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Evaluation of the implementation of an insulin patient decision aid for patients with type 2 diabetes in an academic primary care clinic in Malaysia: a mixed method study

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Abstract

Background Literature surrounding patient decision aid (PDA) focus on testing effectiveness such as measuring patient or practice outcomes, while few studies looked into evaluation of implementation outcomes. It is important to assess implementation outcomes because in order for PDA to deliver its intended effects, they should first be effectively implemented. This study aimed to evaluate the implementation of an insulin PDA in an academic primary care clinic specifically measuring implementation outcomes.

Methods A mixed-methods sequential explanatory design was used. This study was conducted at a primary care clinic in an academic hospital from April – November 2018. The insulin PDA was implemented using a tailored implementation intervention, which comprised of 11 strategies aiming to overcome 13 prioritised implementation barriers.

Evaluation data were collected from: healthcare administrators such as the head of department, the clinic coordinator, and the nursing officer who oversees the clinic operations, doctors whose tasks were to deliver the insulin PDA to patients, nurses who were responsible for making sure the insulin PDAs were available, and patients with type 2 diabetes who were offered the insulin PDA. The study commenced with the quantitative approach to assess 'Reach', 'Adoption', 'Implementation' and 'Maintenance' of the insulin PDA. Subsequently, qualitative approach was employed and qualitative interviews were conducted with the relevant stakeholders to explain the quantitative outcomes. A total of six IDIs and six FGDs were conducted with healthcare providers (healthcare policymakers: 3, doctors: 35, and staff nurses: 5), and 62 IDIs were conducted with patients.

Results For 'Reach', 88.9% ($n = 48/54$) of doctors and 55% ($n = 11/20$) of nurses attended the insulin PDA training workshops. This was attributed to their self-motivation and the mandate from the Head of Department. 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. Doctors' 'Adoption' of the PDA was high (83.3%, $n = 45/54$) due to the positive personal experience with the usefulness of the PDA. Only 65.7% ($n = 94/143$) of patients who received the PDA read it. The degree of

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'Implementation' of the PDA varied for different tasks (ranged from 19.2 to 84.9%) and was challenged by patient and system barriers. For 'Maintenance', 80% of the doctors were willing to continue using the PDA due to its benefits.

Conclusion This study highlighted that the implementation of an insulin PDA in a primary care setting is promising. Addressing the issues of social hierarchy, and healthcare providers' roles and responsibilities can further improve implementation outcomes.

Keywords Implementation science, Implementation outcomes, Implementation strategy, Patient decision aid, Shared decision making, Evaluation

Background

Shared decision making (SDM) is a key component of patient-centered health care, whereby patients collaborate with clinicians to arrive at a treatment consensus after considering evidence-based information about treatment options, risks and benefits, and patients' values [1]. SDM can be facilitated by tools known as patient decision aids (PDA), that explicitly state the healthcare decision that needs to be made, the pros and cons of the available treatment options, and elicit patient's preferences and values. PDAs have been shown to improve patient's knowledge, increase patient's involvement in decision-making, help patients make informed decisions, and improve patient-doctor communication [2].

Despite the effectiveness and availability of PDAs [3, 4], their implementation into routine clinical practice has been poor [5, 6]. In a national survey conducted in the United States to assess use of PDAs for clinically localized prostate cancer, only 35.5% of radiation oncologists and urologists stated that they currently used a DA in their clinical practice [5]. Similarly, another study which aimed to embed a PDA for treatment of children with juvenile idiopathic arthritis in routine settings did not achieve their goal of having at least 65% use of the PDA as part of medication discussions between patients and clinicians [6]. A myriad of barriers have been found to contribute to poor uptake of PDAs and many of them are related to implementation barriers such as difficulty in integrating PDA into existing patient care pathways or healthcare providers' (HCPs) workflow [7], competing quality improvement initiatives in the healthcare setting [8], lack of teamwork [9], and organizational policies and regulation [10].

Currently, in PDA literature, studies on effectiveness of PDAs are abundant whereby the outcomes are related to measuring what a PDA is supposed to achieve such as patient outcomes (i.e., decision conflict, decision quality, decision regret) or practice outcomes (i.e., uptake of treatment) [11, 2]. There is a lack of focus on implementation aspects of PDA such as evaluation of implementation outcomes. Implementation outcomes are proximal indicators of implementation processes such as "reach", "adoption", "fidelity", and "maintenance", and they serve as the intermediate outcomes for effective patient or

practice outcomes [12]. In other words, for an evidence-based innovation such as a PDA to deliver what they are intended to deliver, they should first be effectively implemented, and hence the importance and need for assessing implementation outcomes.

Further, there is currently a dearth of body of literature on PDA implementation in the Asian region as majority of PDA implementation studies are conducted in the West. Asia differs from the West whereby the societies are more collectivist by nature [13], and the concept of SDM and PDA is relatively new [13, 14] hence the PDA implementation barriers face may be different and require different approaches to implementation. Malaysia, located in Southeast Asia is a developing country [15] with a population of 32.7 million. Type 2 diabetes is a major health problem in Malaysia and its prevalence continues to rise [16]. Early insulin initiation can prevent the early onset of diabetes complications and premature deaths. However, patients face difficulties in making decisions about insulin therapy due to factors such as fear of injection and misconceptions surrounding insulin [17–21]. An insulin PDA has been developed to help type 2 diabetes patients to make informed decisions about starting insulin but also recognises the value of offering patients other treatment options. The implementation of the insulin PDA can help to improve doctors' management of type 2 diabetes by helping patients to make informed decisions about insulin therapy. When patients make an informed decision about their health treatment, they are more likely to adhere to their treatments choice and this could improve their health outcomes [2, 22].

Despite the availability of the insulin PDA, it has never been formally implemented in the routine clinical setting. In 2018, a tailored implementation intervention (a bundle of implementation strategies target to address prioritised barriers) was developed to integrate the use of the insulin PDA in routine clinical practice [23]. A systematic review has shown that tailored intervention to implementation is more effective than no intervention or a intervention not tailored to barriers [24]. This study aims to evaluate the implementation outcomes of the implementation of the insulin PDA. The findings of this study can help to improve future PDA implementation efforts particularly in the Asian region.

Methods

Evaluation framework

This study adopted the RE-AIM framework to evaluate the implementation outcomes of the insulin PDA. RE-AIM is an acronym which stands for Reach, Effectiveness, Adoption, Implementation and Maintenance [25]. RE-AIM offers a systematic framework for evaluating the impact of an implementation in a logical sequence of translation of knowledge to practice; from the innovation 'reaching' to the intended audience, 'effectiveness' or efficacy of the innovation in meeting its outcomes, 'adoption' of the innovation by organisation or staff, 'implementation' of the innovation according to the implementation protocol, and lastly, 'maintenance' or sustainability of the implementation [26]. This study focuses on the four domains of the RE-AIM framework namely 'Reach', 'Adoption', 'Implementation' and 'Maintenance'. The 'Effectiveness' dimension was not undertaken because this study aimed to focus on translatability of PDA as this is the main issue surrounding the field of PDA and SDM.

Study design

The evaluation of the insulin PDA implementation adopted a mixed-method sequential explanatory design [27]. This study commenced with the quantitative approach to understand the extent to which the insulin PDA was implemented in terms of 'Reach', 'Adoption', 'Implementation' and 'Maintenance' [26]. Once the extent of the insulin PDA implementation was understood, qualitative approach was employed to explain the quantitative outcomes.

Study setting and participants

This study was conducted at the primary care clinic of the Universiti Malaya Medical Centre (UMMC), an urban government teaching hospital in Kuala Lumpur. The reason this clinic was chosen was because it has a large population of patients with type 2 diabetes (average 10,000 diabetes patients annually). At the time of this study, there were 54 doctors, and 20 registered nurses in the clinic. Only doctors (i.e. family medicine specialists and medical officers) were allowed to prescribe insulin to patients. Nurses tasks were mainly to assist doctors in the consultation rooms. Generally, patients in the clinic do not get to decide which doctor to see; hence, they may not consult the same doctor during the follow up. In this study, data were collected from: (1) healthcare administrators such as the head of department, the clinic coordinator, and the nursing officer who oversees the clinic operations, (2) doctors whose tasks were to deliver the insulin PDA to patients, (3) nurses who were responsible for making sure the insulin PDAs were available, and (4) patients with type 2 diabetes who were offered the insulin PDA.

The implementation intervention

The implementation of the insulin PDA was guided by the Knowledge to Action Framework [28], whereby a tailored implementation approach was used. Initially, barriers to the insulin PDA implementation were elicited through qualitative interviews with various clinic stakeholders, and patients with type 2 diabetes who attend the clinic [29, 30]. Subsequently, the barriers were prioritised using the multivoting approach [31]. Then, relevant implementation strategies were selected based on evidence from the literature, the Expert Recommendations for Implementing Change (ERIC) taxonomy [32], Michie's BCCTv1 taxonomy [33], and discussion among researchers to address the prioritised barriers. The implementation intervention, which comprised of 11 strategies aiming to overcome 13 prioritised barriers was finalised through a clinic stakeholders meeting. Details on the development of the implementation intervention, the procedures, and materials in the intervention can be found in a previous publication [23]. The prioritised barriers and strategies are shown in Table 1. For detailed information on how the strategies were implemented (who, how, where, when, how much, modifications of the intervention) refer to Supplementary file.

Quantitative data collection

Sampling

As this research study aims to implement the insulin PDA in routine practice, all the doctors and nurses in the clinic were involved in this study. The implementation was carried out from April to November 2018. In Malaysia, only doctors can prescribe insulin to patients, hence in this study, doctors were tasked to identify patients who are eligible to use the insulin PDA and deliver the PDA to patients during their consultations. Patients who were eligible to receive the insulin PDA were those who had poor glycaemic control despite tried to control their diets and exercise, and were already on 3–4 types of diabetes tablets (maximum number). Patients who received the insulin PDA from doctors were asked to use the PDA at home before discussion in their follow-up consultation.

Instruments

Insulin PDA tracking log A paper-based insulin PDA tracking log was developed to identify doctors who adopted the PDA and to track how many insulin PDAs were given to patients. Each time doctors gave an insulin PDA to a patient, they recorded it in the tracking log.

Pre- and post- implementation questionnaire The pre-implementation questionnaire was administered at the start of the implementation to collect information on socio-demography and working experience (9 items), and reasons for attending the insulin PDA training workshop

Table 1 The insulin PDA implementation intervention and prioritised barriers

Strategy	Targeted barrier	Description of the strategy
1. Mandate change	Lack of clear directive from the top management	Head of department mandates the use of insulin PDA via department meeting and sign off invitation letters to attend workshop
2. Training workshop	HCPs are too busy as there are too many patients HCPs tend to make decisions for their patients instead of practising SDM Patients rely on doctors to make health decisions Patients are not confident to use the insulin PDA by themselves	Doctors were taught ways they can use the insulin PDA with patients within the limited consultation time. Doctors were taught on the concepts and benefits of SDM and PDA Doctors were informed to encourage patients to ask questions and write down their concerns to discuss in their next visit
3. Involve patients' family members or caretakers (embedded within the training workshop)	Patients cannot read or understand the insulin PDA	Doctors were trained to ask patients if they have anyone (e.g. family members) who can help them during the training workshop.
4. Framing/reframing (embedded within the training workshop)	HCPs are too busy to use the insulin PDA Patients feel that the insulin PDA is to persuade them to start insulin	Doctors were informed that the insulin PDA could potentially decrease consultation time Doctors were trained to inform patients that the insulin PDA is to help them make informed decision.
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 were informed to encourage patients to ask questions and express their concerns during the training workshop.
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 SDM HCPs want to finish their work quickly HCPs are not motivated to try new innovations	HCPs were informed of the advantages of practising SDM and insulin PDA.
7. Juxtapose PDA in preferred language with patient's PDA in their preferred language to help with translation (embedded within the training workshop)	Language barrier	HCPs were informed that they can use the PDA in their preferred language while patient are given the PDA in their own preferred language.
8. Define roles and responsibilities	HCPs are not in-charge of the use of PDA in the clinic	HCPs were informed of their specific implementation tasks during the training workshop. Implementation tasks sheets were also given.
9. Systematic documentation	HCPs are not be able to see the same patient to follow up on the PDA	A systematic documentation process of the insulin PDA use was developed that so that doctor would be prompted to follow up with patients on the insulin PDA during the patient's subsequent visit.
10. Provide feedback	HCPs are not motivated to try new innovations	Individual implementation feedback report which detailed the cumulative number of PDA given to patients, and adherence to implementation tasks was given to doctors and nurses four times throughout the implementation period (second, fourth, fifth, and sixth month of the implementation)
11. Place the insulin PDA booklets in doctors' consultation rooms	HCPs don't know where to get the PDA	The insulin PDA booklets were placed at a strategic location in the consultation rooms to allow easy access.

(1 item). The post implementation questionnaire was administered at the end of the implementation period to collect data on socio-demography and working experience (9 items), their insulin PDA use (3 items), and willingness to continue to use the insulin PDA (2 items). 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 captured whether the HCPs adhered to the implementation protocol (Sup-

plementary file). There were five items in the checklist and they were based on the HCP's implementation tasks (e.g. Did the doctor make a note in patient's EMR to indicate PDA has been given?; Did the doctor provide an appointment (≤ 3 months) to the patient for PDA follow-up?; Did the doctor make a note in patient's appointment book that PDA was given?). The researcher (WTT) reviewed the patients' medical records, checked patient appointment books, and interviewed patients to assess if the HCPs adhere to the implementation tasks, and recorded them in the checklist.

Evaluation dimensions, outcome measures and data collection process

Table 2 describes the evaluation domains, outcome measures, study instrument, and data collection approaches. For 'Reach', the proportion of type 2 diabetes patients who received the insulin PDA could not be measured as data on the total number of patients with type 2 diabetes patients who were eligible to use the insulin PDA (denominator) were unavailable. In this study, 'maintenance' was defined as "the intention to continue with the use of insulin PDA" (rather than assessing actual long-term usage of the PDA) due to limitation of the short study period [26].

Quantitative data analysis

Quantitative data from the insulin PDA tracking log, pre- and post-implementation questionnaires, and research (i.e.: number of doctors who were invited to the PDA training workshop), and clinic administrative data (i.e.: number of PDAs given to patients obtained from the electronic medical record (EMR)) were analysed using SPSS version 19 software [34]. Descriptive statistics were performed to obtain frequencies and proportions for selected variables (Table 2).

Qualitative data evaluation

Study approach

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 adopted was interpretive description [35]. This design was selected to generate of practical findings that can help to inform clinical practice [35]. 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 [36], 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.

Study population and sampling

Purposive sampling was adopted whereby participants were invited to join the study based on the participant inclusion criteria. The inclusion criteria were clinic manager, sister, doctors and nurses who were involved in the insulin PDA implementation, and patients who were given the insulin PDA to explore their experiences with the insulin PDA implementation. Doctors who did not use the insulin PDA in their practice and patients who received the insulin PDA but did not use it were also

recruited to provide insights on why they did not want to adopt the insulin PDA.

Instrument

An interview guide was developed based on 'Reach', 'Adoption', 'Implementation' and 'Maintenance' dimensions of the RE-AIM framework. To align with the mixed-method sequential explanatory design, findings from the quantitative approach were also incorporated in the interview guide to seek explanations on the results. The main question that was asked of them was their experience with the insulin PDA implementation. The interview guide was discussed among researchers to include any topics or questions that were missed, and were further refined before finalisation through 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.

Data collection process

Individual in-depth interview (IDI) with patients took place when they returned to the clinic for their follow-up visit after receiving the PDA. IDIs were carried out instead of focus group discussion (FGD) 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.

Interviews with healthcare policymakers, and HCPs were conducted at the end of the implementation period after quantitative data analysis was completed. HCPs who did not participate in the insulin PDA implementation were also invited to understand the reasons for non-participation. The healthcare policymakers and HCPs were invited via text message or were approached at the clinic to seek their approval to participate at their convenient time. IDIs were conducted with clinic coordinators, while FGDs were conducted separately for doctors and nurses given that their implementation tasks were different.

During the interviews, healthcare policymakers and HCPs were informed that the purpose of the interview 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. They were 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 [35] broad questions were asked pertaining to the insulin PDA implementation such as 'What are their thoughts about the insulin

Table 2 Evaluation domains, outcome measures, study instruments and data collection approach

RE-AIM dimension (Definition) [26]	Study definition	Outcome measure	Study instrument / Source of data	Data collection approach
Reach (<i>"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."</i>)	The number and proportion of doctors and nurses who are willing to participate in the insulin PDA implementation	<ul style="list-style-type: none"> Number of doctors who attended the insulin PDA training workshop / Number of doctors who were invited to the insulin PDA training workshop Number of nurses who attended the insulin PDA training workshop / Number of nurses who were invited to the insulin PDA training workshop 	<ul style="list-style-type: none"> Workshop attendance sheet Research administrative data 	Review on workshop attendance sheet to determine the number of doctors who attended
	The number of patients who are willing to participate in the insulin PDA implementation	<ul style="list-style-type: none"> Doctor's reasons for attending the insulin PDA training workshop Number of patients who received the insulin PDA 	<ul style="list-style-type: none"> Pre-implementation questionnaire Insulin PDA tracking log 	Pre-implementation questionnaire was administered immediately after the insulin PDA training workshop Insulin PDA tracking logs were placed with the insulin PDAs in the consultation room for doctors to record the number of patients who were given the insulin PDA
Adoption (<i>"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."</i>)	The number and proportion of doctors who adopted the insulin PDA	<ul style="list-style-type: none"> Number of doctors who adopted the insulin PDA / Number of doctors who attended the training workshop 	<ul style="list-style-type: none"> Insulin PDA tracking log Research administrative data 	Insulin PDA tracking logs placed in the consultation room were reviewed to determine the number of doctors who gave the insulin PDA to patients
	Adoption was also measured at the patient level, which was defined as the number of patients who read the insulin PDA.	<ul style="list-style-type: none"> Number of patients who read the PDA / Number of patients who received the insulin PDA and received a follow-up 	<ul style="list-style-type: none"> Patient self-reported information Research administrative data 	Patients were followed-up at their next appointment if they have read the insulin PDA.

Table 2 (continued)

RE-AIM dimension (Definition) [26]	Study definition	Outcome measure	Study instrument / Source of data	Data collection approach
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.”)	HCPs’ fidelity to the various implementation tasks as set in the insulin PDA implementation protocol.	<ul style="list-style-type: none"> 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 PDAs given to patients Number of times doctor made a note that the insulin PDA is given in patient’s appointment book / Number of patients who were given the PDA and followed-up Number of times doctor provided ≤ 3 months appointment to patient for the insulin PDA follow up / Total number of PDAs given to patients Number of times doctor follow up with patient on the insulin PDA use / Number of times insulin PDA were noted in the EMR 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 patient’s appointment book that the insulin PDA was given Nurses’ adherence to their implementation task: Number of insulin PDA available in the consultation rooms 	<ul style="list-style-type: none"> Fidelity checklist Clinic administrative data 	<ul style="list-style-type: none"> Review of patient medical records in the EMR Review of patient’s appointment book during follow-up Review of records in the EMR Feedback from patient & and review of notes in the EMR Review of records in the EMR
Maintenance (“The extent to which a program or policy becomes institutionalized or part of the routine organisational practices and policies” (RE-AIM Workgroup, 2020).	Willingness of doctors to maintain the implementation	<ul style="list-style-type: none"> Number of doctors who were willing to continue to implement the insulin PDA / number of doctors who were practising in the clinic 	<ul style="list-style-type: none"> Research administrative data Post-implementation questionnaire 	<ul style="list-style-type: none"> Manual count of the insulin PDA in the consultation rooms at the end of the fourth to seventh month of the implementation. Post-implementation questionnaire were administered at the end of implementation period to assess willingness to continue to implement the PDA.

EMR electronic medical record

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.

All the interviews were conducted at a private room in the clinic and were audio-recorded. IDIs with patients were between 30-40 min long. IDI with the clinic coordinator was one hour, while FGDs with doctors and nurses were all slightly more than one hour. Once the interviews ended, the researcher wrote down reflections to capture the essence of the interviews, which helped inform the data analysis. The audio-recordings were later transcribed for data analysis.

Data analysis

Data management and analysis were conducted using the qualitative data management software NVIVO [37]. The data analysis was conducted by the researcher, WTT. Thematic analysis was carried out whereby findings were generated based on codes and themes grounded in the data [38]. Initially, WTT 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. 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 policymakers and HCPs, and patients.

Next, the researcher applied the coding frameworks to the remaining healthcare policymakers and HCPs, and patient transcripts respectively. Any new codes or categories that emerged were added to the coding framework after discussion with other researchers (YKL, CJN, PYL). Constant comparative method was employed throughout the analysis. 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, themes that emerged were matched based on their relevance to each of the RE-AIM dimensions, and were presented in a coherent narrative to explain the quantitative outcomes.

The findings are reported in accordance with the SQUIRE reporting guideline [39] (Supplementary file).

Establishing rigour

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 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, WTT 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 among researchers to confirm the data. WTT was challenged on some of the data interpretations by the coresearchers and she had to 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.

Ethical considerations

This study received ethics approval from the University of Malaya Medical Centre Medical Ethics Committee (reference: MECID.NO: 20158 – 1600). Informed consent to participate was obtained from all the participants in a written consent form. All methods in this study were performed in accordance with the relevant guidelines and regulations, and with the Declaration of Helsinki.

Results

Characteristics of participants

Quantitative results

A total of 48 doctors in the clinic participated in the implementation. The mean age of the doctors was 33.5 (\pm 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 (\pm SD 1.44) years (range: 3 months–7 years), and the average number of patients counselled on insulin initiation was 9.9 per month (range: 1–30 patients). Detailed socio-demographic information of doctors can be found in Supplementary file.

Qualitative results

A total of 62 patients participated in the IDIs. The mean age of the patients was 58.0 years old (\pm SD 12.1) (range: 26–83). 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%).

A total of six IDIs and six FGDs were conducted with HCPs (healthcare policymakers: 3, doctors: 35, and staff nurses: 5). The mean age of the HCPs was 34.1 (\pm 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%). Detailed socio-demographic information of the patients and HCPs can be found in Supplementary file.

Reach

HCPs

Overall, 88.9% ($n=48/54$) of doctors and 55% ($n=11/20$) of nurses attended the insulin PDA training workshops. The two most common reasons for attending the workshop among the doctors was an interest to learn more about the insulin PDA (77.1%, $n=37/48$), and the Head of Department's letter about the clinic's intention to implement the insulin PDA (54.2%, $n=26/48$). Table 3 presents data from the qualitative interviews, noting that the reach of the insulin PDA implementation to doctors was facilitated by their self-motivation to try out an innovation in the clinic. Another reason that facilitated reach was the mandate from the Head of Department. However, the mandate was found to be perceived differently by different individuals with some who saw it as a coercion to participate in the implementation, while others saw the mandate as an indication that the insulin PDA was an important clinic initiative.

Patients

The insulin PDA reached 387 patients over 7 months. Based on the interviews, it was found that doctors delivering the insulin PDA to patients contributed to patients' acceptance of the insulin PDA. Patients also accepted the insulin PDA because they wanted to know more information about insulin. However, one patient revealed that he did not want to accept the PDA initially as he has no intention to initiate insulin, however, he took the PDA because he did not want to make the doctor unhappy. Interview with doctors revealed that the lack of interest to start insulin therapy was the main reason why patients refused to accept the insulin PDA (Table 3).

Adoption

Doctor

A high proportion 83.3% ($n=45/54$) of the doctors adopted the insulin PDA during the study. In the

interviews with doctors, positive experience, and the usefulness of the insulin PDA was commonly reported as the reason for adoption. Many also attributed their adoption to the training workshop which helped them to understand the purpose of the insulin PDA, how to use it, and their implementation tasks (Table 3).

However, some doctor expressed that, although they were actively using the PDA initially, they reduced or stopped using it after several encounters with patients who did not read the insulin PDA given as it affected their motivation (Table 3).

Many doctors felt that the feedback given during the implementation period was not effective in motivating them to adopt the insulin PDA. They used the PDA because of patients' needs rather than to achieve higher adoption rate. One of the healthcare administrators noted that insulin uptake rate might be a better indicator to feedback to the HCPs (Table 3).

Patient

Among 143 patients who returned to the clinic for their follow-up appointments, only 65.7% ($n=94$) reported that they read the insulin PDA given. Among those who used the PDA, the most common reason was the same as the reason on why they accepted the PDA in the first place, which was the desire to gain more information about insulin. Another reason for using the PDA was because they were advised by doctor to use it. The main reason for not using the insulin PDA was busy-ness (Table 3).

Implementation

Doctors' adherence to their implementation tasks

There were variations in the extent to which the doctors adhered to the four types of implementation tasks (Table 4).

The task of making a note in the EMR registered highest adherence (84.9%). When the doctors were asked on why many had adhered to this task, they revealed that they considered giving the insulin PDA to patients as part of patient management (Table 3). On the other hand, the task of making a note in patient's appointment card (19.2%) was least adhered to, and they explained that writing patient's management plan in their appointment cards was not something that they are used to doing.

Appointment clerks' adherence to their implement task

Appointment clerks' adherence to their implement task was low. Out of the 27 notes made by doctors in the patients' appointment card to indicate the insulin PDA had been given, only 25.9% ($n=7/27$) were indicated in the EMR 'Remark' section by appointment clerks.

Table 3 Themes and interview excerpts related to the 'reach', 'adoption', 'implementation' and 'maintenance' of the RE-AIM framework

RE-AIM dimension	Theme	Interview excerpts
Reach (HCPs)	Doctors' self-motivation	"I think to reach 90% (PDA reach to doctors) is very high as this is a busy clinic. // 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 and don't want to miss out." – IDI 4_Healthcare policymaker_20 years of experience working in the clinic
	The mandate of the insulin PDA implementation	"I thought (the letter from the head of department) was kind of like forcing us (laugh) because I still remember that time, we were so stressed with our exam but yet we still have to attend (the PDA training workshop) [laugh]." – FGD 1_Doctor 5_Distributed 2 PDAs "I think it was the fear of the implication of not attending [the PDA training workshop] is what compelled me [laugh] to attend because the head of department's signature is there (on the letter). If I am not there, what will be the consequences." – FGD 1_Doctor 3_Distributed 22 PDAs "Is not because I'm scared of my boss (that's why I use the PDA). But is like, this is something that is really serious for this department and to be implemented. So, I try to join." – FGD 4_Doctor 1_2 years of experience working in the clinic_Distributed 7 PDAs
Reach (Patient)	Doctors delivering the PDA to patients	"(I wonder) Why did the doctor gave me this book when they can just explain. I think there must be something special inside. That's why I took the book." – IDI 22_Patient_35 years old_2 years living with diabetes_2 years seeking treatment in the clinic_
	Patients desire to know more about insulin	"I want to increase my understanding of insulin." – IDI 5_Patient_60 years old_11 years living with diabetes_5 years seeking treatment in clinic
	Patients were not keen on insulin	"My thinking is that (having the need to start insulin) is serious. This means the sugar level is high and they need to use insulin. I took (the PDA) home but I didn't read because I think I can try to do something to reduce the sugar level (first)." – IDI 5_Patient_58 years old_1 year living with diabetes_1 year seeking treatment in clinic "I don't want this (insulin). I don't want (to take the PDA), but I still took it with me because the doctor will be [patient non-verbal communication– face mimic unhappy]. If I take (the PDA). . . the doctor will feel ok." – IDI 56_Patient_72 years old_10 years living with diabetes_10 years seeking treatment in clinic "Sometimes when you want to start talking about insulin, they will say 'Doctor I don't want insulin.' So, you cannot proceed (to use the insulin PDA with patient). They already stop you there." – FGD 2_Doctor 2_3 months of experience working in the clinic_Distributed 3 PDAs
Adoption (Doctors)	Positive experience with the insulin PDA use	"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)." – FGD 6_Doctor 3_4 years of experience working in the clinic_Distributed 7 PDAs "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 does not understand." – FGD 6_Doctor 3_4 years of experience working in the clinic_Distributed 7 PDAs
	The effectiveness of the training workshop	"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 don't think they will prescribe the PDA without the workshop." – FGD 6_Doctor 3_4 years of experience working in the clinic_Distributed 7 PDAs
	Patients' non-use of the insulin PDA affects doctors' motivation to adopt the insulin PDA	"Starting point I was quite active in giving out the insulin PDA. After a while, 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)." – FGD 6_Doctor 4_2 years of experience working in the clinic_Distributed 4 PDAs

Table 3 (continued)

RE-AIM dimension	Theme	Interview excerpts
	The lack of effectiveness of the strategy 'Provide feedback'	"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 [of PDA adopted] in the graph (in the feedback report)." – FGD 5_Doctor 4_Doctor 24_3 years of experience working in the clinic_Distributed 4 PDAs "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." – IDI 6_Doctor_2 years of experience working in the clinic_Did not use PDA "The feedback that they want to know is information such as uptake of insulin after PDA rather than, 'I've not been using it.'" – IDI 3_Healthcare policymaker_10 years of experience working in the clinic
Adoption (Patient)	To gain more knowledge about insulin	"I read it because I wanted to know the content of this book, and what is insulin about. So I did went through it page by page." – IDI 57_Patient_10 years living with diabetes_4 years seeking treatment in the clinic
	Doctor advise to use the PDA	"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." – IDI 8_Patient_15 years living with diabetes_3 years seeking treatment in the clinic
	Patients were busy	"I went through a few pages but I didn't finish using the book. I was busy with my work because my work involved a lot of moving around. So, I did not have the time." – IDI 41_Patient_58 years old_20 years living with diabetes_2 years seeking treatment in the clinic
Implementation	Task was part of patient clinical management	"The insulin PDA is like part of our management plan. That's why we tend to do that (note in the EMR)." – FGD 3_Doctor 3_4 months of experience working in the clinic_Distributed 10 PDAs "Making notes in the EMR is easier because you are typing it immediately after giving intervention to the patients. But writing intervention on the appointment card is not really our habit. Sometimes we miss this step." – IDI_Doctor 10_1 year working in the clinic_Distributed 32 PDAs
	Patient factors hampered provision of appointments within 3 months to patients and conduct of the insulin PDA follow-up.	"This step (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 busy or they have no one to bring them over. We can't force them." – IDI_Doctor 1_1 year working in the clinic_Distributed 32 PDAs
	System barrier to provide appointment within three months to patients	"Giving a less than three months appointment sometimes is difficult, because the counter (appointment clerks) would inform me that my appointment is already full till next year. So, I can't give a three-month appointment." – FGD 5_Doctor 1_5 months working in the clinic_Distributed 13 PDAs
	Nurses' attitudes	"Even though nursing officer said you have to do this but some nurses don't bother about that. Some nurses are irresponsible towards their tasks. 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." – FGD 8_Staff nurse 4_14 years experience working in the clinic "I asked the team leader (about the PDA supply). She said 'No, they didn't give the stock'. When the insulin PDAs are finished, you cannot just say don't have and don't take any action. That is when I called you (the research team) for the insulin PDA supply" – FGD 8_Staff nurse 4_14 years experience working in the clinic
Maintenance	Usefulness and benefits of the insulin PDA to patients	"I will continue (to use the PDA). It helps with educating the patients about insulin." – FGD 6_Doctor 6_2 years experience working in the clinic_Distributed 7 PDAs

Staff nurses' adherence to their implementation task

Based on the count of the number of the insulin PDA booklets in the consultation rooms at the end of the month between June to October during the implementation, it was found that PDAs in specific languages were unavailable in some of the consultation rooms. The interviews revealed that nurses' attitude and behaviour was raised as a major challenge for the insulin PDA

implementation. Nurses' role in the implementation was to replenish the insulin PDA in the consultation room. In a qualitative interview, 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. Furthermore, nurses in the clinic are on a rotation to be a team leader for two weeks (i.e., team leader are responsible to ensure clinic operations run smoothly

Table 4 Doctors' adherence to the 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 has been given to patient / Total number of PDAs given to patients	84.9 (331/390)
Number of times doctors make a note that the insulin PDA is given in patient's appointment card / Number of patients who were given the PDA and received followed-up	19.2 (27/143)*
Number of times doctor provided ≤ 3 months appointment to patients for the insulin PDA follow-up / Total number of 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 (13/331)**

*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

including inventory management), however, some team leaders did not take action to replenish the insulin PDA despite being asked about the insulin PDA supply (Table 3).

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. The usefulness and benefits of the insulin PDA to patients was the reason for the continued willingness to use the PDA (Table 3).

Discussion

This study found that with a tailored implementation strategy to promote PDA use, there was a relatively high degree of reach and adoption among doctors, although patient adoption of the insulin PDA was only moderate. At the end of the study period, a high proportion of doctors indicated a willingness to continue using the insulin PDA. Qualitative findings shed light on the interplay between selected strategies and implementation outcomes. While some barriers and facilitators to PDA implementation were common (e.g. too busy, finding the PDA useful and beneficial [40, 41], patient desire for more information), we found that factors unique to the Malaysian health setting (HCPs' roles and responsibilities) and culture (social hierarchy) influenced the implementation outcomes in unexpected ways.

In this 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 (89%) in the insulin PDA workshops among the doctors. 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 [42]. In another 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, which resulted in 97.1% of the HCPs participating [43]. However, one study which appointed a research assistant (rather than an influential physician) to help with recruitment of community primary care practices to implement cancer screening PDAs only has a recruitment rate of 6% [44]. These findings together with the findings of this current study indicated that using an organisational leader or influential HCP to make personal invitations (i.e. individualised letters, personal face-to-face meeting) is an important facilitator to promote PDA implementation among HCPs. This facilitator may also be more important to implementation of PDAs given the lack of awareness and knowledge of the concept of SDM and PDA in Malaysia, which necessitates push from an authority person. Unlike the implementation of clinical practice guideline, which HCPs are more familiar with, the need for an organisational leader to promote guideline uptake is not necessary as it was not reported as a common strategy for guideline implementation [45].

The strategy mandate change is reported elsewhere as a facilitator for PDA implementation studies as it leads HCPs to believe that PDA implementation is an organizational priority [46, 47]. However, this study found that while this strategy can influence PDA adoption, it was tied to more negative punitive beliefs as doctors reported fear of implications for not following orders from their higher authority. Malaysia has a hierarchical society, and in healthcare settings, junior HCPs tend to obey senior HCPs or the higher authorities. Hence this may be another reason why this strategy was effective to facilitate the insulin PDA implementation. Nevertheless, there is a need for better understanding on the mechanism of how the strategy mandate change exerts its effect, for example, would negative influence (i.e.: mandate result in the feeling of coercion to be involve in the implementation) or positive influence (i.e.: mandate result in positive belief that the implementation is important and useful) of mandate has a better effect in facilitating implementation as such is lacking in the literature.

This current study had adopted the strategy 'provide feedback' to motivate HCPs to adopt the insulin PDA.

However, this strategy was perceived to be less effective compared to other strategies that influenced doctors to adopt the insulin PDA. Other studies reported positive effects of feedback that rendered HCPs' feeling motivated and having an increased sense of commitment to using the PDAs [42, 47–49]. One of the reasons for the discrepancy between this current study and other studies in terms of the effectiveness of the 'provide feedback' strategy lies in the content of the feedback. Other studies included patient positive feedback, satisfaction, knowledge and decision quality [42, 47–51]. In this current study, feedback content mainly focused on doctors' PDA adoption rate, and their adherence to implementation tasks.

The participants of this study highlighted that they would use the insulin PDA based on the patients' needs. For future PDA implementation efforts that utilise 'provide feedback' strategy, it is important that patient outcomes are incorporated in the feedback to HCPs as they are more valued.

This study found that some nurses did not perform their task for the insulin PDA implementation despite aligning the nurses' insulin PDA implementation task with their existing duty in this current study (i.e., refilling supplies). Social hierarchy, organisational work culture, and the clear role and responsibilities of different HCPs in Malaysia might have contributed to nurses' lack of motivation to carry out their task. In Malaysia, doctors are perceived to be more knowledgeable, have more authority, and they are the only HCP who can prescribe medication such as insulin to patients. Nurses are given limited roles such as administering medications and treatments according to doctor's orders. Some studies have reported nurses in Malaysia to be dissatisfied, stress, and felt that their job as a nurse was under-respected [52–55]. In the Western countries, nurses have reported to perform tasks without physician oversight such as physical examinations, order and interpret diagnostic tests, and write prescriptions [56, 57]. Teamwork is an essential key determinant of implementation outcomes. In order to promote teamwork for PDA implementation, 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 recognising nurses' abilities and giving them more responsibility for clinical decision making in patient care so that they would feel empowered in carrying out their duties. Interprofessional approach has been promoted to facilitate PDA implementation [58] as different HCPs can play different roles in the implementation hence disperse the workload that is needed to implement SDM and PDA. For example, nurses can take the responsibilities to familiarise patients with the PDA [59], or provide decision coaching before patients meet with clinicians [60, 61], while clinicians can carry out the

SDM discussions with patients. This will help to alleviate the burden of operationalising PDA delivery by physicians, which have consistently being reported to be not effective [6, 44, 62–65].

This study highlighted that doctors were demotivated to continue using the insulin PDA when many of their patients who were given the PDA did not read it. This can affect sustainability of PDA implementation as doctors lose motivation over time as they could not see the positive impact of the PDA. Conversely, one of the facilitators for PDA adoption among doctors found in this study was the personal positive experience and perceived usefulness of the insulin PDA. This indicates that if doctors experienced the value and benefits of delivering the PDA to patients, this could overcome barrier such as "HCPs are busy" as they may find ways to integrate PDA use in their busy consultation. Perceived positive contribution of PDA to patients and practice have been shown to be factors associated with the sustainability of PDA implementation [8, 59]. Future implementation effort should leverage on the strategy of making HCPs to understand the value and benefits of PDA. One way that can be done is through continuous feedback provision focusing on patient positive feedback, satisfaction, knowledge and decision quality [42, 47–51]. Notwithstanding, efforts are also needed to promote PDA use among patients. In this study, patients did not read the insulin PDA because they have psychological resistance to insulin therapy. Future PDA implementation may need to include initially assessment of patients acceptance of the treatment options and counsel accordingly before the PDA is offered to the patient.

Study strengths and limitations

The strengths of this study are that this is one of the few PDA implementation studies that assessed implementation outcomes, and that were conducted in the Asian settings. Secondly, this study was conducted in routine clinical practice with minimal interference. Hence the findings have considerable external validity and may be applicable to other settings. Thirdly, this study utilised various sources of data (literature review, administrative data (EMR), questionnaire, interviews), and adopted perspectives from a wide range of stakeholders (healthcare policymakers, doctors, pharmacists, nurses, patients), which enhances the credibility of the findings of this study.

This study has a few limitations. First, there is a possibility of underreporting of the number of PDAs given to patients using the insulin PDA tracking log (Reach-patient, Adoption-doctor), 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 (Implementation) as these findings relied on doctors self-reported data. Secondly, the number of

patients who were eligible to use the insulin PDA could not be determined (Reach-patient). This limits the understanding of the true extent to which the insulin PDA reached the patients. Thirdly, the definition of the RE-AIM “implementation” dimension in this study referred to HCPs’ fidelity to the various implementation tasks as set in the insulin PDA implementation protocol, and not HCPs’ fidelity to how they use the PDA with patients using the SDM approach. It would be of greater value, if HCPs fidelity to SDM approach can also be measured to ensure that SDM are truly being practised, and not mere handing out PDAs to patients. Fourthly, the thematic analysis was conducted by only one researcher (WTT), however, she constantly checked her analysis with the other coresearchers of this study (YKL, CJN, PYL) to ensure the findings interpretations were accurately described. Fifthly, the implementation of the insulin PDA was conducted in 2018, and prior to the COVID-19 pandemic, hence the findings needs to be interpreted with caution given the current context.

Study implications and recommendations

The findings of this study are useful for PDA implementers who may want to target specific implementation outcome (‘reach’, ‘adoption’, ‘implementation’, and ‘maintenance’), and adopt or improvise the strategies reported in this study to facilitate PDA implementation efforts. Some of the recommendations for future PDA implementers are: there is a need for an organisation leader or influential physician to show visible support for the PDA implementation and send personal invitations to the staff who would be involved in the implementation particularly for settings where the concept of SDM and PDA are not well known in order to encourage HCPs to be involved in PDA implementation. As perceived usefulness and benefits of PDAs are crucial for sustainability of PDA use among HCPs, continuous feedback provision particularly on patient outcomes are important. The Malaysian healthcare work culture should shift towards more empowered nurses roles in order to promote true interprofessional collaboration to PDA implementation.

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. These outcomes are useful as feedback to doctors to motivate them to use the PDA with their patients. Future studies can consider adopting the hybrid effectiveness-implementation study design whereby both implementation and effectiveness outcomes are measured [66].

Conclusions

This study highlighted that PDA implementation is promising given the high reach and adoption, and there is continued willingness to use the insulin PDA in practice among doctors. This was mainly attributed to the personal positive experience with the usefulness and benefits of the PDAs. Addressing the issues of social hierarchy, and HCPs roles and responsibilities can further improve implementation outcomes.

Abbreviations

HCPs	Healthcare providers
PDAs	Patient decision aids
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
SDM	Shared decision making

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12913-025-12588-x>.

Supplementary Material 1.

Acknowledgements

The authors would like to thank the University of Malaya Research Grant (UMRG) – RP041C-15HTM and the University of Malaya Postgraduate Research Grant (PPP) (PG264-2016A) for funding this study.

Authors’ contributions

All authors (WTT, YKL, CJN, PYL) of this study conceived and designed the study, analyzed the data and contributed to the discussion and wrote and edited the manuscript. WTT, YKL and NCJ conducted the interviews. WTT wrote the first draft of the manuscript. All authors read and approved the final manuscript.

Funding

This study was funded by the University of Malaya Research Grant (UMRG)–RP041C-15HTM and the University of Malaya Postgraduate Research Grant (PPP) (PG264-2016A).

Data availability

All data generated or analysed during this study are included in this published article.

Declarations

Ethics approval and consent to participate

This study received ethics approval from the University of Malaya Medical Centre Medical Ethics Committee (reference: MECID.NO: 20158 – 1600). Informed consent to participate was obtained from all the participants in a written consent form.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 20 April 2023 / Accepted: 16 March 2025

Published online: 27 March 2025

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