# SOFTWARE REQUIREMENTS SPECIFICATION AND INTERFACE DESIGN FOR A MOBILE HEALTH (MHEALTH) APPLICATION FOR DIABETES MEDICATION MANAGEMENT



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PROJEK YANG DIKEMUKAKAN UNTUK MEMENUHI SEBAHAGIAN
DARIPADA SYARAT MEMPEROLEH IJAZAH
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**DECLARATION**

I hereby declare that the work in this thesis is my own except for quotations and summaries which have been duly acknowledged.

18 July 2024

CHONG YI QI
P119300

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## ABSTRAK

Ketidakpatuhan terhadap rawatan ubat merupakan isu yang lazim dihadapi oleh pesakit kronik, termasuk kencing manis jenis dua (*T2DM*) dalam pengurusan ubat kendiri. Walaupun terdapat banyak aplikasi kesihatan mudah alih (*mHealth*) untuk tujuan pengurusan ubat, kajian melaporkan bahawa terdapat perbezaan yang ketara antara aplikasi-aplikasi tersebut dari segi kualiti, isi kandungan, dan fungsi, disebabkan oleh kekurangan dalam penyelarasan dengan amalan berasaskan bukti (*evidence-based practice*) serta penglibatan daripada pihak berkepentingan seperti pesakit dan ahli profesional kesihatan, semasa pembangunan aplikasi. Kajian ini bertujuan untuk membangunkan prototaip aplikasi mHealth khusus untuk pengurusan ubat *T2DM* serta menyediakan maklumat asas mengenai spesifikasi keperluan perisian (*SRS*) dan reka bentuk antaramuka pengguna (*UI*) dari perspektif pesakit *T2DM* dan ahli farmasi. Kajian ini menggunakan kaedah penyelidikan kualitatif digabungkan dengan aktiviti pembangunan perisian model *Rapid Application Development* (RAD), dan dijalankan dalam dua fasa penyelidikan. Fasa 1 kejuruteraan keperluan melibatkan beberapa kaedah seperti sesi pemerhatian, sumbang saran, temu bual individu dengan pesakit dan ahli farmasi, analisis dokumen dan penilaian landskap teknologi, untuk mengumpul, menganalisis, dan mendefinisikan keperluan pengguna. Keperluan pengguna ini menyumbang kepada proses spesifikasi keperluan dan reka bentuk *UI* yang seterusnya. Fasa 2 reka bentuk melibatkan proses prototaip dan ujian kebolehgunaan secara iteratif dengan pengguna untuk mereka bentuk, menguji, dan memperbaiki prototaip. Isu kebolehgunaan prototaip telah dikenalpastikan dan diselesaikan, agar model reka bentuk *UI* dimuktamadkan untuk pelaksanaan masa depan. Prototaip akhir merangkumi beberapa fungsi utama yang ditetapkan oleh pengguna akhir, iaitu: fungsi pengingat, dokumentasi sejarah ubat lengkap, perekodan pengambilan ubat, pelaporan kepatuhan ubat, perekodan bacaan (seperti paras gula darah, tekanan darah dan berat badan), pemesejan segera, sistem notifikasi untuk pemantauan status pesakit, modul pendidikan, dan mesej motivasi. Dokumen *SRS* dan model reka bentuk *UI* yang dihasilkan bagi prototaip aplikasi mudah alih ini bertujuan untuk menyumbang kepada usaha menangani ketidakpatuhan ubat dalam golongan pesakit *T2DM* dengan pendekatan yang lebih holistik.

## ABSTRACT

Medication non-adherence is a common issue affecting patients with chronic diseases, including Type 2 diabetes mellitus (T2DM), in their medication self-management. Despite the availability of numerous mobile health (mHealth) applications for medication management, studies have reported significant variations in their quality, content, and features due to a lack of alignment with evidence-based practices, as well as inadequate involvement of relevant stakeholders, such as patients and healthcare professionals (HCPs), in their development. This study aimed to develop a mHealth application prototype specifically for T2DM medication management and to provide baseline information on the software requirements specification (SRS) and user interface (UI) design from the perspectives of patients with T2DM and pharmacists. The study employed a qualitative research design in conjunction with the software development activities of a Rapid Application Development (RAD) model, consisting of two research phases. Phase 1 (requirements engineering) involved observations, brainstorming, individual interviews with patients and pharmacists, document analysis and technology landscape assessment to elicit, analyse, and define user requirements. These requirements informed the subsequent requirements specification and UI design process. Phase 2 (design) involved iterative prototyping and usability testing with intended users to design, test, and refine the prototype. Usability problems were identified and resolved, and the UI design model was established for future implementation. The final prototype included several key functionalities requested by end users: customisable reminders, complete medication history documentation, medication intake logging, medication adherence reporting, measurements logging, an instant messaging feature, patient status monitoring alerts/notifications, educational content, and personalised motivational messages. The finalised SRS and UI design model of this mobile app prototype aim to contribute to a more holistic approach to addressing medication non-adherence among patients with T2DM.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| ADR | Adverse drug reactions |
| HCP | Healthcare professional |
| mHealth | Mobile health |
| OAD | Oral antidiabetic agent |
| OTC | Over-the-counter |
| RAD | Rapid application development |
| SDLC | Software development life cycle |
| SRS | Software requirements specification |
| T2DM | Type 2 diabetes mellitus |
| UI | User interface |

# CHAPTER I

# INTRODUCTION

## 1.1 RESEARCH BACKGROUND

Diabetes mellitus (DM) has become a global health concern due to a drastic surge in global incidence particularly of type 2 diabetes mellitus (T2DM), as observed in recent years (International Diabetes Federation 2021). Due to its complex nature as a chronic disease, T2DM management heavily rely on continuous efforts not only from the patients, but also from the health care professionals (HCPs) team. Similar to other chronic health conditions, extensive self-management behaviours are very much needed from the patients in diabetes management, e.g. making lifestyle modifications (healthy diet and physical activity), maintaining good medication adherence, recognising and responding to symptoms, and handling acute episodes (Sabaté 2003). Therefore, patient education and self-management have long been considered the key strategy of diabetes care to reduce risk factors and prevent diabetes-related complications (Olesen et al. 2020).

Medication self-management is one of the crucial yet complex DM self-management skill for patients with T2DM. Managing multiple medications concurrently or initiating a new prescription can pose challenges for many patients (Millar et al. 2019). These difficulties may encompass understanding the medication regimens, incorporating the medication-taking routine into one's daily schedule at the appropriate timing, and handling issues regarding the safety and efficacy of the prescribed medication (S. C. Bailey et al. 2013; Capoccia et al. 2016). To address these needs and difficulties, the importance of a reliable and user-friendly tool for T2DM medication management cannot be emphasised enough.

Advancements in smartphone technologies have brought vast opportunities to manage health concerns and evolved into a new field known as mobile health (mHealth). MHealth is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" (World Health Organisation 2011). With the adoption of smartphones by general public and the incorporation of mobile applications into daily lives (Car et al. 2017), mHealth applications are increasingly becoming a popular tool in medication management for chronic diseases over past decades. Many benefits of mHealth have been reported in diabetes care, such as improved patient health behaviour, enhanced clinical outcomes, and greater healthcare accessibility (Eberle et al. 2021). The widespread ownership of smartphones among Malaysians (91.5%) (Malaysian Communications and Multimedia Commission 2021) may support the potential of mHealth applications as a practical solution for addressing T2DM patients' challenges in medication management.

Today the vast number of mobile applications available provides opportunities to assist patients in managing outpatient medication use for a wide range of medical conditions. However, recent evidence pointed out the gaps in these applications that fall short of users' needs and lacked the functionalities important for supporting medication adherence and safety (Huang et al. 2019). Moreover, it has been reported that less than 20% of Malaysians were familiar with mHealth and actively used it (Lee et al. 2020). Several factors were found to be related with the low rate of mHealth adoption, such as perceived complexity in usage, usability issues, and lack of personalised features (Jacob et al. 2022). Previous research has explored the user requirements regarding mobile medication management applications for various health conditions (Ali et al. 2019; Anglada-Martínez et al. 2017; Bernhard et al. 2018; Márquez Fosser et al. 2021; Sedlmayr et al. 2019), but there has been limited focus on patients with diabetes and those studies were mainly conducted in the Western healthcare backgrounds. Therefore, this suggests a need for further research to delve into how the mHealth application can align with users' requirements by gaining a deep understanding of the target population in the local settings to ensure that the designed mHealth application is usable and engaging to the intended users.

## 1.2 PROBLEM STATEMENT

Medication adherence, generally defined as the practice of following prescribed medication regimens as directed by healthcare providers (Osterberg & Blaschke 2005), is essential for effectively managing chronic health conditions such as T2DM. Studies highlighted that the problem of poor medication adherence is common among patients with diabetes (Krass et al. 2015). Various factors such as forgetfulness, poor understanding of own medications, adverse drug effects, and polypharmacy (taking five or more types of medication therapy) (Capoccia et al. 2016) may pose challenges to patients with T2DM in self-managing their medications and maintaining adherence. Poor medication adherence has been shown to reduce treatment effectiveness and blood glucose control, which in turn result in higher risk of hospital admission and mortality (C. J. Bailey & Kodack 2011). Therefore, this calls for proper medication management strategies with the assistance of useful tools and technology.

Currently there is low digitisation of health records in Malaysia, where most medical records are still paper based mainly due to the lack of funding. Recent statistics reported that EMR implementation rolled out to only 29% of government health facilities nationwide (Mohd Fadli 2023). Medication-related information is mainly compartmentalised and stored within pharmacy and institutional electronic health records, which hinders the availability and accessibility of data related to medication use. Patients with T2DM may encounter difficulties in performing simple medication management tasks, such as establishing a current list of medications, maintaining accurate medication histories, and tracking medication-related side effects and symptoms. Medication errors may be more likely to occur, especially in cases like frequent modifications in medication or dosage, mismatched medication records, and inadequate medication reconciliation during transitions of care (Mira et al. 2015). Consequence of medication errors can be serious and sometimes life-threatening (Assiri et al. 2018), therefore a reliable medication management tool which helps improve medication safety and patient outcomes becomes crucial.

Despite that large number of mobile medication management applications are currently available, it is still unclear if the content and functionalities of these

applications are aligned with evidence-based recommendations and best practices (Jimenez et al. 2019). The involvement of relevant stakeholders i.e. patients and HCPs in the development of these mobile applications is questionable. A study revealed significant variation in the quality, content, and feature of these mobile applications (S. C. Bailey et al. 2014) and emphasised the importance of further research on the design of these applications from patients' perspectives. Tabi et al. (2019) identified that not more than 15% of the medication management applications available in the marketplaces were developed in collaboration with HCPs. Previous research has highlighted that HCPs involvement of mHealth app development is pivotal to increase patients' participation and sustain use over time (Goyal et al. 2016). In this aspect, pharmacists will have important contributions because of their unique position in medication management (Hughes et al. 2017). To date, there is a paucity of evidence on the user requirements and interface design of mobile medication management application, let alone specifically for T2DM. Existing studies are either focused on specific diseases and patient populations, or limited to the perspectives of patients within the context of Western healthcare settings (Ali et al. 2019; Anglada-Martínez et al. 2017; Bernhard et al. 2018; Márquez Fosser et al. 2021; Sedlmayr et al. 2019), suggesting the need for relevant studies locally.



With this background and knowledge gaps highlighted, this research sought to develop a mHealth application prototype specifically for T2DM medication management and provide baseline information on the software requirements specification (SRS) and user interface (UI) design from the perspectives of patients and pharmacists.

## 1.3 RESEARCH QUESTIONS

This research sought to provide an answer to the following key research questions:

1. What are the software requirements specifications for a diabetes medication management application?
2. How can the UI of a mobile diabetes medication management application be designed?

## 1.4 RESEARCH OBJECTIVES

The main goal of this research was to propose a mHealth mobile application as a solution to support patients with T2DM in self-managing their medications, as well as to assist the practising pharmacists in delivering pharmaceutical care and services to this patient population.

This goal was achieved by gathering and analysing the perspectives of T2DM patients and pharmacists from the government primary care health clinics with the following objectives:

1. To investigate the current practice of diabetes care and management in Malaysia.
2. To gather user requirements on the design of a mobile health application for medication management in T2DM.
3. To develop SRS for a mobile health application for medication management in T2DM.
4. To design the UI of a mobile T2DM medication management application.

## 1.5 SCOPE OF RESEARCH

The current research falls under the domain of health informatics which encompasses the utilisation of knowledge in computer science and healthcare field in solving problems encountered in the healthcare sector. This dissertation mainly focuses on proposing the design of a mHealth application used to support medication self-management and resolve medication-related problems among patients with T2DM. Elements of a software development life cycle (SDLC) model such as requirements engineering and design, were involved to ensure the design of the mentioned mobile application tailored to the needs of Malaysian T2DM patient population and local diabetes care and practice. The findings yielded from the data collection and analysis were then organised and utilised in developing the proposed design of UI of a mobile medication management application and the software requirements specification document. A detailed breakdown of the research methodology is elucidated in the following chapters.

# CHAPTER II

# LITERATURE REVIEW

## 2.1 DIABETES MELLITUS

In recent decades, diabetes mellitus (DM) has become increasingly prominent in literature and discussions among the general public, researchers, healthcare policymakers and providers (World Health Organisation 2016). Being one of the leading causes of debilitating co-morbidities and premature mortality worldwide (World Health Organisation 2016), DM and its complications not only bring about poor quality of life in diabetic patients, but also cause considerable financial burden to patients and their families, as well as to healthcare systems and national economy in the form of higher healthcare expenditures and lost productivity and incomes (American Diabetes Association 2018).



### 2.1.1 Aetiology

DM is a detrimental and chronic metabolic condition characterised by persistently high glucose levels in the blood. The abnormal elevation of blood glucose in this disease is attributed to either insufficient insulin production, insulin resistance (the body's inability to efficiently utilise the insulin), or both. Currently, there are four clinical classifications into which this metabolic disorder is categorised, namely: Type 1, Type 2, gestational, and other specific forms of diabetes related to other causes (American Diabetes Association Professional Practice Committee 2022; International Diabetes Federation 2021).

Type 2 diabetes mellitus (T2DM) is commonly referred to as adult-onset diabetes and comprises 90–95% of all diabetes cases (Banday et al. 2020). This research and dissertation will primarily revolve around T2DM due to its high

prevalence in the DM patient population. As opposed to Type 1 diabetes mellitus (T1DM) and gestational diabetes, optimal blood glucose control can be achieved in T2DM through behavioural and lifestyle modifications (International Diabetes Federation 2021).

Poor control of high blood glucose levels in long-term has been associated with increased likelihood of developing microvascular complications such as neuropathy (causing nerve damage and potential amputation), nephropathy (kidney dysfunction and failure), and retinopathy (which can result in eye disorders and eventually blindness), as well as macrovascular complications like cardiovascular diseases (which increase the risk of heart attack and stroke). Furthermore, these diabetic complications primarily contribute to morbidity and mortality related to diabetes (American Diabetes Association Professional Practice Committee 2022; Banday et al. 2020; Papatheodorou et al. 2018).



### 2.1.2 Epidemiology

#### a. Global prevalence

The incidence of DM is rapidly soaring on a global scale. According to the official report by International Diabetes Federation (2021), the number of adults (aged 20 – 79 years) living with DM has nearly quadrupled over the past two decades, rising from an estimated 151 million in year 2000 to 540 million in year 2021. The projection demonstrates an alarming increase of 46% in the predicted prevalence of DM by 2045, indicating that approximately 783 million adults will be living with diabetes. More than 90% from the projected population of diabetes will have T2DM. The rise in DM prevalence worldwide is associated with several factors e.g.population expansion, aging populations, and a growing inclination to sedentary lifestyles, unhealthy dietary habits, and obesity. The distribution of DM prevalence was found to be uneven across the geographical regions, as the majority of diabetes patient population (81%) come from low and middle-income countries. The estimated proportions of DM cases in the IDF Western Pacific and South-East Asia regions are the highest, accounting for almost half (48%) of the entire diabetes population worldwide. Countries with the

highest proportions of adults living with DM in year 2021 were China, India, and Pakistan (International Diabetes Federation 2021).

**b. Prevalence in Malaysia**

DM is one of the most common non-communicable diseases (NCDs) in Malaysia. Malaysia was ranked as the fifth country in IDF West Pacific region with the highest number of adults with diabetes, reaching approximately 4.4 million in year 2021 (International Diabetes Federation 2021). According to the data reported by the National Health and Mortality Survey (NHMS), a tremendous increase of 68% was observed in the overall prevalence of DM (including both known and undiagnosed cases) among Malaysian adults (aged 18 years and above), from 13.4% in year 2015 to 18.3% in year 2019. This points to an alarming health concern that 1 in every 5 Malaysian adults is living with this condition (Institute for Public Health et al. 2020).

The report also revealed an increasing prevalence of diabetes by age. The trend climbed from 5.4% in the group of young adults with age 20 – 24 years, reached the highest at 43.4% in the elderly group of age 65 – 69 years. The DM prevalence did not differ much between both genders but varied greatly among different ethnicities. Indian was the ethnic group with the highest DM prevalence (19%), followed by Malay (11%), Chinese (9%) and Bumiputera Sarawak (8%). It was shown that DM cases were more common in individuals without formal education and those from the low-income group. No significant variation in the DM prevalence was observed for both rural and urban areas. However, the distribution of DM prevalence varies across different states. Negeri Sembilan recorded the highest prevalence (33.2%) whereas the lowest (9.8%) was reported in Sabah (Institute for Public Health et al. 2020).

Nearly 86% of people diagnosed with DM in Malaysia were taking oral antidiabetic medications, whereas 26% were receiving insulin regimen. Traditional and complementary medicines were being used by 23% of the adults with diabetes as a means of treating the condition. When it comes to the choice of healthcare facilities where the people of diabetes seek medical consultation and treatment, most (68%) received their treatment at the government health clinics. The government hospital (15%) was the second common choice of health facilities for seeking diabetes

treatment, followed by private health clinics (12%) and private hospitals (3%). Very few people with DM (0.4%) engaged in self-medication behaviour without consulting doctor and bought their supply of antidiabetic medications straight from the pharmacies. Only a small proportion of people (0.2%) consulted traditional and complementary medicine practitioners for their diabetes treatment. However, there were individuals with diabetes who did not seek any form of treatment for their condition, accounting for 2% of cases (Institute for Public Health et al. 2020).

### 2.1.3 Costs and burden

Due to its chronic nature and complications, DM is considered as one of the costly diseases which imposes a significant economic impact not only on people with diabetes, but also on their families, the health systems, and the national economy. According to IDF estimates, the total direct costs incurred from DM was estimated to reach US$966 billion in 2021, with US, China, and Brazil being the top three countries with the highest DM-related health expenses. In Malaysia, DM care and management was estimated to cost nearly US$670 million, and 70% (US$458 million) of the total cost was borne by the government in the year 2011 (Feisul et al. 2017). As DM management takes up more healthcare resources, less will be available to address other conditions, which will eventually affect healthcare quality and outcomes (International Diabetes Federation 2021).



DM patients and their families or caregivers might endure huge pressure when managing the condition. If the DM is not well-controlled and results in complications, it can adversely affect the work productivity and quality of life of both patients and their caregivers (Ogunmodede et al. 2019). Exorbitant medical expenses coupled with reduced or lost ability to work can place the patients and their families in financial hardships and emotional distress. With the ongoing increase in global DM prevalence, the total healthcare expenses associated with DM is projected to rise even further, reaching an estimated value surpassing US$1 trillion by the year 2030 (International Diabetes Federation 2021). Thus, it is crucial to delay and prevent the progression of DM to manage the burden of high healthcare expenditures from this disease.

## 2.2 MANAGEMENT OF DIABETES MELLITUS

DM is a long-standing medical condition which needs long-term care and management. It is important for clinicians to have access to evidence based clinical practice guidelines (CPG) during their clinical decision making because these guidelines provide recommendations for best practice in the DM management with reference to the current evidence (Yi et al. 2021). The following section elucidates the recommended practices of DM management based on the guidelines.

### 2.2.1 Diabetes education

Patient education is a key aspect in chronic disease management. Diabetes self-management education has been shown to be linked with improved DM knowledge (Ernawati et al. 2021; Shiferaw et al. 2021), improved glycaemic control (Bekele et al. 2021), lower all-cause mortality risk (He et al. 2017), better quality of life (Davidson et al. 2022), and reduced healthcare expenditure (M. L. Smith et al. 2021). Moreover, the implementation of diabetes self-management education in the form of a structured and scheduled programme in Malaysia primary health clinics demonstrated an improvement in HbA1c values of the participants (Ramli et al. 2016).



Diabetes education is recommended to be delivered not only at time of diagnosis with yearly reinforcement and review, but also at other time points, e.g. when glycaemic targets are unmet, during transition of life or care, and when any complicating factors affecting self-management arise (American Diabetes Association 2024). The involvement of patients' families and caregivers in the education programmes is highly encouraged. The scope of DM self-management education content may include but are not limited to: diet, exercise, medications, complications, self-monitoring of target parameters (e.g. blood glucose, blood pressure and body weight), diabetes foot care, smoking cessation, DM-related problem-solving skills (managing hypoglycaemia), psychosocial support and adaptation to DM and other related issues (Malaysian Endocrine and Metabolic Society et al. 2020).

### 2.2.2 Blood glucose control and self-monitoring

#### a. Glycaemic control targets

The glycaemic targets are normally individualised based on different patient characteristics. For general T2DM population, the Malaysia CPG recommends aiming for a HbA1c level ranging from 6.6 – 7.0% through the management with a combination of lifestyle modification interventions and/or mono/dual drug therapy. The prescribed treatment is reviewed after 3 – 6 months and adjusted according to patients' response to treatment. However, the recommended HbA1c target level is more stringent (<6.5%) for the following patient populations: newly/recently diagnosed, younger age, longer life expectancy, without complications or co-morbidities, and low risk of hypoglycaemia (abnormally low blood glucose levels). A less tight control (7.1 – 8.0%) is recommended for patients who are elderly, with co-morbidities, shorter life expectancy, unaware of or susceptible to hypoglycaemia and having higher risk of harmful consequence from hypoglycaemia (Malaysian Endocrine and Metabolic Society et al. 2020).



#### b. Glycaemic control monitoring

HbA1c readings have been shown to be a strong predictive value for microvascular and macrovascular complications of DM. It is recommended that patients should repeat HbA1c assessment at the intervals of 3 – 6 months, until a stable and optimised HbA1c reading is obtained on the same treatment. For those patients on stable treatment and glycaemic control, the recommended frequency of HbA1c assessment is at the interval of 6 months (Malaysian Endocrine and Metabolic Society et al. 2020).

#### c. Self-monitoring of blood glucose

Regular self-monitoring of blood glucose (SMBG) is an essential part of DM management as it helps patients and clinicians in gauging glycaemic control and preventing the risk of hypoglycaemia. It should be recommended for T2DM individuals on insulin regimens (American Diabetes Association 2024). Recent evidence suggested a modest reduction effect of SMBG on HbA1c values in this patient group (Mannucci et al. 2018; Zhu et al. 2016). SMBG frequency and timing

are normally individualised based on patients' characteristics, such as glycaemic targets and status, types of medication regimen, and personal lifestyles (Malaysian Endocrine and Metabolic Society et al. 2020).

### 2.2.3 Lifestyle modifications

For most individuals newly diagnosed with T2DM, lifestyle changes are of great importance to attain optimal blood glucose control. The lifestyle modification interventions involve medical nutritional therapy, weight management, physical exercise, and smoking cessation. Patients with T2DM should receive personalised diet counselling and nutrition care service by dietitians when newly diagnosed with DM, or when the weight or blood glucose control is not optimal. Moreover, overweight patients are advised to achieve weight loss of at least 5–10% for weight management (Malaysian Endocrine and Metabolic Society et al. 2020). All patients are encouraged to do mild-to-moderate physical activities for at least three times per week (for a cumulative period of minimum 150 minutes per week); however, they should undergo pre-exercise assessment before starting any vigorous exercise regimen (Chudyk & Petrella 2011). Integrating smoking cessation intervention with DM management is beneficial because smokers with T2DM were shown to have poorer blood glucose control and carry an increased risk of cardiovascular diseases and premature death when compared to non-smokers with the condition (Pan et al. 2015).



### 2.2.4 Pharmacological approach

Medication regimens may usually be needed to reduce blood glucose levels in patients who are newly diagnosed with T2DM while undergoing lifestyle modifications. According to Malaysia CPG, metformin is recommended as the first-line pharmacological treatment for T2DM. Patients are provided with advice and counselling on healthy dietary and lifestyle adjustments and medication adherence in order to achieve target HbA1c level of < 6.5% and a fasting blood glucose of <7 mmol/L (Malaysian Endocrine and Metabolic Society et al. 2020).

Medication therapy is tailored to suit the patient's needs and clinical condition. Several factors are considered when the prescriber formulates a pharmacological

treatment plan, such as initial blood glucose status, individualised glycaemic targets, presence of co-morbidities, long term benefits of the medications for the patient, risk of medication adverse effects and medication costs. Patient's response to the prescribed treatment is assessed in 3 – 6 months after initiation of therapy. Based on the glycaemic control status, the medication regimen can be either maintained the same (if glycaemic targets are met), withheld/substituted with other anti-diabetic medication (if patient cannot tolerate adverse effects), or intensified (if HbA1c levels are not controlled) by increasing medication dose or adding the combination of two/three/more non-insulin anti-diabetic medications or insulins. Follow-up on the patient's HbA1c is performed every 3 – 6 months to assess treatment effectiveness and glycaemic control (Malaysian Endocrine and Metabolic Society et al. 2020).

## 2.3 MEDICATION MANAGEMENT AND MEDICATION ADHERENCE IN DIABETES MELLITUS

### 2.3.1 Medication self-management in diabetes mellitus

Medication self-management is an essential yet complex self-care skill for patients living with T2DM. It is a series of tasks which must be undertaken by patients to ensure good medication adherence and safe medication use for long-term. It is a rather complicated process involving multiple steps, such as filling/obtaining the prescription supply, understanding the medications, planning/organising the medication regimen into daily routine, taking the medications appropriately, self-monitoring intake, and maintaining safe medication use (S. C. Bailey et al. 2013).

Similar to other self-care activities for managing chronic diseases, not only does medication self-management demand the patients to practise a significant level of control, but it also requires them to exercise autonomy, decision-making and problem-solving abilities when managing and adjusting their regimens (Gallant 2003). A study reported that patients with T2DM encounter several challenges when they self-manage their medications. These problems may arise from various factors ranging from patient health condition, personal status and resources, to medication regimen characteristics, and to the healthcare system and professionals (Bernhard et al. 2017).

If these challenges are not well-addressed, it can lead to inappropriate medication use, adverse drug events and medication non-adherence (C. J. Bailey & Kodack 2011).

### 2.3.2 Medication adherence in diabetes mellitus

#### a. Definition of medication adherence

According to World Health Organisation (WHO), medication adherence has been defined as "the extent to which a person's behaviour (including medication taking) corresponds with agreed recommendations from a healthcare provider" (Sabaté 2003). It is one of the several behaviours indispensable for DM self-management and achieving clinical goals.

The terminologies "adherence" and "compliance" are often interchangeably used in the clinical practice and research studies (Lehane & McCarthy 2009), however both terms are not synonymous. The term "adherence" indicates the agreement and active participation from patients in their medical care with them voluntarily undertaking responsibility for own health. Patients are more proactive in making their decisions about when and whether to follow through with the recommendations from their healthcare providers (Mir 2023). In contrast, the term "compliance" suggests a passiveness in the patient's behaviour in which the patient's role is to merely follow the list of treatment regimens prescribed by the healthcare provider without considering his/her agreement (Lam & Fresco 2015). This term has been criticised in recent years, as it was thought to paint a negative picture of the clinician-patient relationship (Mir 2023). Therefore, "adherence" is mainly used rather than "compliance" in this study as we encourage clinician-patient collaboration as well as active participation of patients in managing their condition.

There are several methods used to measure medication adherence in the clinical practice and research studies, such as self-reporting questionnaires, clinician assessments, pill counts, database analysis (e.g. prescription refill records, electronic prescription systems, and pharmacy insurance claim records), electronic monitoring (using Electronic Medication Packaging [EMP] devices with Medication Event Monitoring System [MEMS]) and biochemical measures (i.e. testing drug-related

biomarkers in the lab). Each measurement method has its advantages and disadvantages and may yield different estimation results of medication adherence (Lam & Fresco 2015). Electronic monitoring with MEMS has been described as the "gold standard" of medication adherence measurement in the literature because it provides real-time monitoring of patients' medication-taking behaviour and automatic compilation of medication dosing histories in clinical trial settings. MEMS involves incorporating computer chips into the prescription medication packaging of various designs, which digitally records the time stamps and movements when packaging are opened to dispense medication (El Alili et al. 2016). Biochemical urine analysis with liquid chromatography was found to be another new approach that objectively measure medication adherence in patients with T2DM; however more large-scale studies are needed to further confirm its efficacy (Patel et al. 2019).

**b. Medication adherence in diabetes mellitus**

Poor medication adherence in individuals with chronic diseases has been a global health concern with significant magnitude. Based on a report on medication adherence published by WHO (Sabaté 2003), it was found that adherence to long-term regimens averages only ~50% in the developed nations; the rate is even lower in the developing countries. A similar situation of medication adherence was also observed among patients with DM. A study conducted on patients with T2DM revealed that more than half (54.4%) did not take the antidiabetic medications as prescribed (Aminde et al. 2019). A review conducted by (Azharuddin et al. 2021) also demonstrated that the rate of non-adherence to antidiabetic medication was 43.4%, indicating that medication non-adherence remains a huge barrier to optimal glycaemic control in DM.

**c. Importance of medication adherence in diabetes mellitus**

As mentioned in previous section 2.2.4, pharmacological treatment has been a key strategy of maintaining long-term glycaemic control in T2DM (Malaysian Endocrine and Metabolic Society et al. 2020). Clinical studies have well corroborated the benefits of pharmacotherapy in T2DM management, such as enhanced blood glucose control (Eng et al. 2014; Shyangdan et al. 2011; Vos et al. 2016), decreased microvascular complications (Saenz et al. 2005), reduced cardiovascular event risk

(Saenz et al. 2005), lower mortality (Saenz et al. 2005), and improved quality of life (Bode et al. 2010; Davies & Speight 2012). These may be directly translated into reduction in healthcare resource utilisation, hospitalisation and emergency department admission rates and healthcare expenses (Menzin et al. 2010).

Non-adherence to long-term treatment of chronic diseases including T2DM remains a significant challenge globally which hinders successful treatment efforts. The promising clinical benefits of pharmacological treatment, as described in the previous paragraph, were often demonstrated in clinical studies under controlled settings. With suboptimal adherence to the prescribed therapy, those benefits may not be fully derived, and eventually lead to the discrepancy between efficacy and effectiveness in the real practice. Medication non-adherence can lead to a multitude of consequences, such as medication wastage (Yu et al. 2018), poor disease progression (Denicolò et al. 2021), declined functional capacities, reduced life expectancy (Shalaeva et al. 2022) and lower quality of life (Majeed et al. 2021). A number of studies have also related medication non-adherence with higher healthcare costs and increased healthcare resources utilisation (Ipingbemi & Erhun 2021). Thus, it is necessary to identify factors and challenges related to medication non-adherence and to explore novel solutions that help to enhance patients' medication adherence.



Several factors which may pose as challenges to achieving good medication adherence specifically in T2DM have also been discussed in the literature. These include provider-patient relationship and communication, complex regimens and administrations, inadequate knowledge about disease and regimen, past negative experiences and beliefs regarding the medications, fear and concerns about the safety or appropriateness of the medications, and financial issues (Kvarnström et al. 2021). These challenges suggest the importance of HCPs' involvement in fostering better medication adherence among patients with T2DM, through identifying patients at risk for non-adherence, developing strategies to facilitate proper medication-taking behaviour, and providing continuous support and assessment of adherence (Wilhelmsen & Eriksson 2019).

### 2.3.3 Technology for improving medication management and adherence

The evolving role of technology in the healthcare field, especially in the continuum of chronic disease management, has been evident over the past decade. Patients now have the opportunity to easily keep track of their condition and communicate with their HCPs without having to schedule additional clinic appointments. Likewise, HCPs can even perform remote monitoring of their patients' health condition and access detailed patient information instead of waiting 3 – 6 months for patients' updates during their in-person visits (Young & Nesbitt 2017).

Many innovative digital health technologies have been developed for the management of chronic diseases including T2DM. The use of mobile health technology (also known as mHealth) in supporting healthcare is becoming common through mobile devices, such as telecommunications services, smartphone applications, web-based technologies, and wearable devices. The effectiveness of mHealth technologies in chronic disease management have been examined in several research studies through various aspects e.g.risk screening, patient education, remote monitoring, lifestyle interventions, medication adherence, and rehabilitation support (Fan & Zhao 2022). A systematic review reported that significant reductions in HbA1c were observed among T2DM patients in the mHealth intervention groups when compared to those receiving standard care (Youfa Wang et al. 2020).



The advent of smartphones has revolutionised the way how people manage their medications. Mhealth applications offer novel and exciting opportunities for enhancing medication management and adherence through a wide array of functionalities, e.g.medication scheduling, medication reminder, adherence monitoring, information provision, and communication with HCPs (Huang et al. 2019). The evidence is rapidly accumulating and evolving on the utility of mHealth technology in medication management and adherence and this will be further discussed in the next section.

## 2.4 MOBILE HEALTH (MHEALTH)

Mobile health, commonly referred to as mHealth, involves the utilisation of mobile devices (e.g.mobile phones and tablets) and wireless telecommunication technology to improve healthcare delivery and outcomes with a multitude of functions, from monitoring health-related metrics to delivering health education resources and facilitating remote communication with healthcare providers (Fan & Zhao 2022).

The mHealth technologies employ the main functionalities of the mobile phone, including voice and short messaging service (SMS), global positioning system (GPS), third/fourth/fifth generation (3G/4G/5G) mobile network technology, Bluetooth technology, as well as mobile applications. The rapidly increasing attention and development in mHealth is depicted with accumulating evidence from the literature in this area, as well as increasing mHealth initiatives executed by many countries worldwide as a complementary approach to enhance the current healthcare system (World Health Organisation 2011).



Mobile applications (apps) were first introduced in the Apple's App Store in the year 2008, and greatly transformed the way people communicate and carry out their daily lives ever since. Today, the global number of mobile applications has proliferated to millions, around 350,000 of which are related to the healthcare field, based on the data estimates from IQVIA (Baumgartner et al. 2021). The advent of 5G mobile network technology and the wide availability of mobile devices (approximately 3 – 4 billions smartphones and 8 billions connected devices available worldwide) has accelerated and propelled mHealth even further in the role of supporting healthcare practices in the recent years (Baumgartner et al. 2021). The mHealth apps available nowadays are developed with a broad range of purposes e.g. diagnosis, treatment, monitoring, prevention, education, and wellness. The following section discusses about the evidence of mHealth application in diabetes care and medication management, as well as the potential of this technology in T2DM medication management.

### 2.4.1 Pharmacists' roles in medication management for diabetes mellitus

Comprehensive DM care and management is a complex mission which involves the collaboration of an entire team of HCPs in delivering optimal multidisciplinary care for patients. The healthcare team which consists of medical doctors, nurses, dieticians and pharmacists helps to achieve the glycaemic targets, reduce DM-related complications and improve quality of life in T2DM patients (Shareef et al. 2015).

Nevertheless, when it comes to pharmacists, many people think of their community health specialists who merely dispense medication and offer healthcare advice; they may not be aware of the evolving role of pharmacists today, especially in the realm of chronic diseases management. Pharmacists who are well-trained and equipped with the knowledge of disease states and pharmacotherapy (e.g.indications, dosing, side effects, interactions, and drug alternatives based on the patient condition) play an indispensable role in the medication management. Nowadays, pharmacists are increasingly taking on greater responsibilities in DM care. They apply their clinical expertise in reviewing and monitoring medication regimens, and providing education and assistance to patients in managing their conditions. Moreover, they also serve as a resource to other HCPs by providing interventions and drug information to ensure a safe, appropriate and cost-effective use of DM medications (Shareef et al. 2015).



Previous literature has also reported the positive impact of pharmacist roles in clinical outcomes and patient empowerment. For example, a study was conducted on a pharmacist-managed DM medication management clinic in Malaysia, where 43 patients with poorly controlled DM (HbA1c > 8.0%) attended eight sessions of individual consultation with pharmacists for DM education, glycaemic control and adherence assessment, and medication therapy titration. A significant improvement was observed in the average HbA1c readings and medication adherence scores among the participating patients (Lim & Lim 2010). Another research also demonstrated significantly improved glycaemic control and better medication adherence among patients who underwent a 12-month pharmacist pharmaceutical care programme in a health clinic in the United Arab Emirates (Al Mazroui et al. 2009).

With the clinical expertise and practice experience in pharmaceutical care, it is clear that pharmacists hold a key position in DM medication management to enhance medication therapy outcomes. For this reason, pharmacists were selected as the main HCP stakeholder involved in this study.

### 2.4.2 mHealth applications in diabetes mellitus

The recent decade has witnessed a rise in mHealth initiatives emphasising on DM management and care. The clinical efficacy of the mHealth apps have been reported in decreasing HbA1c values through behavioural change interventions, telemonitoring and patient education (Sun et al. 2019; Yanmei Wang et al. 2019; Zhang et al. 2019). A meta-analysis demonstrated that the use of mHealth apps in T2DM management can lead to a statistically significant ($p<0.001$) decrease of 0.44% in average HbA1c values, and a possible improvement in patient awareness in self-care by providing health education (Bonoto et al. 2017). Another meta-analysis also showed similar results that mHealth apps specific to DM care results in a clear and significant improvement in glycaemic control (0.54% reduction [$p<0.05$] in HbA1c) as well as positive inclinations toward better self-care and self-efficacy in patients with DM (Eberle et al. 2021). Therefore, these mHealth apps may be integrated with standard practice or care in view of their compelling evidence of positive clinical effectiveness.



### 2.4.3 mHealth applications in medication management

With the tremendous growth in the aging population and the rising prevalence of chronic diseases, the mHealth digital landscape has greatly expanded in recent years with a myriad of mobile applications created to help people with life-long conditions manage medications and improve adherence.

Although limited, the evidence is gradually accumulating on the clinical effectiveness of mHealth apps for medication management in chronic diseases. For instance, a study testing a medication self-management app with elderly patients on multiple medications reported less missed doses and medication errors and better perceived independence in medication management (Mira et al. 2014). Another randomised controlled trial evaluated the effectiveness of using a medication reminder

app in patients with coronary heart disease, and demonstrated a higher self-reported medication adherence score compared with usual care; however, no significant improvement was found in blood pressure and cholesterol levels (Santo et al. 2019).

The results from a meta-analysis by Zhou et al. (2022) indicated that mHealth apps can significantly improve medication adherence of patients with chronic diseases, attributed to their useful functionalities such as regular medication reminders system, patient educational support, and patient history documentation function. Besides that, mHealth apps also contribute to reinforcing the perception of self-efficacy among these patients and enhancing their quality of life to some extent (Zhou et al. 2022). Another meta-analysis presented a similar observation that mHealth apps, when compared with standard care, are found to be effective to help improve medication adherence among adult patients living with chronic diseases (Peng et al. 2020). Despite the results seem promising, the article highlighted that future studies should identify the app functionalities or features preferred by the targeted users, and perform improvements for better usability, security, and effectiveness.



### 2.4.4 Limitations of mHealth in medication management for diabetes mellitus

Although many mHealth apps have been designed for supporting medication management currently, the usage of medication self-management apps is yet to be widely used in the patient populations, nor become a part of any standard clinical care. The current phenomenon of app under-utilisation is common in chronic diseases management, including DM, and it is possibly attributed to several gaps in the design and practice of mHealth apps. Table 2.1 shows an overview of reviewed sources.

Table 2.1 The overview of reviewed sources

| Author/Year | Type of source | Purpose | Relevant findings |
|---|---|---|---|
| Tabi et al. (2019) | Research | To review the characteristics of the existing mobile apps for medication management in the market. | ▪ A total of 328 apps from Android and Apple app store was included for reviewed.<br>▪ Less than 15% of the reviewed apps were developed with HCP involvement. |

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|---|---|---|---|
| Ahmed et al. (2018) | Research | To review available medication adherence apps in terms of their evidence base, HCP involvement in development, and strategies used to facilitate behaviour change and improve adherence | ▪ Only 13.6% of free apps and 4.4% of paid apps were developed with HCP involvement<br>▪ Not more than 1% of free apps and 0.5% of paid apps had documented evidence base related to the app. |
| Huang et al. (2019) | Research | To systematically assess the medication management features in diabetes self-management apps and their accordance with best-practice evidence-based criteria. | ▪ A large proportion of diabetes self-management apps lacked features for improving medication adherence and safety.<br>▪ 58.0% apps had a medication reminder feature; 16.8% had a feature to review medication adherence; 39.9% allowed entry of medication-taking instructions; 5.6% provided medication information; and 4.2% displayed motivational messages to encourage medication-taking. |
| Martinez et al. (2017) | Review | To review all the available diabetes-related apps in the iOS App Store and evaluate which app is more interactive and offers a wide variety of function | ▪ 50% apps had a medication adherence function.<br>▪ None of the apps could sync data directly to the prescribers. |
| Islam et al. (2022) | Review | To systematically review high-quality apps freely available to the public in Apple App Store and Google Play Store for diabetes medication adherence | ▪ 50% high-quality apps publicly available for free provided low medication adherence.<br>▪ 25% apps promoted high adherence and another 25% apps achieved moderate adherence. |
| van Velsen et al. (2013) | Discussion | To discuss the app overload phenomenon in health apps and ways to prevent the occurrence. | ▪ The public and HCPs are currently facing health app overload and difficulty to find the right app. Information and features are fragmented over too many apps, limiting the usefulness.<br>▪ Three ways for app developers to tackle app overload: one, join the open-source movement; two, standardise content; third, personalise content based on individual characteristics. |
| Lithgow et al. (2017) | Research | To investigate patient experiences related to the use of smartphone apps for the management of type 1 diabetes | ▪ Participants reported that they had not encountered any app that included all functions that they had used. |



It was observed that many mHealth apps available in the market lack features for medication management in chronic diseases. For instance, a study by Huang et al. (2019) conducted a systematic, evidence-based evaluation on the medication

management features of the available mHealth apps specific to DM self-management. The study revealed that about 47% of the DM self-management apps did not have any form of medication management functions (Huang et al. 2019), and this observation corroborated with another study which also presented a similar result (50%) (Martinez et al. 2017). Likewise, A systematic review done on mHealth apps publicly available for free revealed that 50% of these apps did not offer moderate to high medication adherence (Islam et al. 2022). Huang et al. (2019) also highlighted that many apps identified with medication management features did not carry the necessary functionalities for improving medication adherence and safety, such as functional reminder system, ability to input medication instructions, drug allergy documentation and medication adherence assessment. Without the essential functionalities, those apps may not be as effective in assisting users to follow their medication schedules.

Often, the apps intended for self-management of diseases and medications do not include features that support communication and data sharing with HCPs. Owing to the unavailability of local electronic health record (EHR) systems and the challenges in safeguarding healthcare data privacy and security, many of these mHealth apps function independently as standalone apps without integration with EHR systems. For instance, Huang et al. (2019) found that nearly 89% of apps did not contain functionality for users to contact HCP with medication queries. Data export was not available in approximately 40% of the apps (Huang et al. 2019). App features for information sharing and electronic messaging may allow patients to promptly reach out to HCP for any problem arising from their treatment and condition. The option to export data in those apps (such as medication adherence data, self-monitoring readings) can help HCP and patient to review treatment outcomes.

Currently, it has been reported that more than 300 apps designed for medication management are available on the Apple and Android app marketplaces (Tabi et al. 2019). The issue of app overload has arisen due to the escalating number of apps, and this poses challenges for patients and HCPs in navigating and selecting apps appropriate for their needs. Another consequence from app overload is that features and information are fragmented and scattered across too many health apps, diminishing their usefulness (van Velsen et al. 2013). For example, Type 1 DM

participants in a qualitative study expressed that they had yet to come across any one app offering all the features necessary for managing their condition (Lithgow et al. 2017). As a result, the intended users are either unable to find a suitable app or opt not to download one, due to limited added value of a single app (van Velsen et al. 2013).

In view of the current background and gaps in mHealth apps for medication management in diabetes mellitus, this research sought to develop an app prototype with medication management functions specifically for T2DM and provide baseline information on the software requirements specification (SRS) and user interface (UI) design from users' perspectives. This study prioritised the direct involvement of the intended users (i.e., patients and pharmacists) in requirements specification, design, and testing process. This approach ensures that the app design closely aligns with their needs, thereby enhancing its effectiveness in supporting medication management.



## 2.5 SOFTWARE DEVELOPMENT METHODOLOGY

### 2.5.1 Methodology used in Malaysian public sectors

In Malaysia public sectors, Malaysian Administrative Modernisation and Management Planning Unit (MAMPU) is the central agency responsible for modernisation and transformation and has developed process model and methodology guidelines for the Information Communication and Technology (ICT) project management and application development. Since developing mHealth apps is a part of ICT projects, there are three ICT methodologies related/applicable to mHealth app development, namely ICT Project Management Guideline for Public Sector (PPrISA), Guidelines for Preparation of Public Sector Digitalisation Strategic Planning (PerSPSA), and Malaysian Public Sector Application Development Guideline (KRISA).

PPrISA provides comprehensive guidance for the government servants who are assigned with the responsibility as Project Managers to implement and manage ICT projects in government agencies, whether implemented internally, externally/outsourcing (i.e. using services from external parties such as universities, private companies or overseas) or co-sourcing (a combination of both). It can also be used as a reference for representatives from private sector involved in implementing

ICT projects in public sectors. PPrISA contains procedures for implementing ICT projects in four phases: initiation, planning, implementation and control, and termination. Each phase contains templates that can be used as official documents in managing ICT projects (Malaysian Administrative Modernisation and Management Planning Unit (MAMPU) 2024a). However, this methodology does not cover information on requirement engineering for the app development project.

KRISA is a comprehensive guideline for assisting Malaysian government agencies with software and application development and project management. This guideline was developed based on the previous experience and practice in the system/software development methodology practiced in the industry and public sector. Similar to the traditional SDLC methodology, KRISA consists of six phases in the software and application development: initiation, analysis, design, development, testing, and implementation (MAMPU 2019). Table 2.1 demonstrates a breakdown of activities and deliverables (documentation) for each phase in KRISA methodology.



Table 2.2 Phases, activities and deliverables in KRISA methodology

| Initiation | Analysis | Design | Construction | Testing | Implementation |
|---|---|---|---|---|---|
| **Activities (28)** | | | | | |
| • System Development Plan Preparation<br>• Business Requirements Determination<br>• Business Function Modelling<br>• Business Process Modelling<br>• Business Requirements Specification Preparation | • Use Case (Functional) Modelling<br>• System Function Modelling (DFD)<br>• Data Requirements Modelling (ERD)<br>• System Process Modelling<br>• Determination of Non-Functional Requirements<br>• Preparation of System Requirements Specifications | • Architect Design<br>• Technology Determination<br>• Database Design<br>• User Interface Design<br>• System Transaction Design<br>• Preparation of Design Specifications<br>• System form<br>**Data Migration**<br>• Data Migration Plan Provision<br>• Design and Provision of Data Migration Specifications<br>**Data Integration**<br>• System Integration Plan Provision<br>• Design and Provision of System Integration Specifications | • Database Development<br>• Application Programming<br>• System Testing | • Preparation of Test Master Plan<br>• Preparation of Test Preparation Documentation<br>• Preparation of Test Plan (UAT and PAT)<br>• User Acceptance Test (UAT)<br>• Provisional Acceptance Test (PAT)<br>• Preparation of Acceptance Test Report | • Implementation of Data Migration<br>• Final Acceptance Test (FAT)<br>• Preparation of User Manual<br>• Submission of Application System |
| **System Documentation (18)** | | | | | |
| • System Development Plan<br>• Business Requirements Specification (BRS) | • System Requirement Specification (SRS) | • System Design Specification (SDS)<br>• Data Migration Plan<br>• Data Migration Specifications | • Database Documentation<br>• Source Code Documentation<br>• System Test Report | • Master Test Plan<br>• Acceptance Test Plan (UAT/PAT)<br>• UAT/PAT Report | • Data Migration Report<br>• Test Termination Report<br>• System User Manual<br>• System Delivery Report |

As mentioned in the KRISA methodology, several key considerations need to be considered for successful implementation of the application system development project, in addition to ensuring that the developed application system is of high quality and meets the user needs. The main considerations are project management and governance, stakeholders' involvement, change management, software quality assurance, application safety and system size measurement (MAMPU 2019).

PerSPSA explains the Digitisation Strategic Plan development methodology designed and improved specifically for public sector agencies. The Digitisation Strategic Plan (*Pelan Strategik Pendigitalan* – PSP), formerly known as the ICT Strategic Plan (*Pelan Strategik ICT* – PSICT), is a blueprint for planning the implementation of ICT project in the government agency for a period of at least three to five years. The PSP needs to be in line with the organisation's strategic plan based on the period that has been set to ensure that it considers the department's service needs and the latest ICT technology developments. The PSP also must be monitored and reviewed periodically to ensure that the strategic direction of ICT and digitisation remains relevant to the agency's organisational environment. PerSPSA serves as a reference for government agencies in developing a new PSP or implementing the existing PSP Midterm Review. There are five phases involved in this guideline, namely Mobilisation, Analysis, Strategy, Formulation and Documentation. Each phase contains processes and deliverables that need approval from the management to produce a complete and comprehensive PSP document (MAMPU 2024b).



### 2.5.2 Rapid Application Development (RAD) model

To plan the research design of developing the proposed mobile app in this study, a Software Development Life Cycle (SDLC) methodology was selected, which was Rapid Application Development (RAD) model. Compared to other SDLC models, RAD is a fast-track version of the full spectrum of SDLC processes consolidated in four phases, namely requirements planning, design, construction, and implementation (Figure 2.1). This model is widely employed today due to rapid delivery of functioning software/systems with lower costs, shorter development periods and higher success rates.

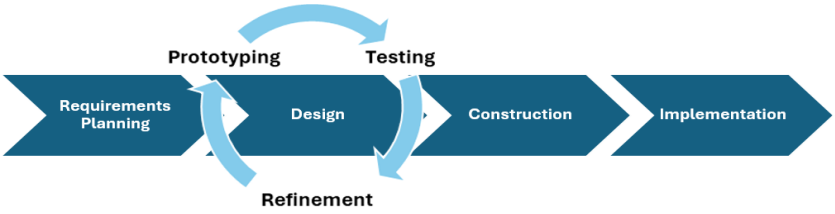


Figure 2.1 The phases in Rapid Application Development (RAD) model

Contrary to the linear and rigid software development process of the Waterfall model, RAD model implements an incremental and iterative prototyping approach to generate deliverables in phases with emphasis on end-user participation. Users are involved in the prototype evaluation and feedback early on, and the prototype is further refined to align more closely with the users' requirements. This process continues and repeats through several iterations until the software/system is fully developed to the users' satisfaction (Tilley 2019). Several studies have reported that RAD model has contributed to successful development of mHealth apps within a relatively short period for different conditions and settings (Ongadi et al. 2022; Rahayu et al. 2022; Ramadhana et al. 2023; Shaker et al. 2023; Tan et al. 2023; Tarsono & Fachrie 2024). Table 2.3 demonstrates the description of studies which employed RAD model in developing the mHealth apps.



Table 2.3 The description of studies which developed mHealth apps using RAD model

| Author/Year | Country | Condition/ settings | Outcomes |
|---|---|---|---|
| Tarsono & Fachrie (2024) | Indonesia | Maternal health / outpatient setting | ▪ An Android-based app was developed to provide real-time consultation (with medical personnels) and education to pregnant women. |
| Tan et al. (2023) | Singapore | COVID-19 / hospital | ▪ The project team collaborated with interdisciplinary and multiprofessional stakeholders and developed an app within 2 months to facilitate remote monitoring and continuity of care for COVID-19 patients.<br>▪ The app functions included secure tele-social communication, back-end patient monitoring and personalised push messaging. |
| Ongadi et al. (2022) | Kenya | HIV/AIDS / hospitals and clinics | ▪ The team developed a mobile-based app that can accurately define HIV-1 drug-resistance mutations in the HIV pol gene for use at the point of care.<br>▪ The app offered accurate and easily accessible management strategy to HIV health care providers with a short turnaround time. |

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| Shaker et al. (2023) | Denmark | Borderline personality disorder (BPD) / psychiatric outpatient setting | ▪ An evidence-based app was successfully developed within 6 months for patients with BPD on a waitlist to start psychotherapy<br>▪ The app contained features that provided information about the condition, prepared patients for treatment during waiting period, and instilled hope for changes.<br>▪ Support feature was also provided by giving free anonymous counselling for those in crisis or at risk of suicide through telephone, online, and chat. |
| Ramadhana et al. (2023) | Indonesia | Mental health / nonprofit organisation | ▪ A mobile app was developed as the main platform for accessing "Ubah Stigma" (a nonprofit social and mental health foundation) work programs, especially "Safe Space" program, counselling session registration, and educational podcasts regarding mental health.<br>▪ The user acceptance test, conducted through a questionnaire survey, demonstrated that the app positively influenced user mental health awareness. |
| Rahayu et al. (2022) | Indonesia | Tuberculosis (TB) / health centre | ▪ The application which aimed to help detect active TB cases in the community, was developed in two versions: mobile app for users and web-based system for administrators.<br>▪ The app contained functions such as early TB screening, TB education, latest information update and profile management.<br>▪ The system usability scale (SUS) questionnaire survey showed an average score of 76, indicating that the app is highly usable. |



## 2.6 REQUIREMENTS ENGINEERING

Requirements engineering, also known as software specification, involves understanding and defining the requirements for a software system. This process is exceptionally important within the software development stages, as improper execution can cause significant difficulties in later stages. It consists of three main activities: (1) requirements elicitation and analysis, (2) requirements specification, and (3) requirements validation. Producing a requirements document specifying the system requirements agreed by the stakeholders is the main goal of requirements engineering process (Laplante & Kassab 2022; Tilley 2019).

Software/system requirements can be categorised as functional and non-functional requirements. Functional requirements refer to the services/functions delivered by the system, its response to certain stimulus, its performance under specific conditions, or actions the system should avoid. On the other hand, non-functional requirements describe the constraints applied to the overall system, such as timing, development processes, or imposed standards. In actual cases, both functional and non-functional requirements are not entirely independent and may be interleaved, with one requirement potentially creating or restricting another (Tilley 2019).

### 2.6.1 Requirements elicitation

Requirements elicitation, also called as fact-finding is the process of gathering requirements from the stakeholders for the software system with a combination of different methods, such as (Laplante & Kassab 2022; Tilley 2019):

1. Interviews: involves in-person communication with stakeholders either individually or in a small group; can be unstructured (conversational/informal session), structured (formal session with planned questions) or semi-structured (a combination of both).
2. Observation: used to understand operations/procedures and generate software requirements supporting the procedures; requires researcher to immerse in the stakeholders' environment to gather any implicit requirements.
3. Brainstorming: involves conducting small group discussion among stakeholders to generate general objectives or preliminary requirements for the system/software; fosters the generation of new ideas, encourages collaboration, and helps participants expand on each other's inputs; can be formal or informal.
4. Document review: involves obtaining and reviewing the documents and forms used by stakeholders in present, such as reports, records, data entry documents, operational logs etc.
5. Questionnaires/surveys: uses a document containing standard questions to obtain input from large stakeholder groups and define scope boundaries rapidly

6. Prototyping: creates a working (executable codes or simulations) or non-working (UI mock-ups or storyboards) models of the software/system to gather new functions or usability requirements.

The list of techniques mentioned above is not exhaustive, as there are many other methods not described here.

### 2.6.2 Requirements specification

Requirements specification refers to the process of recording and organising the descriptions about the user requirements into the form of a requirements document in a comprehensive, clear and easy-to-understand manner.

There are two types of requirements specification: user requirements and system requirements. User requirements are high-level, abstract statements of the functions/services provided by the system, described in natural (or layman) languages and diagrams understandable to system users and managers without technical knowledge. In contrast, system requirements are the detailed specification and definition of the system's functions/services and constraints. They are normally extended from the user requirements and written in structured format with notations specifically for professionals like system/software developers (Sommerville 2016).



In general, software/system requirements can be documented in two ways: natural language specification and structured specification. Natural language specification describes the requirements using layman languages in an expressive and intuitive manner. In contrast, structured specification defines the system requirements using a standard template with structured language notations (Sommerville 2016).

#### a. Software Requirements Specification (SRS)

The SRS, also referred to as the software requirements document, is a technical document detailing the requirements, design, expectations, standards and constraints of a software/system. Both user requirements and an in-depth outline of the system requirements may be written in the document.

The readers or users of a SRS document can be quite diverse, ranging from system users or top management in an organisation, to the professional software/system developers. Therefore, the level of detail included in its content must be adapted to fit the intended readers. The type of system/software and the development procedures can influence the information included in the requirements document. For instance, precise and comprehensive specifications are needed for complex/critical systems and outsourced system development, while less details may be needed for in-house software developed with iterative process (Sommerville 2016).

The organisation for the SRS document commonly used today is based on IEEE standard – ISO/IEC/IEEE 29148-2018 (as shown in Figure 2.2), which is the most widely known standard for requirements documents (IEEE 2018). It provides a generic/standard template that allows adaptation or modifications for different uses.



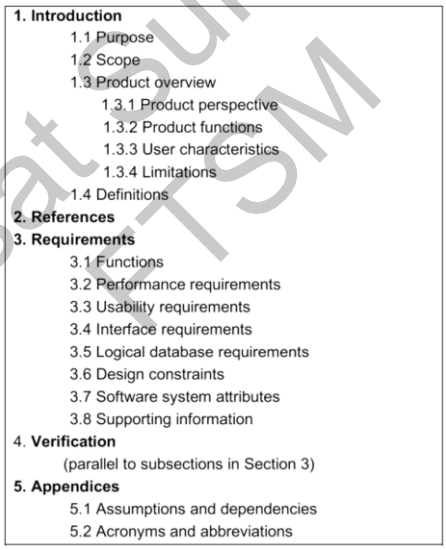



Figure 2.2 Organisation of contents (ISO/IEC/IEEE 29148-2018)

Source: IEEE 2018

### 2.6.3 Requirements validation

Requirements validation involves verifying and validating the definitions/specification of the requirements for the software/systems with the stakeholders. Requirements validation is a critical step because it is more costly and difficult to rectify the requirement errors in the later stages of the software development process than in

requirements engineering. There are several requirements validation techniques which can be used either individually or in combination (Tilley 2019):

1. Prototyping: involves constructing and testing a model of the software/system with the stakeholders and obtaining their feedback for improvement.
2. Requirements review: involves systematic analysis for any errors or inconsistencies by a group of reviewers.
3. Test-case generation: involves designing and developing test-cases from the user requirements to check for testability and discover any problems.

## 2.7 SUMMARY

Effective T2DM management is important for preventing severe complications, improving patients' quality of life, and alleviating healthcare costs and burden. Pharmacological treatment is one of the key strategies for maintaining long-term glycaemic control; however, medication non-adherence remains a common problem in this patient population. Medication self-management is crucial in T2DM management but is a complex and challenging skill for many T2DM patients.

In this chapter, the evidence on mHealth apps particularly for medication management were explored and reviewed. It was found that despite numerous mHealth apps available for medication management, many studies reported significant gaps in their design and functionality, such as lack of involvement of patients and HCPs during app development, leading to inadequate and inefficient support for chronic disease medication management. RAD model, the software development methodology chosen for this study was examined. Successful implementation of this model has been reported in previous studies on developing mHealth apps in a short timeframe with direct involvement of intended users. Given the importance of user requirements in app development, the requirements engineering processes were also studied. By integrating the RAD model and comprehensive requirements engineering, this study aimed to successfully develop the SRS and UI of a mobile app which was user-friendly, effective, and tailored to support medication adherence and self-management in T2DM.

# CHAPTER III

# METHODOLOGY

## 3.1 INTRODUCTION

### 3.1.1 Research design

This research employed the qualitative research methodology which also incorporated the activities of a software development life cycle (SDLC) model, known as Rapid Application Development (RAD) model. A typical RAD model encompasses four main stages: requirements planning, design, construction, and cutover/implementation (Tilley 2019).

The scope of this research mainly emphasises on the development of SRS and UI design of the mobile medication management app, instead of building a working model of the app. Therefore, the RAD model was modified and adjusted to the research scope by incorporating only the former two stages into the current research design. The study was carried out in two main phases: Phase 1, requirements engineering and Phase 2, design. The main participants involved in this study were the patients with T2DM and pharmacists who were recruited from the government health clinics in Selangor. The methodology and subsequent analysis were explained in detail in the following sections. Figure 3.1 shows the general flow of research activities.

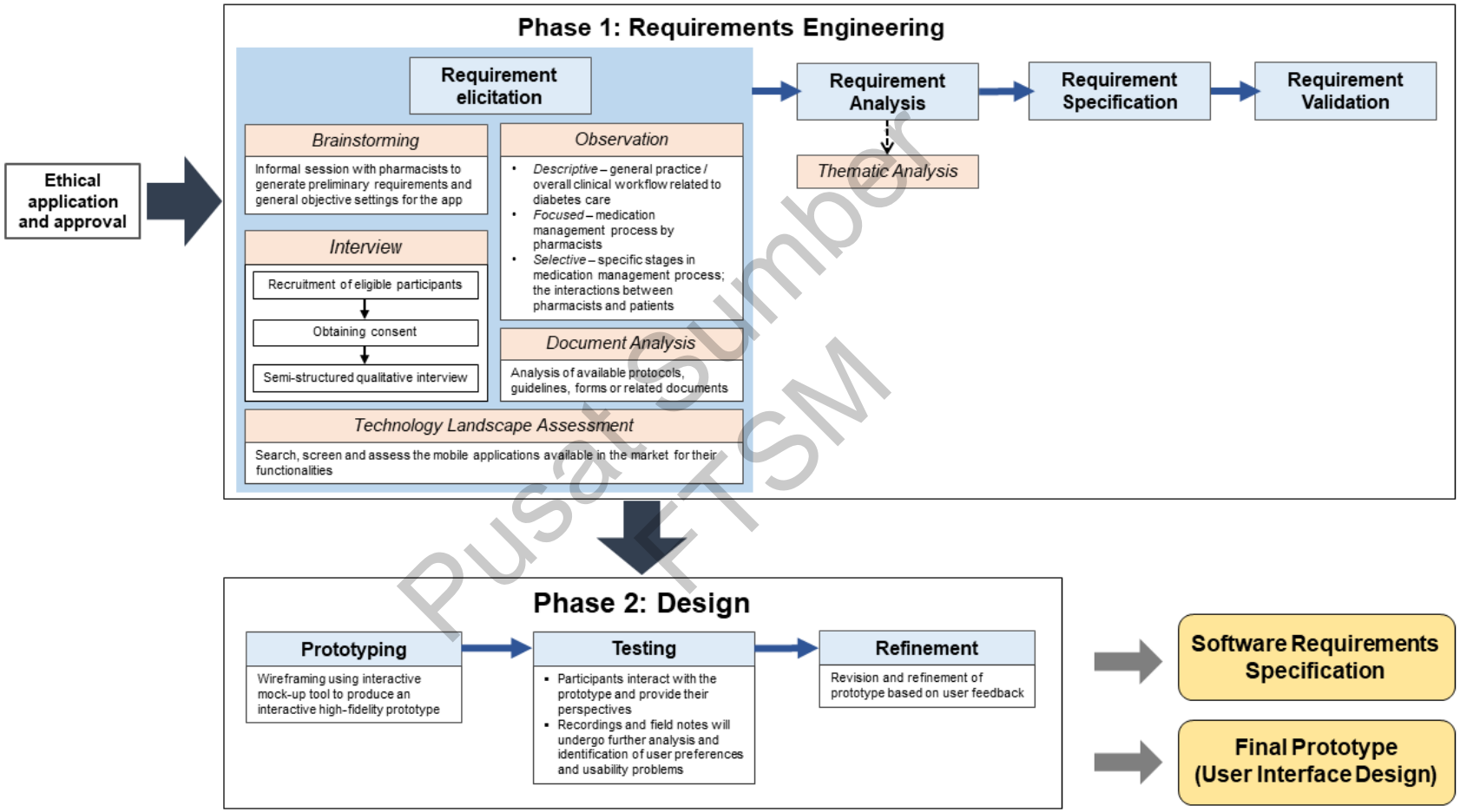



Figure 3.1 Flowchart of research activities

### 3.1.2 Ethical considerations

The nature of the current research was observational as it was mainly based on the participants' responses to the design of a potential mHealth app and did not involve any form of medical intervention. The study was conducted in compliance with the ethical principles outlined in the Declaration of Helsinki (Korstjens & Moser 2017; World Medical Association 2022) Malaysian Guidelines on Good Clinical Practice (National Pharmaceutical Regulatory Agency & Ministry of Health Malaysia 2018). Ethics approval was granted by Medical Research and Ethics Committee (MREC), Ministry of Health (NMRR ID-24-00807-YKH).

The participation was voluntary, and all participants provided informed consent before study enrolment. Participants were aware of their rights to withdraw from the research at any time if they no longer wish to participate. To protect participants' privacy and confidentiality, all potentially identifying information in the research data were promptly anonymised following the data collection, and the participants were individually assigned with a study identification code. The access to study data was restricted to only the research team members.



## 3.2 REQUIREMENTS ELICITATION

Requirement engineering phase is the process of understanding and defining the user requirements, which involves key activities such as requirements elicitation, requirements analysis, requirements specification and validation (Sommerville 2016). Data collection and analysis in Phase 1 were carried out in an iterative manner until thematic saturation is reached, i.e., until preliminary analysis indicated that strong patterns were becoming apparent in data collection and no new information or perspective can be obtained (Moser & Korstjens 2018).

During requirements elicitation, several techniques were used to explore and collect information on the user requirements of the mobile medication app from the relevant stakeholders i.e. pharmacists and patients.

### 3.2.1 Observation

Non-static observations were performed in three stages with different focuses (Moser & Korstjens 2018):

1. Descriptive observations – on the general clinical practice or workflow related to multidisciplinary diabetes care in the healthcare settings.
2. Focused observations – on the overall medication management process involved in diabetes care.
3. Selective observations – on the specific stages of medication management process (namely dispensing and counselling), as well as the interactions between pharmacists and T2DM patients.

The observation process was conducted at the selected primary health clinics. The researcher recorded the findings in the form of field notes which were then discussed and validated with the participating HCPs after the observation.



### 3.2.2 Brainstorming

Brainstorming is a session where the stakeholders engage in informal group discussions to outline the general objectives of the system/software, potentially identifying some preliminary requirements as well (Laplante & Kassab 2022). Pharmacists who agreed to participate were invited to the brainstorming discussion. A topic guide (Appendix A) was used to guide the discussion. Before the session started, the participating pharmacists were allowed to brainstorm on their own for the first 20 minutes, and then they were asked to contribute their ideas to the group for discussion. The discussion was audio-recorded with the participants' informed consent. The researcher acted as the moderator who facilitated the discussion session and recorded the ideas contributed by the participants.

### 3.2.3 Semi-structured interviews

Pharmacists and patients were recruited for individual interviews to gain more in-depth information about their attitudes, preferences, and requirements about the

medication management app. The recruitment criteria for each group are detailed in the following paragraphs. Pharmacists from the government primary care clinics with at least one-year experience in direct care for adult patients with diabetes were invited to participate. A purposive sampling strategy based on age, gender and duration of practice was used to elicit a broad range of opinions and experiences.

Patients with a T2DM diagnosis who were prescribed and self-administered antidiabetic medications (oral antidiabetic agents [OAD] only, or insulin only, or OAD and insulin), 21 years of age or older, able to speak and understand English or Malay language, and had basic knowledge to use smartphones were approached personally during routine appointments at government health clinics. The purposive sampling technique was also employed to ensure diversity in patient characteristics (e.g. age, gender, education level, duration of diabetes, and medication regimen) to obtain a diverse range of experiences, perspectives, and requirements.



Semi-structured individual interviews were conducted with the recruited pharmacists and patients either in English or Malay language, depending on the participants' preferences. The interviews were conducted in person, or using telephone or video conferencing via Zoom / Google Meet at the participants' convenience. Two interview guides were prepared for patients (refer to Appendix B) and pharmacists (refer to Appendix C) respectively to ensure that the interview findings were consistent with the research scope. This helped in standardising the interviews and decreasing the possibility of individual biases and assumptions.

The interview guides in general contained open-ended questions and probes that encouraged the participants to extensively discuss their views, needs, requirements, and expectations regarding a potential mobile diabetes medication self-management app. Interview guide for patients was designed to understand their experiences with their medication management, attitudes, and opinions about using a mobile medication management app and its content and technical requirements. On the other hand, interview guide with pharmacists was constructed to explore their experiences with managing T2DM patients, their attitudes and perspectives towards a

mHealth medication management app for their T2DM patients, along with the app features and information presentation that pharmacists expected from such a tool.

The interviews were audio-recorded with participants' consent, and field notes were also taken down as supplementary information. The recruitment of new participants ceased once thematic saturation was reached, i.e. preliminary analysis showed that no new themes emerged in the interviews.

### 3.2.4 Document analysis

Related documents such as protocols, guidelines, forms and other relevant materials used in diabetes care and medication management were obtained (as listed in Table 3.1) and analysed to confirm and supplement the information collected from observations and interviews.

Table 3.1 List of documents obtained for document analysis

| Document Type | Document Name |
|---|---|
| Clinical practice guidelines | Clinical Practice Guidelines Management of Type 2 Diabetes Mellitus, 6th Edition |
| Protocols | Diabetes Medication Therapy Adherence Clinic (DMTAC) Protocol, 3rd Edition |
| | DMTAC Workflow (First Visit) |
| | DMTAC Workflow (Subsequent Visit) |
| | DMTAC Workflow (Phone/Virtual Call Visit) |
| Forms and checklists | DMTAC Pharmacotherapy Review Form |
| | PhIS Documentation for DMTAC Session |
| | DMTAC Session Checklists |
| | Education Modules for Diabetes Patients |
| Clinical tools | Malaysia Medication Adherence Assessment Tool (MyMAAT) |
| | Diabetes Caregiver Handbook (*Buku Panduan Penjaga Diabetes*) |

### 3.2.5 Technology landscape assessment

A technology landscape assessment was carried out on the mHealth apps related to medication management in diabetes currently available in the market (Apple App Store and Google Play Store). This helped to gain a better understanding of the existing apps and their features. The keywords used in the English language to filter and search for the apps were: “medication”, “pill”, “reminder”, and “diabetes”, which produced a list of app names for screening. Other inclusion criteria included: (1) free app, (2) in English, (3) with a rating of 4 stars and above, (4) last updated date was within 2 years from the date of assessment, (5) able to download and function properly, and (6) contained a basic medication reminder function.

## 3.3 REQUIREMENTS ANALYSIS

The data analysis was carried out concurrently with the data collection process to ensure data saturation. The audio recordings of brainstorming discussion and individual interviews were transcribed verbatim. Participants were anonymised and assigned identifying codes for data management and privacy protection purposes. After the transcription process was completed, audio recordings were safely disposed, whereas the transcribed data were encrypted and stored securely with only the researcher accessing them. The field notes were also synthesised and incorporated with the data for analysis.



The transcripts and field notes were exported to a qualitative data analysis software package called Atlas.ti for data processing and management. Qualitative content analysis was employed to iteratively analyse the data and organise them into codes, categories (also known as themes) and subcategories (Elo et al. 2014; Hsieh & Shannon 2005). This method not only formed the themes based on predefined objectives outlined in the brainstorming discussion and interview guides, but also accommodated the emergence of any new thematic categories from the analysis.

The process was started with data familiarisation through repeated reading of transcripts and field notes. The data were initially analysed in a deductive approach where initial thematic categories were assigned in accordance with the interview

guides. Inductive approach was then used to analyse the data associated with each category to further refine the subcategories. New thematic categories were constructed inductively when new information that did not fit the initial categories were identified from the data. The inductive analysis approach entailed identification of meaning units, consolidation into codes, and grouping of codes into common subcategories (Braun & Clarke 2006). The iterative process of requirement analysis continued to reveal the commonalities, differences, or new patterns regarding the data, until the point where thematic saturation was achieved.

### 3.4 REQUIREMENTS SPECIFICATION AND VALIDATION

Once the data collection and analysis for the observations, interviews, brainstorming discussion, and document analysis were complete, these findings were organised and documented towards the definition of software requirements specification (SRS) document, which inform the design of functionalities and features of DMed, the mobile medication management app in the later phase.



The list of user requirements was initially structured into twelve potential modules for the initial prototype design, namely: medication list, drug allergy and ADR history, complementary medicines/supplements/OTC drugs use history, medication adherence, reminders, appointments, measurements, settings, patient education, chat feature, patient profile, and alerts. After discussion and review with selected pharmacist participants, the modules were then reorganised into ten modules.

The development of graphical system models to represent the mobile app software was also conducted as part of the requirements specification process in this study. System modelling refers to the process of constructing abstract models of the system from different perspectives to illustrate the interactions between the system and its surroundings (Sommerville 2016). The graphical system models developed in this study were represented by Unified Modelling Language (UML) to document the proposed system structure and operation, and elucidate the requirements for intended users and other system stakeholders. The context diagram and use case diagram of the potential app were documented under SRS in the next chapter Results.

Once the content in the SRS was organised, the information was checked and validated again with the selected participants for any errors or inconsistencies before proceeding to the next phase. Prototyping, which is also another requirements validation technique to check the alignment of defined requirements with users' needs, was conducted in Phase 2 of research. The SRS defining the user requirements of the mobile app in this research is elucidated in the Chapter 4 Results.

## 3.5 PROTOTYPE DEVELOPMENT

Phase 2 Design mainly encompasses three key activities: prototyping, testing and refinement. The information in the SRS document prepared in the earlier stage was then utilised in designing the wireframes and prototype of the mobile medication management app.

In the development of the prototype, wireframing is the preliminary stage in conceptualising the design of digital interfaces, which establishes the general information layout and user flows with the visual representation and outline of the mobile app. Wireframing facilitates in exploring app design alternatives, arranging information layout, experimenting navigation flows, and evaluating user interactions within the mobile app. These wireframes (as shown in Figure 3.2) subsequently formed the foundation for designing the high-fidelity prototype of the mobile app, using an interactive mock-up tool named Figma. Upon finalising the overall content layout and navigation flows, the visual elements (e.g. colours, graphics) were incorporated to produce a high-fidelity prototype.

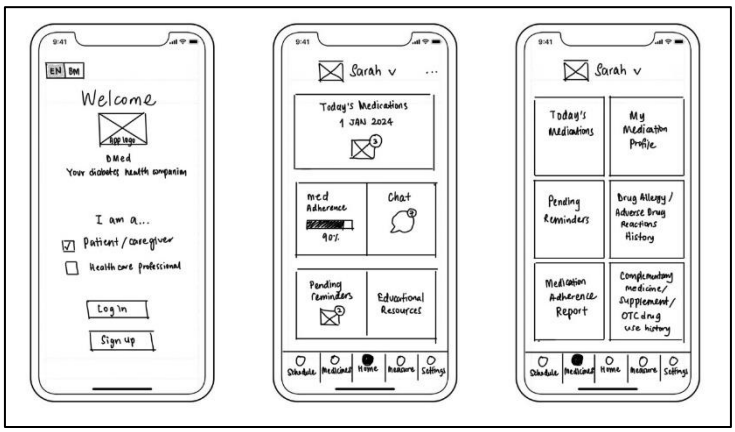



Figure 3.2 Extracts of app wireframes created during prototype development

The bottom navigation bar served as a starting point of the design process. In the initial design of the patient interfaces, the navigation bar included five tabs: schedule, medicines, shortcuts (home), measurements, and settings, presented from left to right (Figure 3.3a). The navigation bar for the pharmacist interfaces also contained five tabs, but with different elements: adherence, patients, shortcuts (home), chats, and settings (Figure 3.3b). As the design for bottom navigation bar evolved, so did the screen design for each feature.

(a) (b)

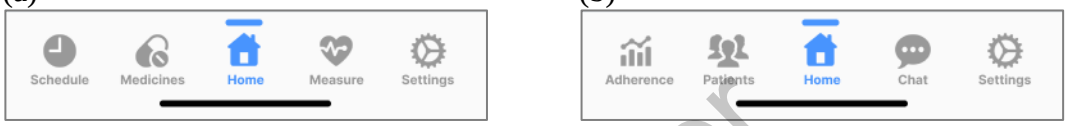



Figure 3.3 Elements in the bottom navigation bar: (a) patient interfaces, (b) pharmacist interfaces



## 3.6 PROTOTYPE TESTING AND REFINEMENT

Once the high-fidelity prototype was developed, usability testing was conducted with end users, i.e. patients and pharmacists in this study. Testing sessions lasted approximately 45 – 60 minutes and were performed either individually or in groups, depending on user availability and preferences. Informed consent was obtained from all participants prior to testing, and no specific training was provided beforehand.

After a brief introduction about the purpose of testing session and the mobile app, the participants engaged in a think-aloud test, where they interacted with the prototype to complete a list of tasks depicted in several scenarios and verbalised their thoughts during the interactions (Nielsen 2012). The scenarios help guide the test users through the prototype and explore its functionalities, as they represent the real tasks performed by patient and pharmacist users in the mobile app to support medication management. For instance, Figure 3.4 shows the navigation path through the prototype for the pharmacist user task and scenario of “Check patient measurements”. Table 5.1 and 5.2 describe the user tasks and the related scenarios used in the usability testing for patient and pharmacist users respectively.

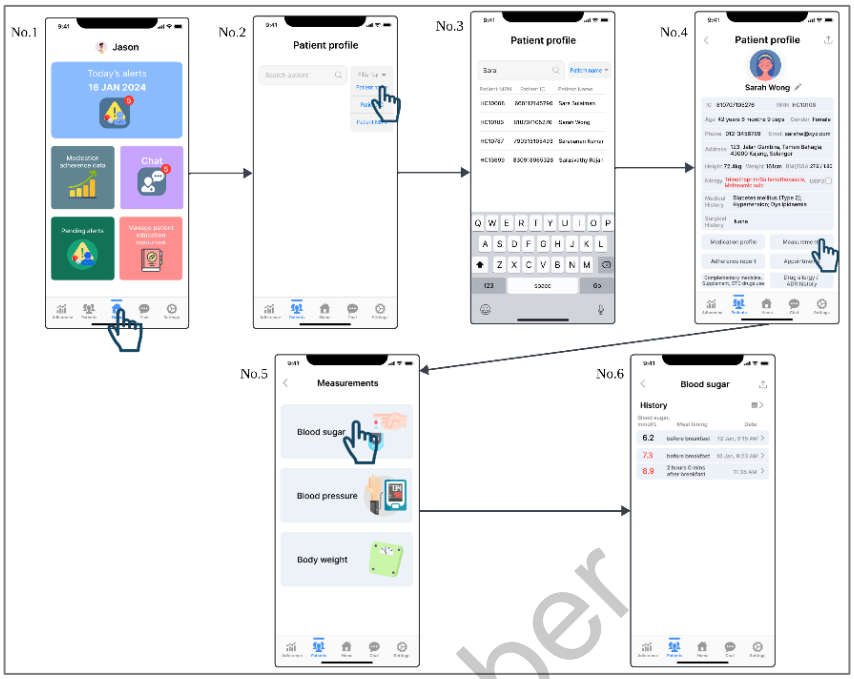



Figure 3.4 Extract of the interactive prototype showing the pharmacist user task of "Check patient measurements"



Table 3.2 User tasks and scenarios for patient test users

| No. | Task | Scenario |
|---|---|---|
| 1 | Trace current medication profile and allergies | You visit a community pharmacy to buy some medicine for cough and flu. The pharmacist on duty asks if you are currently taking any medication and if you have any history of drug allergies. Open the app and show her the information. |
| 2 | Responds to reminders and logging medication intake | The app sends you a reminder that it's time to take your diabetes medications (Gliclazide MR and Metformin tablets) in the morning. You have just taken four tablets of Gliclazide MR 30mg before breakfast. Metformin tablets are supposed to be taken after the meal, but since you have not finished your breakfast, you want to postpone it for 30 minutes. Open the app and:<br>1. Mark the intake status for Gliclazide MR as 'taken on schedule'.<br>2. Postpone the Metformin reminder for 30 minutes. |
| 3 | View and log self-monitoring measurements | It's 7am and you measure your blood sugar before breakfast. The reading is 4.9mmol/L. You also want to review your previous readings. Open the app and:<br>1. Log the reading.<br>2. Check past readings. |
| 4 | Self-track medication adherence | Since it's the end of the week, you want to check how well you have adhered to your medication schedule and see if you missed any doses. Open the app and check your medication adherence score. |
| 5 | View and manage appointment schedule | You know you have several upcoming clinic appointments but are unsure of the dates. Open the app and check the appointment schedule. You attended a doctor's appointment last Friday (12 January). Open the app and look for past appointments, then mark your attendance for that appointment. |

to be continued …

… continuation

| | | |
|---|---|---|
| 6 | Edit reminder settings | You usually eat breakfast at 7am, but recently you changed your morning routine and now eat breakfast at 6am. You leave home at 8am for work and want to set a reminder for bringing your medications before heading out. Open the app and edit the reminder settings. |
| 7 | Communicate in chat feature | You receive a few messages from your attending pharmacist, Jason Lee. Open the app to check and reply to the messages. |
| 8 | Access educational resources | Your pharmacist informed you that his team has updated some educational content about DM and encouraged you to review it when you have free time. Open the app and have a look at the new content. |

Table 3.3 User tasks and scenarios for pharmacist test users

| No. | Task | Scenario |
|---|---|---|
| 1 | Check patient status alerts | It's Tuesday at 9:40am in the medication therapy adherence clinic, and you want to check for any alerts regarding the patients under your care. Open the app and check the alerts. |
| 2 | Trace patient's current medication profile and allergies | A new patient, Sarah Wong, has been referred to your medication therapy adherence clinic. You want to review her full medication profile, including her current medication list, history of drug allergies and ADRs, and use of complementary medicines, supplements, and OTC drugs. Open the app and check this information. |
| 3 | Manage patient medication profile | Dr. Fara Helmi has adjusted the medication for patient Sarah Wong by adding a new medication: Tablet Vildagliptin 50mg OD, starting from 16 January 2024 to 29 March 2024. Please update her medication list by adding this new medication. |
| 4 | Check patient measurements | Your patient, Sarah Wong started her insulin regimen and a new blood pressure medication last week. You advised her to measure her blood sugar and blood pressure. You want to see how her readings have been this week. Open the app and check her history of blood sugar and blood pressure readings. |
| 5 | Manage appointment schedule | Your patient, Sarah Wong has a new appointment scheduled on 29 Mar 2024, 9:00am. Another appointment for diabetes education class on 1 March 2024 has been rescheduled from 10:00am to 11:30am. Open the app and:<br>1. Add the new doctor's appointment.<br>2. Edit the appointment details for diabetes education class |
| 6 | Generate medication adherence data | Your team wants to conduct an intervention program for patients with poor medication adherence. Open the app and generate a list of patient names with medication adherence levels of less than 80% for the past month (December 2023). |
| 7 | Communicate in chat feature | You have received some chat messages from your patients. Open the app to check and reply to the messages. |
| 8 | Manage patient educational resources | It's January, and your team has decided to revise/review some of the educational content for patients in the app during the meeting. You have been assigned this task. Open the app and review the content. |

A topic guide (Appendix D) containing a list of questions designed with Nielsen's usability model, was used to gather end users' perspectives on the app's UI and user experience. The Nielsen's usability model was employed as this model investigated usability in five aspects: learnability (the ease of users learning and using the app for the first time), memorability (the ease of users recalling the app use after a period of time), efficiency (the ease and speed of the users performing tasks after learning how to use the app), error (the frequency of users making an error during the app use and the ease of users recovering from the errors), and satisfaction (how pleasant the app use experience was) (Nielsen 1993). The sessions were audio-recorded with participants' consent, and user reactions and comments were manually noted during the process. The audio recordings and manual notes were analysed for identifying usability issues and user preferences. The prototype was further refined and revised based on the end users' feedback.

After applying refinement suggestions from the usability testing into the prototype and making the necessary revisions to the SRS document, the final versions of the SRS document and UI design for the mobile app were established as the basis for future implementation.

# CHAPTER IV

# RESULTS

## 4.1 INTRODUCTION

This chapter presents the findings obtained and analysed from the current study. Section 4.2 describes the results gathered in Phase 1 Requirements Engineering, which included observation, brainstorming, interviews and app analysis (technology landscape assessment). Section 4.3 presents the software requirements specification (SRS) derived from the analysis of these research findings. Section 4.4 displays the user interface (UI) design screen mock-ups of the mobile app prototype. Section 4.5 reports the usability testing results and the outcomes of prototype refinement.



## 4.2 GENERAL FINDINGS FROM REQUIREMENTS ENGINEERING

### 4.2.1 Observations

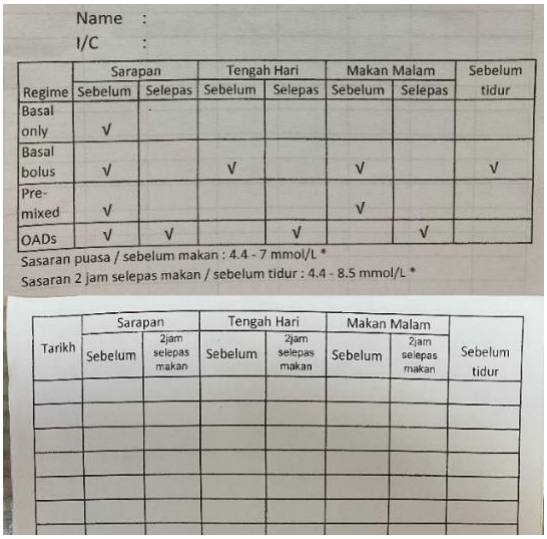
The observation process was conducted over a total of 12 hours at selected primary health clinics and included activities such as clinic visits, diabetes education classes, and pharmacist-managed diabetes medication therapy adherence clinic sessions.

#### a. Clinic visit shadowing

Observing the interaction between patient with T2DM and clinicians (e.g. doctors, nurses, pharmacists etc) during routine clinic visits was helpful and valuable in gaining understanding on the general clinical workflow of diabetes care in Malaysian government primary care clinic settings. A total of six patient clinic appointment visits were observed. Patients and their caregivers as well as the involved HCPs were asked for permission prior to the observation.

The process of a routine appointment started with the patient registration at the front counter and obtaining a waiting number. The patient then proceeded to the nurse counter when his/her waiting number was being called. The nurse checked the patient's vital signs, blood glucose level (with finger-prick test using glucometer) and blood pressure (using a blood pressure machine). Body weight, height and waist circumference were also measured to check for patient's BMI and any weight gain/loss. Patient's feet were also inspected for any wound or abnormalities as an early detection or prevention of diabetic foot infection. All these examination/measurement results were recorded in the patient record book.

Next, the patient waited to be called into the doctor's room. The doctor performed some physical examination and questioning with the patient, and screened through nurse's notes and recent laboratory test or scan results. For additional information on the patient's glycaemic control at home, the doctor would often request to review a handwritten SMBG (self-monitoring of blood glucose) record done at home by patient/caregiver. Patient/caregiver were encouraged to use a paper log provided by the clinic to record the blood glucose levels based on the context of each reading, which are normally defined by meal timings (e.g. breakfast, lunch and dinner) and bedtime. The frequency of SMBG testing might vary according to the patient's medication regimen. Figure 4.1 shows the pictures of SMBG paper log provided by the clinic. This data served as a cross-reference for HbA1c result taken in the previous months, and also helped doctor to better understand the overall picture of patient glycaemic control. The doctor would then discuss with the patient and recommend appropriate changes (either in insulin/oral medication dosage, diet, or physical activity levels) to help regulate blood sugar levels. However, it was observed that some patients claimed to have forgotten to bring the paper log of home SMBG readings or even admitted to losing it. Some did not perform SMBG recording at all, citing reasons such as forgetfulness or inconvenience with keeping a manual log.



Name :
I/C :

| Regime | Sarapan | | Tengah Hari | | Makan Malam | | Sebelum tidur |
|---|---|---|---|---|---|---|---|
| | Sebelum | Selepas | Sebelum | Selepas | Sebelum | Selepas | |
| Basal only | √ | | | | | | |
| Basal bolus | √ | | √ | | √ | | √ |
| Pre-mixed | √ | | | | √ | | |
| OADs | √ | √ | | √ | | √ | |

Sasaran puasa / sebelum makan : 4.4 - 7 mmol/L *
Sasaran 2 jam selepas makan / sebelum tidur : 4.4 - 8.5 mmol/L *

| Tarikh | Sarapan | | Tengah Hari | | Makan Malam | | Sebelum tidur |
|---|---|---|---|---|---|---|---|
| | Sebelum | 2jam selepas makan | Sebelum | 2jam selepas makan | Sebelum | 2jam selepas makan | |
| | | | | | | | |
| | | | | | | | |
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| | | | | | | | |

Figure 4.1 The SMBG paper log provided by the clinic to the DM patients

After assessing the patient's general condition and glycaemic control, the doctor would decide whether the patient required further treatment/examination, or current medication regimen needed any adjustment. The doctor also conveyed the lab/scan results to patient and provided relevant medical advice. If patient was found to have confusion or complex problem in the use of antidiabetic medications (e.g. inappropriate timing or dosage, incorrect insulin injection techniques, non-adherence etc), the doctor would make a referral to the pharmacist for medication counselling. Before ending the session, the doctor would create the laboratory test/scan/procedure orders and medication orders either manually or electronically, depending on the availability and type of electronic health record system in the clinics. The patient proceeded to the appointment desk to book the appointment for next clinic visit, or other procedures/examination if necessary. After that, the patient went to the pharmacy counter and waited to collect their medication supply.

The entire process of a clinic visit was found to take about 2 – 3 hours of the patient's time. The clinic visits might often exceed the expected duration because of other scheduled procedures/activities, such as blood-taking procedure, routine eye assessment, dietitian appointment, physiotherapy session, pharmacist medication therapy management clinic (known as DMTAC, Diabetes Medication Therapy Adherence Clinic) appointment, quit smoking clinic (also known as KBM, *Klinik Berhenti Merokok*) appointment etc. The clinic visits and procedures/activities were scheduled at the intervals of 1 – 6 months.

Apart from that, it was observed that the duration of direct doctor-patient interaction typically averaged around 10 – 20 minutes, varying based on patient's condition. Shorter doctor consultation time, which is likely to occur in healthcare settings with heavy patient load, may be inadequate for both patients and doctors to effectively communicate and address all concerns in a single appointment. This could lead to overlooking treatment-related issues encountered by the patients, such as inappropriate medication use, medication side effects, fear of needles, lack of medication knowledge, and misconceptions about medications. Unaddressed healthcare issues and diminished depth of understanding due to short visits can result in various consequences, including non-adherence to treatment plans. (Linzer et al. 2015). Arrangement of frequent clinic visits or longer doctor consultation may be challenging and less feasible for healthcare providers nowadays, due to the escalating patient load according to the Annual Report by Ministry Health of Malaysia (2022). Therefore, this suggests the possible utility of a mobile medication management app in facilitating real-time, effective communication between T2DM patients and healthcare providers outside of routine clinic appointments.



**b. Diabetes education class**

To better understand the educational content commonly delivered by HCPs and what self-management involves for DM patients, a diabetes education class offered in the government health clinic was observed. It was typically conducted on Fridays on a bi-weekly basis and often lasted about 30 minutes to 1 hour. This group-based education session was offered to anyone interested and was recommended to patients with newly diagnosed DM or those with poor glycaemic control (HbA1c >8.5%). The class involved multidisciplinary care, with representatives from different HCP group: a doctor, diabetes nurse educator, pharmacist, dietitian, and physiotherapist, depending on their availability. Each HCP would deliver patient-centred diabetes education to the patients with focus on the following topics: introduction to DM (symptoms, diagnosis, prevention, complications) antidiabetic medications, self-monitoring blood glucose, management of high and low blood glucose, dietary planning, physical exercise, lifestyle modification, foot care, and common myths related to DM. After each HCP's talk, there would be a round of Q&A for patients to address their doubts.

This was an effective approach to raise awareness of DM, and to enhance diabetes self-management knowledge and skills among patients living with T2DM.

**c. Diabetes medication therapy adherence clinic**

To understand medication management process, as well as the interactions between pharmacists and T2DM patients, four sessions of Diabetes Medication Therapy Adherence Clinic (DMTAC) visits were observed. DMTAC are the medication therapy management services programme coordinated and operated by pharmacists in collaboration with doctors under Malaysian government hospitals and health clinic settings. The programme aimed at improving medication adherence and glycaemic control among patients with uncontrolled DM despite treatment optimisation, medication non-adherence, multiple comorbidities and complex regimens, DM-related complications, or frequent low blood glucose (Ministry of Health Malaysia Pharmaceutical Services Program 2022). These patients were enrolled into the programme through doctor referrals or identified by pharmacists during regular visits.



Besides the usual doctor consultation, recruited patient would receive additional counselling sessions from the pharmacist and need to attend a minimum of four follow-up visits. Pharmacist would perform a baseline assessment to gauge patient condition and review treatment issues and goals in the first DMTAC visit. For subsequent follow-up visits, pharmacists would perform a wide range of medication management activities with patients on top of the normal process of medication refill, dispensing and counselling. These activities may include providing diabetes education and medication counselling, assessing medication adherence (using a self-reporting questionnaire), evaluating medication knowledge and understanding, assessing device techniques (e.g. insulin injection devices or glucometers), identifying and managing any medication-related problems, and reviewing glycaemic clinical outcomes (HbA1c and SMBG readings). Patients would be discharged from DMTAC programme once they attained HbA1c targets for minimum two readings consecutively, or achieved a satisfactory medication knowledge score and good medication adherence.

Observing the DMTAC session confirmed some of the observations from the shadowing at the clinic visit and diabetes education class, and revealed some other

challenges encountered by the patients when managing their medications. During DMTAC visits, pharmacists focused on educating their patients about practicing SMBG at home, and regularly reviewed their SMBG profiles. However, a similar situation was also observed in DMTAC sessions, where some patients failed to bring or perform SMBG readings. This could pose challenges for pharmacists in assessing patients' glycaemic control and risk of low blood glucose, which is particularly important when adjusting patient's insulin dosage. Furthermore, it was found that certain patients on insulin therapy experienced difficulties in self-adjusting their insulin dosage at home. Despite its potential benefits, SMBG continues to be underutilised by many DM patients, who often lack knowledge about how to interpret its results and make necessary adjustments to their treatment regimen. Many patients only had their doses titrated by their clinicians during their scheduled monthly follow-up appointments, which is a rather time-consuming process.

Medication adherence was also assessed by DMTAC pharmacists using self-reporting questionnaire. The questionnaire required patients to recall and provide information on their medication-taking behaviour in the past months, including any missed doses and their frequency. However, the accuracy of the reported results was often subjected to the patient's ability to recall correctly and their willingness to report honestly (Wilson et al. 2009). It was also noted that some patients reported having trouble remembering their medications due to reasons such as forgetfulness, unexpected changes to their daily routine, being busy with work, or traveling away from home. Other medication-related problems were also observed. For instance, when pharmacists inquired, some patients were unaware or unsure of the intended purpose and dosages of their prescribed medications. They occasionally became confused and even mixed up multiple medications they were taking.

Thus, this implied the potential of a mobile medication management app in assisting diabetes patients in improving their medication-related knowledge, adherence and glycaemic control.

### 4.2.2 Brainstorming discussion

Five (5) pharmacists who agreed to participate were invited to the brainstorming discussion. The discussion which lasted for about 45 minutes. The session first began with an overview of the current challenges faced by patients with T2DM in managing their medications and the objectives of pharmaceutical care. Each pharmacist participant shared insights from their professional experiences, emphasising the need for a comprehensive and user-friendly mobile health app. As a result of the brainstorming session, the following were suggested as the key features of the app:

1. Reminders: The app should contain a feature that would enable users to set up customisable reminders for taking medications and for upcoming appointments for routine clinic follow up, prescription refills, laboratory tests, and other activities.

2. Medication intake monitoring and reporting: Patients would be able to document their medication intake with the click of a button to indicate the doses taken. The app would also allow patient to self-track and review their medication intake pattern or adherence by comparing the scheduled intake and actual intake.

3. Measurements documentation and review: This feature would include an easy-to-use interface allowing patients to conveniently record their self-monitored blood sugar readings at home. HCPs would easily review these SMBG measurements within the app and perform necessary adjustments to medication regimens.

4. Complete medication profile: Since many patients struggled to keep track of their current medications, whether by memory or paper-based documentation, this feature would offer a structured form of presentation for their complete medication list or history. The full medication profile would also enable the documentation of patient's history of drug allergies to improve medication safety.

5. Patient education: The app should include a dedicated section to support the provision of information and knowledge related to diabetes self-management and medications for patients. This information will be curated in simple language to ensure easy understanding.

The brainstorming session effectively laid the groundwork for outlining and conceptualising the app. It also guided the formulation of questions for semi-structured interviews to determine suitability of specific features for targeted users.

### 4.2.3 Semi-structured interviews

A total of eleven (11) pharmacists and fifteen (15) patients with T2DM were recruited for participating the interview. The duration of individual interview session varied in length from approximately 30 to 45 minutes.

#### a. Participant characteristics

Fifteen (15) patients with T2DM and eleven (11) pharmacists agreed to participate the interview. Majority of the patients (n = 11, 73.3%) were on complex medication regimens, taking more than 5 different types of medications every day, including but not limited to antidiabetic medications. A significant number of patients (n = 10, 66.7%) had 2 or more comorbidities other than diabetes. Half of the patient participants had been diagnosed with T2DM for over 5 years. As for the pharmacist participants, most were female (n = 10, 90.9%) and above 30 years old (n = 9, 81.8%) with more than 5 years of clinical experience in diabetes care (n = 9, 81.8%). Table 4.1 and 4.2 present the demographics of the recruited patients and pharmacists.

Table 4.1 Demographic characteristics of patients with T2DM who participated in the interviews

| Characteristic | Number of Participants | Percentage (%) |
|---|---|---|
| Total sample | 15 | 100 |
| **Gender** | | |
| Female | 9 | 60.0 |
| Male | 6 | 40.0 |
| **Age** | | |
| 21 – 30 | 2 | 13.3 |
| 31 – 40 | 3 | 20.0 |

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… continuation

| | | |
|---|---|---|
| 41 – 50 | 5 | 33.3 |
| 51 – 60 | 3 | 20.0 |
| 61 – 65 | 1 | 6.67 |
| >65 | 1 | 6.67 |
| **Race** | | |
| Malay | 7 | 46.7 |
| Chinese | 4 | 26.7 |
| Indian | 2 | 13.3 |
| Others | 2 | 13.3 |
| **Level of education** | | |
| Primary education | 1 | 6.67 |
| Secondary education | 8 | 53.3 |
| Tertiary education | 6 | 40.0 |
| **Employment status** | | |
| Employed | 11 | 73.3 |
| Unemployed | 4 | 26.7 |
| **Presence of comorbidities (other than diabetes)** | | |
| 0 | 2 | 13.3 |
| 1 | 3 | 20.0 |
| 2 | 6 | 40.0 |
| 3 or more | 4 | 26.7 |
| **Number of regular medications taken daily (not limited to diabetes medications)** | | |
| 1 – 2 | 2 | 13.3 |
| 3 – 4 | 2 | 13.3 |
| 5 – 6 | 7 | 46.7 |
| 7 or more | 4 | 26.7 |
| **Duration of diabetes diagnosis** | | |
| 6 months or less | 1 | 6.67 |
| >6 months – 1 year | 2 | 13.3 |
| >1 – 5 years | 4 | 26.7 |
| >5 – 10 years | 6 | 40.0 |
| >10 years | 2 | 13.3 |
| **Current diabetes medication regimen** | | |
| Oral medication only | 7 | 46.7 |
| Oral medication and insulin | 5 | 33.3 |
| Insulin only | 3 | 20.0 |

Table 4.2 Demographic characteristics of pharmacists who participated in the interviews

| Characteristic | Number of Participants | Percentage (%) |
|---|---|---|
| Total sample | 11 | 100 |
| **Gender** | | |
| Female | 10 | 90.9 |
| Male | 1 | 9.1 |
| **Age** | | |
| 30 and below | 2 | 18.2 |
| 31 – 40 | 7 | 63.6 |
| 41 and above | 2 | 18.2 |
| **Race** | | |
| Malay | 5 | 45.5 |
| Chinese | 3 | 27.3 |
| Indian | 2 | 18.2 |
| Others | 1 | 9.1 |
| **Duration of clinical experience in diabetes care** | | |
| 1 – 5 years | 2 | 18.2 |
| more than 5 years | 9 | 81.8 |



**b. Key themes identified from the analysis**

**i. Patients' challenges in managing medications**

In designing a mobile app for medication management in T2DM, it is crucial to understand the challenges patients face in managing their medications. The analysis of the responses from patients and pharmacists yielded six subcategories which highlights several key issues (Table 3.4), including (1) forgetfulness, (2) complex medication regimens, (3) lack of medication knowledge/understanding, (4) interference from daily lives/routines, (5) patient-HCP relationship, and (6) lack of psychosocial support.

Forgetfulness was reported as one of the significant challenges. Patients revealed they frequently forgot taking their medication, had trouble remembering whether they had taken it, and often failed to refill their prescriptions before running

out of supply. This can lead to missed doses and poor adherence, which can adversely affect treatment outcomes. Furthermore, the complexity of medication regimens was perceived as another major barrier to medication self-management. For instance, any patients, especially those living with multiple chronic diseases besides T2DM, often had to manage complex medication schedules involving more than five medications. This complexity is further compounded when multiple daily dosings (more than three times daily) are involved, as expressed by some patients:

*"I need to take a lot of different medications… I have like six of them… and some needs to be taken two to three times a day… so sometimes I am not sure if I can remember taking all of them because it's just too many to remember."* (IPT3)

Table 4.3 Challenges encountered by patients with T2DM in self-managing their medications

| **Subcategory** | **Codes** |
|---|---|
| Forgetfulness | Forget to take medication<br>Difficulty in remembering medication intake<br>Forget to refill medication before running out of supply |
| Complex medication regimens | Polypharmacy (taking more than 5 or more medications)<br>Multiple daily dosing (more than three times a day)<br>Complex medication administration (e.g. injectables)<br>Frequent modifications in medication |
| Poor knowledge/ understanding about medications | Limited health literacy<br>Limited access to health/medication educational resources<br>Negative beliefs about medications |
| Interference from daily lives/routines | Disruption from daily activities that affect medication management task<br>Cultural/religious practices that may interfere medication tasks/schedules<br>Managing medicine outside the home |
| Patient-HCP relationship | Inadequate/lack of patient involvement<br>Poor communication |
| Lack of psychosocial support | Living alone<br>Insufficient/lack of self-management support |



Patient also expressed difficulty in maintaining medication adherence due to inability of dealing with frequent changes in their medication regimens and the complex medication administration and timing (e.g. insulin injectables). These complexities often interfere with patients' daily activities and overall quality of life:

*"I am injecting insulin four times a day… and doing the injection is not easy, especially when I first started… My sugar is not doing well, and the doctor keeps switching the dose… up and down… sometimes it's hard to keep up with it."* (IPT11)

Poor knowledge and understanding about medications significantly impacts patients' ability to manage their treatment effectively. Pharmacists reported that many patients have low health literacy and may face difficulty in comprehending medical/medication information. Limited access to proper/quality health and medication educational resources can also exacerbate this issue. Some patients described difficulties in interpreting complex information and assessing the quality of medication/medical-related information, especially when finding those information online. Pharmacist participants revealed that some patients had negative beliefs about medications, whether based on misinformation or previous experiences of adverse effects, and expressed reluctance in adhering to prescribed treatments.

Moreover, patients described difficulty in carrying out medication management tasks due to interference from daily lives/routines. The demands of everyday life (e.g. work schedules, daily errands, house chores etc.) can disrupt the timing and administration of medications, leading to missed or incorrect doses. Some patients mentioned that cultural and religious practices, such as fasting during Ramadan month, can also interfere with medication schedules. There were patients who need to take medications outside the home may often forget to bring their medications with them, which further complicate medication adherence.

Many patients perceived that the relationship between patients and HCPs played an important factor in medication management. Some stated that their involvement in decision-making processes was inadequate and often felt disconnected from treatment recommendations they received. A few patients complained they did not have sufficient communication with their HCPs during consultation due to time constraints, which may lead to misunderstandings and non-adherence:

*"Hours of waiting (for appointment at the clinic) and I finally got to see the doctor, but she only gets to see me for ten minutes maximum... I want to ask questions*

*but I can't take her too much time… because she also needs to see other patients… sometimes I feel I am uninformed… but what can I do?"* (IPT8)

Some patients described difficulty to self-manage their condition effectively due to the lack of necessary psychosocial support. Those living alone were devoid of the family assistance/support in medication administration, as well as the physical company when experiencing unfavourable circumstances (e.g. drug adverse effects, low blood sugar or other discomfort/sickness). Other patients explained that they struggled to manage their health and medications independently due to insufficient self-management support from healthcare systems.

**ii. Functional requirements for the app**

The expectations from patient and pharmacist participants regarding the functional requirements of the potential mobile app were divided into nine subcategories (Table 4.4): (1) reminders, (2) medication history documentation, (3) medication intake logging and reporting, (4) measurements logging and reporting, (5) electronic messaging, (6) alert messages for patient status, (7) patient education resources, (8) caregiver involvement, and (9) motivation.



The reminder function was highly requested and discussed by both patient and pharmacist participants during the interviews. Most perceived that the app should provide robust reminder functionalities to support treatment adherence and self-management, including medication-taking reminders, appointment reminders (such as pharmacy refills, clinic appointments, blood tests etc), and self-monitoring measurement reminders. Some participants suggested that a postpone or snooze function would be useful to allow users to delay reminders when needed:

*"Sometimes when the alarm reminder rings, I'm in the middle of something and can't stop to take my meds... so a snooze button that lets me choose how long to delay the alarm until I'm finished would be really helpful."* (IPT5)

Participants also stated their preference for customisable settings for reminder timing to make sure that notifications can align with mealtimes, daily routines or

personal schedules for convenience. Several patient participants mentioned their previous experience of missing doses because they forgot to bring their medications before leaving for work in the morning; thus they requested a reminder feature to notify them to carry their medications before leaving home. The option to sync reminders with the phone calendar was mentioned by the participants as well.

Table 4.4 Functional requirements of the mobile app

| **Subcategory** | **Codes** |
|---|---|
| Reminders | Medication reminders<br>Appointment reminders<br>Self-monitoring measurement reminders<br>Postpone/snooze function<br>Customisable settings for medication reminder timing to match with mealtimes or other daily routines<br>Reminder to bring medications before leaving home in the morning<br>Sync data with phone calendar |
| Medication history documentation | Complete list of current medication<br>Previous medication histories<br>History of drug allergies and adverse drug reactions (ADR)<br>Documentation of complementary medicines, supplements and over-the-counter (OTC) drugs use<br>Documentation should be done by pharmacists<br>Allow data export and sharing |
| Medication intake logging and reporting | Record medication intake (dosage & timing)<br>Document additional information/events related to medication intake (e.g. side effects, symptoms)<br>Patients can self-track medication adherence<br>Pharmacist can generate medication adherence data/report |
| Measurements logging and reporting | Log measurements (blood sugar, blood pressure and body weight)<br>Generate measurements trend/report |
| Electronic messaging | Instant messaging between patient and pharmacist<br>Instant messaging between pharmacists<br>Support images, text and voice messages |
| Alert messages for patient status | Trigger alert messages about patient status (e.g. abnormal readings, missed medications/appointments, declined/poor adherence) to pharmacists |
| Patient education resources | Educational content managed by pharmacists<br>Information/knowledge focused on diabetes and medications<br>Available in multimedia format (e.g. graphics, text, videos)<br>Search function for medication information |
| Motivation | Motivational messages to encourage/reinforce self-care behaviour in patients |
| Caregiver involvement | Support for multiple user profile<br>Allow sharing of patients' medication/appointment schedule with caregiver<br>Trigger notification messages to caregiver if missed dose<br>Allow caregiver access to patients' medication profile, allergy/ADR history<br>Enable sharing of patients' measurement log with caregiver |

Comprehensive documentation of medication history is another important requirement that received great attention in the interviews. Both patients and pharmacists expressed similar expectations that the app should be able to generate a structured presentation of a complete medication record comprising of current medication list and previous medication histories. Some pharmacists emphasised the function of documenting history of drug allergies and adverse drug reactions (ADRs) should also be included together. Several pharmacists highlighted the benefits of including information on the use of complementary medicines, supplements, and over-the-counter (OTC) drugs. They noted that this feature would enhance the thoroughness of the medication history. To facilitate information retrieval and sharing, most participants requested to be able to export or send the medication history electronically. However, most pharmacists mentioned concerns on the accuracy of data input by patients due to their limited health and digital literacy, and stressed that the data entry for medication history should be entirely managed by pharmacists to ensure accuracy and reliability:

*"Patients don't know much about drugs and medical jargons… Letting them enter the drug (data) themselves is not a good idea… I am more concerned of the accuracy… It would be better if pharmacists are the ones doing it."* (IPH5)

*"Some (patients) are not that tech-savvy… so it might be difficult for them… and we are not sure if the info (entered by patients) is accurate or not…"* (IPH10)



The function of medication intake logging emerged as a critical requirement in the interviews. Participants stated that the app should allow patients to record their medication intake status (taken or skipped), dose and time taken, as well as add information related to medication intake, such as symptoms and side effects. Many participants suggested a feature that generates data insights and reports from medication intake records, allowing patients to self-track their own medication adherence and pharmacists to monitor adherence and perform necessary interventions.

Most participants, especially pharmacists, supported the idea of adding the function of logging measurements of blood sugar, blood pressure, and body weight,

for the ease of documentation and data sharing. Those measurements are the important self-monitoring parameters in DM management. In addition, participants stated that the app should generate trends and reports based on these measurements to offer patients and pharmacists with valuable insights into the DM control over time.

Electronic messaging was mentioned in the interviews mostly by patient participants as a useful functionality for the app. Participants suggested that the messaging function should facilitate instant communication between patients and pharmacists, as well as among pharmacists, and support various formats of messaging, including images, text, and voice messages. Some pharmacists mentioned the potential utility of the electronic messaging for communication with other pharmacist colleagues regarding patients' treatment regimens. Besides that, many pharmacists requested that the app should be capable of triggering alert messages about patient status, such as abnormal self-monitoring readings, missed medications/ appointments, and poor/declining adherence. These alerts should be sent promptly to pharmacists to allow timely interventions and support for their patients.

Provision of educational resources was perceived by many participants as a crucial component of the app for its potential to empower patients. Pharmacist participants emphasised that the content should be reviewed and managed by pharmacists to ensure quality, with a focus on diabetes and medication information. To facilitate learning and accessibility, participants highlighted that the educational materials should be available in multimedia formats, such as graphics, text, and videos. Some participants suggested including medication information search function that allows patients to find relevant details about their prescribed medications easily. Other than that, some pharmacist participants recommended that the app should deliver motivational messages regularly to encourage and reinforce self-care behaviour in patients. They noted that these messages can help maintain patient engagement and adherence to their treatment regimens.

### iii. Non-functional requirements for the app

Participants' expectations for the non-functional requirements of the mobile app were organised into five subcategories: (1) reliability/availability, (2) privacy, (3) security, (4) usability and (5) compatibility (Table 4.5).

Table 4.5 Non-functional requirements of the mobile app

| Subcategory | Codes |
|---|---|
| Performance | Available for use without lagging or downtime during peak time<br>Able to support increasing number of patient user population |
| Privacy | Customisable user control of access to profile/account<br>Hide sensitive information (e.g. related to disease/treatment) on lockscreen<br>Enable app lock with passcode (need passcode before each access) |
| Security | Private user account management (login with credentials)<br>Secure handling of confidential data |
| Usability | Easy to navigate and use<br>Intuitive app design and navigation<br>Large font size<br>Layman language for patient interfaces |
| Compatibility | Able to download and function on most phone models |



One of the primary requirements expressed by participants was the performance of the mobile app. Pharmacist participants emphasised that the app must be highly available and minimise the occurrence of downtime or lagging, particularly during peak usage times (which is the clinic working hours) to avoid disruption of healthcare service delivery. Likewise, patients also requested for consistent/reliable performance of the app to allow access to all functionalities without interruption. Pharmacists also emphasised that the app should be scalable to accommodate the growing number of patient users, as the DM patient population is expected to increase in the future.

Privacy was perceived by all participants as an essential requirement as the potential app would handle sensitive and confidential information related to patients' health and treatment. Participants wished to be able to customise the control of user access to their profile. Other privacy protection features suggested by participants include the option to hide sensitive information on the phone lockscreen (to prevent unauthorised viewing) and an app lock (which requires passcode input before each

access). Security was also another crucial component of the app in the participants' view. Some participants stated that it was important for the app to have private user account management, which required login with credentials, to ensure that only authorised users can access the app system. A few participants pointed out that secure handling of confidential data is crucial to protect users' health data from potential cyber threats and unauthorised access.

Both patients and pharmacists described similar expectations for the usability aspect of the app. They emphasised that the app should feature an intuitive design and easy navigation to allow users to quickly locate the information or functionality they need. Participants also expected the app to be easy to learn for new users so that they can benefit immediately from its features. Other usability-related requirements suggested by participants included large font sizes and the use of layman language for patient interfaces to make the app more accessible to users with varying levels of health literacy and digital proficiency.

Some participants highlighted that the app must be compatible with most phone models widely available in the current market (such as iPhones and Android smartphones), to allow a more diverse user base to download and use this app. They stated that the app should function smoothly across different operating systems and phone models for better accessibility and usability, in order to support larger population of patients managing T2DM.



### 4.2.4 App analysis results

A search for mobile apps in the app store using specific keywords and inclusion criteria, yielded a total of 15 apps from the Apple App Store and 10 from the Google Play Store for further review. Based on the main functionalities identified from the requirements elicitation process outlined in Table 4.4, only 5 apps from the Apple App Store and 3 from the Google Play Store contained 4 or more of these functionalities (as shown in Table 4.6).

Although all reviewed apps featured reminder and medication intake logging functions, not all included the capability to document the user's medication history. A

deeper analysis of the apps that did include basic medication history functions revealed that not all offered comprehensive documentation of other details, such as drug allergy and ADR history, and records of complementary medicines, supplements, and OTC drugs. The caregiver support feature, which supported multiple user profiles, was found in almost all apps. More than half of the apps enabled users to log self-monitoring measurements. Less than half had features that provide motivation. However, none included functionalities involving HCP engagement (e.g. electronic messaging and remote monitoring capabilities) and patient education.

Table 4.6 Reviewed apps which contained 4 or more of the functionalities identified from requirements elicitation

| AppStore | App name | No. of features | Features* | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Apple App Store | CareClinic Tracker, Reminder | 6 | / | / | / | / | | | | / | / |
| | Pill Reminder, Tracker | 6 | / | / | / | / | | | | / | / |
| | Mr. Pillster: Medication tracker alarm app | 4 | / | | / | / | | | | / | |
| | MediSafe Medication Management | 4 | / | / | / | | | | | / | |
| | Tochi – Health & Pill Reminder | 4 | / | | / | / | | | | | / |
| Google App Store | CareAide – Meds & Pill Reminder | 6 | / | / | / | / | | | | / | / |
| | MediSafe Pill & Med Reminder | 4 | / | / | / | | | | | / | |
| | Pill Reminder & Tablet Tracker | 4 | / | / | / | | | | | / | |

*Features numbered 1 – 9 were as follows: (1) reminders function, (2) medication history documentation, (3) medication intake logging/reporting, (4) measurements logging/reporting, (5) electronic messaging, (6) alert notifications for HCPs, (7) education, (8) caregiver involvement, and (9) motivation



## 4.3 SOFTWARE REQUIREMENTS SPECIFICATION (SRS)

### 4.3.1 Purpose of the SRS

The Software Requirements Specification (SRS) for the DMed app was developed as part of a master's thesis. DMed is a prospective mobile health (mHealth) app designed to assist patients with Type 2 diabetes mellitus (T2DM) and pharmacists in managing diabetes and medications. The document outlines all user requirements from the perspectives of the main users and provides a comprehensive description of the app's

purpose, usage, and development concepts. It was intended to serve as preliminary documentation for end users, and as a guide/basis for the app development and testing teams to better understand the full scope of the app. However, it should be acknowledged that some requirements specified in the document may be subjected to further change during the app development process in future.

### 4.3.2 Scope of the app

The DMed app, herein referred to as "The App", is a potential mobile app used as a part of diabetes care in healthcare facilities to provide support to patients with T2DM and Pharmacists in carrying out medication management tasks. The design of the App aims to improve patients' medication/disease knowledge, treatment adherence, and blood sugar control, and to ensure proper medication use and safety.

### 4.3.3 Product overview

#### a. The overview of mobile app architecture

This App is a self-contained mobile app with three types of users: patient user, pharmacist user and administrator (admin) as shown in Figure 4.2. The patient and pharmacist users interact with the App via smartphones (iPhones or Android smartphones) with internet connectivity. Application Programming Interface (API) acts as an intermediary that allows communication and facilitates data exchange and operations between the smartphones and back-end services. API also interacts with the database and file storage in back-end to retrieve and store data when necessary.

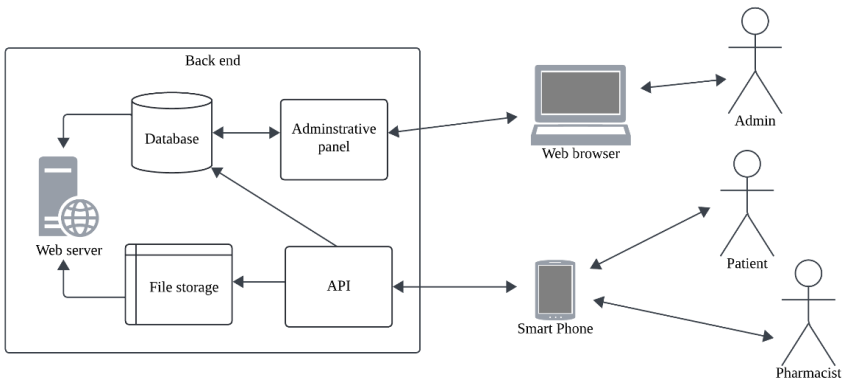


Figure 4.2 Mobile app architecture diagram

The admin interacts with the App through administrative panel (a web-based interface) in web browser over the internet to perform administrative tasks (e.g. user profile management, content updates, and configuration changes). The server hosts the App and handles requests from both the API and the administrative panel. It communicates with the database and file storage to process these requests.

**b. The overview of the app functions**

The App shall provide the following functionality:

1. Allow documentation of a complete medication profile including current medication list, history of drug allergy or adverse drug reactions, and the use of complementary medicine / supplements / over-the-counter (OTC) drugs.
2. Provide reminders to patient for taking medication and attending appointments.
3. Enable logging and monitoring of medication intake and generate reports for medication adherence and medication intake pattern.
4. Enables logging and monitoring of blood sugar, blood pressure and body weight readings.
5. Provide educational resources related to DM self-management and medications for patients.
6. Enable direct and convenient communication between pharmacist and patient (or between pharmacists) with instant messaging.
7. Assist pharmacists in monitoring their patients by delivering important notifications/alerts about patients' condition, e.g. medication-intake behaviour, blood sugar/blood pressure measurement trends, adherence levels etc.
8. Provide motivational messages to patients regularly to encourage them in maintaining good medication adherence and self-care.
9. Support caregivers in managing their dependents' DM condition and medications by providing access to dependents' medication profile and delivering reminder alerts about medications, self-monitoring measurement and scheduled appointments.

**c. The context diagram of the app**

The context diagram for DMed App presented below (Figure 4.3) depicts the interactions and the data flows between the App and the users. The “DMed App” process is at the centre of the diagram and three entities surround the process.

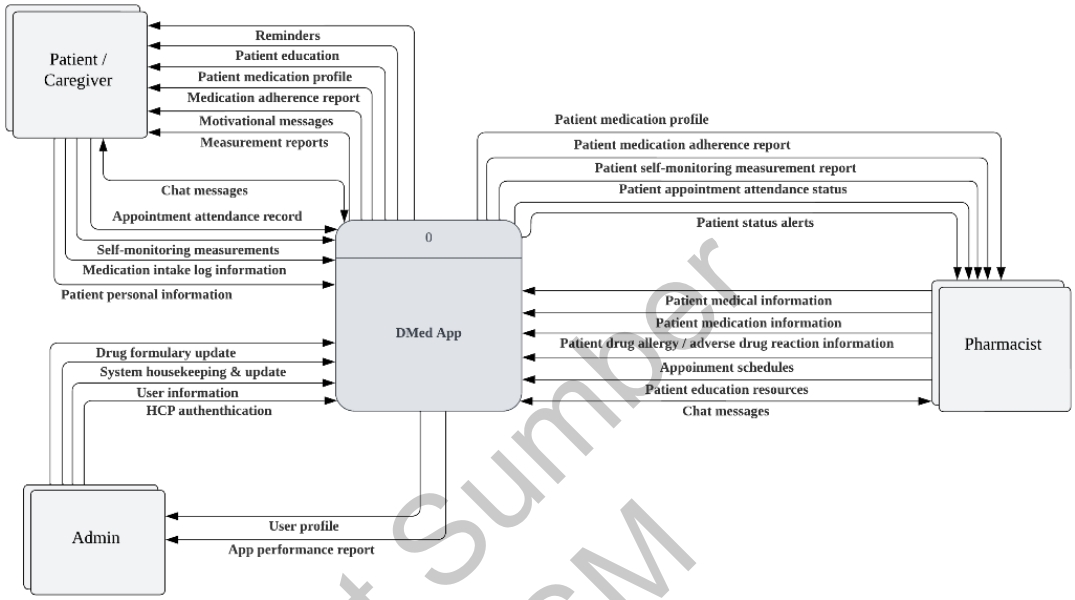


Figure 4.3 Context diagram of DMed app

The entity “Patient/Caregiver” has seven incoming data flows from the app (for “reminders”, “patient education”, “patient medication profile”, “adherence reports”, “motivational messages”, “measurement reports” and “chat messages”) and five outgoing data flows to the app (for “chat messages”, “patient personal information”, “medication intake log information”, “self-monitoring measurements and appointment attendance records”). The entity “Pharmacist” has six incoming data flows from the app (for “patient medication profile”, “patient medication adherence report”, “patient self-monitoring measurements”, “patient appointment attendance status”, “patient status alerts”, “chat messages”) and six outgoing data flows to the app (for “patient medical information”, “patient medication information”, “patient drug allergy/ADR information”, “appointment schedules”, “patient education resources”, “chat messages”). The entity “Admin” has two incoming data flows from the app (for “user profile”, “app performance report”) and four outgoing data flows (for “drug formulary update”, “system update”, “user information”, “HCP authentication”).

**d. The use case diagram and user characteristics of the app**

Use case diagram describes the interaction of the actors with the software/system. Use cases describes the software/system's functional requirements in response to user inputs (Tilley 2019). To generate the use cases, the actors of the app were identified. An actor represents a role played by a person who interacts with the system. Any actor of the app has some access rights on certain functions. Based on the access rights, three types of user classes were generated, namely administrator, pharmacist and patient users. Patient user refers to a person who is diagnosed with DM and registered to receive medical treatment and care under the government healthcare facilities. Pharmacist user is an authorised pharmacist who delivers pharmaceutical services to patients. Admin user is an authorised IT personnel who manages the operation of the entire app system. After identifying the actors, the users were categorised to the expected functions based on the user requirements of the app. The users and use cases are clearly shown in the use-case diagram (Figure 4.4).



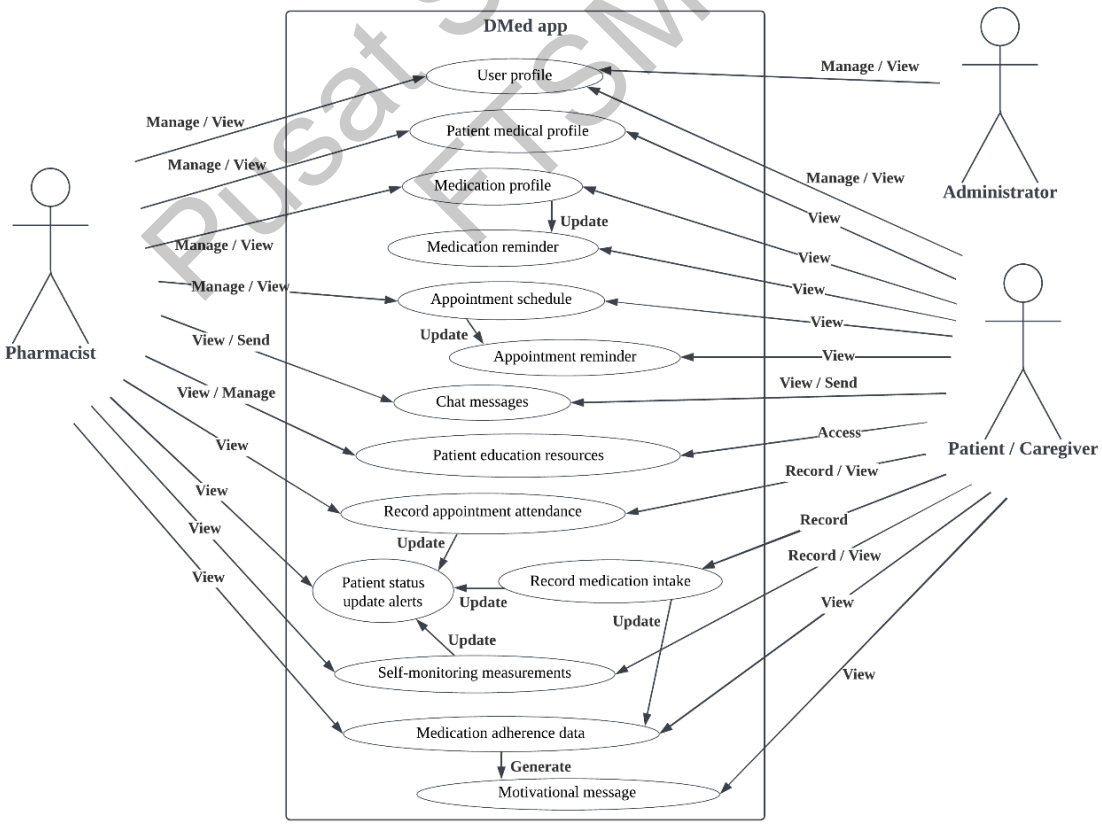


Figure 4.4 Use-case diagram of DMed App

All functions require the users (patients and pharmacists) to log in to the system. Before logging in, the users must create an account in the app. A patient user can usually access the app's main functions such as medical and medication profile, appointment schedule, reminders, chat, patient education module, self-monitoring measurements and medication adherence report. A pharmacist user generally has access to more functions than those available for a patient user. For instance, the pharmacist user can access modules/functions similar to those by patients but with additional controls (i.e. manage/edit functions). They are also able to access and track patient status alerts. An administrator has access rights to perform critical system functions and user profile management, thereby ensuring the app in good maintenance for use by all users.

### 4.3.4 Requirements for the app

#### a. Functions breakdown

#### i. System features, purposes and priorities

Based on the functional requirements analysed and outlined in Phase 1 of research (refer to Table 4.4), a total of 33 functions were expanded from the general user requirements and designed for the app system. Table 4.7 describes the system features with their purposes and priorities (ranging from low to high).



Table 4.7 System features and their purposes and priorities

| No. | System feature | Purpose of feature | Priority |
|---|---|---|---|
| 1 | Register user | Allows user to register new account | High |
| 2 | Authenticate pharmacist user account | Allows admin to authenticate pharmacist user accounts | High |
| 3 | Log in to user account | Allows patient or pharmacist user to log in to account with credentials | High |
| 4 | Maintain patient user profile | Allows patient to view and manage personal details in the profile | High |
| 5 | Maintain pharmacist user profile | Allows pharmacist to view and manage personal details in the profile | High |
| 6 | Maintain patient medical profile | Allows user to view and manage patient medical history | High |

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| | | | |
|---|---|---|---|
| 7 | Caregiver mode | Allows user to take on caregiver role to help manage dependent's disease and medications | Medium |
| 8 | Maintain dependent profile | Allows patient (who has turned on caregiver mode) to view and manage dependent personal details in the profile | Medium |
| 9 | Maintain medication list | Allows user to view and manage the list of medications | High |
| 10 | Maintain drug allergy history | Allows user to view and manage the history of drug allergies | High |
| 11 | Maintain adverse drug reaction report history | Allows user to view and manage the adverse drug reaction report history | High |
| 12 | Maintain complementary medicine, supplement or OTC drug use | Allows user to view and manage the record of complementary medicine, supplement or OTC drug use | Medium |
| 13 | Set up medication-taking reminder | Allows patient to manage settings of reminders for taking medication | High |
| 14 | View or respond to medication-taking reminder | Allows patient to view or respond to medication-taking reminder | High |
| 15 | Record medication intake | Allows patient to record whether the medication is taken or skipped, as well as the dose taken and timing | High |
| 16 | Record event associated with medication intake | Allows patient user to log any event or remark related to the medication intake (symptoms, side effects etc.) | High |
| 17 | Sync medication-taking schedule with phone calendar | Allows patient to sync the medication-taking schedule with phone calendar | Medium |
| 18 | Generate medication adherence data | Allows user to view or export the medication adherence data | High |
| 19 | Receive motivational message based on medication adherence level | Allows patient to receive motivational message based on medication adherence level | Medium |
| 20 | Maintain blood glucose, blood pressure or body weight measurements | Allows patient to view and manage blood glucose, blood pressure or body weight measurements | High |
| 21 | Set up reminder for blood glucose, blood pressure or body weight measurement | Allows patient to manage settings of reminders for blood glucose, blood pressure or body weight measurement | High |
| 22 | Maintain appointment schedule | Allows user to view and manage the appointment schedule | High |
| 23 | Set up appointment schedule reminder | Allows patient to manage settings of reminders for appointment schedules | High |
| 24 | Record appointment attendance | Allows patient to record whether the scheduled appointment is attended, missed or rescheduled | Medium |
| 25 | Sync appointment schedule with phone calendar | Allows patient to sync appointment with phone calendar | Medium |

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|---|---|---|---|
| 26 | Chat | Allows users to communicate by sending and receiving text, images or voice messages | High |
| 27 | Maintain educational resource content | Allows pharmacist to manage educational content | High |
| 28 | Access and read educational resources | Allows patient to access and read the educational resources | High |
| 29 | Receive alert notifications about patient status | Allows pharmacist user to receive alert notifications about patient status | High |
| 30 | Maintain drug formulary | Allows admin to manage and update drug formulary stored in the system | High |
| 31 | Maintain users | Allows admin to manage user profiles | Low |
| 32 | Housekeeping user profiles | Allows admin to perform housekeeping by archiving user profiles which have been inactive for > 3 years | Low |
| 33 | Perform daily system backup | Perform full back-up of the system daily at night | Low |

### ii. Functional requirements

Each system feature listed in the previous section was then dissected into more refined functional requirements. The following table, Table 4.8 presents the functional requirements under each system feature. The functional requirement is identified with a requirement number (Req#) in the form of Req-*n* and Req-*n/n*).



Table 4.8 Functional requirements and their descriptions

| **Req#** | **Functional requirement** | **Description** |
|---|---|---|
| Req-1 | Register user | Allows user to register or create new account |
| Req-2 | Authenticate pharmacist user profile | Allows admin to authenticate pharmacist user accounts |
| Req-3 | Log in to user account | Allows user to log in to account with credentials |
| Req-4 | Maintain patient user profile | Allows patient to view and manage personal details in the profile |
| Req-4/1 | Update patient user profile | Patient shall be able to update personal details in the profile. |
| Req-4/2 | View patient user profile | Patient shall be able to view personal details in the profile. |
| Req-5 | Maintain pharmacist user profile | Allows pharmacist user to view and manage personal details in the profile |
| Req-5/1 | Update pharmacist user profile | Pharmacist shall be able to update personal details in the profile. |

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|---|---|---|
| Req-5/2 | View pharmacist user profile | Pharmacist shall be able to view personal details in the profile. |
| Req-6 | Maintain patient medical profile | Allows user to view and manage patient medical history and profile |
| Req-6/1 | Update patient medical profile | Pharmacist shall be able to update patient medical history and profile. |
| Req-6/2 | View patient medical profile | Patient and pharmacist shall be able to view patient medical history and profile |
| Req-6/3 | Export patient medical profile | Patient and pharmacist shall be able to export patient medical history and profile |
| Req-7 | Caregiver mode | Allows patient to take on caregiver role to help manage dependent's disease/medications |
| Req-7/1 | Enable or disable caregiver mode | Patient shall be able to enable or disable "Caregiver mode" |
| Req-7/2 | Receive alerts or reminders about dependent's medication or appointment | Patient shall be able to receive dependent's medication and appointment reminders and missed medication/appointment alerts. |
| Req-8 | Maintain dependent profile | Allows patient user (who has turned on caregiver mode) to view and manage dependent personal details in the profile |
| Req-8/1 | Create dependent profile | Patient shall be able to create dependent profile (after turning on caregiver mode) |
| Req-8/2 | Edit dependent profile | Patient shall be able to edit dependent profile (after turning on caregiver mode) |
| Req-8/3 | Delete dependent profile | Patient shall be able to delete dependent profile (after turning on caregiver mode) |
| Req-8/4 | View dependent profile | Patient shall be able to view dependent profile (after turning on caregiver mode) |
| Req-9 | Maintain medication list | Allows user to view and manage the list of medications |
| Req-9/1 | Add new medication to the list | Pharmacist shall be able to add new medication to the patient medication list |
| Req-9/2 | Edit medication list | Pharmacist shall be able to edit patient medication list |
| Req-9/3 | Cancel medication on the list | Pharmacist shall be able to cancel medication on the patient medication list |
| Req-9/4 | View medication list | Patient and pharmacist shall be able to view medication list |
| Req-9/5 | Export medication list | Patient and pharmacist shall be able to export the medication list in the pdf file format |
| Req-10 | Maintain drug allergy history | Allows user to view and manage drug allergy histories |
| Req-10/1 | Add new drug allergy | Pharmacist shall be able to add new drug allergy |
| Req-10/2 | Edit drug allergy history | Pharmacist shall be able to edit drug allergy history |
| Req-10/3 | Delete drug allergy | Pharmacist shall be able to delete drug allergy |
| Req-10/4 | View drug allergy history | Patient and pharmacist shall be able to view drug allergy history |
| Req-11 | Maintain ADR report history | Allows user to view and manage the ADR report history |
| Req-11/1 | Add new ADR report | Pharmacist shall be able to add new ADR report |

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|---|---|---|
| Req-11/2 | Edit ADR report history | Pharmacist shall be able to edit ADR report history |
| Req-11/3 | Delete ADR report | Pharmacist shall be able to delete ADR report |
| Req-11/4 | View ADR report history | Patient and pharmacist shall be able to view the ADR report history |
| Req-12 | Maintain complementary medicine, supplement or OTC drug use | Allows user to view/manage record of complementary medicine, supplement, OTC drug use |
| Req-12/1 | Add new complementary medicine, supplement or OTC drug | Pharmacist shall be able to add new complementary medicine, supplement or OTC drug |
| Req-12/2 | Edit complementary medicine, supplement or OTC drug use | Pharmacist shall be able to edit complementary medicine, supplement or OTC drug use |
| Req-12/3 | Delete complementary medicine, supplement or OTC drug | Pharmacist shall be able to delete complementary medicine, supplement or OTC drug use |
| Req-12/4 | View complementary medicine, supplement or OTC drug use | Patient and pharmacist shall be able to view complementary medicine, supplement, OTC drug use |
| Req-13 | Set up medication-taking reminder | Allows patient user to manage settings of reminders for taking medication |
| Req-13/1 | Enable or disable medication-taking reminder | Patient shall be able to enable or disable medication-taking reminder |
| Req-13/2 | Edit medication-taking reminder timing and other settings | Patient shall be able to edit medication-taking reminder timing and other settings |
| Req-14 | View or respond to medication-taking reminder | Allows patient user to view or respond to medication-taking reminder |
| Req-14/1 | View medication-taking reminder | Patient shall be able to view medication-taking reminder |
| Req-14/2 | Snooze/postpone medication-taking reminder | Patient shall be able to postpone medication-taking reminder to a later time |
| Req-15 | Record medication intake | Allows patient user to record medication intake status, dose taken and timing |
| Req-15/1 | Record medication intake status | Patient shall be able to record medication intake status, such as “taken now”, “taken on schedule”, “taken at another time” and “skipped” |
| Req-15/2 | Edit medication intake status, timing or dose taken | Patient shall be able to edit recorded medication intake status, timing or dose taken |
| Req-15/3 | View medication intake record | Patient shall be able to view medication intake record details (status, timing and dose) |
| Req-16 | Record event associated with medication intake | Allows patient to log any event or remark related to medication intake (symptoms, side effects etc.) |
| Req-16/1 | Add event associated with medication intake | Patient shall be able to add event associated with medication intake |
| Req-16/2 | Edit event associated with medication intake | Patient shall be able to edit event associated with medication intake |
| Req-16/3 | Delete event associated with medication intake | Patient shall be able to delete event associated with medication intake |

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|---|---|---|
| Req-16/4 | View recorded event associated with medication intake | Patient shall be able to view recorded event associated with medication intake |
| Req-17 | Sync medication-taking schedule with phone calendar | Allows patient user to sync the medication-taking schedule with phone calendar |
| Req-18 | Generate medication adherence data | Allows user to view or export the medication adherence data |
| Req-18/1 | View medication adherence data | Patient and pharmacist shall be able to view medication adherence data |
| Req-18/2 | Export medication adherence data | Patient and pharmacist shall be able to export medication adherence data |
| Req-19 | Receive motivational message based on adherence level | Allows patient user to receive motivational message based on adherence level |
| Req-20 | Maintain blood glucose, blood pressure or body weight measurements | Allows patient user to view and manage blood glucose, blood pressure or body weight measurements |
| Req-20/1 | Add new blood glucose, blood pressure or body weight measurement | Patient shall be able to add new blood glucose, blood pressure or body weight measurement |
| Req-20/2 | Edit blood glucose, blood pressure or body weight measurement | Patient shall be able to edit blood glucose, blood pressure or body weight measurement |
| Req-20/3 | Delete blood glucose, blood pressure or body weight measurement | Patient shall be able to delete blood glucose, blood pressure or body weight measurement |
| Req-20/4 | View blood glucose, blood pressure or body weight measurements | Patient and pharmacist shall be able to view blood glucose, blood pressure or body weight measurements |
| Req-21 | Set up reminder for blood glucose, blood pressure or body weight measurement | Allows patient user to manage settings of reminders for blood glucose, blood pressure or body weight measurement |
| Req-21/1 | Enable or disable reminder for blood glucose, blood pressure or body weight measurement | Patient shall be able to enable or disable for blood glucose, blood pressure or body weight measurement |
| Req-21/2 | Edit reminder timing and other settings | Patient shall be able to edit medication-taking reminder timing and other settings |
| Req-22 | Maintain appointment schedule | Allows user to view and manage the appointment schedule |
| Req-22/1 | Add new appointment schedule | pharmacist shall be able to add new appointment schedule |
| Req-22/2 | Edit appointment schedule | pharmacist shall be able to edit appointment schedules |
| Req-22/3 | Cancel appointment schedule | pharmacist shall be able to cancel appointment schedules |
| Req-22/4 | View appointment schedules | Patient and pharmacist shall be able to view appointment schedules |
| Req-23 | Set up appointment schedule reminder | Allows patient user to manage settings of reminders for appointment schedules |
| Req-23/1 | Enable or disable reminder for appointment schedules | Patient shall be able to enable or disable reminder for appointment schedules |

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|---|---|---|
| Req-24 | Record appointment attendance | Allows patient user to record appointment attendance |
| Req-24/1 | Add appointment attendance status | Patient shall be able to add appointment attendance status to indicate whether the scheduled appointment is attended, missed or rescheduled |
| Req-24/2 | Edit appointment attendance status | Patient shall be able to edit appointment attendance status |
| Req-25 | Sync appointment schedule with phone calendar | Allows patient user to sync appointment with phone calendar |
| Req-26 | Chat | Allows users to communicate by sending and receiving text, images or voice messages |
| Req-26/1 | Send text, image or voice messages to pharmacists | Patient and pharmacist shall be able to send text, image or voice messages to pharmacist users |
| Req-26/2 | Send text, image or voice messages to patients | pharmacist shall be able to send text, image or voice messages to patients |
| Req-26/3 | Delete text, image or voice messages | Patient and pharmacist shall be able to delete their text, image or voice messages |
| Req-26/4 | Receive and view text, image or voice messages from pharmacists | Patient and pharmacist shall receive and view text, image or voice messages from pharmacists |
| Req-26/5 | Receive and view text, image or voice messages from patients | pharmacist shall be able to receive and view text, image or voice messages from patients |
| Req-27 | Maintain educational resource content | Allows pharmacist user to manage educational content intended for patient users |
| Req-27/1 | Add new educational resource content | pharmacist shall be able to add new educational resource content |
| Req-27/2 | Edit educational resource content | pharmacist shall be able to edit educational resource content |
| Req-27/3 | Delete educational resource content | pharmacist shall be able to delete educational resource content |
| Req-27/4 | View educational resource content | pharmacist shall be able to view educational resource content |
| Req-28 | Access and read educational resources | Allows patient user to access and read the educational resources |
| Req-29 | Receive alert notifications about patient status | Allows pharmacist user to receive alert notifications about patient status |
| Req-29/1 | Receive and view alerts if patient misses medication | pharmacist shall be able to receive and view alerts if patient misses medication |
| Req-29/2 | Receive and view alerts if patient misses appointment | pharmacist shall be able to receive and view alerts if patient misses appointment |
| Req-29/3 | Receive and view alerts if patient adherence falls below threshold | pharmacist shall receive and view alerts if patient adherence level falls below 90% and 80% |

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|---|---|---|
| Req-29/4 | Receive and view alerts if patient's blood glucose or blood pressure reading is abnormal | pharmacist shall be able to receive and view alerts if patient's blood glucose or blood pressure reading is abnormal |
| Req-30 | Maintain drug formulary | Allows admin to manage and update drug formulary stored in the system |
| Req-31 | Maintain users | Allows admin to manage user profiles |
| Req-32 | Housekeeping user profiles | Allows admin to perform housekeeping by archiving user profiles inactive for >3 years |
| Req-33 | Perform daily system backup | Ful back-up of the system daily at night |

**b. Performance requirements**

The App shall be highly available and capable of supporting simultaneous use by pharmacists and patients (with the exact number to be determined in future research) at all times. The App must be lightweight and allow receiving and delivering messages instantly. During peak period (working hours, from 8:00am to 5:30pm), the App shall have a maximum response time of 2 seconds for critical functions as shown in Table 4.4. For other functionalities, any interface between a user and the App shall have a response time of not more than 4 seconds.



Table 4.9 Critical functionalities that require maximum response time of 2 seconds

| **Critical functionalities** |
|---|
| Log in |
| Register user |
| Maintain patient medical profile |
| Maintain medication list |
| Maintain drug allergy history |
| Maintain adverse drug reaction report history |
| Generate medication adherence data |
| Maintain blood glucose, blood pressure or body weight measurements |
| Maintain appointment schedule |
| Receive alert notifications about patient status |

**c. Usability requirements**

1. The App should ensure that the content is clear and readable across various sizes of mobile screens and operating systems (Xcertia 2019). The App's screen designs and elements should follow a standard design format with consistent text hierarchy, font sizes, colours, and positioning of elements and buttons across all screens (Al-Razgan et al. 2014; Nasr et al. 2023; Xcertia 2019).

2. The App should use layman language, ensuring content is free of technical jargon, acronyms, and complex text which are difficult to read and understand for users without clinical knowledge, while maintaining consistent terminology across all screens (Aldekhyyel et al. 2021; Nasr et al. 2023; Xcertia 2019).

3. The App should feature easy and proper navigation with intuitively labelled menu options, minimum actions (number of taps, swipes, and screens) required for navigation, reversible actions to return to previous pages, and a main menu and navigation bar that are easy to navigate (Al-Razgan et al. 2014; Xcertia 2019).

4. The App should provide appropriate feedback on user input or actions, such as giving successful feedback messages upon action completion, and confirmation messages for critical actions like deletions and cancellations. The App should also ensure appropriate timing between actions and outcomes to match users' cognitive processing abilities (being neither too fast nor too slow) (Al-Razgan et al. 2014; Nasr et al. 2023; Xcertia 2019).

5. The App should reduce the user's memory load by prioritising recognition over recall, displaying key information on screen, using intuitive icons or images for buttons, placing items in recognisable or familiar locations, and grouping similar functions together (Al-Razgan et al. 2014; Xcertia 2019).

6. The App should be carefully designed to prevent data entry errors by offering selectable options instead of text entries, showing data entry requirements at input fields (e.g. numbers only), and displaying error messages for unacceptable or incorrect data inputs (Aldekhyyel et al. 2021; Xcertia 2019).

### d. Interface requirements

#### i. User interfaces

The user interfaces define how end users interact with the App. The screens shall work on all smartphones that support this App. The graphics and messages shown in the App shall be easy-to-understand (jargon-free for the patient version) and self-descriptive/self-explanatory. To enhance usability and readability, the font size should be at least 12 points (Aldekhyyel et al. 2021; Al-Razgan et al. 2014; Xcertia 2019). Table 4.10 below lists the user interfaces that users will encounter for main functions.

Table 4.10 User interfaces in DMed app

| No. | User | UI Number / Name | Description |
|---|---|---|---|
| 1 | All | DMA01 / Welcome page | Welcome screen when the app first launch. It contains the app logo and brief description, and buttons for log in or sign-up user account. |
| 2 | All | DMA02 / Log in | Login Screen – requires user to provide a valid email and password to access the app. |
| 3 | All | DMA03 / Sign up | This is the new user account registration screen, where users must select their role (patient/caregiver or pharmacist), provide an email, and set up a password to create a new account. |
| 4 | All | DMA04 / Maintain user profile | User profile management screen – viewing and editing personal details. |
| 5 | All | DMA05 / Chat list screen | General chat message list screen – lists all received and sent chat conversations. |
| 6 | All | DMA06 / Chat messages | Individual chat conversation screen – a) shows received and sent chat messages to individual user; b) contains buttons for sending images, text and voice messages. |
| 7 | Patient | DMPC01 / Home screen | DMed App Home Screen – contains buttons/ shortcuts for a) Medication reminders due today, b) Pending reminders, c) Medication adherence score, d) Chat, e) Patient education |
| 8 | Patient | DMPCMD01 / Medicines module | Medicines Module Screen – containing a) Medication reminders due today, b) Pending reminders, c) Medication adherence score, d) Medication profile, e) History of drug allergy or ADR, f) Complementary medicine, supplement or OTC drug use. |
| 9 | Patient | DMPCMD02 / Today's medication | Today's Medications Screen – a) lists all the medication reminders due today; b) contains buttons to indicate intake status (taken/skipped/postpone), timing and dose. |

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|---|---|---|---|
| 10 | Patient | DMPCMD03 / Pending reminders | Pending Medication Reminders screen – a) lists all the pending medication reminders that have not been marked with intake status, containing buttons to mark intake status (taken/skipped/postpone), timing and dose. b) includes a warning against taking a double dose to catch up on missed doses. |
| 11 | Patient | DMPCMD04 / Medication profile | Medication Profile Screen – a) lists all the medications that patient is currently taking; b) contains buttons for i) exporting the current medication list and ii) view previous medication history. |
| 12 | Patient | DMPCMD05 / Drug allergy & Adverse drug reactions (ADR) | Drug allergy & Adverse drug reactions (ADR) history screen – a) lists all the history of Drug allergy or ADR events experienced by patient; b) contains button to export the list. |
| 13 | Patient | DMPCMD06 / Complementary medicine, supplement or OTC drug use | Complementary medicine, supplement or OTC drug use record screen – a) lists all types of complementary medicine, supplement or OTC drug used by patient; b) contains buttons to export the list. |
| 14 | Patient | DMPCMD07 / Medication adherence score | Medication Adherence Report Screen – a) displays medication adherence scores at a glance for today, this week, this month, this year, and overall; b) provides a breakdown of medication adherence scores for individual medications across different time scales: daily, weekly, monthly, quarterly, and yearly. |
| 15 | Patient | DMPCMD07 / Motivational messages | Motivational Messages Screen – displays words of motivation and encouragement to patients, varying based on their medication adherence levels. |
| 16 | Patient | DMPCMS01 / Measurements | Measurements Screen – a) displays selections of different self-monitoring measurements (blood sugar, blood pressure and body weight); b) contains buttons and fields for recording measurements; c) contains buttons for setting measurement reminders. |
| 17 | Patient | DMPCAS01 / Appointment schedule | Appointment Schedule Screen – a) lists all the upcoming or past appointments; b) contains buttons to turn on/off appointment reminders; c) contains buttons for i) marking past appointment attendance status (Yes/No/ Postponed), ii) syncing appointment schedule with phone calendar. |
| 18 | Patient | DMPCE01 / Educational resources | Educational Resources Screen – (a) displays the available educational resources about DM and medications prepared by pharmacist, (b) include medication information search function |
| 19 | Patient | DMPCST01 / Settings | Settings Screen – contains buttons for personalised settings: a) Caregiver mode; b) Reminder configuration; c) Language; d) Privacy; e) Change password. |
| 20 | Pharmacist | DMPH01 / Home screen | DMed App Home Screen – containing buttons/ shortcuts for a) Today's patient status alerts; c) Pending patient alerts, d) Chat, e) Manage patient education resources. |

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|---|---|---|---|
| 21 | Pharmacist | DMPH02 / Patient status alerts | Patient Status Alerts Screen – displays all the alert notifications about patient statuses that may require attention. |
| 22 | Pharmacist | DMPHP01 / Search patient profile | Search Patient Profile Screen to search for patients by name/IC/MRN. |
| 23 | Pharmacist | DMPHP02 / Patient profile | Patient Profile Screen – a) displays patient personal details and medical history; b) includes buttons for exporting data and editing |
| 24 | Pharmacist | DMPHMD01 / Patient medication profile | Patient Medication Profile Screen – a) lists all the medications that patient is currently taking; b) contains buttons for i) adding, editing or cancelling medication ii) exporting the current medication list iii) viewing previous medication history |
| 25 | Pharmacist | DMPHMD02 / Add new medication | Add New Medication Screen – requests data on: Drug name, dose, administration route, frequency, dosage schedule, start/end date, dose tapering, indication, prescriber name. |
| 26 | Pharmacist | DMPHMD03 / Drug allergy & Adverse drug reactions (ADR) | Drug Allergy & Adverse Drug Reactions (ADR) History Screen – a) list all the history of Drug allergy or ADR events experienced by patient; b) containing button for i) editing data ii) exporting the list. |
| 27 | Pharmacist | DMPHMD04 / Complementary medicine, supplement or OTC drug use | Complementary Medicine, Supplement Or OTC Drug Use Record Screen – a) lists all types of complementary medicine, supplement or OTC drug used by patient; b) contains button for i) editing data ii) exporting the list. |
| 28 | Pharmacist | DMPHMD05 / Patient medication adherence report | Patient Medication Adherence Report Screen – a) displays individual patient medication adherence scores at a glance for today, this week, this month, this year, and overall; b) provides breakdown of adherence scores for each medication across different time scales: daily, weekly, monthly, quarterly, and yearly. |
| 29 | Pharmacist | DMPHMS01 / Measurements | Measurements Screen – displays record history of different self-monitoring measurements (blood sugar, blood pressure and body weight); b) contains button for exporting the data |
| 30 | Pharmacist | DMPHAS01 / Appointment schedule | Appointment Schedule Screen – a) lists all the upcoming or past appointments; b) displays past appointment attendance status (Yes/No/Postponed); c) contains buttons for adding, editing or cancelling appointment |
| 31 | Pharmacist | DMPHMA01 / Medication adherence report | Medication Adherence Report Screen – a) displays individual global medication adherence scores with filter based on date, drug name, drug group or overall; b) generates patient name lists filtered by date, adherence level, drug name, or drug group. |
| 32 | Pharmacist | DMPHE01 / Manage educational resources | Manage Educational Resources Screen – displays buttons to view/manage the educational resources for patients. |
| 33 | Pharmacist | DMPHST01 / Settings | Settings Screen – contains buttons for personalised settings: a) Language; b) Privacy; c) Change password. |

**ii. Hardware interfaces**

Since the App is accessible on smartphones and its full functionality depends on internet connectivity, the hardware requirements include an iPhone running iOS version 12.0 or above, or an Android smartphone running OS version 5.0 or above, with an internet connection via cellular data or Wi-Fi.

**iii. Software interfaces**

The App shall interact with several built-in smartphone software, including the camera, photo library, voice recorder, and calendar apps within the operating system. The camera, photo library, voice recorder apps shall be used in the chat feature for sending images and voice messages, while the calendar app shall be involved in syncing the patient user's medication or appointment schedule.

**iv. Communications interfaces**

The App shall connect to the remote database server for user authentication and data transmission through a secured encrypted connection over internet using HTTPS protocol to prevent data leakages.



**e. Design constraints of the app**

Due to project scope and time constraint, some functionalities are beyond the scope of the current research but could be added in future releases. There are several potential additions to the App:

1. Introducing other roles of different HCPs, such as doctors and nurses to the app.
2. Introducing more gamification (game-based design) aspects in modules related to medication-taking and adherence to increase patient engagement.
3. Working on interoperability or integration with the existing electronic medical record (EMR) systems used at the healthcare facilities.

**f. Software system attributes**

**i. Reliability**

The App system shall be highly reliable and must minimise downtime to prevent disruptions in healthcare service delivery.

**ii. Scalability**

The App shall be capable of processing the existing patient population size served by the healthcare facilities. Since the T2DM patient population is projected to increase further in the future, the App shall be also able to scale up and accommodate the growing patient base.

**iii. Safety**

While there are no specific safety requirements, this app shall be designed in compliance with Malaysia healthcare laws and regulations. Users must be warned that this app is not intended for medical emergencies, definite diagnosis and treatment. In case of a medical emergency, user should contact 999 or seek immediate medical assistance from healthcare facilities.



**iv. Security**

To protect the confidentiality and security of patient personal health data, the following requirements shall be fulfilled:

1. The App shall have a login functionality which requires personal credentials and a secure password before each login to prevent unauthorised access.
2. The authenticity of new pharmacist users must be verified by the admin to prevent false claims and unauthorised use of the App. This can be done by manual authentication of new pharmacist user accounts by the administrator.
3. Health data shall be hosted in secure servers and encryption shall be applied to stored data at rest (being stored) and in transit (being transferred) to ensure secure data storage and transmission.

4. The App shall incorporate an automatic disconnect/logout functionality that logs the user out after a certain period of user inactivity in the App.
5. The App shall include a feature where the login password expires periodically, requiring the user to reset it with a new password.
6. The back-end servers storing the App data shall only be accessible to authenticated/authorised administrators.

**v. Privacy**

The App shall make the end users aware of its privacy policy or information practices before data collection to ensure compliance with the Personal Data Protection (PDPA) Act 2010, General Data Protection Regulation (GDPR), and Malaysian Communications and Multimedia Commission (MCMC) Act 1998 standards.

**vi. Compatibility**

The App shall be compatible with iOS version 12.0 or above as well as Android OS version 5.0 or above.

## 4.4 USER INTERFACE (UI) SCREEN MOCKUPS

This section presents and elucidates the design of the app screen mock-ups of the high-fidelity prototype, illustrating the design and functionality of these interfaces and demonstrating the layout and features that users will encounter.

### 4.4.1 Welcome screen

When the mobile app is first launched, a welcome screen (Figure 4.5a) displaying the app name, logo, headline, and tagline, is loaded for users to select either logging into existing account or creating a new account. Users need to provide a valid email address and password to log in (Figure 4.5b). In case of forgetting password, the app has a password recovery feature that allows users to reset password. For new account registration (Figure 4.5c), users must select their role ("Patient/Caregiver" or "Healthcare Professional"), provide their name and email, and set up a password.



(a) (b) (c)

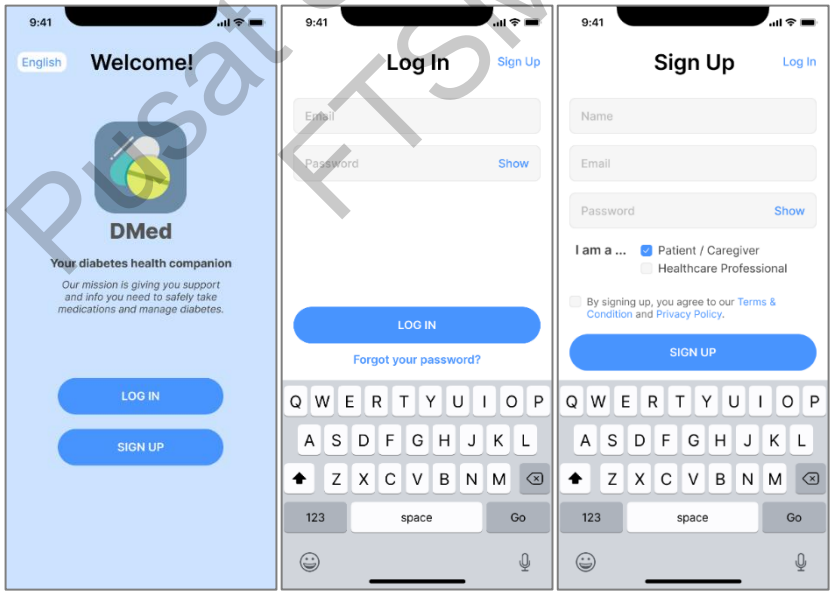


Figure 4.5 Welcome screen design when the App first launches for end users: (a) Welcome page (b) Log in page (c) Sign up page

### 4.4.2 User interfaces for patients

#### a. Home screen

After successfully logging into their personal account, patient users are taken to the app's home screen (Figure 4.6). The home screen shows the patient's name at the top, and features several buttons or shortcuts to important app functions for easy navigation: Today's Medications (reminders for medications to be taken today), Pending Reminders (missed medication reminders), Medication Adherence Score at a Glance, Chat, and Educational Resources. These functionalities will be explained in detail in the following sections.

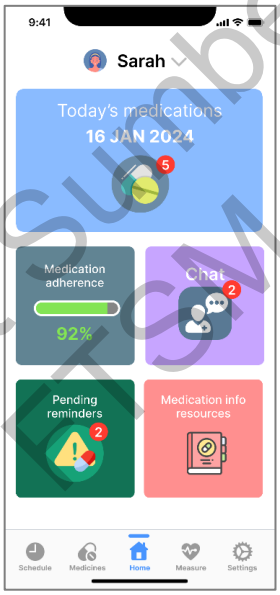


Figure 4.6 Home screen (Patient interface)



#### b. Medicines module

##### i. Main menu

When users tap on the "Medicines" icon on the bottom navigation bar, they are led to the Medicines module main menu as shown in Figure 4.7. The six buttons on the main menu screen will take the users to other features under this module, namely "Today's Medications" (reminders for medications to be taken today), "Pending Reminders" (missed medication reminders), "Medication Adherence Report", "My Medication

Profile", "Drug Allergy/Adverse Drug Reactions", and "Complementary Medicine, Supplements, OTC Drug Use".

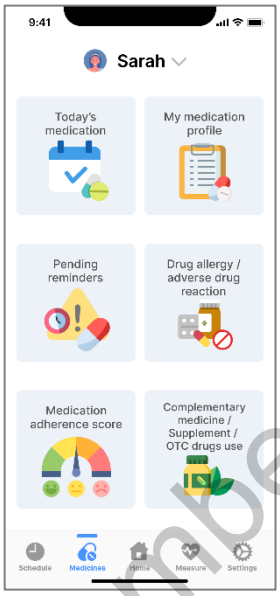


Figure 4.7 Medicines module main menu



**ii. Medication reminders and intake logging**

Users receive medication reminders when it is time to take their medication. The "Today's Medications" screen (Figure 4.8a) displays reminders for the current day's medications to be taken by the user. Users can indicate whether they have taken their medication by either marking it as "Taken now", "Taken on schedule" or "Taken at another time" and specifying when it was taken earlier (Figure 4.8 b & c). If users wish to postpone intake, they can select "Postpone" and set the postpone period, so the same reminder will appear and notify them again later (Figure 4.8 e & f).




Figure 4.8 Medicine intake logging function: (a) Today's medications main screen, (b) Options after choosing "Taken" button, (c) Option to record specific intake time after choosing "Taken at another time", (d) Medication intake status change after confirmation (circled) (e) Time options available after choosing "Postpone" button, (f) Reminder timing change after postponing (circled)

Under "Settings" > "Reminder Configuration" and "Medication Reminder Setup", users can personalise the app's reminder settings by turning reminders on or off, and customising the reminder timings to fit their normal daily routines (Figure 4.9). For instance, medication reminders can be set in accordance with mealtimes, waking up, bedtime, or any specific time of day (Figure 4.9c). The app also allows

users to organise different alarm schedules for workdays and holidays. Once set, the alarms can generate reminders even without an internet connection.

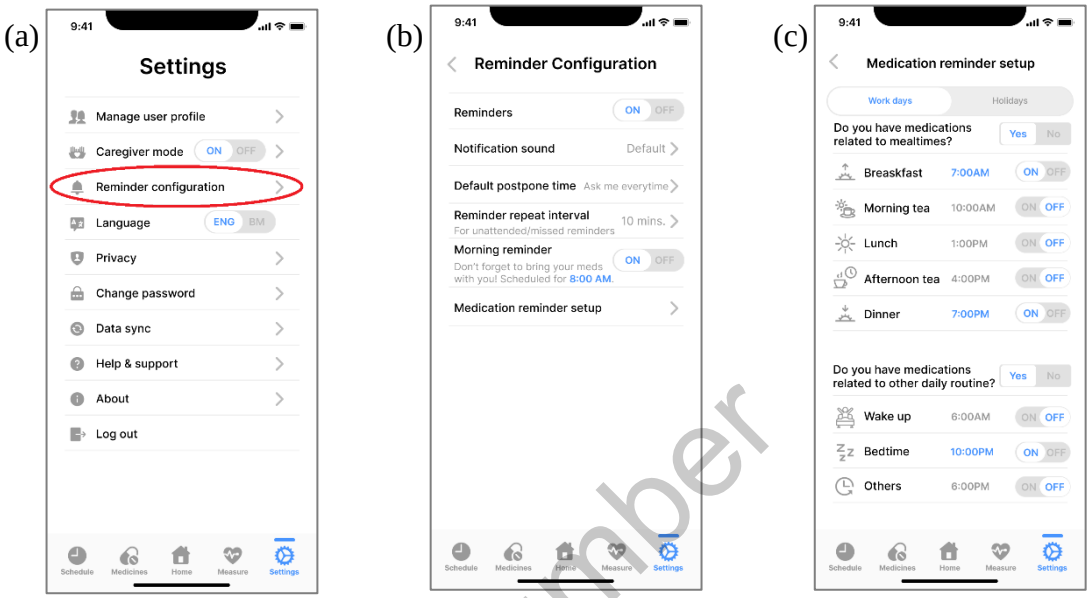


Figure 4.9 Personalised medication reminder settings: (a) Reminder Configuration on Settings main menu, (b) General reminder configuration, (c) Medication reminder timing setup



Other reminder settings that allow for personalisation (Figure 4.9b) include setting a default postpone time for medication intake (so users do not have to select a postpone time each time they delay a reminder), configuring reminder repeat intervals (for unattended or missed reminders to reappear), and setting a morning reminder to ensure users remember to bring their medications before leaving home.

Medication reminders that have been missed and not yet confirmed by the user are displayed under “Pending Reminders” (Figure 4.10). This feature serves as a checklist, allowing users to verify at the end of the day whether they have taken their medication. This is particularly useful for times when users do not have their smartphone handy or are too busy/occupied to confirm the intake status. A cautionary message in a red banner is displayed at the top of the screen, warning patients not to take a missed dose if it’s too close to the next dose, and not to take a double dose to make up for the missed dose. This is very crucial because taking a double dose can cause harm or adverse effects.

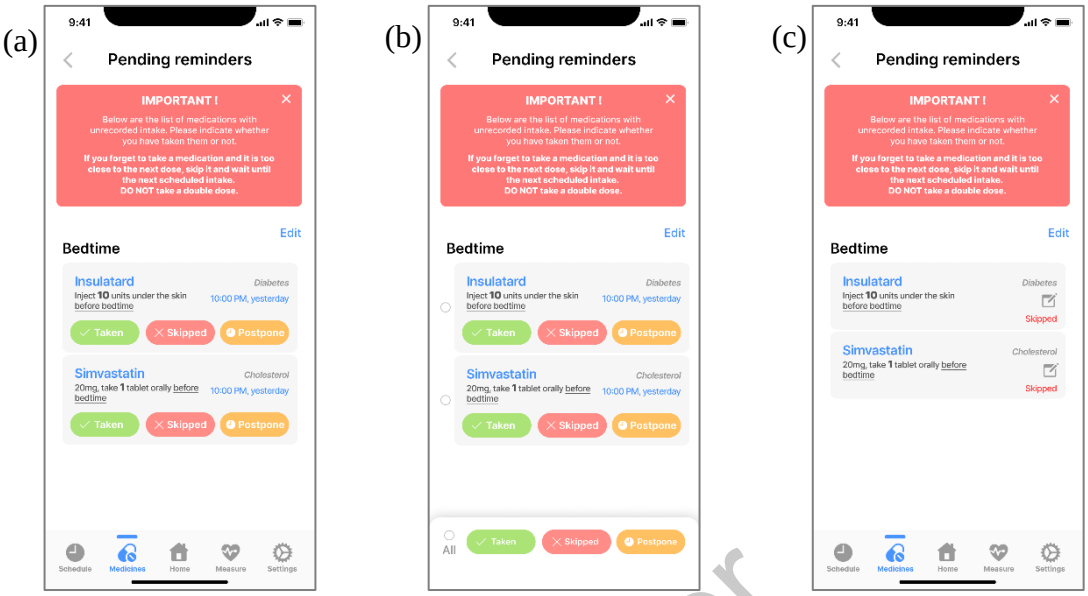


Figure 4.10 Pending reminders: (a) Main screen, (b) Option to select and mark all missed reminders with the same status (Taken/Skipped/Postpone), (c) Medication intake status change to "Skipped" after confirmation

### iii. Medication adherence reporting

The medication intake log data recorded by users are calculated by the app to generate medication adherence scores (Figure 4.11a). This allows patients to easily track their adherence over time. For example, the upper part of the screen displays the total medication adherence score for all medications the user is taking for the previous day, week, month, and year. The lower part shows a breakdown of adherence for each medication over the past day, week, month, quarter, and year.

To make the adherence score even more engaging and motivating, it is presented in the form of a health bar similar to those in video games, which refills and changes colour based on different adherence levels: green for good adherence (> 90%), orange for moderate adherence (80 – 89%), and red for poor adherence (< 80%). This health bar is placed on the home screen prominently for easy visibility (Figure 4.11b). Users also receive motivational messages tailored to their adherence levels (Figure 4.11c). These features are designed to emphasise the importance of medication adherence and encourage users to stay committed to their treatment regimen.

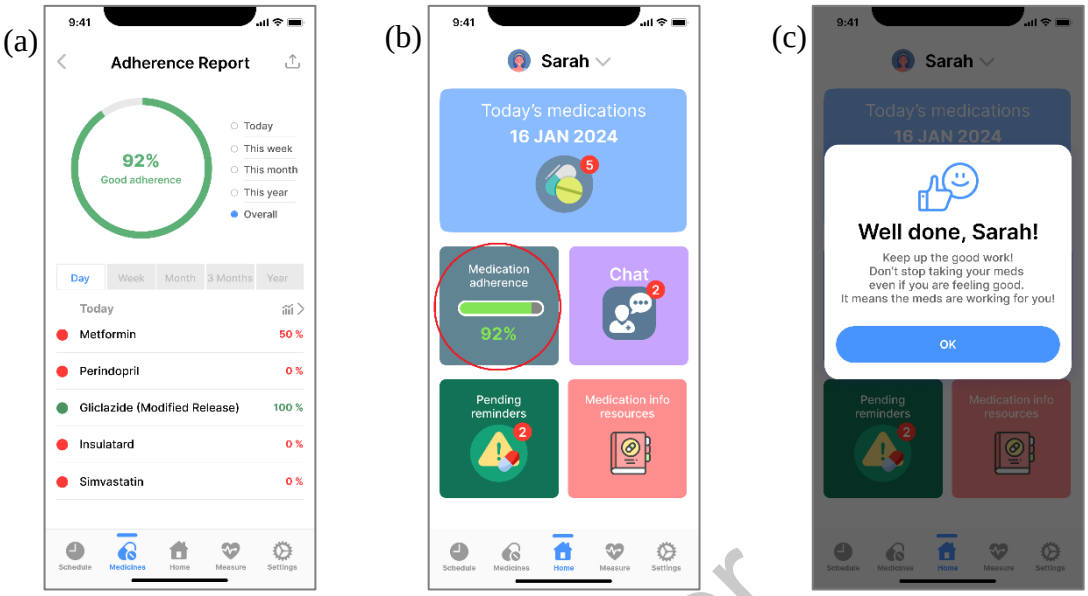


Figure 4.11 Medication adherence reporting feature: (a) Main screen, (b) Medication adherence score in the form of game-like health bar shown on the home screen (circled), (c) Personalised motivational messages based on adherence levels



### iv. Complete medication profile

The "My Medication Profile" feature under the "Medicines" module in the app maintains a complete list of the user's current medications as well as their medication history (Figure 4.12a). Only pharmacist users are authorised to input and update the medication profile (which will be discussed further under section 4.4.3b User interfaces for healthcare professionals), preventing errors that could occur if patient users were to make these changes. The app also allows for the documentation of drug allergies and ADRs (Figure 4.12b), recording the details of the drugs and reactions. In addition, the app can record the use of complementary medicines, supplements, or OTC drugs (Figure 4.12c), helping pharmacists identify potential interactions between these and prescription medications. Users can easily share all this information with their healthcare providers by tapping the "Export" icon button at the top right corner of the screen. These features, which enable comprehensive documentation of patient medication profiles and histories, help improve patient safety and reduce the risk of preventable harm from medication errors and adverse effects.

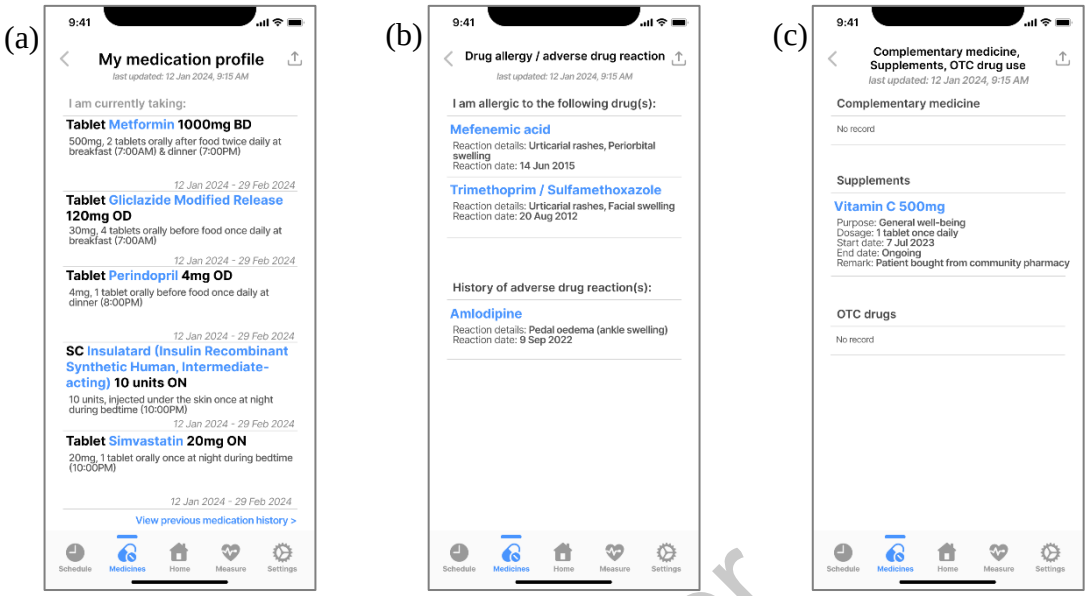


Figure 4.12 Features that enable full documentation of patient medication profile: (a) My medication profile, (b) Drug allergy/adverse drug reactions, (c) Complementary medicine, supplements, OTC drug use

### c. Measurements module

When users tap the "Measurements" icon on the bottom navigation bar, they are taken to the Measurements module main menu (Figure 4.13a), which offers three self-monitoring options: blood sugar, blood pressure, and body weight.

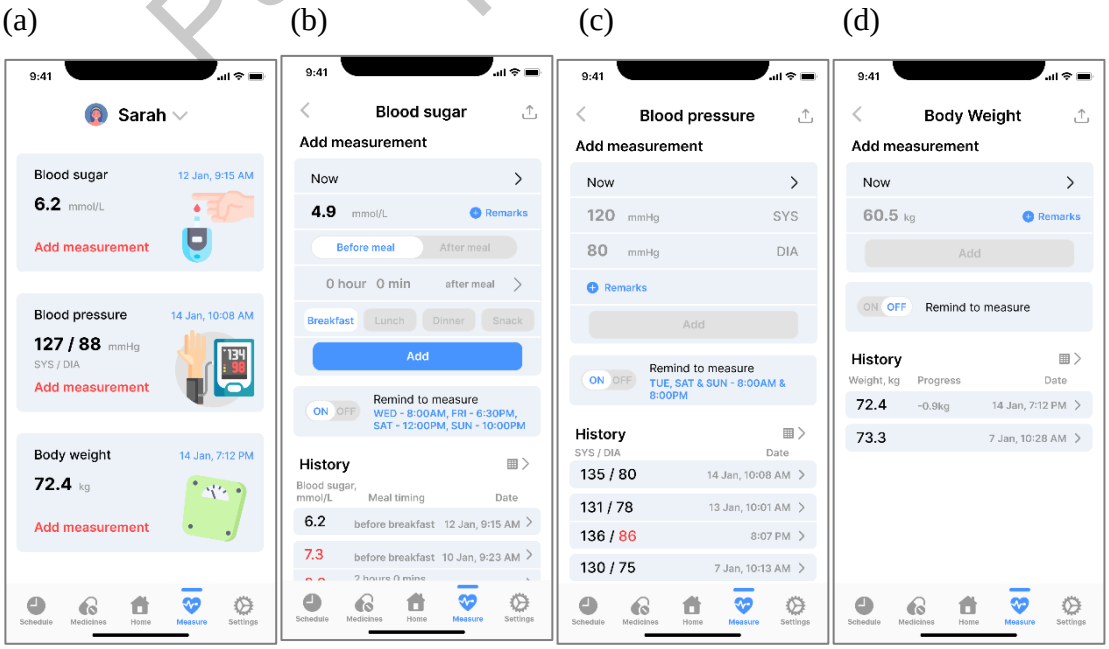


Figure 4.13 Self-monitoring measurements module: (a) Main menu, (b) Blood sugar measurements, (c) Blood pressure measurements, (d) Body weight measurements

Users can record their self-measured readings by entering the values and other relevant details (such as measurement timing, before/after meal status, remarks, etc.) into the fields under the "Add Measurement" header (Figure 4.13 b, c, & d). All past measurement records can be retrieved from the "History" section and viewed in a tabulated form for easier reference. Abnormal readings that fall outside the normal range are flagged in red for easy identification. Customised reminders can be set to prompt users to take measurements at specific times and days (e.g. every Wednesday and Saturday at 8:00 am).

**d. Chat messaging**

The “Chat” icon on the Home Screen (Figure 4.6) directs users to the main chat screen (Figure 4.14a), displaying a list of conversations with pharmacists. Patient users can communicate with their pharmacists by sending and receiving instant text messages, voice messages, and images (Figure 4.14b). This chat feature serves as a useful communication tool, enabling patients and pharmacists to contact each other directly and conveniently regarding any issues related to their condition and treatment regimens.



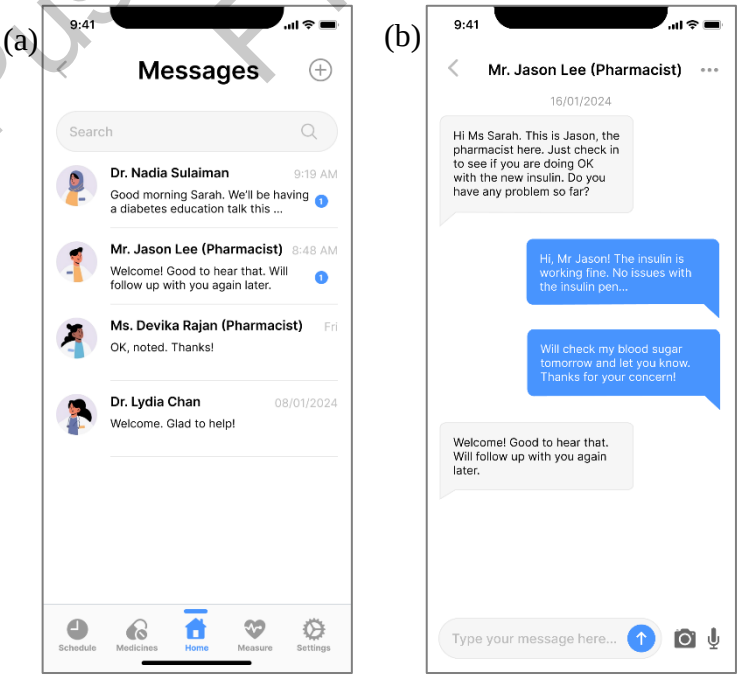


Figure 4.14 Patient chat screens: (a) Chat list view (b) Conversation screen