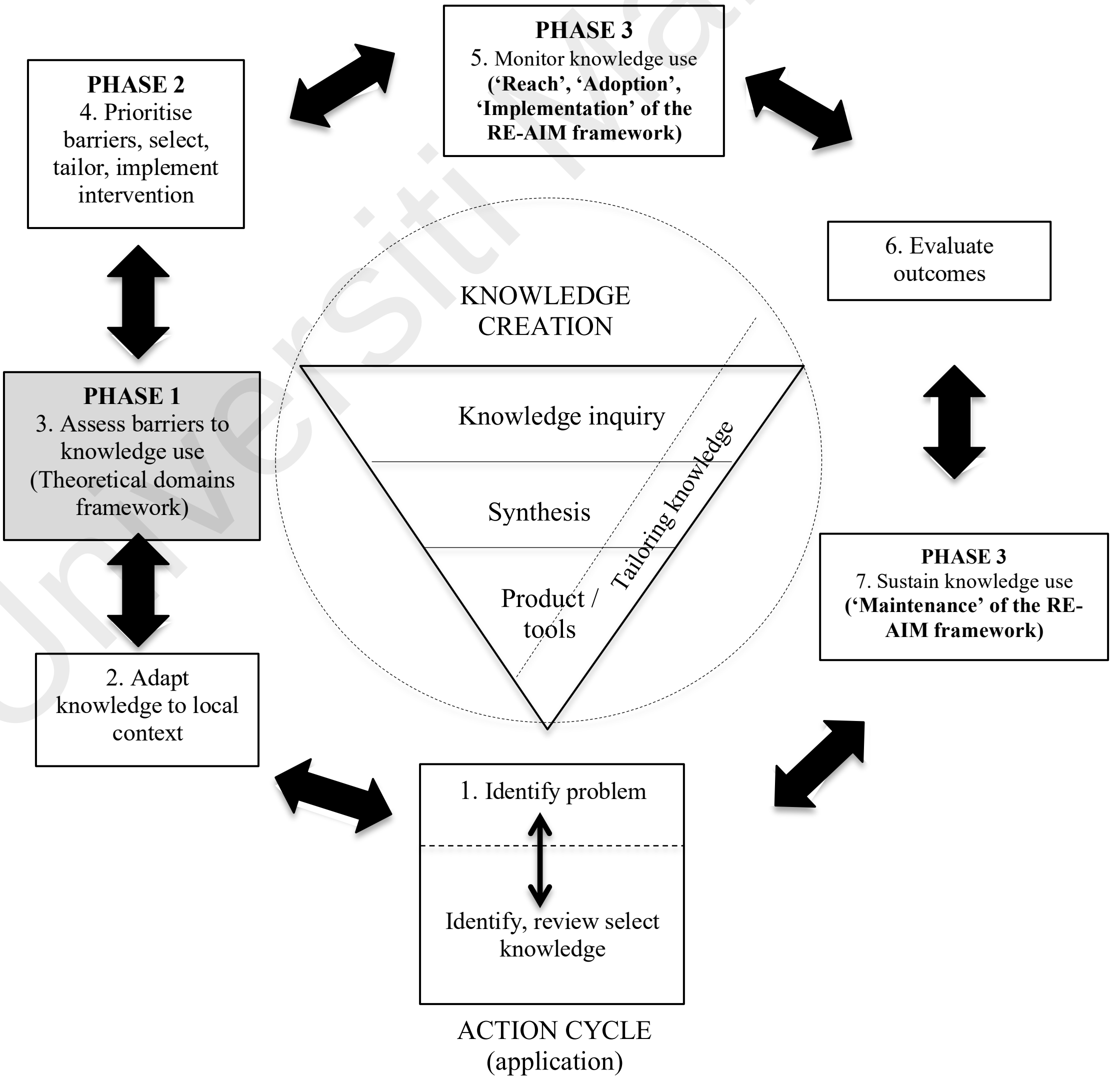


Figure 3.1: Phase 1 of the study in the study conceptual framework

3.2.1 Methods

3.2.1.1 Study design

This study adopted a qualitative study design to explore the barriers and facilitators to implement the insulin PDA. This study design was chosen because it allowed the researcher to explore and understand the issues of implementation of health innovation, particularly on the implementation of insulin PDA in the Malaysian context, which is understudied. As alluded in the Introduction, the majority of studies on PDA implementation are conducted in Western countries hence their findings may not apply to the local Malaysian context. Qualitative study design is used when there is a need to explore a topic or issue, especially when information from literature may not be adequate or suitable to be applied (Creswell, 2013). This is especially for implementation research, which is highly contextual (The BMJ, 2013).

The qualitative approach used in this study was interpretive description (Thorne, Kirkham, & MacDonald-Emes, 1997). This study design was borne in the field of nursing science to address the limitation of traditional qualitative study designs that generate findings that may not be applicable to clinical practice (Thorne, Kirkham & MacDonald-Emes, 1997). Traditional qualitative approaches such as phenomenology (Groenewald, 2004), ethnography (Teherani, Martimianakis, Stenfors-Hayes, Wadhwa, & Varpio, 2015) and grounded theory (Glaser & Strauss, 1967), which were derived from the field of philosophy, anthropology, and sociology, respectively focus on understanding problems or phenomena such as human experience, how people behave, and generation of theory. While interpretive description shares same methodological tools with phenomenology, ethnography, and grounded theory qualitative study designs, the difference lies with the generation of findings that are practical and applicable to clinical practice (Thorne, 2016). Unlike the traditional qualitative approaches such as phenomenology and the grounded theory which focus on common experiences and generating findings that are more philosophical and theoretical, interpretive description also accounts for individual cases (Thorne, Kirkham, & O'Flynn-Magee, 2004) and this enabled practical application to be derived. Another strengths of this design lies in the use of HCP knowledge as the focus to orient the research leading to findings that could yield clinical implications (Thorne, Kirkham, & MacDonald-Emes, 1997). This approach is suitable to apply to the topic of health innovation implementation because HCPs are frontline users, thus their experiences using these innovations in clinical settings can help to provide input that can offer practical solutions to implementation challenges in healthcare practices. The chosen qualitative data collection methods for this phase were IDIs and FGDs.

3.2.1.2 Study settings

The study settings was based on the Malaysian public healthcare, specifically at an academic primary care clinic in an urban government teaching hospital (Universiti Malaya Medical Center (UMMC)) and five public community clinics located in the area of Klang Valley area, Malaysia. The reason why these two healthcare settings were selected was to enable exploration of as many as possible the potential barriers and facilitators to the insulin PDA implementation in the Malaysian healthcare settings.

The public healthcare setting was chosen because a majority of diabetes patients are managed in the public sector where healthcare services are subsidised by the government. Hence, the insulin PDA would be able to reach a larger target population. Furthermore, all public healthcare settings are under the governance of Ministry of Health Malaysia, and generally share common healthcare delivery systems and structure. Therefore, the findings of this study would be helpful in implementing the insulin PDA in other clinics under the public health sector.

In Malaysian public healthcare, all the primary care clinics provide outpatient care and only doctors are allowed to prescribe insulin to patients. However, there are some differences between academic clinics and community public health clinics. While doctors in community clinics focus on clinical work, doctors in an academic setting have to juggle between clinical work, teaching, and studies. The medical officer turnover rate for academic settings is high as those who pursue their postgraduate studies may be posted to other clinics during their studies for external training and leave once their studies are completed. In community clinics, most of the doctors work on a long-term basis and focus only on clinical work.

To identify as many barriers and facilitators to the insulin PDA implementation in Malaysian public healthcare settings, five community clinics were selected based on their location, the socio-economic status of the community in the clinic area, patient population profile, and the presence of leadership and manpower for diabetes management. The researcher contacted several clinic managers by e-mail to ask about these characteristics of their clinics before inviting the five clinics to participate in this study.

At the UMMC primary care clinic, the two HCP groups involved in insulin initiation in the clinics were the doctors and diabetes educators. Diabetes educators are staff nurses who completed the Advanced Diploma in Diabetes Education course whereby they were trained on diabetes education, treatment and nursing of diabetes patients (including on insulin initiation). There is a Diabetes Education Counseling Unit in the clinic where three diabetes educators provide patient education on diabetes, blood glucose monitoring, insulin initiation, and injection techniques. Patients are directed here through doctor referrals.

As for the community clinics, diabetes teams were present in each clinic to cater to the high diabetes patient load. The diabetes team usually consists of 1-2 doctors, one diabetes educator, and 1-3 staff nurses. In some clinics, trained staff nurses carry out the duties of a diabetes educator if a diabetes educator is not available. In the community clinics, pharmacists also play a role in diabetes management by addressing patient medication adherence and providing patient education on diabetes through a service known as the Diabetes Medication Therapy Adherence Clinic. This service is available in all community clinics in Malaysia. At the UMMC primary care clinic, pharmacists are not involved in patient diabetes management except dispensing medication.

3.2.1.3 Study participants

The participants of this study were purposively sampled and consisted of:

1. healthcare managers (hospital director, endocrine and primary care medicine managers, hospital matrons and community clinic managers)
2. HCPs (doctors, diabetes educators, pharmacists, staff nurses), and
3. patients with type 2 diabetes.

Table 3.1 shows the inclusion criteria for the participants.

Table 3.1: Phase 1 participants' inclusion criteria

Stakeholder	Inclusion criteria
Healthcare managers	Individuals who set standards of care, have the authority to decide which health innovation should be implemented in the clinic, and implement programmes to improve diabetes care.
HCPs	Individuals who are involved in advising patients about starting insulin.
Patients	Patients with type 2 diabetes who have been seeking diabetes treatment in the clinics for more than one year and are advised to use or are currently using insulin.

In order to achieve maximal variation, the researcher recruited participants of different socio-demographic backgrounds (ethnicity, gender) as well as those with and without experience in using the insulin PDA. It should be noted that the insulin PDA was previously pilot-tested with a small group of HCPs in the UMMC primary care clinic to test its acceptability during its development of (herewith: acceptability study) (Lee et al., 2014). A few of them had continued using it after the acceptability study had ended. Healthcare managers from the UMMC primary care clinic were not involved in the acceptability study.

3.2.1.4 Study interview guide

The interviews were conducted with the aid of a semi-structured interview guide which was developed based on the TDF (Cane, O'Connor & Michie, 2012), literature review on factors influencing PDA implementation and, discussions among researchers.

The TDF is an overarching framework of 14 theoretical domains synthesised from behaviour change constructs found in 33 behaviour change theories (Cane, O'Connor & Michie, 2012). It was developed to identify and describe factors that influence HCPs' behaviours in relation to implementation of health innovation (Cane, O'Connor & Michie, 2012). The 14 domains in the framework are:

1. knowledge (e.g., of scientific rationale for implementation),
2. skills (e.g., ability)
3. social/professional role and identity (e.g., group norms),
4. beliefs about capabilities (e.g., self-efficacy),
5. optimism,
6. beliefs about consequences (e.g., outcome expectancies),
7. reinforcement,
8. intention,

9. goals,
10. memory, attention, and decision processes (e.g., attention control),
11. environmental context and resources (e.g., resources),
12. social influences (e.g., leadership),
13. emotion (e.g., burnout),
14. behavioral regulation (e.g., feedback)

The TDF was chosen to identify the barriers to implementation of the insulin PDA as behaviour change is a major contributing factor when adopting an innovation. Additionally, the TDF covers emotional aspect that could influence behavior change in an individual, apart from the rational and cognitive aspects. The TDF is also a comprehensive framework in the sense that organisational and resources factors as potential influences to implementation are also accounted for in the framework under the 'environmental context and resources' domain. Furthermore, the TDF contains a manageable number of constructs that can be addressed and are easy to understand compared to other frameworks such as the Consolidated Framework for Implementation Research (Damschroder et al., 2009) and the TICD checklist (Flottorp et al., 2013) that have an extensive number of constructs (39 and 57 respectively). The TDF has been used in many clinical behaviour change implementation research projects (Francis, O'Connor, & Curran, 2012), which is why it is appropriate to use in this study to explore the barriers and facilitators influencing implementation of the insulin PDA. The TDF was used to create questions and prompts according to the domains in the framework (Appendix B).

3.2.1.5 Data collection process

The data collection took place from January to September 2016 and began in the UMMC primary care clinic followed by the community clinics. Healthcare managers, HCPs, and patients who fulfilled the study inclusion criteria were invited to participate in the study. Doctors in the clinics helped identify eligible patients during their practice and referred them to the researcher who were present at the clinic. Interview appointments were made with eligible participants through telephone calls. The data collection process is illustrated in Figure 3.2.

- Study information sheet was given and explained to the participants verbally (Appendix C)

↓

- Obtained written informed consent.

↓

- The researcher presented the insulin PDA, its objective and content, and the concept of SDM to participants using PowerPoint and a video.

↓

- Participants completed a socio-demographic information form (Appendix D)

↓

- The researcher conducted the interviews using the interview guide. The interviews were audio-recorded.

↓

- Field notes were written to document content of the discussions and information that could not be recorded such as patient expressions and gestures.

↓

- Interview reflections were written as soon as interviews ended.

Figure 3.2: Data collection process

All the interviews were face-to-face and conducted in clinic consultation rooms during rest times in between clinical consultations, or in the offices of the healthcare managers and HCPs. Patient interviews were also conducted in private rooms in the clinics except one, which was conducted at the participant's home. All the interviews lasted between 50 to 90 minutes.

The researcher conducted a majority of the interviews, with an initial few supervised by the researcher's supervisors Yew Kong Lee (YKL), and Chirk Jenn Ng (CJN). Out of the 37 IDIs and 15 FGDs conducted, the researcher's supervisors conducted six IDIs and three FGDs when some interviews had to be conducted concurrently. Fifteen of the interviews were conducted in Malay, and the rest in English. The data collection ceased when data saturation was achieved (Lincoln & Guba, 1985); that is when the barriers or facilitators that emerged from the data became repetitive.

3.2.1.6 Data analysis

Data analysis was performed concurrently with data collection at the clinics. All the interviews were transcribed verbatim by the researcher as well as by a part-time experienced transcriber. The part-time transcriber was asked to incorporate notes made by the note-taker on the participants' non-verbal gestures and use the transcription symbols provided. Table 3.2 highlights the transcription symbols used for this study.

Table 3.2: Key to transcription symbols used in this study

Symbol	Meaning
…	A pause during participants' stories telling
( )	Denotes researcher's alteration for clarity
[ ]	A non-verbal response
//	Indicates material deleted from the interview excerpts

All the transcripts were checked for accuracy by the researcher before being imported into the qualitative data software NVIVO (QSR International, 2016) for thematic analysis (Braun & Clarke, 2008). Thematic analysis is a method for identifying pattern and themes within qualitative data (Braun & Clarke, 2008). Initially, the transcripts from each clinic were read to get an overview of the broader issues within each clinic before moving on to the minutiae of the data. This helped the researcher with a more coherent analysis when combining smaller data unit. Subsequently, the researcher and her supervisors read in detail and familiarised themselves with the first three transcripts from the UMMC primary care clinic and coded the transcripts independently. A code is short text or paragraphs that represents the meaning of a text segment. Codes that have similar meaning were grouped together to form a category, and later the categories were compared and merged into bigger themes (Glaser, 1978). They then discussed the categories and themes that emerged from their individual analysis. They referred to field notes and interview reflections to understanding and interpret the data better. Emerging categories and themes were discussed and finalised once discrepancies were resolved through a consensus. This created a coding framework that the researcher used to analyse the remaining transcripts from the UMMC primary care clinic.

The same coding framework was also used to analyse data for transcripts from the community clinics. New codes and categories that emerged were added to the coding framework while those that were irrelevant were removed. The researcher coded all the transcripts for the community clinics while YKL coded transcripts from two community clinics (Clinic B and C) and CJN coded for Clinic E. A research collaborator, Ping Yein Lee (PYL) coded for Clinic D, independently. They all then discussed the emerging categories and themes from their individual analysis with the researcher to ensure the final codes and themes were credible. Any new codes and categories were added to the list of themes and categories upon consultation with the research team. During the data analysis, the researchers went through the transcripts, field notes, and interview reflections for both HCPs and patients from each clinic to thoroughly understand the data. The written field notes and interview reflections were triangulated with the results to ensure that the findings were correctly interpreted and no information was missed out, and to supplement the interview findings. By going through the data back and forth, the patterns of commonalities and differences in the barriers and facilitators across the clinics became clear to the researcher. In view that the barriers identified in this study would be used to develop the intervention, the researcher also extracted any potential strategies or processes that could address barriers raised or facilitate the insulin PDA implementation.

3.2.1.7 Reflexivity

Qualitative research relies on the researcher to collect, analyse and interpret the data themselves. Hence it is inevitable that the interpretation of the findings could be subjected to the researcher’s bias as any individual has their own beliefs, assumptions and values towards a particular matter. As the researcher of this study, this is also applied to me as I tried to interpret the perceived barriers and facilitators to the insulin PDA implementation among the participants. I hereby provide an account of my background, working experiences, and personal assumptions that might have influenced the validity of the findings.

Background in health research

Following completion of my bachelor’s study in the field of Biology, I began working research officer at the Faculty of Medicine, University of Malaya in 2009. Prior to undertaking this PhD study in 2016, I was involved in numerous health-related research projects on topics such as type 2 diabetes, sexual and reproductive health, and medical education. My research and work experience has resulted in multiple scientific publications (Publons: Q-4993-2017) and innovations such as a teaching module on research and publication ethics and, a system to monitor the course progress of medical students (Copyright: LY2014000655). I could understand the amount of time, effort, and resources that are invested in conducting research and developing innovations, hence so I believe they should be utilised in everyday practice.

Interest in the issue of poor glycaemic control among type 2 diabetes patients

My master's research involved studying people living with type 2 diabetes with poor glycaemic control despite using insulin. I realised that eventhough patients were prescribed treatments that could potentially improve their health, like insulin, they may not follow it if it is not aligned with their values and needs (Tong, Vethakkan, & Ng, 2015). I identified that there is a need for patients to make informed decisions about their diabetes treatment. I was aware that there was a PDA specifically for insulin decision-making which could be implemented to help people living with type 2 diabetes make informed decisions about starting insulin. The insulin PDA is a useful tool as it could bring benefits not only to patients but to HCPs as well in terms of starting discussions about insulin initiation and information delivery to patients.

Perception of the positive impact of the insulin PDA

Based on my past experiences with research data collection in the Malaysian public healthcare setting as a research officer, barriers such as time constraints and patients' attitudes are commonly faced by HCPs. It is difficult for HCPs to use a new tool in their limited consultation time when it creates additional tasks for them. Hence, HCPs may not want to use a new innovation if it incurs extra time. Patients who decline to use the innovation would deter HCPs from adopting it. However, I believe that the insulin PDA can be successfully implemented if its benefits are clearly explained to HCPs and patients, and if the processes involved in the implementation are not a burden or require too many steps. Furthermore, the insulin PDA is in a booklet format that is fairly easy to be use. It can even potentially reduce consultation time. I believe that the insulin PDA can be successfully implemented if its benefits are clearly explained to HCPs and patients, and if the processes involved in the implementation are not a burden or require too many steps. Furthermore, the insulin PDA is in a booklet format that is fairly easy to be use. It can even potentially reduce consultation time.

My background, experience and personal beliefs described above might have introduced a bias during the interview and data analysis. In efforts to implement the insulin PDA, I might have disregarded barriers that were noted on its implementation. I acknowledge that I could not totally cast aside my personal assumptions or perspectives when carrying out this study. However, I tried my best to keep an open mind and distance my personal judgement when carrying out the data collection and analysis. In this study, I ensured that proper qualitative research protocols are followed so that my biases will not compromise the quality and the validity of the findings. The strategies adopted to establish study rigour are described in the following section.

3.2.1.8 Establishing study rigour

To ensure the qualitative study rigour in this phase, credibility, confirmability and transferability were adopted (Houghton, Casey, Shaw, & Murphy, 2013).

Credibility

The credibility of the findings was established by a number of ways. Firstly, to ensure that participants gave honest feedback, they were informed that their participation was voluntary, that they may withdraw from the study at any point of time, that there are no right or wrong answers, that their identity would be anonymous, and the information provided would not affect their work or study. This enabled the participants to freely express themselves without feeling pressure or feel worried about the consequences for disclosing any sensitive information. In addition, ‘iterative questioning’ were also adopted by going back to a particular topic noted by participants to check if their responses were the same as mentioned earlier.

Secondly, study findings were also validated through triangulation (Guion, Diehl, & McDonald, 2011). During data analysis, the intial few transcripts were analysed by several researchers independently and the codes and themes were compared. Codes that differed were discussed until the most suitable meaning that represented the data was found. This ensured that the findings were correctly interpreted. The field notes and interview reflections were crosschecked with the study findings to ensure that similar information was found and the data were accurately interpreted.

Confirmability

The confirmability of the study findings was established by having constant discussions to discuss the outcome of the data analysis to minimise researchers' bias with YKL, CJN and PYL. CJN and PYL are clinical lecturers who specialise in family medicine and are familiar with treatment protocols and health policies in Malaysian public health clinics. Hence, they could challenge the developed codes from their perspectives. This process helped to enhance the credibility of the findings. The themes were only finalised once all the researchers reached a consensus.

Transferability

In terms of transferability of the study, the study settings chosen were of various characteristics (location, socio-economic status of the community in the clinic area, patient population profile, clinic's priority and leadership for diabetes, and, presence of insulin support and manpower for diabetes management) in order to identify as many potential barriers and facilitators to the insulin PDA implementation. The findings may be applied to other public healthcare settings for future insulin PDA implementation studies. Detailed descriptions on the data collection methods, participants' background information, study settings, the number and length of data collection sessions and the time period of data collection contributed to the contextualisation of the study findings and the extent that the findings may be transferable to other settings.

3.2.1.9 Ethical considerations

Prior to conducting Phase 1 of this study, ethical approval was obtained from the University Malaya Medical Centre Medical Ethics Committee (Date of approval: 19 Oct 2015; Reference: 20158-1600) and, the Ministry of Health Malaysia Medical Research & Ethics Committee (Date of approval: 12 Nov 2015; Reference: NMRR-15-1598-27260).

Several ethical issues emerged in this phase and measures were taken to offset them. HCPs might have felt uncomfortable to answer questions regarding their clinic or current practices in managing people living with type 2 diabetes as they fear getting penalised if they were not practising according to the clinical practice guideline. They might have also felt vulnerable to judgment and evaluation by colleagues. Patients might have felt uncomfortable in providing negative feedback about the clinic where they seek health care. To offset this, the participants were assured that their answers were confidential, there was no right or wrong answers, and their participation would not affect their work, studies, or health care.

To protect the participants' confidentiality, note-takers and transcribers were informed to treat the data with confidentiality. The written notes were returned to the researcher as soon as the interviews ended. Any identifying details in the transcripts that would reveal the participant's identity was removed. Once data analysis was completed, the interview audio recordings and transcripts were kept in a password-protected personal computer and in the researcher's hard disk that was stored privately only known to the researcher.

3.2.2 Results

3.2.2.1 Participants' socio-demographic information

A total of 85 participants were approached to participate in this study. One staff nurse from the UMMC primary care clinic declined to participate due to time constraints. The participation rate was 98.8% (n=84/85). A total of 15 FGDs and 37 IDIs were conducted with various stakeholders: healthcare managers (n=11), doctors (n=22), diabetes educators (n=8), staff nurses (n=6), pharmacists (n=6), and, patients (n=31).

Among the healthcare managers and the HCPs, their mean age was 39.4 (± standard deviation (SD) 9.7) years (range: 28-57) and 86.8% were female. The mean duration of practice since entering workforce was 14.7 (± SD 10) years (range: 3-35). Six of them had experience using the insulin PDA from the acceptability study.

Among the 31 patients, their mean age was 63.0 (± SD 11.6) years (range: 36-79) and there was slightly more male participants (51.6%). The mean duration of having diabetes was 12.8 (± SD 7.9) years (range: 4 months – 30 years) while the mean duration of them seeking diabetes treatment in the clinic was 8.58 (± SD 5.9) years (range: 2 months – 20 years). Almost half of them were Malays (48.4%) followed by Chinese (32.3%) and Indians (19.3%). Slightly more than half of the patients (54.8%, n=17/31) were using insulin at the time of the interview. Table 3.3 shows the participants' socio-demographic information.

Table 3.3: Participants' socio-demographic information

	Overall (n=84)	
	Healthcare managers and HCPs (n=53)	**Patients (n=31)**
Age (years) Mean ± SD (Range)	39.4 ± 9.7 (28-57)	63.0 ± 11.6 (36-79)
Duration of practice since graduation (years) Mean ± SD (Range)	14.7 ± 10 (3-35)	n.a
No of patient counseled on insulin initiation for the past one month Mean ± SD (Range)	24 ± 39.7 (0-200)	n.a
Duration of diabetes (years) Mean ± SD (Range)	n.a	12.8 ± 7.9 (4 months – 30)
Duration of seeking treatment at the study clinic (years) Mean ± SD (Range)	n.a	8.58 ± 5.9 (2 months – 20)
Sex		
Male	7 (13.20%)	16 (51.61%)
Female	46 (86.79%)	15 (48.38%)
Ethnicity		
Malay	30 (56.60%)	15 (48.39%)
Chinese	10 (18.86%)	10 (32.35%)
Indian	13 (24.52%)	6 (19.35%)
Highest education level		
Primary	0 (0%)	4 (12.9%)
Secondary	0 (0%)	16 (51.6%)
Diploma	0 (0%)	4 (12.9%)
Tertiary	53 (100%)	7 (22.58%)
Position		
Healthcare manager	11 (20.75%)	n.a
Doctor	22 (41.50%)	n.a
Diabetes educator	8 (15.09%)	n.a
Staff nurse	6 (11.32%)	n.a
Pharmacist	6 (11.32%)	n.a
Insulin PDA use		
Yes	6 (11.32%)	n.a
No	47 (88.68%)	n.a
Currently using insulin		
Yes	n.a	17 (54.83%)
No	n.a	14 (45.16%)

SD: standard deviation; n.a: not applicable

3.2.2.2 Emerging barriers and facilitators

The qualitative analysis uncovered a total of 26 barriers and 11 facilitators categorised into HCP, patient, organisational, and innovation factors.

*(a) **HCP factors***

HCP factors refer to barriers or facilitators related to HCPs such as their knowledge, attitudes, beliefs, and skills that can affect their involvement in the insulin PDA implementation. A total of eight barriers and five facilitators related to HCP factors emerged from the data analysis and are shown in Table 3.4.

Table 3.4: HCP barriers and facilitators, descriptions, and the representative quotes

	Description	**Representative quote**
Barrier		
1. Barrier: Lack of awareness of the insulin PDA	The insulin PDA would not be adopted if HCPs are not aware that such a tool exists.	*“Maybe initially it will be very difficult (to implement the insulin PDA) because one thing you don’t know about this (insulin PDA).” – UMMC_Doctor 13*
2. Barrier: Lack of familiarity with the insulin PDA	When HCPs are not familiar with the insulin PDA they are not able to guide patients through the content.	*“I think if you don’t know what this book is about [tapping on the book], then you may not guide the patient through. If you know what it is, then you can tell the patient ‘I see you are not so sure about insulin. You said you don’t like needles’, then they can guide the patient through.” – UMMC_Healthcare manager 1*
3. Barrier: Lack of SDM	HCPs who have paternalistic attitudes tended to make treatment decision for patients. In addition, patients tended to play a passive role in decision-making and trusted the physicians to make the decision for them. This could lead to the lack of need for SDM and use of the insulin PDA.	*“I think is our practitioners’ approach to patient. We don't give patients a chance to decide on their own in many things. We like to tell and direct the patient what to do. Then in this case, they don't see the need for this book (insulin PDA). It is our providers’ attitude. // I think in our Asian context, we still have this idea of doctor telling you what to do. I think this shared decision approach is a concept that developed countries have but I don’t know whether our culture has reached this stage or not. // The patients still have the mindset of ‘You tell me what to do. It’s not my decision, it is your decision, I just follow you’. I don’t know whether our patients are up for the shared decision part.” – UMMC_Diabetes educator 1*

Table 3.4, continued

	Description	**Representative quote**
Barrier		
4. Barrier: Role boundary	The clear role boundary between the doctors and the nurses make collaborative implementation of the insulin PDA challenging. Doctors felt that they should be the key person to introduce and use the insulin PDA with patients because the decision to initiate insulin treatment lies with them after reviewing patient's glycaemic control and health profile. Furthermore, only doctors have the authority to prescribe insulin for patients. Assigning staff nurses to use the insulin PDA with patients would not be accepted as they felt it was outside the scope of staff nurses' current duties.	*"I think the initiation (to use insulin PDA) has to come from the doctor because we are the one who will know whether it is appropriate to recommend insulin. I think only doctors would understand the circumstances surrounding the patient such as, if the patient has cataract and has no social support, then he or she might not be able to inject insulin by him or herself or. Rather than at the pharmacist end 'Oh, your Hba1c is very bad. You should be on insulin, here, take this book', I think that is not right." – UMMC_Doctor 8* *"We only want to do work that is related to nursing. We don't want to do beyond that. 'I'm a nurse, why should I do this. This is nothing concerning me. This is doctor's job, not my job'." – UMMC_Staff nurse 2*
5. Barrier: Perception that insulin PDA use is an added workload	HCPs may not want to implement the insulin PDA as it is perceived to be additional work.	*"It (Insulin PDA implementation) means added workload. Need to photocopy the books. There will be more work burden and the doctor's time (consultation time) will be lengthened." – UMMC_Diabetes educator 3*
6. Barrier: HCPs want to finish their work quickly	Doctors get pressure from nurses and patients to finish their consultations quickly and this might cause them not to use the insulin PDA or deliver its contents ineffectively.	*"The problem here (in this clinic) is, we aim is to finish seeing patient as soon as possible. All the diabetes patients here want things to be done quickly. In my previous clinic, we took time to explain to patient. But here, I received a complaint recently because I was slow. So the working culture here is, you see the patient and if there is no problem, you just give medicine and they go home." - Community clinic C_Doctor 2* *"Not all doctors are patient. Some they want to hurry through (the consultation). They do not make good doctors to explain this (insulin PDA). If you explain in a hurried way, it's not going to be effective." – Community clinic A_Patient 2*

Table 3.4, continued

	Description	**Representative quote**
Barrier		
7. Barrier: Peer influence	Even if a HCP might be motivated to implement a new innovation, their colleagues who feel otherwise might influence them. In the end, they are demotivated from implementing the innovation.	*"One nurse would be nice and the next one will go and "poison" the other one. // A few of them would take the initiative. They set their mind 'I'm going to do this'. But some just won't. 'This (insulin PDA use) is not my job'. Then you become demotivated. You are pushing yourself so hard but the rest are not doing. Then you also join them." – UMMC_Staff nurse 2*
8. Barrier: HCP's poor communication skills	Some HCPs had poor communication skills where they were not clear and talked too fast which resulted in a lack of understanding of the information among patients.	*"One of the nurse talked so fast like a train. I cannot understand. We are old and our hearing is not so good. I cannot understand her. I would prefer if she give me this book then I'll go back and read." – UMMC_Patient 22*
Facilitator		
1. Facilitator: Belief that PDA is useful and beneficial	The belief that the insulin PDA is useful and beneficial can influence HCPs to adopt its use.	*"If you read and know the insulin PDA content, that it is actually very good and comprehensive. Then, it will be from within ourselves that we actually start giving (the insulin PDA) to patients." – UMMC_Doctor 7*
2. Facilitator: Trust in the PDA credibility	The awareness that the insulin PDA is developed by a credible source can help gain patients' trust.	*"Another important factor is knowing that it (the insulin PDA) comes from Universiti Malaya. When people see this, then they trust it. They are confident. Institution is very important. "– Community clinic A_Patient 1*
3. Facilitator: Motivation to try new innovation	HCPs' motivation to try new innovations to see if it brings positive effects can influence them to adopt the insulin PDA.	*"I think the motivation is there since there is a tool that can help patients to get a better control of their diabetic and to prevent the complication". – Community health clinic C_Doctor 1*
4. Facilitator: Having reminders	Repeated reminded to HCPs can prompt them to adopt the insulin PDA.	*"Every day we would really need the push. I think we have to keep on emphasising (on the insulin PDA)." - UMMC_Healthcare provider 10*
5. Facilitator: Awareness of the positive outcomes of the insulin PDA	Being aware of the positive outcomes of the insulin PDA can motivate HCPs to adopt it.	*"If my colleague says is beneficial, for example, it is not time consuming, then I will use it." – UMMC_Doctor 1*

*(b) **Patient factors***

Patient factors refer to barriers and facilitators related to patients such as their characteristics, attitudes, beliefs, skills, and resources that can affect their involvement in the insulin PDA implementation. A total of nine barriers and two facilitators related to patient factors emerged from the data analysis and are shown in Table 3.5.

Table 3.5: Patient barriers and facilitators and their descriptions, and the representative quotes

	Description	**Representative quotes**
Barrier		
1. Barrier: Patients cannot read or understand the insulin PDA	Patients' inability to use the insulin PDA due to low literacy level, vision problems and needing someone to help them use the PDA.	*"Unless the patient is learned then it is going to be a problem. Majority of the patients are elderly. They can't read. They need somebody to help them. Who is going to sit there and read for them?" – UMMC_Staff nurse 2*
2. Barrier: Patient rely on doctors to make health decisions	Patients are afraid of making wrong medical decisions and would prefer to listen to their doctors. Patients who tend to rely on their HCPs or family members to make health decisions can hamper PDA implementation.	*"Patient when they come to certain age, they will say 'I don't want to read anything. You tell me what to do, I will do'. They already come to a stage where they just accept. They just listen to doctor. 'Ok you say start, I start (insulin)'." – UMMC_Staff nurse 2* *"Doctor should explain to you because I'm afraid that I will do something wrong. Even if I read the book, I will still need help from doctor. If I read the book alone, I have no confidence. I must let the doctor tell me 'Is good if you can do this' because I might do something wrong." – UMMC_Patient 21*
3. Barrier: Patients lack of effort to improve health	Patients' don't try to improve their health. They admitted that they are lazy to read and to find out information given by HCPs.	*"I think another barrier with the patient is how motivated they are to want the knowledge in the insulin PDA. // There are patients who are not motivated. They just take it and then they put in their bag and that's the end of it." – UMMC_Doctor 8* *"People are lazy. Like me sometimes I couldn't care less. Okay if I die, then die. Just lazy to read, lazy to want to know." – Community clinic C_Patient 4*
4. Barrier: Patient do not like to read	Some patients lack interest in reading the insulin PDA and prefer to get verbal information from HCPs.	*"Generally, the patients here are not highly educated and even with the educated patients, some do not like to read. They prefer to get information directly from somebody. I noticed it's not in our culture to read." – UMMC_Healthcare manager 3*

Table 3.5, continued

	Description	**Representative quotes**
Barrier		
5. Barrier: Patient may feel push to use insulin when receiving the insulin PDA	Some patients noted that receiving the insulin PDA is akin to receiving news that that their diabetes is at a critical stage since they require insulin. Patients who are not keen on insulin might be discouraged if they think the insulin PDA is to persuade them to start insulin.	*"For patients who are not ready to start insulin, they might think that we are using this book to convince them to start insulin." – UMMC_Doctor 3* *"The first thought if I received this book is, 'I need to start on insulin' because the doctor is asking me to read [laugh]. Of course, I don't want to read. I will look for alternative. 'Doctor, can we try oral medication for three months first to see if I can control. I don't want to start (on insulin)'." – Community clinic B_Patient 1*
6. Barrier: Patients are busy	Patients might not use the insulin PDA because they are busy and preoccupied with other responsibilities.	*"Doctors tell them 'You go and read'. They said 'Okay' just to please the doctor. But when they go home, they just chuck it to one side, especially like women who are bogged down with housework and all that. At that time, they would have forgotten all this." – Community clinic A_Patient 2*
7. Barrier: Patients are not willing to pay for the insulin PDA	Patients were informed of the cost of the insulin PDA to be around RM5 (USD 1.30). Patients who are already financially burdened with medication costs may not want to spend extra money to buy a booklet. Furthermore, patients may feel that they can access information in the Internet for free or expect HCPs to explain to them.	*"Patient won't buy (the insulin PDA) because they have to pay for their diabetes medication, diabetes strips. No money! [laughs]." – UMMC_Diabetes educator 2* *"No, I don't think so (patients would be willing to pay for the insulin PDA). Rather than paying for this, I might as well go to the website. That will not cost me anything." – UMMC_Patient 6*
8. Barrier: Language barrier between HCP and patient	If the HCP and patient do not share a common language to converse in, this might cause difficulty in discussing the insulin PDA as they would not be able to understand one another.	*"Another thing is language. Even though I am an Indian but I don't really understand Tamil. So if an Indian patient can only understand Tamil and the Tamil PDA is given to the patient. I can't explain if they ask me about the PDA in Tamil. If we don't know the language it's going to be difficult for us to explain." – UMMC_Doctor 3*

Table 3.5, continued

	Description	**Representative quotes**
Barrier		
9. Barrier: Difficulty to return to the clinic for PDA follow-up	The participants were asked if it would be possible for patients to return to the clinics for follow-up two weeks after the insulin PDA was given. Patients might have difficulty returning to the clinic due to work or transportation.	*"I am worried patient might not be able to come back in 2 weeks for the PDA follow up. Some patients actually request for 3 to 6 months (for their next appointment). Two weeks is too soon. Maybe 2 to 3 months. Is the transport problem and some are working or taking care of their grandchildren" – Community health clinic D_Doctor 1*
Facilitator		
1. Facilitator: Patients' trust in doctor	As compared to nurses, patients would be more receptive towards using the insulin PDA if it is delivered by doctors as they trust the doctors more especially when it comes to decisions related to important clinical matters such as insulin.	*"Nurses and pharmacists can recommend (insulin PDA), but it will be more impactful if doctors are the one recommending because usually patients do not question doctors' recommendations. When doctors talk, patients will listen but not so much to nurses." – UMMC_Patient 6*
2. Facilitator: Belief that insulin PDA is beneficial	The belief that the insulin PDA can help to increase knowledge about diabetes and make an informed decision about diabetes treatment can influence patients to adopt the insulin PDA.	*"I will read it. We can get information and at least we will know what is good or bad for us." - Community clinic C_Patient 1*

(c) Organisational factor

Organisational factors refer to barriers and facilitators related to the clinics such as leadership, work culture, healthcare systems, and resources that could affect the insulin PDA implementation. A total of seven barriers and three facilitators related to organisational factors emerged from the data analysis and are shown in Table 3.6.

Table 3.6: Organisational barriers and facilitators and their descriptions, and the representative quotes

	Description	Representative quote
Barrier		
1. Barrier: Time constraints due to high patient load and lack of manpower	HCPs were concerned about taking extra time to go through the insulin PDA with patients during consultations as they were already stretched due to high patient load and the lack of manpower.	*"Time is a problem because there are a lot of patients. Whether we have the time to go through the PDA with the patient."* - UMMC_Doctor 4 *"If we have more diabetic educators and nurses then they can also help to assist the doctors in providing the PDA to patients. But we only have one diabetic educator. Our nurses are doing various tasks because of the lack of manpower."* – Community clinic B_Healthcare manager
2. Barrier: Lack of accessibility to the insulin PDA	Doctors who used the insulin PDA in the acceptability study shared that they faced problems in getting hold of the insulin PDA.	*"The booklets were placed in the diabetic education room, so we have to go all the way there just to get the booklets."* – UMMC_Doctor 8
3. Barrier: Lack of funding to print the insulin PDA booklets	Most of the clinics have a tight budget hence it was felt that the hospital authority would not allocate additional funding to print the insulin PDA booklets.	*"I don't think the hospital will do it (print of the insulin PDA booklets) because it is costly. You may think it is probably just three ringgit (USD 0.70) for a booklet, but if you need two thousand copies, then it is six thousand ringgit (USD 1430). The hospital is quite tight with budget right now. The message to us is no extra spending. So if you are talking about having this insulin PDA to be printed, cost would be an issue."* – UMMC_Healthcare manager 1

Table 3.6, continued

	Description	**Representative quote**
Barrier		
4. Barrier: Lack of continuity of care	HCPs are unable to see the same patient again to follow-up on the insulin PDA, resulting in a lack of continuity of care. Additionally, the lack of systematic documentation process of the insulin PDA use means some doctors were unaware if the patient had already been introduced to the insulin PDA and do not know what the previous HCP discussed with the patient. Another issue with continuity of care was the doctors' turnover. Trainee doctors leave after completing their training and new doctors may be unfamiliar with the PDA.	*"Basically, continuity of care is not there because doctors don't get to see the same patient. We might give this PDA to a patient this visit but in their next visit, you may not be the one who sees the patient but another doctor. Then this has to start from zero (for the other doctor)" – UMMC_Doctor 4* *"There is no continuity on whether if the patient gets the book or not. We didn't really document it in the EMR (electronic medical record). // The book was in the diabetic education room. So I referred the patient there so that the nurse can explain. But I'm not sure whether if the nurse did explain to the patient and what she said" –UMMC_Doctor 5* *"They (doctors) can deploy the book, but then they may not be around next month to even follow up. – UMMC_Healthcare manager 2*
5. Barrier: Lack of teamwork	A lack of teamwork from various stakeholders might also hamper the insulin PDA implementation. Some staff tend to work independently and have their own ways of managing their work. This can affect implementation that requires a collaborative effort.	*"The quit smoking clinic closed down. Nobody cooperate. Psychiatry team and medical team were supposed to be involved. Is supposed to work and useful. The drugs were already there. There was no teamwork." – UMMC_Staff nurse 2* *"In terms of working culture, people here are very much working on their own. They have their own mindset of how they should manage. So, they don't get input about how other people do their things." – UMMC_Healthcare manager 1*
6. Barrier: Competing programmes in the clinic	Different HCPs have their own priority programmes to implement hence the insulin PDA implementation might be affected by other competing programmes.	*"We can tell them to implement (the insulin PDA) but whether they actually do it or not is a different matter because they have many other programmes to carry out. Everybody is chasing their own program." – Community clinic E_Healthcare manager 7*
7. Barrier: Lack of rooms in the clinic for insulin PDA discussions	The limited rooms in the clinics meant a lack of privacy.for discussions, which could hamper the insulin PDA implementation.	*"The feeling would be different because everyone will know what you are talking about. A very small room for this (insulin PDA discussions) will do." – UMMC_Patient 19*

Table 3.6, continued

	Description	Representative quote
Facilitator		
1. Facilitator: Directive from higher authority	An effective way to ensure an innovation will be implemented is if it is a directive from a higher authority as HCPs would usually follow their instructions.	*"If our boss issue a black and white letter, give order to us that it's a compulsory thing to do then we will do it [laugh]. That would be the most effective way [laugh]." – Community health clinic B_Doctor 1*
2. Facilitator: Leadership and staff motivation	The clinic leader acknowledging their staff's work can lead to higher motivation in implementing the insulin PDA.	*"The leader implementing (the insulin PDA) should acknowledge the staff. Not just said 'this is my project'. I think acknowledging what the staff is doing is also very important." – Community health clinic D_Doctor 1* *"If you have a senior person saying that it is good then most likely others will follow suit." – UMMC_Doctor 4*
3. Facilitator: Having dedicated staff to carry out the implementation	Having an assigned person or team can facilitate in implementing the PDA as they are given the time to perform their duty. The implementation would also be carried out in a standardised manner since they are carried out routinely.	*"I think implementing this should not be a problem if there is a team, for example a diabetic team because they are doing it like everyday. It becomes a routine." – Community health clinic A_ Doctor 19*

(d) Innovation factors

Innovation factors refer to barriers and facilitators related to the insulin PDA itself, such as its content and design, that could hamper its implementation among HCPs and patients. A total of two barriers and one facilitator related to innovation factors emerged from the data analysis and are shown in Table 3.7.

Table 3.7: Innovation barriers and facilitators and their descriptions, and the representative quotes

	Description	**Representative quotes**
Barrier		
1. Barrier: Insulin PDA has poor design	The insulin PDA has too many words and pages and this may deter patients from reading it.	*"This booklet is very good, very helpful but maybe too many pages. Most of the patients' education level is a bit low. I don't think they will be comfortable with this". – UMMC_Doctor 6*
2. Barrier: Perception of negative consequences from the insulin PDA use	Belief that the insulin PDA would lead to negative consequences such as delaying insulin initiation or replacing consultation.	*"I'm concern if the insulin PDA is given, this may delay them in initiating insulin. If their HbA1c is already poor, we want our patients to start insulin now." – UMMC_Doctor 4* *"I am afraid that some might use it as a replacement of the consultation." – UMMC_Doctor 14*
Facilitator		
1. Facilitator: Insulin PDA comprehensive and informative	The comprehensiveness and systematic presentation of information in the insulin PDA is a motivator for HCPs to adopt it to help provide information to patients.	*"There were a few doctors who came to me seeking the book. Many doctors like it. The insulin PDA helps in terms of providing information to patients. Is comprehensive and systematic so you just follow the headings." – UMMC_Staff nurse 1*

(e) ***Strategies proposed by participants in Phase 1 to facilitate the insulin PDA implementation***

As this study aimed to develop an intervention tailored to identified barriers, the potential strategies and processes that were noted by the participants during the interviews were also extracted. A total of 31 strategies emerged from the data analysis and are shown in Table 3.8.

Table 3.8: Strategies proposed by Phase 1 participants to facilitate the insulin PDA implementation

Strategy	Description	Representative quote
1. HCPs to inform the purpose and the benefits of the insulin PDA to patients	Patients may not be keen to use the insulin PDA when they do not know what it entails and how it can benefit them. HCPs should introduce and explain to patients the purpose and advantages of using the insulin PDA.	*"You need to explain to the patient because if you just put it (the PDA) there, they won't know what is inside. Like I come for check-up, a nurse recommend 'We are having a new book. Good for your health so maybe you can change'." – Community clinic A_Patient 3*
2. HCPs to go through the insulin PDA with patients	HCPs should spend time to explain the insulin PDA and go through it with patients to clarify their doubts.	*"No matter what we give to the patients, we need to make ourselves available to answer their queries. Maybe there are some information that they are not sure." – UMMC_Doctor 3*
3. HCPs to press on insulin PDA use among patients	Doctors need to press on the importance of using the insulin PDA with patients so they take it seriously.	*"I think if the doctor tells me 'You seriously read about this and get back to me. Think carefully, this is going to help you.'. I think I will use it. The doctor plays an important role here." – UMMC_Patient 1*
4. To get HCPs to introduce the insulin PDA to patients	Patients would rather trust to accept the insulin PDA from HCPs, especially doctors, than people outside of the medical profession.	*"For my generation, we always look up to doctors. Whatever doctor says means it's correct. I would accept it. If I received it from a doctor, I would pay attention to it." –UMMC_Patient 9*
5. Involve patients' family members or caretakers	Many participants suggested engaging with family members or caretakers when using the insulin PDA during consultations. Based on their experience, it's helpful due to communication barriers and dealing with patients who cannot read or understand the PDA.	*"I can't speak Tamil so I will have to rely on the patient's carer. The easiest way is to get carers involved. Sometime carers come with the patient during consultation so I engaged them with the booklet." – UMMC_Doctor 8* *"If there is a relative with them is much better. Older persons may have vision problems. They need to have someone with them. Whenever I teach, I prefer their family members to be there as well because the patient needs support. Their family members must be able to understand the information, so when two people read and of the same opinion then it is easier to make decision." – UMMC_Staff nurse 1*

Table 3.8, continued

Strategy	Description	Representative quote
6. Inform HCPs on the advantages of the insulin PDA use	Inform HCPs on the advantages of using the insulin PDA in order to motivate them to use.	*“Conduct talks to inform the staff of the importance of this booklet. Explain about it and once the staff understand, they will start using it.” – UMMC_Diabetes educator 3*
7. Refer patients to HCPs who can speak the same language as the patients	To overcome language barrier issues, patients should be referred to HCPs who speak the same language as them.	*“The diabetes educator can only speak in Malay and English so they might have to send the patient to another diabetes educator who can speak the patient’s language.” – UMMC_Doctor 13*
8. Get HCPs to communicate to patient about the insulin PDA in a non-threatening manner	HCPs should deliver the PDA and approach the subject of insulin use in a non-threatening way with patients. HCPs should promote the PDA in a positive light to encourage the patients to use it. They should also take time to explain how to use the insulin PDA to patients in a clear, direct, and layman's language.	*“You should let the patient know that using insulin is not the end game. Have a more pleasant way of approaching the subject so that the patient doesn’t feel threatened, in the sense that insulin is the last resort. Give the PDA with the impression that is not end game but that the patient can even get better. // Speak positive things about it. Motivate the patient.” – UMMC primary care clinic_Patient 9*
9. Reminders	When HCPs are reminded repeatedly, this will prompt them to adopt the insulin PDA.	*“I think it is kept being reminded that there is such a thing.” – UMMC_Healthcare manager 1*
10. Advertise the insulin PDA by putting up posters, banner, or notice or advertise on TV in the clinic	To create awareness on the insulin PDA, strategies include the use of mass media to advertise the insulin PDA through posters, on TVs, and through campaigns were suggested.	*“Put posters in the clinic so that carers and patient can see. Then, patient also can remind doctors about the book.” - UMMC_Doctor 13*
11. Conduct campaign	Patients also proposed conducting campaigns to create awareness on the availability of the insulin PDA.	*“Conduct campaign to inform that there is a new book.” – FGD 15_Community clinic D_ Patient 1*

Table 3.8, continued

Strategy	Description	Representative quote
12. Conduct SDM and insulin PDA training	Training sessions to equip HCPs with the necessary knowledge and skills were proposed. For example, understanding how to use the insulin PDA and explaining the concept of SDM.	*“There would be a need for training for the doctors to understand what is SDM. The PDA can be alien to the doctors. They have never seen this ‘What am I supposed to do with this?’. They need to know what to do with it.” – Community clinic E_Healthcare manager*
13. Conduct educational group sessions for patients	Administering the insulin PDA in a patient group session was proposed in view of time constraints during doctor consultation times. Patients who forget to read the PDA at home can also use the session as an opportunity to raise concerns and questions that can be clarified immediately.	*“Conduct seminar. Means on a pre-selected date the patients will come. I would definitely come [laugh]. Then save the doctors’ time.” – FGD 10_UMMC primary care clinic_ Patient 2* *“There are some who probably take back the book and forget to bring. But do it in a group setting of insulin priming by the staff, that is also quite good because of the time constraint and all patient don’t want to take back the book. Patient may say ‘I got no time (to read the PDA)’ so that means during that setting I must be able to see.” - Community clinic D_Doctor 1*
14. To involve diabetes educators or nurses to use insulin PDA with patients	HCPs such as diabetes educators or nurses can be trained to use the insulin PDA with patients. Due to the limited consultation times, doctor can introduce the PDA to patients and then refer them to nurses or diabetes educators to further explain the PDA in detail.	*“Your doctor can assign the patient to a diabetic expert so you reduce the time.”- UMMC_ Patient 11*
15. Systematic documentation	To ensure patients who had already received the insulin PDA would have a follow-up on their PDA usage, many raised the need for documentation.	*“Usually we see other doctor’s patients. So we are not sure how much of the information the previous doctor had informed the patient. So we don’t want to repeat again the same thing again. So I think if we want to implement, then we need to make note like ‘Book given’, ‘KIV to start insulin’ or ‘advice given’. We have to make some notes so that the next doctor knows and can follow up on the PDA.” – UMMC_Doctor 1*
16. Monitor and provide feedback	Many HCPs noted that providing feedback on the number of PDAs that have been given may influence doctors to distribute more PDAs to patients.	*“If there is some sort of feedback mechanism to actually check on how many books have been given then I think we will give to more patients.” – UMMC_Doctor 7*

Table 3.8, continued

Strategy	Description	Representative quote
17. Have a champion	Have a champion who could convince other staff to use the insulin PDA.	*"Somebody influential to start first. Then that person can tell and support their subordinate to try it out." – UMMC_Diabetes educator 1*
18. Place the insulin PDA booklets in doctors' consultation rooms	The insulin PDA should be placed in the doctors' consultation rooms for accessibility and as a reminder to use it.	*"Put the books in the consultation room because if you have to get out of your room to look for nurse, this will take time." – IDI 7_UMMC primary care clinic_Healthcare manager* *"Need to place the insulin PDA on the table [laughs]. The thing needs to be seen all the time (to remind them to use)." - Community clinic B_Diabetes educator*
19. Get sponsorship from pharmaceutical company or diabetes associations	Some participants suggested obtaining sponsorship from private companies, diabetes-related associations, or pharmaceutical companies to financially support and maintain the insulin PDA implementation.	*"To maintain it, you need funding. Maybe we can ask diabetes associations or a company that has an educational grant. For example, Pharma A for their educational research. I think we might need to look at that as well." - UMMC_Healthcare manager 1*
20. Issue directive to implement the insulin PDA	Issuing a directive was noted to be the most effective way to get HCPs to implement the insulin PDA, as they would be compelled to do it.	*"Directive (laugh). That's the only way we can make it happen. If you make it compulsory then they will try and do it. But once they see the benefits, they will start using it without asking why I need to do this." – Community clinic C_Healthcare manager*
21. Provide incentive or reward	Provision of incentives or rewards to doctors who adopt the insulin PDA would make them feel acknowledged and appreciated. This would motivate them to use the insulin PDA.	*"You can give incentive or acknowledgement to doctors who use the PDA. So they will feel excited about using it and at the same time feeling appreciated." – UMMC_Diabetes educator 4*
22. Incorporate PDA use as part of key performance index, standard operating procedures or in the diabetes management guideline	Incorporating the insulin PDA use in staff key performance index, clinic's standard operating procedures, or guidelines for diabetes management can influence HCPs to implement the insulin PDA.	*"You can make it like it is a compulsory thing to do. For example, we must refer diabetic patients to one-stop diabetic centre for the eye and foot check. So this PDA can be a part of that. Put in the standard operating procedure then the doctor will follow." –UMMC_Doctor 1*

Table 3.8, continued

	Strategy	Description	Representative quote
23.	Create the insulin PDA implementation flow	Creating an implementation pathway was suggested to help HCPs know the implementation processes as well as their respective tasks in the insulin PDA implementation.	*"Create a work flow so everyone like pharmacist, diabetes educator or doctors would know their roles. When we see the insulin PDA we will know what to do" – Community clinic B_Diabetes educator*
24.	To have a person in charge for the insulin PDA implementation	Having a person in-charge of the insulin PDA implementation was proposed so others can seek help regarding the implementation. As the individuals who are responsible for the insulin PDA implementation would be given the allocated time to use the insulin PDA with patients, this can help to address the issue of time constraint in the clinic.	*"Because of the lack of time and manpower here, it is very time consuming to actually explain to patients. So is better that there is a designated person to actually counsel, explain to them but then this involves manpower." - Community clinic C_Pharmacist*
25.	To lend the insulin PDA to patients	To reduce the insulin PDA printing cost, some participants suggested a lending system whereby patients could borrow the PDA.	*"Lend the PDA to patient. After reading, they may not read again. This helps to save money. Is not cheap." – IDI 31_Community clinic A_ patient 1*
26.	HCP to focus only on important topics when using the insulin PDA with patients	To address the time constraints in using the PDA during the limited consultation time, many participants suggested that doctors could focus only on important topics or issues rather than going through the entire PDA with the patient.	*"There are a lot patients waiting for us so usually we just run through the salient points. We reply to what the patient ask us. Then patient can take the book and read at home. If any problem, we can discuss again." – UMMC_Doctor 11*

Table 3.8, continued

Strategy	Description	Representative quote
27. To let patients read the insulin PDA at their own time and discuss in the next visit	Many also felt that in view of the time constraints in the clinic, doctors would not be able to use the PDA in detail with patients. Rather, patients should be given the PDA to read on their own as they may need time to go through the information, discuss with their family members and friends. Then, the insulin PDA can be discuss with patients in their next visit.	*"I think this is not something they go through page by page with the patient. It is going to be something like 'Look, there's something for you to read. Why don't you read and the next time you come back, we will discuss it'. So, if they have certain questions, they will point out and it gives you a more directed discussion. If I were to use it, I am not going to go through it page by page. I will probably be looking at my watch and say 'Oh, no this was taking too long'." – UMMC_Healthcare manager 1*
28. To get patients to use the insulin PDA prior to consultation	Patients can be given the insulin PDA while they are waiting to enter the consultation room as this can enable effective use of patient's waiting time as well as prepare patients for insulin PDA discussions prior to seeing the doctor.	*"Probably you catch them at the waiting bay and the nurses can give to patient. Then by the time they go into the consultation room, they would have read clearly and understood because we're chasing for time." – Community clinic E_Healthcare manager*
29. To give an earlier appointment to patients for the insulin PDA follow-up	A patient's next appointment that is far away might render them to forget about the insulin PDA hence it was suggested that an appointment between 2 weeks to one month would be needed.	*"I think if you are going to give this PDA to patient then the appointment must be earlier instead of the usual 4-5 months because we want to assess whether they are ready or not to be on insulin. So give shorter appointment, maybe 2-4 weeks. // But if you give 3-4 months appointment, certainly they will forget." – Community clinic B_Healthcare manager*
30. Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation	To overcome language barrier, a few doctors suggested juxtaposing PDA with patient's PDA in their preferred language to overcome language barriers. This strategy had been adopted by some doctors and was felt to be effective.	*"If I have a Chinese patient, he/she will point out to me this word (in the PDA in their preferred language), then I can translate (using my own PDA) then they will know I'm talking about hypoglyacemia. I don't know how to say hypoglycaemia in Chinese right, so then I just go to the section on hypoglycaemia in the PDA and then show. So it had been very useful for me in this sense."- UMMC_Doctor 3*
31. To identify patients who are eligible to use the insulin PDA	To select patients who would be willing to participate in SDM, are able to read and understand, and want to use the insulin PDA.	*"You might need to choose your patient correctly. Patients who are going to benefit, knowledgeable, can read. Those who are quite proactive in the sense that they want to do share decision making. Otherwise I don't think some will even bother." – Community clinic B_Healthcare manager*

3.3 Phase 2: Development of the intervention

This phase provides a detailed description of the methods taken to systematically develop the intervention to implement the insulin PDA followed by a presentation of the finalised intervention and its implementation at the UMMC primary care clinic. Figure 3.3 highlights Phase 2 of this study in the study conceptual framework.

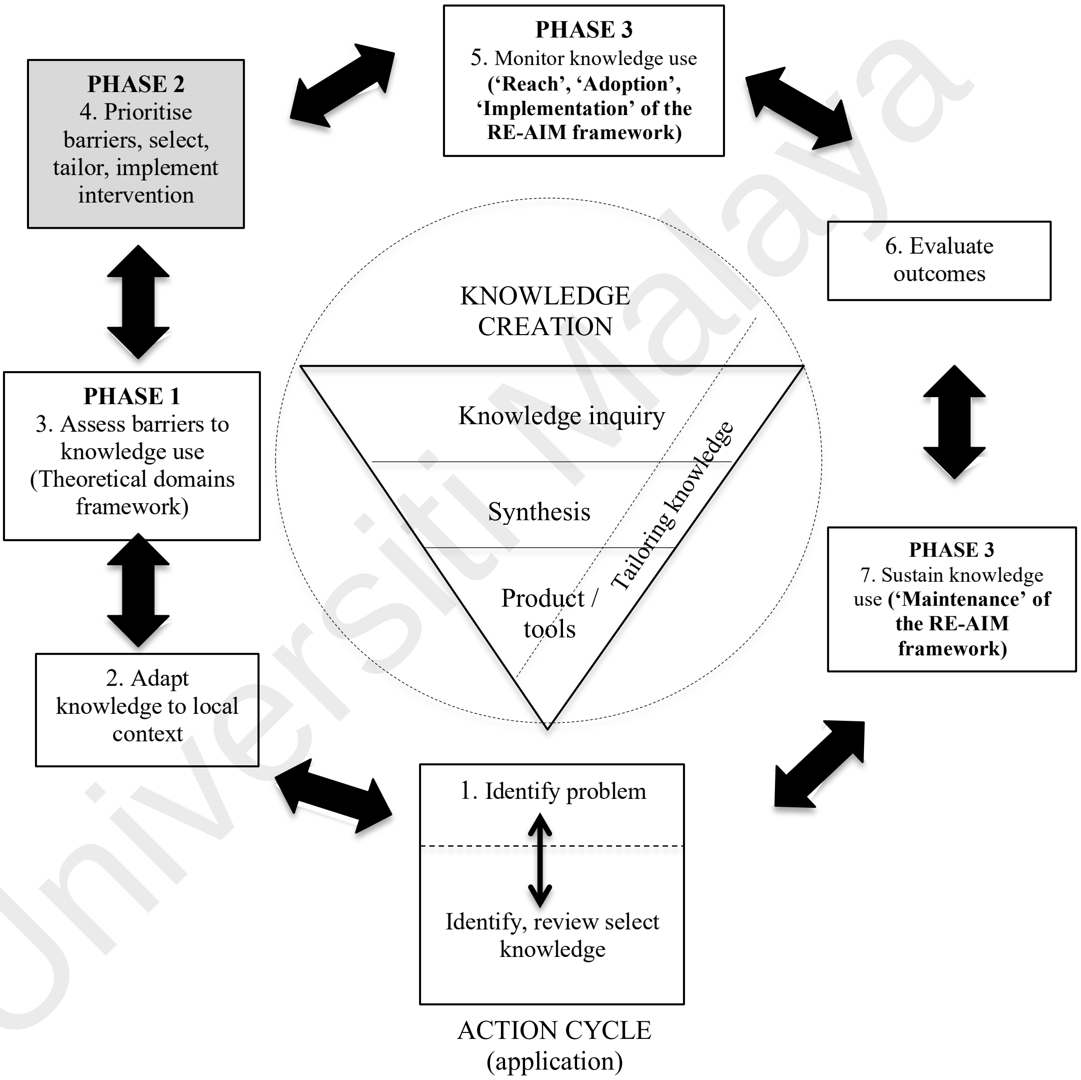


Figure 3.3: Phase 2 of this study in the study conceptual framework

The four steps of the intervention development include the following methods:

Step 1: Prioritisation of barriers,

Step 2: Select and tailor strategy to overcome the prioritised barriers,

Step 3: Operationalisation of the strategies, and

Step 4: Finalisation of intervention and pathway through a clinic stakeholders meeting

These steps are described in detailed followed by presentation of their findings. Then, descriptions on how the intervention was implemented are provided at the last section of this phase.

3.3.1 Methods

3.3.1.1 Step 1: Prioritisation of barriers

(a) Study design

In the previous phase, many barriers were identified and it was not possible to address all of them. The development of the intervention for the insulin PDA began with the prioritisation of barriers. In this step, a stakeholder multivoting technique (American Society for Quality, 2017) was employed to prioritise the barriers. This technique had been used as one of the methods for prioritising key health problems in the area of public health (National Association of County and City Health Officials, 2013). The multivoting technique is a systematic process using a few voting rounds to reduce a list of factors or barriers according the top chosen.

The multivoting technique was selected as it involves an objective and democratic process whereby every stakeholder in the clinic, from doctors to nurses to patients, have an equal say in which barrier they think would hamper the insulin PDA implementation, regardless of their position. Furthermore, the multivoting technique is non-competitive and participative in that, the participants involved have the rights to vote independently on which barrier they think is the most important to them. Barriers, which are voted by all, will rise to the top even if it may not be a top priority for an individual. This makes the list of key barriers generated in the end to be the ones that are important for all stakeholders and this is crucial, as every stakeholder will most likely have a direct role in the insulin PDA implementation.

(b) ***Study setting***

At the juncture of this study, a decision was made that the implementation of the insulin PDA would be conducted at the UMMC primary care clinic. The reason why only one clinic was selected was because it has been recommended that implementation should begin small-scale by involving a limited number of motivated individuals, teams or institutions to improve the intervention before expansion (Grol & Wensing, 2013). As this is the place where the insulin PDA was developed, it may have already benefitted from some degree of 'opinion leadership'. The researcher's supervisors, CJN, is a Professor and family medicine specialist at the clinic while YKL is a senior lecturer at the Department of Primary Care Medicine, which is affiliated with the UMMC primary care clinic. Furthermore, focusing only on one clinic would enable close examination of the detailed implementation processes, how the strategies work, and understanding the context that leads to effective or ineffective implementation of the insulin PDA. Additionally, a multisite implementation study would be too large and resource-intensive for the researcher's doctorate study.

(c) ***Study participants***

The researcher approached the head of department and the clinic coordinator at the UMMC primary care clinic to obtain approval and support to implement the insulin PDA in the clinic. The clinic coordinator then identified staff and patients who could provide input on implementation of health innovations in the clinic in general, or specifically for diabetes care, and those who were likely to have a role to play in the insulin PDA implementation. Patients from the UMMC primary care clinic who were involved in Phase 1 were also recruited given their familiarity with the insulin PDA and the clinic setting.

(d) ***Study instrument***

To achieve the aim of prioritising barriers for implementation action, an instrument known as a Voting Form was developed. This form lists all possible barriers to insulin PDA implementation that were relevant to the UMMC setting. To list the items in the Voting Form, the researcher had to constantly review the themes, categories and interview excerpts to ensure the voting items were correctly interpreted and as specific as possible. This was to ensure that specific strategies could be selected to overcome the key barriers.

Barriers adapted from the community clinics and barriers adapted from facilitators were also included after some additional steps were taken. For barriers from the community clinics, the concern was that these barriers would not be relevant for the UMMC setting. The clinic coordinator was consulted to decide which of the barriers should be included in the Voting Form even when the UMMC participants did not mention them. The included barriers are listed in Table 3.9 indicated by the asterisk (*) symbol. The researcher acknowledged that while both barriers and facilitators influence implementation, having both barriers and facilitators in the Voting Form would complicate the simple instructions to vote for barriers most likely to hinder the insulin PDA implementation. Thus, facilitators identified in Phase 1 were revised as barriers by expressing the idea in the form of a negative statement. For example, the facilitator 'Directive from higher authority' was rephrased to 'There is no clear directive from higher authority to use the insulin PDA'. This allowed the researcher to find out if the 'opposite' or absence of the facilitators would be a prioritised barrier for implementation.

The process of moving from a barrier or facilitator to a Voting Form item is shown in detail in Table 3.9. Each barrier or facilitator was abstracted as a theme, which then was converted to an item under one of four categories of barriers (organisational, HCP, patient and PDA). The finalised Voting Form can be found in Appendix E.

Table 3.9: Development of items in the Voting Form

Category	**Theme**	**Voting items in the Voting Form**
Organisational		**I think HCPs will not use the PDA in the clinic because...**
Barrier: Time constraint due to high patient and work load	B: Time constraint due to high patient load and lack of manpower	1. they are too busy as there are too many patients
Barrier: Lack of manpower		
Barrier: Cannot access the insulin PDA	B: Lack of accessibility to the insulin PDA	2. they don't know where to get the PDA
Barrier: Lack of awareness on where to get the insulin PDA		
Barrier: Lack of funding to print the insulin PDA booklets	B: Lack of funding to print the insulin PDA booklets	3. it is difficult to implement the PDA in the clinic because there is a lack of funding to print the PDA booklets
Barrier: Lack of continuity care	B: Lack of continuity of care	4. they will not be able to see the same patient to follow up on the PDA
Barrier: Uncertain of the insulin PDA implementation process		
Barrier: Lack of teamwork	B: Lack of teamwork	5. they already have their own way of doing things
Barrier: Competing programmes in the clinic	B: Competing programmes in the clinic	6. there are many other health programmes in the clinic
Facilitator: Directive from higher authority	F: Directive from higher authority	7. there is no clear directive / circular from the top management to use the PDA[#]
Facilitator: Having a senior role model	F: Role model and staff motivation	8. senior persons in the clinic do not motivate them to use it[#]
Facilitator: Acknowledgement on using the insulin PDA by clinic leader		9. there is no one championing the use of PDA in the clinic[#]

Table 3.9, continued

Category	Theme	Voting items in the Voting Form
Organisational		**I think HCPs will not use the PDA in the clinic because...**
Facilitator: Having a dedicated staff or team to carry out the implementation*	Facilitator: Having a dedicated staff or team to carry out the implementation	10. there is no person-in-charge to oversee the use of the PDA in the clinic[#]
		It is hard to use insulin PDA in the clinic because…
Barrier: Lack of rooms in the clinic for insulin PDA discussions	Barrier: Lack of rooms in the clinic for insulin PDA discussions	11. there is not enough rooms in the clinic for PDA discussions
HCP		
Barrier: Perception that insulin PDA use is a doctor's task	Barrier: Role boundary	12. using PDA is not part of their job scope
Barrier: Perception that using the insulin PDA is not within their job scope		
Barrier: Lack of awareness of the insulin PDA	Barrier: Lack of awareness of the insulin PDA	13. they are not aware of the insulin PDA
Barrier: Perception that insulin PDA use is an added workload	Barrier: Perception that insulin PDA use is an added workload	14. using the insulin PDA is extra work for them
Barrier: Lack of familiarity with the insulin PDA	Barrier: Lack of familiarity with the insulin PDA	15. they are not familiar with the insulin PDA booklet (e.g: purpose, content, usage)
Barrier: HCPs want to finish their work quickly	Barrier: HCPs want to finish their work quickly	16. they want to finish their work quickly
Barrier: HCPs lack of shared decision making approach	Barrier: Lack of shared decision making	17. they tend to make decisions for their patients instead of practising shared decision making
Barrier: HCPs paternalistic attitude i.e. make health decisions for patients		
Barrier: Doctors do not like patients to ask many questions		18. they do not want the patient to ask them more questions after using it

Table 3.9, continued

Category	Theme	Voting items in the Voting Form
Organisational		**I think HCPs will not use the PDA in the clinic because...**
Barrier: Peer influence	Barrier: Peer influence	19. their colleagues influence them not to use the PDA
Barrier: HCPs are not clear when delivering information to patients	Barrier: HCP’s poor communication skills	20. HCPs are not clear when giving information to them
Barrier: HCPs talk to fast to patients		21. HCPs talk too fast
Facilitator: HCPs talk in simple and laymen terms to patients*		22. HCPs use difficult words when talking to patients[#]
Facilitator: HCPs belief that the insulin PDA is useful	Facilitator: Belief that PDA is useful and beneficial	23. they believe that insulin PDA is not useful[#]
Facilitator: HCPs belief that insulin PDA is beneficial		
Facilitator: Trust in the credibility of the insulin PDA	Facilitator: Trust in the PDA credibility	24. they think that it is not credible (reliable and trustworhty)[#]
Facilitator: HCPs curiosity on the effectiveness of the innovation	Facilitator: Motivation to try new innovation	25. they are not motivated to try new innovations[#]
Facilitator: HCPs desire to improve on personal advancement and patient care		
Facilitator: Having reminders	Facilitator: Having reminders	26. they will forget to use it[#]
Facilitator: Awareness of the positive outcomes of the insulin PDA	Facilitator: Awareness of the positive outcomes of the insulin PDA	27. they heard negative things about the insulin PDA[#]

Table 3.9, continued

Category	Theme	Voting items in the Voting Form
Patient		**I think patients will not use the PDA in the clinic because...**
Barrier: Patients cannot understand the insulin PDA	Barrier: Patients cannot read or understand the insulin PDA	28. they cannot read or understand the PDA
Barrier: Patients' health condition (e.g: poor vision) render difficulty in using the insulin PDA		29. their poor vision makes it difficult to read the PDA
Barrier: Patients are not willing to pay for the insulin PDA	Barrier: Patients are not willing to pay for the insulin PDA	30. they are not willing to pay for the PDA
Barrier: Patients let doctors or relative to make health decisions for them	Barrier: Patient rely on doctors to make health decisions	31. they rely on doctors to make health decisions
Barrier: Patients lack of confidence in using the insulin PDA by themselves to make decision		32. they are not confident to use the PDA by themselves
Barrier: Patients lack of motivation and effort to improve health	Barrier: Patients lack of motivation and effort to improve health	33. they are not motivated to use it
Barrier: Patients do not like to read	Barrier: Patient do not like to read	34. they do not like to read
Barrier: Patients may feel push to use insulin when receiving the insulin PDA	Barrier: Patient may feel push to use insulin when receiving the insulin PDA	35. they feel that the PDA is a tool to persuade them to start insulin
Barrier: Patients are busy	Barrier: Patients are busy	36. they are too busy
Barrier: Language barrier between HCP and patient	Barrier: Language barrier between HCP and patient	37. of language barrier
Barrier: Difficulty to return to the clinic for PDA follow-up	Barrier: Difficulty to return to the clinic for PDA follow-up	38. they have to make extra trips to the clinic for PDA follow up*
Facilitator: Patients' trust in doctor	Facilitator: Patients' trust in doctor	39. they do not trust the doctor$^{\#}$
Facilitator: Belief that PDA is beneficial*	Facilitator: Belief that insulin PDA is beneficial	40. they feel that the PDA is not useful$^{\#}$

Table 3.9, continued

Category	**Theme**	**Voting items in the Voting Form**
Innovation		**I think HCP/patients will not use the PDA in the clinic because...**
Barrier: Insulin PDA has too many pages and wordy	Barrier: Insulin PDA has poor design	41. it has too many pages
		42. it is too wordy
Barrier: Insulin PDA is not visually attractive		43. it is not visually attractive
Barrier: Insulin PDA may delay treatment in patient	Barrier: Perception of negative consequences from the insulin PDA use	44. they are concerned that the PDA may delay patients' treatment decision
Barrier: Insulin PDA may replace consultation		45. they are concerned that the PDA may replace their consultation
Barrier: Disagree with the options of doing nothing or alternative treatment in the insulin PDA		46. they are concerned about giving patient the options of "alternative treatment" or "do nothing" *
Barrier: Insulin PDA may cause patients to feel confuse		47. it is confusing
Barrier: Insulin PDA may cause patients to feel anxious		48. it makes patients feel anxious
Facilitator: Insulin PDA comprehensive and informative	Facilitator: Insulin PDA comprehensive and informative	49. it is not informative enough#

Barrier adapted from facilitator; * Barrier or facilitator identified in the community clinics but not in the UMMC primary care clinic

(e) Data collection process and analysis

The multivoting exercise took place in October 2017 during a half-day meeting (approximately three hours). Initially, the researcher explained the study objective and procedures to the participants using a study information sheet (Appendix F). They were informed that the purpose of the exercise was to narrow down the list of barriers to the insulin PDA implementation, that were identified in a previous qualitative study (Phase 1) so that most important barriers can be identified for development of targeted intervention. Subsequently, written informed consent were obtained followed by administration of a participant socio-demographic information form.

Before the voting process, the researcher presented the insulin PDA and the concept of SDM to the participants using PowerPoint slides. In addition, examples of how the insulin PDA can be used in the clinic were also provided to enable the participants to think about the processes of the insulin PDA implementation, and what are the main barriers that could hamper its implementation in the UMMC primary care clinic.

Once the participants were familiar with SDM and the insulin PDA, the Voting Form was distributed. They were asked to review the initial list of 49 barriers and identify the major barriers in the clinic. Then, they were asked to vote for the barriers that they think should be prioritised. Participants were given individual voting forms and asked to vote privately to prevent them from influencing one another. Once voting forms were completed, they were immediately entered into an excel spreadsheet and tabulated. Barriers that received votes equivalent to or less than half the number of participants were eliminated. As there were 12 participants in the exercise, barriers that received less than six votes were removed. Once the list of barriers was condensed, a second voting form with 18 barriers was immediately generated.

Then, a second voting round was conducted to further condense the list. There were no discussions about the first voting round results to avoid influencing the participants in the second voting round. As there were 18 barriers in Voting Form 2, the participants were asked to vote for their top 10 highest priority items of the list. This would reduce the number of barriers to approximately 10 items, which the researcher and supervisors had discussed and decided would be feasible for the development of the tailored intervention prior to the multivoting process. The multivoting process is illustrated in Figure 3.4.

Step 1: Round 1 voting

- Using the Voting Form developed (49 barriers), the participants voted as many items as they wish.

↓

Step 2: Round 1 analysis

- Once votes are tabulated, barriers with a vote count equivalent to or more than half the number of participants remain on the list.
- Second Voting Form generated.

↓

Step 3: Round 2 voting

- Using the second Voting Form, (18 barriers) the participants voted for their top 10 highest priority items of the list

↓

Step 4: Round 2 analysis

- Round 1 analysis repeated.
- Key barriers identified.

Figure 3.4: The multivoting process

The multivoting process ended once the completed Voting Form 2 was collected from all participants. The participants were not informed of the results but were told that they would be invited again to participate in a meeting to discuss and finalise the intervention that would be developed to overcome the proritised barriers.

Similar to the first round voting process, the votes from the second voting process were entered into an excel spreadsheet and tabulated. Barrier that received votes equivalent to or less than half the number of participants were eliminated. Barriers that received less than six votes were removed and the remaining barriers were prioritised.

(f) Ethics approval

Prior to conducting Phase 2 and Phase 3 of this study, ethical approval was obtained from the University Malaya Medical Centre Medical Ethics Committee (Date of approval: 25 Sept 2017; Reference: 201797-5554).

3.3.1.2 Step 2: Selection and tailoring of strategies to overcome the prioritised barriers

Following the prioritisation of the barriers, the next step was selecting and tailoring strategies to overcome the prioritised barriers. This involved searching for potential strategies, understanding the clinic context, and mapping the selected strategies to specific barriers.

(a) Searching for potential strategies

Various sources were looked into when searching for potential strategies that could overcome the prioritised barriers. First, the researcher conducted a literature search specifically on PDA implementation studies with findings on the effectiveness of strategies in overcoming a specific barrier. Due to the scarcity of evidence, the researcher then looked into PDA implementation studies with recommendations for potential strategies. There was no information on strategies that have been utilised to address specific barriers namely patients' literacy level and communication and language barriers in PDA implementation. Hence, random searches were conducted on literature that suggested potential strategies to overcome these barriers in medical consultations.

Besides literature, strategies and processes suggested by participants in Phase 1 was another source for strategy identification and selection. These findings were deemed relevant as they were proposed by healthcare managers, HCPs, and patients. As they are familiar with the clinic culture and systems, the strategies proposed might be more feasible.

Next, implementation taxonomies like the Expert Recommendations for Implementing Change (ERIC) taxonomy (Powell et al., 2015) and the Michie's BCCTv1 taxonomy (Michie et al., 2013) were examined for any other relevant strategies that could be utilised. Implementation taxonomies are lists of strategies that have been defined and grouped into various domains and implementation processes that implementation researchers can use (Mazza et al., 2013). The ERIC taxonomy was a consolidation of strategies described in health and mental health literature by implementation scientists and initially comprised of 68 strategies which were grouped according to six key implementation processes: planning (conduct local needs assessment, involve executive boards), educating (e.g.: distribute educational materials, conduct educational meetings), financing (e.g.:Use capitated payments/ penalise), restructuring (e.g.: revise professional roles, create new clinical teams), managing quality (e.g.: develop and organise quality monitoring systems, remind clinicians), and attending to the policy context (e.g.: change accreditation or membership requirements, change liability laws) (Powell et al., 2012). The list was later refined and the number of strategies were increased from 68 to 73 (Powell et al., 2015).

The Michie's BCCTv1 taxonomy is different from the ERIC taxonomy in that the strategies can be used for development of intervention at a more granular level (Michie et al., 2013) as the strategies are comprised of behavior change techniques (BCTs). BCTs are defined as "*observable, replaceable, irreducible component of an intervention* *designed to alter or redirect causal processes that regulate behavior."* (Michie et al., 2013, p. 82). BCT represents the mechanism of change of strategies and is described as "active ingredient" that can cause change to determinants of practice (Michie et al., 2013). The Michie et al.'s (2013) BCT Taxonomy version 1 comprised of 93 BCTs hierarchical clustered into 16 groups: goals and planning, feedback and monitoring, social support, shaping knowledge, natural consequences, comparison of behavior, associations, repetitions and substitutions, comparison of outcomes, reward and threat, regulation, antecedents, identity, scheduled consequences, self-belief and, covert learning (Michie et al., 2013). BCTs target and affect mechanisms of actions, which are constructs specified in theories of behavior and behavior change that can mediate intervention effects such as knowledge, skills, beliefs about capabilities, behavioural regulations, social influences, subjective norms and environmental context and resources (Carey et al., 2019). BCTs are derived from the science of behavior change and therefore provide theoretical grounding to development of implementation interventions and have been used in a wide range of behavioural domains including HCPs' behaviours (Treweek et al., 2014)**.** Relevant strategies found in both the taxonomies were mapped to the barriers that they can potentially address. This resulted in the development of a matrix in which relevant strategies were mapped to the specific barriers.

(b) ***Understanding the clinic context***

There is a need to understand the context of the clinic to know the availability of resources before selecting the appropriate strategies. Additionally, it will help knowing when to introduce the insulin PDA in the patient care pathway. The researcher conducted observations and engaged in informal conversation with the clinic staff to understand the type 2 diabetes patient care pathway. The key clinical contexts gathered for informing the insulin PDA implementation were:

- How were patients offered insulin therapy? (e.g.: where, by who, when)
- What happens to patients when a decision about insulin is made?
- What were the specific roles played by the various HCPs in the clinic?
- What were the available resources in the clinics (i.e.: infrastructure, staff)?

Knowing this information allowed the researcher to select strategies that would be appropriate to implement in the clinic, including incorporating them into the clinic's daily work processes without requiring too many changes.

(c) ***Mapping selected strategies to specific barriers***

Once the clinic context was understood, the researcher went through each of the strategies identified and assessed its appropriateness based on evidence on its effectiveness and feasibility in implementing in the UMMC primary care clinic. The researcher tailored the strategies to overcoming barriers through discussions with YKL and CJN, who were able to provide feedback based on their knowledge, research and clinical experience. CJN has more than 20 years of experience practising in the clinic, and is familiar with the operations and work culture of the UMMC primary care clinic's system.

During strategy selection, sustainability of the insulin PDA implementation was also kept in mind. For example, the strategy 'Identify and prepare champion' was not selected even though there was evidence that having a champion is a facilitator for effective implementation. This is because the UMMC primary care clinic has a regular turnover of medical officers as it is situated in an academic hospital. Hence, a trained champion might leave the clinic which rendered this strategy unsustainable. This process reduced the identified strategies to a selected few that were most appropriate to overcome the prioritised barriers.

3.3.1.3 Step 3: Operationalisation of the strategies

In Step 3, each of the discrete strategies that formed the draft tailored intervention developed was operationalised based on the UMMC primary care clinic context. The operationalisation was according to recommendations by Proctor, Powell & McMillen, (2013) who suggested that strategies should be specified according to seven dimensions, namely (Proctor, Powell & McMillen, 2013):

1. the actor (who will enact the strategy: e.g. doctors, patients etc.),
2. the action (actions, steps, or processes that need to be enacted by the actor),
3. the action target (conceptual target or the determinants of change that strategy that is trying to impact),
4. temporality (when the strategy is used),
5. dose (intensity of the intervention: e.g.: number of times),
6. the implementation outcome affected (identify and measure the implementation outcome(s) likely to be affected by each strategy), and
7. the justification for selection of the strategy.

The strategies were specified to determine if they would be feasible to carry out in the clinic context. Also, when a strategy is described in sufficient detail, it can be replicated and scaled up in other research and practices (Proctor, Powell & McMillen, 2013). Sustainability of the strategies was kept in mind by ensuring that the right staff were chosen to carry out the strategies as well as the timing and dosage of strategies. For example, the strategy ‘educational workshop’ would be conducted twice a year (dose) following doctor turnover in the clinic to ensure new doctors are trained on using the insulin PDA.

Once the implementation strategies were operationalised, they were embedded into the existing diabetes patient care pathway in the clinic. Through the processes described above, the details of the draft tailored intervention were developed.

3.3.1.4 Step 4: Finalisation of intervention

A meeting (herewith: intervention finalisation meeting) was conducted with clinic stakeholders in January 2018 to discuss and finalise the intervention. Participants (healthcare managers, HCPs and patients) from the multivoting exercise in Step 1 were invited. An open discussion was conducted to enable the various stakeholders to provide their opinions on the draft tailored intervention based on their roles and then to come to a consensus about the implementation. Each stakeholder also had the opportunity to voice their opinions regarding the proposed intervention. Figure 3.5 illustrates the process of conducting the open discussion.

Participants were informed the purpose of the meeting which was to discuss and to come to a consensus on the proposed intervention.

↓

Written informed consent and socio-demographic information was obtained from the participants

↓

The 13 prioritised barriers that emerged from the previous multi-voting exercise and the proposed strategies to overcome the specific barriers were presented.

↓

The PDA implementation flow diagram and HCPs' respective implementation tasks were presented and explained in detail. This information was also provided in hardcopy.

↓

During the open discussion, participants were given time to review the proposed strategies to address the specific barriers, to go through the task list sheet, and to deliberate if the proposed intervention would be effective and feasible to implement in the clinic setting.

↓

A self-developed discussion guide (Appendix G) was used to elicit information pertaining to the feasibility of the intervention and the proposed implementation processes.

↓

The open discussion ended when consensus was reached on the finalised intervention.

Figure 3.5: The processes of conducting the open discussion

The open discussion enabled various stakeholders to counter and support each other's opinions on the proposed implementation plan. This led to agreement on which strategies to be retain or drop. The meeting lasted for one and a half hours.

3.3.2 Results

3.3.2.1 Prioritised barriers

*(a) **Participants' socio-demographic information***

A total of 11 HCPs and five patients were invited to participate in the multivoting exercise. However, two doctors could not attend due to time constraints while two patients had to attend to other appointments. The total number of participants involved in the barrier prioritisation exercise was 12 and this included the clinic coordinator, three doctors, two diabetes educators, three staff nurses and three patients.

The mean age of the participants was 40.6 (± SD 10.6) years. Among the HCPs, their mean years practising in the clinic was 10.2 (± SD 11.6) years, ranging from 2-36 years while among the patients, their mean years seeking treatment at the clinic was 10.0 (± SD 5.0) years, ranging from 5-15 years. Most of them had heard of the insulin PDA before (n=10) but only four HCPs had experiences using the insulin PDA. Table 3.10 shows the participants' background.

Table 3.10: Background of participants in the barrier prioritisation exercise

	HCP (n=9)	**Patient (n=3)**
Age (years) Mean ± SD (Range)	40.5 ± 10.6 (31-56)	67.0 ± 1.0 (66-68)
Years of practice at clinic Mean ± SD (Range)	10.2 ± 11.6 (2-36)	n.a
Years of seeking treatment at the study clinic Mean ± SD (Range)	n.a	10.0 ± 5 (5-15)
Sex		
Male	1	1
Female	8	2
Ethnicity		
Malay	5	3
Chinese	3	0
Indian	1	0
Highest education level		
Secondary	0	1
Diploma	5	1
Tertiary	4	1
Position		
Healthcare manager	1	n.a
Doctor	3	n.a
Diabetes educator	2	n.a
Staff nurse	3	n.a
Insulin PDA use		
Yes	4	0
No	5	0

n.a: not applicable; SD: Standard deviation

(b) Prioritised barriers

The multivoting exercise reduced the initial list of 49 barriers to 13 prioritised barriers. Table 3.11 shows the 26 barriers that were removed and the 13 barriers that were prioritized after the two rounds of the multivoting process. Bolded texts indicate the 13 prioritised barriers.

Table 3.11: The 13 prioritised barriers

No	Barrier	Round 1 No of votes	Round 2 No of votes
1.	Patients will not use the PDA because they do not trust the doctor	0*	-
2.	Patients will not use the PDA because it is not informative enough	1*	-
3.	HCPs will not use the PDA in the clinic because they are concerned that the insulin PDA may replace their consultation	1*	-
4.	HCPs will not use the PDA in the clinic because they are concerned that the PDA may delay patients' treatment decision	1*	-
5.	HCPs will not use the PDA in the clinic because they do not want the patient to ask them more questions after using it	1*	-
6.	HCPs will not use the PDA in the clinic because they are concerned about giving patient the options of "alternative treatment" or "do nothing"	2*	-
7.	HCPs will not use the PDA in the clinic because their colleagues influence them not to use the insulin PDA	2*	-
8.	HCPs will not use the PDA in the clinic because they already have their own way of doing things	2*	-
9.	Patients will not use the PDA because they feel that the insulin PDA is not useful	3*	-
10.	Patients will not use the PDA because it is confusing	3*	-
11.	HCPs will not use the PDA in the clinic because they heard negative things about the insulin PDA	3*	-
12.	HCPs will not use the PDA in the clinic because they will forget to use it	3*	-
13.	HCPs will not use the PDA in the clinic because they think that it is not credible (reliable and trustworhty)	3*	-
14.	HCPs will not use the PDA in the clinic they believe that insulin PDA is not useful for improving patient care and outcomes	3*	-
15.	HCPs will not use the PDA in the clinic using PDA is not part of their job scope	3*	-
16.	HCPs will not use the PDA in the clinic because senior persons in the clinic do not motivate them to use it	3*	-
17.	HCPs will not use the PDA in the clinic because there are many other health programmes in the clinic	3*	-
18.	It is hard to use the PDA in the clinic because there is not enough rooms in the clinic for insulin PDA discussions	4*	-

Table 3.11, continued

No	Barrier	Round 1 No of votes	Round 2 No of votes
19.	Patients have difficulty to use the PDA with HCPs because HCPs talk too fast	4*	-
20.	Patients have difficulty to use the PDA with HCPs because HCPs are not clear when giving information to them	4*	-
21.	Patients will not use the PDA because they have to make extra trips to the clinic for insulin PDA follow up	4*	-
22.	Patients will not use the PDA because it is not visually attractive	4*	-
23.	Patients will not use the PDA because it makes patients feel anxious	4*	-
24.	Patients will not use the PDA because they are too busy	4*	-
25.	Patients will not use the PDA because their poor vision makes it difficult to read the insulin PDA	4*	-
26.	Patients will not use the PDA because it has too many pages	4*	-
27.	HCPs use difficult words when talking to patients	5*	-
28.	Patients will not use the PDA because it is too wordy	5*	-
29.	HCPs will not use the PDA because using the insulin PDA is extra work for them	5*	-
30.	HCPs will not use the PDA because there is no one championing the use of PDA in the clinic	5*	-
31.	It is difficult to implement the PDA in the clinic because there is a lack of funding to print the PDA booklets	5*	-
32.	Patients will not use the PDA because they are not willing to pay for the insulin PDA	6	2**
33.	HCPs will not use the PDA in the clinic because they are not familiar with the insulin PDA booklet (e.g: purpose, content, usage)	8	4**
34.	Patients will not use the PDA because they do not like to read	7	5**
35.	Patients will not use the PDA because they are not motivated to use it	7	5**
36.	HCPs will not use the PDA in the clinic because they are not aware of the insulin PDA	7	5**
37.	**HCPs will not use the PDA in the clinic because they want to finish their work quickly**	**7**	**6**
38.	**HCPs will not use the PDA in the clinic because there is no clear directive / circular from the top management to use the PDA**	**7**	**6**
39.	**HCPs will not use the PDA in the clinic because they are not motivated to try new innovations**	**8**	**6**

Table 3.11, continued

No	Barrier	Round 1 No of votes	Round 2 No of votes
40.	**HCPs will not use the PDA in the clinic because they don't know where to get the PDA**	**10**	**6**
41.	**Patients have difficulty to use the PDA with HCPs because of language barrier**	**7**	**7**
42.	**Patients will not use the PDA because they are not confident to use the insulin PDA by themselves**	**8**	**7**
43.	**HCPs will not use the PDA in the clinic because there is no person-in-charge to oversee the use of the PDA in the clinic**	**9**	**7**
44.	**Patients will not use the PDA because they feel that the insulin PDA is a tool to persuade them to start insulin**	**6**	**8**
45.	**Patients will not use the PDA because they rely on doctors to make health decisions**	**7**	**8**
46.	**HCPs will not use the PDA in the clinic because they tend to make decisions for their patients instead of practising shared decision making**	**6**	**9**
47.	**Patients will not use the PDA because they cannot read or understand the insulin PDA**	**10**	**9**
48.	**HCPs will not use the PDA in the clinic because they will not be able to see the same patient to follow up on the PDA**	**10**	**9**
49.	**HCPs will not use the PDA in the clinic because they are too busy as there are too many patients**	**11**	**11**

*Eliminated in Round 1; **Eliminated in Round 2; - Removed

3.3.2.2 Tailored strategies to overcome the prioritised barriers

(a) Potential strategies to address barriers

Through literature review and findings on proposed strategies from Phase 1, it was found that while there was a variety of strategies found that can be adopted to overcome barriers such as ‘time constraints’ and ‘patient cannot read or understand the insulin PDA’, other barriers such as ‘the lack of continuity of care’ and ‘HCPs will not use the PDA in the clinic because they want to finish their work quickly’ had fewer strategies that can be adopted. Table 3.12 shows an example of the potential strategies found from various sources that could potentially address a specific barrier. The complete matrix can be found in Appendix H.

Table 3.12: Potential strategies to address specific barriers in the insulin PDA implementation from various sources

No	Barrier	Effective strategies from literature on PDA implementation	Strategies proposed by participants in Phase 1 study	Strategies recommended in the literature on PDA implementation	Strategies recommended in other literature (not PDA implementation literature) to address specific barriers	Strategies identified in the ERIC taxonomy and the BCT version 1 taxonomy
1.	HCPs will not use the PDA in the clinic because they are too busy as there are too many patients	• Conduct training to increase healthcare professionals' knowledge and skills in using patient decision aids (Holmes-Rovner et al., 2011; Natalie Joseph-Williams et al., 2017; Lloyd & Joseph-Williams, 2016; K. R. Sepucha et al., 2016; Stacey et al., 2015; Wirrmann & Askahm, 2006)	• Conduct SDM and insulin PDA training • Involve diabetes educators or nurses to use insulin PDA with patients • HCPs to focus only on important topics when using the insulin PDA • Let patients read the insulin PDA in their own time and discuss in their next visit	• Demonstration how PDAs can be used during consultations (French et al., 2012). • Inform HCPs that PDA does not necessarily increase consultation time and can help save time in the future (Lepine 2016; Watson, 2008) • Remind clinicians (K. Sepucha & Simmons, 2011; Uy et al., 2014)		• Conduct educational meetings • BCT: Demonstration of behaviour

Table 3.12, continued

No	Barrier	Effective strategies from literature on PDA implementation	Strategies proposed by participants in Phase 1 study	Strategies recommended in the literature on PDA implementation	Strategies recommended in other literature (not PDA implementation literature) to address specific barriers	Strategies identified in the ERIC taxonomy and the BCT version 1 taxonomy
		• Giving PDA to patients pre-visit (Brackett et al., 2010; Scalia et al., 2017; Schroy et al., 2014) • Using IT system to delivery PDA to patients (e.g: EMR) (C.L. Lewis et al., 2011; Miller et al., 2012) • Involvement of staff other than doctors in the implementation (G. A. Lin et al., 2013; Scalia et al., 2017)	• Get patients to use PDA prior to consultation • Have a person in charge or a dedicated staff or team for the insulin PDA implementation			

(b) ***Selected strategies mapped to specific barriers***

The researcher identified 11 strategies to overcome the 13 key barriers based on the list of potential strategies identified from various sources and understanding the clinic context. The strategies that were prioritised during selection were those that were proven effective in PDA implementation literature and those proposed by Phase 1 participants. When there were no appropriate strategies from these two sources, strategies recommended (effectiveness not reported) in PDA implementation studies, in other literature (none PDA implementation studies) and those listed in the ERIC taxonomy and Michie BCCTv1 taxonomy were looked into.

Some strategies were similar across the various sources. For example, the strategy 'To involve diabetes educators and nurses to use the insulin PDA with patients' was related to the strategy 'Revise professional role' as diabetes educators' and nurses' roles need to be revised so they can use the insulin PDA with patients. Both strategies were consolidated and termed as 'Revise professional role'. Another strategy, 'Inform HCPs on the advantages of the insulin PDA use' was similar to the BCT strategies 'Information about social and environmental consequences' and 'Information about emotional consequences'. These strategies were combined and termed 'Inform HCPs on the advantages of the insulin PDA use' that includes social and emotional benefits. The following section details the strategy selected and the rationale on why they were selected; evidence in the literature and/or clinic context.

Strategy: Mandate change

This strategy was selected to address the barrier 'Not having a clear directive from the top management' to use the insulin PDA. This strategy had been defined as "*have leadership declare the priority of the innovation and their determination to have it implemented"* (Powell et al., 2015, p. 9). This strategy was selected because it has been shown that when organisational leader showed clinicians that SDM was an important organisational priority, it led clinicians to believe that SDM was part of the organisation's work practice and not something that was imposed on them (Hsu, Liss, Westbrook, & Arterburn, 2013; Joseph-Williams et al., 2017; Lloyd, Joseph-Williams, Edwards, Rix & Elwyn, 2013) **(evidence).** Based on the clinic context, the Head of Department or the clinic coordinator organise monthly unit meetings, where all clinic staff (doctors, diabetes educators, staff nurses, appointment clerks) gathers to discuss matters related to the clinic, Hence, this provides opportunity to implement this strategy in a unit meeting **(clinic context).** Participants from Phase 1 also noted that directive from higher authority was an effective way to implement the insulin PDA. Furthermore, this strategy was perceived to be more feasible compared to other strategies such as incorporating the insulin PDA use as part of key performance index or standard operating procedure. This is because the latter strategies would require approvals from hospital authorities and bureaucratic paperwork that are time consuming **(clinic context).** Declaration from the clinic authority may influence the clinic staff to see that the insulin PDA implementation is a clinic's priority and will influence them to be involved in the implementation.

Strategy: Training workshop

Conducting training workshop was selected to address the barrier 'HCPs tend to make decisions for their patients'. In many PDA implementation studies, training workshops was found to helped HCPs understand how SDM differed from their current ways of working and shifted their thinking from provision of information to provision of support to patients and to consider patient values (Joseph-Williams et al., 2017; Stacey et al., 2015; Wirrmann & Askahm, 2006) (**evidence**). Phase 1 participants also noted that HCPs need to be taught the concept of SDM and the insulin PDA. Given that the researcher's supervisors are both experts in the field of SDM and affiliated with the UMMC primary care clinic, hence there was expertise available to conduct the SDM training workshop **(clinic context).** In this strategy, a lecture would be given to HCPs focusing on the SDM concept to develop their knowledge and understand its benefits. In addition, they can understand that SDM and the insulin PDA use would lead to positive outcomes such as improved quality patient care and move away from the paternalistic approach.

Conducting training workshop was also selected to address the barrier 'HCPs are too busy to use the insulin PDA during consultation as there are too many patients'. There are studies that have shown that PDA use does not necessarily increase consultation time (Stacey et al., 2014). It might help save time in the future as informed decision making can be achieved quicker (Green et al., 2004) (**evidence**). One study suggested having a mentor or peer expert to demonstrate how the insulin PDA can be incorporated into a standard clinical consultation in order to allay fears over increased time (French et al., 2012). Participants from Phase 1 suggested that HCPs tailor PDA use to their patients, discussing only the information that the patient needs to know instead of going through the entire PDA. HCPs can be informed of the information above during the training workshop to change their perception that PDA use would take more time than usual care. This strategy is intended to target doctors' skills and their perception that they would not be able to use the insulin PDA within limited consultation times.

Strategy: Involve patients' family members or caretakers

This strategy was selected to address the barrier 'patient not being able to read or understand the insulin PDA'. Many participants from Phase 1 proposed this strategy based on their experiences when faced with patients who were illiterate during consultations. Doctors would be taught to ask patients if they have family members or friends to help them use the insulin PDA.

Strategy: Framing/reframing

This strategy was selected to help change HCPs' perception that using the insulin PDA would take up a lot of time in an already a busy clinic setting. 'Framing/reframing' is defined as "*suggest the deliberate adoption of a perspective or new perspective on behavior (e.g.: its purpose) in order to change cognitions or emotions about performing the behavior"* (Michie et al., 2013, p. 20). A study found that one clinician viewed PDAs as a tool that could facilitate decision-making in on-going consultations that could help make durable decisions to "save time in the future" (Watson, Thomson & Murtagh, 2008) (**evidence**). In this strategy, the researcher would inform HCPs that using the insulin PDA might potentially help them reduce the consultation time needed to achieve an informed decision with patients. Eventhough the first consultation might take more time, insulin decision-making discussions over subsequent consultations may be shorter. Furthermore, when patients read the PDA at home before their next consultation, less time would be needed for these discussions.

‘Framing/reframing’ was also selected to change patients’ perception that using the insulin PDA meant they had to start using insulin. One participant from Phase 1 has highlighted that the insulin PDA should be introduced to patients in a positive and non-threatening manner. In this strategy, HCPs would be taught to emphasise to patients that using the insulin PDA did not mean that they had to initiate insulin but to help them make an informed decision about diabetes treatment. They would also be taught to inform patients that there are various diabetes treatment options and patients can read the insulin PDA at home and think about their decision. This was intended to make patients’ to be more receptive towards using the insulin PDA.

Strategy: To engage patients in treatment discussions by getting them to ask questions and express concerns

This strategy was selected to address the patient barriers namely ‘patient rely on doctor to make health decision’ and ‘patient are not confident to use the insulin PDA by themselves’. Literature has shown that strategies whereby patients were prepared for an active consultation with doctors or prepared an agenda for their clinic visit can improve patient engagement. For example, getting them to ask their HCPs three questions: 1) What are my options?, 2) What are the benefits and harms?, and 3) How likely are these? (Lloyd & Joseph-Williams, 2016; Tai-Seale, 2011) (**evidence**). When doctors engage with patients in discussions, patients may feel more supported and confident in their ability to use the insulin PDA. Thus, they will have more active participation in their health management.

Strategy: Inform HCPs on the advantages of the insulin PDA use

This strategy was selected to address the three barriers namely, ‘HCPs tend to make decision for their patients’, ‘HCPs wants to finish their work quickly’, and ‘HCPs are not motivated to try new innovations’. This strategy was also similar to the BCTs ‘Information about social and environmental consequences’ which was defined as “*Provide information (e.g: written, verbal, visual) about social and environmental consequences of performing the behavior”* (Michie et al., 2013, p. 8), and ‘Information about emotional consequences’, which was defined as “*Provide information (e.g: written, verbal, visual) about emotional consequences of performing the behavior”* (Michie et al., 2013, p. 9). A systematic review evidenced that PDA implementation is facilitated by HCPs’ perception that SDM and PDA will have a positive impact on the health care processes and patient outcomes (Gravel Legare & Graham, 2006) (**evidence**). Phase 1 participants highlighted the need to inform HCPs on the advantages of the insulin PDA use so that they would understand its purpose and be motivated to use it. This strategy aimed to inculcate the perception that insulin PDA use would result in positive social and emotional outcomes among doctors and nurses in order to gain their interest and motivation in practising SDM and use the newly introduced insulin PDA. They may then move away from paternalistic approach and use the insulin PDA without trying to rush through their consultation in order to finish their work quickly. HCPs would be informed that using the insulin PDA could help improve their skills in exploring patient’s ideas, concerns and expectations about their health treatment, skills-providing information, and in discussing difficult decisions with patients thereby leading to improved patient-doctor communication. In addition, they might feel more satisfied with the quality of service given to patients and have an increased sense of accomplishment in their work.

Strategy: Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation

This strategy was selected to teach HCPs on how to overcome the 'language barrier' when using the insulin PDA with patients. Phase 1 participants reported seeking help from ad-hoc interpreters like family members or other HCPs, to address language barriers during consultations. However, the researcher was concern that family members might misinterpret the information. Hence, it was decided to advise HCPs to juxtapose the PDA in their preferred language with a PDA in the patient's preferred language to address the language barrier. One of the doctors in Phase 1 noted this strategy to be effective. This strategy would be less resource-intensive compared to hiring professional language interpreter service, which is not feasible based on UMMC primary care clinic's tight operation budget as disclosed by participants in Phase 1 (**clinic context**).

Strategy: Revise professional role

This strategy has been defined as "*shift or revise roles among professionals who provide care, and, redesign job characteristics"* (Powell et al., 2015, p. 10) and was selected in this study to help address the barriers 'HCPs are too busy as there are too many patients', 'Patients cannot read or understand the insulin PDA', 'Patients are not confident to use the insulin PDA by themselves' and 'HCPs will not use the PDA because they are not in-charge of the use of PDA in the clinic'. PDA implementation studies have shown that involving staff other than clinicians, such as nurses, in PDA implementation can help alleviate the time needed for doctors to use the PDA with patients (Joseph-Williams et al., 2017; Lin et al., 2013; Scalia, Elwyn & Durand, 2017) (**evidence**). At the UMMC primary care clinic, the diabetes educator is responsible for educating patients on insulin use, managing possible side effects such as hypoglyacemia and self-monitoring of blood glucose. Sometimes, they also received referrals from doctors to educate patients who were indecisive about starting insulin as they have the time, knowledge and skills to counsel patients. If they are trained, they can also execute the PDA use and SDM conversation with patients (**clinic context**). Participants from Phase 1 also suggested training diabetes educators to use the insulin PDA with patients to address doctors' time constraints. Furthermore, diabetes educators could also identify eligible patients for the insulin PDA and provide them with one for reading while they are waiting for their doctor's consultation. This will enable effective use of patient's waiting time and prepare them for insulin PDA discussions before seeing the doctor. Diabetes educators can also be assigned to monitor and order the supply of insulin PDA booklets given their specific role in terms of diabetes management in the clinic (**clinic context**).

Strategy: Systematic documentation

This strategy was selected to address the barrier 'HCPs not able to see the same patient for follow up on the PDA'. Doctors at the UMMC primary care clinic have their own assigned patients but due to external postings, they might not be at the clinic at all times which makes it difficult to see the same patient. While getting doctors to use the insulin PDA with their assigned patients can ensure they see the same patient again, however, this would limit the reach of the PDAs to many patients. That is, a doctor might not give an eligible patient the insulin PDA as they are not the doctor's assigned patient. In an academic healthcare setting, it is hard to have a system that can guarantee patients to see the same doctor every time. Until it is possible, the strategy to enhance information continuity is warranted where shared information links patient care between HCPs (Haggerty et al., 2003). Therefore, rather than focusing on ensuring doctors get to see the same patient, a strategy that focus on information continuity of care would be adopted. Phase 1 participants noted the need for systematic documentation of the insulin PDA use to ensure follow-up with patients and preventing doctors from giving the PDAs to patients who have received it before. Based on the clinic context, the UMMC primary care clinic has an EMR system which helps to facilitate patient information continuity whereby doctors in the clinic can see a patient's medical history, relevant health information, and management by previous doctors **(clinic context).** The EMR system would be utilised to help facilitate the systematic documentation of the insulin PDA use.

Strategy: Provide feedback

This strategy was selected to address the barrier 'HCPs are not motivated to try new innovation'. Insulin PDA implementation studies show that HCPs are more motivated to use PDAs when they receive positive feedback from patients (Silvia & Sepucha, 2006), data on improvements of patient satisfaction, knowledge or other outcome measures (Arterburn, Westbrook, & Hsu, 2016; Feibelmann, Yang, Uzogara, & Sepucha, 2011; Hsu, Liss, Westbrook, & Arterburn, 2013; J. King & Moulton, 2013; Lloyd, Joseph-Williams, Edwards, Rix & Elwyn, 2013; Tietbohl et al., 2015) **(evidence).** Participants in Phase 1 also suggested providing feedback to HCPs to influence them to adopt the insulin PDA. This strategy aims to target social influences where high PDA adoption rates by their colleagues in the feedback may influence HCPs to do the same as they thought they are not doing as much like everyone else. The clinic's monthly unit meetings also provide a suitable avenue for feedback provision given that most of the clinic staff would usually be present **(clinic context).**

Strategy: Place the insulin PDA booklets in doctors' consultation rooms

This strategy was selected to address the barrier of 'HCPs not knowing where to access the PDA'. One study showed that PDAs were adopted and distributed more when they were placed within HCPs' reach (Lin et al., 2013) (**evidence**). Many Phase 1 participants suggested placing the insulin PDA booklets in the consultation rooms to enable doctors to access them easily. At the UMMC primary care clinic, staff nurses are responsible for replenishing medical supplies that are being used in the clinic hence this strategy could be included in the nurses' work flow (**clinic context**). Table 3.13 shows specific strategy mapped to specific barriers.

Table 3.13: Strategy mapped to overcome specific barriers

Strategy Barriers	1 Manda-te change	2 Training workshop	3 Involve patients' family members or careta-kers	4 Framing/ reframing	5 To engage patients in treatment discus-sions by getting them to ask questions and express concerns	6 Inform HCPs on the advanta-ges of the insulin PDA use	7 Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation	8 Revise professio-nal roles	9 Systema-tic docume ntation	10 Provide feedback	11 Place the insulin PDA booklets in doctors' consulta-tion rooms
1. HCPs are too busy as there are too many patients		X		X				X			
2. HCPs tend to make decisions for their patients		X				X					
3. HCPs want to finish their work quickly						X					
4. HCPs are not motivated to try new innovations						X				X	
5. Patients cannot read or understand the insulin PDA			X					X			
6. Patients rely on doctors to make health decisions					X						
7. Patients feel that the insulin PDA is a tool to persuade them to start insulin				X							
8. Patients are not confident to use the insulin PDA by themselves					X			X			
9. Language barrier							X				
10. HCPs not able to see the same patient to follow up on the PDA									X		
11. HCPs will not use the PDA in the clinic because they are not -in-charge to use of the PDA in the clinic								X			
12. HCPs will not use the PDA in the clinic because they don't know where to get the PDA											X
13. HCPs will not use the PDA in the clinic because there is no clear directive to use the PDA	X										

3.3.2.3 Strategies operationalised

Once the strategies were selected, they were operationalised based on the recommendation by Proctor, Powell & McMillen (2013). Full descriptions were provided for six (actor, action, action target, temporality, dose, implementation outcome affected) out of seven domains for each strategy mapped to a specific barrier. Justification for selection of the strategy had already been described above and thus was not included as part of the operationalisation. The strategies ‘Involve patients’ family members or caretakers’, ‘Framing/reframing’, ‘Inform HCPs on the advantages of the insulin PDA use’, and ‘To engage patients in treatment discussions by getting them to ask questions and express concerns’ were embedded within the strategy ‘Conduct educational meeting’ as the choice of delivery.

The operationalisation of the strategies also took consideration of the clinic context. As the UMMC primary care clinic is an academic institution, doctor turnover occurs twice a year in December and June when those who completed their Masters in Family Medicine training leave and new trainees join the clinic. Hence the training workshop was planned twice a year according to the doctor’s turnover period in the clinic. Table 3.14 shows the operationalisation of the selected strategies to overcome the prioritised barriers based on the clinic context.

Table 3.14: Strategies operationalised to address the prioritised barriers based on the clinic's context

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
1. Mandate change	I think HCPs will not use the PDA in the clinic because there is no clear directive from the top management to use the PDA	Head of department or clinic coordinator	Declare to all staff about clinic's intention to implement and support the practice of SDM through the use of insulin PDA during unit meeting	Social influence: All clinic staff (doctors, diabetes educators, staff nurses, appointment clerks) would be influenced by the clinic authority to implement the insulin PDA	At the nearest unit meeting towards the insulin PDA training workshop	Two times per year following doctor turnover in clinic	• Reach (doctor) • Adoption (doctor)
			Issue official letter to doctors and nurses to be involved in the insulin PDA implementation and to attend the training workshop		After the declaration of the insulin PDA implementation at the unit meeting and before the insulin PDA training workshop		

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
2. Training workshop	HCPs will not use the PDA in the clinic because they are too busy as there are too many patients	Researcher and supervisors	Teach doctors how they can use the insulin PDA within their limited consultation time Inform doctor that they can discuss important information rather than going through the entire PDA with patient Provide a 10-minutes reading session and quiz to familiarize HCPs with the insulin PDA	Doctors' skills: Skills in using the insulin PDA during consultation Doctors' belief about capabilities: To improve doctors' ability in using the insulin PDA within limited consultation time	After the official letter was issued to doctors and nurses	Two times per year following doctor turnover in clinic	• Adoption (doctor)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
	I think HCPs will not use the PDA in the clinic because they tend to make decisions for their patients instead of practising SDM	Researcher and supervisors	Provide a lecture on the SDM concept and what is insulin PDA	Doctors' knowledge: Knowledge about SDM and the insulin PDA Doctors' belief about consequences: Belief that SDM and the insulin PDA use would lead to positive outcomes such as quality patient care	After the official letter were issued to doctors and nurses	Two times per year following doctor turnover in clinic	• Adoption (doctor)
	Patients will not use the PDA because they rely on doctors to make health decisions		Inform HCPs to encourage patients to be more involved in their health-decision making by getting them to ask questions and write down their concerns to discuss in their next visit				• Adoption (doctor) • Reach (patient)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
	Patients will not use the PDA because they are not confident to use the insulin PDA by themselves	Researcher and supervisors	Inform HCPs to encourage patients to be more involved in their health decision-making by getting them to ask questions and write down their concerns to discuss in their next visit	Doctors' knowledge: Knowledge in using the insulin PDA with patients who are not confident in using it by themselves Belief about capability: Patients' belief that they are capable of making decisions	After the official letter were issued to doctors and nurses	Two times per year following doctor turnover in clinic	• Adoption (doctor) • Reach (patient)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
3. Involve patients' family members or caretakers (embedded within the training workshop)	Patients will not use the PDA because they cannot read or understand the insulin PDA	Researcher	Train doctors to ask patients who are unable to read or understand the insulin DA if they have anyone (e.g. family members) who can help them	Doctor's knowledge: Knowledge in using the insulin PDA	During the insulin PDA training workshop (Strategy: Conduct educational meeting)	Two times per year following doctor turnover in clinic	• Adoption (doctor)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
4. Framing/reframing (embedded within the training workshop)	HCPs are too busy to use the insulin PDA	Researcher	Inform HCPs that when patients use the PDA prior to consultation, less time will be needed to provide information to patients during consultation. Inform HCPs that while the first consultation using the insulin PDA may take a longer time, insulin decision making over subsequent consultations may be shorter, and reduces delay in decision-making.	Doctors’ belief about consequences: Belief that insulin PDA would not increase but lead to a more effective use of their consultation time	During the insulin PDA training workshop (Strategy: Conduct educational meeting)	Two times per year following doctor turnover in clinic	- Adoption (doctor)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
4. Framing/ reframing (embedded within the training workshop)	Patients will not use the PDA because they feel that the insulin PDA is a tool to persuade them to start insulin	Researcher and supervisors	Inform patients that the insulin PDA is not to persuade them to start insulin but to help them make informed decisions about diabetes treatment.	Doctors' skills: Skills in delivering the insulin PDA to patient Patients' emotion: Patient emotion towards the insulin PDA	During the insulin PDA training workshop (Strategy: Conduct educational meeting)	Two times per year following doctor turnover in clinic	• Reach (patient)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
5. To engage patients in treatment discussions by getting them to ask questions and express concerns (embedded within the training workshop)	Patient rely on doctor to make health decision Patient are not confident to use the insulin PDA by themselves	Doctors	Train doctors to engage patients in discussions about the insulin PDA. To encourage patients to ask questions and express concerns about treatment options	Doctor’s knowledge: Knowledge in using the insulin PDA	During the insulin PDA training workshop (Strategy: Conduct educational meeting)	Two times per year following doctor turnover in clinic	• Adoption (doctor)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
6. Inform HCPs on the advantages of the insulin PDA use (embedded within the training workshop)	HCPs tend to make decisions for their patients instead of practising shared decision making HCPs want to finish their work quickly HCPs are not motivated to try new innovations	Researcher	Inform HCPs of the advantages of practising SDM and insulin PDA use such as promoting patient centered care, improving patient-doctor communication, reducing delay in decision making, decrease consultation time, feeling more satisfied with quality of service given to patients and increased sense of accomplishment	Doctors' and nurses' knowledge about the advantages of using the insulin PDA	During the insulin PDA training workshop (Strategy: Conduct educational meeting)	Two times per year following doctor turnover in clinic	• Adoption (doctor)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
7. Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation (embedded within the training workshop)	Patients have difficulty to use the PDA with HCPs because of language barrier	Researcher	Inform HCPs they can use the PDA in their preferred language while patient are given the PDA in their own preferred language. During discussions, the patient can point out at areas that they want to discuss and the HCP can refer to their own insulin PDA version and clarify with patients	Doctors' knowledge: Doctor to be aware on how to use the insulin PDA when faced with language barrier	During the insulin PDA training workshop (Strategy: Conduct educational meeting)	Two times per year following doctor turnover in clinic	• Adoption (doctor) • Reach (patient)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
8. Revise professional roles	HCPs are too busy as there are too many patients Patients cannot read or understand the insulin PDA Patients are not confident to use the insulin PDA by themselves HCPs will not use the PDA because they are not in-charge of the use of PDA in the clinic	Research and the Head of department or clinic coordinator	Expand diabetes educators' or staff nurses' roles to engage patients in discussions about insulin initiation Assign the diabetes educator as the person in-charge to identify patients who are eligible to use the insulin PDA, to give patients the insulin PDA ahead of consultation and keeping and monitoring the supplies of the insulin PDA booklets for the clinic	Diabetes educators' or staff nurses' social/professional role and identity: diabetes educators and staff nurses to embrace their role in conducting insulin decision-making counseling with patients using the insulin PDA	Prior to the implementation	One time	• Adoption (diabetes educator or staff nurses)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
9. Systematic documentation	HCPs are not be able to see the same patient to follow up on the PDA	Doctor	Make a note in patients' medical notes in the EMR for PDA follow-up Provide a follow-up appointment within 3 months to patients Make a note in patient's appointment card that PDA is given	Doctors' memory, attention, decision processes: Doctors' would be reminded or prompted to follow-up about the insulin PDA with patients	Throughout the implementation period	Every time an insulin PDA is given to a patient	• Adoption (doctor)
		Appointment clerk	Make a note in the EMR (Remark section) that patient received PDA based on the note in the patient's appointment card			Every time patient appointment card received indicate that insulin PDA has been given	• Adoption (doctor)

Table 3.14, continued

		Dimensions to specifying a strategy					
Strategy	**Target barrier**	**Actor**	**Action**	**Action target**	**Temporality**	**Dose**	**Implementation outcomes likely affected**
10. Provide feedback	HCPs are not motivated to try new innovations	Researcher	Prepare individualised feedback report to all clinic staff	Social influences (social norm): When a HCP saw high PDA adoption rates by their colleagues in the feedback, they may be influenced to do the same as they thought they are not doing as much like everyone else	Starting from the second month of the implementation period	Once per month (May to Oct: six times) until the end of the implementation period	• Adoption (doctors, diabetes educator, staff nurses)
		Clinic coordinator	Provide feedback during unit meeting		Starting from the second month since insulin PDA use in the clinic		
11. Place the insulin PDA booklets in doctors' consultation rooms	HCPs will not use the PDA in the clinic because they don't know where to get the PDA	Staff nurse	Replenish the insulin PDA supply in doctor's consultation room	Doctors environmental context and resources: Doctors' access to the insulin PDA	Throughout the implementation period	When there is a lack of the insulin PDA booklets in the consultation rooms	• Adoption (doctor)

Integration of the strategies into the type 2 diabetes patient care pathway

Strategies selected were then integrated into the type 2 diabetes patient care pathway in the clinic. The strategies 'Mandate change', 'Conduct educational meeting', 'Involve patients' family members or caretakers', 'Framing/reframing', 'Inform HCPs on the advantages of the insulin PDA use', and 'Revise professional roles' were planned to be implemented in the pre-implementation period before the actual use of the insulin PDA in the clinic. These strategies involved preparing the clinic setting and training the HCPs. The strategies 'Systematic documentation', 'Provide feedback' and 'Place the insulin PDA booklets in doctors' consultation rooms' were planned to be carried out during the implementation period. These strategies involved the processes of delivering the insulin PDA to patients.

The evidence in the literature, clinic context, and several PDA implementation processes suggested by Phase 1 participants were also taken into consideration when planning the flow of insulin PDA implementation. Many PDA implementation studies have show that pre-visit PDA use by patients led to more effective use of consultation time as doctors focused on discussions about treatment choices rather than communicating facts and information (Brackett, Kearing, Cochran, Tosteson & Blair Brooks, 2010; Scalia, Elwyn & Durand, 2017; Schroy, Mylvaganam & Davidson, 2014). Therefore, delivering the insulin PDA to patients to use before consultation as suggested by Phase 1 participants was also included. As diabetes educators in the clinic provide diabetes education to patients, they would be tasked to identify eligible patients through the EMR to receive the insulin PDA when they arrive at the clinic. Patients can choose to read by themselves or ask the diabetes educator or staff nurse to help them to go through the insulin PDA before their consultation with doctors.

Furthermore, the insulin PDA implementation also planned to deploy the approach whereby patients can take the insulin PDA home so they have more time to go through the information and discuss with their family members. This was also proposed by Phase 1 participants. Hence, this necessitated an insulin PDA follow-up appointment. At the clinic, doctors usually give a 2-week follow-up appointment to patients who agree to initiate insulin to check if the given insulin dosage is appropriate, and if patients had any problems with the insulin therapy. Nevertheless, the insulin PDA follow-up duration was set to be within 3 months. As found in the Phase 1 interviews, giving a follow-up appointment too soon might not be feasible as patients reported difficulties in attending clinic appointments and the clinic's system might be burdened due to its high patient load. However, an appointment that is too far might lead to patients forgetting about the insulin PDA. The 3-month period was based on the average appointment given to patients by doctors in the clinic.

The strategies and the processes were integrated into the insulin PDA implementation patient care pathway hence resulting in the draft intervention developed for the insulin PDA implementation as illustrated in Figure 3.6. Bolded texts in the figure indicate the strategies.

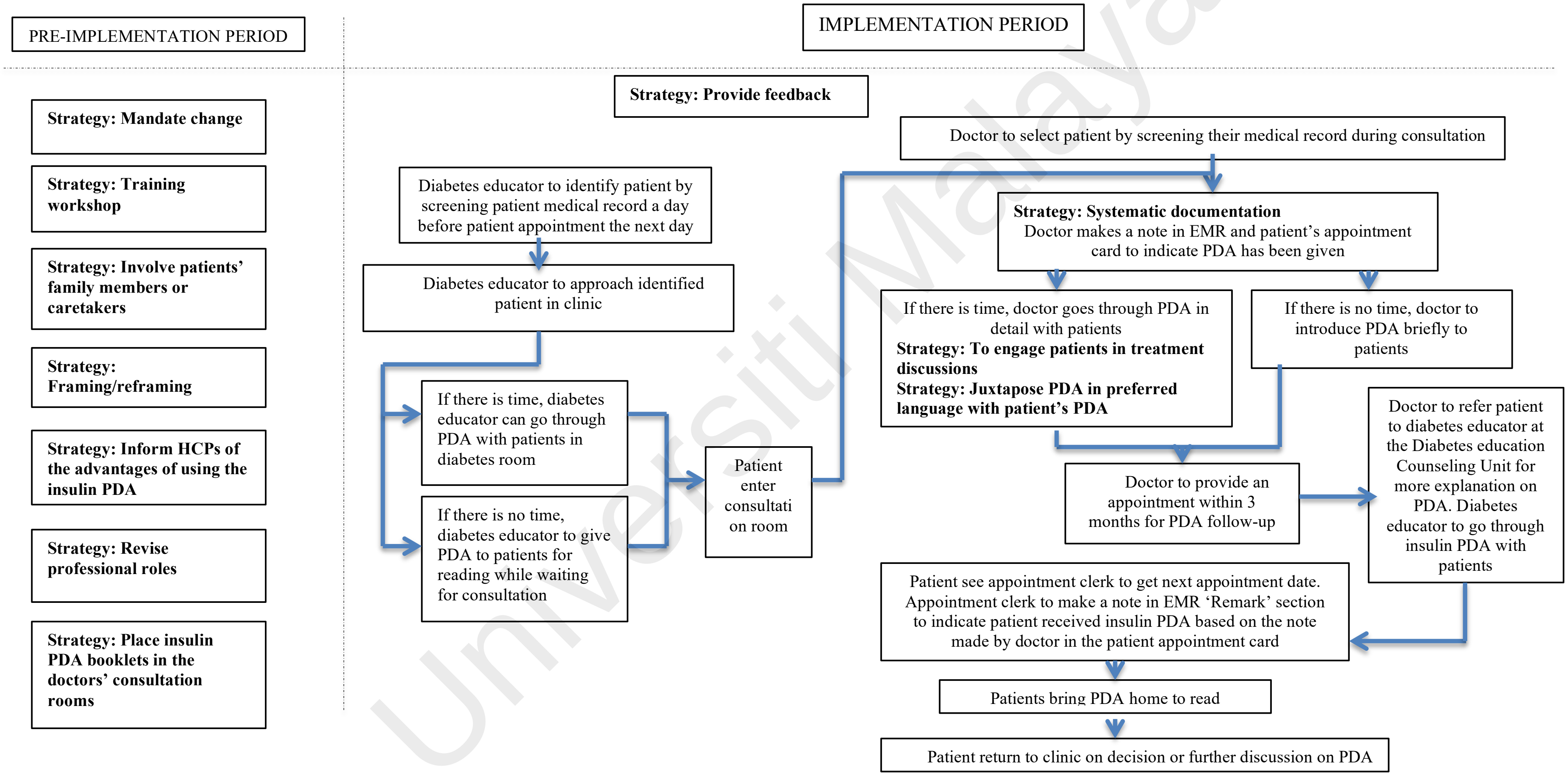


Figure 3.6: The draft implementation intervention

3.3.2.4 Finalised intervention

(a) Participants in the stakeholders meeting

The participants from the Phase 2 multivoting process were invited again to discuss and finalise the draft intervention during the clinic stakeholders meeting in Jan 2018. However, one doctor, one diabetes educator, and one patient could not attend the meeting due to time constraints while another diabetes educator had retired at that point of the study. Three new participants were recruited as suggested by the clinic coordinator; a family medicine specialist, a nursing officer, and a staff nurse. The family medicine specialist was invited because she would be taking the role as the new clinic coordinator (herewith: clinic coordinator 2) as the existing clinic coordinator (herewith: clinic coordinator 1) was going on sabbatical leave.

The total number of participants involved in the finalisation meeting was 12. There were two clinic coordinators, one nursing officer, two doctors, one diabetes educator, four nurses, and two patients. The mean age of the participants was 46.7 (± SD 12.7) years. Among the HCPs, their years of practice in the clinic ranged from 2-36 years (mean years: 11.4 (± SD 10.8)) while among the two patients, their years of seeking treatment at clinic ranged from 10-15 years. The socio-demographic information of the participants in the finalisation meeting is presented in Table 3.15.

Table 3.15: Background of participants in the finalisation meeting (n=12)

Characteristic	**Mean ± SD (range)**
Age (years)	46.7 ± 12.7 (31-66)
Duration of practice at clinic (for HCPs) (years)	11.4 ± 10.8 (2-36)
Duration of seeking treatment at the study clinic (for patients) (years)	12.5 ± 3.5(10-15)
	n
Sex	
Male	1
Female	11
Ethnicity	
Malay	7
Chinese	2
Indian	2
Highest education level	
Diploma	8
Tertiary	5
Position	
Healthcare manager	3
Doctor	2
Diabetes educator	2
Staff nurse	4
Patient	2
Insulin PDA use	
Yes	4
No	9

SD: standard deviation

(b) Discussions during the stakeholders meeting

General views on the proposed draft intervention

During the open discussions in the meeting, the doctors were pleased with the approach of allowing patients to take the insulin PDA home as they felt that they might not have the time to go through it with patients. The patients felt that they would be willing to try the insulin PDA. However, they highlighted the need for the HCP to deliver and follow up on the insulin PDA rather than a non-healthcare personnel. They noted that patients build their confidence from communicating with HCPs.

Prominent issue raised

One prominent issue raised by the participants on the proposed intervention was the absence of diabetes educators in the clinic in the near future. Due to efforts to streamline diabetes services in the hospital, all the diabetes educators in the clinic would be transferred to the hospital's One-Stop Diabetes Center.

Strategy affected

If diabetes educators are not available in the clinic, this meant that the strategy 'Revise professional roles' would not be feasible. To maintain the possibility that diabetes educators could still be involved in the implementation, the participants suggested to involve the One-Stop Diabetes Center. However, it was also noted that patients would be incurred charges if they seek services from the center. The patient representatives then noted cost would be a barrier should patients need to pay to use the insulin PDA.

Ways to resolve the issue

In view of the cost issue, the researcher suggested to assign a staff nurse as a decision coach to use the insulin PDA with patients. The staff nurse would be trained by SDM experts on decision coaching. The nursing officer objected to the proposal as she noted that there was a lack of staff nurses. At that point of the study, there were only 12 nurses available in the clinic and each nurse was in charge of assisting eight doctors in the consultation rooms at one time. Furthermore, staff nurses themselves may not be confident to use the insulin PDA with patients due to a lack of skills. The nursing officer felt that a diabetes educator would be more suitable to use the insulin PDA with patients, as they are equipped with the knowledge on how to answer patients' queries regarding diabetes. Staff nurses in the meeting also expressed doubts and were concern about giving wrong information when providing decision support patients using the insulin PDA.

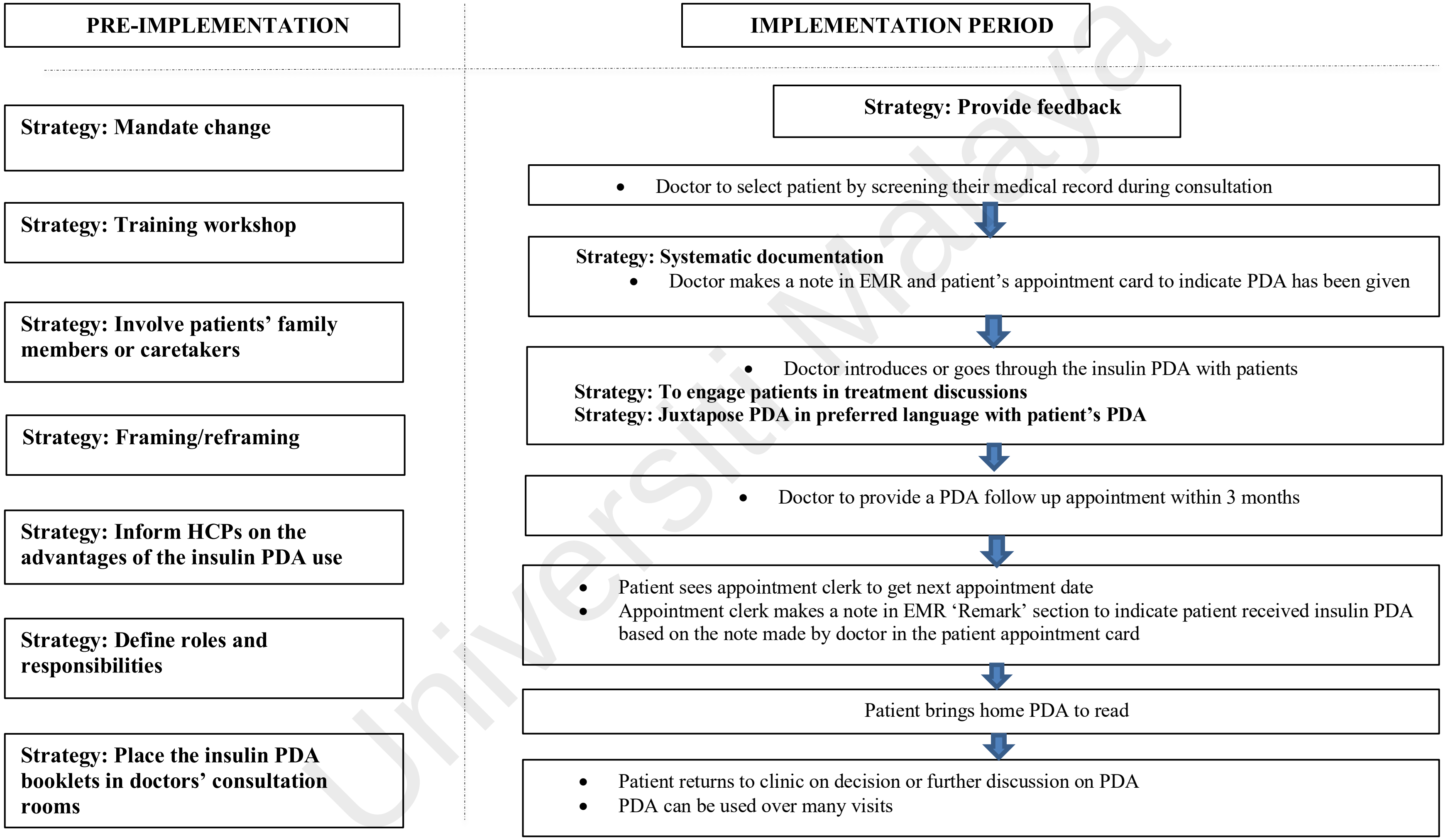
Due to the lack of support staff in the clinic who could use the insulin PDA with patients, the strategy ‘Revise professional roles’ had to be removed from the intervention. Eventhough this strategy had to be removed, the barriers ‘HCPs are too busy as there are too many patients’, ‘Patients cannot read or understand the insulin PDA’, ‘Patients are not confident to use the insulin PDA by themselves’ could still be addressed by other strategies as noted in Table 3.13 above.

As for the barrier ‘HCPs will not use the PDA because they are not in-charge of the use of PDA in the clinic’, all the clinic staff agreed that they were willing to carry out their respective implementation tasks hence there was no need to have a person to be in charge of the insulin PDA implementation. The strategy **‘Define roles and responsibilities’** would be employed. In this strategy, all the clinic staff (doctor, staff nurses, and appointment clerks) would be informed of their specific task in the insulin PDA implementation (**action**). This strategy aimed to make HCPs embrace the implementation tasks given to them as part of their professional roles (**action target**). Clear role definitions have been reported to facilitate PDA implementation (Frosch et al., 2011; Tietbohl et al., 2015) (**evidence**) by enabling clinic staff to be aware of one’s own responsibility but at the same time also aware of other’s unique contribution to the implementation and work together to accomplish tasks through shared responsibility (Tietbohl et al., 2015). The assignment of implementation tasks to various HCPs would be done one time (**dose**) prior to the implementation (**temporality**). The implementation outcome that would be affected by this strategy is doctor ‘Adoption’ (**implementation outcome**).

None of the clinic staff raised issues pertaining to their given implementation tasks. The open group discussions lasted for one and a half hours. Once a consensus was reached on the intervention, an implementation date was set.

(c) The finalised intervention

The finalised intervention comprised of 11 strategies identified to overcome the 13 prioritised barriers to implementation of the insulin PDA in the clinic. Figure 3.7 shows the finalised intervention.



PRE-IMPLEMENTATION

Strategy: Mandate change

Strategy: Training workshop

Strategy: Involve patients' family members or caretakers

Strategy: Framing/reframing

Strategy: Inform HCPs on the advantages of the insulin PDA use

Strategy: Define roles and responsibilities

Strategy: Place the insulin PDA booklets in doctors' consultation rooms

IMPLEMENTATION PERIOD

Strategy: Provide feedback

- Doctor to select patient by screening their medical record during consultation

Strategy: Systematic documentation
- Doctor makes a note in EMR and patient's appointment card to indicate PDA has been given

- Doctor introduces or goes through the insulin PDA with patients

Strategy: To engage patients in treatment discussions
Strategy: Juxtapose PDA in preferred language with patient's PDA

- Doctor to provide a PDA follow up appointment within 3 months

- Patient sees appointment clerk to get next appointment date
- Appointment clerk makes a note in EMR 'Remark' section to indicate patient received insulin PDA based on the note made by doctor in the patient appointment card

Patient brings home PDA to read

- Patient returns to clinic on decision or further discussion on PDA
- PDA can be used over many visits

Figure 3.7: The finalised intervention

3.3.2.5 Implementation of the intervention

(a) Implementation timeline

The implementation of the intervention commenced in March 2018 with the strategy 'Mandate change'. 'Conduct educational meeting' was carried out twice; at the beginning of the implementation in the month of April and later in August. The strategy 'Provide feedback' in terms of provision of an individual report was conducted four times in the month of May, July, August, and September while provision of feedback during unit meetings were performed three times in the month of July, August, and October. Table 3.16 shows the timeline of the strategies carried out.

Table 3.16: Timeline of the strategies implemented

Period	Date	Strategy implemented
PRE-IMPLEMEN-TATION	20 Mar 2018	Mandate change (Announcement by the Head of Department)
	02 Apr 2018	Mandate letter (Official letter by the Head of Department)
		Place the insulin PDA booklets in doctors' consultation rooms (by researcher)
	10 Apr 2018	Training workshop 1 Framing/reframing Inform HCPs on the advantages of the insulin PDA use Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation Define roles and responsibilities
IMPLEMEN-TATION (Start insulin PDA use in clinic)	Throughout implementation period	Place the insulin PDA booklets in doctors' consultation rooms (by nurses)
	21 May 2018	Provide feedback (individual report 1)
	5 July 2018	Provide feedback (individual report 2)
	17 July 2018	Provide feedback (Unit meeting feedback 1)
	6 Aug 2018	Provide feedback (individual report 3)
	21 Aug 2018	Mandate change 2 (Announcement by HOD)
	21 Aug 2018	Mandate letter 2 (Official letter by HOD)
	21 Aug 2018	Provide feedback (Unit meeting feedback 2)
	28 Aug 2018	Training workshop Framing/reframing Inform HCPs on the advantages of the insulin PDA use Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation Define roles and responsibilities
	28 Sept 2018	Provide feedback (Feedback individual report 4)
	30 Oct 2018	Provide feedback (Unit meeting feedback 3)

(b) ***Implementation of the strategies***

Strategy: Mandate change

The Head of Department announced to all the clinic staff about the insulin PDA implementation during a unit meeting. The meeting addressed the rationale, importance and advantages of the insulin PDA implementation. The Head of Department used a persuasive but non-authoritative tone when declaring the clinic's intention to implement the PDAs. Staff present in the meeting were doctors whom majority were family medicine trainees, nurses, appointment clerks, and medical attendants. During the unit meeting, doctors and nurses were encouraged to attend the insulin PDA training workshop to acquire the knowledge and skills to practise SDM and use the insulin PDA. This information were also presented in a workshop flyer which was projected on a screen during the unit meeting.

Official letters to doctors and nurses (Appendix I) about the implementation of the insulin PDA and the insulin PDA training workshop were issued following the training workshop. The official letters also informed that evaluation data would be collected and a study information sheet was attached to explain the risks of their participation in the implementation (Appendix J). The letters also informed doctors and nurses who did not attend the unit meeting about the insulin PDA implementation. This strategy was repeated in August to cater to new doctors who joined the clinic.

Strategy: Training workshop (The strategies 'Involve patients' family members or caretakers', 'Framing/reframing', 'Inform HCPs on the advantages of the insulin PDA use', 'Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation' were embedded within the training workshop as delivery method)

The insulin PDA training workshops were conducted on Tuesday afternoons when doctors and nurses were free from clinic duties. The workshop was conducted by the researcher, YKL and CJN. The workshop lasted three hours and consisted of lectures, video viewing, an insulin PDA reading exercise, and a quiz through a game-based classroom response system (Kahoot!) https://kahoot.com/.

The topics included in the training workshop were: (Appendix K).

1. What is PDA and SDM,
2. Benefits of the insulin PDA,
3. How to practice SDM and use PDA using six steps,
4. Solutions to overcome challenges to implementation,
5. The implementation plan in UMMC primary care clinic, and
6. Staff tasks in the implementation

To familiarise the doctors and nurses with the insulin PDA, 10 minutes were allocated to let them read and go through the insulin PDA. Subsequently, they were then taught the steps to practise SDM using the insulin PDA.

A specific section was conducted to teach doctors on how to overcome the six challenges to insulin PDA use during practice namely,

1. time constraint,
2. patient rely on doctor on decisions,
3. patient not confident to use PDA themselves,
4. patient feel pushed to use insulin,
5. patient cannot read and understand,
6. language barrier.

For the time constraint barrier, the HCPs were taught ways they can use the insulin PDA with patients within the limited consultation time:

1. They could screen their daily patient list to determine eligibility and pass the PDA to the patients while they are waiting for consultation.
2. They could identify patients during their consultation, let them read the PDA outside the consultation room, and then call them back in for discussion.
3. They can briefly introduce the insulin PDA, let patients read at home and follow-up in the next consultation.

The doctors were also informed that they are free to tailor the PDA use to their patients based on whether they want to focus on important topics only or the entire PDA. In addition, the advantages of the insulin PDA use were explicitly stated.

Subsequently, the doctors and nurses were guided through the insulin PDA implementation plan and their specific implementation tasks. At the end of the workshop, continuous professional development points and a certificate of attendance were given to attendees. The second insulin PDA training workshop, which was initially planned for June was only carried out in August due to difficulty getting an available date to conduct the workshop. Figure 3.8 illustrates the insulin PDA training workshop conducted.

Figure 3.8: The insulin PDA training workshop

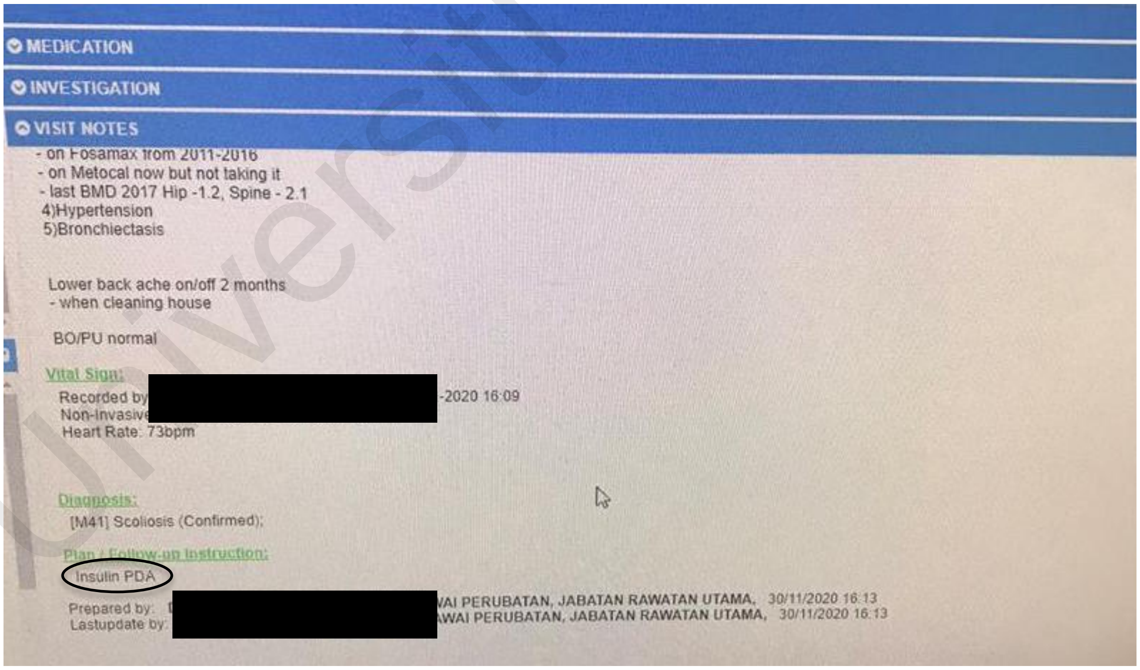
Strategy: Define roles and responsibilities

Doctors and nurses were informed explicitly of their specific implementation tasks during the training workshop. The information was also given to them in printed sheets (Appendix L). The flow of the insulin PDA implementation was explained so that everyone would be aware of their responsibilities.

Apart from doctors and nurses, appointment clerks were also informed that they would need to note in the 'Remark' section of the EMR to indicate that the insulin PDA had been given when they are scheduling appointments for patients based on the doctor's note in the patient's appointment card. As appointment clerks were not present during the insulin PDA training workshops, the researcher met with the clinic's chief clerk to provide a brief explanation on appointment clerks' role in the insulin PDA implementation and seek his help to disseminate the information to all the appointment clerks in the clinic. Their implementation task and the rationale for the action were explained in a printed sheet distributed to each of the appointment clerks by the chief clerk (Appendix L).

Strategy: Systematic documentation

This strategy was carried out by doctors and appointment clerks during the implementation period based on their implementation tasks. Doctors documented the use of the insulin PDA in the EMR (Figure 3.9) and patient's appointment card (Figure 3.10). They also provided a follow-up appointment within 3 months (Figure 13).



- on Fosamax from 2011-2016
- on Metocal now but not taking it
- last BMD 2017 Hip -1.2, Spine - 2.1
4)Hypertension
5)Bronchiectasis

Lower back ache on/off 2 months
- when cleaning house

BO/PU normal

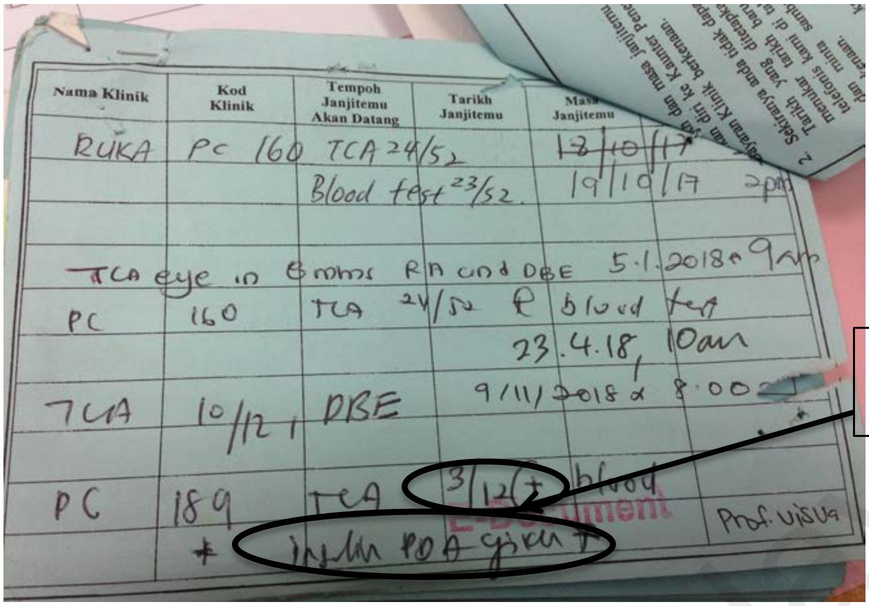
Vital Sign:
Recorded by [redacted] -2020 16:09
Non-invasive
Heart Rate: 73bpm

Diagnosis:
[M41] Scoliosis (Confirmed);

Plan / Follow-up Instruction:
Insulin PDA

Prepared by: [redacted] AI PERUBATAN, JABATAN RAWATAN UTAMA, 30/11/2020 16:13
Lastupdate by: WAI PERUBATAN, JABATAN RAWATAN UTAMA, 30/11/2020 16:13

Figure 3.9: Documentation of the insulin PDA use in the EMR by doctor



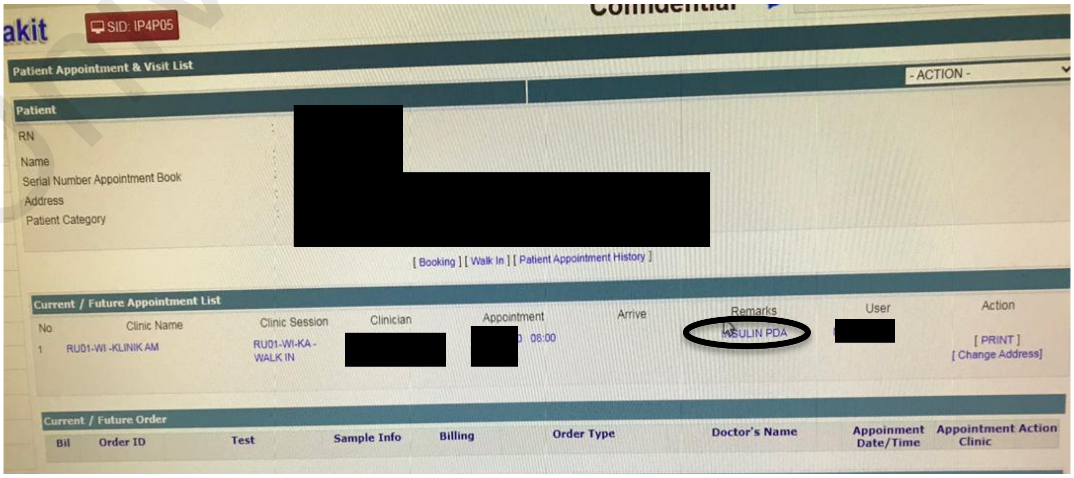
Nama Klinik	Kod Klinik	Tempoh Janjitemu Akan Datang	Tarikh Janjitemu	Masa Janjitemu	
RUKA	PC 160	TCA 24/52		~~13/10/17~~	
		Blood test 23/52.		19/10/17	2pm
TCA eye in	6 mths	RA and DBE		5.1.2018	9am
PC	160	TCA 24/52 ē blood test			
				23.4.18,	10am
TCA	10/12,	DBE	9/11/2018	8.00	
PC	189	TCA	3/12 (+ blood		Prof. Visua
	* insulin PDA given *				

A 3-month appointment was given

A note that the insulin PDA was given to patients

Figure 3.10: Documentation of the insulin PDA use and the duration of patient's next appointment in a patient's appointment card

Appointment clerks made a note in the EMR appointment system that patients had received the insulin PDA based on the note made by their doctors in the patient's appointment card (Figure 3.11).



akit SID: IP4P05

Patient Appointment & Visit List

- ACTION -

Patient

RN :
Name :
Serial Number Appointment Book :
Address :
Patient Category :

[redacted]

[Booking] [Walk In] [Patient Appointment History]

Current / Future Appointment List

No	Clinic Name	Clinic Session	Clinician	Appointment	Arrive	Remarks	User	Action
1	RU01-WI -KLINIK AM	RU01-WI-KA - WALK IN	[redacted]	[redacted] 08:00		INSULIN PDA	[redacted]	[PRINT] [Change Address]

Current / Future Order

Bil	Order ID	Test	Sample Info	Billing	Order Type	Doctor's Name	Appoinment Date/Time	Appointment Action Clinic

Figure 3.11: Documentation by appointment clerk in the EMR appointment system

Strategy: Provide feedback

The strategy ‘Provide feedback’ was conducted as soon as doctors were able to use the insulin PDA in the clinic. The researcher followed evidence-based approaches when designing and delivering feedback to the clinic staff. Feedback has been shown to be more effective when the data collected is based on the individual’s recent performance, when individual change data over time is provided, when data of the recipient is compared to others, when the content of the feedback contains only few important information that requires less effort to process the information, when the feedback is provided by a supervisor or colleagues, provided more than once and, delivered in both verbal and written formats (Colquhoun et al., 2017; Ivers et al., 2012; Ivers et al., 2014).

Doctor’s individual feedback report detailed the number of doctors who adopted the insulin PDA in the clinic, individual adoption rate of the insulin PDA over time, patient’s feedback and doctors’ adherence rate to the specific implementation tasks. However, patient’s feedback was only included in the first month but not in the subsequent monthly feedback reports due to the amount of time needed to transcribe patient interview recordings and analysis of the transcripts. Hence, patients’ feedback could not be generated in time to be included in all the monthly feedback reports and in the unit meetings.

Nurse’s feedback report detailed the cumulative number of insulin PDAs that were given out weekly by doctors. This was to highlight to them the number of insulin PDAs that were given to patients so they would be prompted to replenish the insulin PDAs in the consultation rooms. The researcher delivered these reports in the clinic by approaching individual doctors and nurses. The frequency of feedback report provision was lesser compared to what was planned (six times) as shown in Table 3.17.

Table 3.17: Provision of individual feedback report and unit meeting feedback during the implementation period

	May	Jun	Jul	Aug	Sept	Oct
Doctor and nurse individual feedback report	FR1	-	FR2	FR3	FR4	-
Unit meeting feedback	-	-	UM1	UM2	-	UM3

- : No feedback provided; FR1: Feedback report 1 (Appendix M); FR2: Feedback report 2 (Appendix N); FR3: Feedback report 3 (Appendix O); FR4: Feedback report 4 (Appendix P); UM1: Unit meeting feedback 1 (Appendix Q); UM2: Unit meeting feedback 2 (Appendix R); UM3: Unit meeting feedback 3 (Appendix S)

No feedback report was given in June because the first feedback was given almost at the end of the second month (21 May). The second feedback report was only given on 5 July to enable more data to be collected.

The researcher also prepared PowerPoint slides on the implementation progress as feedback to all the clinic staff during unit meeting. In the unit meetings, the clinic coordinator presented the doctor weekly adoption rate, doctors', nurses', and appointment clerks' adherence to the implementation tasks, patient's feedback, and adoption of the insulin PDA. Doctors, nurses and appointment clerks were also reminded of their implementation tasks. The frequency of feedback provision during unit meetings was also lesser compared to what was planned. There were no unit meetings conducted in May and September during the implementation period. An ad-hoc unit meeting was conducted by the department in June hence feedback could not be provided.

Strategy: Place the insulin PDA booklets in doctors' consultation rooms

During the implementation period, staff nurses replenished the insulin PDAs by placing the booklets in various languages (English, Malay, Indian and Chinese) in all the consultation rooms (Figure 3.12).

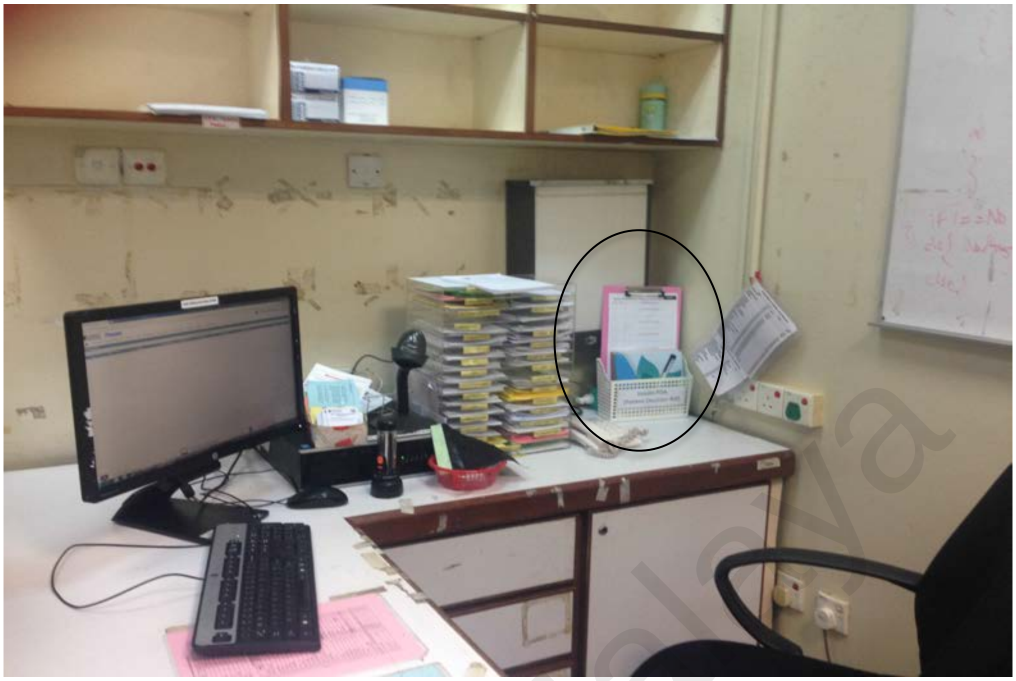


Figure 3.12: Placement of the insulin PDAs in the consultation rooms

3.4 Phase 3: Evaluation of the implementation intervention

This phase describes the methods and findings for the evaluation of the insulin PDA implementation. The aim of the evaluation was to find out if the intervention led to positive implementation outcomes. There were two parts to the evaluation. The first part aimed to capture the quantitative outcomes in terms of the extent the insulin PDA was implemented in routine practice based on ‘Reach’, ‘Adoption’, ‘Implementation’ and ‘Maintenance’ dimensions of the RE-AIM framework. The second part aimed to find the explanations for the RE-AIM quantitative findings. This section will describe the RE-AIM framework, the rationale for using the sequential explanatory mixed-method design, the quantitative component methods, and the qualitative component methods of this study. Then, results which focused on quantitative measures of ‘Reach’, ‘Adoption’, ‘Implementation’ and ‘Maintenance’ dimensions of the RE-AIM framework will be presented followed by explanations for the findings.

3.4.1 Methods

3.4.1.1 The RE-AIM framework

The evaluation of the insulin PDA implementation was guided by the RE-AIM framework. This framework was developed in 1999 in the public health field as a response to the lack of impact of health promotion and disease management innovations in the real world (Glasgow, Vogt, & Boles, 1999). It was intended to improve reporting findings of implementation of public health innovations by getting researchers to be more transparent and consider internal and external validity when conducting efficacy and translational research (Dzewaltowski, Estabrooks, & Glasgow, 2004; Estabrooks & Gyurcsik, 2003). Later, its use was extended to planning and evaluating implementation of health innovations (Glasgow, McKay, Piette, & Reynolds, 2001; King, Glasgow, & Leeman-Castillo, 2010; Klesges, Estabrooks, Dzewaltowski, Bull, & Glasgow, 2005).

RE-AIM is an acronym, which stands for 'Reach', 'Effectiveness', 'Adoption', 'Implementation', and 'Maintenance' (RE-AIM Workgroup, 2020). The definition of each of the RE-AIM dimension is shown in Table 3.18.

Table 3.18: RE-AIM dimension and their definitions

Dimension	**Definition**
Reach	*"The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not."*
Effectiveness	*"The impact of an intervention on important outcomes. This includes potential negative effects, quality of life, and economic outcomes. Also important to understand variability across subgroups (heterogeneity) and why."*
Adoption	*"The absolute number, proportion, and representativeness of settings and staff who are willing to initiate a program or approve a policy, and reasons why or why not. Note settings and staff can each be multi-level: delivery staff nested under supervisors, clinics or schools, health systems, communities, etc."*
Implementation	*"At the setting level, implementation refers to how closely staff members follow the program that the developers provide. Importantly, this includes consistency of delivery as intended, adaptations made to the intervention or implementation strategies, and the time and cost of the program."*
Maintenance	*"At the setting level, the extent to which a program or policy becomes part of the routine organizational practices and policies. Newer guidance includes tailoring the time frame of maintenance to specific issues and programs, and evaluation of adaptations made for sustainment."* *"At the individual level, maintenance refers to the longer-term effects of a program on outcomes after the most recent intervention contact. Time frame of maintenance assessment should be tailored to the program and health issue."*

Reference: (RE-AIM Workgroup, 2020, http://www.re-aim.org/about/frequently-asked-questions/)

RE-AIM was selected as the evaluation framework in this study because it expands the usual traditional clinical or treatment outcome measurements (i.e. efficacy/effectiveness) to implementation outcomes that are critical for broader impact. RE-AIM offers a structured and systematic framework for evaluating the impact of an implementation in a logical sequence of translation of knowledge to practice. RE-AIM can help to measure HCPs' adoption of the insulin PDA ('Adoption' dimension), whether the HCPs implemented the insulin PDA according to the implementation protocol ('Implementation' dimension), whether the insulin PDA reached to the intended audience (e.g.: patients) ('Reach' dimension), if the insulin PDA was effective in meeting its outcomes (‘Effectiveness’ dimension), and if the implementation was sustainable (‘Maintenance’ dimension). The framework can also help to identify which aspect of the implementation needs to be improved should it be ineffective.

Secondly, PDAs were shown to be poorly utilised in routine practice across various populations, settings and health conditions (Elwyn et al., 2013). The RE-AIM framework provides measures for external validity through representativeness of study population and protocol fidelity. Representativeness refers to the similarities and differences in socio-demographic characteristics between individuals who participate in the implementation and those who did not despite being eligible (RE-AIM Workgroup, 2020). The premise of representativeness is that if there is no difference between those who participate and those who did not, this indicates that the intervention can be generalised to real world settings. Protocol fidelity is measured under the ‘Implementation’ dimension of RE-AIM and refers to HCPs’ adherence to the implementation protocol. Information on how the insulin PDA is delivered and if the protocol was adapted allow the intervention to be reproduced. Measuring representativeness and protocol fidelity can help shed light on awareness, accessibility and implementability of the insulin PDA in this current study setting. The findings may help to inform transferability of the planned strategies for PDA implementation to other settings.

Thirdly, the use of the RE-AIM framework would add to the body of literature about understanding PDA implementation utilising this framework (LeBlanc et al., 2012; O’Connor et al., 2019). RE-AIM‘s robust structure that is applicable across various settings, populations, topics and interventions (Harden et al., 2018) can help to yield generalisable and practical knowledge that can help to advance the field of PDA implementation in general.

3.4.1.2 Mixed-methods sequential explanatory study design

The insulin PDA evaluation adopted the mixed-methods design. Mixed-methods is the use both the quantitative and qualitative approach in terms of philosophies, designs, strategies, analytic approaches, and interpretations when conducting a research (Johnson, Onwuegbuzie, & Turner, 2007). The central premise of using this approach is that using both approaches is superior than using either approach alone to draw a better and more complete understanding of research findings (Robins et al., 2008). Quantitative findings can provide a 'breadth' of understanding such as to what extent an innovation was implemented. Qualitative findings can provide the 'depth' of understanding such as the context or reasons for the quantitative findings (Teddlie & Tashakkori, 2003). In implementation research, apart from assessing whether an implementation is successful or not, the context and processes that led to the outcomes are equally important to learn the best strategies or lessons that can improve future implementation efforts.

Implementation is a complex endeavor as it involves various perspectives and multiple types of outcomes that result from multiple types of causal pathways. Hence the mixed methods design provides a practical approach for evaluation by utilising both numbers and words. The use of the mixed-methods design have been increasingly recognised in implementation research, particularly to understand implementation outcomes and processes (Aarons, Fettes, Sommerfeld, & Palinkas, 2012). However, there is currently a lack of PDA implementation studies that utilise the mixed-methods approach when adopting RE-AIM as the evaluation framework.

This study adopted the mixed-method sequential explanatory design (Creswell, 2009). This study design is characterised by conducting quantitative approach followed by qualitative approach (Creswell, 2009). Aligning with the sequential explanatory design, the evaluation of the insulin PDA implementation was divided into two parts. Part 1 began with the quantitative approach to understand the extent the insulin PDA was implemented in terms of ‘Reach’, ‘Adoption’, ‘Implementation’ and ‘Maintenance’ dimensions of the RE-AIM framework. Once the extent of the insulin PDA implementation was understood, the qualitative approach in Part 2 was employed to understand the reasons that contributed to the Part 1 implementation outcomes.

In this study, both quantitative and qualitative approaches were treated as equal components given that they play important roles in answering last two research objectives of this study, which were to evaluate the insulin PDA implementation outcomes, and to understand the reasons that contributed to the outcomes, respectively. Data collection was obtained using multiple methods (questionnaire, observations, IDIs and FGDs), from various stakeholders (healthcare managers, HCPs and patients) and data analysis was performed rigourously in each of the quantitative and qualitative component.

Mixing of the quantitative and qualitative components occurred during the data collection and interpretation phases. Once the quantitative findings were analysed, they were immediately incorporated in the qualitative interview guide to ensure explanations on the quantitative findings are obtained during interviews. During the results interpretation, the researcher focused on complementarity function whereby the quantitative data was used to provide outcomes while the qualitative findings were used to provide in-depth understanding of the quantitative findings (Greene, Caracelli, & Graham, 1989).

3.4.1.3 Quantitative approach

(a) Study design

The quantitative component of the evaluation in this study adopted a prospective pragmatic observational study design. As the name of the study design implies, the evaluation was prospective and observational as the specific RE-AIM outcomes were allowed to emerge without the researcher's interference following intervention implementation. It was pragmatic as the strategies were implemented to accommodate real-world running processes of the clinic with little experimental control and selective biases (Barnish & Turner, 2017). This allows implementation and evaluation of the insulin PDA to occur in a natural environment. Hence the findings obtained represent PDA implementation in routine clinical practice conditions, which is an advantage to generalise the findings to daily practice and may help to inform PDA implementation in other settings (Wensing & Grol, 2013).

(b) Study setting and population

Data collection was conducted at the UMMC primary care clinic where the insulin PDA was implemented. The participants were the various key stakeholders involved in the insulin PDA implementation namely:

1. Healthcare managers from the clinic such as the Head of Department, the clinic coordinator and the nursing officer who oversees the running of work processes in the clinic,
2. Doctors whose tasks were to deliver the insulin PDA to patients during their practice,
3. Staff nurses who were responsible for making sure the insulin PDA was available in the clinic, and

4. People living with type 2 diabetes who were given the insulin PDA.

(c) ***Study instruments***

Three instruments were utilised to collect the quantitative data:

1. Insulin PDA tracking log,
2. Pre- and post-implementation questionnaires, and
3. Fidelity checklist.

Insulin PDA tracking log

A paper-based insulin PDA tracking log (Appendix T) was developed to identify doctors who adopted the PDA and to track how many insulin PDAs were given to patients. Every time doctors gave an insulin PDA, they had to record the date and paste the patient's identification label sticker in the tracking log, which was placed with the insulin PDAs in the consultation rooms.

Pre- and post- implementation questionnaire

In this study, two questionnaires were developed; a pre-implementation questionnaire (Appendix U) administered immediately after the insulin PDA training workshop, and a post-implementation questionnaire (Appendix V) administered at the end of the implementation. These questionnaires were self-developed based on the context of the insulin PDA implementation at the UMMC primary care clinic.

These questionnaires were face and content validated with experts who had experience with the implementation of health innovation at the UMMC primary care clinic (n=5), development of PDAs (n=1), and questionnaire validation (n=2). The experts were asked to assess if the questionnaire was relevant, clear, simple, and comprehensible. They were also asked to provide alternate suggestions if any phrases were unclear.

Then, the questionnaire was pilot tested with 13 HCPs (doctors (n=11) from Phase 1 who had left the clinic and were not involved in the actual implementation of the insulin PDA in Phase 3. The questionnaires were e-mailed to them with instructions that they highlight any items or words that they could not understand and to provide suggestions on items can be better phrased. Changes made were to a few items in the post-implementation questionnaire for better clarity and to provide a better flow in the order of sections.

In the finalised version, the pre-implementation questionnaire consisted of two sections (Appendix U):

1. Section A: Socio-demography and working experience (9 items)
2. Section B: Reason for attending the insulin PDA training workshop (1 item)

The post-implementation questionnaire consisted of four sections (Appendix V):

1. Section A: Socio-demography and working experience (9 items)
2. Section B: Insulin PDA use (3 items)
3. Section C: Strategies to implementing the insulin PDA (18 items)
4. Section D: Willingness to use the insulin PDA (2 items)

In this study, the pre- and post-implementation questionnaires were only administered to doctors as a majority of the questionnaire items were related to doctors' adoption of the insulin PDA during consultation.

Fidelity checklist

A fidelity checklist (Appendix W) was developed to reflect the essential steps HCPs should adhere to when implementing the insulin PDA:

1. Did the doctor make a note in patient's EMR to indicate PDA has been given?
2. Did the doctor provide an appointment (≤ 3 months) to the patient for PDA follow-up?
3. Did the doctor make a note in patient's appointment book that PDA was given?
4. Did the doctor follow-up with patient on the PDA use?
5. Did the clerk enter notes in the EMR 'Remark' section as indicated by doctor in the patient's appointment book?

These items were based on the HCP's implementation tasks and were on a present/absent scale.

(d) Evaluation dimensions, outcome measures and data collection process

The quantitative outcome measures were the specific RE-AIM dimensions namely 'Reach', 'Adoption', 'Implementation', 'Maintenance' as well as the perceived effectiveness of strategies implemented, which would help to explain the reasons for the RE-AIM outcomes.

i Reach

In RE-AIM, ‘Reach’ is defined as *“The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not.”* (RE-AIM Workgroup, 2020). ‘Reach’ seeks to understand whether the innovation, specifically the insulin PDA in this current study reached its intended users (Glasgow et al., 2019). In this study, ‘Reach’ was addressed at the HCP and patient level and was defined as the number and percentage of HCPs (doctors and nurses) and the number of patients who were willing to participate in the insulin PDA implementation. At HCP level, ‘Reach’ was measured by assessing doctors’ and nurses’ participation rate in the insulin PDA training workshops. To understand participation reasons, a quantitative measure was taken of doctors’ reasons for attending the training workshop.

At patient level, ‘Reach’ was measured as the number of patients who accepted the insulin PDA. The proportion and representativeness of people living with type 2 diabetes who received the insulin PDA could not be measured as information on the population of people living with type 2 diabetes in the clinic who would be eligible to use the insulin PDA (denominator) was unavailable. The EMR system in the clinic was not sophisticated to produce the information while a manual count of patients who attend the clinic during the evaluation period was also not possible as it would involve increased manpower and time.

'Reach' outcome measures

The specific outcome measures for 'Reach' were:

1. Number of doctors who attended the insulin PDA training workshop / Number of doctors who were invited to the insulin PDA training workshop,
2. Number of nurses who attended the insulin PDA training workshop / Number of nurses who were invited to the insulin PDA training workshop,
3. Doctor's reasons for attending the insulin PDA training workshop, and
4. Number of patients who received the insulin PDA.

Data collection process for 'Reach'

The number of doctors and nurses who attended the insulin PDA training workshop was identified using the attendance sheet. Data on the number of doctors and nurses who were invited to attend the insulin PDA training workshop was obtained using research administrative data.

The pre-implementation questionnaire was administered immediately after the insulin PDA training workshop and assessed the doctors' reasons for attending. Before administering the questionnaire, doctors were informed that various data would be collected to evaluate the insulin PDA implementation during the implementation period, which would last for six months. They were also informed that they would be receiving monthly feedback on the progress of the insulin PDA implementation and a post-implementation questionnaire would be administered at the end of the implementation period. The HCPs were told the participation risks, that their participation was voluntary, and they may withdraw from the study anytime (Appendix X). HCPs gave their written informed consent using a consent form (Appendix Y). Those who agreed to participate were then asked to complete the pre-implementation questionnaire.

The insulin PDA tracking log tracked the number of patients who received the insulin PDA. The researcher checked the tracking logs weekly to note how many insulin PDAs were given to patients and how many doctors delivered PDAs to patients.

ii Adoption

In RE-AIM, *'Adoption'* is defined as *"The absolute number, proportion, and representativeness of settings and staff who are willing to initiate a program or approve a policy, and reasons why or why not. Note settings and staff can each be multi-level: delivery staff nested under supervisors, clinics or schools, health systems, communities, etc."* (RE-AIM Workgroup, 2020). As this study is a pilot implementation of the insulin PDA, it only focused on one setting. Hence, 'Adoption' in this study was only addressed at an individual level and was defined as the number, proportion, and representativeness of doctors who adopted the insulin PDA. Adoption was also measured at the patient level, which was defined as the number of patients who read the insulin PDA.

'Adoption' outcome measures

The outcome measures for 'Adoption' were:

1. Number of doctors who adopted the insulin PDA / Number of doctors who attended the training workshop,
2. Weekly insulin PDA adoption rates (The total number of PDA adopted by week),

3. Socio-demographic information of doctors who adopted and those who did not adopt the insulin PDA (Representativeness), and
4. Number of patients who read the insulin PDA / Number of patients who received the insulin PDA and received a follow-up.

Data collection process for 'Adoption'

The insulin PDA tracking log identified the number of doctors who adopted the insulin PDA whereas research administrative data identified the number of doctors who were invited to attend the insulin PDA training workshop.

In terms of doctors' socio-demographic information, this data was obtained from the pre- and post-implementation questionnaires as well as the post-implementation qualitative interview socio-demographic forms.

Patient use of the insulin PDA was assessed based on self-reported information. The researcher approached patients who returned to the clinic after their consultation with the doctor. The researcher explained to the patients that she would like their feedback on their experiences with the insulin PDA and invited them to participate in an IDI. Information such as the study purpose, procedures, potential risks, and voluntary nature of participation was explained to patients (Appendix X) and then informed consent was obtained (Appendix Y). Next, patients were asked if they read the PDA at home and if the doctor followed-up with them on the insulin PDA during their consultation. Subsequently, the researcher conducted the IDIs. For patients who were unable to participate in the IDI, only verbal consent was obtained to get the information if they have read the PDA.

iii Implementation

In RE-AIM, ‘Implementation’ is defined as *“At the setting level, implementation refers to how closely staff members follow the program that the developers provide. Importantly, this includes consistency of delivery as intended, adaptations made to the intervention or implementation strategies, and the time and cost of the program.”* (RE-AIM Workgroup, 2020). Generally, it helps to shed light if the innovation (i.e. the insulin PDA) was implemented properly (Glasgow et al., 2019). In this study, ‘Implementation’ was defined as HCPs’ fidelity to the various implementation tasks as set in the insulin PDA implementation protocol. Doctors’, appointment clerks’, and staff nurses’ adherence to their implementation tasks were assessed. Cost of the intervention in terms of time was measured by assessing the perceived amount of time taken by doctor to deliver the PDA to patients during their consultation and whether they thought that the insulin PDA use increases, decreases or had no effect on their consultation time. Monetary cost was not measured in this study given that the insulin PDA implementation was embedded within routine clinical delivery, thus, the running costs for the insulin PDA implementation was expected to be minimal.

‘Implementation’ outcome measures

The outcome measures for ‘Implementation’ were:

1. Number of times doctors made a note in patient’s clinical record in the EMR to indicate the insulin PDA has been given to patient / Total number of insulin PDAs given to patients,

2. Number of times doctors make a note that the insulin PDA is given in patient's appointment book / Number of patients who were given the insulin PDA and received a follow-up,
3. Number of times doctor provided ≤ 3 months appointment to patients for the insulin PDA follow-up / Total number of the insulin PDAs given to patients,
4. Number of times doctors followed up with patients on their insulin PDA use / Number of times the given insulin PDAs were noted in the EMR,
5. Number of times appointment clerks made note in the EMR 'Remark' section that patient received the insulin PDA / Number of times doctors made a note in patients' appointment books that the insulin PDA was given,
6. Number of the insulin PDA available in the consultation room,
7. Doctors' perceived amount of time taken to deliver the insulin PDA to patients during consultation, and
8. Doctors' perception of whether the insulin PDA use increases, decreases or had no impact on consultation time

Data collection process for 'Implementation'

The fidelity checklist was used to assess whether HCPs adhere to the essential elements of the implementation protocol. This was done by reviewing patient's medical notes in the EMR, patient's appointment book, and feedback from patients on doctor's behaviour when delivering the insulin PDA to them during consultation.

Assessment on whether doctors made a note that the insulin PDA was given in patient's appointment book was conducted by checking patients' appointment card when they returned to the clinic for their follow-up. A total of 141 patients returned to the clinic for follow-ups during the implementation period. Once these patients finished their consultation, they were approached and asked if the doctor followed-up with them on the insulin PDA during their consultation. For patients who forgot to bring their appointment card to the clinic and those who returned to the clinic consultation after the implementation, the researcher reviewed the medical notes in the EMR to check if insulin PDA discussions were noted to obtain a comprehensive findings on the insulin PDA follow-up. Insulin PDA follow-up was considered to have occurred when the texts 'insulin PDA' was noted.

The EMR was reviewed to assess if appointment clerks made a note that patients had been given the insulin PDA based on the notes made by doctors in the patients' appointment book. This occurred when patients returned to the clinic for their subsequent appointment.

The perceived amount of time taken by doctors to deliver the PDA to patients during consultation and the perception of whether the insulin PDA use increased, decreased, or did not change consultation time was assessed based on self-reported information in the post-implementation questionnaire. The questionnaire was administered to doctors who experienced all the strategies implemented (n=40) after the implementation period from November to December 2018.

A monthly count of the number of the insulin PDA in the consultation rooms occurred between June to October to assess if staff nurses replenished the insulin PDA booklets.

iv Maintenance

In RE-AIM, 'Maintenance' is addressed at two levels; setting and individual. At setting level, 'Maintenance' is defined as "*The extent to which a program or policy becomes institutionalized or part of the routine organisational practices and policies"* (RE-AIM Workgroup, 2020). At individual level, it is defined as *"The long-term effects of a program on outcomes after a program is completed. The specific time frame for assessment of maintenance or sustainment varies across projects"* (RE-AIM Workgroup, 2020). As this current study was conducted as a doctoral study, the measure of 'Maintenance' was not possible as more time was required. Hence, 'Maintenance' was addressed as an intention to maintain the implementation and this has been recommended by the developers of the framework workgroup (RE-AIM Workgroup, 2020).

'Maintenance' outcome measures

The outcome measures for 'Maintenance' were:

1. Number of doctors who were willing to continue to implement the insulin PDA / Number of doctors who were practising in the clinic, and
2. Number of doctors who were willing to recommend the insulin PDA use to their colleagues / Number of doctors who were practising in the clinic.

Data collection process for 'Maintenance'

Data on doctors' willingness to implement and to recommend the insulin PDA use to their colleagues were collected using the post-implementation questionnaire.

v Perceived effectiveness of strategies

Apart from the RE-AIM quantitative outcomes. Quantitative measures of perceived effectiveness of the strategies implemented were also assessed to explain the quantitative RE-AIM outcomes achieved in this study.

Data collection approach for 'Perceived effectiveness of strategies'

Perceived effectiveness of the strategies was assessed using the 18 statements in the post-implementation questionnaire (Section D) which were on a 5-point Likert scale from 1: strong disagree, 2: disagree, 3: neutral, 4: agree and 5: strongly agree.

(e) ***Data analysis***

Quantitative data from the insulin PDA tracking log, pre- and post-implementation questionnaires, and research and clinic administrative data were analysed using SPSS for Windows version 19 (IBM, 2009). Descriptive statistics were performed to obtain frequencies, proportions and means for selected variables.

For the item 'Willingness to implement the insulin PDA' in the post-implementation questionnaire, which was on a 5-point Likert scale (1: Very unwilling, 2: Unwilling, 3: Not sure, 4: Willing, 5: Very willing), 'Very unwilling' and 'Unwilling' were grouped together to form 'Unwilling' while 'Very willing' and 'Willing' were grouped together to form 'Willing' for data analysis.

Perceived effectiveness of strategies was measured by tabulating the proportion of doctors who rated their agreement with the 18 statements on a five point Likert scale from 1: Strongly disagree, 2: Disagree, 3: Neutral, 4: Agree and 5: Strongly agree. For data analysis, ‘Strongly disagree’ and ‘Disagree’ were grouped together to form ‘Disagree’ while ‘Strongly agree’ and ‘Agree’ were grouped together to form ‘Agree’.

(f) Ethical considerations

The implementation of the insulin PDA employed practice-based research hence this posed unique ethical problems due to its methodological features. The insulin PDA was implemented at the UMMC primary care clinic and all the HCPs and clinic staff were in a way ‘subjected’ to participate in the implementation. To address this issue, the HCPs were informed that their participation was voluntary, their identity would be kept confidential and their involvement in the research would not affect their study and work. They could choose not to participate simply by not using the insulin PDA or not providing any of the evaluation data that the researcher request. They could also choose to withdraw their participation at any time. The HCPs received an explanation on this and additional information in the study information sheet during the insulin PDA training workshop. Individual informed consent was obtained for data collection.

Some patients might not have received the insulin PDA if a doctor had chosen not to participate or could not adopt the insulin PDA during their practice. Doctors may have a potential risk of being accused of providing sub-standard care to patients who did not receive the insulin PDA. To overcome this issue, the doctors were informed to continue with their usual practice of discussing insulin decision-making with patients if they could not discuss the insulin PDA. While this is still not fair as the patients have already been disadvantaged at not receiving the insulin PDA, however, they were not an additional risk and were still receiving the standard care. Doctors were also trained to screen patients for eligibility to receive the insulin PDA so no patients would be missed out. Patient-eligible criteria to receive the insulin PDA were detailed in the HCP implementation task sheet (Appendix L), which was provided during the insulin PDA training workshop.

Some patients might have been emotionally affected when they were asked to use the insulin PDA to consider insulin treatment as a choice and to make a treatment decision. In fact, this issue is related to the two prioritised barriers to insulin PDA implementation that emerged in this study: ‘Patients feel that the insulin PDA is to persuade them to start insulin’ and ‘Patients rely on doctor to make health decisions’. The strategy that had been selected and tailored to address these two barriers were ‘Framing/reframing’ and ‘Conduct training workshop’ whereby the doctors were trained to inform patients that the insulin PDA is not to persuade them to start insulin but to help them to make informed decisions. HCPs were also informed during the PDA training workshop that patients should be given the choice on whether they want to use the insulin PDA and should not be forced.

During patient follow-ups at the clinic to find out if they read the insulin PDA, did the doctor followed-up with them on the insulin PDA use, and if the doctor made a note in their appointment book that the insulin PDA was given to them, only verbal informed consent was obtained from the patients rather than written consent because some were rushing to leave the clinic after doctor consultations. Nevertheless, the study information sheet was provided to them. However, for patients who agreed to participate in the IDIs, written informed consent was obtained.

3.4.1.4 Qualitative approach

(a) Study design

The qualitative component of the evaluation in this study aimed to explore what contributed to the quantitative outcomes of ‘Reach’, ‘Adoption’, ‘Implementation’ and ‘Maintenance’ of the insulin PDA implementation. The study design that was adopted was similar to phase 1 which was interpretive description (Thorne, Kirkham, & MacDonald-Emes, 1997). This design was selected for the same reason it was utilised in Phase 1, which was generation of practical findings that can help to inform clinical practice (Thorne, Kirkham, & MacDonald-Emes, 1997). This is relevant for this study as findings or explanations for the quantitative RE-AIM outcomes can help to inform future implementation improvement efforts as well as implementation of other PDAs or health innovations. As interpretive description also accounts for individual cases (Thorne, Kirkham & O'Flynn-Magee, 2004), this is important for explaining peculiar findings that might arise from the quantitative findings in this study, especially when such inevitably occur in real world implementations of health innovations.

(b) Study setting and population

The participants recruited were healthcare managers, HCPs (doctors and nurses) and patients who were involved in the insulin PDA implementation. HCPs and patients who did not adopt the insulin PDA were also recruited to provide insights into their decision. All the interviews were conducted at the UMMC primary care clinic.

(c) Study instrument

An interview guide was developed based on the RE-AIM dimensions. To align with the mixed-method sequential explanatory design, findings from the quantitative approach were incorporated in the healthcare managers' and HCPs' interview guide to seek explanations on the quantitative findings as well as barriers and facilitators to 'Reach', 'Adoption', 'Implementation' and 'Maintenance'. Additionally, participants' perceived effectiveness of the strategies implemented was explored to see if they contributed to the success or failure of the insulin PDA implementation. The researcher discussed with her supervisors about the topics or questions that were missed in the interview guide, before refining it and finalising it through a consensus. The interview guide was adapted according to the roles and involvement of various stakeholders (clinic coordinator, nursing officer, doctor, and nurse, patient) in the insulin PDA implementation.

(d) ***Data collection process***

i Data collection process with patients

The qualitative data collection commenced in May 2018 as soon as the first patient who received the insulin PDA returned to the clinic for a follow-up. IDIs were carried out instead of FGDs as each patient were present in the clinic at different dates and timing for their follow-up appointments. The interviews were conducted with patients who agreed to participate in IDIs after checking if they had read the insulin PDA.

Prior to the IDI, patients were given the socio-demographic information form and provided their written informed consent. The researcher used questions in the post-implementation interview guide (Appendix Z) to facilitate the interviews. Patient interviews lasted an average 20 minutes.

ii Data collection process with healthcare managers and HCPs

Qualitative interviews with HCPs were carried out from November 2018 to March 2019, after completing the quantitative data analysis. Invitations were sent out to healthcare managers and HCPs who were involved. The researcher also sent invitations to those who did not participate in the insulin PDA implementation to understand their reasons. The invitation included a digital copy of the study information sheet, which detailed the interview purpose and the procedures involved. FGDs were conducted separately for doctors and nurses given that their implementation tasks were different. IDIs were conducted with clinic coordinators.

During the interviews, healthcare managers and HCPs were informed again that the purpose was to gain insight on their experiences with the insulin PDA implementation. Findings from the quantitative study were shared with the participants to gain feedback on the results (Appendix Z). They were also reassured that the interviews were not meant to criticise their actions related to the insulin PDA implementation. To align with the interpretive description methods of inquiry (Thorne, Kirkham, & MacDonald-Emes, 1997), broad questions were asked pertaining to the insulin PDA implementation such as ‘What are their thoughts about the insulin PDA implementation in general?’. Then, they were asked to explain the minutiae of the quantitative findings, such as reasons for their adherence or the lack of for specific implementation tasks. The researcher also framed her questions by asking “Why” and “How” in order to achieve fuller and meaningful feedback from the participants.

For FGDs, a note-taker was present to write the interview contents and take notes on important information that cannot be captured by the audio-recorder, such as participants’ non-verbal gestures. This information helped the researcher to contextualise the narratives during data analysis. The HCP interviews lasted an average 50-90 minutes.

Interviews with HCPs and patients ceased when data saturation was achieved, i.e. there were no more new findings that emerged from the interviews (Lincoln & Guba, 1985). Once the interviews ended, all the participants were compensated monetarily (HCP: RM30 = USD8; Patient: RM20 = USD 5) as a token of appreciation for time and effort spent. The researcher wrote down reflections to capture the essence of the interviews once they were over, which helped inform the data analysis.

(e) ***Data analysis***

The qualitative data analysis was similar to the process undertaken in Phase 1. Initially, the researcher immersed herself in the data by reading each transcript thoroughly to get an overview of the broad issues as this helped to stimulate a more coherent analysis. Subsequently, thematic analysis was applied (Braun & Clarke, 2008). Data analysis was inductive whereby findings were generated based on codes and themes grounded in the data. As the analysis progressed, formed codes were connected and this was when interpretation of the data occurred. Two separate coding frameworks were developed to analyse the data for healthcare managers and HCPs, and patients.

Next, the researcher applied the coding frameworks to the remaining healthcare managers and HCPs, and patient transcripts respectively. Any new codes or categories that emerged were added to the coding framework after discussion with supervisors. Constant comparative method was employed throughout the analysis (Thorne, 2000). Emerging categories and themes from the various participants' data set were reviewed against one another to find patterns of commonalities and differences. Attention was also given to individual cases. For example, while a majority of the doctors viewed the strategy ‘Mandate change’ negatively, one doctor had provided a different perspective and this helped to provide insights on how the strategy could work. Finally, all the themes that emerged were matched based on their relevance to each of the RE-AIM dimensions and were presented in a coherent narrative.

(f) ***Reflexivity***

It is important for me to clarify my stance in this qualitative phase, which aimed to seek explanations for the quantitative implementation outcomes obtained in Part 1. The intervention was tailored to the barriers relevant to the clinic and strategies were selected based on evidence and consensus from the various clinic stakeholders. Therefore, the intervention should be effective in leading to a high degree of ‘Reach’, ‘Adoption’, ‘Implementation’ and ‘Maintenance’ of the insulin PDA implementation. As the researcher of this study who was involved in the entire process of the intervention development, I might have desired for more positive feedback from the participants in regards to implementation outcomes. I was aware of this bias and tried my best to remain neutral to participant responses. When participants noted negative feedback about certain points in the intervention, for example, the step on making notes in the patient’s appointment card which was felt to be unnecessary, I tried probing them why they felt that way.

As I am not a HCP with experience working in a clinic setting, particularly at the UMMC primary care clinic, I might have been desensitized to the HCPs’ working culture, environment and needs. Hence, I expected the HCPs to adhere to the implementation protocol that was developed. I am aware of this bias given my position as an outsider researcher and not a member of the study population (Dwyer & Buckle, 2009). I tried to offset this bias by ensuring I set aside my own prejudices when interviewing the participants. I also tried to place participant's narratives into context based on the clinic context I observed.

As I am not a diabetes patient, I could not truly understand the difficulty of making a diabetes treatment decision. I had expected that many people living with type 2 diabetes would be willing to accept and read the insulin PDA given that it is a free tool they could use to make informed decisions. However, I was surprised to hear during the interviews that some patients did not read the insulin PDA due to various reasons. I acknowledge that I am not a type 2 diabetes patient but I tried my best to understand their reasons for not using the insulin PDA.

(g) Establishing study rigour

Ways to establish the study rigour in this phase was similar to the phase 1 qualitative study whereby credibility, confirmability, and transferability were taken into consideration.

Credibility was achieved by ensuring honest feedback was obtained from the participants. During the interviews, the researcher made it clear to participants that the purpose was to learn from their experiences implementing the insulin PDA rather than to find fault in them. The participants were informed them that their feedback was to improve how the clinic can effectively implement PDAs or even other health innovations in the future. They were welcome to provide any feedback, even if it was negative.

To offset personal biases during data analysis, interview reflections were written as soon as the interviews ended to note the important points discussed by the participants and the researcher's personal thoughts about the discussion. 'Bracketing' was practised to set aside personal beliefs, assumptions, and pre-conceived notions when analysing the reasons for the success or failure of the insulin PDA implementation based on the participants' narratives (Tufford & Newman, 2010). The researcher referred to the interview reflection notes to avoid personal biases and cross-checked study findings to ensure the findings interpretations were accurately described.

Discussions were conducted with supervisors to confirm the data. The researcher was challenged on some of the data interpretations by her supervisors and had go back to the data sources to look for their true meanings. This ensured that the findings were clearly derived from the data. Findings were then confirmed when a consensus was reached.

Transferability of the findings was achieved by provision of a rich description of the data collection process and the findings. Information on participant recruitment, study instruments, data collection processes, and thick descriptions supplemented by interview quotes enabled the findings of this study to be meaningful and applicable to others.

(h) Ethical considerations

Ethical standards were adhered to when carrying out the qualitative data collection. This included:

1. Giving participants' the autonomy to decide if they wanted to participate and the rights to withdraw from the study at any time.
2. Obtaining informed consent from the participants.
3. Ensuring participants' confidentiality by removing identifiers in transcripts and keeping the audio-recordings in a password-protected computer.

3.4.2 Results

3.4.2.1 Background of participants

(a) Background of participants (Quantitative approach)

All the doctors (n=48) who attended the insulin PDA workshops completed the pre-implementation questionnaire. The mean age of the doctors was 33.5 (± SD 3.1) years old, ranging from 28 to 50 years old. There were more female doctors (72.9%) and almost equal proportion of those were of Malay (41.7%) and Chinese (43.8%) ethnicity. The mean duration of experience practising in the clinic was 1.86 (± SD 1.44) years old (range: 3 months-7 years) and the average number of patients counseled on insulin initiation was 9.9 per month (range: 1-30 patients). Table 3.19 presents the socio-demographic information of doctors who completed the pre-implementation questionnaire.

Table 3.19: Socio demographic information of doctors who completed the pre-implementation questionnaire

Characteristic (n=48)	**Mean ± SD (Range)**
Age (years)	33.5 ± 3.1 (28-50)
Years of practice since graduation (years)	1.86 ± 1.44 (3 month – 7)
No of patient counseled on insulin initiation for the past one month	9.9 ± 7.54 (1-30)
	n (%)
Sex	
Male	13 (27.1)
Female	35 (72.9)
Ethnicity	
Malay	20 (41.7)
Chinese	21 (43.8)
Indian	4 (8.3)
Others	3 (6.3)
Current year of study (n=47)	
Year 1	9 (19.1)
Year 2	14 (29.8)
Year 3	16 (34.0)
Year 4	8 (17.0)

SD: standard deviation

(b) Background of participants (Qualitative approach)

i Patients

A total of 97 patients were approached to participate in IDI after their follow-up consultation with doctors and 62 agreed to participate. The response rate was 63.9%. Those who declined to participate gave reasons such as time constraints (n=20), not interested (n=5), did not want to be audio-recorded (n=5), and not feeling well (n=5).

The mean age of the patients was 58.0 (± SD 12.1) (range: 26-83 years old). There were slightly more female (51.6%) compared to male (48.4%) patients. Most of the participants ethnicity was Malay (43.5%) followed by Indian (30.6%), Chinese (21.0%), and Others (4.8%). Slightly more than half of the participants attained secondary (51.6%) education followed by tertiary (24.2%), diploma (14.5%), and primary education (9.7%). Table 3.20 shows the background information of the qualitative participants.

ii HCPs

Out of 61 HCPs in the clinic who were invited to participate in the qualitative interviews, 43 agreed. The response rate was 70.5%. Eighteen HCPs did not participate due to time constraints (n= 14) and some were practising out of the clinic (n=4). A total of six IDIs and six FGDs were conducted with three healthcare managers, 35 doctors, and five staff nurses. The mean age of the HCPs was 34.1 (± SD 4.9) (range: 28-50) years old. There were more females (74.4%) than males. Slightly more than half of them were of Malay ethnicity (53.5%) followed by Chinese (32.6%), Indian (9.3%) and Others (4.7%). All of the doctors interviewed adopted the insulin PDA (94.3%) except two (Table 3.20).

Table 3.20: Participants' background information (Qualitative)

	HCP (n=43)	Patient (n=62)
Age (years) Mean ± SD (Range)	34.1 ± 4.9 (28-50)	58.0 ± 12.1 (26-83)
Years of practice since graduation Mean ± SD (Range)	2.6 ± 3.7 (3 months – 20 years)	n.a
No of patient counseled on insulin initiation for the past one month Mean ± SD (Range)	10.5 ± 7.8 (1-30)	n.a
Duration of diabetes (years) Mean ± SD (Range)	n.a	12.4 ± 8.7 (1-35)
Duration of seeking treatment at the study clinic (years) Mean ± SD (Range)	n.a	8.1 ± 6.7 (6 months – 30)
	n (%)	**n (%)**
Sex		
Male	11 (25.6)	30 (48.4)
Female	32 (74.4)	32 (51.6)
Ethnicity		
Malay	23 (53.5)	27 (43.5)
Chinese	14 (32.6)	13 (21.0)
Indian	4 (9.3)	19 (30.6)
Others	2 (4.7)	3 (4.8)
Highest education level		
Primary	0	6 (9.7)
Secondary	0	32 (51.6)
Diploma	5 (11.6)	9 (14.5)
Tertiary	38 (88.4)	15 (24.2)
Position		
Healthcare manager	3 (7.0)	n.a
Doctor	35 (81.4)	n.a
Staff nurse	5 (11.6)	n.a
Occupation		
Manager / professional	n.a	12 (19.4)
Skilled worker	n.a	7 (11.3)
Semi-skilled worker	n.a	19 (30.6)
Low-skilled worker	n.a	2 (3.2)
Housewife / Not working	n.a	22 (35.5)
Insulin PDA use during implementation period (Doctors only) (n=35)		
Yes	41 (95.3)	n.a
No	2 (4.7)	n.a

SD: standard deviation; n.a: not applicable

3.4.2.2 The insulin PDA implementation outcomes (Quantitative)

(a) Reach (Doctors and nurses)

Overall, 88.9% (n=48/54) of doctors and 55% (n=11/20) of nurses attended the insulin PDA training workshops.

(b) Reach (Patients)

During the implementation period, a total of 390 insulin PDAs reached 387 patients. Three patients received the insulin PDA again when they returned for their follow-up visit. Based on doctor's notes in the EMR, two of the patients had misplaced the insulin PDAs given previously while another claimed that he did not receive one in his last visit.

(c) Adoption (Doctors)

Overall, the insulin PDA implementation saw that 83.3% (n=45/54) of doctors in the clinic adopted the insulin PDA. The flow chart on the number of doctors participating in the insulin PDA implementation is illustrated in Figure 3.13.

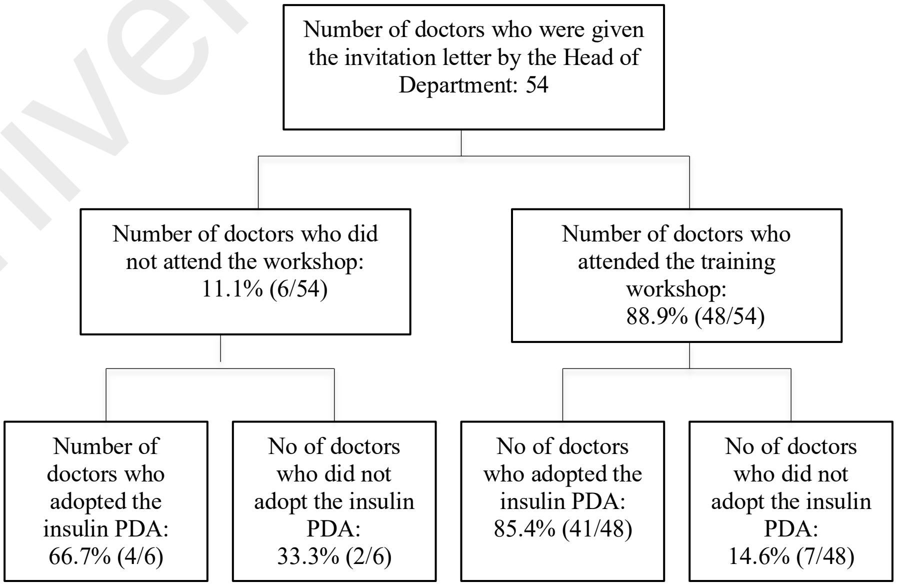


Figure 3.13: Number of doctors participating in the insulin PDA implementation

i Weekly insulin PDA adoption throughout the implementation period

The weekly distribution numbers for the insulin PDA was observed to assess the pattern of adoption throughout the implementation period. There was a high adoption rate in the first week following the first training workshop (16-20 April) then decreased in the following weeks. There was a lower number of PDAs adopted during these dates: 23 April- 1 May; 8-19 October; 11-22 June; and 10-14 September (Figure 3.14).

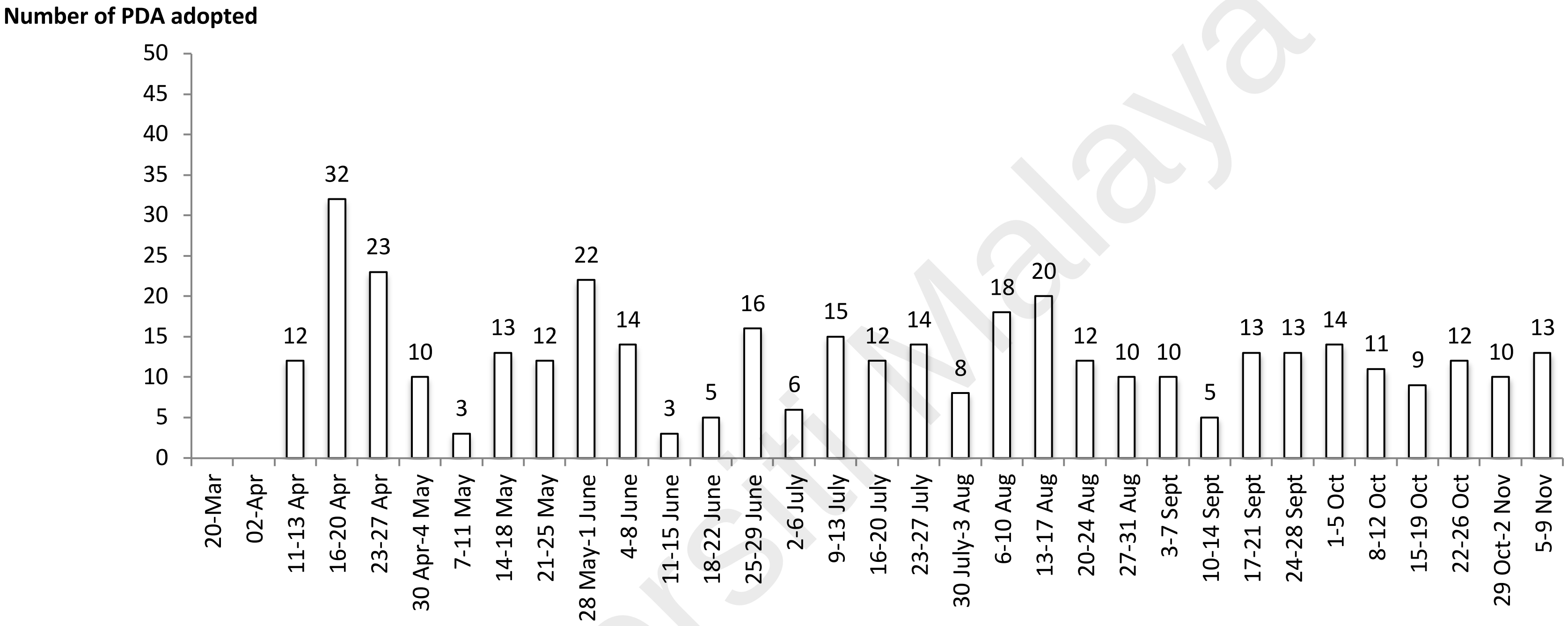


Figure 3.14: Weekly insulin PDA adoption throughout the implementation period

ii *Representativeness (Comparison of socio-demographic characteristics between those who adopted and did not adopt the insulin PDA)*

The socio-demographic characteristics were not too different between doctors who did not adopt the insulin PDA and those who did, and this appeared to follow the distribution of the doctor population in this study (Table 3.21).

Table 3.21: Socio-demographic information of doctors who adopt and did not adopt the insulin PDA

	Adopted PDA (n=45)	**Did not adopt PDA (n=9)**
Age (mean ± SD)	33.4 ± 3.2	33.1 ± 1.4
25-29	1	0
30-34	37	7
35-39	6	2
More than 40	1	0
Sex		
Male	13	3
Female	32	6
Ethnicity (n=43)		
Malay	20	3
Chinese	16	5
Indian	4	1
Others	4	0
Year of study		
Year 1	6	2
Year 2	8	2
Year 3	19	1
Year 4	9	0
Completed study	1	4
Years working in clinic (years)	1.8 ± 1.5	1.9 ± 0.8
≤ 1	21	3
≥ 1	24	6

SD: Standard deviation

(d) Adoption (Patient)

Out of the 143 patients who received a follow-up, 65.7% (n=94/143) reported that they read the insulin PDA.

(e) Implementation

i Doctors' adherence to their implementation tasks

The findings showed that the task doctors adhered to the most was ensuring that notes were made in patients' records in the EMR to indicate they had given patients the insulin PDA. The task that was least adhered to was noting that they had given patients the insulin PDA in the patient's appointment book. Only one-third of the patients who were given a PDA received a follow-up. Doctors' adherence to the specific implementation tasks is shown in Table 3.22.

Table 3.22: Doctors' and appointment clerks' adherence to their specific implementation tasks

Implementation task	% (n)
Number of times doctors made a note in patients' clinical records in the EMR to indicate the insulin PDA was given/ total number of PDAs given to patients	84.9% (331/390)
Number of times doctors made a note in patient's appointment book that the insulin PDA was given / number of patients who were given the PDA and received followed-up	19.2% (27/143*)
Number of times doctor provide ≤ 3 months appointment to patients for the insulin PDA follow-up / total number of insulin PDAs given to patients	66.7% (260/390)
Number of times doctor followed up with patients on the insulin PDA use / number of times insulin PDA were noted in the EMR	34.1% (113/331**)

*Denominator was based on 143 patients who received a follow-up during the implementation period; ** Denominator was based on 331 notes that were indicated in the EMR that the insulin PDA was given to the patient

ii Appointment clerks' adherence to their implement task

Appointment clerks' adherence to their implement task was low. Only 25.9% (n=7/27) of the notes in patients' appointment books were indicated in the EMR 'Remark' section that patient received the insulin PDA.

iii Staff nurses' adherence to their implementation task

Staff nurses' adherence to their implementation task, which was replenishing the insulin PDA booklets in the consultation rooms, was assessed by counting the number of the insulin PDA booklets in the consultation rooms at the end of the month. The count was conducted from the third (June) to the seventh (October) month of the implementation. It was found that there was absence of English and Malay versions of the insulin PDA in some of the consultation rooms (Figure 3.15). On the other hand, there were also many PDAs available in some of the consultation rooms compared to the initial five copies for each language that were provided at the start of the implementation.

Month	June					July					August					September					October			
Room	**E**	**M**	**C**	**T**		**E**	**M**	**C**	**T**		**E**	**M**	**C**	**T**		**E**	**M**	**C**	**T**		**E**	**M**	**C**	**T**
Room 01	4	4	4	4		4	4	4	3		5	6	3	4		4	5	3	3		4	5	3	3
Room 02	6	6	3	4		6	0	3	4		5	7	5	4		4	6	4	4		3	4	4	4
Room 03	4	4	4	3		3	3	4	3		6	5	5	4		3	5	5	4		3	5	5	4
Room 04	4	4	5	2		4	6	5	2		6	6	5	4		6	6	3	2		6	6	3	2
Room 05	3	3	4	3		1	2	4	3		5	5	4	3		5	5	5	6		4	5	5	6
Room 06	5	5	5	5		5	3	5	5		1	7	5	5		9	9	4	6		9	8	4	6
Room 07	3	3	3	2		3	2	3	2		5	4	3	2		7	6	5	4		6	4	5	4
Room 08	3	3	5	4		1	0	5	3		4	4	5	3		4	6	7	3		4	6	7	3
Room 09	1	1	4	2		1	6	4	2		6	6	4	6		3	6	3	6		3	6	2	6
Room 10	5	5	4	5		5	5	4	5		5	6	4	5		4	3	4	5		4	4	4	5
Room 11	6	6	3	4		6	3	3	4		6	4	2	3		6	3	2	3		6	2	2	2
Room 12	5	5	4	4		5	5	4	4		4	6	4	4		4	6	4	4		4	5	4	4
Room 13	4	4	5	5		4	4	5	5		4	4	5	5		4	4	5	5		4	4	5	5
Room 14	3	3	3	5		3	4	3	5		4	4	3	5		4	4	3	5		4	4	3	5
Room 15	4	4	1	4		3	2	1	4		1	2	1	4		1	2	1	4		1	2	1	4
Room 16	1	1	5	5		3	2	5	5		2	1	5	5		2	1	4	5		3	1	4	6
Room 17	0	0	4	4		4	2	3	2		4	1	3	2		2	0	3	2		3	1	4	5
Room 18	0	0	5	4		2	3	5	4		2	3	5	4		0	1	5	3		0	0	5	2
Room 19	3	3	4	4		3	1	4	4		3	0	4	4		1	0	4	3		2	0	7	3
Room 20	0	0	3	4		0	0	3	4		0	0	3	4		0	3	3	3		0	3	3	3
Room 21	2	2	5	2		1	0	5	2		0	0	5	1		3	1	5	4		3	1	5	4
Room 22	2	2	5	4		0	0	5	4		0	0	5	3		2	2	5	4		2	1	5	3
Room 23	0	0	5	4		0	3	5	4		0	0	5	4		1	1	4	3		1	1	4	3
Room 24	3	3	4	5		3	2	4	5		2	2	4	5		1	2	3	5		1	0	3	5
Room 25	2	3	4	4		3	2	5	5		1	3	4	5		1	3	4	5		1	3	3	5
Room 26	2	2	4	3		2	1	3	2		2	1	3	2		2	0	3	2		1	1	3	2
Room 27	3	3	4	4		2	2	3	4		1	2	3	3		1	2	3	3		1	2	3	3
Room 28	3	3	5	4		3	4	5	4		2	4	6	4		1	2	6	2		0	1	5	2
Room 29	3	3	4	4		3	2	4	3		3	1	4	3		2	0	4	3		1	0	4	3
Room 30	4	4	4	4		3	4	4	4		2	4	4	3		2	2	4	3		0	2	4	3
Room 31	3	3	5	2		1	1	5	2		1	1	4	2		0	0	4	1		0	0	3	1

E: English; M: Malay; C: Chinese; T: Tamil insulin PDA booklets Note: Shaded boxes indicate unavailability of the insulin PDAs in specific languages in specific consultation rooms

Figure 3.15: Number of insulin PDA booklets available in respective language in consultation room by month

iv Average time taken to deliver the insulin PDA to patients during consultation

The average time taken by each doctor to deliver the PDA to patients during their consultation (only when using the insulin PDA) was 7.26 (± SD 4.5) (range: 2-20) minutes.

v Doctors' perception of whether the insulin PDA use increase, decrease or did not affect consultation time

There were more doctors (46.2%, n=18/39) who reported that the insulin PDA reduced their consultation time. Slightly more than one-third (33.3%, n=13/39) reported that their consultation time did not change with the insulin PDA use while 20.5% (n=8/39) reported that it increased.

(f) Maintenance

At the end of the implementation period, 80.0% (32/40) of the doctors agreed that they were willing to continue using the insulin PDA in their practice while 82.5% (33/40) would recommend using the insulin PDA to their colleagues.

3.4.2.3 Explanations for the RE-AIM outcomes

(a) Reach (Doctors and nurses)

Facilitators

i Doctors' self-motivation

'Reach' to HCPs was high and this was observed in the high doctors' attendance in the training workshops (88.9%). The most common reason reported for attending the workshop among the doctors was an interest to learn more about the insulin PDA (77.1%, n=37/48). One of the healthcare managers noted that the high participation rate was attributed to doctors' self-motivation. She noted that doctors in the clinic are usually keen to try new innovations.

> *"I think to reach 90% is very high. This is a busy clinic. // So far in our clinic, we don't really have difficult doctors. // Whenever there is a new thing they would want to be the first to try it. They are inquisitive. They want to know what is going on. // I still feel that it's just their nature that they want to try new things, of wanting to be in the same boat to try new things and don't want to miss out." - Healthcare manager 2*

ii The mandate of the insulin PDA implementation

The Head of Department's letter about the clinic's intention to implement the insulin PDA (54.2%, n=26/48) was the second most commonly reported reason for attending the PDA training workshop. During the interviews, the doctors expressed that they felt pressured to attend the training workshop after receiving the letter as they feared the consequences of not attending. They attended the workshop even though they were not keen as they were busy with exams.

> *"I thought (the letter from the head of department) is kind of like forcing us to attend [laugh] because I still remember that time we were so stressed with our exam but yet we have to attend [laugh]." - Doctor 5_Distributed 2 PDAs*

> *"I think it was the fear of the implication of not attending [the workshop] is what compelled me [laugh] to attend because the head of department's signature is there. 'if I am not there, what will be the consequences'." - Doctor 16_ Distributed 22 PDAs*

On the other hand, one doctor noted that it was not due to fear of the higher authority that made her adopt the insulin PDA, but rather, she saw the letter as an indication that the insulin PDA was an important clinic initiative. Hence, she was willing to participate in the insulin PDA implementation.

> *"Is not because I'm scared of my boss. No. But is like, this is something that is really serious for this department and to be implemented. So I try to join." - Doctor 34_ Distributed 7 PDAs*

Around one-third of the doctors reported attending the training workshop to obtain CPD points (35.4%, n=17/48) and training certificates (33.3%, n=16/48).

Barrier

iii Timing of the insulin PDA workshop

There were six doctors who did not attend the PDA training workshop, as three of them had other work commitments while the other three were on leave. As for the nine nurses who did not attend the workshop, the training workshop coincided with their unit meeting. The timing was noted as a barrier to attend the insulin PDA training workshop. The workshops were conducted on a Tuesday afternoon when HCPs were free from clinic duties. However, some HCPs took this time to attend to other matters or took their leave.

> *"It clashed with my unit meeting, which I already scheduled that Tuesday. Sometimes on Tuesday afternoon, we have our continuous medical education teaching for nurses, so I will send them as we are only free on Tuesday." - Healthcare manager 3*

> *"Some will take the half-day off," - Staff nurse 3*

Furthermore, some HCPs could not complete their clinical tasks in the morning due to a high workload and were unable to attend the workshop in the afternoon.

> *"Eventhough is conducted on Tuesday afternoon, sometimes when they have not finished with their clinic duties, they cannot attend." - Staff nurse 2*

(b) ***Reach (Patients)***

Facilitators

i Doctors delivering the PDA to patients

Many patients noted that they accepted the insulin PDA because the doctor asked them to read it. Some already knew about insulin but were curious why the doctor had given them the PDA.

> *"Why the doctor give me this book when they can just explain. I think there must be something special inside. That's why I took the book." - Patient 22*
>
> *"The doctor asked me to read so of course I will read to understand it. Not to say that insulin is something new to me because I have been hearing about it." –Patient 8*

ii Patients desire to know more about insulin

Patients also accepted the insulin PDA because that they wanted to know more information about insulin.

> *"I want to increase my understanding of insulin." – Patient 5*
>
> *"You give me something I have to read. I want to see what's the pros and cons of insulin." – Patient 13*

Barriers

iii Patients were not keen on insulin

This study did not obtain the number of patients who were eligible but did not accept the insulin PDA. However, interviews with the doctors revealed that some patients rejected the insulin PDA. One of the main reasons was that some patients were not keen to initiate insulin.

> *"Sometimes when you want to start talking about insulin, they will say 'Doctor I don't want insulin'. So you cannot proceed (with the insulin PDA). They already stop you there." - Doctor 8_ Distributed 3 PDAs*

> *"Those patients who were determined that they do not want insulin was a barrier (to PDA use). They already decided that they did not want [to initiate insulin] from the beginning." - Doctor 12_Distributed 27 PDAs*

iv Patients' attitudes towards their health

Despite some doctors explaining the purpose of the insulin PDA to patients, which was to help them to make an informed decision and not to persuade them to start insulin, there were still some patients who refused to accept the insulin PDA. This was particularly among those who seemed resigned to having poor health.

> *"Some of them do not really care or concern about their health. For them, taking medication is enough already. They said 'I don't want to read this one'." - Doctor 18_ Distributed 3 PDAs*

> *"Some patients are just not interested. It's a no from them from the beginning. Whatever you give them has always been a no." - Doctor 32_Distributed 32 PDAs*

(c) Adoption (Doctors)

Facilitators

A high PDA adoption was observed among the doctors (83.3%) and this was a surprise to one of the healthcare managers as she was initially worried that the uptake might be poor.

> *"I think (the doctor's adoption rate) is very good because it is more than 80% that were taking it up. I was afraid actually that they might not like it because they think it will take up their consultation time. That was my worry. But now I think a lot of them think that the insulin PDA is very helpful." – Healthcare manager 1*

i Positive experience with the insulin PDA

Doctors' adoption of the insulin PDA was facilitated by a positive experience with using the insulin PDA. The doctors expressed that they were able to provide information to patients within their short consultation time by using the insulin PDA.

> *"It reduces the time we need to explain every single thing to them [laugh]. So that's why we gave it so that they can read in detail. We can then focus on information that patient do not understand." - Doctor 17_Distributed 7 PDAs*

> *"I think what motivated me to use the insulin PDA was because of the time constraint. I cannot explain all the information during consultation time, so that's why I gave the insulin PDA to the patient." - Doctor 24_Distributed 4 PDAs*

The insulin PDA also enabled them to deliver information to patients in a comprehensive and systematic manner.

> *"This book is like a checklist for me to run through the information with patients before I pass it to them. Is like a reference when you provide information to patients, so that's why I used it." - Doctor 32_ Distributed 32 PDAs*

> *"It is quite difficult to give advice to patients about insulin initiation. But if you have a guide [the insulin PDA], you just show this, this, this. That's why I remember (to use the PDA)." - Doctor 27_ Distributed 7 PDAs*

Another reason for adopting the insulin PDA was that it enabled patients to make an informed decision, which allowed appropriate treatment to be given.

> *"With this PDA, patient will say 'I don't want this', then we can go on a different line of management rather than discussing about insulin all the time. When a patient doesn't make a decision, you are just not managing. But if the patient decided 'I'm ok with having a poor HbA1c', then I know not to focus on HbA1c but prevent complications for the patient." - Doctor 3_Distributed 22 PDAs*

> *"When the patient is informed, I could intervene safer. If the patient is not sure what she is going to get, I would also be half-hearted in giving the intervention. So, if they are sure that they want insulin or something else then I'm happy to intervene accordingly." - Doctor 32_Distributed 32 PDAs*

ii Usefulness of the insulin PDA

Another main reason for adopting the insulin PDA was its usefulness. Many doctors noted that the insulin PDA provided tangible information for patients to take home and read compared to when they could only listen to verbal information.

> *"I think it is good to have some written information which patient can bring home. Sometimes when we asked them to make a life changing decision during consultation where we only have 10 to 15 minutes, it is difficult for them to make decision on the spot. So, if they have information that they can take home and look through then it will be helpful with their decision making." - Doctor 21_ distributed 13 PDAs*

The doctors also noted that they used the insulin PDA as an introduction to insulin for patients who were afraid to ask them for more information or felt pressured to start insulin.

> *"Some patients have these pre-conceived ideas about insulin. They worried about needles and all. So, it's [the insulin PDA] like an icebreaker as well. Just to let them ease in on insulin, like when they have time then they can read on their own, rather than coming from us, which they might feel pressured to start insulin." - Doctor 5_Distributed 1 PDA*

> *"Sometimes patients don't want to ask us questions because they felt that we might judged them. So with the PDA, patients got answers to their queries from there. Sometimes when we answered their questions, we might sound very judgmental but when it is shown in a book, the patients will feel ok." - Doctor 3_ Distributed 22 PDAs*

Some doctors noted that they would adopt the insulin PDA even without a directive from the higher authority given its usefulness. This explains the findings where doctors felt that the announcement by the Head of Department (73.7%, n=28/39) and the official letter by the Head of Department (56.4%, n=22/39) influenced them to use the insulin PDA.

> *"Even if the bosses didn't ask you to use this PDA, I think it's very helpful."- Doctor 15 _ Distributed 51 PDAs*

There were nine doctors who adopted the insulin PDA before attending the insulin PDA training workshop. These doctors joined the clinic in June but only attended the workshop in August. They noted the perceived usefulness of the insulin PDA when asked on why they had adopted the insulin PDA prior to attending the workshop. They had also enquired the purpose of the insulin PDA from their colleagues and felt that it contained good information and was useful for their patients. They were also motivated to use the insulin PDA after going through it by themselves.

> *"When I noticed the insulin PDA, I asked around and they said this is to help patients to better understand about insulin. I looked through it and found it useful then I gave it a try. I gave it to patients and they think it's good." - Doctor 13_Distributed 16 PDAs*

> *"I noticed this thing [insulin PDA] and I asked my few colleagues. I went through and thought it had the information that would benefit patients. So, that's why I gave it to patients." - Doctor 30_Distributed 7 PDAs*

iii The effectiveness of the training workshop

The training workshop also facilitated the doctors in their adoption of the insulin PDA. A high proportion of doctors agreed that the training workshop:

- increased their awareness of the benefits of the insulin PDA (97.5%, n=38/39),
- helped them to adapt using the insulin PDA in a busy clinic (92.3%, n=36/39),
- changed their consultation approach to involving patients more in decision making (79.5%, n=31/39),
- taught them how to use the insulin PDA with a patient who speaks a different language (79.5%, n=31/39),
- taught them how to use the insulin PDA with patients who rely on doctors to make health decisions (76.9%, n=30/39),
- taught them how to increase a patient's confidence to use the insulin PDA by themselves (76.4%, n=29/39),
- convinced them to use the insulin PDA with patients given the potential time it could save during consultation (71.8%, n=28/39),
- taught them how to use the insulin PDA with patients who cannot read or understand the insulin PDA (71.0%, n=27/39),

- taught them how to manage patients who felt that the insulin PDA is a tool to persuade them to start insulin (64.1%, n=25/39), and
- convinced them not to rush when using the insulin PDA with patients (61.5%, n=24/39).

Many of the HCPs shared that the training workshop helped them understand the purpose of the insulin PDA, how to use the insulin PDA, and their implementation tasks. They noted that the training workshop was necessary in order to get doctors to prescribe the PDA to patients.

> *"The training workshop is needed. It guided us and taught us how to explain (the insulin PDA to the patients). We were taught page by page, how to do it and what to write on the patient's card and in the EMR. So I think without the workshop, I don't think they will prescribe the PDA." – Doctor 27_ Distributed 7 PDAs*

> *"The main reason I started using it was because of the training workshop. It [training workshop] explains the insulin PDA purpose and the fact that it was emphasised that it's not to convince the patient (to start insulin). I think it was meaningful for me. Going through (the insulin PDA) on how to use it was important." - Doctor 18_Distributed 32 PDAs*

> *"After attending the insulin PDA, we do feel that it is our responsibility, so I would replenish. The workshop is actually good to provide information for all the staff." – Staff nurse 5*

Barriers

iv Absence from the clinic affects doctors' motivation to resume PDA use

There were nine doctors who did not adopt the insulin PDA. Based on clinic administrative records, seven of them had left the clinic approximately two months after the insulin PDA implementation commenced. Four of them left after completing their masters training, two dropped out of the training, and one had left for an external posting. Among these seven doctors, four had completed their family medicine training, two was in year one and one was in year three.

In the UMMC primary care clinic, doctors in the first year of their study do not practise in the clinic. Those in their final year spend only two days a week in the clinic as they have to do attachments at other clinics as part of their family medicine training. In their interviews, doctors in the final year of their study explained that being away from the clinic meant they could not administer the insulin PDA to patients. In addition, they also noted that they did not see many patients who required insulin when they were in the clinic.

> *"We are often not in the clinic. We only come back 2 days a week so naturally the frequency of the usage is reduced. Aanother reason is, mostly for that 2 days we are seeing our follow up patients with chronic conditions and they are already either on insulin or might not require insulin." - Doctor 4_ Distributed 11 PDAs*

Some of them added that when they returned to the clinic after a long absence, they tended to forget about the insulin PDA and their motivation decreased due to lack of use.

> *"(Low PDA adoption) because I did attachments at hospice for three weeks and one month in emergency department. So for that period of time, it was like zero (didn't use the PDA with patients). // Initially when you have something new, you will be*

> *enthusiastic and has the urge to use it but once you left it for awhile, you don't have the urge to use it anymore. When I came back to the clinic, I only use like once or twice. I felt demotivated after not using it for some time." - Doctor 1_Distributed 10 PDAs*

v Lack of familiarity with the insulin PDA

There were only two doctors who did not adopt the insulin PDA despite present in the clinic throughout the implementation period. One doctor explained that he did not adopt the insulin PDA because he was not familiar with it as he did not attend the insulin PDA training workshop.

> *"I am not familiar on how to use the PDA. I have actually seen patients with the insulin PDA who came for follow-up but I didn't know what it was. I asked other colleagues and they told me that there will be a workshop where we will be introduced to the PDA and you should start using the PDA after that. I was waiting for the workshop but on the day of the workshop, I couldn't attend." – Doctor 33_did not use PDA*

Another doctor who attended the workshop but did not adopt the insulin PDA noted it was not clear what her involvement was in the insulin PDA implementation.

> *"I was not clear that that we were asked to use the insulin PDA during the workshop. I thought it (training workshop) a drug talk. I was not clear on the content of the booklet and what we need to do. If I am clear that I can take part then I'll pay more attention to it." – Doctor 34_ Did not use PDA*

vi Availability of doctors in the clinic

The weekly insulin PDA adoption showed an inconsistent trend throughout the implementation period. One of the healthcare managers explained that exam periods and public holidays could have affected the low insulin PDA adoption during these events.

During exam periods, there would be fewer doctors in the clinic and remaining practising doctors were busier than usual as they had to attend to more patients. As doctors were busier, they did not have the time to use the PDA. Public holidays also affected the insulin PDA adoption as there were fewer patients in the clinic.

> *"May is exam month, so there were not enough doctors and too many patients that they didn't have the time to use. June is when we get new doctors. So all the ones who were trained were not around. They have gone somewhere. // September is the month that we have a lot of holidays so the numbers of patients use were much less. Then again in October, we have got exam. It's related to the number of doctors available." – Healthcare manager 1*

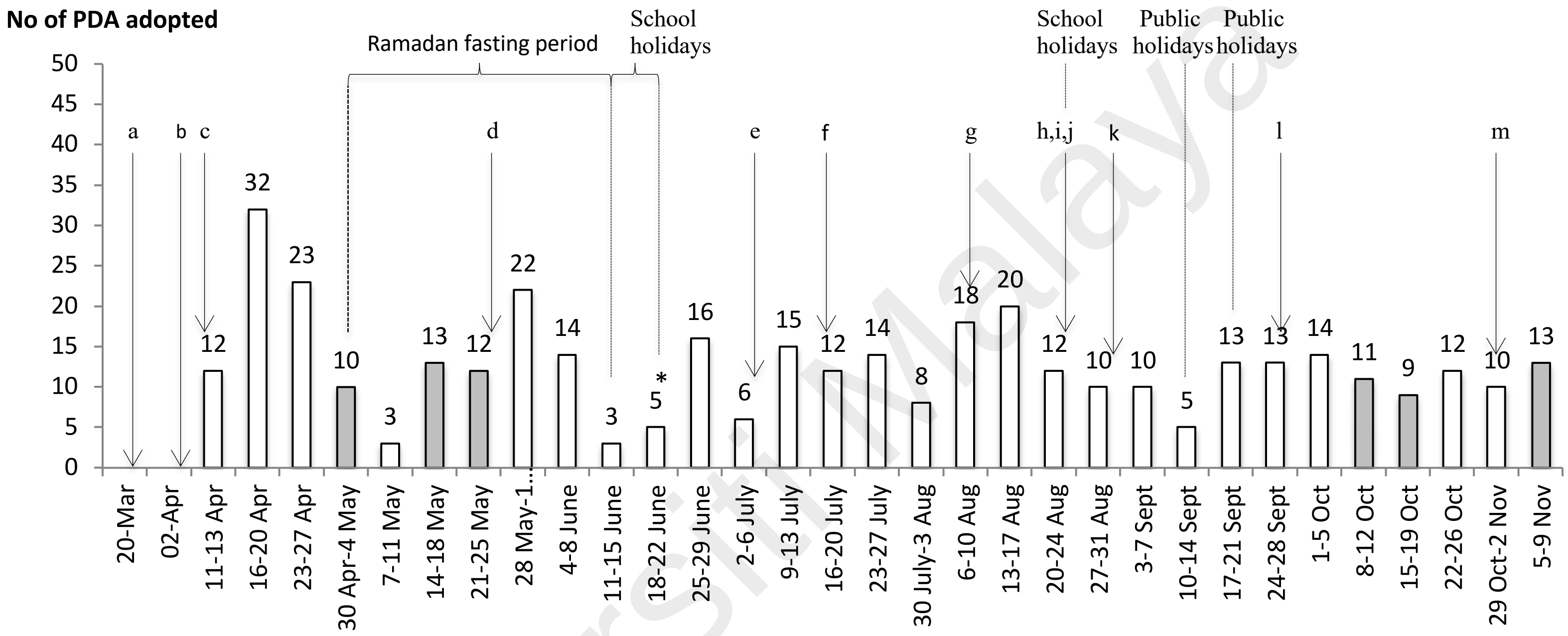
This was also corroborated by one of the doctors.

> *"It's also limitation from our side. Every time exam month, we have shortage of doctors. It's very busy for us." – Doctor 15_ Distributed 51 PDAs*

However, another healthcare manager noted that the insulin PDA adoption rate picked up during the doctors' turnover period. When the second year students completed their exams and the new doctors joined the clinic in June, there was a bigger cohort in the clinic hence contributed to the increase in adoption rate in August.

> *"Once the year 2 students passed their exams in June, they become year 3 and they are still working in the clinic so the cohort is bigger. They picked up their momentum habit and the adoption rate goes up. In August, this is the cohort that may be biggest in using the PDA. The new term change in June. So that's when you get the turnover of new doctors." - Healthcare manager 2*

Based on the participants' narratives on what could have contributed to the trends, the weekly insulin PDA adoption rates were plotted with events such as holidays, exam periods, doctors' turnover period, and the strategies implemented (Figure 3.16). It can be observed that there was a lower number of PDAs adopted during exam periods (23 April to 11 May; 8-19 October) as well as school holidays (11-22 June) and public holidays (10-14 September). There was also a slight increase in the number of PDAs adopted in the week following implementing the strategy 'Provide feedback' indicated by the alphabets 'd', 'e', 'f', 'g', 'l' and 'm' in Figure 3.16.



	Date	Event / strategy implemented		Date	Event / strategy implemented
a)	20 March	Mandate change (Announcement by HOD)	g)	6 August	Individual report feedback 3
b)	2 April	Mandate letter (Official letter by HOD)		18-26 August	School holiday
c)	10 April	Insulin PDA training workshop	h)	21 August	Mandate change (Announcement by HOD)
▨	2-4 May	Exams for Y1 students	i)	21 August	Mandate letter (Official letter by HOD)
▨	15-16 May	Exams Y3 students	j)	21 August	Unit meeting feedback 2
▨	22 May	Exam Y4 students (18 doctors)	k)	28 August	Insulin PDA training workshop
▨	16 May	Fasting month started		9-11 September	Public holiday
d)	21 May	Individual report feedback 1		16-17 September	Public holiday
	14 June	Fasting month ended	l)	28 Sept	Individual report feedback 4
*	20 June	Doctor turnover period	▨	9-10 Oct	Exams Y1 students (10 doctors)
	9-24 June	School holiday	▨	15-16 Oct	Exams Y3 students
e)	5 July	Individual report feedback 2	m)	30 Oct	Unit meeting feedback 3
f)	17 July	Unit meeting feedback 1	▨	7-8 Nov	Exams for Y1 (13 doctors)

Figure 3.16: Weekly insulin PDA adoption rate based on events or strategies implemented

vii Doctors were too busy as there were too many patients

Some of the doctors also admitted that they did not use the insulin PDA always. They noted that when the clinic had too many patients, they tended not to use the insulin PDA since they could not spend the time to explain the PDA to patients.

> *"It does happen to me at some days when we are very short of people. Although there was a need to use the insulin PDA but I didn't give because when you give the insulin PDA, you have to explain what it is to the patient." - Doctor 24_ Distributed 4 PDAs*

viii Patients' non-use of the insulin PDA affects doctors' motivation to adopt the insulin PDA

Some doctor professed that initially they were actively using the PDA but later reduce their adoption. Once they found out that their patients did not read the insulin PDA, it affected their motivation. They expressed that when they were faced with such patients, they had to explain the insulin PDA again and felt it wasted their time. After several encounters with patients who did not read the insulin PDA, they began to feel that the PDA was not useful and they started using it less.

> *"As the months passed by, when I asked patients 'where is your PDA?' during the follow up, they said 'Oh I forgot'. They tend to say they have read it but they didn't notice the section [in the PDA] where they have to fill up or answer questions on why are they reluctant to start insulin on the pages at the back. So, in the end, I would need to explain again. Personally, I think it is a waste of time. After several encounters of patients not using the PDA, I began to think that maybe the PDA is not effective. So this actually affects me in giving out more." - Doctor 25_ Distributed 5 PDAs*

> *"Starting point I was quite active in giving out the insulin PDA. After awhile, the number (of the insulin PDA given out) got less and less. Some patients just don't care about it. Maybe they are not interested [laughs]. No point (giving)." – Doctor _Distributed 4 PDAs*

ix The lack of effectiveness of the strategy 'Provide feedback'

Only 43.6% (n=17/39) of the doctors felt that receiving the monthly feedback on their performance in the insulin PDA implementation motivated them to adopt the insulin PDA. The insulin PDA adoption trend shown in Figure 19 also shows that there was only a slight increase following implementation of the strategy. While a few doctors noted that the feedback report they received pushed them to use the insulin PDA, it was albeit in a negative way.

> *"Is a stress reminder." – Doctor 5_ Distributed 1 PDA*
>
> *"When you have been 'stagnant' [not using the PDA] for a few months, then maybe 'Ok I'll use one for this month'. In a way because of pressure." – Doctor 1_ distributed 10 PDAs*

There were more doctors who thought the strategy was ineffective. They reasoned that the adoption of the insulin PDA is depended on patients' needs rather than the need to achieve better results in the feedback report.

> *"Honestly, it does not motivate me. My decision to adopt the PDA depends on my patients. If I think maybe I can consider offering the insulin PDA to this patient then I'll give. But if I think the patient is one who strongly refuses insulin, I won't give the PDA since it won't be useful. So the decisions to give (the insulin PDA) depends on my evaluation on the patients whether they will start on insulin. It does not depend on the report." –Doctor 11_Distributed 4 PDAs*

> *"It really depends on patients' needs. If it is really necessary to give the insulin PDA to the patient then I will give. Is not because of the number in the graph (in the feedback report)." – Doctor 24_Distributed 4 PDAs*

The lack of effectiveness of the feedback report also attributed to its content. The doctor who did not adopt the insulin PDA throughout the implementation period was claimed she was already aware that she was not using the insulin PDA hence the feedback report did not affect her.

> *"It doesn't motivate me to use the PDA. I know I am not doing (using the insulin PDA) so I know which category of user I belong to." – Doctor 34_Did not use PDA*

One of the healthcare managers noted that information on insulin uptake among patients after using the insulin PDA might have been better feedback to provide to the HCPs.

> *"The feedback that they want to know is information such as uptake of insulin after PDA rather than, 'I've not been using it'." – Healthcare manager 1*

(d) ***Adoption (Patient)***

Barriers

i Patients were busy

There was a low proportion of patients who read the insulin PDA (34.2%). Patients often cited being busy as the reason for not reading the insulin PDA.

> *"I went through a few pages but I didn't complete the book. I was busy with my work because my work involved a lot of moving around. So I did not have the time." – Patient 41*

ii Patients' lackadaisical attitude

Some patients admitted that their lackadaisical attitude was another reason for not reading the insulin PDA. One patient explained how she procrastinated in reading the insulin PDA thinking she still had some time before her next clinic appointment but wasn't able to finish it.

> *"I left it halfway because my appointment is not so soon. I was carefree about it." – Patient 5*

iii Perceived adequate knowledge about diabetes and insulin

Some patients also noted that they already had knowledge about diabetes and insulin from HCPs and friends. Hence, they did not read the insulin PDA.

> *"I already knew (the information). Some of my friends are already using this. So I already have the general understanding." – Patient 20*

> *"The doctor asked to read. But I already know all the information. So that's why I didn't read the book." – Patient 23*

(e) ***Implementation***

Facilitator

i Task was part of patient clinical management

Doctors' adherence to their implementation tasks varied for different aspects of the implementation. The task of making a note in the EMR registered highest adherence (84.9%). When asked why many had adhered to this task, they revealed that they considered giving the insulin PDA to patients as part of patient management. Hence, they recorded it in the EMR to follow-up with patients. Furthermore, they noted that it was a fairly easy task to do.

> *"The insulin PDA is like part of our management plan. That's why we tend to do that (note in the EMR)." - Doctor 14_Distributed 10 PDAs*
>
> *"(We would note in the EMR) because we always reflect back on the last appointment and see what was the plan, what had been done and follow up from there." - Doctor 17_Distributed 7 PDAs*
>
> *"This is an easy job." – Doctor 10_ Distributed 1 PDA*

Barrier

Doctors least adhered to the task of noting that they had given the PDA in the patient's appointment card (19.2%). They explained that they tended to forget this step. They reasoned that writing the patient's management plan in their appointment cards was not something that they are used to doing as they usually use the EMR. Patient's appointment cards were mainly for noting a patient's next appointment, hence this was not part of their habit and they would forget to write the management plan.

> *"Making notes in the EMR is easier because you are typing it immediately after giving interventions to the patients. But writing intervention on the appointment card is not really our habit. Sometimes we miss this step." – Doctor 32_distributed 32 PDAs*
>
> "*Usually, we don't write management plans in the card but only the duration of the next appointment for patient. Writing 'PDA given' is like a plan for us to be written in the EMR." - Doctor 14_Distributed 10 PDAs*

ii Perception that the step of making notes in the patients' appointment card was unnecessary

Another barrier noted for implementation was that many doctors felt the step on making notes in the patients' appointment card was redundant since they had already made the note in the EMR.

> *"I'm not sure if this step is essential. If you can reduce one step, most likely the percentage of giving out the insulin PDA will be better." - Doctor 25_Distributed 13 PDAs*

> *"Writing on the appointment card is not necessary. I'm not sure whether there is any difference (compared to making a note in the EMR) because the person we want to convey this information is actually the next doctor who will be seeing the patient, so the information is already there in the EMR where we have to type." - Doctor 3_Distributed 22 PDAs*

iii Too many documentation steps

As doctor already had a lot of other tasks to do, the added documentation steps made it more difficult for them to follow.

> *"I did not do this as well. We have a lot of things to write, TCA, blood investigation and other things." - Doctor 19_Distributed 3 PDAs*

> *"When you ask them to write EMR and then to write on the card, it is a lot of work for them." Healthcare manager 2*

iv Patient factors hampered provision of appointments within 3 months to patients and conduct of the insulin PDA follow-up.

Adherence to the task of providing appointment within 3 months to patient was only moderate (66.7%) and was challenged by a patient barrier. Only 51.3% (n=20/39) of the doctors agreed that providing appointment within 3 months to patient helped them follow-up with patients on the insulin PDA. The doctors explained that eventhough they wanted to give an earlier appointment, some patients refused citing they were busy or transportation issues.

> *"This one (giving an appointment within 3 months) is difficult to achieve because many patients do not want to come back in 3 months. Despite us telling them that delaying their diabetes management is not good. They still can't come. They are going somewhere, they are busy or they have no one to bring them over. We can't force them." - Doctor 32_Distributed 32 PDAs*
>
> *"They want a further appointment because sometimes their home is far. Sometimes they come with their children and their children could not take so many leave. So usually they request for a much later appointment." - Doctor 18_Distributed 3 PDAs*

Despite a high percentage of agreement among the doctors that the implementation step of making a note in the EMR system reminded them to follow-up with patients on the insulin PDA (92.3%, n=36/39), they were only able to do so with about one-third of the patients (34.1%). This was mainly because patients did not read the insulin PDA and thus doctors could not conduct the follow-up.

> *"Some of them came back but no response. It's like all the time that you had spent on the patient previously is wasted. Then is either you re-introduce, re-educate, re-emphasise or you want to give them another PDA which may go down into the drain again." - Doctor 25_Distributed 5 PDAs*

v System barrier to provide appointment within three months to patients

The doctors also explained it was challenging to give an appointment within three months due to the appointment system in the clinic. Doctors in the clinic are usually assigned a number of patients to attend to every day. Once their patient quota is filled for a specific date, they cannot add additional appointments which made the 3-month follow-up period difficult.

> *"Giving a less than three months appointment sometimes is difficult, because the counter (appointment clerks) would informed me that my appointment is already full till next year. So, I can't give a three-month appointment." - Doctor 21_Distributed 13 PDAs*

> *"We are quite limited in appointment also. Some of us are full until almost 1 year, so we cannot really give 3 months appointment." - Doctor 14_Distributed 10 PDAs*

vi Lack of awareness of the need to refill the insulin PDA in the consultation rooms among the nurses

It was found that PDAs in specific languages were unavailable in some of the consultation rooms. Nurses explained that some of them who did not attend the insulin PDA training workshop might have been unaware of the task to replenish the insulin PDA.

> *"Only some nurses replenish the PDA books. Not all. Nurses who attended the workshop replenished the PDAs and the others did not." - Staff nurse 4*

There was also a lack of awareness among nurses on where to obtain the PDAs to refill in the consultation rooms. One of the nurses who had attended the PDA training workshop was still unaware that the PDAs were available in the nurse operation room, citing that he was not briefed about it. The nurses noted that they would usually take PDAs from adjacent consultation rooms to doctors who needed them.

> *"I don't know where to get the PDAs. Maybe I forgot. Doctors have asked me. I took from next door (next consultation rooms). No one briefed me that I have to take from the nurse operation room." - Staff nurse 1*

> *"I did not know that the insulin PDAs were at the nurse operation room. So I just took PDAs from other rooms and refill at rooms where the PDAs were lacking." -Staff nurse 3*

However, based on the nursing officer's narratives, she claimed to have reminded the nurses to replenish the insulin PDA monthly. The nursing officer also did not seem to think there were issues with the replenishment of the insulin PDA implementation in the consultation rooms. She observed that the number of insulin PDA booklets in the nurse operation room was getting less, hence indicating they were taken to be replenished.

> *"I see they got less. If they didn't replenish the stock, the PDAs would be in the room only [laugh], not getting less. This means nurses are filling up. I also kept reminding them. I informed the team leader and and the nurses through Whatsapp [messaging app] every month. Some nurses who are competent will top up. We must push everyday [laugh]. // So far nobody mentioned any problems" – IDI 4_healthcare manager 3*

vii Involvement of medical assistants in performing nurses' tasks

The nurses highlighted that many medical assistants were instructed by the higher authority to assist doctors in the consultation rooms as there was a lack of nurses in the clinic. Thus, medical assistants who were unaware of the insulin PDAs and the need to replenish them in the consultation rooms hampered the insulin PDA implementation.

> *"Nowadays, the rooms are run by all the medical assistants because we have fewer staff nurses now. This could be one of the reasons why the insulin PDAs was not refilled. The medical assistants didn't know they have to refill and where to get the PDAs." - Staff nurse 4*

> *"Does the medical assistants know? Because the number of medical assistants now is almost the same as nurses and they are also in-charge of the consultation rooms. If they don't know (about the insulin PDA), so they wouldn't refill." - Staff nurse 2*

viii Nurses' attitudes

Nurses' attitude was raised as a challenge for the insulin PDA implementation. One nurse expressed that despite the nursing officer reminding staff nurses to refill the PDAs in the consultation rooms, some of them did not listen. She shared an example of the irresponsible behaviour of her colleagues towards their usual tasks, such as failing to refill the Ventolin solution that is used every day in the clinic. Some nurses took advantage that their colleagues would refill the solution.

> *"Even though nursing officer said you have to do this but some nurses don't bother about that. Some nurses are irresponsible attitude towards their tasks. For example, we give patients the ventolin solution for doing the puffs. If your patient is the last one to use the solution before it is emptied, you should refill it. When I want to go to get the solution for my patient who is the next patient, it is empty. Isn't it irresponsible? I think the PDA would be harder for them to top up because they*

> *are already not refilling the ventolin solution that we are using every day. This one is attitude. They think that other people can refill for them." - Staff nurse 4*

The nurse also cited that some team leaders showed a lackadaisical attitude when there were no more PDA booklets in the nurse operation room. This prompted her to call the researcher herself to ask for more insulin PDAs.

> *"I asked the team leader. She said 'No, no, they didn't give the stock'. When the insulin PDAs are finished, we cannot just say don't have. Then I call you." – Staff nurse 4*

The nursing officer also highlighted that some nurses did not refill the PDA because they assumed that since the programme is still under research, that there were dedicated research personnel to carry out the task. Hence, some nurses would not perform their task.

> *"Maybe they say this one is under research, why we want to take this so seriously. They got researcher, they got own person. The nurses will think like that. That's why sometimes they let go only. They give slow moving." – Healthcare manager 3*

The clinic coordinator also shared the same sentiment about some nurses in the clinic who lack motivation and dedication to carry out their tasks in the clinic.

> *"No doubt there are also nurses who are very motivated and hardworking but there are also those at the other end. The issue that we have now with nurses is not only we are getting less nurses, we also are not getting those who are type that we want. Those motivated and dedicated one. That's one of the big challenges." – Healthcare manager 2*

Nevertheless, 92.3% (n=36/39) of the doctors reported that the placement of the insulin PDA booklets in the consultation rooms helped them to access the insulin PDA whenever they needed it. A few doctors did experience that PDAs in certain language but were not available in the room when they needed them. When this occurred, they would get the PDAs from neighbouring consultation rooms.

> *"Access to the PDA was not a problem. It's always restocked. Only once I needed to get from another room." – Doctor 32_ Distributed 32 PDAs*

(f) Maintenance

Facilitator

i Usefulness and benefits of the insulin PDA to patients

The quantitative findings show that many doctors were willing to continue using the insulin PDA and recommend its use to their colleagues. The reasons were that they noted the usefulness and benefits of the insulin PDA to patients.

> "*I will continue. It helps with educating the patients about insulin." - Doctor 28_ Distributed 7 PDAs*

> *"I would continue to use it. Is a good visual tool because is easier for patient to have a picture are the options available to them as well have having something for them to bring home." - Doctor 21_Distributed 13 PDA*

3.5 Chapter summary

This chapter detailed the methods and results in each phase of this study. In the first phase, the qualitative design was chosen to explore barriers and facilitators to implementation of the insulin PDA given that PDA implementation is understudied in the Malaysian context. IDIs and FGDs were conducted with various stakeholders including patients at one academic primary care clinic and five community clinics. A total of 26 barriers and 11 facilitators to the insulin PDA implementation at the Malaysian public healthcare settings were found; They were categorised into HCP, patient, organisation and innovation factors.

In Phase 2, a pragmatic and systematic approach was employed taking evidence and contextual considerations in the development of an intervention to implement the insulin PDA at the UMMC primary care clinic. The development of the intervention commenced with the prioritisation of barriers through a multivoting exercise. Barriers that were voted by a majority of the clinic stakeholders that included healthcare managers, doctors, nurses and patients were identified as important barriers to address. A total of 13 barriers were prioritised from an initial list of 49 barriers. Based on the 13 prioritised barriers, strategies were selected and tailored based on evidence in the literature, proposed strategies by participants in Phase 1, the ERIC and the BCTTv1 taxonomy and the clinic context. The intervention was later finalised through discussions in a clinic stakeholders meeting. A total of 10 strategies were selected to overcome the 13 prioritised barriers. These strategies were integrated into the clinic's workflow and the intervention was developed.

The intervention was implemented for approximately 7 months and implementation outcomes were assessed based on the 'Reach', 'Adoption', 'Implementation' and 'Maintenance' dimensions of the RE-AIM framework. The sequential explanatory mixed methods design was employed for evaluation. A high 'Reach' was observed among doctors and was attributed to their self-motivation, mandate of the insulin PDA implementation, and timing of the insulin PDA workshop. The insulin PDA reached 387 patients and was facilitated by the doctors who delivered the insulin PDA to them and their own desire to know more about insulin. Barriers reaching patients were their attitudes towards their health and lack of interest to initiate insulin.

Doctor's adoption of the insulin PDA was high (83.3%) and was attributed to a positive experience with the insulin PDA use, the usefulness of the insulin PDA, and the effectiveness of the training workshop. However, barriers to adoption included doctor's absence in the clinic, lack of familiarity with the insulin PDA, availability of doctors in the clinic, patients' non-use of the insulin PDA, and the lack of effectiveness of the strategy 'Provide feedback'. Patient's adoption was only moderate with only 65.7% reading the given insulin PDA. A lackadaisical attitude towards their health and insulin, perceived adequate knowledge about diabetes and insulin, and being busy were among the reasons for not reading the insulin PDA.

In terms of 'Implementation', adherence to implementation tasks varied for different tasks. Doctors adhered to tasks that were part of patient clinical management the most. Challenges to implementation included the perception that the step of making notes in the patients' appointment card was unnecessary, too many documentation steps, patient barrier, clinic's appointment system barrier, lack of awareness of implementation task, involvement of medical assistants in performing nurses' tasks, and nurses' attitudes.

A high degree for 'Maintenance' was found among the doctors who reported that they were willing to continue using the insulin PDA as they saw its benefits and would recommend its use to their colleagues at the end of the implementation period. The next chapter discusses the study findings.

CHAPTER 4: DISCUSSION

4.1 Introduction

This chapter gives an overall discussion of the findings of this study. The first part of this chapter discusses barriers and facilitators to PDA implementation that were found to be unique or more prominent in Malaysian public healthcare settings. Next, this chapter discusses the intervention development process to implement the insulin PDA at the UMMC primary care clinic, specifically pertaining to prioritisation of barriers, involvement of the clinic stakeholders in identifying and mapping strategies to prioritized barriers, involvement of patients in intervention development, and the process of mapping strategies to barriers. Then, the findings based on 'Reach', 'Adoption', 'Implementation', and 'Maintenance' dimensions of the RE-AIM framework would be discussed in relation to other studies. Recommendations for intervention development and implementation of PDAs in routine clinical settings are then provided. Lastly, the study strengths and limitations are then presented followed by the chapter summary.

4.2 Barriers and facilitators to PDA implementation

This study provides insight into the barriers and facilitators influencing implementation of PDAs in the Malaysian primary care setting. This study adds to the limited number of studies reported on the implementation of PDAs in Asia, particularly in routine practice (Huang et al., 2016; Liao et al., 2017). In this current study, some barriers and facilitators were not too different from those commonly reported in predominantly Western literature including: HCPs' lack of awareness (Alden, Friend & Chun, 2013; Stacey et al., 2005), lack of familiarity with SDM and PDA (Lin et al., 2013), patient literacy level (Feibelmann, Yang, Uzogara, & Sepucha, 2011; King, Davis, Gorman, Rugge & Fagnan, 2012; Scalia, Elwyn & Durand, 2017), time constraints (Legare, Ratte, Gravel, & Graham, 2008; Shultz & Jimbo, 2015), access to PDAs

(Holmes-Rovner et al., 2000; Uy, May, Tietbohl & Frosch, 2014); and the facilitators: HCPs' belief that PDA is useful and beneficial (Gravel, Legare & Graham, 2006; Rees, Shaw, Bennert, Emmett & Montgomery, 2009) and leadership (Tietbohl et al., 2015).

Less commonly reported barriers that emerged in this study were role boundary and the lack of continuity of care. Besides these two barriers, other barriers such as the lack of SDM culture, language, patient literacy level, and facilitators such as reminders and patient willingness to pay for the PDA have unique perspectives due to Malaysia's multicultural and low resource settings. In the following section, each of these key findings is discussed in detail.

4.2.1 Role boundary

In this study, role boundary between doctor and nurses was noted as a barrier for implementation. In actuality, role boundary may act both as a facilitator or barrier for the implementation of the insulin PDA. Being clear of one's job responsibilities helped HCPs decide if they were the right person to use the insulin PDA. For example, all the participants in Phase 1 of this study felt that doctors should introduce and use the insulin PDA given their authority to prescribe insulin and familiarity with the patient's health profile. However, relying solely on doctors would hinder an interprofessional team approach to using PDAs (Dawn & Légaré, 2015). Involvement of other HCPs besides physicians may help to disperse the work needed in providing decision support. For example, compared to primary care doctors who have to see a high number of patients with various conditions, diabetes educators have more time to provide patient counseling as they only see diabetes patients. Many Western studies have also shown that HCPs other than doctors such as nurses, social workers, psychologists, and allied health professionals play a significant role in ensuring PDAs are implemented successfully by identifying eligible patients, contacting patients about the PDA, and providing decision coaching

(Silvia, Ozanne, & Sepucha, 2008; Stacey, Chambers, Jacobsen & Dunn, 2008; Stacey et al., 2015). The existence of a clear role boundary between doctors and nurses in Malaysia may be because only doctors can provide a diagnosis and prescribe medication such as insulin to patients, while diabetes educators and nurses are usually confined to the limited roles such as administering medications and treatments according to doctor's orders. This is in contrast to some countries, particularly in the West, where nurse practitioners have a similar scope of practice as general practitioners, including providing diagnosis and prescribing medications (Dahrouge et al., 2014) hence were involved in PDA implementation (Silvia & Sepucha, 2006).

To increase the involvement of diabetes educators and nurses in insulin PDA implementation, they can be trained in decision coaching skills, which has been found to be effective in guiding patients to make an informed decision (Stacey et al., 2008). Decision coaching is a process whereby a HCP supports and prepares patients in their decision-making needs in a non-directive manner prior to their doctor's consultation, such as assessing the patients' decision-making needs, providing information on treatment options, risks (e.g. using PDA), clarifying patients' values and preferences, building their skills in deliberating, communicating, accessing support, screening for barriers to implementation, and facilitating progress in decision-making (Stacey et al., 2012). However, the final treatment option decision is made between the patient and a doctor during consultation, taking into consideration the patient's values and preferences and the doctor's medical expertise (Stacey et al., 2012). SDM and decision coaching training can be included in the Advanced Diploma in Diabetes Education course and even basic nursing programmes. In addition, doctors also need to be trained to work as a team with the nurses to implement PDAs in the clinic.

4.2.2 Continuity of care

Another important aspect of the implementation of the insulin PDA is the need to follow-up with patients (ideally by the same HCP) to ensure there is continuity in the delivery of the insulin PDA. The use of PDAs is not a one-off event as SDM is a continuous interactive process between HCPs and patients; hence, continuity of care is crucial in ensuring effective delivery of the insulin PDA. There were HCPs who did not seem to think there was a need to follow-up with patients after giving them a PDA and this may be due to the perception that the PDA is just another informational material (Newsome, Sieber, Smith & Lillie, 2012). Patients have reported health decision-making barriers related to continuity of care issues such as the inability to discuss their care with the same HCP due to staff turnover (Doherty & Doherty, 2005; Sainio, Lauri & Eriksson, 2001), inability to choose their preferred doctor (Belcher, Fried, Agostini, & Tinetti, 2006), too many HCPs involved and, suboptimal patient information handover between HCPs (Larsson, Sahlsten, Segesten & Plos, 2011). In terms of PDA implementation, the lack of continuity of care may cause difficulties for patients to raise or discuss issues pertaining to the PDAs that were brought up in the previous consultation (Stapleton, Kirkham & Thomas, 2002). It also prevents rapport building between HCPs and patients that could facilitate informed decision-making (Thorne, Oliffe, & Stajduhar, 2013).

In a developing country such as Malaysia, continuity of care is a challenge in healthcare delivery due to a high patient load, lack of manpower, time constraints (Khoo, Lim, & Vrijhoef, 2014; Lee, Lee & Ng, 2012), lack of family physicians, and uncoordinated referral mechanisms (Cheng, Hou, & Chen, 2011). Continuity of care is also particularly difficult in an academic healthcare setting, where there is a high turnover of staff after the medical trainees have completed their training (Baker & Streatfield, 1995; Fisher, Sloane, Edwards, & Gamble, 2007; Lee, Lee & Ng, 2012). Potential strategies to address this barrier are systematic documentation of the PDA use and discussions with patients to facilitate information continuity between different doctors who follow-up with the same patients. Furthermore, new HCPs need to be educated on decision support and PDA use. Such training can be introduced during the orientation programme for new HCPs, having a resource person to provide more information about the PDA in the implementation setting, and having on-going training and support to familiarise HCPs with the concept of SDM and the use of PDAs. Enabling patients to view a PDA prior to clinic consultation (Hsu, Liss, Westbrook, & Arterburn, 2013) may also help overcome the continuity of care barrier as patients arrive at the consultation with knowledge of the PDA and are ready for SDM and PDA discussions. However, providing PDAs to patients before consultations has its own logistical challenges and should be planned properly.

4.2.3 SDM culture

In this study, low awareness and receptivity to SDM among the HCPs could hinder the implementation of PDAs in the Malaysian primary care setting. The Phase 1 participants of this study were doubtful if the concept of SDM was culturally acceptable in Malaysia due to HCP paternalism and patient submissiveness towards doctors. This resistance to SDM can hinder its adoption and subsequently lead to non-use of the insulin PDA. There is a distinct contrast in developed countries where SDM and the use of PDAs have already been implemented at policy and legislation levels (Department of Health, 2010; Harter, van der Weijden & Elwyn, 2011; Senate and House of Representatives, 2010; Washington State Legislature, 2007) while developing countries in Asia see slower progress in adopting SDM and PDAs (Huang et al., 2015; Ng et al., 2013). This may be due to limited healthcare resources and an overburdened healthcare system in many Asian countries which have rendered SDM and PDA use difficult to implement, coupled with cultural reasons. There is a hierarchical social pattern in Asian culture whereby doctors are placed at a higher societal stratum (Claramita, Nugraheni, van Dalen & van der

Vleuten, 2013) and patients tend to consign their healthcare decisions to HCPs. Furthermore, patient healthcare decisions are also strongly influenced by their families and communities in Asian society (Ruhnke et al., 2000). Patients in public health facilities may feel they do not have control over their health decisions as they only pay a nominal fee (i.e.'I get what I pay for'). In addition, they do not have much freedom to choose the HCP they want. The insulin PDA implementation may be deterred by doctors who may not wish to offer patients a choice as it is considered a good practice to initiate insulin in patients with T2DM who are unable to achieve glycaemic control despite taking maximal oral medications.

Nevertheless, Asian studies have shown that many patients preferred an autonomous (active and shared) role in decision-making (Hou, Pang, Lu, Xu, & Zhou, 2014; Sekimoto et al., 2004). Thus, to facilitate the use of PDAs, the concept of SDM needs to be promoted among HCPs and patients in developing countries. Zhang et al., (2006) highlighted that one way to increase patient involvement in making treatment decisions is to increase healthcare professionals' knowledge about this concept (Zhang et al., 2006). HCPs also need to be trained on respecting patients' autonomy and on engaging with patients in making decisions about their health care. The Ottawa Patient Decision Aids Research Group has created continuous education such as online tutorials, interactive workshops, performance feedback and structured protocols in providing decision support (The Ottawa Patient Decision Aids Research Group, 2015). Efforts are also needed to empower patient to be more involved in their healthcare, and one way to do that is to conduct public health campaigns (Ng et al., 2013). Among other proposed strategies was to promote SDM in clinical practice, however, at the macro level in Malaysia are the following: (a) incorporation of SDM in clinical practice guidelines, (b) advocating the use of PDAs or other decision support tools in patient care, (c) inclusion of patient involvement in decision-making as a quality indicator and (d) payment/reimbursement for practices which implement SDM or use PDAs (Ng et al., 2013).

4.2.4 Language

For PDAs to be implemented effectively to facilitate the SDM process, communication between HCPs and patients plays a major role. In a multiethnic country such as Malaysia where the national language is Malay, some ethnicities may not be fluent in this language. Thus, doctors and patients may be mismatched linguistically which can lead to ineffective communication that can hamper SDM (Peek et al., 2010). Language barrier has been noted to limit interaction and served as a major obstacle for HCPs to deliver health information to patients (Vimala & Omar, 2016). In fact, video PDAs have been shown to be effective in increasing knowledge among patients with varying language proficiency (Volandes, Ariza, Abbo, & Paasche-Orlow, 2008) and many PDAs are available in various languages to patients of different ethnic and cultural backgrounds. However, in this study, participants still brought up the language barrier despite being informed that the insulin PDA booklets are available in several languages. The HCPs were unsure how to discuss the insulin PDA with patients who uses the PDA in a language that they are not familiar with. This is a positive finding as it may reflect participants' understanding that PDA implementation is not only about getting patients to use the PDAs them but involves implementation of a true dialogue and SDM attributes, values and preferences between doctor and patient.

In fact, the issue of language barrier in PDA use is similar to the issue of language barrier to effective health care provision in practice and perhaps similar strategies can be employed. Among the strategies proposed to overcome the issue of language barrier in medical consultations were employing a diverse or bilingual healthcare workforce and using ad-hoc or professional interpreters (Li, Pearson, & Escott, 2010), however, these are limited solutions to fully address the issue of language discordance between HCPs and patients as miscommunication may still occur due to HCPs' linguistic and cultural competence in English and the minority language (Baker, Parker, Williams, Coates, & Pitkin, 1996; Haffner, 1992). The use of professional interpreters has always been endorsed as they are related to a higher quality of care (Flores, 2005), however, supporting patients to use decision tools through interpreters was found to be challenging. In a study which assessed how a PDA for osteoarthritis was used in clinical encounters with the presence of a professional interpreter, it was found that patients had little involvement in discussion of treatment options with an average of only four words articulated when they had an opportunity to speak. The discussions on treatment options were mainly between the clinician and the interpreter. The interpreters also seemed to alter the information that was communicated to patients as well as from patients to clinicians (Wood, Phillips, Edwards, & Elwyn, 2017). Professional interpreters or translation services are costly and cannot be afforded by healthcare institutions with low resources. The Malaysian public healthcare settings are devoid of such services and HCPs mainly rely on ad-hoc interpreters such as patients' family members, relatives, or their colleagues to help with interpreting information to patients (Vimala & Siti Zobidah, 2016). The use of family members as interpreters has largely been discouraged in the literature as family members lack medical context, vocabulary, may misinterpret key concepts, filter information, or intervene in the assessment and treatment process. In addition, there are also issues with confidentiality and privacy (Fatahi, Mattsson, Lundgren, & Hellström, 2010; Ho, 2008). A study showed that in interpreted medical consultations, family members imposed their own agenda (vs. the patient's one) and controlled the consultation process (Leanza, Boivin, & Rosenberg, 2010; Rimmer, 2020). Nevertheless, as much as family members are discouraged to be interpreters, the use of ad-hoc interpreters would be inevitable in health care until professional interpreter service is provided. Ho (2008) has argued that using family members as interpreters should not be completely rejected as their close bonds with patients rendered them as the patient's advocates, and decision-making unit (Ho, 2008). Some patients prefer their family members to interpret for them as they felt a sense of security and trust (Ho, 2008; Kuo & Fagan, 1999). In many countries in Asia, family members or relatives play a significant role by providing emotional support, facilitating communication and decision-making, and overcoming the language barrier in primary care consultations (Andrades, Kausar, & Ambreen, 2013). This can also be seen in the Malaysian healthcare setting whereby patients seek advice from family members and they play a significant role in patient health decision-making (Ambigapathy, Chia, & Ng, 2016; Lee, Low, Lee, & Ng, 2015). Therefore, perhaps family members can be involved as interpreters for PDA implementation when language barrier exists between HCP and patient.

4.2.5 Literacy level

In this current study, patient inability to use the insulin PDA due to low literacy and health literacy levels was also brought up by the Phase 1 participants as a potential challenge to its implementation. This view is not unfounded as it was reported in 2015 that only 6.6% of Malaysian adults have adequate health literacy in 2015 (Institute for Public Health, 2015). A review showed that that patients with lower health literacy are less able to use PDAs effectively and have less desire to engage in SDM (McCaffery et al., 2013). On the other hand, patients' low health literacy level may also affect HCPs in selecting patients who they think would most likely benefit from using a PDA (Graham et al., 2003; Rees, Shaw, Bennert, Emmett & Montgomery, 2009).

Indeed, patients will have difficulty using PDAs if they are unable to read or understand the information (Engelen, Vanderhaegen, Van Poppel & Van Audenhove, 2017). Nevertheless, patients' involvement in SDM and PDA use is still possible by changing the format and delivery of PDAs. Computer or web-based PDAs allow the use of information and communications technology, thus, incorporation of animation, videos, and audio-visual aids may enable patients with low health literacy to understand information better (Ng, Lee, Lee, & Abdullah, 2013). The use of images in video PDAs have been shown to help reduce decision uncertainties among patients with lower objective health literacy (Volandes, Barry, Chang, & Paasche-Orlow, 2010). In another study comparing a computerised entertainment-based PDA to an audio-booklet PDA, patients with low health literacy who were exposed to the former showed lower decisional conflict and greater self-advocacy such as mastering and obtaining information about screening compared to those who were given the audio-booklet (Volk et al., 2008).

Patients have voiced that they want someone to give them straightforward aid in PDA using plain language, and want the information delivery to be tailored to individual patients in terms of the information levels (Crothers et al., 2016). It was also suggested that HCPs should deliver PDAs rather than non-medical personnel to facilitate patients with low literacy levels (McCaffery et al., 2013). HCPs need to be aware that patients with low literacy or limited education would benefit most from PDAs (Munro et al., 2019) as it can improve their knowledge and increase their involvement in health decision-making. Patients should not be excluded from PDA use based on their low literacy. Furthermore, many PDAs were developed using plain language at grade 8 level or less (Yu et al., 2019) as recommended in the International Patient Decision Aids Standards guideline, including the insulin PDA (Lee et al., 2012). In Malaysia, adult (15+) literacy rate is at 95.9% (Ministry of Education Malaysia, 2018) hence it is rare that a patient with type 2 diabetes would not be able to read or write at all. Indeed, there are patients who are truly illiterate such as those who are of much older age group and are usually accompanied by family members to their medical consultations. Similar to the strategy of overcoming the language barrier as discussed above, perhaps involving family members can engage patients in SDM and PDA use.

4.2.6 PDA cost

In PDA implementation literature, very few studies discuss patients' willingness to pay for PDA use. However, in this study, the cost of the insulin PDA was noted as a concern. HCP participants in Phase 1 opined that patients generally would not be willing to pay to use the insulin PDA. This was also found among patients in another study with the reasons being that there is free information on the Internet, patients can directly ask their physicians, they did not see the PDA being applicable to their clinical situation, and expected the PDA to be part of standard medical care (Bozic et al., 2014). Patients who were willing to pay saw the value of PDAs in providing continuity of care and empowering them to make decisions (Bozic et al., 2014). It is important to consider the cost for patients when implementing the PDA. In Malaysia, 72.7% of patients reported to be unwilling to pay for drugs in primary care clinics (Puteh, Ahmad, Aizuddin, Zainal, & Ismail, 2017). If patients are unwilling to pay for needed medications, it is also unlikely that they would pay for the insulin PDA. To address the cost barrier, PDA developers can explore migrating from booklet to web-based PDAs which are easier and cheaper to update. Furthermore, mobile Internet penetration is high even in underdeveloped or developing countries, thus facilitating access to web-based PDA for patients (Liew et al., 2009).

4.2.7 Reminders

One of the facilitators for PDA implementation brought up by Phase 1 participants of this study was a reminder network. High patient load and the need to perform various tasks during consultation may cause HCPs to forget about using the insulin PDA. The use of EMR or an information technology system was noted as an effective reminder platform to implement SDM and PDA; for example, they can be used to identify eligible patients for PDAs (Légaré & Witteman, 2013) before their clinic visit, and to prescribe PDAs and to cue for PDA use (WHO, 2012). While HCPs have reported they are more likely to use the PDAs if they were reminded through EMR (Lin et al., 2013), some felt that an electronic, interactive PDA linked to a computerised reminder system may not necessarily be better compared to traditional paper resources because of technical issues.

The integration of PDA reminders into EMR will require technology support, which can be a significant barrier in some developing countries that are still using paper-based systems (WHO, 2012). If technology cannot be adopted to facilitate implementation, peer support would be another useful reminder, which was also raised by participants in this study. For peer support to be effective, the working culture needs to be one that believes that the use of PDA is the preferred practice style. Efforts are needed to create awareness on the benefits of PDAs so that HCPs will be willing to use them. A physician champion plays an important role in creating awareness about the availability and the importance of PDAs, and to encourage the staff to use them; this has been reported as one of the key factors in the successful implementation of PDAs (Silvia & Sepucha, 2006). Another reminder that was raised was having posters and notices to promote the insulin PDA. Promotional brochures placed at exam rooms have been implemented to increase patients' interest in PDAs (Lin et al., 2013; Uy, May, Tietbohl & Frosch, 2014). However, one study found that while posters prompted discussions about PDAs, it did not significantly lead to physicians prescribing PDAs to patients (Uy, May, Tietbohl & Frosch, 2014). More studies are needed to look at how effective it is having promotional materials such as posters or notices to help HCPs remember to use the PDAs as well as for patients to initiate discussions with HCPs about PDAs. Ultimately, HCPs and patients need to be aware that long-term patient engagement in self-management for chronic conditions like diabetes is crucial in improving diabetes control and outcomes. This would then obviate the need for reminders. The use of PDAs should be integrated into the training on longitudinality of care whereby HCPs and patients be made aware that insulin is an option as diabetes progresses and that PDAs are available to help them make this decision.

4.3 Development of intervention

4.3.1 Systematic approach to intervention development

In this current study, the intervention development for the insulin PDA implementation consisted of five steps: (a) conducting FGDs and IDIs with various clinic stakeholders to explore barriers and facilitators, (b) prioritising barriers using the multivoting technique, (c) identifying and mapping of strategies to specific barriers, (d) operationalising strategies, and (e) finalising the intervention through a clinic stakeholder meeting. The steps taken in this study, namely barrier identification, mapping of strategies to barriers, theory use, and engaging stakeholders were also commonly found in many other intervention development efforts and these steps were considered fundamental when designing a tailored intervention (Colquhoun, Squires, Kolehmainen, Fraser, & Grimshaw, 2017). Other steps done by other studies but not in this current study were the systematic process of selecting an implementation framework (Ross et al., 2018), formation of a clinic or implementation team (Lewis, Scott, & Marriott, 2018; Vogel et al., 2016), conducting a predictive study to identify variables that could predict behavioural intention so appropriate behavior change methods can be selected (Foy et al., 2007), defining performance objectives or target behaviours or change such as studies that used the intervention mapping approach (Foy et al., 2007; Porcheret et al., 2014; Schmid, Andersen, Kent, Williams, & Damush, 2010; Taylor, Lawton, Slater, & Foy, 2013), conducting mixed-methods analysis (Kourouche, Buckley, Van, Munroe, & Curtis, 2019; Lewis, Scott & Marriott, 2018), and pre-testing the intervention before implementation (van Bokhoven, Kok, & van der Weijden, 2003).

It is important to consider the steps that need to be done for intervention development as each additional step would add to the complexity of the development process such as burden to stakeholders, and the resources and time needed (Chandler et al., 2014; Lewis, Scott & Marriott, 2018; McEachan, Lawton, Jackson, Conner & Lunt, 2008). Powell et al., (2017) proposed the use of concept mapping, group model building, conjoint analysis, and intervention mapping for intervention development. While these methods are highly participatory and provide concrete steps for facilitating selection and tailoring of strategies, however, these methods also required training and methodological consultation as methods such as group model building and concept mapping involve methematical modelling and the use of proprietary software (Powell et al., 2017). Modifications of conjoint analysis and the intervention mapping approach were found in some studies to lower costs, increase accessibility of the participation of the stakeholders in the process (Lewis, Scott & Marriott, 2018), and reduce complexity for intervention development (Kwak et al., 2007).

Albeit various steps to develop an intervention were reported in many studies, it is hard to tell which step or process (a combination of steps and their sequence) is more superior to others. Each of these step or processes has its own merit in terms of leading to a more robust intervention being developed. Nevertheless, in this current study, the entire development process of the insulin PDA intervention was relatively low cost, simple, pragmatic, and not overly burdensome to stakeholders; hence making it potentially replicable in other resource-constrained settings. The multivoting exercise (prioritisation of barriers) and the clinic stakeholders meeting (finalisation of the intervention) incurred a time cost of approximately three hours. Clinic stakeholders were engaged formally twice during these two sessions without incurring too much burden on them.

To inform future intervention development processes, there is a need for more studies to report about their development process, provide explanations for steps undertaken, report on the acceptability and feasibility of the process among researchers and stakeholders, if the barriers and strategies uncovered were accurate and comprehensive, as well as cost evaluation so that comparisons can be made between processes to identify which is more feasible and effective for a particular context.

4.3.2 Approaches to identifying barriers

One of the key questions surrounding the prospective identification of barriers and facilitators for tailoring intervention is how barriers and facilitators can be comprehensively and accurately assessed (Powell et al., 2019). In this study, the barriers and facilitators to the insulin PDA implementation was prospectively identified using IDIs and FGDs to investigate factors influencing the insulin PDA implementation that are relevant to the Malaysian context. Many of the prospective barriers and facilitators that emerged in this current study matched with those reported in the literature. Nevertheless, there were also some that were unique or more prominent in this current study setting, as discussed above. The general positive outcomes of the insulin PDA implementation such as the high 'Reach', 'Adoption', and 'Maintenance' suggests that the barriers that were prospectively identified in this study were relevant. Nevertheless, there were some barriers that emerged post-implementation that were not identified pre-implementation namely 'Perceived adequate knowledge about diabetes and insulin' and 'Patient non-use of the insulin PDA'. However, these two barriers could have been difficult to identify until after the insulin PDA was implemented.

The use of a combination of methods have been suggested to identify prospective barriers and this includes the conducting brainstorming sessions supplemented with structured group discussion and one additional method (e.g., interviews of HCPs, interviews of patients) to identify a high number and important determinants (Krause et al., 2014). However, selecting the number and the types of methods has time, resource, and cost implications and must be considered carefully when identifying barriers (Hanbury, Farley, & Thompson, 2015). In one study, using more than one method was not necessarily more useful. In that study, a pre-survey and FGDs were utilised to identify barriers, facilitators, and strategies to implement maternal and perinatal health guidelines at four lower income countries. The pre-survey obtained understanding on the key priorities to the guidelines and factors affecting its uptake in each country. FGDs were subsequently conducted to further identify the priorities, barriers, and facilitators to the guideline implementation. The findings from the pre-survey were presented to the participants to provide additional information for consideration prior to the FGDs. The authors of the study highlighted that while the survey was useful in informing discussions, they felt that the diversity of the various stakeholders in the FGDs was a more important determinant for success (Vogel et al., 2016).

The issue of unanticipated barriers that emerged following implementation highlighted in this study suggested that perhaps pre-testing the implementation of the innovation can be carried out with a pilot group before rolling it out to the entire clinic (van Bokhoven, Kok & van der Weijden, 2003). Nevertheless, it should be noted that barriers are constantly changing in real-world implementation, hence, the importance of ongoing monitoring and iterative adaptations over time which has been highlighted as an important element for sustainability in the Knowledge to Action Framework (Graham et al., 2006). More research is needed to examine the relationship between employed approaches and the findings on the barriers to determine if the methods adopted were adequate in generating comprehensive and relevant barriers.

Eventhough the utilisation of IDIs and FGDs were unable to comprehensively explore all the potential barriers to implementation in this study, nevertheless, they should be included as one of the methods for barrier identification as they can help to explore barriers within the context of specific settings and provide a rich picture (Baker et al., 2015). Questioning and probing the clinic's HCPs and patients during FGDs and IDIs helps to understand how the barriers and facilitators would manifest at the UMMC primary care clinic. Furthermore, conducting interviews at implementation sites also provided opportunity for rapport building with clinic staff and increased their buy-in to the implementation (Curran, Mukherjee, Allee, & Owen, 2008).

4.3.3 Simplifying the barrier prioritisation process

In this study, a relatively easy and simple approach namely the multivoting technique was selected to prioritise the list of barriers identified in Phase 1. Relevant clinic stakeholders and patients focused on identifying the most important barriers to the insulin PDA implementation in a two-round voting process during a 3-hour meeting. The use of the multivoting approach provided a systematic and democratic process of reaching key barriers that need to be overcome compared to methods adopted in other studies whereby barriers were prioritised based on the ones that were most commonly brought up during FGDs (de Visser et al., 2018) and discussions among the research team (Go et al., 2016).

Prioritisation may be based on various priority criteria such as the impact of problem, size of the problem, urgency of solving the problem, availability of solutions, availability of resources, and, cost and/or return on investment (Public Health Foundation, 2010). However, in this study, the participants were only asked to vote for barriers they thought would most likely hamper the insulin PDA implementation. Other studies reported to use more than one prioritisation criteria. In a study to prioritise barriers associated with implementation of clinical care elements for acute stroke management, HCPs and bed managers were asked to rank barriers in relation to their perceived influence of the barriers in preventing the performance of the clinical care elements (influence attribute) and perceived difficulty in overcoming the barriers (difficulty attribute) (Craig et al., 2017). In another study on the implementation of guideline recommendations for polypharmacy in multimorbid patients, barriers were prioritised based on ‘relevance’ and ‘modifiability’ (Jäger, Szecsenyi, & Steinhäuser, 2015). When there is a large number of barriers present and participants are required to think of barriers against one or more criterion, it can be an overwhelming and exhausting process. In Aakhus, Oxman, & Flottorp’s (2014) study, 352 determinants were identified and then prioritised based on ratings on the importance of the determinant (plausibility) and the extent to which the determinant could be addressed (feasibility) by the researchers (Aakhus, Oxman, & Flottorp, 2014). While this approach was feasible to be conducted by the researchers themselves, it might be harder to execute with participants if there is a limited time to carry out the prioritisation exercise. More importantly, participants might feel fatigue when there is a large number of determinants involved resulting in the possibility of identifying inaccurate key barriers (Aakhus, Granlund, Oxman, & Flottorp, 2015).

A drawback of using two criteria for barrier prioritisation was also highlighted in another study. In that study, barriers were ranked based on the attributes ‘Influence in preventing behavior change’ and ‘Difficulty to overcome’ and, barriers perceived as ‘High influence; and ‘Easy to overcome’ were categorised as highly desirable. However, prioritisation may be difficult for barriers that did not fall into clear distinctions, for example, barriers that were perceived as ‘quite high’ influence and ‘easy’ to overcome or ‘high’ influence but ‘quite difficult’ to overcome. To prioritise barriers that fall into these categories, there is a need to know how important the barrier is in relation to its difficulty to overcome and thus would require further input from implementers in the clinical settings (Craig et al., 2017).

In some studies, barriers were prioritised based on the participant's view on availability of solutions. However, one potential issue with this approach is that sometimes participants may not be aware of the existence of a potential solution that can address a particular barrier hence the barrier may be thought as not amenable. In SDM implementation, barriers such as old age, ethnicity, and education level were often thought as being non-modifiable, however, these barriers can be linked to attitudes and prejudices that can be addressed as well as provision of alternative strategies (Joseph-Williams, Elwyn, & Edwards, 2014). For example, patients who are of old age who believe that they should not challenge clinicians (Bastiaens, Van Royen, Pavlic, Raposo, & Baker, 2007) may be addressed by patient activation strategies (Shepherd et al., 2011). Older people with dementia can be addressed by providing different design, format, and delivery style of PDAs (Bilodeau et al., 2019). This was one of the reasons why the participants of this study were only asked to focus on prioritising barriers based on the influence attribute that would prevent the insulin PDA implementation. The researcher selected the strategies to overcome the barriers based on literature review as well as taking account of the proposed strategies from Phase 1 participants and the clinic context.

4.3.4 Stakeholders engagement in mapping implementation strategies

In this study, the initial process of identifying and mapping of strategies to the prioritised barriers was conducted by the researcher and the draft intervention was later presented to the clinic stakeholders for refinement. This approach was also found in another study, which aimed to implement a diabetes digital health intervention in the UK NHS (Ross et al., 2018). In some other studies, an expert panel or relevant stakeholders were directly involved in identifying strategies and mapping them to barriers (Ezeanolue et al., 2016; Go et al., 2016; Huntink et al., 2014; Lewis, Scott & Marriott, 2018). However, involving relevant stakeholders in mapping strategies to barriers was challenging due to the lack of understanding of strategies or familiarity with the implementation context. In the study to identify effective strategies to integrate methadone maintenance therapy and HIV service in Vietnam, the difference in familiarity of context and strategies between the Vietnamese stakeholders and the implementation science experts affected scoring of the strategies as the stakeholders were unfamiliar with the strategies while the implementation science experts expressed that they lacked context-specific knowledge (Go et al., 2016). When selecting strategies to address barriers, it is important to understand the knowledge of both the organisational and cultural context as well as knowledge of the strategies and their effectiveness is understood. Some studies addressed clinic stakeholders' lack of awareness and familiarity with strategies by presenting strategies identified in the literature to them and letting them select what they favour or as a stimulus to create new strategies that would be more context-appropriate (Huntink et al., 2014; Jäger, Szecsenyi & Steinhäuser, 2015; Lewis, Scott & Marriott, 2018). However, as alluded above, there may be a risk of information overload during the process that may render ineffective strategies mapped to barriers. Although the identification and mapping of strategies to barriers in this study was conducted by the researcher without involving the clinic stakeholders, one study has shown that the types of strategies generated by different stakeholders (healthcare researchers, healthcare professionals, quality improvement officers, healthcare authorities such as insurers or healthcare purchasers) for implementing evidence-based practice were similar (Huntink et al., 2014). Coupled with the literature review conducted on the effectiveness of strategies as well as informal observations and conversations with clinic staff, the researcher was well equipped with knowledge of strategies and the clinic context that enabled the identification and mapping of strategies to barriers to be performed with considerable rigour.

While the clinic stakeholders in this current study were not involved in the initial process of selecting and mapping of the strategies to the prioritised barriers, nevertheless, their input on potential strategies that can be adopted (findings from phase 1) was taken into consideration. Furthermore, the draft intervention that was developed was also discussed with the clinic stakeholders and then refined based on their suggestions during the clinic stakeholders meeting. Using the findings of proposed strategies by participants in Phase 1 for intervention development was a practical strength and an efficient approach as it took into considerations the strategies and processes that were likely to be feasible to be implemented in the setting as well as helped to reduce the cost in terms of the need to regularly engage clinic stakeholders in the strategy-barrier mapping process, which could be resource intensive (Taylor, Lawton, Slater & Foy, 2013).

4.3.5 Patient involvement in intervention development

Patient involvement in the process of development of intervention in implementation research was found to be lacking (Ahmadian, Khajouei, Nejad, Ebrahimzadeh, & Nikkar, 2014; Craig et al., 2017; El-Harakeh & Lotfi, 2020; Fretheim, Oxman, & Flottorp, 2004; Ross et al., 2018; van Helvoort-Postulart et al., 2009). One of the reasons may be that implementation research focuses on understanding and changing HCPs’ behaviours as opposed to patient behaviours (Nilsen, Ståhl, Roback, & Cairney, 2013). Nevertheless, this current study involved patients throughout the intervention development process to ensure their perspectives were taken into consideration so that the insulin PDA would be better received among patients. It has been pointed out that patients' literacy levels and skills (Jimbo et al., 2013), age (Silvia, Ozanne, & Sepucha, 2008), language, ethnicity, culture (Uy, May, Tietbohl & Frosch, 2014), resources (Jimbo et al., 2013), attitude towards participation in decision-making and use of PDA (Graham et al., 2003; Silvia, Ozanne, & Sepucha, 2008; Uy, May, Tietbohl & Frosch, 2014) are potential barriers to PDA implementation. Hence, focusing only on HCPs' perspectives of barriers and facilitators to implementing PDAs may be inadequate when designing implementation strategies and it may be necessary to consider patients' perspectives.

The feedback provided by the patients in this study were similar with patients from other studies related to PDA implementation, such as the need for HCPs’ to guide patients in making decisions rather than leaving it solely to them (Bhavnani & Fisher, 2010; Crothers et al., 2016), the importance of HCPs to explicitly explaining the PDAs' objectives and benefits, the need for HCPs to motivate patients to use the PDA (Newsome, Sieber, Smith & Lillie, 2012), unwillingness to pay for PDA use (Bozic et al., 2014) and time constraint barrier to PDA use during consultations (Crothers et al., 2016; Engelen, Vanderhaegen, Van Poppel & Van Audenhove, 2017; Stapleton, Kirkham & Thomas, 2002). These findings shed light on topics to engage patients so they can provide feedback for the intervention development process.

In a study aimed at identifying and prioritising barriers to implementation of clinical practice elements related to the area of strokes, various stakeholders that included physicians, nurses, speech pathologists, and bed managers were asked to ranked barriers that were only related to their area of clinical practice (e.g.: speech pathologists were asked to rank barriers related to swallowing while nurses ranked barriers for targeted behaviours relevant to them) (Craig et al., 2017). However, in this current study, the patients were also asked for their opinions related to HCPs, organisational and system domains during the IDIs in Phase 1. Furthermore, apart from voting for barriers on patient domain in the multivoting exercise, they also voted for barriers from the HCP and organisational domains that they felt could hamper the insulin PDA implementation. Patients noted that the insulin PDA implementation might be challenged by HCPs who wants to finish their work quickly (HCP factor), other competing programmes in the clinic, and the lack of rooms (organisational barrier). This indicates that there is value in getting patients to provide opinions relating to other implementation determinants eventhough the determinants are not directly related to them. Patients recruited in Phase 1 and phase 2 of this study had been seeking diabetes treatment in the clinic for 9-10 years. Their vast experience may have enabled them to make observations on the running processes in the clinics. Therefore, when seeking feedback from patients on implementation, the discussion topics should not be confined to areas that are known to patients (e.g.: patient's ability to use the innovation) but their opinions on the clinic's resources and exploring HCPs working culture. Furthermore, it was found that the types of strategies suggested by patients or their relatives do not differ from those of researchers, HCPs, and quality officers so they can contribute significantly to intervention programmes (Huntink et al., 2014).

However, it should be noted that there were only three patients who participated in the Phase 2 barrier prioritisation exercise and two in the clinic stakeholders meeting, respectively. The composition of the various stakeholders in a meeting can affect the representativeness of the findings; i.e., when HCPs outnumber patients, it renders clinicians more visibility and perhaps they are also more vocal in the design of the intervention (Iedema et al., 2010). There is a need for guidance on how to capture and identify the impact of the different views from various stakeholders in the intervention development process such as in a clinic stakeholders meeting. In this study, care was taken to ensure that every stakeholder had a chance to voice their opinions by posing questions related to their roles in the implementation. Furthermore, the patients that were invited in Phase 1 and Phase 2 were those who were able to provide feedback. Strategies that have been adopted by other researchers to increase patient engagement in improving quality of care were clarifying the objectives, roles, and expectations of the engagement for patients and carers, familiarising patients with the context and cultural issues, increasing patients' confidence and commitment to the engagement process, and maintaining their involvement throughout the process (Bombard et al., 2018).

4.4 Comparison of implementation outcomes of the insulin PDA implementation to other studies

This study aimed to find the best approach to implement PDAs in routine clinical practice using a tailored implementation approach. This is one of the few studies known to use the RE-AIM framework and included both qualitative and quantitative data to evaluate the impact of PDA implementation (Belkora et al., 2015; Matlock et al., 2020). The results of this study show that the intervention, which comprised of 11 strategies tailored to 13 prioritised barriers, led to a relatively high degree of reach and adoption among doctors albeit with lower reach and adoption among the nurses. Findings varied for different aspects of implementation of the insulin PDA. Patient adoption of the insulin PDA was only moderate. Nevertheless, the high proportion of doctors who were willing to continue using the insulin PDA in their practice as well as were willing to recommend the insulin PDA to colleagues suggests a positive outlook for maintenance. The following sections discuss the key findings and action points to increase each of the RE-AIM dimensions' uptake in this study.

4.4.1 Reach

4.4.1.1 To promote PDA implementation among HCPs, there is a need to use an organisational leader or influential physician to make personal invitations

In this current study, the insulin PDA implementation was promoted to clinic staff by the Head of Department through an announcement in a unit meeting as well as provision of official letters to all the doctors and nurses. 'Reach' to HCPs was found to be relatively high as indicated by the high attendance rate in the insulin PDA workshops among the doctors albeit nurses registered a lower attendance rate. This finding is comparable to the

Group Health SDM demonstration project whereby a high attendance rate was also observed where 90% of their clinicians attended the SDM training provided. This was attributed to the high priority placed on the training by the institution and specialty-service-line chiefs (King & Moulton, 2013). Other dissemination approaches carried out in other studies to create awareness and seek HCPs' interest to implement the PDAs were making phone calls and sending emails (Feibelmann, Yang, Uzogara, & Sepucha, 2011; Frosch, Singer & Timmermans, 2011; Silvia, Ozanne, & Sepucha, 2008; Silvia & Sepucha, 2006). In one study, a nurse coordinator was appointed at each implementation site and was responsible for approaching physicians and nurses personally to get them to participate in the SDM programmes resulting in 97.1% of the HCPs participating (Holmes-Rovner et al., 2000). However, in the study by Frosch, Singer & Timmermans (2011), which aimed to recruit community primary care practices to implement cancer screening PDAs, practice recruitment rate was only at 6%. One of the reasons was the lack of involvement of an influential physician to help with the recruitment process as the study appointed a research assistant to perform the task (Frosch, Singer & Timmermans, 2011). These findings together with the findings of this current study highlighted that using an organisational leader or influential physician to make personal invitations (i.e. individualised letters, personal face-to-face meeting) is an important facilitator to promote PDA implementation among HCPs.

4.4.1.2 Self-motivation plays a major role for effective reach of PDAs among HCPs

This current study highlighted doctors' self-motivation as the main contributing factor for effective reach of the insulin PDA. One reason could be the fact that doctors in this study were family medicine trainees who were undergoing specialty training at an academic primary care clinic hence they were more receptive to learning and implementing new innovations embedded in a research-focused environment. Community doctors may not have the same level of interest (Frosch, Singer &

Timmermans, 2011) as time constraints, heavy workloads and a lack of resources were often reported as barriers to programme participation (Asch, Connor, Hamilton, & Fox, 2000; Silvia, Ozanne, & Sepucha, 2008).

Another PDA implementation study reported that clinicians' receptiveness to SDM was due to their understanding of patients' burden in making a preference-sensitive decision and the need to prevent patients from making a decision that they would regret later (Matlock et al., 2020). This may also explain doctors' inherent self-motivation in this current study to participate in the PDA implementation given they understand the complexities of insulin decision-making.

4.4.1.3 HCPs' attendance in training workshop is an important facilitator for PDA implementation

The benefits of training workshops in facilitating PDA implementation is well established, however, another important related issue is HCPs' inability to attend them. This was found in this current study where the insulin PDA training workshops were conducted on Tuesday afternoons as it was the most suitable time since HCPs and clinic staff were free from clinic duties. However, some HCPs were unable to attend for various reasons. Similarly, for the Group Health SDM project, full attendance was not achieved despite rearranging the operating room schedule to permit its surgeons to attend a half-day SDM training session (King & Moulton, 2013). It is important to note that many other programmes and meetings were also planned on Tuesday afternoon at the UMMC primary care clinic, hence the insulin PDA implementation was competing with others for a suitable date and time to conduct their activities. This was also one of the reasons why the second insulin PDA training workshop, which was supposed to be held in June due to doctor's turnover in the clinic could only be carried out in August. Not only that, a majority of the nurses were unable to attend the second insulin PDA training workshop as it coincided with the nurses' meeting that the nurse officer had planned.

When HCPs did not attend the training workshop, they may not be motivated to use the innovation as they do not know what it entails or they fear misusing it as indicated by the findings of this current study. A similar issue was also reported in the study of implementation of PDAs at four urology departments of the NHS Hospital Trusts. As part of its implementation intervention, a face-to-face training by a SDM expert was provided to teach nurses on the concepts of decision support and decision quality, the role of PDAs and development of skills in providing decision support. However, due to staff availability and budget constraints, the training was only conducted as a single day event. As a result, not all the nurses who were responsible for the implementation were trained due to the timing and training location. Furthermore, the training did not specifically relate to the PDAs nor focused sufficiently on practical implementation issues thus their benefits were not maximized (Wirrmann & Askahm, 2006). Training workshop are a crucial component of any implementation endeavor as it helps to create awareness on the innovation and imparts the knowledge and skills required for HCPs and clinic staff to perform the implementation tasks. Studies have reported a lack of training to be contributing factors to lack of engagement of patients in SDM and proper use of PDAs (Hahlweg et al., 2019; Lin et al., 2013). The importance of training is well evidenced and it should be a pre-requisite for PDA implementation (Légaré et al., 2012). There is a need for strategies to ensure that HCPs who are responsible for PDA implementation attend training workshops.

4.4.1.4 Delivery of PDA to patients by doctors is inevitable in resource-constrained setting but could lead to a modest degree of reach of the PDA to patients

It is well established that PDA delivery to patients that relies only on physicians is not effective for various reasons such as time constraints, clinicians' attitude, forgetfulness, and infrastructure barrier which lead to lower rates of patients receiving one (Brinkman et al., 2017; Conrad, 2011; Elwyn et al., 2013; Friedberg, Van Busum, Wexler, Bowen & Schneider, 2013; Frosch et al., 2011; Sepucha et al., 2016). Despite this evidence, this current study involved doctors to introduce and use PDA with patients at the point of consultation due to unavailability of diabetes educators or staff nurses in the clinic to deliver the insulin PDA prior to doctor's consultation. The fact that patients also expressed a desire for doctors to discuss matters related to insulin with them was another reason for adopting this approach. While the proportion of patients who were reached could not be determined in this study, there is a considerable number of patients who received the insulin PDA. The comparison of patient reach in this study to other studies is hard to be made due to many reasons such as the number of settings involved, the size of the setting, and the types and number of PDAs delivered. However, if a rough estimation is to be considered, the patient reach of this study based on average PDAs distributed per month is 55.2 and is slightly higher than the study by Lin et al., (2013) which reported 51.7 PDAs distributed by clinicians per month (Lin et al., 2013).

The lack of effectiveness of relying physicians to distribute PDAs to patients led to testing or implementation of innovative PDA distribution strategies such as patient-directed strategies (Sepucha et al., 2016), mailing-out PDAs to patients before their clinic visits (Brackett, Kearing, Cochran, Tosteson & Blair Brooks, 2010), and involvement of other individuals such as a dedicated staff to identify and give PDA to patients (Miller, Brenner, Griffith, Pignone & Lewis, 2012). The use of mHealth has been encouraged to facilitate PDA implementation given the many advantages that it can offer such as high accessibility to patients and, incorporation of visuals and interactive media that can help to provide better understanding to patients (Abbasgholizadeh Rahimi et al., 2017). In Malaysia, the use of mobile app to facilitate PDA implementation may be considered given that mobile penetration is high in Malaysia as the percentage of Internet users at national level is 87.4% in 2018, and, nine out of ten Internet users used smartphone (93.1%) to go online (Malaysian Communications and Multimedia Commission, 2018). Therefore, the insulin PDA may be able to reach a large proportion of the Malaysian population. A study which developed a mobile application to support SDM on contraceptive counselling found that it helped HCP and patient to have a more focused discussion, provided reassurance to women on their choices and increased their confidence (Witkop et al., 2021). However, these strategies require a patient population that is familiar with the purpose of a PDA, and infrastructure and manpower that can support their implementation. Hence, in settings where utilising physicians to distribute PDAs to patients is inevitable such as in this current study, strategies that target the physicians is necessary. One way is incentivising PDA use, by motivating HCPs to be involved in the implementation and specifically making PDA use as an alternative means of informed consent to protect HCPs from ‘failure to inform’ lawsuit (Moulton & Pope, 2016). At the broader level, there is a need to inculcate SDM culture and PDA use among HCPs. HCPs need to understand their role in SDM in terms of providing quality information to patients and supporting patients in their deliberation of the treatment option. Hence, HCP training is warranted. Studies have reported that a lack of training to be a contributing factors to the lack of engagement from patients in SDM and the proper use of PDAs. In the Lin et al.’s (2013) study which reported a lower PDA distribution rate among physicians as compared to this current study, one of the reasons noted was the lack of communication and SDM skills training which was not extensively incorporated in the implementation intervention (Lin et al., 2013).

4.4.1.5 Patient-directed strategies should be incorporated in the implementation intervention to facilitate patients' receptiveness towards PDA

This current study found that the reach of the insulin PDA to patients was challenged by their acceptance towards their poor health and the lack of desire to consider new treatment options such as insulin. It should be noted that there were no patient-directed strategies employed in this current study despite the presence of patient barriers. Due to limited time and resources, this study undertook a parsimonious approach to intervention development, hence all the patient barriers in this study were addressed through HCP-mediated strategies; strategies provided to HCPs but aimed at mediating patients' attitudes, knowledge, skills, behaviours and/or health outcomes.

The current implementation work may be improved by incorporating patient-directed strategies such as patient-directed social marketing (Stevens, Thompson, Watson, & Miller, 2016), which is the use of mass media, interpersonal communication and message placement promotion, dissemination, and community level outreach to influence health behavior change (Evans, 2006). These approaches can help create awareness on SDM and PDA among patients and public (Lin et al., 2013; Uy, May, Tietbohl & Frosch, 2014) thereby making them understand the true purpose of PDAs which is to help them make informed decisions rather than swaying them to a particular treatment option. The use of posters, which were placed in clinics' exam rooms, were able to generate patient inquiries about the PDAs (Uy, May, Tietbohl & Frosch, 2014). Nevertheless, the effectiveness of social marketing on PDA uptake and patient participation in SDM has yet to be evaluated as many PDA implementation studies use this strategy as part of a multifaceted implementation intervention hence making its direct impact difficult to be evaluated (Stevens, Thompson, Watson & Miller, 2016).

4.4.2 Adoption

4.4.2.1 Comparison of PDA adoption in this current study with other studies

Doctor’s adoption of the insulin PDA in this study was relatively high (83.3%) thus comparing favourably with studies on the higher end of the adoption range, such as 91% in a study where HCPs provided decision support to callers facing cancer-related decisions at the Australian statewide call center (Stacey, Chambers, Jacobsen & Dunn, 2008). Another Stacey et al.’s (2015) study on the implementation of a cystic fibrosis lung transplant referral PDA at 18 clinics reported PDA adoption at 85% following a multifaceted intervention (Stacey et al., 2015). In contrast, in a cross-sectional study by Graham et al., (2007) whereby relevant PDAs were sent to 580 eligible HCPs to assess their perceptions, intention and subsequent use of the PDAs found that only 32% of them actually adopted the PDAs in the following three months via phone call follow-up (Graham et al., 2007). Low PDA adoption was also observed in the UK NHS Direct study whereby 57 HCPs from 22 clinics were asked to refer patients to web-based PDAs, but only 33.5% referrals were made out of the 1060 eligible patients who were eligible for the osteoarthritis knee, amniocentesis and breast cancer PDAs, (Elwyn, Rix, Holt, & Jones, 2012). One explanation for the high adoption rate in this current study and Stacey et al., studies compared to the other studies is the utilisation of the tailored implementation approach whereby barriers to adoption were addressed prior and during the implementation. HCPs in Elwyn, Rix, Holt, & Jones’s (2012) study reported that they did not refer patients to the web-based PDAs because of the lack of motivation to use the PDAs (Elwyn, Rix, Holt, & Jones, 2012). This barrier was also found in this current study but was addressed by the strategy ‘Inform HCPs on the advantages of the insulin PDA use’ which was delivered through the training workshop.

4.4.2.2 Perceived and experiential benefits of using PDAs are a major driver for PDA adoption

The adoption of the insulin PDA by the doctors in this current study was primarily driven by having a tool that helped them provide information to patients in their busy clinic environment as well as helping them to initiate insulin therapy discussion with patients. Doctors who did not attend the insulin PDA training workshop were also found to adopt the insulin PDA in their practice after learning its content of the insulin PDA themselves and perceived it to be useful. Perceived and experiential benefits of using PDAs have been well established as the key factors for PDA adoption (Alden, Friend & Chun, 2013; Brinkman et al., 2017; Matlock et al., 2020). In this current study, the strategy 'Inform HCPs on the advantages of the insulin PDA use' motivated the HCPs to implement the insulin PDA use in their practice. Indeed, provision of information about the innovation and its advantages is a logical approach when implementing any innovation, however, the way to operationalise this strategy to ensure that the effects are durable is needed. Hence, strategies to enhance HCPs' anticipated positive experience with PDA use should be developed. One study included role-play in their training whereby HCPs reviewed the SDM and PDA content, had the chance to critique the role modeling of the trainer and a simulated patient, and practised provider-patient scenarios in pairs. During the training, the providers were engaged and interested. Following the implementation of the SDM programme, 82% of responding providers reported using the PDA in SDM encounters (Holmes-Rovner et al., 2011).

4.4.2.3 Ongoing support for PDA adoption is warranted for continuous motivation to adopt PDA among doctors

This study also found that when doctors did not adopt PDA for a period of time due to reasons such as absence from the clinic, exam periods and holidays, they were less motivated to resume PDA use. This finding suggests that besides conducting training workshops at the time of doctors' turnover at the UMMC primary care clinic, regular SDM and PDA booster sessions that incorporates motivational support is needed. In Stacey et al.'s (2015) study, conference calls were provided for ongoing support at every three and six months during the first and second year of implementation whereby HCPs shared their experiences with the PDA use and discussed strategies to overcome implementation issues (Stacey et al., 2015). Another strategy is to embed SDM and PDA training into post-graduate residency or HCPs' ongoing training and personal development programme (Chen et al., 2016; King, Taylor, Williams & Vanson, 2013). This may help to foster SDM culture in the organisation and PDA use would be viewed as something that everyone does. To date, there are only few SDM trainings at an undergraduate level and even fewer at a medical residents level (Siyam et al., 2019).

4.4.2.4 Patients who did not read the insulin PDA negatively affected doctors' motivation to continue to use PDA

This study also found that doctors were demotivated to continue adopting the insulin PDA when they experienced that many of their patients did not read it. HCPs need to understand that SDM and using PDAs is not a one-off event as it may involve engaging patients in several discussions to understand their preferences and values. They should try to understand patients' reasons for not using the PDA and address the barriers. This indicates that the concept of SDM needs to be reinforced and continuous training is warranted as alluded above.

On the other hand, strategies to ensure patients read the PDA can be considered. Some studies have employed approaches whereby patients can self-screen and decide if they want to participate. This helps to ensure that only patients who truly want to participate in SDM use PDAs. At the Massachusetts General Hospital, patients can order PDAs by using order sheets created by staff, and medical assistants would place the orders in the

EMR. The PDAs would then be mailed to patients. This strategy enabled patients to select PDAs that they want and this led to an increased use of PDAs (Sepucha et al., 2016). At the University of North Carolina Internal Medicine Clinic, patients were asked to complete an electronic Patient Health Survey prior to their visit with the provider. The survey generated data that targeted a PDA to that particular patient's needs and they were asked if they wanted to receive the PDA in the clinic or by mail. From July 2010 to November 2010, 52% of 438 patients who were eligible for a PDA requested for one (Lewis et al., 2011). However, in the Malaysian settings, patient self-access to PDAs may be challenged by lack of awareness and familiarity with SDM and PDAs. In regard to the insulin PDA, some patients may not know that they require insulin as it is usually offered by doctors. This coupled with a negative perception towards insulin therapy may render this strategy as not effective. A more simple and useful approach is perhaps by simply getting HCPs to explicitly ask patients if they are interested to use the PDA. This approach can also prevent doctors from selecting patients who they think are more likely to use the insulin PDA. However, patients must first be informed why they need to be engaged in making the decision and understand that a preference-sensitive decision needs to be made (Politi, Dizon, Frosch, Kuzemchak, & Stiggelbout, 2013). In addition, HCP training on SDM communication skills in terms of preparing patients for SDM discussions is needed (Müller et al., 2019; Politi, Dizon, Frosch, Kuzemchak & Stiggelbout, 2013).

4.4.2.5 Patients' outcomes should be incorporated in feedback for HCPs to promote PDA adoption

This current study had adopted the strategy 'Provide feedback' to motivate HCPs to adopt the insulin PDA. However, this strategy was perceived to be the least effective compared to other strategies that influenced doctors to adopt the insulin PDA. The feedback report was effective to some degree, albeit in a negative manner as some of the doctors reported to feeling stressed as if they were being monitored and pressured due to their lack of performance compared to other colleagues. On the other hand, other studies reported positive effects of feedback that rendered HCPs' feeling motivated and contributed to increased sense of commitment to using the PDAs (Arterburn Westbrook, & Hsu, 2016; Hsu, Liss, Westbrook, & Arterburn, 2013; King & Moulton, 2013; Silvia & Sepucha, 2006). One of the reasons for the discrepancy between this current study and other studies lies in the content of the feedback. Other studies included patient positive feedback, satisfaction, knowledge and decision quality (Arterburn, Westbrook, & Hsu, 2016; Hsu, Liss, Westbrook & Arterburn, 2013; J. King & Moulton, 2013; Lloyd, Joseph-Williams, Edwards, Rix & Elwyn, 2013; Silvia & Sepucha, 2006). In this current study, feedback content mainly focused on doctors' PDA adoption rate and their adherence to implementation tasks. This might have rendered the doctors of this current study to feel as though they were being monitored, hence the feedback was not viewed as being constructive. This indicates that patient outcomes are more valued and should be incorporated in strategies involving provision of feedback in future PDA implementation studies.

In fact, this current study had included patient feedback in the first few feedback given. Due to the amount of time needed to transcribe patient interview recordings and analysis of transcripts, patients' feedback could not be generated in time to be included in all the monthly feedback reports and in the unit meetings. Researchers who are utilising the 'Provide feedback' strategy need to consider the time and resources needed to generate information in time for feedback delivery. The use of infrastructure technology such as the EMR and electronic patient portal can help facilitate collection of information in a timely and effective manner for evaluation and quality improvements. At the University of North Carolina Internal Medicine Clinic and the Dartmouth-Hitchcock Medical Centre, patients' PDA use information, treatment preferences, questions, and other decision-making data were captured in the EMR and this allowed physician to review the information prior to consultation (Andrews, Kearing, & Vidal, 2016; Berg, Collins Vidal & Clay, 2011; Lewis et al., 2011).

4.4.2.6 Delivery of PDA to patients by doctors facilitated patients' PDA adoption but can be improved by including reminders

There was a relatively high PDA viewing rate among patients in this current study and one of the reasons was because they were approached and asked to use the PDAs by doctors. Patients are more likely to accept and agree to use the PDAs when doctors deliver PDAs (Frosch et al., 2011; Lewis & Pignone, 2009). When compared to other PDA delivery approaches such as mailing the PDAs to patients, one study found that only 8% viewed the PDA (Lewis, Brenner, Griffith, & Pignone, 2008). While a mailing out approach reaches a greater number of patients (Brackett, Kearing, Cochran, Tosteson & Blair Brooks, 2010; Lewis & Pignone, 2009) compared to distribution by HCPs, getting patients to view PDAs using this approach may be hampered by patients who may not be comfortable in going through medical information by themselves at home (Brackett, Kearing, Cochran, Tosteson & Blair Brooks, 2010; Sepucha & Simmons, 2011), patients who are unfamiliar with PDAs, and patients who are not keen to accept new treatment options such as patients in this current study.

However, the patient PDA viewing rate in this current study is lower compared to Belkora et al.'s (2015) study whereby the patient PDA viewing rate was reported to be 82% (Belkora et al., 2015). The reason could be that, in Belkora et al.'s (2015) study, patients were called two to three weeks prior to their clinic visit to review the PDAs before they were involved in a question listing session with the pre-medical interns to come up with a question list for discussion two to three days before their consultation with doctors (Belkora et al., 2015). In this study, apart from asking patients to read the insulin PDA, there were no reminders for patients to use the PDA prior to their next clinic appointment and no formal instructions for doctors to inform patients that they need to complete the values exercise in the insulin PDA. Future improvements to the insulin PDA implementation should include strategies such as text or telephone reminder.

Nevertheless, the patient PDA viewing rate in this study is higher compared to another study, which registered PDA viewing rates of 56% and 32% for two PDAs. In that study, patients viewed the PDA in-clinic before or after their clinic visits on a portable DVD player (Miller, Brenner, Griffith, Pignone & Lewis, 2012). Patients in-clinic PDA viewing would be ideal as it makes it more likely for patients to use the PDA (Lewis & Pignone, 2009), however, it reportedly faced with logistical challenges. In the implementation of breast cancer PDAs at an academic center, patients were called to come earlier for their appointment to view a PDA before meeting their surgeons, however, many patients did not manage to do so as they had to go for medical scans (Silvia & Sepucha, 2006).

4.4.3 Implementation

4.4.3.1 Treating PDA use as part of patient management plan is a facilitator for PDA implementation

In this current study, the insulin PDA implementation process was streamlined into the existing patient care pathway and HCPs' work tasks. The findings show that adherence to implementation protocol varied for different tasks among the doctors. There was a higher fidelity towards tasks that were aligned with their routine work such as 'Making notes in the EMR' and 'Providing appointment to patients', compared to the task of 'Making note in patients' appointment cards' which was not something that they usually do thus they tend to forget. The qualitative findings revealed that some doctors treated the insulin PDA as a tool that is part of patient health care management and a majority of the insulin PDA given to patients was indicated in the EMR for follow-up. This finding is encouraging as it reflects that the insulin PDA was not likened to conventional informational materials that they give or refer patients to without the need for further discussions as found in another study (Newsome, Sieber, Smith & Lillie, 2012). Future insulin PDA implementation can be improved by using EMR such as at the University of North Carolina Internal Medicine Clinic whereby clinicians prescribe PDAs to patients using an electronic prescription form and the PDAs would be delivered to patients. The health information system in the clinic can also send patients' reported data and PDA use information to the EMR that can be reviewed by physicians prior to the patient's office visit (Lewis et al., 2011).

The purpose of getting doctors to make notes on patients' appointment card was to indicate that the insulin PDA was given to the patient and was the same with the step of 'Making note in the EMR'. Both were intended to reinforce one another in facilitating continuity of care by alerting doctors that they need to follow-up with patients on the insulin PDA in case they missed either one of the notes. However, the step of 'Making a note in the appointment card' was largely unsuccessful because the doctors were unaccustomed to this task. The doctors also questioned the need for this step since they had already indicated in the EMR that the PDA was given to patients. Furthermore, the notes that were to be indicated in the EMR 'Remark' section by appointment clerks based on the note made on patients' appointment card by doctors was also very low and this may be attributed to the fact that appointment clerks were not invited to the insulin PDA training workshop. They were not invited because they did not have a clinical role and the tasks of setting up appointments and making notes in the EMR were already part of their work routine. The lack of understanding of the importance of the insulin PDA might have affected how they performed their task. The appointment clerks were only informed of their tasks through a printed task sheet, which was delivered to them by the chief clerk prior to implementation.

Given the lack of effectiveness of the step on ‘Making a note on patients’ appointment card’, this step will be removed from the insulin PDA implementation protocol in the future. It can be expected that the removal of this step would not affect the insulin PDA implementation as it was perhaps superfluous to begin with.

4.4.3.2 The need to recognise nurses’ abilities and nurse role expansion to facilitate PDA implementation

Nurses’ task of ensuring the insulin PDA booklets in various languages were available in the consultation rooms was integrated with their job scope of refilling and maintaining stock of supplies in the clinic. However, the finding indicates that some insulin PDAs in specific languages were not available in some of the consultation rooms for up to two consecutive months and this suggests that they were not regularly replenished. While it was noted that some nurses were not aware of the need to refill the insulin PDA because they did not attend the insulin PDA training workshop, however, such could have been circumvented by individual feedback reports that were distributed to all the nurses in the clinic as well as feedback during unit meetings where nurses would also be present. Furthermore, the nursing officer also highlighted that she had reminded the nurses to replenish the insulin PDAs in the consultation rooms monthly through Whatsapp.

Based on the qualitative interviews with the nurses, it was found that not all of them share the same level of commitment for the insulin PDA implementation. While some nurses were dedicated to their task of refilling supplies in the clinic, there were also nurses who were reported to have poor attitudes and behaviors during the qualitative interviews. These nurses’ attitude contrasted with nurses’ from other PDA implementation studies who were found to be supportive of PDAs or decision support programmes and took initiatives to identify and offer PDAs to patients (Holmes-Rovner et al., 2000; Silvia, Ozanne, & Sepucha, 2008) and contributed to higher rates and better quality of PDA distribution.

The poor attitude of some of the nurses in this current study may be related to job dissatisfaction and work stress among nurses in Malaysia as highlighted in many studies, due to nursing staff shortage, heavy workload, and low remuneration (Alam & Mohammad, 2009; Atefi, Abdullah, & Wong, 2016; Ghawadra, Abdullah, Choo, & Phang, 2019). In the implementation of the enhanced primary care intervention in Malaysia, which comprised of nine interventions to improve management and clinical outcomes of type 2 diabetes and hypertensive patients at public health clinics, nurses were found to experience higher work stress compared to other HCPs, were the only HCP group that reported dissatisfaction due to the additional tasks that they had to carry out following the intervention, and felt that their job as a nurse was under-respected (Wong et al., 2020). Despite aligning the nurses' insulin PDA implementation task with their existing duty in this current study, the nurses might have viewed the task of refilling the insulin PDA as an additional burden. Coupled with the perception that the insulin PDA implementation is a research endeavour, this might have further fueled their disinterest of being involved.

Nurses in other studies have been reported to take on bigger tasks in PDA implementation such as facilitating a discussions to familiarise patients with the PDA (Scalia, Elwyn & Durand, 2017) and providing decision coaching before patients meet with clinicians (Berger-Höger, Liethmann, Mühlhauser, Haastert, & Steckelberg, 2019; Rahn et al., 2018). In this current study, staff nurses and diabetes educators were offered training to become decision coaches during the clinic stakeholders' meeting but this was turned down by the nursing officer and even the nurses themselves due to lack of staff, and perceived inadequate knowledge and skills in engaging in insulin initiation discussions with patients. In fact, at the UMMC primary care clinic, nurses are suitable to be trained in decision coaching because they have a role in providing patient education and counseling. However, not all nurses were involved in patient counseling and they were often given more functional tasks such as taking blood, injections or wound dressing. There is a need for a paradigm shift on the way of thinking about nurses' roles in patient care and this needs to start from leadership recognising nurses' abilities and giving them more responsibility for clinical decision making in patient care.

Notwithstanding, should the lack of clinic staff be the main reason for inability to exercise team-based approach for PDA implementation, employing approaches such as utilisation of pre-medical interns as found in the Belkora et al.'s (2015) study at the UCSF Breast Care Center (Belkora et al., 2015) can be considered. The Centre received an annual revolving of pre-medical interns who are recent college graduates applying to medical or related graduate programs. These interns worked at the centre for one to two years before leaving for their further studies. They were trained in a two-day workshop by the center's director on how to administer PDAs and communication aids to patients. New interns received supervision by departing interns during an overlapping period (Belkora, Teng, Volz, Loth & Esserman, 2011). Using pre-medical interns was sustained for up to seven years and has led to positive outcomes on all the RE-AIM domains (Belkora et al., 2015). This approach may be feasible at the current study setting as the UMMC primary care clinic receives recent medical graduates from its affiliated university, Universiti Malaya, since 2017 for the pre-houseman training programme. The training programme aims to improve medical graduates' knowledge and skills before they leave for housemanship at other public hospitals (Menon, 2017). Medical graduates who join the programme are attached to the clinic for two to six months, so they can be trained to provide decision coaching in the insulin PDA implementation. Alternatively, diabetes educators from non-governmental organisation such as the Malaysian Diabetes Educators

Society can be engaged (Malaysian Diabetes Educators Society, 2020). Volunteers from the National Diabetes Institute, which provides free counseling service to diabetes patients can also be trained to provide decision coaching (NADI, 2021). However, it should be noted that decision coaching is usually provided by HCPs (Stacey et al., 2012).

Another important finding that affected the insulin PDA refill in the consultation room is the unexpected involvement of medical assistants in performing nurses' tasks in the clinic, which was the reason why they were not included in the implementation process. This finding highlighted that an implementation setting cannot be treated as a static unit and that there is a need for constant monitoring of changes in the context so that timely improvements can be implemented.

4.4.4 Maintenance

A high proportion of doctors indicated their willingness to continue to use and recommend others to use the insulin PDA following the seven-month implementation period due to the benefits of the insulin PDA in providing information to patients. This is encouraging to further efforts to improve the insulin PDA and SDM implementation at the UMMC primary care clinic. There are reasons to believe that the insulin PDA can be sustained as findings such as clinician support and perceived positive contribution of the PDA to patients and practice (Feibelmann, Yang, Uzogara, & Sepucha, 2011; Scalia, Elwyn & Durand, 2017) have been shown to be factors associated with the sustainability of PDA implementation and were also found in this current study. However, more can be done to further enhance sustainability such as provision of feedback that includes patients' satisfaction (King & Moulton, 2013) as well as patient-directed strategies, such as creating patients' and public awareness of PDAs and decision support services (Stacey et al., 2015).

4.5 Study strengths and limitations

4.5.1 Study strengths

One of the strengths of this study is that this is one of the few and perhaps the first prospectively planned implementation effort to integrate PDA use into routine practice especially among developing countries. Given that it is implemented in a real-world environment, the methodology and findings have considerable external validity and may be applicable to other settings particularly in those that have a high doctor turnover, low utilisation of technological infrastructure in the healthcare system, multilingual patient base, and limited manpower resource. The intervention and implementation plan that were developed in this study were simple, straightforward, not overly burdensome to the HCPs and patients, and resource intensive.

This study adds to the dearth of literature on the intervention development process, not only for PDA implementation but implementation of other innovations as well. The systematic and transparent description of all the steps in the intervention development as well as operationalisation of the strategies using Proctor, Powell & McMillen's (2013) recommendations (Proctor, Powell & McMillen, 2013) that provide information on how the strategies would address the barriers enables future implementers to assess and adapt the program where necessary or to replicate the steps described when developing a similar intervention.

The step on barrier prioritisation particularly the use of the multivoting technique, is a novel approach for the development of a tailored intervention. The multivoting technique provides a quick and simple way to prioritise barriers. This approach makes an important methodological contribution to intervention development and can be compared with other approaches.

While this study focused on addressing barriers to implementation, facilitators was also taken into consideration. During the development of the multivoting form, facilitators were turned into barrier statements. This indirectly enabled some of the facilitators, which had been voted as key barriers, to be leveraged in this current study. This approach may be used as a shortcut to intervention development that targets both barriers and facilitators.

The intervention developed and the findings of this current study were strengthened by the various sources of evidence such as from the literature review, potential effective strategies to overcome barriers from Phase 1 participants, meetings with the clinic stakeholders and patients, usage of clinic and research administrative data, conduct of questionnaire surveys and IDIs and FGDs. Triangulation of data that included self-reported information through the questionnaire survey, IDIs and FGDs, as well as observational data using clinic and research administrative data enhanced the credibility of the findings.

4.5.2 Study limitations

This current study has a number of limitations hence the findings need to be interpreted with caution. During the development of the multivoting form in Phase 2, barriers that were found only in community clinics but not at the UMMC clinic were selected by the clinic coordinator to be included in the multivoting form. On hindsight, this step may not have been necessary. Perhaps, it could have been better if all the findings from Phase 1 were listed in the multivoting form regardless of their setting as the UMMC primary care clinic stakeholders would vote for barriers that were felt to be important and relevant to their clinic during the multivoting exercise.

The multivoting exercise resulted in identifying a total of 13 key barriers to be addressed, a number decided between the researcher and the supervisors arbitrarily. It is unknown if more or less barriers prioritised would have improved the outcomes of the insulin PDA implementation. Perhaps a discussion with the clinic stakeholders should have been conducted to assess the 13 prioritised barriers to see if they were truly relevant and feasible to overcome. Barriers such as patients not being able to read or understand the insulin PDA and language are general issues faced by HCPs when providing clinical care, hence they might already have existing strategies to address these issues and therefore focus could have been given to other barriers.

There were only three patients who participated in the Phase 2 barrier prioritisation exercise and two in the clinic stakeholders meeting, respectively. This might have an impact on design of the intervention due to underrepresentation of patients' perspectives.

The insulin PDA implementation was conducted at the UMMC primary care clinic where it was developed and where the researchers' supervisors worked. Hence, the clinic authorities such as the Head of Department and clinic coordinator as well as the HCPs might have been more receptive to engage in the implementation. The findings of this study may not be generalisable to other settings such as public community health clinics and private healthcare settings as they may not be as receptive to implementing a research-driven implementation study (Law, Wright, & Mylopoulos, 2016).

There is a possibility that participants of this current study could have provided positive responses or socially desirable answers, as they did not want to criticise their own practice or be seen as unsupportive of an innovation that is endorsed by their training institution. Nevertheless, the researcher tried to offset this bias by assuring them that their performance in the insulin PDA implementation would not affect their work or career.

As there were extensive topics included in the post-implementation interview guide, some of the topics were not covered. For example, strategies such as 'Involve patients' family members and caretakers', 'Juxtapose PDA in preferred language with patient's PDA in their preferred language to address language barrier', 'Framing/reframing', 'Define roles and responsibilities' and 'Place the insulin PDA booklets in doctors' consultation rooms' were not sufficiently explored. However, this was also due to the prioritized barriers 'Language barrier', 'Patient cannot read or understand the insulin PDA', 'Not having a person-in-charge to use of the PDA in the clinic' and 'HCPs don't know where to get the PDA' that were not brought up as barriers during the post-implementation interviews. One way to overcome this issue is to arrange additional interview sessions to cover all the topics in the interview guide. While this may increase participants' burden on the need to attend a second interview, however, the interview session may be less exhausting as it would cover less topics and results in a shorter interview.

Much of the work in facilitating the insulin PDA implementation was performed by the researcher, such as organising the insulin PDA training workshops, collecting of data for the feedback report preparation, and distribution of feedback reports to the HCPs in the clinic. This rendered a lack of engagement from clinic staff in the implementation. When HCPs are engaged in the process of intervention development, it can help to inculcate a sense of ownership over the implementation strategies and thus facilitate the implementation processes (Lloyd & Joseph-Williams, 2016). Moreover, relying on the researcher to carry out the strategies also rendered the intervention unsustainable once the study ends. Future studies should ensure that there is a greater involvement of HCPs in the implementation process such as collection of evaluation data and preparing feedback reports.

This current study had planned for feedback (individual feedback reports and unit meeting feedback) to be given monthly (five times during the implementation period), however, this was unachievable. Unit meetings were sometimes cancelled or brought forward unexpectedly. On hindsight, provision of monthly feedback report might have not been appropriate as the researcher had difficulty preparing the reports in time. Moreover, more time was needed to generate the data to be included in the reports. Future implementers should take note of these issues when selecting this strategy as their intervention.

Some of the strategies in this current study namely ‘Framing/reframing’, ‘Inform HCPs on the advantages of the insulin PDA use’ and ‘Involve patient/consumers and family member’ were embedded in the strategy ‘Conduct educational training” as the mode of delivery. This lessened the work required to execute the strategies. It remains an empirical question if a more intensive mode of delivery of these strategies would lead to better implementation outcomes. For example, rather than simply informing HCPs that the insulin PDA could potentially save consultation times, they can be shown videos of consultations with and without the insulin PDA use. Another example is the strategy ‘Involve patient/consumer and family member’, rather than informing doctors to ask patients if they have family members who can use the insulin PDA with them, perhaps HCPs can call patients’ family members to ensure they help patients with the insulin PDA use. However, more time and resources would be needed to develop such a strategy.

There is also the possibility of underreporting the number of PDAs given to patients using the insulin PDA tracking log, notes made in the EMR and notes made on patients’ appointment books among the doctors, as well as reporting on follow-up with patients by the doctor. Findings from the post-qualitative evaluation data such as perception of the effectiveness of the strategies implemented might have also been subjected to memory bias. Strategy such as the training workshop was conducted in the earlier months of the implementation period (April and August) while the post-implementation questionnaire and interviews were only conducted at the end of implementation period (November). Similarly, interviews with patients were only conducted when they returned to the clinic for their follow-up, hence findings on their experiences when given the insulin PDA by doctors during their first visit might not have been comprehensively captured. Indeed, telephone interviews could have been conducted with the patients at the end of their first clinic visit and in fact the researcher had attempted this approach with three patients. However, patients' responses to the interviews were poor as many were disinterested and were eager to end the call. The information captured through the telephone call was not meaningful and the researcher stopped using this approach.

The proportion and representativeness of patients who are willing to use the insulin PDA could not be determined as the number of patients eligible to receive the insulin PDA during the implementation period cannot be obtained. This limited the researcher's understanding on whether or not the insulin PDA intervention was effective in reaching patients from various backgrounds. In addition, qualitative interviews were not conducted with these patients, which could have provided insight on the barriers to why they declined to participate. However, this limitation was addressed by interviewing doctors of this current study on the reasons why patients refused to accept the insulin PDA.

It should be noted that out of the 235 patients who were expected to return to the clinic during the implementation period, the researcher was unable to follow up with 92 patients as some skipped their appointment (n=55), walked in earlier than their given appointment (n=13), could not remember receiving the insulin PDA (n=6), refused to participate (n=5), and some were referred to other community clinics (n=4). The researcher tried her best to prevent missing data by checking the clinic's appointment system for new appointments made by patients or by calling patients. When new appointments were detected, researcher would follow-up with patients on the new appointment date. Some patients were unable to be contacted over the phone.

One limitation of conducting an implementation study within the remit of a research study is the potential of the Hawthorne effect that can affect participants' behaviours when they know they are being studied. Due to ethical reasons, it was not possible to conceal from the HCPs and patients that the insulin PDA implementation was a research. It was found in this current study that some nurses might have not replenished the insulin PDA booklets in the consultation rooms because they thought it was the responsibility of the research personnel. On the other hand, participants who are positive about being involved in research might overdo the activities that were expected of them. The researcher was aware of this limitation and tried to address this by informing the HCPs that the insulin PDA would still be available in the clinic after the research data collection ended.

While this current study engaged perspectives from various stakeholders including healthcare managers, HCPs, and patients, evaluation data was not collected from medical assistants and appointment clerks. Hence, understanding issues on the insulin PDA refills in the consultation rooms and the insulin PDA follow-up were not comprehensive. Input from nurses on the insulin PDA implementation was also limited. Participation in the post-implementation qualitative interviews was on a voluntary basis and only five nurses participated. Those who did not participate might be an indication that they were not interested in the insulin PDA implementation and interviewing these nurses would have provided a more critical insight on their unwillingness or barriers to participate in the implementation. Future implementation researchers must take note that information from individuals who did not participate in an implementation effort is crucial and must not be neglected.

The Knowledge to Action framework highlighted the need for continuous monitoring of barriers and development of solutions, however, this study only conducted a one-time prospective tailoring of barriers to inform the development of the tailored intervention. This was because the researcher wanted to find out if the current strategies implemented were effective and if any new improvements were to be made, they would serve as confounders. Nevertheless, the findings from this current study can be used to adjust and improve the current implementation plan as the insulin PDAs are still available in the clinic for use.

4.6 Study recommendations

4.6.1 Development and implementation of intervention

Based on the experience of intervention development and the findings obtained in this current study, several lessons were learned and the following recommendations can be incorporated into adaptations of this current study intervention's development process:

1. The multivoting technique can be adopted as a quick, simple, and less resource-intense method to prioritise barriers that need to be addressed to facilitate intervention development. Once the list of barriers are prioritised, discussions should be conducted among clinic stakeholders and patients to deliberate if the barriers identified are truly relevant, feasible to be addressed, and if more or less barriers need to be prioritised.
2. This study prioritised 13 barriers and selected 11 strategies. The difficulty of providing a timely monthly feedback report in addition to carrying out other implementation tasks was highlighted. If more barriers were to be prioritised in a tailored implementation, this may necessitate more strategies, hence adding to the

complexity and resources required for implementation. Therefore, it is recommended that implementation efforts should not focus on too many barriers so that quality strategies can be carried out. Nevertheless, the number of barriers to overcome should be discussed among clinic stakeholders.

3. It is important that the process of mapping of strategies to barriers involves individuals who are familiar with the implementation context as well as the available strategies. This current study employed the approach of having researchers map the strategies to the barriers and then finalise the intervention with the clinic stakeholders. This approach is recommended for implementation efforts that are unable to engage with clinic stakeholders frequently, however, the researchers must have a thorough understanding of the implementation context.
4. The findings from patients in this study highlighted that patients can provide useful feedback in terms of how an innovation can be implemented, who should be delivering the innovation to patients, and when and how the innovation can be delivered. When developing an intervention, patients can be involved not only in the barrier assessment phase but also when mapping strategies to overcome specific barriers and the finalisation of the intervention as whole. It is also crucial to ensure that patients are well represented in these exercises by making sure they are given the opportunity to voice out their opinions, having a balanced number of patients and HCPs, and getting patients who are able to provide feedback involved.
5. HCPs should be involved in preparing and implementing materials that are part of the implementation intervention such as collection of data evaluation and preparation of feedback. This helps create a sense of shared responsibility and increases HCPs commitment to the implementation. In addition, this can also help ensure maintenance of the implementation.

4.6.2 Implementation of PDA in routine clinical practice

The findings of this study highlighted several areas that can be targeted to improve PDA implementation in routine clinical settings.

1. To attract HCPs in engaging in PDA implementation, an organisation leader or influential physician should show visible support for the PDA implementation and send personal invitations to the staff who would be involved in the implementation.
2. This current study points to the importance and benefits of the insulin PDA training in facilitating the insulin PDA implementation. The HCPs participants highlighted that training was necessary to get the clinic staff to implement the insulin PDA. One doctor who did not attend the training workshop did not adopt the insulin PDA due to fear of using it incorrectly. Training should be conducted for any PDA implementation endeavor. Information on the objective, benefits, and how to go about implementing the PDA in their settings should be incorporated in the training. Training should also be conducted periodically to provide continuous support and motivation to HCPs on SDM and PDA use, especially in an academic-based setting where doctors are in and out of the clinic due to their specialty training.
3. Conducting training workshops would not be effective unless there is high HCPs' participation. Among the strategies to consider is ensuring HCPs are trained by making training mandatory (King, Taylor, Williams, & Vanson, 2013) or having several training sessions, although this requires more time and resources. Should face-to-face training workshops are not feasible, online training can be considered. Stacey et al., (2015) used the online Ottawa Decision Support Tutorial to train HCPs who were unable to attend their training workshop (Stacey et al., 2015), and such resource can be adapted for use in the local context. Another

strategy is having a resource person in the clinic who can provide more information about the PDA in the implementation setting. PDA training workshops should include communication skills training that focus on preparing patients for the SDM process and PDA use.

4. Future PDA implementers who use the strategy ‘Provide feedback’ should include patient data such as their positive feedback and satisfaction towards SDM and PDA use, knowledge and decision quality in order to motivate HCPs to implement PDAs. In addition, there is also a need to carefully consider the frequency of feedback provision. Provision of feedback as a strategy may not need to be monthly as there may be insufficient time to analyse data and gather sufficient meaningful data to present. If monthly feedback is favoured, then there is a need for strategies whereby rapid data collection and analysis can be done. The rapid ethnography approach, which involves activities such as shadowing participants, conducting opportunistic interviews, and rapid analysis of data is one way to expedite information collection and may be useful for feedback delivery in implementation although a multidisciplinary team would be needed (Saleem et al., 2015). Another way to gain evaluation data quickly is the use of infrastructural technology such as the EMR to help record information such as patients’ treatment preferences, questions, and other decision-making data and share this with clinician as found at the Dartmouth-Hitchcock Medical Centre (Andrews, Kearing, & Vidal, 2016; Berg, Collins Vidal, & Clay, 2011).
5. This current study placed a majority of the implementation burden on doctors due to unavailability of diabetes educators and staff nurses to carry out tasks, such as identifying eligible patients, introducing and delivering the insulin PDA, or providing decision coaching. An interprofessional team approach where HCPs from various disciplines collaborate to provide integrated care to patients

(D'Amour & Oandasan, 2005) should be developed as it can create a more coordinated and efficient PDA implementation process (Scalia, Elwyn & Durand, 2017). In settings where more permanent staff such as diabetes educators and nurses are unable to be involved in providing decision coaching to patients in PDA implementation, utilising staff who are premedical interns or pre-houseman can be considered provided they are available in the setting. Doctors also need to be trained to work as a team with other HCPs to implement PDAs in the clinic.

6. In settings where barriers such as low patient low literacy and HCP-patient language discordance exist, involving family members in the PDA implementation can be explored. HCPs can gauge if the patient's family member is able to interpret for them based on their familiarity with the patient's medical history, clinical conditions, and their comfort level with medical terminologies. Patients should be asked if they are willing to let their family members interpret for them as well and be part of the SDM process.
7. The prevailing barriers and unexpected involvement of medical assistants in the clinic operations (in replacing nurse duties) in this current study indicate that ineffective strategies and processes need to be removed (e.g.: the step on making a note in patients' appointment cards) and new or improved strategies should be developed (e.g.: patient-directed strategies) for effective implementation. Sustainable PDA implementation would require an iterative approach to implementation to respond to new emerging barriers and changing context.

4.7 Future research

This current work identifies further research needs in the field of PDA implementation. Future research could benefit from implementing the insulin PDA at community public health clinics or private healthcare settings. In community clinics, doctors focus on clinical work and there is also lesser doctor turnover whereas in private healthcare practices, doctors tend to see the same patient. Implementing the insulin PDA in these settings may lead to different PDA implementation outcomes as compared to this current study. This current study highlighted that patients' attitude and behaviors towards PDAs can affect PDA adoption among doctors. When patients did not use the given PDA, it affected doctors' willingness to continue to use it in their practice. Future studies can consider testing patient-directed strategies to promote PDA uptake among patients. Some studies have shown promising results in terms of increasing patient awareness about SDM and engagement (Lloyd & Joseph-Williams, 2016; Tai-Seale, 2011). Furthermore, the use of mass media (e.g: poster, brochure) is advantageous as it is not labour-intensive and does not need a high-level infrastructure design (Stevens, Thompson, Watson, & Miller, 2016).

One challenge faced during intervention development was the lack of detailed information in designing an intervention in the literature. Although implementation strategies and plans were reported in some PDA implementation studies, there is insufficient information on how they were developed and whether they were based on identified barriers. As tailored implementation is a large endeavor involving many variables (innovation, settings, determinants, strategies, outcome variables) and steps (barrier identification, prioritisation of barriers, linking strategies to barriers, use of theories and frameworks, evaluation), comprehensive descriptions of an implementation study are often not found. Future PDA implementers should provide details on the intervention development process, how the strategies were operationalised and reporting the outcomes so that all can learn from the successes and failures of implementing PDAs.

This current study did not evaluate the 'effectiveness' of the insulin PDA implementation specifically the impact of the insulin PDA implementation on SDM and

PDA-related outcomes such as patients' decisional conflict, patients' involvement in the SDM process, clinicians' satisfaction with PDA use, and clinicians' discussions with patients. It should be noted that the focus of this study was on implementation and is similar to the aim of the type 3 effectiveness-implementation hybrid design, whereby the primary outcome was on implementation outcomes and the secondary focus was on effectiveness or the innovation outcomes (Curran et al., 2012). The type 3 hybrid is essentially an implementation trial plus an evaluation of patient outcomes (Landes et al., 2019). In this design, several healthcare settings are randomised to receive strategies and then their implementation outcomes were compared but at the same time, the effectiveness of the innovation are examined observationally (Landes et al., 2019). However, this study did not adopt the type 3 hybrid design because the aim of this study was to focus on implementation aspects of the insulin PDA given that the effectiveness of PDA has been well established in a Cochrane review (Stacey et al., 2017) and even in routine practice when they were adopted (Belkora et al., 2012). Hence, the evaluation of the effectiveness of the insulin PDA on patient or clinical outcomes was not undertaken. In addition, while fidelity was measured in this study, its impact on clinical outcomes was not measured and this was another limitation of this study. Furthermore, addtional outcome measures to evalute the effectivensss of the PDA (e.g. decisional conflict and knowledge) requires data collection, which requires additional time and resources, which was not feasible within the PhD time frame. Evaluation of effectiveness outcomes would be conducted in the next phase of this current study.

4.8 Chapter summary

Overall, this chapter discussed the findings at each phase of this current study. Barriers such as role boundary, the lack of continuity of care, language barrier, patient literacy level, and patient willingness to pay for the PDA were found to be prominent in this current study but rarely discussed in the literature. Role boundary may act as both a facilitator or barrier for PDA implementation. Being clear of one's job responsibilities helped HCPs decide if they were the right person to use the insulin PDA. However, relying solely on doctors would hinder an interprofessional team approach to using the PDA. Many studies conducted in the West have shown that HCPs other than doctors have played a significant role in ensuring PDAs are implemented successfully by identifying eligible patients, contacting patients about the PDA and providing decision coaching. An interprofessional approach to PDA implementation should be developed for PDA implementation. Continuity of care is crucial in ensuring effective delivery of PDAs, however, it is a challenge in healthcare delivery due to a high patient load, lack of manpower, time constraints, and high turnover of staff. The lack of awareness and receptivity to SDM among HCPs could hinder PDA implementation, particularly in Asia where HCP paternalism and patient's submissiveness towards doctors exist. However, Asian studies have shown that many patients preferred an autonomous (active and shared) role in decision-making and thus efforts are needed to promote the concept of SDM in Asia and developing countries. Language mismatch between doctor and patient posed as a challenge to SDM and PDA use, especially in a multiethnic country such as Malaysia. In healthcare settings where professional interpreters or translation services are not available, using family members as interpreters can be considered as they sometimes play the role of patient advocates and are part of the decision-making unit team with the patient. Patients with low literacy level will have difficulty using PDAs if they are unable to read or understand the information. However, their involvement in SDM and PDA use is still possible through using computer or web-based PDAs which allow incorporation of animation, videos, and audio-visual aids that may help them to understand the information better. Charging patients for printed or video PDAs is an important consideration for PDA implementation as some patients may not be willing to pay as they felt that they could ask physicians directly for information, did not see the PDA as applicable to their clinical situation, and expected the PDA to be part of standard medical care. To address the cost issue of printed PDAs, web-based PDAs can be considered as they are easier and cheaper to update, and accessible even in developing countries where mobile Internet penetration is high. A reminder system is an important facilitator for PDA implementation to address the issue of forgetfulness and can trigger HCPs' interest to prompt them to use PDAs.

In terms of the development of an intervention, it is hard to tell which combination of steps and methods and their sequence is more superior than others. Nevertheless, it is important to consider the steps to be undertaken for intervention development, as each additional step would add to the complexity of the process of intervention development such as burden to stakeholders, and the resources and time needed. The utilised steps in this current study, specifically barrier identification, identifying strategies, linking of strategies to barriers, and engaging stakeholders were also commonly found in many other intervention development efforts and therefore these steps may be considered fundamental when designing a tailored intervention.

While prioritisation exercises have been commonly conducted for guideline development and health research prioritisation, there is a lack of emphasis on this step in intervention development. Using the multivoting technique is an easy and simple approach to prioritise barriers rapidly that also considers views of various stakeholders without incurring too much burden on them. Involving clinic stakeholders in identifying and mapping of strategies to the prioritised barriers requires that they are familiar with the implementation context as well as strategies. Familiarisation of strategies with clinic stakeholders may cause information overload and render inaccurate strategies selected and mapped to barriers. A more efficient way to map a strategy to a barrier is to conduct the process with individuals who are familiar with the strategies and clinic context, and taking into consideration the proposed strategies by clinic stakeholders during the strategy-barrier mapping process. Subsequently, the draft intervention can be presented to the clinic stakeholders for refinements. Patient involvement in the intervention development process in implementation research is lacking, although their views are important as they are the end users of an innovation. Patient were usually involved in the barrier or needs assessment phases, however, they can also provide contributions on how an innovation can be implemented such as who should deliver the innovation and how the delivery can be done. Apart from providing a patient's perspectives, they can also provide opinions on the HCP and organisational aspects eventhough they may not be directly involved in them.

In terms of 'Reach', 'Adoption', 'Implementation', and 'Maintenance' of PDAs, broad reach among HCPs can be attained by involving an organisational leader or influential physician to make personal invitations to promote HCP participation in PDA implementation. Training workshops are crucial to create awareness on the innovation and to build the knowledge and skills required by clinic staff to perform the implementation tasks. This should be made a pre-requisite for any PDA implementation endeavor. The lack of manpower in this current study necessitated that doctors deliver the insulin PDA to patients at the point of consultation, although evidence has shown that PDA delivery to patients that relied on physicians was not effective. Nevertheless, this approach led to 387 patients receiving the insulin PDA during the seven-month implementation period. Doctors or clinic staff personally delivering the PDA is a facilitator for PDA uptake among patients. In addition, providing patients with tasks related to PDA use may also help facilitate their PDA adoption. While in-clinic PDA view may make it more likely that patients view the PDA, however, such may not be feasible in resource-constrained settings. Nevertheless, this does not mean that letting patients use the PDA at home would be ineffective as some patients prefer to take their time to deliberate the information and consider the options. This current study demonstrated that by getting doctors to introduce the PDA to patients and letting them read the PDA at home which is a relatively feasible approach.

The main driver to PDA adoption among HCPs appeared to be the perceived and experiential benefits of using PDAs. Strategies to enhance HCPs' anticipated positive experience with PDA use should be developed. Findings of patient outcomes are highly valued and should be included in the strategy audit and providing feedback, should this strategy be part of an intervention. There is also a need for regular SDM and PDA booster sessions to provide motivational support to HCPs, especially in settings where doctors are in and out of the clinic. Doctors' motivation to adopt PDAs is affected by patients who did not use the given PDA. HCPs need to understand that SDM and using PDAs is not a one-off event as it may involve engaging patients in several discussions to understand their preferences and values. In addition, strategies that ensure patients would read the PDA is needed and one way is by only getting patients who truly want to participate in SDM and use PDAs. Approaches that can be undertaken are getting patients to self-screen and decide if they want to participate in SDM and use PDAs or simply getting HCPs to explicitly ask patients if they are interested.

In terms of implementation, adherence to implementation protocol was facilitated by implementation tasks that were considered part of patient clinical management whereas tasks that were not aligned with their work habit and deemed unnecessary were often not executed. In PDA implementation efforts that advocate the delivery model where patients can take the PDA home, follow-ups are a crucial step. Doctors had the perception that it is difficult to follow-up with patients who had been given a PDA previously by a different doctor. However, many studies have shown that other HCPs have been involved in the delivery of PDAs to patients before meeting doctors for decision discussions. Again, an interprofessional approach to SDM and PDA use needs to be fostered among HCPs.

In terms of maintenance, clinician support and HCPs’ perceived positive contribution of the PDA to patients and practice are important factors for PDA sustainability. The next chapter will conclude the study.

CHAPTER 5: CONCLUSION

This study outlines a systematic process of developing PDA implementation intervention and adds to the body of literature on the process of implementation intervention development to embed evidence-based innovation use in routine practice. The insulin PDA intervention development steps included identification of barriers and facilitators, prioritisation of barriers using the multivoting technique, identifying and mapping of strategies to the prioritised barrier, finalisation of the intervention through a clinic stakeholder meeting, and intervention evaluation. The step on barrier prioritisation was unique as there is a lack of implementation studies that detail how barriers are selected from a list of barriers that are usually generated in barrier assessment. The innovative use of the multivoting technique as part of the intervention development process provided a relatively simple, rapid, and straightforward method for barrier prioritisation. This approach is an important methodological contribution to intervention development and can be considered by future implementers as well as testing with other approaches.

The intervention development process which utilised evidence of the effectiveness of strategies in the literature, proposed strategies from stakeholders, implementation taxonomies for the barrier-strategy mapping exercise, and involvement of stakeholders and patients in barrier proritisation exercise and in an intervention finalisation meeting led to an intervention that is evidence-based, acceptable, and feasible to be implemented. Another strength of this current study is patient engagement in every phase to obtain their views on factors influencing PDA implementation as well as taking into considerations of their suggestions that could help with effective implementation of the insulin PDA. The entire intervention development process in this current study was low cost, simple, pragmatic, and not overly burdensome to stakeholders. Hence it is potentially replicable particularly in other resource-constrained settings.

The findings on the implementation outcomes of this current study demonstrated that PDA implementation is feasible in a setting where there is high doctor turnover, low utilisation of technological infrastructure in the healthcare system, multilingual patient base, and limited manpower resource. When implementing PDAs, it is crucial to consider the healthcare culture and system. Focusing on implementation efforts such as training to improve providers' knowledge and skills, organisational leaders' support and utilising a documentation system to facilitate follow-ups can foster PDA use. Apart from HCP and organisational strategies, patient-directed strategies should also be included in implementation as patients' attitude and behavior have an influence on doctors' PDA adoption.

This study demonstrated that the insulin PDA implementation shows a moderate success. Some of the prioritised barriers in this current study were also common barriers found in the literature, therefore, future implementers may consider adopting the effective strategies found in this study if the same barriers are encounter.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

Publications:

1. Wen Ting Tong, Yew Kong Lee, Chirk Jenn Ng, Ping Yein Lee. Factors influencing implementation of an insulin patient decision aid at public health clinics in Malaysia: A qualitative study. PLOS ONE. 2020;15(12):e0244645.
2. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. What will make patients use a patient decision aid? A qualitative study on patients' perspectives on implementation barriers and facilitators. J Eval Clin Pract. 2020;26(3):755-764.
3. Wen Ting Tong, Yew Kong Lee, Chirk Jenn Ng, Ping Yein Lee. Factors influencing implementation of a patient decision aid in a developing country: an exploratory study. Implementation Science. 2017;12(1):40.

Awards:

1. Young Investigator Award. "Development of an implementation strategy to implement health intervention in clinical practice". The 14th World Congress of Biological Psychiatry, Vancouver, Canada - 2-6 June 2019
2. Young Investigator Travel Award. "What should be considered when implementing a patient decision support intervention?: Policy makers' and healthcare providers' views". The 48th Asia-Pacific Academic Consortium for Public Health Conference, Tokyo, Japan – 16-19 September 2016
3. Consolation Prize - University of Malaya Medical Center Quality Improvement Team Project Competition 2018. "Implementation of an insulin-choice patient decision aid to promote patient-centered care in the UMMC primary care clinic", University of Malaya Medical Center, 2018.

Papers presented:

1. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. Development of an implementation strategy to implement health intervention in clinical practice. The 14th World Congress of Biological Psychiatry, Vancouver, Canada, 2-6 June 2019. (Oral presentation)
2. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. Implementation interventions in facilitating adoption of evidence-based interventions in clinical practice: what works and what doesn't? The 14th World Congress of Biological Psychiatry, Vancouver, Canada, 2-6 June 2019 (Poster presentation)
3. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. Overcoming barriers to implementation of an insulin-choice patient decision aid in a primary care clinic in Malaysia. 22nd WONCA World Conference of Family Doctors, Seoul, Korea, 17-21 October 2018. (Oral presentation)
4. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. Prioritizing barriers to effective implementation of an insulin-choice patient decision aid in a primary care clinic in Malaysia. 22nd WONCA World Conference of Family Doctors, Seoul, Korea, 17-21 October 2018. (Poster presentation)
5. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. Challenges in implementing an insulin patient decision aid for patients with type 2 diabetes in Malaysian public health clinics: A qualitative study. Diabetes Asia 2017 Conference, Kuala Lumpur, Malaysia, 12-15th October 2017. (Oral presentation)
6. Wen Ting Tong, Chirk Jenn Ng, Yew Kong Lee, Ping Yein Lee. Patients' views on factors influencing implementation of patient decision aid in an academic primary care clinic. The 9th International Shared Decision Making Conference, Lyon, France, 2-5th July 2017. (Oral presentation)

7. Yew Kong Lee, Chirk Jenn Ng, Wen Ting Tong, Ping Yein Lee. Malaysian healthcare professionals' views on how to implement a patient decision aid for insulin initiation in type 2 diabetes in an academic hospital setting. The 9th International Shared Decision Making Conference, Lyon, France, 2-5th July 2017. (Oral presentation)
8. Chirk Jenn Ng, Wen Ting Tong, Yew Kong Lee, Ping Yein Lee 'A Tale of Two Clinics': Implementing a patient decision aid at two public health clinics in Malaysia. The 9th International Shared Decision Making Conference, Lyon, France, 2-5th July 2017. (Poster presentation)
9. Wen Ting Tong, Yew Kong Lee, Chirk Jenn Ng, Ping Yein Lee. What should be considered when implementing a patient decision support intervention?: Policy makers' and healthcare providers' views. 48th Asia-Pacific Academic Consortium for Public Health Conference (APACPH), Tokyo, Japan – 16th – 19th September 2016.
10. Ping Yein Lee, Wen Ting Tong, Yew Kong Lee, Chirk Jenn Ng. Implementing a PDA in a developing country: Physician adoption and sustained use of an insulin-choice PDA following implementation interventions.10th International Shared Decision Making Conference, Quebec, 7-10 July 2019. (Oral presentation)
11. Yew Kong Lee, Wen Ting Tong, Chirk Jenn Ng, Ping Yein Lee. Implementing a PDA in a developing country: Using a multi-voting process and stakeholder meetings to tailor an implementation strategy,10th International Shared Decision Making Conference, Quebec, 7-10 July 2019. (Oral presentation)