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## **STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN**

### **OFFICIAL TITLE**

A Randomised Controlled Trial to Compare MedBook Portal and Standard Care in Medication Reconciliation at Transitions of Care from Hospital Discharge to Primary Healthcare Settings

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## **LIST OF ABBREVIATIONS**

BD	Twice Daily
HC	Health Clinic
MR	Modified Release
PRN	When necessary
OD	Once Daily
TDS	Three times a day

## **CHAPTER 1**

### **INTRODUCTION**

#### **1.1 Study Background**

The complex processes and human interactions involved in transitions of care between different healthcare settings harbour a great risk of medication errors, particularly among patients with multiple comorbidities and complex medication regimens. Medication reconciliation is thus one of the key strategies to improve medication safety across transitions of care. It is the formal process of creating the accurate and complete list of medications through the partnership between healthcare providers and patients at all interfaces of cares to reduce potential medication errors and patient harm (1).

The four steps involved in medication reconciliation are: (1) verification: obtain the current medication list; (2) clarification: check the medication dosages; (3) reconciliation: compare and document newly prescribed and previous medications and (4) transmission: communicate the updated and verified medication list to the next healthcare provider (1). These processes involve multiple stakeholders (doctors, nurses, pharmacists, and patients) and all parties are interdependent and accounted to improve transitional care medication safety.

#### **1.2 Problem Statement**

Numerous studies showed that medication discrepancies and errors are prevalent during admission and discharge (2, 3). Reconciliation of patient's past medications upon admission has been an established routine for more than a decade among clinical pharmacists, especially in the general medical wards at tertiary healthcare institutions in Malaysia. Nonetheless, medication reconciliation upon and after hospital discharge has not been implemented in a



structured process, potentially putting patients at risk of medication errors during transitions of care from hospital to the primary healthcare setting.

Very often, local healthcare providers find it difficult to retrieve previous medical records as the healthcare information system has not been integrated across the healthcare facilities in Malaysia. This problem gets worse when patients do not compile and keep their discharge summary properly when they are discharged and followed up at the primary health clinics. Tracing the record is either involving a lengthy process or to no avail due to vague information provided by the patient or caregiver. The referred facility could have continued with the previous medications without knowing the patient's latest disease state. Thus, scattered sources of medication information among different levels of care and lack of integrated computerised healthcare information system pose a great challenge to ensure medication safety. Besides the above barriers, some other potential predictive factors associated with medication errors were patient characteristics, clinical conditions, number of medications, specific pharmacological agents, length of hospital stay and inexperienced prescribers (4).

To the best of our knowledge, there has been no study conducted in Malaysia, that aims to reduce the medication errors when patients were discharged from a tertiary or secondary hospital to primary health clinic. Past studies conducted in western countries provided limited generalizable evidence on the efficacy of their interventions in dealing with the problem in local context due to different healthcare delivery system and practices (5, 6). In addition, relevant studies conducted in Malaysia merely explore the prevalence and factors contributing to the problem and the perception of stakeholders on the feasibility of implementing medication reconciliation program upon hospital discharge (7, 8). Hence, this warrants the development of an effective measure to overcome the problem. Apart from exploring the prevalence and predictors of medication discrepancies upon discharge, an innovative intervention that aims to

reduce the medication discrepancies upon transition of care will also be introduced and implemented at the major divisions in Sarawak as our first move.

### **1.3 Research Question**

The research question of the current study is “is MedBook Portal effective in reducing medication discrepancies upon transition of care from hospitals to primary health clinics?”.

### **1.4 Objectives**

In general, this study aims to assess the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics, comparing MedBook Portal to standard care.

In specific, this study aimed:

- i. To assess the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics, comparing MedBook Portal to standard care.
- ii. To determine the prevalence of the type of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics.
- iii. To determine the prevalence of the type of medication discrepancies in discharge prescription.
- iv. To identify the predictors associated with medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics.
- v. To identify the predictors associated with medication discrepancies in discharge prescription.

## **1.5 Study Hypotheses**

The study hypotheses are formulated based on the study specific objectives. For the first specific objective, the hypothesis is about the impact of MedBook Portal on the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics.

In terms of the second and third objectives, the hypotheses are based on the previous study conducted the hypotheses are based on the previous study conducted by Law and Chong (2017) in Malaysia. This study reported 49% of the discharge prescription were found to have a least one medication discrepancies (8).

For the fourth and fifth specific objectives, there are five variables are included as the secondary outcome of the study, namely age of patient, number of comorbidities, number of medications, type of medication (ATC categorization), and experience of prescriber (category of prescriber). All the five secondary outcomes are hypothesized to be the predictors of medication discrepancies. The hypotheses are tabulated in Table 1.1.

Table 1.1: Study Hypotheses

Specific objective 1: To assess the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics, comparing MedBook Portal to standard care.	
H1a	There will be a significant difference of medication discrepancies rates between the intervention group and the control group after the intervention. The estimated difference of the medication discrepancies rates is 15%, with intervention group having lower medication discrepancies rates than control group.
Specific objective 2: To determine the prevalence of the type of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics.	
H2a	The prevalence of each type of medication discrepancy ranges from 5 – 60%, with Drug omission as the most common medication discrepancy in the first prescription upon transition of care from hospitals to primary health clinics.
Specific objective 3: To determine the prevalence of the type of medication discrepancies in discharge prescription.	
H3a	The prevalence of each type of medication discrepancy ranges from 5 – 60%, with Drug omission as the most common medication discrepancy in discharge prescription.
Specific objective 4: To identify the predictors associated with medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics.	
H4a	There is a significant association between age of patient, number of comorbidities, number of medications, type of medication (ATC categorization), experienced of prescriber (category of prescriber) and medication discrepancy in the first prescription upon transition of care from hospitals to primary health clinics.

continued

Specific objective 5: To identify the predictors associated with medication discrepancies in discharge prescriptions.	
H5a	There is a significant association between age of patient, number of comorbidities, number of medications, type of medication (ATC categorization), experience of prescriber (category of prescriber) and medication discrepancy in discharge prescription.

## 1.6 Conceptual Framework

The conceptual framework of the study is based on the rationale and design of the “Multicenter Medication Reconciliation Quality Improvement Study” (MARQUIS) (9). Bidirectional medication information transfer across settings via electronic health records shall ease the medication reconciliation process. Subsequently, a reduction in medication discrepancy will be the outcome of the study. In addition, predictors correlated with medication discrepancies might impact the prevalence of medication discrepancies. Figure 1.1 depicts the conceptual framework of the study.

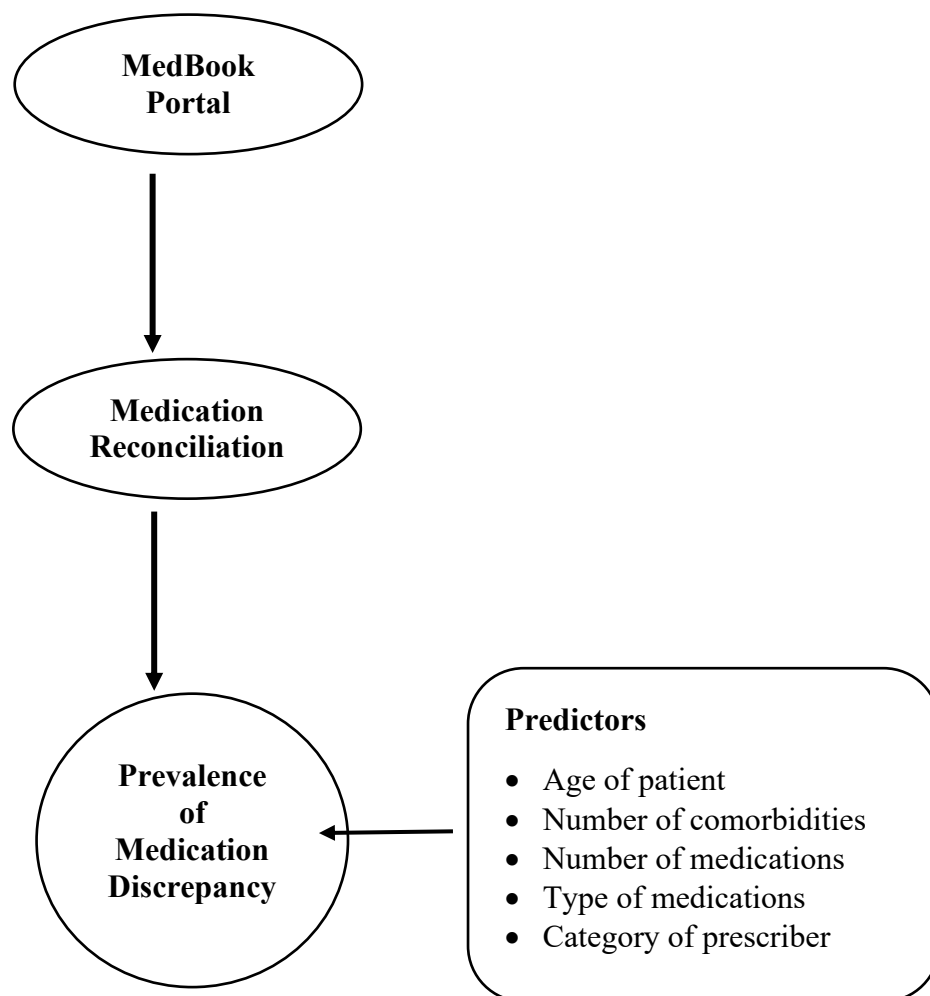


Figure 1.1: Conceptual Framework

## **1.7 Significance of Research**

Proper documentation in hospital discharge summary is essential to ensure continuity of care as patient is involved in multiple care transitions. At hospital discharge, reconciliation is done by checking pre-admission medication list and inpatient medication chart prior to the finalisation of the discharge medication list. Pharmacists serve as the last row of defence to ensure the accuracy of the prescribed medications, couple with discharge counselling to enhance medication understanding and adherence.

In Sarawak, every patient who undergoes medical follow-up at a primary public healthcare setting possesses a personal medical record which will be presented to the doctor during health clinic follow-up and upon hospital admission. Nonetheless, the information upon hospital discharge and clinic follow-up at the secondary or tertiary healthcare setting are not incorporated in the same personal medical record. The discharge summary is provided in separate copies, and the record of clinic follow-up at secondary or tertiary healthcare settings is kept at the clinic. Due to the scattered information, the redundancy of medications with the same or different dosing regimens from various clinics follows up across primary to tertiary healthcare settings is a common issue. Subsequently, this has created confusion and dilemma for the patients as to which regimen to follow, deprived their rights to a holistic treatment approach and jeopardized their health condition.

Recognising the missing part in the healthcare system, enhanced focus on medication reconciliation upon and after hospital discharge could bridge the gap to promote medication and patient safety. By implementing the medication reconciliation upon hospital discharge by pharmacists based in the wards, coupling with patient education and discharge medication plan communication, and followed with the introduction of a medication portal to the prescriber upon discharge which eventually serve as a compilation of personal medication records.

Subsequently, during clinic follow-up, medication reconciliation and updating of the patient medication list in the medication portal will be carried out by the pharmacist in the primary healthcare setting.

In a nutshell, this study may greatly benefit the patients through anticipated medication discrepancies reduction via an innovative intervention. Besides, this intervention is also deemed easy to implement, thus enhancing the duplications and generalizability of the intervention to the healthcare facilities in Malaysia.

## **1.8 Chapter Summary**

Medication reconciliation is one of the key strategies to improve medication safety across transitions of care. Local healthcare providers find it difficult to retrieve previous medical records as the healthcare information system has not been integrated across the healthcare facilities in Malaysia. Thus, an electronic health record that aims to reduce medication discrepancies upon transition of care will be introduced. The study's findings are essential to healthcare professionals in implementing electronic health records. Due to the limited resources at healthcare facilities, healthcare professionals shall prioritise the patients that need medication reconciliation.



## **CHAPTER 2**

### **METHODOLOGY**

#### **2.1 Study Design**

Given the nature of the research question, a randomised controlled trial is developed to compare the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics between MedBook Portal and standard care. This study is a prospective and multicentre randomised controlled trial with a 1:1 allocation ratio to two groups, namely the intervention group and the control group. MedBook portal is a webpage that enables sharing of patient medication profile among healthcare facilities under the Ministry of Health.

#### **2.2 Operational Definition of Terms**

##### **2.2.1 Medication Discrepancies**

Medication discrepancy is defined as any variation or difference in medication regimen identified when comparing an old medication list and the newly prescribed medications.

##### **2.2.2 Intentional Medication Discrepancy**

Intentional medication discrepancy is defined as a justified discrepancy by a change in the patient's clinical condition.

##### **2.2.3 Unintentional Medication Discrepancy**

Unintentional medication discrepancy is defined as unjustified discrepancy after checking with prescriber. It is a medication error, specifically prescribing error.

#### **2.2.4 Types of Medication Discrepancies**

Medication discrepancy is classified into:

- i. Discrepant dose
- ii. Discrepant frequency
- iii. Polypharmacy
- iv. Drug Omission
- v. Drug Addition
- vi. Inappropriate drug

Table 2.1 lists the description and example of each type of medication discrepancy identified during medication reconciliation at hospital discharge. Table 2.2 lists the description and example of each type of medication discrepancy identified during medication reconciliation at the first follow-up at health clinics after discharge from the hospital. Figure 2.1 illustrates the example of medication discrepancies detected during medication reconciliation at hospital discharge and the first follow up at the health clinic.

**Table 2.1:** Description And Example Of Each Type Of Medication Discrepancy Identified During Medication Reconciliation At Hospital Discharge

Type of Medication Discrepancy	Description	Example
Discrepant dose	A different dosage of a medication is prescribed in the discharge prescription compared to the old medication list in the medication history assessment form and inpatient medication charts.	A patient was treated with Atorvastatin 20mg before admission and during admission; however, the patient was discharged with Atorvastatin 40mg.
Discrepant frequency	A different frequency of medication prescribed in the discharge prescription compared to the old medication list in the medication history assessment form and inpatient medication chart.	A patient was treated with Metoprolol 50mg OD before admission. In the ward, the patient has been given Metoprolol 50mg BD and has been discharged with Metoprolol 50mg BD.
Polypharmacy	Multiple agents from the same therapeutic class.	Metoprolol is listed in the medication history assessment form. In the ward, Metoprolol is stopped, and the patient is started with Bisoprolol. During discharge, metoprolol is restarted and given together with Bisoprolol.

Table 2.1 continued

Drug Omission	Medication is not prescribed in the discharge prescription but is listed in the medication history assessment form and inpatient medication chart.	Metoprolol is listed in the medication history assessment form. However, Metoprolol is stopped in the ward and the patient is discharged without Metoprolol.
Drug Addition	Medication is prescribed in the discharge prescription but not listed in the medication history assessment form and inpatient medication chart.	A patient has been discharged with Gliclazide MR. However, Gliclazide MR is not listed in the medication history assessment form or inpatient medication chart.
Inappropriate Drug	Any medication discrepancies that do not fit into any of the previously mentioned categories, such as a medication that no longer needed but is reordered in new prescription; a different formulation of the same item is prescribed.	<p>Example 1:</p> <p>A patient had diarrhoea in the ward and was given oral Loperamide 2mg TDS or PRN. However, Loperamide 2mg TDS was written on the discharge prescription when the patient no longer had diarrhoea.</p> <p>Example 2:</p> <p>A patient has been discharged with Chloramphenicol ear drops. However, the patient has an eye infection and was treated with Chloramphenicol eye drops in the ward.</p>

**Table 2.2:** Description And Example Of Each Type Of Medication Discrepancy Identified During Medication Reconciliation At The First Follow-Up At Health Clinics After Discharge From The Hospital

Type of Medication Discrepancy	Description	Example
Discrepant dose	A different dosage of a medication is prescribed in the new prescription compared to the discharge prescription.	A patient has been discharged with Losartan 100mg. However, the new prescription on the first visit to the health clinic is Losartan 50mg.
Discrepant frequency	A different frequency of medication prescribed in the new prescription compared to the discharge prescription.	A patient has been discharged with Frusemide 40mg BD. However, only Frusemide 40mg OD is prescribed in the new prescription on the first visit to the health clinic.
Polypharmacy	Multiple agents from the same therapeutic class.	Mefenamic acid and Diclofenac are prescribed concurrently.
Drug Omission	Medication is not prescribed in the new prescription but is listed in the discharge prescription.	A patient was discharged with Metoprolol, Losartan, and Metformin. However, only Metoprolol and Metformin are prescribed in the new prescription on the first visit to the health clinic.

Table 2.2 continued

Drug Addition	Medication is prescribed in the new prescription but not listed in the discharge prescription.	On the first visit to the health clinic, the patient is prescribed with Metoprolol, Losartan and Metformin. However, only Metoprolol and Metformin are listed in the discharge medication list.
Inappropriate Drug	Any medication discrepancies that do not fit into any of the previously mentioned categories, such as a medication that no longer needed but is reordered in new prescription; a different formulation of the same item is prescribed.	<p>Example 1:</p> <p>A patient has been discharged with Budesonide inhaler. However, the patient was prescribed with Budesonide nasal spray.</p> <p>Example 2:</p> <p>A patient has been discharged with Gliclazide 120mg MR OD. However, the patient was prescribed with Gliclazide 120mg OD in the new prescription on the first visit to health clinic.</p>

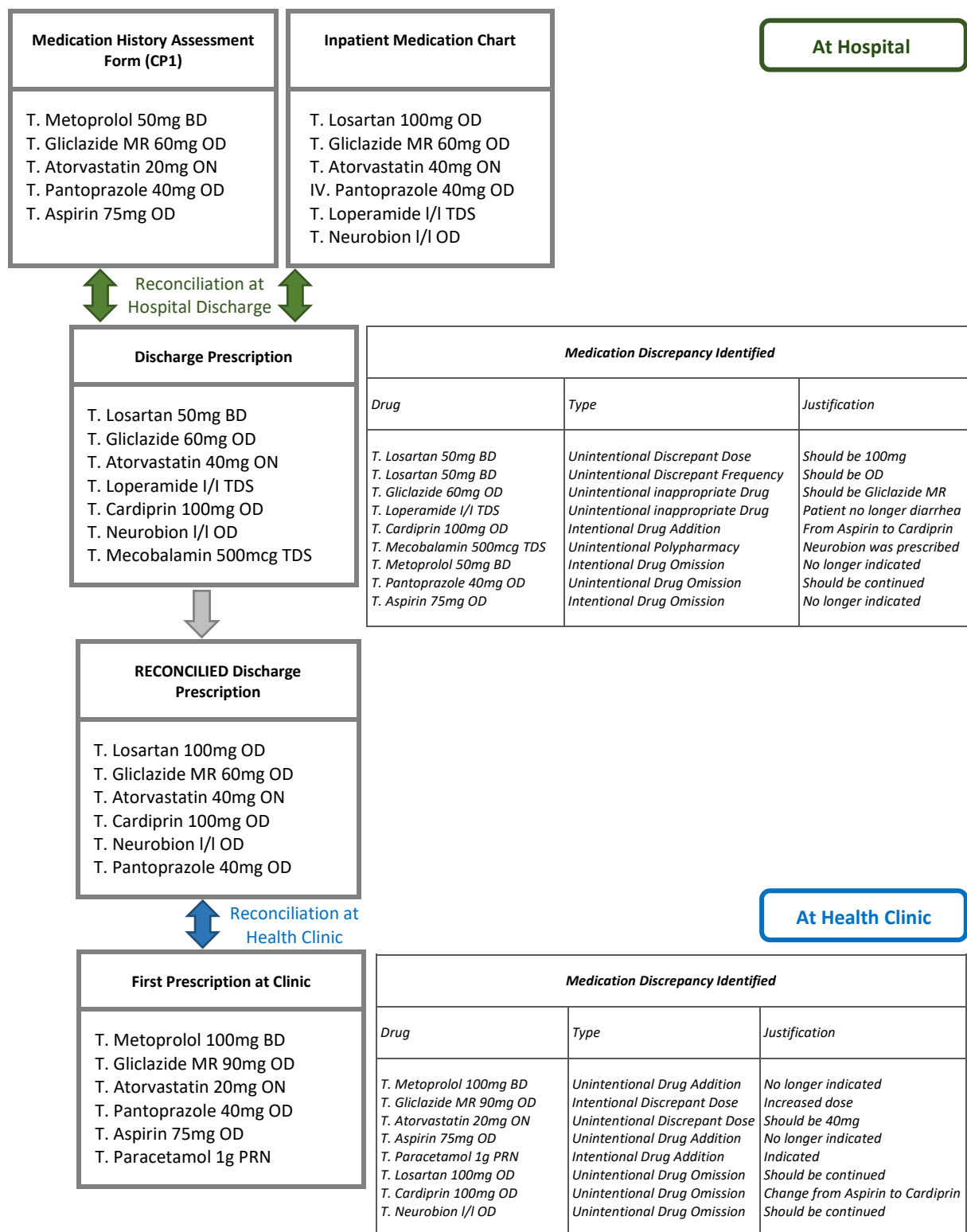


Figure 2.1: Example of medication discrepancies detected during medication reconciliation

### 2.3 Study Population

The targeted population is the adult patients in Sarawak who are discharged from the public tertiary hospitals and referred to the public primary health clinics. These patients will continue to be treated at the selected public primary health clinics.

### 2.4 Study Sample and Locations

This study will be conducted in four public tertiary hospitals and ten public primary health clinics. The four public hospitals that cater for the patients from southern, central, and northern zones in Sarawak are selected. Those are Sarawak General Hospital (southern zone), Sibu Hospital, Sarikei Hospital (middle zone) and Miri Hospital (northern zone).

During this study, ten public primary health clinics which are located nearby to the four selected hospitals are chosen to follow up the participants who will be discharged and referred to these clinics. The healthcare facilities involved in this study are presented in Table 2.3. All patients who fulfil the selection criteria mentioned later will be invited to participate in the study.

**Table 2.3:** Public Major Hospitals and Health Clinics Involved in this Study

Public Major Hospitals	Public Primary Health Clinics
Sarawak General Hospital	Batu Kawa HC, Kota Sentosa HC, Kota Samarahan HC
Sibu Hospital	Jalan Oya HC, Lanang HC, Sibu Jaya HC
Miri Hospital	Miri HC, Tudan HC
Sarikei Hospital	Sarikei HC, Bintangor HC



### **2.4.1 Inclusion criteria**

Patients who fulfil the following criteria will be invited to participate in the study:

- i. Adult patients aged 18 years and above in general medical wards who had any of the following comorbidities: (1) cardiovascular related diseases, e.g.: hypertension, acute coronary syndrome, heart failure, stroke, atrial fibrillation; (2) endocrine related diseases, e.g.: diabetes, thyroid disorders; (3) renal related diseases, e.g.: chronic kidney disease, end stage renal failure; (4) respiratory related diseases, e.g.: asthma, chronic obstructive pulmonary disease.
- ii. Patients who are referred to the selected primary health clinics after hospital discharge.
- iii. Patients with home-based medical card.

### **2.4.2 Exclusion criteria**

Patients discharged during public holidays or weekends will be excluded from this study.

### **2.4.3 Withdrawal criteria**

Patients readmitted to hospitals before the first review at the health clinic shall be withdrawn from the study. Patients can choose to withdraw at any time. Withdrawn patients will not be replaced.

## 2.5 Sample Size Calculation

This study aims to compare the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics between MedBook Portal and standard care. Hence, a two-tailed z-test of proportion between two groups with 80% power and a 5% of level significance will be used (10). The prevalence of medication discrepancies upon discharge reported in a previous study is 49% (8). We estimate the reduction of medication discrepancies via implementation of MedBook is 15%. Thus, a sample size of 322 subjects, 161 subjects in each group, is sufficient to detect a clinically importance difference of 15% between groups. However, with the estimation of a 20% loss to follow up, a total of 386 subjects will be recruited.

In addition, this study also aims to ascertain the prevalence of medication discrepancies and type of medication discrepancies in discharge prescription and in the first prescription upon transition of care from hospitals to primary health clinics. Sample size is calculated by using the following formula (11):

$$n = \frac{Z^2 P(1-P)}{d^2}$$

where  $n$  = sample size,

$Z$  = Z statistic for a level of confidence,

$P$  = expected prevalence or proportion

$d$  = precision

By determining the  $Z = 1.96$  for 95% CI and  $d = 0.05$ , the minimum sample size is 384. Based on the above sample size calculation, a total of 386 patients will be recruited. The sample size allocation for each hospital is determined on a pro-rata basis based on the total bed numbers in general medical wards and Bed Occupancy Rate (Table 2.4).

**Table 2.4: Sample Size Allocation Of Each Hospitals**

<b>Public Major Hospitals</b>	<b>Wards</b>	<b>Total Bed Numbers</b>	<b>Bed Occupancy Rate (%)</b>	<b>Sample Size Allocation</b>
Sarawak General Hospital	Male General Ward	48	114.4	144
	Female General Ward	48	102.0	
Sibu Hospital	Male General Ward 1	36	62.2	106
	Male General Ward 2	36	73.4	
	Female General Ward	32	83.5	
Miri Hospital	Male General Ward	29	114.1	72
	Female General Ward	30	62.8	
Sarikei Hospital	Male General Ward	35	82.4	64
	Female General Ward	35	50.2	
Total	-	329	-	386

## 2.6 Study Duration

This study is estimated to be conducted over 6 months, expecting to commence in August 2023.

## **2.7 Data and Instruments**

### **2.7.1 Data Collection Form**

Medication discrepancies detected will be categorised according to the following groupings, discrepant dose, discrepant frequency, polypharmacy, drug omission, drug addition and inappropriate drug. Other data that will be collected include age, gender, number of medications, type of medication based on Anatomical Therapeutic Chemical (ATC) categorisation in Drug Formulary Ministry of Health Malaysia, comorbidities, and category of prescriber.

There are two electronic data collection forms using Google Form for data entry. The first data collection form (Appendix A) is administered by pharmacist at hospital before allocation. The second data collection form (Appendix B) is to be administered by pharmacist at the health clinic.

### **2.7.2 MedBook Portal**

MedBook portal (<https://aplikasi.jknsarawak.moh.gov.my/medbook>) is a webpage that enable sharing of patient medication records among healthcare facilities under Ministry of Health. Sarawak State Health Department owned and managed this portal. All the information is kept under their server. Doctors in the Health Clinics and Study Pharmacists will be given access to this portal whereby each of the healthcare providers shall log in using their Identification Number and the password created by them. Doctor shall log in to MedBook Portal to check on discharge medication list when reviewing the patient at health clinic. MedBook Portal can be accessed both using a smartphone or a computer. The design of MedBook Portal in the smartphone version is shown in Figure 2.2. The design of MedBook Portal in the computer version is shown in Figure 2.3.

During the discharge process, the study pharmacist at hospital will upload the discharge prescription to MedBook Portal for both the control group and intervention group. When uploading the discharge prescription, the study pharmacist shall select the radio button ‘intervention’ for patients in the intervention group. MedBook Portal allows doctors at health clinics to view the prescription under the intervention group only. Whereas pharmacists at health clinics can view all the prescriptions in both groups. This setting is done based on the user role in MedBook Portal. The purpose of the setting is to ease the study pharmacist at the health clinic to compare the discharge prescription in MedBook Portal and the first prescription at the health clinic to identify medication discrepancies in both groups.

The screenshot displays the MedBook Portal interface on a smartphone. At the top, the browser address bar shows 'kasi.jknsarawak.moh.gov.my'. Below this is a dark header with the 'MedBook' logo and a menu icon. The main content area is divided into two sections: 'A. Maklumat Pemohon' and 'B. Rekod Slip Preskripsi'. Section A contains patient details: 'Name Penuh: SIM FUI GHO', 'Kad Pengenalan: 590613135112'. Section B is a table of prescriptions. At the bottom, there are two buttons: 'Kembali' (Return) and 'Tambah' (Add).

Fasiliti	Tarikh	Slip
Klinik Kesihatan Batu Kawa	30-07-2022	
Klinik Kesihatan Batu Kawa	29-07-2022	
Cawangan Amalan & Perkembangan Farmasi	28-07-2022	
	25-07-2022	

Figure 2.2: MedBook Portal in smartphone version

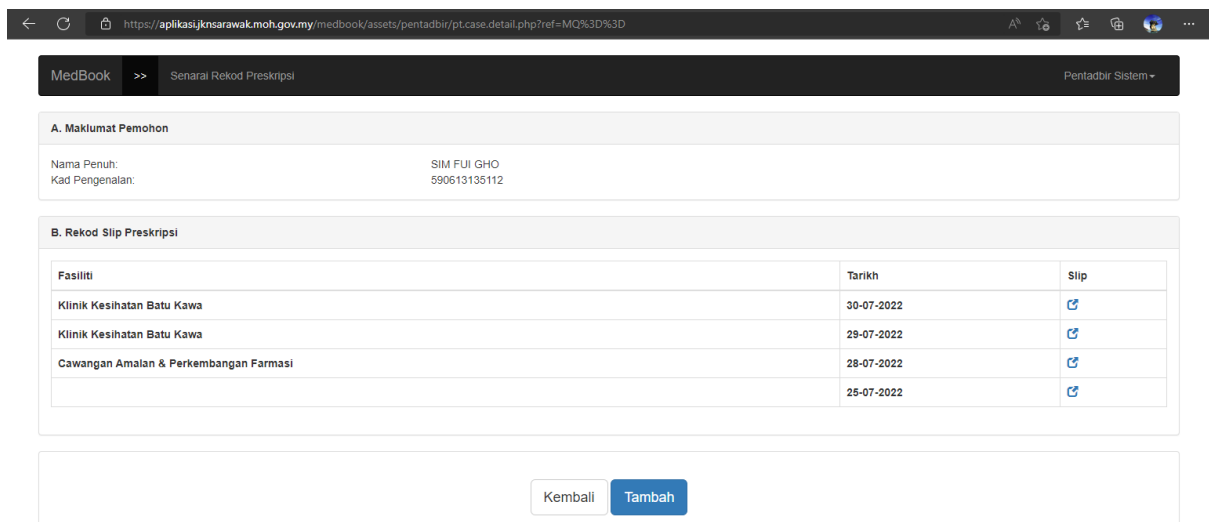


Figure 2.3: MedBook Portal in computer version

### 2.7.3 MedBook Portal Notice

A MedBook Portal Notice will be placed in front of the patient's home-based medical card. Only patients in the intervention group are given MedBook Portal Notice. Hence, the doctors and pharmacists at health clinics can identify the recruited patients in the intervention group. The layout of the MedBook Portal Notice is shown in Figure 2.4.

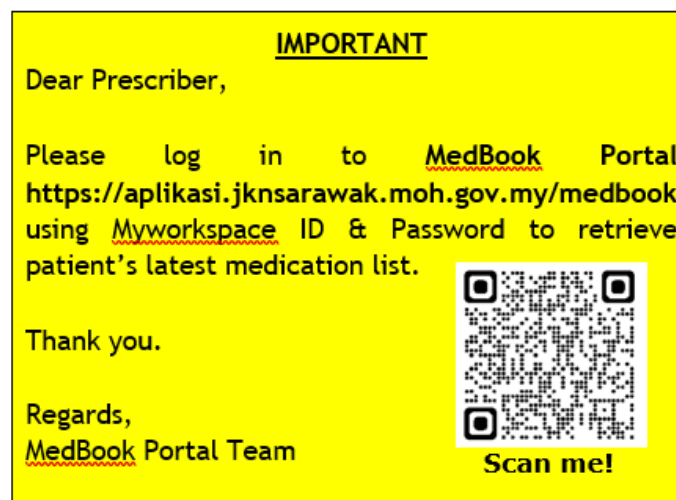


Figure 2.4: MedBook Portal Notice

## **2.8 Recruitment**

In this study, patients who are decided to be discharged from the selected hospital and fulfilled the inclusion criteria will be recruited. The patients will be given a full explanation regarding the study according to the patient information sheet before enrolment. Subsequently, patients will be requested to provide written informed consent (Appendix C) if they agree to participate in the study.

## **2.9 Medication Reconciliation Upon Hospital Discharge**

Medications in the discharge prescription will be considered as the primary source of reference for discharge reconciliation, as this is the list of medications that the pharmacy will refer to for medication preparation and eventually will be given to the patients upon discharge. Study pharmacists will conduct discharge medication reconciliation before randomization. Discharge medication reconciliation will be carried out by comparing the medications in the discharge prescription against the medications in the medication history assessment form (pre-admission medications) and inpatient medication charts (medications started during admission) to detect medication discrepancies before discharge medications preparation. If any differences are detected, study pharmacists will confirm with the doctor to decide intentional or unintentional medication discrepancies-any amendment to be documented on the discharge prescription.

## **2.10 Randomisation and blinding**

The recruited patients will be randomised to the intervention and control groups in a 1: 1 ratio before discharge. Randomisation will be conducted using the online program available at <http://www.graphpad.com/quickcalcs/index.cfm> (12). A research coordinator will be appointed to administer the randomisation and inform the study pharmacist to deliver the intervention according to the assigned group. The research coordinator has no contact with patients, study pharmacists and doctors. In addition, the research coordinator will manage the

patient list with their code and group assignment. Subsequently, the research coordinator will send the patient list to the principal investigator to remind the patient of the follow-up date at the health clinic. Due to the nature of the intervention, patients, doctors, and study pharmacists are not blinded.

## **2.11 Intervention Group**

MedBook Portal Notice will be attached in front of the patient's home-based medical card for the doctors and pharmacists at health clinics to identify the recruited patients. This appointment would be their first follow-up at health clinics after discharge from the hospital.

During the doctor's review of the patient in the intervention group, the doctor shall log in to the MedBook Portal to check on the discharge medication list and review the case based on the previous medical record in the home-based medical card and the discharge note if the patient hand over it to the doctors in their first review. Then, the doctor will conduct medication reconciliation by comparing the list of medications in the discharge prescription against the new prescription prepared.

Study pharmacists at the health clinics are required to screen patients' home-based medical cards presented to the pharmacy upon collecting medications. Once the pharmacists at health clinics identify the recruited patients via the MedBook Portal Notice, the pharmacist shall log in to the MedBook Portal to check the discharge medication list. The pharmacist shall conduct medication reconciliation by comparing the new prescription received against the discharge medication list in the portal. Intervention is to be carried out by the study pharmacists through confirmation with the doctor to determine the intentional or unintentional medication discrepancies.



## **2.12 Control Group**

Patients will receive the standard care in which doctors review patients based on the previous medical record in the home-based medical card and discharge note if the patient hands it to the doctors in their first review. Doctors cannot retrieve a patient's discharge medication list from MedBook Portal. No MedBook Portal Notice is attached to the patient's home-based medical card.

The principal investigator will provide a patient list in the control group to the study pharmacist at the health clinic. By knowing their appointment date, the study pharmacist shall search for the first prescription upon transitioning care from the hospital to the primary health clinic. Subsequently, the study pharmacist shall compare the discharge prescription in MedBook Portal with the first prescription to identify medication discrepancies. If any differences are detected, study pharmacists will confirm with the doctor to decide intentional or unintentional medication discrepancies. However, the study pharmacist might not be able to retrieve the first prescription immediately on the appointment date as there is no MedBook Portal Notice attached. As a result, the study pharmacist can only check with the prescriber on the discrepancy at a later time.

## **2.13 Data Collection**

The prevalence of medication discrepancies during discharge is collected through medication reconciliation by the study pharmacist at the hospital using the electronic data collection form. In addition, the type of medication discrepancies and predictors associated with medication discrepancies will be collected simultaneously using the first data collection form (Appendix A) by the study pharmacist at a hospital before allocation.

To compare the prevalence of medication discrepancies in the first prescription upon transition of care from hospitals to primary health clinics between the MedBook Portal and standard care,

data collection on the number of medication discrepancies will be carried out during the first follow-up at the health clinic after the hospital discharge. A pharmacist will administer the second data collection form (Appendix B) at the health clinic.

Throughout the study, there is only one follow-up visit at the health clinic, the first after hospital discharge. However, the time frame between the discharge date and the appointment date for the first follow-up at the health clinic varies from days to weeks depending on the duration determined by the hospital. Thus, the expected duration of subject participation would range from one week to two months.

To reduce loss to follow-up, the study pharmacist shall contact the patient via WhatsApp or phone call to remind the patient of the follow-up date at the health clinic. The schedule of enrolment, interventions and assessments of the study are presented in Table 2.5. The study flow chart is illustrated in Figure 2.5.

Table 2.5: Schedule of Enrolment, Interventions and Assessments

Timepoint	Study Period			
	Enrolment	Allocation	Post-allocation	Close-out
	-t <sub>1</sub>	0	1 <sup>st</sup> Primary Health Clinic Follow Up	
ENROLMENT:				
Eligibility screen	X			
Participant Information Sheet	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
MedBook Portal		X	X	
ASSESSMENTS:				
Prevalence of medication discrepancies	X		X	
Predictors of medication discrepancies	X		X	

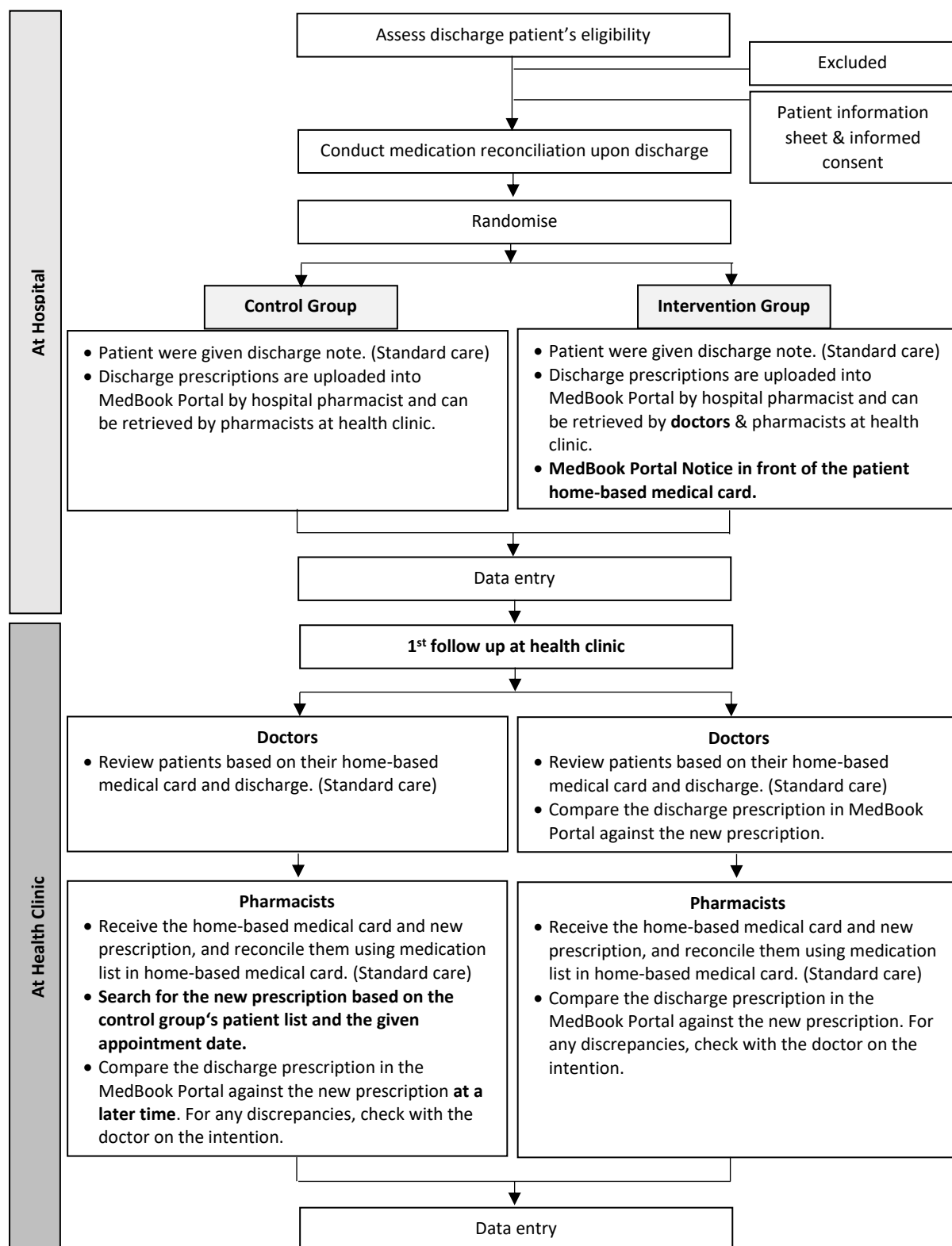


Figure 2.5: Study Flow Chart

## **2.14 Outcomes**

The primary outcome of the study is the percentage of prescriptions with medication discrepancies in the first prescription during the first follow-up visit at the primary health clinic after hospital discharge. A comparison of the prevalence of prescriptions with medication discrepancies in the intervention group and the control group will be conducted.

The secondary outcome of the study is the percentage of prescriptions with medication discrepancies in the discharge prescription. This is measured before the intervention. In addition, the type of medication discrepancies and predictors associated with medication discrepancies in discharge prescriptions and the first prescriptions upon transitioning care from hospitals to primary health clinics will be collected. Predictors associated with medication discrepancies will be analysed using multiple logistic regression.

## **2.15 Data Analysis**

All data will be analysed using The jamovi project (2022) (Version 2.3). Descriptive statistics (frequency and percentage; mean and standard deviation) will be used to describe the socio-demographic characteristics of the participants.

Categorical variables, expressed as numbers and percentages, are compared by the Chi-square test. Continuous variables will be tested for normality using One-Sample Kolmogorov-Smirnov Test and compared using independent t-test for normally distributed data and the Mann-Whitney U test for non-normally distributed data. Data with normal distribution are reported as mean (standard deviation, SD), while non-normally distributed variables are reported as median (interquartile range, IQR).

The predictors associated with medication discrepancies will first be analysed using univariable logistic regression. The variables with p-value  $<0.1$  by univariable analysis will be included in the multivariable logistic regression model. All statistical tests are two-tailed and  $p < 0.05$  is set to be statistically significant.

## **2.16 Chapter Summary**

This is a two-group randomised controlled trial conducted at four public tertiary hospitals and ten public primary health clinics in Sarawak, Malaysia. Adult patients in general medical wards who are discharged from the hospitals and referred to the selected primary health clinics will be recruited in the study. Eligible subjects will be randomised into intervention group and control group in a ratio of 1:1. During the first follow-up at the primary health clinic after discharge from hospital, doctors in the primary health clinics review the patients in the intervention group based on the discharge medication list in the MedBook Portal. Patients in the control group receive the standard care. Study pharmacists conduct medication reconciliation and identify medication discrepancies.

The primary outcome of this study is the percentage of prescriptions with medication discrepancies in the first prescription during the first follow-up visit at the primary health clinic after hospital discharge. A comparison of the prevalence of prescriptions with medication discrepancies in the intervention group and the control group will be conducted. The secondary outcomes are the percentage of prescriptions with medication discrepancies in the discharge prescription, the type of medication discrepancies and predictors associated with medication discrepancies in discharge prescriptions and the first prescriptions upon transitioning care from hospitals to primary health clinics. All data will be analysed using The jamovi project (2022) (Version 2.3). All statistical tests are two-tailed and  $p < 0.05$  is set to be statistically significant.

## **CHAPTER 3**

### **GANTT CHART**

#### **3.1 Gantt Chart**

A Gantt Chart illustrates the duration of the task in the study and the sequencing of each activity. Proper planning for each activity is crucial to ensure the study is completed in the allocated time. The main activity of this study is depicted in Table 3.1.



Table 3.1: Gantt Chart

Activities	2022						2023												2024										
	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11
Literature Review																													
Proposal Write-Up																													
Study Site Meeting																													
Ethics submission & approval																													
Preparation of study materials & training																													
Data Collection																													
Data Analysis																													
Write Up																													
Submission for publication																													

## REFERENCES

1. Medication Safety in Transitions of Care. Geneva: World Health Organization; 2019. Report No.: WHO/UHC/SDS/2019.9.
2. Abu Farha R, Yousef A, Gharaibeh L, Alkhalaileh W, Mukattash T, Alefishat E. Medication discrepancies among hospitalized patients with hypertension: assessment of prevalence and risk factors. *BMC Health Serv Res.* 2021;21(1):1338.
3. Cornu P, Steurbaut S, Leysen T, De Baere E, Ligneel C, Mets T, et al. Effect of medication reconciliation at hospital admission on medication discrepancies during hospitalization and at discharge for geriatric patients. *Ann Pharmacother.* 2012;46(4):484-94.
4. Hias J, Van der Linden L, Spriet I, Vanbrabant P, Willems L, Tournoy J, et al. Predictors for unintentional medication reconciliation discrepancies in preadmission medication: a systematic review. *Eur J Clin Pharmacol.* 2017;73(11):1355-77.
5. Farley TM, Shelsky C, Powell S, Farris KB, Carter BL. Effect of clinical pharmacist intervention on medication discrepancies following hospital discharge. *Int J Clin Pharm.* 2014;36(2):430-7.
6. Kripalani S, Roumie CL, Dalal AK, Cawthon C, Businger A, Eden SK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. *Ann Intern Med.* 2012;157(1):1-10.
7. Hassali MA, Al-Haddad M, Shafie AA, Tangiisuran B, Saleem F, Atif M, et al. Perceptions among general medical practitioners toward implementation of medication reconciliation program for patients discharged from hospitals in Penang, Malaysia. *J Patient Saf.* 2012;8(2):76-80.

8. Law BK, Chong CP. Prevalence and predictors of medication discrepancies upon discharge among adult patients: a prospective study from Malaysia. *Journal of Asian Association of Schools of Pharmacy*. 2017;6(1):1-9.
9. Mueller SK, Kripalani S, Stein J, Kaboli P, Wetterneck TB, Salanitro AH, et al. A toolkit to disseminate best practices in inpatient medication reconciliation: multi-center medication reconciliation quality improvement study (MARQUIS). *Jt Comm J Qual Patient Saf*. 2013;39(8):371-82.
10. Sakpal TV. Sample size estimation in clinical trial. *Perspect Clin Res*. 2010;1(2):67-9.
11. Naing L, Winn T, Rusli BN. Practical Issues in Calculating the Sample Size for Prevalence Studies *Archives of Orofacial Sciences*. 2006;1:9-14.
12. Suresh K. An overview of randomization techniques: An unbiased assessment of outcome in clinical research. *J Hum Reprod Sci*. 2011;4(1):8-11.

APPENDICES

Appendix A: Data Collection Form to be administered by Pharmacist at Hospital  
(<https://forms.gle/wZrjjTpgLtHM8cb59>)

5. Refer to \*

Mark only one oval.

☐ KK Sentosa

☐ KK Batu Kawa

☐ KK Samarahan

☐ KK Jalan Oya

☐ KK Lanang

☐ KK Sibul Jaya

☐ KK Miri

☐ KK Tudan

☐ KK Sarikei

☐ KK Bintangor

6. Comorbidities as per case note (Please list down refer) \*

7. Number of Medication \*

8. Category of prescriber \*

Mark only one oval.

☐ House Officer

☐ Medical Officer

☐ Consultant/ Specialist

MedRecon Data collection Form  
(Hospital)

\*Required

1. ID \*

This ID is the ID assigned during the recruitment of the patient

2. Gender \*

Mark only one oval.

☐ Male

☐ Female

3. Age \*

4. Discharged from \*

Mark only one oval.

☐ Hospital Umum Sarawak

☐ Hospital Sibul

☐ Hospital Miri

☐ Hospital Sarikei

9. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #1

10. Drug Name with Unintentional Medication Discrepancy \*

11. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

12. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #2

13. Drug Name with Unintentional Medication Discrepancy \*

14. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

15. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #3

16. Drug Name with Unintentional Medication Discrepancy \*

17. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

18. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #4

19. Drug Name with Unintentional Medication Discrepancy \*

20. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

21. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #5

22. Drug Name with Unintentional Medication Discrepancy \*

23. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

24. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #6

25. Drug Name with Unintentional Medication Discrepancy \*

26. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

27. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #7

28. Drug Name with Unintentional Medication Discrepancy \*

29. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

30. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #8

31. Drug Name with Unintentional Medication Discrepancy \*

32. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

33. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #9

34. Drug Name with Unintentional Medication Discrepancy \*

35. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

36. Any other Unintentional Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #10

37. Drug Name with Unintentional Medication Discrepancy \*

38. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant dose  
☐ Discrepant frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

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MedRecon Data collection Form (Health Clinic)

\*Required

1. ID <sup>\*</sup>  
*This ID is the ID assigned during the recruitment of the patient*

2. Referred to <sup>\*</sup>

Mark only one oval.

- ☐ KK Sentosa  
☐ KK Batu Kawa  
☐ KK Samarahan  
☐ KK Jalan Oya  
☐ KK Lanang  
☐ KK Sibul Jaya  
☐ KK Miri  
☐ KK Tudan  
☐ KK Sarikei  
☐ KK Bintangor

3. Number of Medication <sup>\*</sup>

Mark only one oval.

- ☐ Medical Officers  
☐ Family Physician Specialist  
☐ Consultant/ Specialist  
☐ Medical Assistant  
☐ Nurse

5. Any Medication Discrepancies? <sup>\*</sup>

Mark only one oval.

- ☐ Yes  
☐ No

Drug #1

6. Drug Name with Discrepancies <sup>\*</sup>

7. Intentional or unintentional <sup>\*</sup>

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

8. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

9. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #2

10. Drug Name with Discrepancies \*

11. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

12. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

13. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #3

14. Drug Name with Discrepancies \*

15. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

16. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

17. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #4

18. Drug Name with Discrepancies \*

19. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

20. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

21. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #5

22. Drug Name with Discrepancies \*

23. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

24. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

25. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #6

26. Drug Name with Discrepancies \*

27. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

28. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

29. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #7

30. Drug Name with Discrepancies \*

31. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

32. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

33. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #8

34. Drug Name with Discrepancies

35. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

36. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

37. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #9

38. Drug Name with Discrepancies \*

39. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

40. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

41. Any other Medication Discrepancies? \*

Mark only one oval.

- ☐ Yes  
☐ No

Drug #10

42. Drug Name with Discrepancies \*

43. Intentional or unintentional \*

Mark only one oval.

- ☐ Intentional  
☐ Unintentional

44. Type of Medication Discrepancies \*

Mark only one oval.

- ☐ Discrepant Dose  
☐ Discrepant Frequency  
☐ Polypharmacy  
☐ Drug Omission  
☐ Drug Addition  
☐ Inappropriate Drug

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## Appendix C: Study Participant Information Sheet and Informed Consent Form in English

### PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

*(for adult subjects and interventional studies)*

**1. Title of study:**

A Randomized Controlled Trial to Compare MedBook Portal and Standard Care in Medication Reconciliation at Transitions of Care from Hospital Discharge to Primary Healthcare Settings

**2. Name of investigator and institution:**

Phang Yen Yen, Pharmaceutical Services Division, Sarawak State Health Department.  
Professor Dr. Kuan Jew Win, Faculty of Medicine and Health Sciences, Universiti Malaysia Sarawak

**3. Name of sponsor:**

Pharmaceutical Services Division, Sarawak State Health Department.

**4. Introduction:**

You are invited to participate in a research study because you will be discharged and will be referred to the health clinics for follow up treatment. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

**5. What is the purpose of the study?**

The purpose of this study is to examine the effectiveness of an intervention, named as MedBook Portal, in reducing medication discrepancies upon transition of care from hospitals to health clinics. MedBook portal is a webpage that enable sharing of patient medication profile among healthcare facilities under Ministry of Health. MedBook Portal aims to promote medication and patient safety.

A total of 386 subjects like you from the four public hospitals will be participating in this study. The four hospitals are Sarawak General Hospital, Sibu Hospital, Sarikei Hospital and Miri Hospital. The subjects will be discharged and referred to the ten public primary health clinics, namely, Batu Kawa Health Clinic, Kota Sentosa Health Clinic, Kota Samarahan Health Clinic, Jalan Oya Health Clinic, Lanang Health Clinic, Sibu Jaya Health Clinic, Miri Health Clinic, Tudan Health Clinic, Sarikei Health Clinic and Bintangor Health Clinic.

The whole study will last about 6 months and your participation will be about 1 week to 2 months depending on your appointment date at the health clinic.

**6. What kind of study products will I receive?**

If you agree to participate in the study, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups.

**Group 1:**

Your discharge prescription will be uploaded to MedBook Portal which will be accessed by your healthcare providers at the health clinic. MedBook Portal Notice will be attached on your home-based medical card. After discharge from hospital, you are required to follow at health clinic according to the appointment date. This would be the first follow-up at the health clinic after discharge from hospital. During this appointment, you shall bring over your home-based medical card with the MedBook Portal Notice attached and any documents that are informed by the hospital or health clinic to your doctor and pharmacist. Your doctor will review your case based on your discharge prescription in MedBook Portal, your previous medical record in the home-based medical card and any documents handed over to he or she. Your doctor and pharmacist will conduct medication reconciliation by comparing the discharge prescription in MedBook Portal against the new prescription prepared at the health clinic.

**Group 2:**

You will be given usual care, in which there is no MedBook Portal and no MedBook Portal Notice provided. After discharge from hospital, you are required to follow at health clinic according to the appointment date. This would be the first follow-up at the health clinic after discharge from hospital. During this appointment, you shall bring over your home-based medical card and any documents that are informed by the hospital or health clinic to your doctor and pharmacist. Your doctor will review your case based on your previous medical record in the home-based medical card and any documents handed over to he or she.

In order to examine the effectiveness of MedBook Portal, the investigator will compare the percentage of prescription with medication discrepancies between both group using statistical tools.

**7. What will happen if I decide to take part?**

You will have to attend the first follow-up at health clinic. You will be contacted by the investigator via WhatsApp or phone call to remind you on the follow up date at health clinic. Investigator will contact you via the telephone number 082-473200 or 01129060439.

**8. What are my responsibilities when taking part in this study?**

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the investigator. You shall bring over your home-based medical card and any documents that are informed by the hospital or health clinic to your doctor and pharmacist during the first appointment at the health clinic after discharge from the hospital. Your participation in this study shall end after the appointment. You will not be paid for participating in this study and you will continue with the follow-up treatment as usual. There will be no additional cost incurred to you to participate in this study.

**9. What are the benefits of being in this study?**

There may or may not be any benefits to you. Information obtained from this study will help improve the management of other patients with the same condition.



**10. What are the potential risks and side effects of being in this study?**

Participation in this study will not possess any potential risk, as this study does not involve any invasive procedure. The investigator will inform you in a timely manner about any new findings or changes about the study. Where necessary, you may be asked to re-consent to participate.

**11. What are my alternatives if I do not participate in this study?**

You do not have to participate in this study to get treatment for your disease or condition. You will be treated according to the usual care as per mentioned in point no.6 (group 2).

**12. Can the research or my participation be terminated early?**

The sponsor may stop the study or your participation at any time. If the study is stopped early for any reason you will be informed.

**13. Will my medical information be kept private?**

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study may be archived for the purpose of analysis, but your identity will not be revealed at any time. You will not be informed of the study findings.

**14. Who should I call if I have questions?**

If you have any questions about the study, please contact the investigator, Mdm Phang Yen Yen at telephone number 01129060439.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407 / 8205 / 8888.

## INFORMED CONSENT FORM

Title of Study: A Randomized Controlled Trial to Compare MedBook Portal and Standard Care in Medication Reconciliation at Transitions of Care from Hospital Discharge to Primary Healthcare Settings

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the investigator's instructions related to my participation in the study.
- I understand that study staff, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree\* for my family doctor to be informed of my participation in this study.  
(\*delete which is not applicable)

### **Subject:**

Signature:

I/C number:

Name:

Date:

### **Investigator conducting informed consent:**

Signature:

I/C number:

Name:

Date:

**Impartial witness:** *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

Signature:

I/C number:

Name:

Date: