ESTABLISHING AN ELECTRONIC BREAST CANCER MEDICAL RECORD MODULE WITH AUTOMATION FOR PATIENT CARE AND RESEARCH: A CLINICAL WORKFLOW-BASED SOLUTION IN UNIVERSITY MALAYA MEDICAL CENTRE

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FACULTY OF SCIENCE
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THESIS SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

INSTITUTE OF BIOLOGICAL SCIENCES
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Field of Study: **BIOINFORMATICS**

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ABSTRACT

Advances in medical domain has led to an increase of clinical data production which offers enhancement opportunities in the clinical research sector. It is important for digital health technology to complement and fit into the existing clinical workflow in a single electronic medical record (EMR). In this study, we propose to expand the scope of EMR in the University Malaya Medical Centre (UMMC) using the Quality Implementation Framework (QIF) in establishing interoperability functions between clinical departments involving diagnosis, screening and treatment of breast cancer and building an automatic system for patient care, clinical audit and potential data mining to improve breast cancer outcomes. The completion of the i-Pesakit© Breast Cancer Module electronic structured clinical documentation complements the actual clinical workflow through data integration of clinical departments towards setting up a research-focused patient data governance model. The four main phases of QIF in this study are initial considerations about host setting, creating structure for implementation, ongoing structure during implementation, and future application improvement. The architectural framework module incorporates both clinical and research needs that comply to the Personal Data Protection Act. The output of i-Pesakit© Breast Cancer Module includes effective clinical data workflow management through an interoperable information technology and research focused governance model. This multidisciplinary collaboration enhanced the data capture quality in patientcare, benefited hospital data monitoring, quality assurance,

registry reporting and research workflow suitable for a middle-income country setting. Future applications include establishing interoperability with other clinical departments, external organization such as the National Registration Department for mortality data, clinical audit for quality assurance and data mining for clinical research.

Keywords: Electronic Medical Record, Breast Cancer, Database Mirroring, Medical System, Quality Implementation Framework

PENUBUHAN MODUL SISTEM REKOD PERUBATAN ELEKTRONIK KANSER PAYUDARA DENGAN FUNGSI AUTOMATIK BAGI PENJAGAAN PESAKIT DAN PENYELIDIKAN BERASASKAN ALIRAN KERJA KLINIKAL DI PUSAT PERUBATAN UNIVERSITI MALAYA

ABSTRAK

Kemajuan dalam bidang perubatan telah meningkatkan penghasilan data klinikal yang membuka peluang dalam menpergiatkan aktiviti kajian penyelidikan. Adalah penting bagi perlaksanaan teknologi kesihatan digital agar seiring dengan aliran kerja klinikal sedia ada berlandaskan sistem rekod perubatan elektronik yang efisyen. Dalam kajian ini, kami mencadangkan perluasan skop sistem rekod perubatan di Pusat Perubatan Universiti Malaya (PPUM) dengan menghubungkan jabatan klinikal yang terlibat dalam diagnosis, pemeriksaan dan rawatan kanser payudara serta membina sistem automatik untuk pemeriksaan klinikal bagi tujuan perlombongan data untuk meningkatkan penyelidikan kanser payudara klinikal pada masa akan datang. Rangka Kerja Pelaksanaan Kualiti telah digunakan dalam pembangunan modul kanser payudara PPUM. Modul Kanser Payudara i-Pesakit © yang ideal melibatkan pengurusan data elektronik yang efektif seiring dengan alur kerja klinikal sebenar, integrasi jabatan klinikal dalaman ke arah penubuhan model tadbir urus data pesakit yang sesuai digunakan dalam kajian kanser payudara. Langkah-langkah perlaksanaan dalam kajian ini adalah pertimbangan awal mengenai penyelesaian, mewujudkan dasar struktur pelaksanaan, pemerhatian dan penilaian pelaksanaan sistem serta penambahbaikan aplikasi untuk masa hadapan. Rangka kerja modul ini menggabungkan keperluan klinikal dan penyelidikan yang mematuhi Akta Perlindungan Data Peribadi. Kerjasama jabatan klinikal pelbagai bidang meningkatkan kualiti pengurusan data dalam perkhidmatan klinikal, memanfaatkan pemantauan servis dan kualiti data klinikal, pelaporan kes pendaftaran kanser dan pengurusan data penyelidikan,

yang berfungsi sebagai rangka kerja dalam melaksanakan sistem rekod perubatan yang responsif yang sesuai dalam situasi negara membangun. Cadangan aplikasi masa hadapan termasuk mewujudkan integrasi dengan jabatan klinikal yang lain, Jabatan Pendaftaran Negara untuk rekod data kematian, audit klinikal untuk pemantauan kualiti serta perlombongan data untuk penyelidikan klinikal.

Kata kunci: Rekod Perubatan Elektronik, Kanser Payudara, Pencerminan Pangkalan Data, Sistem Perubatan, Rangka Kerja Pelaksanaan Kualiti

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LIST OF SYMBOLS AND ABBREVIATIONS

11MP	:	Eleventh Malaysia Plan
9MP	:	Ninth Malaysia Plan
ASR	:	Age-standardized rate
CCHIC	:	Critical Care Health Informatics Collaborative
CDISC	:	Clinical Data Interchange Standards Consortium
CI	:	Confidence interval
CIC	:	Clinical Investigating Centre
CoC	:	Commission on Cancer
CRF	:	Case report form
DMISM	:	DeLone and McLean Information System Success Model
ECIS	:	European Cancer Information System
E-CRF	:	Electronic case report form
ECRIC	:	Eastern Cancer Registry and Information Centre
EHR	:	Electronic health record
EMR	:	Electronic medical record
ER	:	Estrogen receptor
ETL	:	Extract transform load
FNAC	:	Fine-needle aspiration cytology
GP	:	General practice
HCR	:	Hospital-based Cancer Registry
HER2	:	Human epidermal growth factor receptor 2
HIMS	:	Hospital information management system
HL7	:	Health Level-7
HWLB	:	Hookwire localization excision biopsy

HMIS	:	Health management information system
ICD	:	International Classification of Diseases
ICNARC CMP	:	Intensive Care National Audit and Research Centre's Case Mix Programme
ICT	:	Information and communication technology
ICU	:	Intensive care unit
IDI	:	ICT Development Index
IDS	:	Information Documentation System
IP	:	Internet protocol
IT	:	Information technology
MoH	:	Ministry of Health
MDT	:	Multidisciplinary team
MYIPO	:	Intellectual Property Corporation of Malaysia
NAACCR	:	North American Association of Central Cancer Registries
NCI	:	National Cancer Institute
NEHR	:	National Electronic Health Records
NIHR	:	National Institute of Health Research
NPfIT	:	National Programme for Information Technology
NSWCR	:	New South Wales Cancer Registry
PDPA	:	Personal Data Protection Act
POC	:	Point of care
PR	:	Progesterone receptor
QIF	:	Quality Implementation Framework
SEER	:	Surveillance, Epidemiology, and End Results
UMMC	:	University Malaya Medical Centre
US	:	Ultrasound

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CHAPTER 1: INTRODUCTION

1.1 Overview

Breast cancer tops the number of new cases worldwide among women, with approximately 2.1 million diagnoses in 2018 and contributing 11.6% of the total cancer incidence burden (Bray et al., 2018; International Agency for Research on Cancer (IARC), 2018). In women, breast cancer incidence rates overshoot other cancers in both developed and developing countries (The Global Cancer Observatory, 2018a), followed by colorectal cancer in developed countries and cervical cancer in developing countries (International Agency for Research on Cancer (IARC), 2018). As the most commonly diagnosed cancer in women, it is detected widespread in 154 of the 185 countries included in GLOBOCAN 2018, highest in South East Asia with 137 514 (26.9%) incidence (The Global Cancer Observatory, 2018a, 2018b) and 7593 reported cases in Malaysia (The Global Cancer Observatory, 2018c).

Figure 1.1 shows the age-standardized rate (ASR) of breast cancer incidence and mortality in Southeast Asia region 2018 as reported by Globocan 2018 (The Global Cancer Observatory, 2018a). Malaysia ranks highest in cancer mortality rate after Singapore based on estimation from neighboring countries and regional registries in Malaysia.

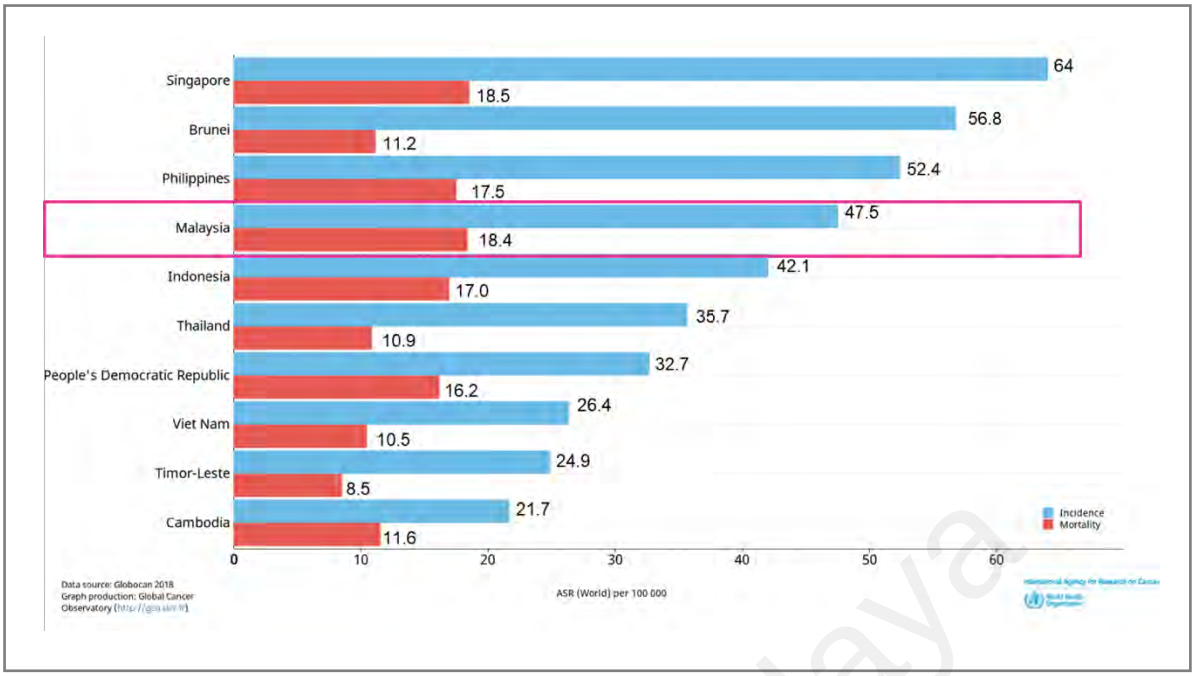


Figure 1.1: Estimated age standardized breast cancer incidence and mortality rates (World) in Southeast Asia 2018. Adapted from "Globocan 2018 breast cancer sheet", by The Global Cancer Observatory (2018a).

A typical breast cancer patient's journey through diagnosis and treatment involves multiple disciplines and departments. Breast cancer diagnostics require input by surgery, radiology and pathology disciplines. As such, aggregating data from different sources in healthcare and research is important (Miriovsky et al., 2012). In such circumstances, efficient data management and computational workflows are needed to generate meaningful clinical data, rather than having textual data and building algorithms to mine retrospective data (Wang et al., 2018). The availability of data extraction techniques in the data repository makes the system accessible to address research questions (Brundin-Mather et al., 2018; Murphy et al., 2007). The effectiveness and data quality of records can be improved through the enhancement of the clinical research database features. Elements needed for a successful clinical research database include engagement of clinicians, utility for research and the ability to integrate with legacy systems (Niland & Rouse, 2010).

Technological revolutions caused by advanced computing power, advanced informatics and communication technology have changed the way clinical data are stored and used. Health systems throughout the world are searching for more cost-effective ways of delivering care. While the focus in the past has been on constraining the growth in cost of care, new emphasis is being given to improve the quality and outcomes of care. Today almost every hospital realizes the need for storing its clinical data sets electronically in order to increase the quality of healthcare service and data. Many countries have embarked into the management of huge amount of clinical data using Electronic Medical Records systems. Examples are National Electronic Health Records (NEHR) in Singapore (Wee et al., 2015), National Programme for Information Technology (NPfIT) NHS Care Records Service in the United Kingdom (Waterson, 2014), The Royal Children's Hospital Electronic Medical Record in Melbourne (The Royal Children's Hospital Melbourne, 2016), eClinicalWorks, EPIC, McKesson, Care 360, Allscripts, Cerner, OPTUM Insight, NextGen, and Greenway in the USA (De La Torre et al., 2013; Hill et al., 2013; Johns Hopkins Medicine, 2012; Ludwick & Doucette, 2009). Despite these successful implementations, holistically the adoption of the EMR is still very low due to several barriers such as privacy concerns and interoperability. In hospital settings, one of the key obstacles to successful EMR implementation is resistance among physicians. Medical practitioners may be reluctant to accept EMR technology for a number of reasons, including the perception that the use of an EMR system requires extensive technical training and interferes with the quality of clinician-patient interaction. Many clinicians are skeptical about claims that EMR systems reduce errors, and increase productivity (Handy et al., 2001). Examples of EMR implementations worldwide are presented in detail in the next chapter.

According to the International Living website (International Living, 2019), Malaysia ranked first with its world-class healthcare services and sophisticated infrastructure with highest rating in the Best Healthcare in the World category (The Star Online, 2019). Malaysia, although being in the forefront in providing one of the best medical care in the world (International Living, 2019; Yorulmaz & Mohamed, 2019), is still at an immature stage concerning clinical data management (Latif et al., 2016). Electronic Medical Records (EMR) and Hospital Information Management Systems (HIMS) in Malaysia are still in the preliminary stage (Health Informatics Centre Planning, 2013). When the Information Documentation System (IDS) Unit in Ministry of Health Malaysia was established in 1980, it was agreed that the clinical data management system should function as a one stop centre on health informatics issues. Unfortunately, 27 years later, the system progress has been slow. The inconsistency of information and communication technology (ICT) infrastructure development has affected the system's consistency, integrity and quality of data. There was an urgent need for IDS to be upgraded to Health Management Information System (HMIS), which monitors and evaluates all health information monitoring and management in the country, hence the Health Informatics Centre in the Malaysia Ministry of Health was established in 2006.

The EMR functions are only limited to clinical data storage and production of reports for health management. On the technological aspect, infrastructure and network in supporting the EMR connectivity is inadequate. The system is slow and unreliable, as well as non-compliant at the operational level, and it incurs additional operational cost to enhance the system. The Ninth Malaysia Plan (9MP) first highlighted on strengthening the Health Information System, to improve the point-of-care service and information access but the success rate has been low (Economic Planning Unit, Prime Minister's Department, 2006). Country Health Plan 2011-2015 highlighted the challenges in health information system implementation include inadequate integrated planning of health

information systems, lack of clinician champions, technical expertise to implement system as well as enforcement of information technology (IT) policies (Ministry of Health Malaysia, 2011). Health Research Priorities in Malaysia for the Tenth Malaysia Plan (2011-2015) acknowledged the national problem of interoperability between ICT applications and systems, and continued the effort in developing tools to facilitate interoperability as well as evaluating hospital information systems (Anuar et al., 2014). During the National Institutes of Health Malaysia Research Dialogue on Health Research Policy in Eleventh Malaysia Plan (2016-2020), one of the things highlighted in the health technology domain is to focus on efforts on producing research output, and data sharing policy into the research areas (Ministry of Health Malaysia, 2017b). With these crucial issues that need to be resolved, there is an absolute urgency in developing a reliable, integrated and interoperable health information management using an implementation framework (Lee et al., 2014).

1.2 Problem Statement

The University Malaya Medical Centre (UMMC) Surgical Breast Unit has produced the first breast cancer outcome data in Malaysia (Bhoo Pathy et al., 2013; Mohd Taib et al., 2008; Ong & Yip, 2003). The institutional survival rates differ tremendously with a published population-based study but further details on stage at presentation and other clinical variables were not available for nationwide outcome analysis (Abdullah et al., 2013). In UMMC, data capture methods had been manual and done retrospectively by tracing notes of patients' clinical and treatment characteristics. This method is expensive with high probability of missing values and inaccuracies. Reducing manual work through automatic data capture systems is cost effective especially in the light of increasing burden of salary costs to hospitals.

This study aims to implement an electronic multidisciplinary clinical workflow system to facilitate structured clinical documentation, system interoperability, clinical audit and reporting to address not only clinical workflow issues encountered by clinicians at UMMC, but also to prepare the current EMR to support secondary data use and research matters through information sharing and exchange among breast cancer clinicians and researchers in the future.

1.3 Research Questions

- What is the best approach to solve breast cancer clinical data management and reporting issues at the University Malaya Medical Centre?
- How do structured clinical documentation and automatic interoperability system affect breast cancer multi-disciplinary clinical workflow?
- How effective is the electronic clinical workflow system and what would be an ideal approach to facilitate secondary data use in breast cancer research system in the University Malaya Medical Centre?

1.4 Objectives of this Study

There are three primary objectives of this study:

- To formulate and implement a digital breast cancer module at University Malaya Medical Centre
- To expand the scope of EMR beyond clinical usage through implementation of automated National Cancer Registry reporting for breast cancer in University Malaya Medical Centre
- To assess the effectiveness of i-Pesakit© Breast Cancer Module compared to the manual legacy paper-based system and evaluate implementation impact on clinicians

1.5 Scope of Study

This study focuses on expanding the electronic medical record system for breast cancer at UMMC by establishing interoperability functions between multiple clinical departments involved in breast cancer diagnosis, treatment and building automatic systems for clinical audits as well as for potential data mining to produce breast cancer research outcomes in the future. Top-down approach and applied research techniques are used as foundations to improve clinical service and research standards. The completion of the UMMC i-Pesakit© Breast Cancer Module requires populating EMR including management of clinical data access, establishing information technology and research focused governance model, and integrating clinical data from multiple internal clinical departments and external sources such as State Department Clinical Registry.

1.6 Organization of Thesis

Chapter One: The first thesis chapter presents an overview of electronic medical records, focusing on breast cancer clinical data management. Problem statement and research questions are explained based on the local issue scenarios in University Malaya Medical Centre. In addition to providing a research rationale, the proposed methodology and scope of study are described in this section.

Chapter Two: In this chapter, an extensive literature review on EMR concepts, functionalities, infrastructures, and framework models in guiding towards this research study are presented. Further investigation on related work from the reference disciplines, in comparing types of EMR for clinical and research use, clinicians' early perceptions regarding the value of EMR and the last describes the global and local scenario of EMRs and clinical research databases.

Chapter Three: This chapter contains the materials and methods in designing the solution, by adopting the 14 steps of Quality Implementation Framework (QIF) method which includes (i) initial considerations regarding host setting, (ii) creating a structure for implementation, (iii) ongoing structure implementation in terms of technical and evaluation processes as well as (iv) improving future applications. System and data analysis approach, ethical considerations and system's post-implementation evaluation are also presented in this section.

Chapter Four: This chapter presents the findings and outputs of system content features and implementation into clinical workflow, secondary use of the newly implemented system, its usability and system evaluation report.

Chapter Five: This chapter discusses the results of implemented breast cancer module system. Research questions are answered in this chapter and current research contributions are compared with existing research studies, discussion about constrains and limitations, declaration of future works in enhancing the system and finally the summarized conclusion of study.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

This chapter provides insights to important concepts relevant to this study such as the Electronic Medical Records and Electronic Health Records implementations, functionalities and infrastructure. Subsequently, some of the successful systems deployed globally are cited to present a holistic overview on the uptake of EMRs in the main hospitals. The Malaysian EMR landscape is also discussed to provide an overview of the local scenario.

2.2 Electronic Medical Record and Electronic Health Record Concepts

Many people in the healthcare industry as well as the public use the terms Electronic Medical Record (EMR) and Electronic Health Record (EHR) interchangeably. However, these concepts are slightly different, and a clear understanding is required in following the work done in this thesis. Table 2.1 explains the resemblance and comparison between EMR and EHR concepts.

Table 2.1: Similarities and differences between EMR and EHR

Electronic Medical Record (EMR)	**Electronic Health Record (EHR)**
Made up of patients' personal information, medical history, diagnosis, treatment, follow-up visits, hospital admissions and pharmacy records	
Internal organizational system	Inter-organizational system
Digital version of patients' chart from an individual practice	Digital clinical records which are made to be shared with other medical providers, where authorized users can instantly access their EHR when patients visit different health care providers
Provides more in-depth data tracking over time and effective clinical workflow monitoring to improve patient care	Multiple sources concept and simplifies sharing up to date info with other providers
Mainly used by an individual practice for diagnosis and treatment	Used to share information with authorized users and providers from multiple organizations
A closed system, not meant to be shared outside the individual practice	Allows patient records to move with them to emergency rooms, laboratory and pharmacies – as well as extended geography regions

EMR is a digital medical record of patient's information within a particular healthcare provider's practice, while EHR refers to a digital medical record that can be accessed, managed, and edited by multiple healthcare providers due to conformity to a standard (Heart et al., 2016). It represents the ability to easily share patient-level medical

information among stakeholders and to have patient's information follow the patient through the various modalities of care engaged by that individual (De Pietro & Francetic, 2017). Stakeholders are composed of clinicians, hospital staffs and management, as well as the government policy makers (Franklin et al., 2017). This environment supports the patient's electronic medical record across inpatient and outpatient environments, and is used by healthcare practitioners to document, monitor, and manage health care delivery within the healthcare institution (Xiao & Acosta, 2016). EMR implementation facilitates the clinician-patient communication in a computerized clinical setting to improve safety and efficiency of system usage (Reis et al., 2013).

The foundation of EMR applications required to improve patient safety and reduce medical errors are clinical data registry, e-prescription system, pharmacy management system, and electronic medication administration record (Amroze et al., 2019; Fuchs et al., 2016). Data in the EMR is the legal record of what happened to the patient during their encounter at the hospital and is owned by the hospital (Ciampi & Sicuranza, 2018). EMR electronically stores such items as medical prescriptions, clinical notes, diagnostic images, treatment plans, follow-up records and other types of medical documentation (Amroze et al., 2019; Thompson et al., 2007).

EHR is a subset of each care delivery organization's EMR (Garets & Davis, 2006). The EHR can be established only if the electronic medical records of the various hospitals have evolved to a level that can create and support a robust exchange of information between stakeholders within a community or region (Heart et al., 2016). Some are used in individual organizations, as interoperating systems in affiliated health care institutions, on a regional level, or nationwide (Lipson, 2015; Robertson et al., 2010). The EHR environment relies on functional EMRs that allow multiple care delivery organizations to exchange clinical data with other healthcare organizations or stakeholders within the

community, regionally, or nationally. This information is easily stored and exchanged with the rise in digital electronic health records (Hing et al., 2016; Mishuris et al., 2016). In maximizing the EHR system interoperability and clinical effectiveness, it is important that these EHR electronic workflow matches the actual clinical healthcare team workflow (Girling, 2014; Katzer et al., 2012; Mishuris et al., 2016; Poissant et al., 2005). However, in Malaysia, it is common to hear EHR and EMR used as interchangeable terms. In this study, the electronic clinical data management system will be referred to as electronic medical record.

2.3 Functionalities of EMR and EHR

EMRs collect and standardize information needed for managing patients' medical records. It also allows clinicians to share records, view trends and discover possible changes in patient history. The basic EMR tools should include patient demographics, history and medication record management, e-prescribing, as well as doctor's clinical documents and notes in present care and treatment plans for patients. In a more advanced setting, speech recognition is used in the system (Hodgson et al., 2018). The technical architectural and security features of an EMR include audit trail, encryption, scalability, data restoration in the event of a system crash, as well as on-premise with a set of backup data (Blobel, 2018; Ergüzen & Ünver, 2018). These electronic medical record features include medical history, current clinical diagnosis, treatment care plans, pathology laboratories and radiology results (Aldosari, 2017; Zhao et al., 2017).

The charting capabilities found in EMR also contribute to how convenient a physician can access the records, such as chart searches, prescription templates, electronic provider order entries and follow up appointment reminders (Hines & Kumar, 2016; S. Y. Park et al., 2012; Xiao & Acosta, 2016). There are also reporting functions that will generate clinical quality reports (El-Jardali & Fadlallah, 2017). Reporting capabilities could

include custom reports, e-prescription reports, computerized physician order entry and ad-hoc reports (Blumenthal & Tavenner, 2010; Brundin-Mather et al., 2018; Heart et al., 2016).

2.4 Electronic Medical Record System Infrastructure

Deploying an efficient EMR system in the right infrastructure development environment is subject to specific factors such as deployment, scalability and technical monitoring as well as support aspects of the system. The two common development environments of EMR are client-server based (Alzghoul et al., 2016; Kemkar & Kalode, 2015) and cloud-based EMR systems (Esposito et al., 2018; Hu et al., 2017). Table 2.2 summarizes the differences between these two infrastructures and how each environment suits each specific condition based on storage capacity, accessibility, system response time, and hardware requirements.

Table 2.2: Comparison between client-server based EMR system and cloud-based EMR system

 **Client-server Based EMR System**	 **Cloud-based EMR System**
Stores patients' data in-house and servers located within the premise of medical facilities	Patients' data are stored and maintained on remote servers (also called as cloud)
Either locally or web-based accessible, as long as users are on network EMR within a specific Internet Protocol (IP) range	More accessible via the web, requiring only a device with an internet connection
Speed of system is usually dictated by the strength of internal network and server equipment rather than factors such as Internet connections, hence server-based EMR system is faster and more capable, making it ideal for hospitals and large health practices	They may have latency or lag time accessing information from across the web, and depend highly on a steady internet connection
Requires hardware and software installation within the clinical practice	Minimal IT requirements are needed, since the system is web-based where no software or hardware needs to be installed

2.5 EMR Strategies and Framework Models

The implementation of the hospital information system may alter social dynamics in an organization (Håland, 2012). EMR systems lead to a redistribution of work, but not necessarily a reduction in it (Dias & Escoval, 2013). Several EMR frameworks have been implemented either through theoretical model, adoption and implementation frameworks. The top three frameworks for each category are DeLone and McLean Information System Success Model (Cho et al., 2015; DeLone & McLean, 2003; Ojo, 2017; Tilahun & Fritz, 2015), Clinical Adoption framework (F. Lau & Kuziemsky, 2016; O'Donnell et al., 2018) and Quality Implementation Framework (Meyers et al., 2012; Mohd Nor et al., 2019; Novins et al., 2013).

2.5.1 DeLone and McLean Information System Success Model

According to the DeLone and McLean Information System Success Model (DMISM), EMR's effectiveness is measured by system quality, information quality, and service quality to achieve individual and organizational impact (DeLone & McLean, 2003; Urbach & Müller, 2011). This model was developed in 1992 and revised in 2003. It comprehensively review different information system success measures and propose a model that includes six factors for IS success measurement: information quality, service quality, intention to use, user satisfaction and net-benefits (Cho et al., 2015; Idzwan et al., 2014; Lee-Post, 2006; Tilahun & Fritz, 2015). Figure 2.1 summarizes the EMR systems success model.

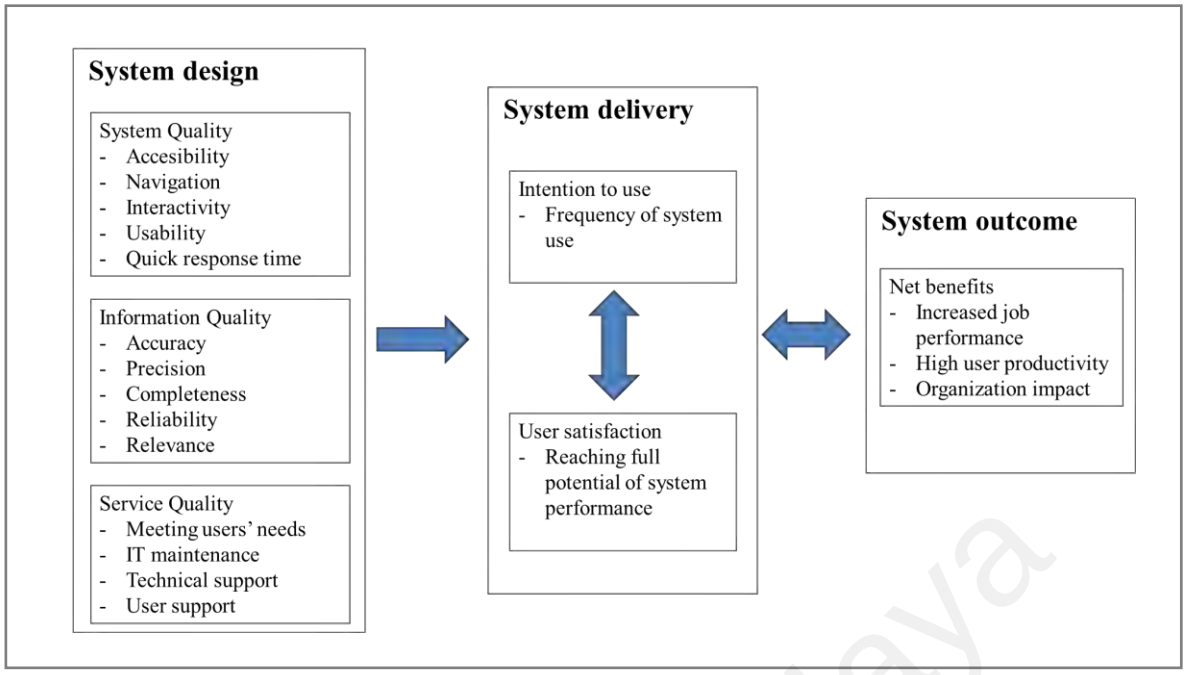


Figure 2.1: DeLone and McLean Information System Success Model (DMISM). Adapted from "E-learning Success Model: An information systems perspective", by Lee-Post (2006).

System quality is divided into four components; accessibility, navigation, interactivity, and usability. These components are expected to predict perceived service quality by system users (Cantiello et al., 2016). System quality includes user interface quality, system response pace, and accessibility and user system usability, and is tested in several studies (Urbach & Müller, 2011). Users have a higher tendency to accept a new system with a high potential of perceived usefulness. A healthcare system is assumed as easy to use when it is stable with the addition of integration and interoperability functions.

Information quality is the quality of output content generated from the system measured by its accuracy, precision, completeness, reliability, and relevance (Urbach & Müller, 2011). From a healthcare IT perspective, information quality is reflected upon its accuracy and reliability of compiling patients' clinical data to produce a comprehensive patient medical history and diagnosis. Service quality is measured by the support quality from system developer (Ojo, 2017; Urbach & Müller, 2011). Technical expertise of IT

personnel, maintenance and support, and training programs are the criteria to evaluate quality of service. In healthcare situations, clinicians evaluate the implemented system and quality of technical support given, network infrastructure and system reliability. The intention to use is measured through the actual frequency of system usage, while user satisfaction is captures clinician's satisfaction with the deployed system. System outcome is reflected from its net benefits, where this determines the success of the system. Either positive or negative, evaluating these measures are important to assess the individual or organizational impact (Urbach & Müller, 2011).

2.5.2 Clinical Adoption Framework

The Clinical Adoption (CA) Framework is built on theories and models from the disciplines of information systems, organization science, and health informatics (F. Lau & Kuziemsky, 2016). It provides three conceptual views of the key dimensions involved in the adoption of health information systems by clinicians in different settings (F. Lau et al., 2011). The CA Framework consists of micro, meso and macro dimensions encompassing: the quality, accessibility and functionality of the EMR system; the people, organization and process involved in EMR implementation; and the societal, political and legislative context (O'Donnell et al., 2018). Table 2.3 narrates the three conceptualizations of the framework in detail.

Table 2.3: Conceptual views of Conceptual Adoption Framework key dimensions in adoption of health information system. Adapted from "Primary care physicians' attitudes to the adoption of electronic medical records: A systematic review and evidence synthesis using the clinical adoption framework" by O'Donnell et al. (2018).

Macro view	**Meso view**	**Micro view**
Addresses the quality of: 1) EMR system information, system and service its use and user satisfaction 2) net benefits (care quality, productivity and access)	Addresses the dimensions involving: 1) people 2) the organization 3) EMR system implementation	Addresses: 1) healthcare standards| 2) funding and incentives 3) legislation/policy and governance 4) societal/political/economic trends as environmental factors that have direct influence on the extent to which the meso dimensions can affect clinical adoption
Successful clinical adoption depends on: **1. EMR quality** -accuracy, completeness and availability of the clinical information content - features, performance and security of the system - responsiveness of the support services **2. Usage quality** - EMR user satisfaction (usefulness, ease of use and competency) **3. Net benefits** - Change in care quality, access and productivity with EMR adoption - Care quality (patient safety, effectiveness and clinical outcomes)	Successful clinical adoption depends on: **1. People;** stakeholders' involvement in EMR system **2. Organization,** how the HIS fits with the organization's strategy, culture, structure/processes, info-/ infrastructure and return on value **3. Implementation;** EMR adoption stages, project management approaches and the extent of the HIS's fit for the practice.	Successful clinical adoption depends on: **1. Healthcare standards,** organizational performance and professional practice standards in place **2. Funding and incentives;** the added values, remunerations and incentive programs **3. Legislation/policy and governance;** the influence of legislative acts, regulations/policies and governance bodies **4. Societal, political and economic trends;** public expectations and the overall socio-political and economic climates with regards to technologies, healthcare and HISs as a whole

2.5.3 Quality Implementation Framework

The Quality Implementation Framework (QIF) incorporates implementation research as well as specific procedures and resources into a model of systems and processes for moving research-based innovations into widespread applications (Garcia et al., 2016). The synthesis identified 14 critical steps that were used to construct the QIF. These steps comprise four QIF phases: initial considerations regarding the host setting, creating a structure for implementation, ongoing structure once implementation begins, and improving future applications (Meyers et al., 2012; Mohd Nor et al., 2019; Novins et al., 2013). This framework highlights on improving future implementation in the world of practice. In this study, QIF is adopted because it synthesizes existing models and research support and offers structured guidelines in setting up implementation efforts to improve clinical workflows as well as provide direction towards secondary data use for reporting and research activities, which is in line with the hospital's vision in upgrading healthcare.

2.6 Clinicians' Perceptions Regarding the Value of Using EMR Technology

Some clinicians are skeptical on using EMR daily that will take up more time in front of a computer that may affect clinician-patient interaction compared to manual work practices (Håland, 2012; Kruse et al., 2016; S. Y. Park et al., 2012; Roberts et al., 2016). However, some clinicians argued that a small level of resistance is useful as it opens up an opportunity to evaluate the electronic work system change in managing the resistant to change (Drenkard, 2013).

At the same time, there is a growing interest in EMR adoption in many countries due to increased awareness that stronger health information technology system is important to achieve a higher quality care at lower costs (Meigs & Solomon, 2016; Odekunle et al., 2011). Due to this, quality improvement in the healthcare industry has evolved over the years (Cantiello et al., 2016).

Despite this progress, many clinicians especially those in smaller and rural hospital settings continue to struggle with implementing an EMR system for patientcare (Weeks et al., 2015). Several studies indicate low levels of satisfaction (D. A. Harris et al., 2018), with overall EMR use and deficiencies in the record-keeping process as currently practiced by health care providers, which leads to medical records that often fail to include and share critical information (Linder et al., 2012). This lack of high quality information often leads to lesser quality and inefficient patientcare; reporting as well as clinical research (Monda et al., 2012). These barriers could cause clinicians to fall short of maximizing the usage of the high potential EMRs (Heisey-Grove et al., 2014).

There is an increased concern about a lack of structure leading to ineffective clinical documentation. Implementation of the EMR has introduced several unintended consequences including complicated workflows and increased documentation demands (Golob et al., 2016). Some clinicians describe using the present EMR causes them to have burnouts (Linder et al., 2012), where it is a bumpy ride; with roadblocks to effectively transcribe, share, and mine clinical findings; achieve integration of knowledge; or improve clinical care workflows and decision-making (Bewley et al., 2010; Campbell et al., 2006; Golob et al., 2016; O'Malley, 2011; Romano & Stafford, 2011).

2.7 Clinical Cancer Registries

A clinical registry is a collection of information about individuals, usually focused around a specific diagnosis or condition. It is also commonly known as clinical research database, disease registry or patient registry (Evans et al., 2016). While EMR keeps track of all patients in the hospital, a clinical registry only keeps track of a sub-population of patients with specific disease conditions. Registries collect observational information about patients with specific disease without dictating a treatment plan, while clinical trials seek participants who are willing to participate in investigational research with a particular treatment plan. Ideally, registries act as a central networking point for all stakeholders around a particular disease, including patient advocacy groups, researchers, clinicians, industry and Government (Lacaze et al., 2017). When these data are populated with accurate and high-quality clinical data over time, it benefits different fields of research in health service planning, epidemiology research, and clinical trial recruitment. Registries may be sponsored by a government agency, nonprofit organization, health care facility, or private company, and provide secondary data of patients with certain conditions, both individually and as a cohort, and over time, to increase understanding of those conditions. Some registries collect information that can be used to track trends about the number of people with diseases, treatments and more. Specific information cancer registries collect include patient demographics, tumour characteristics, stage of disease, treatment and outcomes (National Cancer Institute, 2019). There are several ways in consolidating these data for research and reporting. Table 2.4 shows the two types of clinical cancer registry; single-centre and multi-centre registry, also known as hospital-based and population-based respectively (Mohammadzadeh et al., 2017).

Table 2.4: Types of clinical cancer registries

Criteria	Clinical Research Registry	
	Hospital-based Registry	**Population-based Registry**
Definition	Collection of secondary data related to patients with a specific diagnosis, condition, or procedure	
Type	Single-centre registry	Multi-centre Registry
Purpose	1. Clinical data collection and management - collects different types of data: patient demographics, tumor characteristics, treatment, and outcomes 2. Dissemination (annual report and public health) - cancer statistics such as incidence, mortality, survival, and prevalence - published in the form of fact sheets, reports, publications and media 3. Analysis - covers multiple topics such as stage at diagnosis, survivorship cohort study, incidence trend, epidemiology research 4. Research application - investigates cancer incidence, prevalence, mortality, and survival; understand patterns of care in the cancer patient population and answers specific research questions	
Research roles	Monitoring quality of care, cancer trends report, treatment trend analysis, epidemiology research, surveillance, research publication	
Quality measurement purpose	1. Clinical audit 2. Quality measure -Services provided to patient (time to treatment, time to diagnosis) 3. Outcome measure - Evaluates patient health as result of care received (patients survival rate)	
Policy making purpose	Clinical service planning & development for a population of patients: - Healthcare financing - Healthcare workforce - Medicines use - Medical technology / devices	
Funding body	Ministry of Health / Healthcare institution / Academic institutions or consortia / Non-government organization / Private company	
Type / Example	**1. Healthcare-based registry** - NSW Cancer Registry by the Cancer Institute New South Wales Australia (Cancer Institute NSW, 2010) - Hospital-based Cancer Registry (HCR) by National University Hospital of Singapore (National University of Singapore, 2016) **2. Academic institution registry** - UMHealthResearch.org Research Participant Registry by University of Michigan (Michigan Institute for Clinical and Health Research, 2017)	

Table 2.4, continued**.**

	3. Regional registry - Eastern Cancer Registry and Information Centre (ECRIC) which covers East of England (National Cancer Registration Service (Eastern Office), 2019) - Critical Care Health Informatics Collaborative (CCHIC) by National Institute of Health Research UK (S. Harris et al., 2018) **4. National registry** - Malaysian National Cancer Registry (Ministry of Health Malaysia, 2019) - Canadian Cancer Registry (Canadian Council of Cancer Registries (CCCR), 2019) **5. International registry** - The European Cancer Information System (ECIS) by European Network of Cancer Registries (European Network of Cancer Registries, 2018; Randi et al., 2018) **6. Research consortia registry** - Breast Cancer Surveillance Consortium (Breast Cancer Surveillance Consortium, 2019) ***7.* Patient / advocacy organization registry** - Finnish Cancer Registry by Cancer Society of Finland (Cancer Society of Finland, 2016) **8. Public health registry** - National Cancer Registration and Analysis Service by Public Health England (Public Health England, 2019) **9. Cancer surveillance program registry** - Surveillance, Epidemiology, and End Results (SEER) (National Cancer Institute, 2019)

Clinical data may be available through condition specific disease registries for data, national audits, and other national data collections (Rao et al., 2016). Examples of common disease-specific registries include congenital anomalies, industrial diseases, diabetes and cancer. Based on Table 2.4, the Eastern Cancer Registry and Information Centre (ECRIC) collates data from 13 regional registries around East of England (National Cancer Registration Service (Eastern Office), 2019). Cancer registries were set up to collate new cases of cancer and use this information to produce statistics about

cancer incidence, prevalence, survival and mortality. In recent years the work of cancer registries has expanded from the monitoring of cancer occurrence to include the analysis of different aspects of cancer prevention, treatment outcomes and care.

The NSW Cancer Registry (NSWCR) in Australia manages cancer patients records in New South Wales (NSW) Cancer Institute (Cancer Institute NSW, 2010). The data captured within the registry provides useful insights into the impact of cancers, and its trends over time. Notification of new cancer cases and cancer deaths is required under the Public Health Act 2010 (NSW Parliamentary Counsel's Office, 2013). The NSWCR is the first Australian population-based cancer registry to include data on cancer stage, treatment and quality of care. Treatment delivered in most public hospitals are covered, with data from the remaining hospitals and private hospitals to be included in the future.

Hospital-based Cancer Registry Singapore was developed to accommodate translational research; clinical research; health services research; clinical audit; and ensuring efficient follow-up of cancer patients in National University Hospital Singapore (National University of Singapore, 2016). Datasets and standards of practice set follow the American College of Surgeons Commission on Cancer (CoC) and the North American Association of Central Cancer Registries (NAACCR).

National level registries such as Malaysian National Cancer Registry (Ministry of Health Malaysia, 2019) and Canadian Cancer Registry (Canadian Council of Cancer Registries (CCCR), 2019). Other registries besides breast cancer registries are Alzheimer's Prevention Registry, National Addiction & HIV Data Archive Program, and USIDNET Registry for Patients with Primary Immunodeficiency Diseases (Banner Alzheimer's Institute, 2019; Immune Deficiency Foundation, 2019; National Institute on Drug Abuse, 2019).

Developing linkable multi-centre health care database for research is tricky due to the clinical data sensitivity and patients' privacy. Critical Care Health Informatics Collaborative (CCHIC) was developed through a partnership between the UK's National Institute of Health Research (NIHR) and five leading NHS hospital trusts (S. Harris et al., 2018). The 'Extract Transform Load' (ETL) pipeline model was implemented for extracting, linking, cleaning, encoding and anonymising intensive care unit (ICU) data across multiple secondary healthcare providers. Started in 2014, CCHIC recruited consecutive admissions to the general adult medical and surgical critical care units at the five founding NIHR Biomedical Research Centres at Cambridge, Guy's, Kings' and St Thomas', Imperial, Oxford and University College London (National Insititute of Health Research, 2015). Dataset which are collected on daily basis in respective hospitals are currently exported to CCHIC on a quarterly basis, with the mission to progress to move to near real-time collection. Besides CCHIC, other notable examples of NIHR Health Informatics Collaborative (HIC) clinical research database models are Renal Transplant HIC, Viral Hepatitis HIC, and Ovarian Cancer HIC (Health Informatics Collaborative, 2015; University College London Hospitals NHS Foundation Trust, 2015).

The Intensive Care National Audit and Research Centre's Case Mix Programme (ICNARC CMP) UK was designed for benchmarking not research (S. Harris et al., 2018; Harrison et al., 2004). It is a national audit programme with more than twenty years of data in UK, containing selected data during the first 24 hours of admissions to critical care with summarised outcome measures. Both ICNARC and CCHIC are illustrated as two interactive programmes: one with a wide-angled historical view, and one with a detailed, longitudinal view enriched with secondary sources.

The Surveillance, Epidemiology, and End Results (SEER) Program is the main program that the National Cancer Institute (NCI) uses to support cancer surveillance activities. It is an authoritative source of information on cancer incidence and survival in the United States (National Cancer Institute, 2019). Based on these literature review, many registries serve different purposes. Main objectives were management of cancer control programs and improving of clinical care (Mohammadzadeh et al., 2017). Other purposes include epidemiology research, policy making, and quality measurement in patientcare.

Registries are typically stand-alone systems which are used for specific purpose, developed on different computer platforms, implemented on various software development with varying levels of security and data standards (Bellgard et al., 2015). Such systems are restricted because are available in isolation and updated periodically hence they are lack of point-of-care information (Tan et al., 2016). These registries are made especially for research purposes and they are not linked to the hospital's EMR systems (National Cancer Institute, 2019). The quality of the content is questionable as these registries are managed without validation (Venermo et al., 2017). Data anonymity in these registries is a hindrance to perform patient survivorship cohort studies, as patient identification is required in such analysis. Some clinical research registry data are linked to indirect identifiers such as age, sex, hospital admission date and time (Lawson et al., 2013; Mao et al., 2019). Even though record linkage using multiple indirect personal identifiers is feasible (Setoguchi et al., 2014), the use of a direct personal identifier (personal identification number) is the gold standard for linking datasets (Hsieh et al., 2018). In being a step ahead, our study proposes a multi-level approach for performing disease specific research using direct content from the hospital's EMR through a database mirroring approach that is explained in Chapter 5, where its data collection mechanism is embedded within the hospital information system.

2.8 Global Landscape of EMRs and Clinical Registries Implementation

The development rate of EMR systems worldwide has been much slower than initially anticipated (Duncan et al., 2018). In this section, the current scenario of EMR and clinical registries in high-income countries, upper middle-income countries and low-income countries are presented. Some of the important systems are also cited. The scope of this review covers the best practices, in technical aspects during development process of systems which are already in operation worldwide.

2.8.1 EMR and clinical registries landscape in high-income countries

Health systems in high income countries are mostly mature in development and implementation. The European leaders with nation-wide health system development are Denmark, Sweden, the Netherlands and Switzerland, while the countries which are struggling in accomplishing an integrated EMR system are Germany, Austria and Norway (Fragidis & Chatzoglou, 2017, 2018).

In the Danish healthcare system, majority of the primary care physicians have electronic health records with full clinical functionality and Denmark is widely regarded as a leading country in terms of eHealth integration and healthcare delivery services (Kierkegaard, 2013). The Danish National Health Portal, which was introduced in 2003 and fully implemented in the country in 2007, gives patients electronic access to their electronic health records and facilities between patients and their regional health service. The reorganization of the hospital structure in Denmark has improved the hospital performance, especially in ambulatory care and shorter waiting times (Christiansen & Vrangbæk, 2018). Several factors have enabled Denmark to reach its high level of IT use, such as the national and regional IT strategies in making Denmark a world IT driven nation, availability of technical platforms and facilities in initiating health information exchange, and learning from past eHealth initiatives failures (Kostera & Briseno, 2018).

Australia's electronic health system is known to be one of the most advanced developed system worldwide, fully-equipped with centralized electronic health record-keeping system (Ariffin et al., 2018; Masuda & Yamamoto, 2018). In Canada, the adoption of advanced and interoperable electronic health record is increasing rapidly (Gheorghiu & Hagens, 2016), and Korea shows an increasing number of electronic health system implementation in its public hospitals (Y. T. Park & Han, 2017).

New Zealand has one of the world's most highly automated primary care systems (Care et al., 2010; Gray et al., 2011; Srivastava, 2016) . New Zealand also stands out in terms of interoperability, with primary care providers, hospitals, radiology providers, and pathology laboratories, as well as most specialists able to use standard messaging to communicate with each other. It enables electronic information exchange with clinicians, specialized databases and public-private sector IT collaboration. At present, there is no central or single electronic health record system, but a distributed clinical data management system, which can be accessed from any entity across the nation. The country is aiming to have a single longitudinal view of health information accessible to consumers, carers and decision-makers (Ministry of Health, 2016).

Today, all of New Zealand's 1,100 general practices use a practice-based EHR that supports a broad range of functions, including primary care records, problem lists, clinical progress notes, ordering of tests and medications, managing medication lists and test results, issuing preventive reminders, and providing access to external decision-support systems. Most of the early use of IT was within and between health care organizations, but electronic communication with patients is beginning to occur via use of EHR systems with patient portals that enable patients to access limited subsets of their records from home.

Both Denmark and New Zealand rejected the idea of multiple organizations sharing a single medical record in favor of an approach that facilitates the sharing of information across organizations when needed (Deloitte, 2015). 'Single EHR' solution is the ideal direction that would physically store the information in a consolidated repository, However, data repositories for secondary care (test results, discharge summaries, specialist letters) are being developed at the regional level and significant investments are being made in sophisticated systems for making online referrals.

By 2020, all Swedish residents from 16 years old should will access to their clinical and dental records (Armstrong, 2017). They will be able to view clinical notes, prescribed medications, test results, warnings, diagnosis, maternity care records, referrals, and vaccinations as well as a log of everyone who has accessed the records (Hägglund & Koch, 2015). They can also add comments to notes if, for example, information is incorrect.

In the UK, although the National Program for IT (NPfIT) was initiated in 2002, with the aim to develop a universal electronic health record and securing data exchange throughout the NHS in England (Justinia, 2017), it was abandoned in September 2010, after eight years of significant governmental efforts and over of £6.2 billion of spending (Fragidis & Chatzoglou, 2017). A program of data collection and linkage of electronic health records named *care.data* was developed by the English NHS, which will link patient data from GPs with hospitals and other healthcare organizations but unfortunately this too has closed down in 2016 (NHS England, 2016). The current status of electronic health system in UK is the operation of the Summary Care Record system (NHS Digital, 2019), where a limited range of data of current medication, adverse reactions, and allergies are kept for all patients, apart for those who choose not to have one. It is an electronic clinical record, with data source from general practice (GP) medical records.

In Germany, on the other hand, there were major delays in technical issues, clinical data safety, lack of unique patient identifier specification, and the disapproval of health professional organizations (Fragidis & Chatzoglou, 2018). Hospitals have implemented EHRs to varying degrees but the integration of EHR systems in Germany has not been implemented yet, mainly due to incompatibility of different health information system used between hospitals, and between hospitals and ambulatory care (Fragidis & Chatzoglou, 2017). However, this issue was solved by introducing the electronic health card system which started operating since 1 July 2018. The e-health card, known in other nations as medical smartcards and which allow digital storage and retrieval of patient data, has been plagued in Germany by controversy and delay since it was first proposed in 2002 (Stafford, 2015). Table 2.5 and Table 2.6 summarizes the properties and characteristics of implemented EMRs in high-income countries (Fragidis & Chatzoglou, 2017, 2018).

Table 2.5: Characteristics of selected electronic medical record systems implementation approach worldwide

Properties	Austria	Canada	Denmark	Germany	Korea	New Zealand	Sweden	Switzerland	United Kingdom
Private vendors National organization Regional organization	✓	✓	✓		✓	✓	✓	✓	✓
National healthcare systems Publicly funded Private funded Totally private	✓	✓	✓	* ✓	✓	✓	✓	✓	✓
EHR implementation approach used Top-down Bottom-up Middle-out	✓	✓	✓	#	✓	✓	✓	✓	✓
Personal identifier	✓	x	✓	x	x	✓	✓	✓	✓

Table 2.6: Unique personal identifier usage in electronic health record system

Country	Unique Personal Identifier	Description
Austria	Yes	Each citizen has a unique personal identifier
Canada	No	There is no national patient identifier
Denmark	Yes	Every citizen has a unique identifier which is used in all health databases
Germany	No	Absence of unique patient identifier
Korea	No	There is no unique patient identifier that can be used only for medical purposes
New Zealand	Yes	Every person using health services has a national health index number
Sweden	Yes	Every Swedish has a personal electronic identity number
Switzerland	Yes	Each Swiss resident holds a personal identification number
United Kingdom	Yes	NHS number is assigned to each citizen

In the table below, tick symbol (✓) denotes positive selection, cross (X) represents negative selection, blank space indicates non-obtained information, asterisk symbol (*) indicates the initial approach used and hash symbol (#) represents future direction.

Texas MD Anderson Cancer Center uses a web-based radiation oncology system called Brocade (Pan et al., 2017). It was developed internally at the MD Anderson Cancer Center and deployed system-wide in 2016 (MD Anderson Cancer Center, 2017). It captures key cancer information such as tumour characteristics, surgery, chemotherapy and radiation details (Pan et al., 2016). Initially, Brocade was limited to breast cancer site in 2014 but the quick system adoption has expanded the system functions to other disease sites treated in the oncology department (Pasalic et al., 2018). This web-based electronic data capture is the main repository of randomized clinical trials data which manages structured data with functions such as data storage, patient-tracking status and real-time reporting for outcome analysis. Brocade operates as an intermediary system between MOSAIQ, an oncology data management software, and EPIC, an EHR system (Pan et al., 2017). The Brocade system summary is illustrated in Figure 2.2.

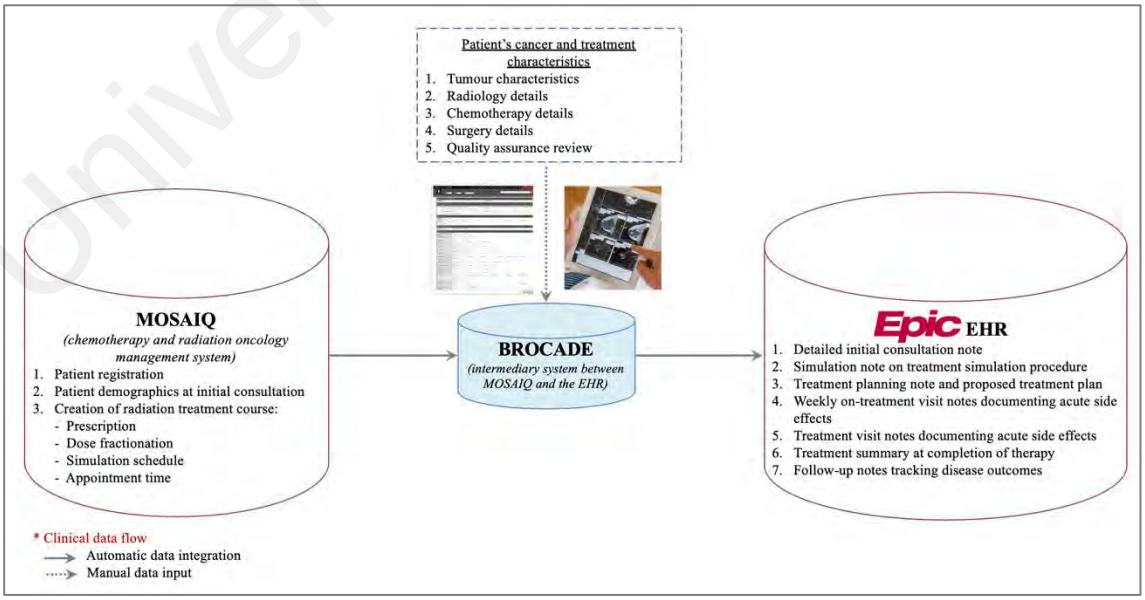


Figure 2.2: Brocade system by Texas MD Anderson Cancer Center

Based on Figure 2.2, patients will first register in MOSAIQ, where the system creates a radiation treatment course related to prescription, dose, appointment schedule and demographic details (Pasalic et al., 2018). Following visits clinical notes will be updated on cancer-site specific template of Brocade system, where it captures structured clinical data content of tumour characteristics, radiology, chemotherapy and surgery details as well as quality assurance review. These information are then automatically transmitted electronically to EPIC (Pan et al., 2017).

ARIA by Boston Medical Center (Russo, 2016; Varian Medical Systems, 2012) is another example of radiation oncology system which is externally linked to the hospital's EMR, and functions as an analytics resource system at the University of Michigan (Pan et al., 2017). ARIA is a commercially available software by Varian Medical Systems, Palo Alto but not widely used (Varian Medical Systems, 2012). An interface link is built between ARIA and the EMR as a measurement so data can be safely imported automatically to the EMR and making these clinical data available real-time on EMR interface.

2.8.2 EMR and clinical registries landscape in upper-middle-income countries

Many countries and regions, especially low-and middle-income countries, have not yet established national or regional registries (Rao et al., 2016). These technologies may be considered in the beginning. An automatic data input method may be adopted by some well-established registries as well.

The EMR system implementation in Thailand is a closed system within the country (Thavichachart, 2007). Thailand lacks legislation which provides for the sharing of health-related data between health care staffs through an electronic medical record at all level of health care services . It means that there is no legislation about the data sharing (i) within the same health care entity and its associated network of care providers, (ii)

with different health care entities (iii) with health care entities in other countries. Moreover, the country does not have legislation (i) which grants the right of access by individuals of their health-related data when held in an EMR (ii) which allows individuals to demand the deletion of personal data and/or health-related data from their EMR (iii) which allows for the transmission and sharing of research data containing personal and health-related data between research entities in different countries and (iv) about the legal right to specify which health-related data from their EMR can be shared with health providers of their choice (Kijsanayotin et al., 2010). Due to the shortage of health care workers, data entry has been inconsistent and has reduced the effectiveness and efficiency of the EMR (Narattharaksa et al., 2016)

Eighty percent (80%) of hospitals in China have implemented the electronic medical record system. However, they exist in many stand-alone and scattered systems across the country as they were built without long-term consideration of sharing information between EHR systems (Gao et al., 2013). Because of the lack of unified national approach, planning and governance framework, the quality of the EHR and EMR systems and the productivity of the development are low. EHR systems and EMR systems are regarded as different systems and operate in parallel respectively. EHRs are entered by community health service centres and EMRs are recorded in hospitals. Currently there is a lack of policy and regulation in China for recording, storing and using personal health information.

2.8.3 EMR and clinical registries landscape in lower-middle-income countries

In 2013, Ministry of Health and Family Welfare notified EHR standards for India (Kavitha et al., 2016; Sharma & Aggarwal, 2016). India has a mixed system of healthcare consisting of a large number of hospitals run by the Central Government and State Government as well as the private sector. In general, the level of use of ICT in the healthcare sector in the country has been lower in comparison to other countries (Srivastava, 2016). However, even in private hospitals, EMRs are rarely exchanged between hospitals. These remain in the same hospital and are referenced when the patient visits again. There is no authentic report on the number of patients whose EMRs have been stored so far.

The EMR usage and data is still scarce in the Philippines due its poor ICT infrastructure. It ranked as the 101st of 176 countries in ICT access and usage, according to ICT Development Index (IDI) 2017 by United Nations International Telecommunication Union (International Telecommunication Union, 2017). According to the Philippines e-Health Strategic Framework and Plan 2014-2020, the implementation of *Kalusugan Pangkalahatan* or Universal Healthcare in 2020 through a responsive health system will improve health outcomes (Philippines Department of Health, 2013).

2.9 Malaysian EMR Landscape and Clinical Registries

In Malaysia, the manual method of collecting clinical data has shifted to a digital system called the Electronic Health Management Information System. Almost all 130 public hospitals with a total of more than 33,000 beds, which represent 75% of the total hospital beds in the country, are linked to the Ministry of Health (MoH) headquarters through the Electronic Health Management Information System (Aljunid et al., 2012).

Clinical data are maintained in disparate systems and are not linked to one another (Ghani et al., 2018). There are at least five different sources of data from the surveillance system in which four of these are collected by various departments under the supervision of the MoH, which are clinic-based surveillance, laboratory-based surveillance, mandatory notification disease surveillance (Laws of Malaysia, 2006), community-based surveillance, as well as data source from foreign workers' medical examination (Ministry of Health Malaysia, 2008). Data from disease registries are maintained and developed by the MoH and professional bodies but these systems are under-maintained and inactive in managing clinical data. Strict regulations need to be implemented to keep the data up to date for secondary research use.

The accuracy of the data is one of the concerns in the country because uncertified deaths are not accurately documented in the death certificates, which go into the database submitted to the MoH. Documentation of diagnosis both in hospitals and in health centers is limited to single primary diagnosis while information on surgical and medical procedures is uncollected. The lack of documentation or in complete collection of data deprives the researchers and decision makers of the information regarding the complexity and severity of cases managed. Furthermore, this may limit the use of information for planning, budgeting, and quality-monitoring purposes. Patient-level data are not routinely collected both at the state level and at the central level which indirectly limits the data for research and policy development.

The Health Informatics Management System Blueprint (Health Informatics Centre Planning, 2013) was published in 2013 in outlining policies and strategies with action plans in the health sector. In 2017, the Malaysian Ministry of Health announced that the country will be starting a pilot project to integrate the health records of all Malaysians into one database, that will be ready by 2022 (B. Lau, 2017). It will then be accessible by

both public and private healthcare providers, where the system is set to store medical records of 300,000 Malaysians in south Malaysia before expanding nationwide. The National Heart Institute will embark on an EMR system next year as part of its strategic information technology plan to be a paperless hospital (Mageswari, 2018). There are many plans in implementing and strengthening the health information system in Malaysia, however it will take time to deploy and be assessed as stable and reliable for clinical use.

2.10 UMMC i-Pesakit©

The University Malaya Medical Centre (UMMC) EMR which is called i-Pesakit© is an established marketed product, made up of clinical content modules that is used to improve clinical care. This system was developed in-house and is an auto-digital data collection and sharing using EMR and auto-mapping of clinical data for secondary-use in clinical research studies and audit reporting. The UMMC i-Pesakit© EMR system was developed in January 2012 by the UMMC Department of Information Technology with seven main modules to cater to patient management activities which include; patient registration, outpatient, inpatient, Emergency Medicine visits, billing, folder tracking and reporting. The system has been operational since 1st July 2012. The expansion project started in September 2013 was extended to Primary Care Medicine clinic and recently the Breast Unit, Department of Surgery in 2016. To date 99% of UMMC clinical areas are using the UMMC EMR. This system effectively extracts clinical data for statistics and reporting of trends and long-term progress in a patient (Mohd Nor et al., 2019).

2.11 Summary

The literature indicates that there are inconsistencies in the present EMR structure in assisting clinicians effectively transcribe, share, and mine clinical findings; achieve integration of knowledge; or improve clinical care workflows and decision-making (Bewley et al., 2010; O'Malley, 2011; Romano & Stafford, 2011). Also, mixed results from the implementation of EMRs in specialized settings suggest that their use has had a limited effect on quality improvement patient care. There is a scarcity of information on EMR implementations on EMR and EHR particularly as most of the technical and development works are protected by data confidentiality issues. Through the literature review efforts, there is no right or wrong strategy in implementing EMR systems. The most important element in the success of EMR is what works best in the environment and current clinical setting. Based on scientific theories as well as clinical experience, this study implements the QIF which possibly serves as an effective framework in the breast cancer interdisciplinary clinical setting. This applied study approach serves as the foundation of direct improvement in diagnosis, treatment and care of patients, and better cost-utilization of health funds (Norwegian University of Science and Technology, 2019).

CHAPTER 3: METHODS IN DESIGNING THE SOLUTION

3.1 Overview

The possibility of technology assisting stakeholders to accurately capture data in a structured manner during clinical encounter through Electronic Medical Record, and with interoperability functions in primary and secondary data use offers a solution to the current EMR design that represents a paradigm shift in healthcare. In this study, the focus of development and implementation strategy was to solve specific EMR system interoperability issues, which include populating EMR including management of clinical data capture in patient care, establishing information technology and research focused governance model plus integrating clinical data from multiple internal clinical departments and external sources for reporting and quality measurement. This chapter presents the steps taken in the process of design, development, implementation and testing of i-Pesakit© Breast Cancer Module system for clinical and research workflow.

The overall strategy used to accomplish the specific aims of the study as described in Chapter 1.3 was focused on clinical workflow-based solution in the UMMC setting. The materials used in this study are described in Section 3.2, while in Section 3.3, the breast cancer clinical workflow in UMMC is presented. We used the Quality Implementation Framework (Meyers et al., 2012) as the methodology concept to implement the i-Pesakit© Breast Cancer Module proposed in this study. The development and implementation processes encompassing description of workflow methods based on Quality Implementation Framework are explained accordingly in section 3.4. The central idea of the EMR breast cancer module is a well-structured, interoperable module system that enhances clinical efficiency, while capturing accurate data from breast cancer clinical encounters and MDT meetings, in the practice of breast cancer in UMMC.

3.2 Materials: Data Source- i-Pesakit© Breast Cancer Paper Proformas

The source materials used in this study were obtained from the UMMC. Data sources include Breast Cancer Registry case report forms (CRF) (Copyright no: LY2018006705) (Figure 3.1, manual legacy Excel sheets (Figure 3.2), National Cancer Registry proforma (Figure 3.3), UMMC in-house EMR system (Figure 3.4) used by the clinicians, and clinical workflow requirements gathered from the front-end users who are the clinicians and nurses (Figure 3.5). i-Pesakit© Breast Cancer Module is designed based on the UMMC Breast Cancer Clinical Proforma, comprising details on diagnosis and treatments as well as other clinical characteristics involved in risk and prognosis of breast cancer patients.

UMMC breast cancer registry proforma is a set of clinical questionnaires used by clinicians to keep track of patients' progress from their encounter of first visit to the clinic, through diagnosis and treatment, as well as follow-up visits. The legacy Excel sheets are manual transcription records maintained by the surgeons as back-up datasets to these digital clinical proforma. Breast care nurses are responsible for the National Cancer Registry reporting, where this was previously transcribed manually and reported annually to the State Health Department.

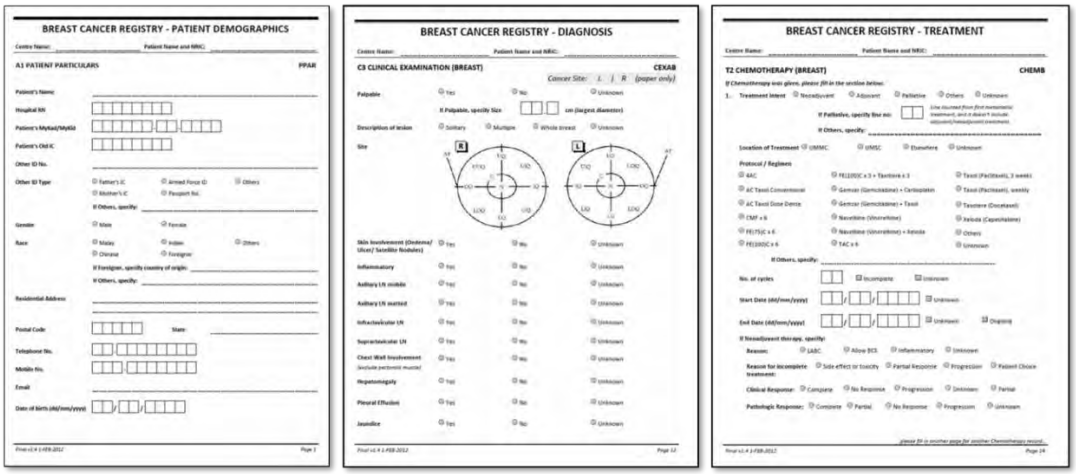
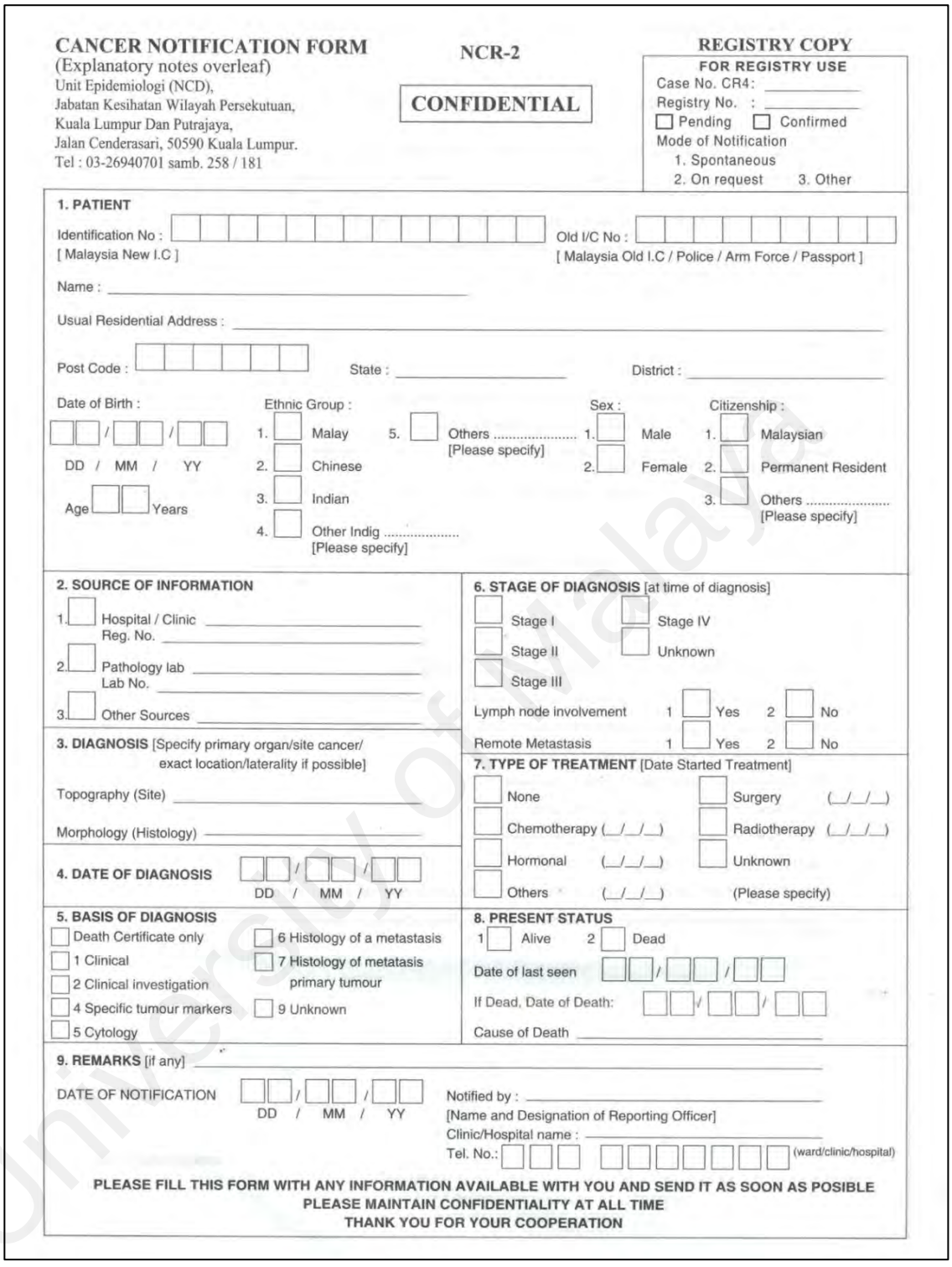


Figure 3.1: Breast Cancer Registry paper-based clinical proforma which started out in 2012 (Copyright no: LY2018006705)

No	NAME	UHRN	BIOPSY METHOD	DATE OF BX	DATE OF DX	STAGE	ER	PR	HER2	GRADE	PATHOLOGY SIZE	LATERALITY	LVI	MARGIN
1	##########	#$%^&*(!!	USCNB	21-Jun-2017	28-Jun-2017	1A	NEGATIVE	NEGATIVE	3+	3	1.9	R	POSITIVE	CLEAR
2	##########	#$%^&*(!!	USCNB	15-Jan-2018	24-Jan-2018	1A	POSITIVE	POSITIVE	1+	1	2.5	L	NEGATIVE	CLEAR
3	##########	#$%^&*(!!	USCNB	20-Mar-2017	28-Mar-2017	0	POSITIVE (>80%	POSITIVE (>80%	-	INTERMEDIATE	3.4	R	NEGATIVE	CLEAR
4	##########	#$%^&*(!!	CNB	5-Jul-2017	10-Jul-2017	2A	POSITIVE	POSITIVE	1+	1	4.5	R	NEGATIVE	CLEAR
5	##########	#$%^&*(!!	USCNB	9-Jan-2017	11-Jan-2017	2B	POSITIVE	POSITIVE	0	3	5	L	NEGATIVE	CLEAR
6	##########	#$%^&*(!!	HWLB	21-Sep-2017	4-Oct-2017	0	POSITIVE	POSITIVE	-	LOW	0.3	L	NEGATIVE	CLEAR
7	##########	#$%^&*(!!	USCNB	27-Apr-2017	3-May-2017	2	POSITIVE	POSITIVE	2+	2	4	R	X	X
8	##########	#$%^&*(!!	EX BX	3-Apr-2017	22-Mar-2017	X	X	X	X	X	2	R	X	X
9	##########	#$%^&*(!!	CNB	5-Apr-2017	28-Mar-2017	0	POSITIVE	POSITIVE	X	LOW	2	L	X	X
10	##########	#$%^&*(!!	US CNB	23-Jan-2017	26-Jan-2017	2B	POSITIVE	POSITIVE	1+	3	2.5	L	NEGATIVE	CLEAR
11	##########	#$%^&*(!!	CNB	6-Sep-2017	20-Sep-2017	1A	POSITIVE	POSITIVE	0	2	2	L	NEGATIVE	CLEAR
12	##########	#$%^&*(!!	USCNB	14-Nov-2016	21-Dec-2016	2A	POSITIVE	NEGATIVE	2+	3	0	R	NEGATIVE	CLEAR
13	##########	#$%^&*(!!	CNB	-	1-Aug-2017	3	POSITIVE	POSITIVE	2+	X	8	R	X	X
14	##########	#$%^&*(!!	CNB		1-Jun-2016	X	X	X	X	X	29	R	X	CLEAR
15	##########	#$%^&*(!!	CNB	27-Mar-2017	5-Apr-2017	3B	POSITIVE	POSITIVE	1+	2	1.1	R	POSITIVE	CLEAR
16	##########	#$%^&*(!!	CNB	18-Nov-2016	1-Dec-2016	1A	POSITIVE	POSITIVE	0	3	1.5	R	NEGATIVE	CLEAR
17	##########	#$%^&*(!!	CNB	8-Nov-2017	21-Jun-2017	2A	POSITIVE	POSITIVE	0	x	2.5	R	NEGATIVE	Anterior Margin
18	##########	#$%^&*(!!	CNB	6-Apr-2017	11-Apr-2017	2B	POSITIVE	NEGATIVE	3+	3	3.5	R	POSITIVE	CLEAR
19	##########	#$%^&*(!!	HWLB AND VAB	26-Feb-2018	1-Mar-2018	0	X	X	X	HIGH	X	R	NEGATIVE	CLEAR
20	##########	#$%^&*(!!	CNB	1-Nov-2016	1-Nov-2016	2B	POSITIVE	POSITIVE	3+	X	COMPLETED PA	L	NEGATIVE	CLEAR
21	##########	#$%^&*(!!	CNB	12-Oct-2017	1-Mar-2017	2A	POSITIVE	POSITIVE	0	2	25	L	NEGATIVE	ANT < 1MM MARGIN
22	##########	#$%^&*(!!	CNB	2014	2014	3	POSITIVE	POSITIVE	0	2	2	L	X	X
23	##########	#$%^&*(!!	CNB	12-Oct-2017	17-Oct-2017	4	POSITIVE	POSITIVE	1+	2	3	L	NEGATIVE	X
24	##########	#$%^&*(!!	CNB	15-Sep-2017	15-Sep-2017	3B	POSITIVE	POSITIVE	2+	2	5	L	NEGATIVE	X
25	##########	#$%^&*(!!	US CNB	1-Oct-2017	16/01/2017	3B	POSITIVE	POSITIVE	2+	2	10	R	NEGATIVE	CLEAR
26	##########	#$%^&*(!!	CNB	22-Feb-2017	22-Feb-2017	2B	POSITIVE	POSITIVE	0	2	3.5	R	POSITIVE	CLEAR
27	##########	#$%^&*(!!	CNB	13-Sep-2017	19-Sep-2017	3C	NEGATIVE	NEGATIVE	3+	3	2.5	L	POSITIVE	CLEAR
28	##########	#$%^&*(!!	CNB	6-Aug-2017	11-Aug-2017	3C	POSITIVE	NEGATIVE	2+	3	10	L	POSITIVE	CLEAR
29	##########	#$%^&*(!!	CNB	22-Feb-2017	2/27/2017	2A	POSITIVE	POSITIVE	0	2	3	R	NEGATIVE	x
30	##########	#$%^&*(!!	CNB	23-Oct-2017	23-Oct-2017	2A	POSITIVE	POSITIVE	0	2	3	R	NEGATIVE	CLEAR

Newly Diagnosed | Recurrence | RRM | SPECIAL CASE

Figure 3.2: Manual legacy Microsoft Excel clinical spreadsheets maintained by clinicians as back-up data sets to these digital clinical proforma



CANCER NOTIFICATION FORM
(Explanatory notes overleaf)
Unit Epidemiologi (NCD),
Jabatan Kesihatan Wilayah Persekutuan,
Kuala Lumpur Dan Putrajaya,
Jalan Cenderasari, 50590 Kuala Lumpur.
Tel : 03-26940701 samb. 258 / 181

NCR-2

CONFIDENTIAL

REGISTRY COPY
FOR REGISTRY USE
Case No. CR4: _____
Registry No. : _____
☐ Pending ☐ Confirmed
Mode of Notification
1. Spontaneous
2. On request 3. Other

1. PATIENT
Identification No : ☐☐☐☐☐☐☐☐☐☐☐☐ Old I/C No : ☐☐☐☐☐☐☐☐☐☐
[Malaysia New I.C] [Malaysia Old I.C / Police / Arm Force / Passport]
Name : _____
Usual Residential Address : _____
Post Code : ☐☐☐☐☐☐ State : _____ District : _____
Date of Birth : ☐☐/☐☐/☐☐ DD / MM / YY
Age ☐☐ Years
Ethnic Group : 1. ☐ Malay 2. ☐ Chinese 3. ☐ Indian 4. ☐ Other Indig ..... [Please specify] 5. ☐ Others ..... [Please specify]
Sex : 1. ☐ Male 2. ☐ Female
Citizenship : 1. ☐ Malaysian 2. ☐ Permanent Resident 3. ☐ Others ..... [Please specify]

2. SOURCE OF INFORMATION
1. ☐ Hospital / Clinic _____ Reg. No. _____
2. ☐ Pathology lab _____ Lab No. _____
3. ☐ Other Sources _____

3. DIAGNOSIS [Specify primary organ/site cancer/ exact location/laterality if possible]
Topography (Site) _____
Morphology (Histology) _____

4. DATE OF DIAGNOSIS ☐☐/☐☐/☐☐ DD / MM / YY

5. BASIS OF DIAGNOSIS
☐ Death Certificate only
☐ 1 Clinical
☐ 2 Clinical investigation
☐ 4 Specific tumour markers
☐ 5 Cytology
☐ 6 Histology of a metastasis
☐ 7 Histology of metatasis primary tumour
☐ 9 Unknown

6. STAGE OF DIAGNOSIS [at time of diagnosis]
☐ Stage I ☐ Stage IV
☐ Stage II ☐ Unknown
☐ Stage III
Lymph node involvement 1 ☐ Yes 2 ☐ No
Remote Metastasis 1 ☐ Yes 2 ☐ No

7. TYPE OF TREATMENT [Date Started Treatment]
☐ None ☐ Surgery (__/__/__)
☐ Chemotherapy (__/__/__) ☐ Radiotherapy (__/__/__)
☐ Hormonal (__/__/__) ☐ Unknown
☐ Others (__/__/__) (Please specify)

8. PRESENT STATUS
1 ☐ Alive 2 ☐ Dead
Date of last seen ☐☐/☐☐/☐☐
If Dead, Date of Death: ☐☐/☐☐/☐☐
Cause of Death _____

9. REMARKS [if any] _____
DATE OF NOTIFICATION ☐☐/☐☐/☐☐ DD / MM / YY
Notified by : _____
[Name and Designation of Reporting Officer]
Clinic/Hospital name : _____
Tel. No.: ☐☐☐ ☐☐☐☐☐☐☐ (ward/clinic/hospital)

PLEASE FILL THIS FORM WITH ANY INFORMATION AVAILABLE WITH YOU AND SEND IT AS SOON AS POSIBLE
PLEASE MAINTAIN CONFIDENTIALITY AT ALL TIME
THANK YOU FOR YOUR COOPERATION

Figure 3.3: National Cancer Registry Proforma for cancer annual incident reporting to the State Health Department used for breast cancer reporting in University Malaya Medical Centre

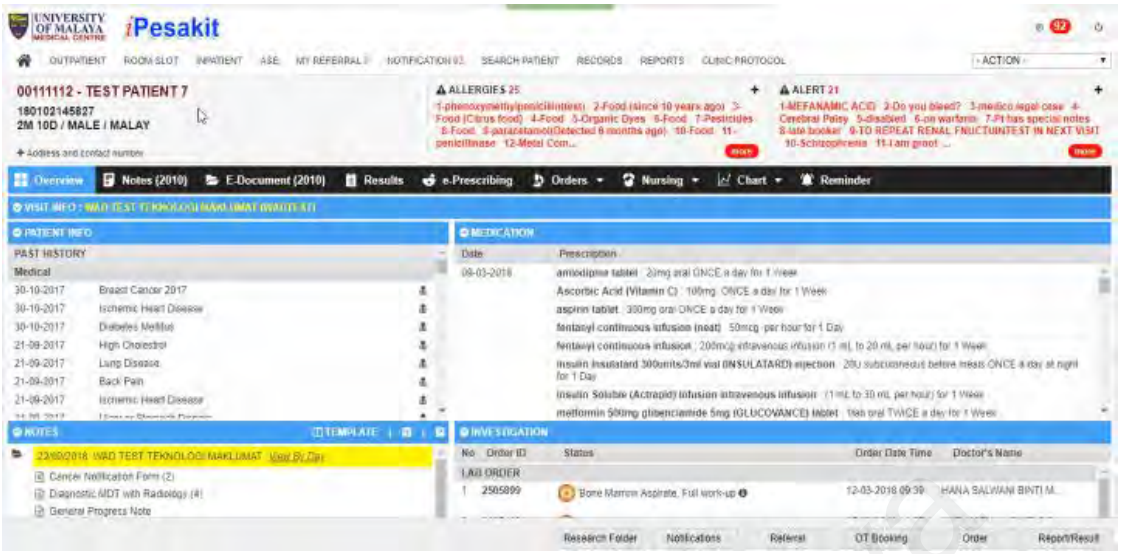


Figure 3.4: UMMC i-Pesakit© Electronic Medical Record dashboard

These multiple data sources were essential in achieving the breast cancer module's full potential through adaption of technology, where the system is implemented in a meaningful manner which covers patient care and clinical research, as well as primary and secondary data use, rather than simply being an electronic form of paper charts.

3.3 University Malaya Medical Center Breast Cancer Clinical Workflow

The basic EMR tools include patient demographics, history and medication record management, e-prescribing, as well as clinical notes in present care, treatment plans and follow-up visits for patients. A reliable EMR must be ICD-10 compliant (World Health Organization, 2016); which is the 10th revision of the International Classification of Diseases (ICD), a diagnostic tool initiated by the World Health Organization that monitors specific disease incidence. It is used to classify medical conditions in official health records, and breast cancer index is coded as malignant neoplasm of breast C-50. The UMMC's in house EMR i-Pesakit© is ICD -10 compliant. Typically, the breast cancer diagnostics workflow require input by surgery, radiology, pathology and pharmacy disciplines. In such circumstances, a systematic clinical data management and computational clinical workflow are needed to assist in generating meaningful clinical

data. The arrangement of digital clinical workflow through breast cancer diagnosis to treatment at the UMMC is described in Figure 3.5. The digital workflow presented in this study is structured according to the actual clinical routine sequence.

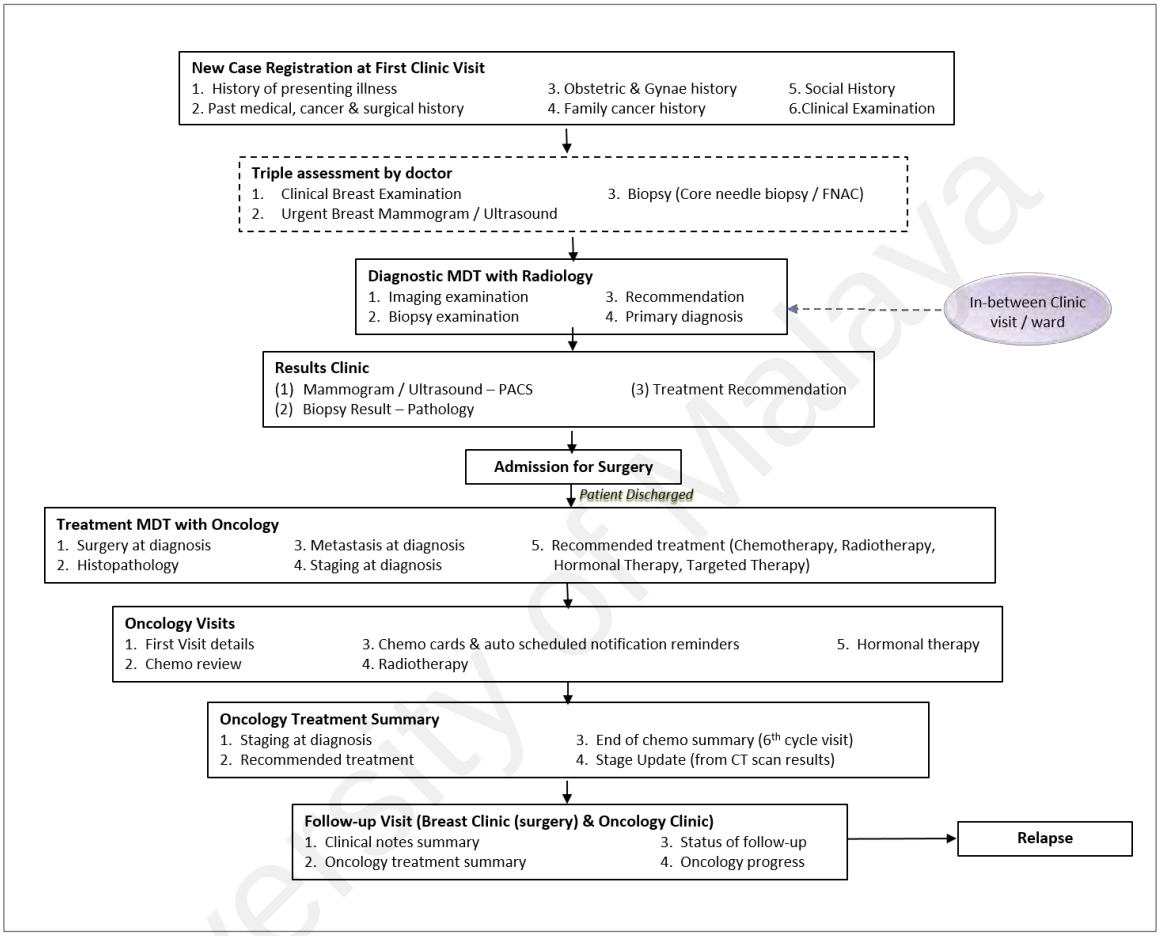


Figure 3.5: Breast cancer digital clinical workflow through diagnosis and treatment at University Malaya Medical Centre

This multidisciplinary work culture involves engagement from various clinical divisions. Each new patient goes to the first clinic visit where clinical breast check-up is done prior to imaging and biopsy examinations. These tests results are assessed and discussed during the diagnostic MDT before clinicians break the news to the patient on their next results clinic visit. Treatment plans are discussed during treatment MDT and oncology treatment is being carried out after that. This process is then continued with

follow-up clinic visits over time. For new patients admitted as emergency or diagnosed outside UMMC, there is a checkbox in the inpatient and first visit form within the electronic breast cancer module. In summary, workflow arrangement begins from encounter of first visit to the clinic, through diagnosis and treatment, as well as follow-up visits.

3.4 Methods Using the Quality Implementation Framework (QIF)

In this study, the Quality Implementation Framework (QIF) is adopted because it synthesizes existing models and research support to provide a conceptual overview of the critical steps that comprise quality implementation (Meyers et al., 2012). The QIF contains four temporal phases and 14 distinct steps as described in Table 3.1.

Table 3.1 Establishing i-Pesakit© Breast Cancer Module at the University Malaya Medical Centre using the Quality Implementation Framework

Phase One : Initial considerations regarding the host setting

Evaluation strategies

1. Conducting needs and resources evaluation
2. Clinical workflow analysis towards planning an automatic system for clinical and research
3. Conducting fit evaluation
4. Review and assessment of existing Breast Cancer Module template and incorporate the clinical stakeholders' input
5. Conducting capacity/readiness evaluation

Decisions about adaptation

6. Possibility for adaptation

Capacity building strategies

7. Formation of multidisciplinary breast cancer working group, with the support of the hospital director as well as hospital management team
8. Building general/organizational capacity
9. Effective pre-innovation staff training

Table 3.1, continued.

Phase Two : Creating a structure for implementation 1. Creating implementation teams and developing an implementation plan - Frequent meetings between stakeholders, system designers and developers in finding solution to establish an efficient digital workflow - Developing template content as closely as the clinical workflow with the advice of clinical stakeholders and content experts
Phase Three : Maintaining structure for continued implementation 1. Technical assistance/coaching/supervision - Provision of retraining clinicians who are the system users in implementing the system in clinics - Ongoing communication between team members and leader about integration of Breast Cancer Module within multiple departments 2. Process assessment - System evaluation survey among users of the Breast Cancer Module 3. Supportive feedback mechanism - Execution of adjustments to Breast Cancer Module and procedures based on feedbacks and updates by users
Phase Four: Improving future application 1. Learning from experience - Development of Breast Cancer Module templates for clinical research module using steps above from lessons learned - Expansion of Breast Cancer Module to other departments such as Pathology and Radiology

These steps comprise four QIF phases:

(i) **Phase one:** Initial considerations regarding the host setting; which involves assessing the UMMC system needs, available resources and readiness in incorporating this framework into existing clinical workflow

(ii) **Phase two:** Creating a structure for implementation; where implementation teams are established and an implementation plan is developed

(iii) **Phase three:** Maintaining structure for continued implementation; where technical assistance/coaching and supervision is engaged in this continuous process for system quality assessment through support feedback mechanism

(iv) **Phase four:** Improving future application; where similar implementation workflow can be adopted for other related departments such as Pathology and Radiology

Summary of the four implementation phases and 14 critical steps in the Quality Implementation Framework (Meyers et al., 2012) that are associated with quality implementation is presented in Figure 3.6.

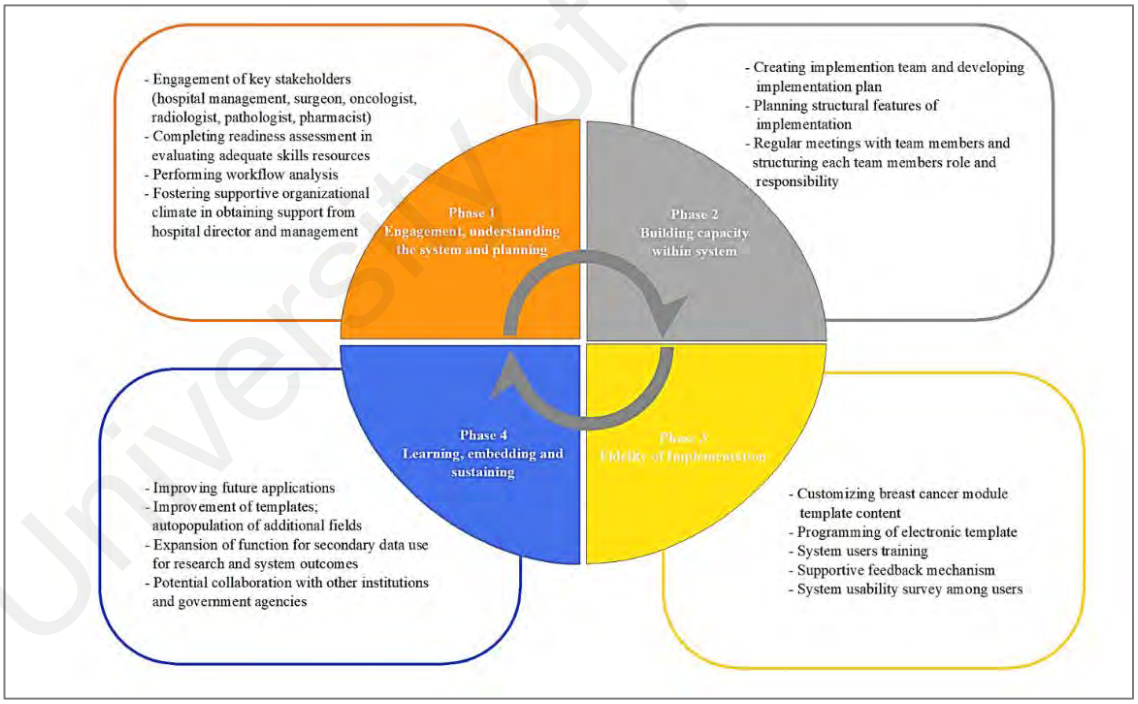


Figure 3.6: Framework and development of i-Pesakit© Breast Cancer Module adopted from 'Quality Implementation Framework (QIF) Model'

The diagram above indicates that first half of the phases are addressed before implementation begins, and the best approach is through combinations of activities that include assessment, collaboration, organized structuring, and, finally and preliminary analysis.

3.4.1 Phase One: Initial considerations regarding the host setting

3.4.1.1 Conducting a needs and resources evaluation

At the initial stage, a group comprising a multidisciplinary team of expertise was formed to evaluate different areas of assessment, in terms of needs, resources and requirements. The Breast Cancer Module is by itself a multidisciplinary clinical practice encompassing Surgery, Oncology, Radiology, Pathology and Pharmacy departments. The stakeholders and content experts are clinicians who are actively involved in day-to-day clinics from diagnosis to treatment and follow-ups, while the structure of system was designed by Bioinformaticians and developed by Information Technology (IT) experts. More importantly, engagement was done with the main stakeholders which are the Hospital Management Board, Ethics Committee and Patient Information Department responsible for policy making on clinical data regarding patient confidentiality. Before venturing into designing a new model for the breast cancer clinical and research data reporting, an assessment was conducted to identify specific issues and concerns in the current practice at the hospital. We identified concerns on data privacy and confidentiality under the Malaysia Personal Data Protection Act (PDPA) 2010 (Laws of Malaysia, 2010). Hence, several discussions to develop a system model and governance that is compliant to both the PDPA and research processes were done with these committees.

(a) ***Compliance to personal data privacy and confidentiality issues***

Personal Data Protection Act 2010 (PDPA) compliance (Laws of Malaysia, 2010); a set of regulations that provides data privacy and security provisions for protecting clinical

information was discussed with the UMMC Medical Records Department which is bound by the Malaysia Health Care Act and the National Archive of Malaysia Act. Data usability for research was conducted through safe and secure use of technology to automate data transfer into the UMMC Clinical Research knowledgebase via de-identification of primary patient records. This prototype fulfils the Health Level-7 standard (HL7), an international standard for data transfer of clinical and administrative information. The details of prototype are illustrated in the Results Chapter (Section 4.2). In the case of using clinical data with identifiers, written permissions were obtained from Medical Research Ethics Committee UMMC throughout the study implementation (MREC ID No: 733.22) (Figure 3.7).

UNIVERSITY OF MALAYA MEDICAL CENTRE

MEDICAL RESEARCH ETHICS COMMITTEE
(Formerly known as Medical Ethics Committee)
UNIVERSITY OF MALAYA MEDICAL CENTER
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE : 03-79493209/2251 FAXIMILE : 03-79492030

NAME OF ETHICS COMMITTEE/IRB Medical Research Ethics Committee, University Malaya Medical Center	**MREC ID NO**: 733.22
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	
PROTOCOL NO(if applicable) :	
TITLE: UMMC Hospital-Based Breast Cancer Registry	
PRINCIPAL INVESTIGATOR : NUR AISHAH BT MOHD TAIB	**SPONSOR** -

The following item [✓] have been received and reviewed in connection with the above study to conducted by the above investigator.

[✓] Application for Amendment/Notification to Research Project (form)	Ver.No : -	Ver.Date : 19-07-2016
[ ] Annual Study Report/Study Closure Report	Ver.No : -	Ver.Date : -
[ ] Serious Adverse Event Report	Ver.No : -	Ver.Date : -
[ ] Other documents		

and the decision is [✓]

[✓] Approved (Expedited)
[ ] Approved (Full Board)
[ ] Rejected (reasons specified below or in accompanying letter)
[ ] Noted

Comments:

-

The investigators are required to:

1) *follow instructions, guidelines and requirements of the Medical Research Ethics Committee.*
2) *report any protocol deviations/violations to Medical Research Ethics Committee.*
3) *provide annual and closure report to the Medical Research Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.*
6) *ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by research grant.*
7) *note that he/she can appeal to the Chairman of Medical Research Ethics Committee for studies that are rejected.*
8) *note that Medical Research Ethics Committee may audit the approved study.*
9) *ensure that the study does not take precedence over the safety of subjects.*

Date of expedited approval : 19-07-2016
Date of notification :
This is a computer generated letter. No signature required.

Figure 3.7: Medical ethics clearance issued by the Medical Research Ethics Committee University Malaya Medical Centre

(b) *Requirements of national cancer registry reporting*

The importance of a national cancer registry lies in the fact that they consolidate accurate and complete clinical cancer data as cancer control and epidemiological research, public health program planning, and patient care improvement. Ultimately, a complete national-level system of cancer registry can assist clinicians and researchers in understanding cancer better and maximize our resources for the best outcomes in treatment and prevention.

(c) ***Assessment of breast cancer reporting***

The UMMC Breast Cancer Registry begun in 1993 with data amounting to over 6000 individual patient data. This single page proforma that was consolidated into a spreadsheet had essential data that enabled UMMC to be the first to publish breast cancer outcomes in Malaysia and had enabled collaboration internationally to establish outcomes in Southeast Asia and Asia (Bhoo Pathy et al., 2013; Mohd Taib et al., 2008; Ong & Yip, 2003). A more complex UMMC Breast Cancer Registry Clinical Proforma was developed in 2009, which included details on diagnosis and treatments and other clinical characteristics involved in risk and prognosis of breast cancer patients. Data were collected manually through patients' visits through diagnosis and treatments prospectively and retrospectively from medical records. The work process was labor intensive and required training of non-medical personnel. Other manual workflow limitation includes the inability to keep track of patients' status, including recurrence and survival status.

3.4.1.2 Conducting a fit assessment

UMMC Electronic Medical Records (EMR) i-Pesakit© system was developed in January 2012 by the UMMC Department of Information Technology with seven main modules to cater for patient management activities which included; patient registration, outpatient, inpatient, Emergency Medicine visits, billing, folder tracking and reporting. The system has been operational since 1st July 2012. The system was further developed to cater for medical records requirements, which included clinical documents, orders and results. The expansion of UMMC EMR project started in September 2013 and was implemented as a pilot study in the staff health clinic a year later. The pilot project was extended to Primary Care Medicine clinic and the Breast Unit, and later Department of Surgery. The system is registered under the copyright act in July 2016 with Intellectual Property Corporation of Malaysia (MYIPO) and has already been commercialized. From

time to time, various iterative improvements had been made to the system to be able to work as required by clinicians. To date 99% of UMMC clinical areas implement the i-Pesakit© EMR.

However, the current i-Pesakit© system, only covered generic patient data which could only generate basic audit reports not aligned to the bigger aspiration of mining data for research outputs. Challenges in providing manual data transcription by salaried personnel provided avenues of building cost effective solutions for data management such as audits and for research. The primary objective was to collate accurate clinical data encompassing risk and prognostic variable and ensuring the ability to integrate with the legacy system. Hence, the assessment of institutional data management and users were aligned to build new solutions, tied up with the current hospital's EMR system which fits the environment and has been used for six years.

3.4.1.3 Conducting a capacity/readiness assessment and decisions about adaptation

Since EMR was implemented in 2012, the loss and misplacement of patient records and x-ray films, originally in physical paper folders, were drastically reduced. Ultimately, an ideal hospital information system should allow seamless connections and integration of other clinical departments to improve clinicians' work performance and produce positive healthcare institutional outcomes. Readiness for adaptation was evident as the department of surgery was slotted for complete breast cancer surgery department prototype module usage in 2016 which was designed and developed from scratch by the critical stakeholders.

In filling out the research data management gaps within this research hospital, the status of EMR implementation process and responses of clinicians on its impact on their routine in patient care has been positive. This feedback has inspired the establishment of ground work for next phase of breast cancer research module.

3.4.1.4 Possibility for adaptation : Development of the i-Pesakit© Breast Cancer Module

In order to improve the efficiency of clinical data management system in i-Pesakit©, restructuring of information-capture process and upgrading the system flow through engagement with the doctors' clinical work processes are crucial. A mechanism to translate paper-based operations to digital data capture is introduced and entries are reflected in the hospital's EMR system, which further extends to clinical audits based on primary data obtained. Uptake of EMR use in Breast Unit was largely due to the age cohort of the users, which are mainly Master of Surgery surgical trainees and medical officers (25 to 35 years old) who are quick to adapt to migration of work routine to a digital clinical workflow.

Due to poor retainment of staff in this public hospital, it is hence practical to move towards digital platforms. While the senior clinicians may perceive the system as hindrance to effective clinical work due to the inconvenience and concentration issues in multitasking between typing, paying attention to the computer screen rather than developing a rapport with the patients, this paradigm shift was timely as the impact of the system implementation contributes to both service and clinical data quality, as well as job performance.

(a) ***i-Pesakit© Breast Cancer Module Construction and Content***

Since the breast cancer workflow encompasses different departments in the hospital, it is ideal to design an interoperable system for sharing records between departments as well as structuring standards for integrating various clinical workflows.

Critical stakeholders from these units were engaged and agreeable to a workflow of interoperable system that would be adaptable to practices in these units. A digital clinical workflow was planned out as closely as the physical workflow as illustrated in Figure 3.5.

The framework and development of i-Pesakit© Breast Cancer Module, adopted from the QIF model is demonstrated in Figure 3.6.

(b) ***System Design and Construction: Mapping out clinical workflows***

The workflow of patient registration, diagnosis and treatment were carefully studied. This was the key in making decisions on the development of the breast cancer module. Standardized data entry forms that were compatible with the EMR system were created, by translating paper-format case report forms of the UMMC-BCR into an electronic case report form (e-CRF) before embedding the e-CRF design into EMR.

The system workflow is illustrated in Figure 3.8 where the design of Breast Cancer Module in EMR consolidates data input from the Surgery, Oncology and Pharmacy departments, which are merged with the existing patient details in EMR. The i-Pesakit© Breast Cancer Module system is used across multiple departments as electronic clinical workflow during clinic visits as well as breast cancer diagnostic and treatment multidisciplinary team meetings. The system design is catered for clinical as well as research workflows.

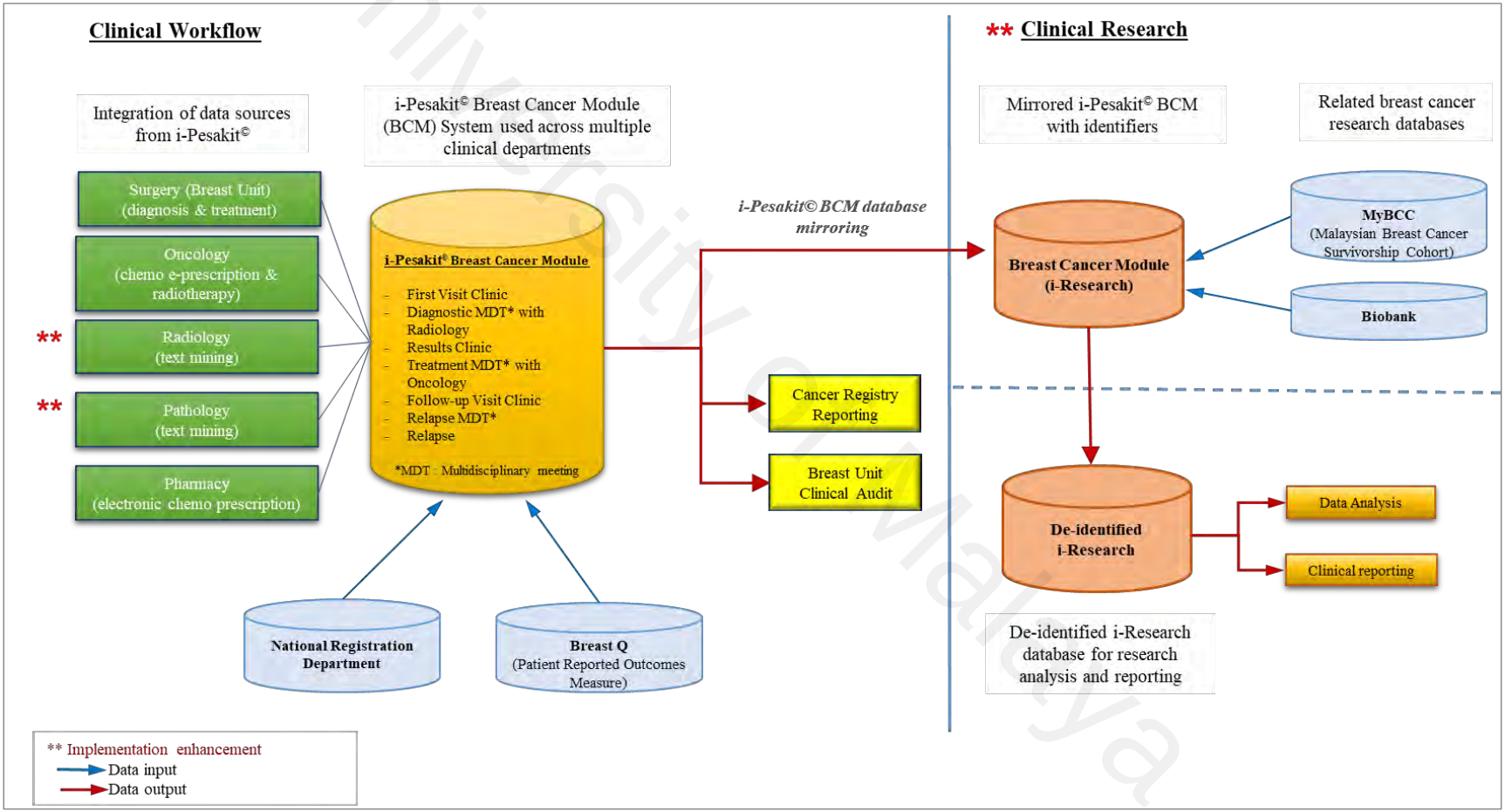


Figure 3.8: Architecture system of the UMMC i-Pesakit© Breast Cancer Module

The construction of the breast cancer module involves studying the requirements of the organization. Based on the workflow, a prototype was built by translating the CRF into computerized web forms, linking with the existing rudimentary patient details available in the EMR. The translation of the CRF into a web-based i-Pesakit© Breast Cancer Module is shown in Figure 3.9. A total of 42 case report forms (CRFs) were translated during the process of developing the breast cancer module; represented by six categories which are First Visit, Diagnostic Multidisciplinary Team (MDT) with Radiology, Results Clinic, Treatment MDT with Oncology, Oncology Visits, and Relapse. In the Pharmacy department, the prescription of chemotherapy regime and cycle have been digitized and incorporated in the Breast Cancer Module electronic prescription system as demonstrated in Figure 3.10.

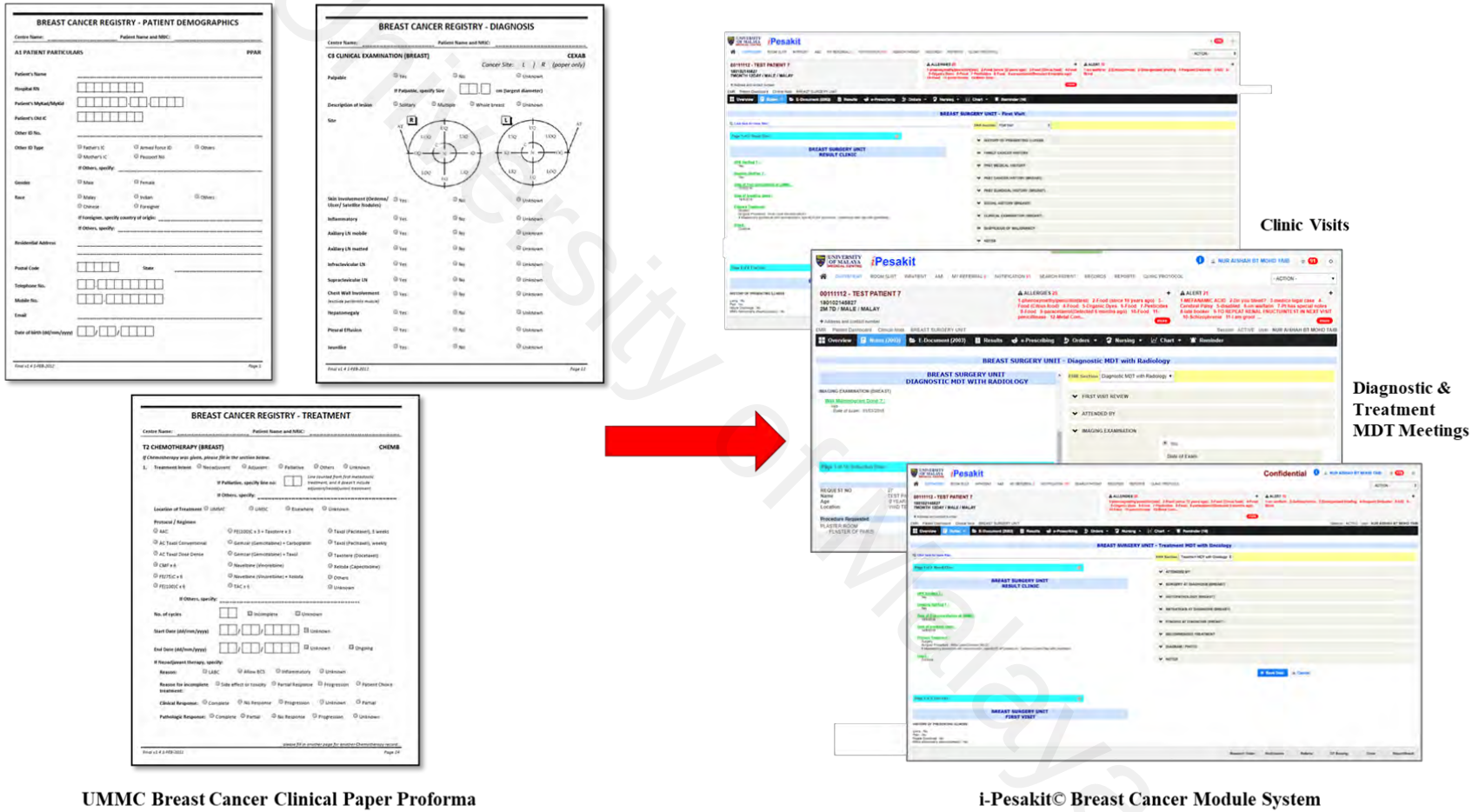
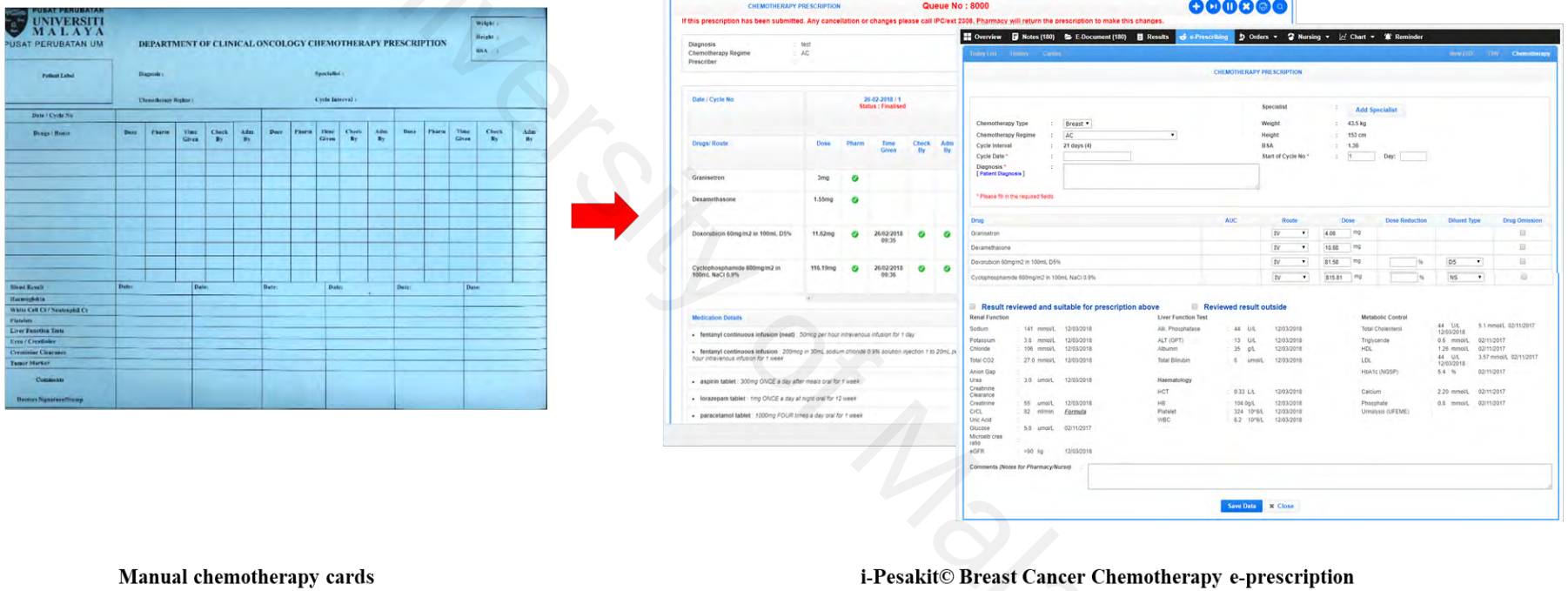


Figure 3.9 Translation of breast cancer proforma into a web-based UMMC i-Pesakit© Breast Cancer Module



Manual chemotherapy cards **i-Pesakit© Breast Cancer Chemotherapy e-prescription**

Figure 3.10: Translation of paper-based clinical oncology chemotherapy prescription to the i-Pesakit© breast cancer chemotherapy electronic prescription

The detailed design of data definition dictionary of the Breast Cancer Module is illustrated in Table 3.2. Each template contains different sets of definition to suit each stage of patients' clinic visits.

Table 3.2: i-Pesakit© Breast Cancer Module data definition dictionary

I-Pesakit© Breast Cancer Module template	**Template description**
First Visit	1. History of presenting illness 2. Family cancer history 3. Past medical history 4. Past cancer history 5. Past surgical history 6. Past gynecological history 7. Clinical breast examination
Diagnostic MDT with Radiology	1. Breast imaging examination - mammogram / ultrasound 2. Breast biopsy examination - FNAC / Core biopsy / Excision biopsy / Stereo biopsy/ US guided biopsy / HWLB / Frozen section
Results Clinic	1. Primary breast diagnosis 2. Primary treatment - curative / palliative
Treatment MDT with Oncology	1. Breast surgery at diagnosis 2. Breast histopathology - Histology type / size / focality of lesion / grade / lymph nodes / ER / PR / HER2 / margins 3. Metastasis at diagnosis 4. Staging at diagnosis - Clinical / pathologic staging 5. Recommended treatment - Chemotherapy / radiotherapy / hormonal therapy / targeted therapy

Table 3.2, continued.

Chemotherapy e-Prescription	1. Chemotherapy regime 2. Chemotherapy cycle 3. Diagnosis
Follow-up Visit	1. Status at follow-up 2. Screening / benign breast follow-up
Relapse MDT	1. Treatment intent - Curative / palliative 2. Recommended treatment - Chemotherapy / radiotherapy / hormonal therapy / targeted therapy
Relapse	1. Progression at follow-up 2. Relapse HPE - Site of biopsy / ER / PR / HER2 3. Oncology progress

The EMR was implemented on MariaDB and open source systems for the system developmental work. Currently, the breast cancer module contains data sources from the Surgery, Oncology and Pharmacy departments. The fully automated EMR breast cancer module is being used in the clinical visits as well as for audits, while further enhancement will be made in integrating other related sources from Radiology and Pathology for a more compact system.

3.4.1.5 Obtaining explicit buy-in from critical stakeholders and fostering a supportive community/organizational climate

The hospital management board, including of the hospital director, Patient Records Department, Hospital Informatics Department were among the crucial stakeholders with decision making power, were engaged very early in the project. The vision for the hospital to apply the 4th Industrial Revolution (Lee et al., 2014) was very much aligned to this project. Hence, the support received to further this project from critical stakeholders was very important in the development process. The second step was through engagement of content experts, clinicians include surgeons, oncologists, radiologists, pathologists, and pharmacists, as key stakeholders in each of these departments. The engagement was done in stages, where surgical and oncology departments as well as e-prescription of chemotherapy with the pharmacy department were engaged for the pilot project.

The collaboration between academics, graduate students and programmers was able to foster close relationships, sharing of tasks despite shortage of manpower within the service sector. The researchers played a role in providing detailed logs of changes and became the conduit between the user and the programmers. The greatest disincentive if we are not able to produce an automated system is challenges to salary personnel to continue manual data collection.

3.4.1.6 Building general/organizational capacity

Organizational capacity includes recruiting more system designers and developers, and task sharing between academia, graduate students and project-based programmers. We discovered organizational policies with regards to developing IT solutions for handling of digital data in the confines of the PDPA needs improvement and proper policy and protocols in place to ensure smooth implementation.

This includes processes of obtaining permission for students and researchers to work within the hospital departments where initial challenges were encountered and resolved when trust and clear boundaries were defined.

3.4.1.7 Staff recruitment/maintenance

The implementers of the system are the clinicians of UMMC, so training and ongoing support will be given to users to build their capacity in knowledge about the system. A breast care nurse is assigned to oversee this day-to-day system use in the clinic and holds the role as a middle person between the implementers and system designers to provide feedbacks about the system. Figure 3.11 describes the core team members involved directly or indirectly in the project from permissions to execution and testing. There are different categories of roles in the implementation team involving the project manager who is the quarterback of the EMR implementation group, project team members include critical key stakeholders; the hospital management, governance team, physician champions, bioinformaticians and IT staffs in designing and building the EMR module, as well as nurse leads for evaluation and quality assurance team in doing on-site testing and user trainings.

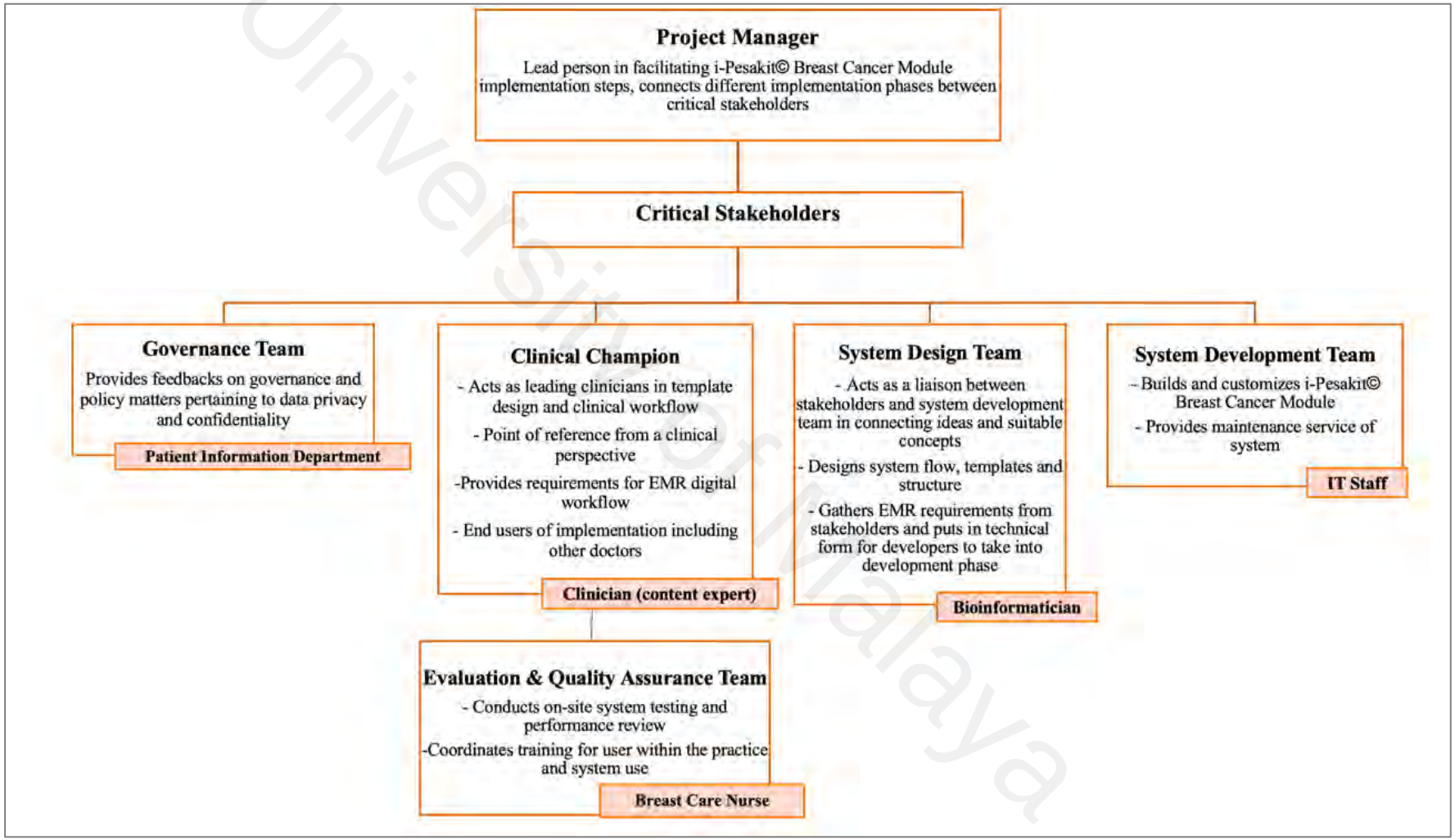


Figure 3.11: Core members of i-Pesakit© Breast Cancer Module implementation team

3.4.1.8 Effective pre-innovation staff training

A protocolled training session is carried out every three months for new rotating medical officers in the unit. This training is conducted by the breast care nurses. Training can positively influence clinicians' willingness to use the breast cancer module effectively and enhance understanding of how the system can be leveraged to improve clinical practice through the use of advanced features.

3.4.2 Phase Two: Creating a structure for implementation

In order to ensure the success of any implementation, the people involved need to have the right expertise and roles and secondly, a viable plan is needed ahead of the development. In this study, our team is multidisciplinary with distinguished roles who have been assigned with dedicated tasks and timelines. A summary of the team members with job scopes is presented in Figure 3.11.

3.4.2.1 Creating implementation teams

As illustrated in Figure 3.11, there are five groups of core members in this EMR implementation; (i) project manager and critical stakeholders include (ii) hospital management and governance team, (iii) physician champions, (iv) system design and development, as well as the (v) evaluation and quality assurance teams. The project manager is the lead person in facilitating these implementation steps, connects different implementation phases and coordinate the planning, design, development, and testing phases between team members. The hospital management and governance team from the Patient Information Department provide feedback on governance and policy matters pertaining to data sharing, privacy and confidentiality. Physician champions have credibility with clinical staffs and hospital administration, to promote value of the innovation through stakeholders engagements. They are also the main point of reference from the clinical perspective, also as content experts and EMR functionalities so the

digital workflow matches closely to the actual clinical workflow. The system designers (bioinformaticians) act as a liaison between physician champions and system development team (IT staff) in connecting ideas and suitable concepts. Bioinformaticians design the digital system workflow, templates and structure through gathering EMR requirements from physician champions and put in technical form for system developers to take into development phase. IT staff are responsible in building, customizing and deploying the breast cancer module, as well as providing maintenance service of the system to be conducted by the evaluation and quality assurance team (breast care nurse). Nurses conduct on-site system testing and performance review and coordinates training for users within the practice and system use.

Workflow analysis is done in the planning stage where bioinformaticians study the existing clinical work processes, looking for opportunities for improved efficiency, assessing and designing new workflows and system structure and developing a transition plan towards a digital clinical workflow environment. Good communication is crucial between bioinformaticians and clinicians, in coming up with the best solution of improvised workflow that is time effective and user friendly for the frontline implementers.

The IT experts are responsible for deploying and constructing the EMR system. Participation of clinical staff in the implementation process increases support for and acceptance of the EMR Breast Cancer Module implementation. In line with the hospital management support and participation of clinical and non-clinical staff, having an interdisciplinary implementation group involves direct stakeholders working together, where a better EMR system can be delivered faster and with less problems.

Some difficulties were foreseen in implementation and monitoring of the busy medical officers hence, qualified staff on-site to oversee and support implementation were played

by breast care nurses. As a central role on the team, they understand these EMR clinical workflows inspire clinical staff to embrace change, and drive consensus among other clinical staff. There is a close collaboration and feedback mechanism between implementers, supportive team (breast care nurses), physician champions, as well as EMR design and development team in fine tuning the system from time to time.

3.4.2.2 Developing an implementation plan

(a) ***Breast Cancer Module within the Electronic Medical Record***

Implementation plan involved designing the pilot system and going live with technical back-up support and specific tasks starting with First Visit template (Figure 3.9) for all new cases, progressing with follow-up for cancer patients. There is a mechanism in place to produce quality entries as medical officers are accountable to document EMR professionally, to ensure the clinical service as well as data are high quality.

Progressively other templates were used, through the development of e-Prescription of chemotherapy from the Oncology department to Pharmacy department (Figure 3.10) as well as specific clinical templates for the departments of Radiology and Pathology.

Eight months after the implementation process began, the prototype system went live on February 2016. Support for users is provided with a two-tiered approach. On-site support is available from the trained breast care nurses who understands the EMR workflow to oversee the system. If the problem persists, an information technology services staff member is called for support by phone. This has allowed the majority of technical problems to be solved locally.

In the first few months after implementation, occasional meetings between clinicians and bioinformaticians were called to address specific issues that arose. Implementing an EMR breast cancer module system is challenging. It requires good planning, strong

physician leadership and supportive clinical and non-clinical staff. The most immediate benefits of the EMR Breast Cancer Module are accurate diagnostics, treatment plans, legible notes, prescriptions, and lower transcription costs.

The focus of the study was extended to integrating and enhancing the system interoperability according to clinicians-specific function requirements, support and maintenance (impact on technical architecture), as well as data availability and sharing amongst clinicians in providing meaningful representation of patient data electronically. In the testing stage, further enhancement effort was done to improve user friendliness, according to accurate clinical and nursing workflows.

(b) ***Clinical Research Registry Design: The database mirroring concept***

A critical factor for successful utilization of available EMR clinical data for research is the access, management and analysis of integrated patient data, within and across different functional domains. For example, most clinical and basic research data are currently stored in disparate and separate systems, and it is often difficult for clinicians and researchers to access and share these data. Equally important is the assurance within EMR systems of security, with confidentiality, integrity and general trustworthiness to meet the requirements for high quality research data.

In innovating a practical approach to develop a clinical research workflow and framework, the EMR System Mirroring was designed to provide an economical solution for rapid, reliable, robust, automatic failover between two database systems, making mirroring the ideal solution in minimizing redundant components and risk of human error transcriptions.

The clinical research registry use and workflow is in line with the Clinical Data Interchange Standards Consortium (CDISC) (Kuchinke et al., 2009; Noumeir, 2008)

which supports the electronic acquisition, exchange, regulatory submission and subsequent archiving of clinical research data. Developing a new system for clinical research is not practical due to overhead cost of programming, generating new requirements specifications, system design and development as well as infrastructure. Hence EMR mirroring for the purpose of clinical research is the best and cost-effective solution. Successful case studies have proposed to automate data transfer from primary EMR models for clinical research (Goodman et al., 2012; Rogers, 2010; Terry et al., 2009) without using vendor specific third party clinical research databases.

As a tertiary hospital, UMMC practices good clinical practice, research and clinical audit which are essential to the provision of good patient care. Epidemiology research, public health surveillance and health service planning, are among the important secondary uses of patient information. For many secondary uses, disclosing only de-identified data or coded information are sufficient. However in some clinical studies where identifiers are needed, it is practicable to disclose information as long as it conforms to the medical confidentiality guideline (Wah et al., 2011). When clinical research and audit are conducted for the purpose of hospital service quality measurement, the information shall be anonymized for clinical reporting purposes. As such, quality assurance mechanisms are needed to ensure that the EMR system adheres to certain quality characteristics. The governance framework and design structure of EMR fulfils the Principles of Confidentiality as stated by Malaysian Medical Council Confidentiality 2011 Guideline (Wah et al., 2011), which supports clinical data usage for research, clinical audit and secondary use. In ensuring the confidentiality of data for secondary use is protected, a multi-level data access and authorization will be implemented where only registered users have access to these data, as well as appropriate level of access among clinicians, researchers and research assistants. Identifiable information is only usable for research if that has obtained the approval from the Research Ethics Committee (Figure 3.7) The

development and implementation of the clinical research workflow components will only be conducted in future enhancement works.

3.4.3 Phase Three: Ongoing structure once implementation begins

3.4.3.1 Technical assistance/coaching/supervision

Training clinicians and nurses to effectively use the breast cancer module into their clinical workflow is an important step to a successful implementation in ensuring data is entered in a standardized manner. Quality, safety, and integrity of data are protected, while it increases the efficiency of clinical care, especially through point of care (POC) adoption in the clinical setting. Ongoing training is conducted from time to time when there are additional functionalities introduced to the system, including producing clinical audits and contribution to national statistics in measuring the hospital's performance.

The challenging environment of staff shortage affects the time taken in updating the systems according to clinical needs. There is a need for programmers to resolve feedback quickly as not to lose momentum and affect the digital clinical workflow. Training of medical officers by breast care nurses, briefing for each new staff to the team is important to ensure the EMR Breast Cancer Module usage is maximized. The breast care nurses' expertise has knowledge on how daily operations work in a clinical setting, so testing and quality reviews can be performed for data security, proper functionality within the department, performance review, and to verify the system closely matches the actual clinical workflow.

The EMR workflow that was created matches closely with the clinical workflow to ease the transition of manual to digital clinical workflow among clinicians. This was a crucial step to prevent potential barriers in implementing this new system where users may resist in using the digital template and may wrongly use the templates in their workflow. The information technology lead is responsible for deployment and operation

of the software and hardware such as workstations, in providing IT support in servers and connection issues. Constant change and improvement of system is conducted from time to time in improving the system usability and performance.

3.4.3.2 Process evaluation

(a) ***System Usability Test and Evaluation***

Initial adaptation of the breast cancer module was tested with the users in the department. The pilot system has gone live since February 2016, and a usability survey was conducted to test the readiness of EMR adaptation in the breast cancer workflow. The system test evaluation survey material (Dhillon et al., 2018) (Appendix A) was adapted from Evaluation of Electronic Medical Records Questionnaire (Lærum, 2003). The questionnaire was designed to measure these aspects:

(i) Details on i-Pesakit© Breast Cancer Module usage for clinical tasks

(ii) General use of the Breast Cancer Module and paper-based medical record

(iii) Clinical work performance when using the breast cancer module system

(iv) Users' satisfaction about the content, usability and timeliness of the i-Pesakit© Breast Cancer Module in the department

(v) Global assessment of the system implementation in the department

(vi) Comments and suggestions by front-line system users to improve the patient care with the newly developed system

Descriptive statistics analysis was conducted to analyze the data gathered from participants' feedbacks survey. These tests include percentages for categorical data (ordinal and nominal) ; averages, and standard deviations as well as confidence intervals for continuous data. The questionnaire (Appendix A) consisted of three demographic items, 31 Likert scale questions (Joshi et al., 2015), six multiple choice questions and one open-ended inquiry for comments and suggestions by the participants. Graphical

summaries of responses were curated for the global assessment of the system implementation in the department. The questionnaires were distributed, and all six participants returned the questionnaires. Although the sample size was small, it represented the total user diversity in a one-day clinic setting; specialists, registrars and senior medical officers. There are three components in the survey which uses Likert scale, and these evaluation scoring is defined in Table 3.3 by questionnaire sections.

Table 3.3: Evaluation of i-Pesakit© Breast Cancer Module using Likert scale scoring

Questionnaire Section	Likert Scale	No of questions
Details on i-Pesakit© Breast Cancer Module usage for clinical tasks	Never/Almost never (+1) Seldom (+2) About half of the occasions (+3) Most of the occasions (+4) Always / Almost always (+5)	8
General use of the Breast Cancer Module and paper-based medical record		3
Users' satisfaction about the content, usability and timeliness of the i-Pesakit© Breast Cancer Module in the department		12
Clinical work performance when using the breast cancer module system	Significantly more difficult (-3) More difficult (-2) Slightly more difficult (-1) No change (0) Slightly easier (+1) Easier (+2) Significantly easier (+3)	8

(b) ***Comparison of completeness and accuracy of medical assessment findings between manual workflow process and a newly implemented i-Pesakit© Breast Cancer Module workflow***

A retrospective study in assessing the accuracy of clinical findings found in paper charts compared to i-Pesakit© Breast Cancer Module system was conducted. 193 clinical records of Breast Oncology Treatment Multidisciplinary Meetings from 1 January 2017 to 31 December 2017, at University Malaya Medical Centre were reviewed. Each data fields were crosschecked independently and verified by a consultant surgeon using predefined criteria to determine whether they were accurate and complete. Descriptive analysis was performed to calculate the frequency of inaccuracies and incompleteness for each EMR information field. This time frame was chosen to capture a full year of implementation of the i-Pesakit© Breast Cancer Module system. To assess the completeness and accuracy of the system, the following parameters from the breast oncology treatment MDT that were selected:

(i) Date of breast surgery

(ii) Type of breast surgery

(iii) Grade of breast cancer (Bloom-Richardson grading)

(iv) Estrogen receptor (ER) status

(v) Progesterone receptor (PR) status

(vi) Human epidermal growth factor receptor 2 (HER2) status

These attributes were chosen as important factors that affect breast cancer prognosis and treatment. The primary outcome was the accuracy of documentation, recorded as being either accurate, inaccurate, omitted (missing values) (Yadav et al., 2017). A clinical finding was considered to be accurate if the expected finding for the diagnosis being evaluated was documented in the clinical assessment portion of the progress note. A

clinical information was considered to be inaccurate if an incomplete record or the opposite of the expected finding for the diagnosis being evaluated was documented. A clinical finding was considered omitted if there was no mention of a clinical assessment associated with the diagnosis. A few examples of these are listed in Table 3.4.

Table 3.4: Pre-defined criteria of accurate, inaccurate and omitted clinical data for i-Pesakit© Breast Cancer Module system evaluation

Clinical Element	**Expected Manual Transcription Finding**	**Expected i-Pesakit© Breast Cancer Module Transcription**
Date of Surgery	Date of Surgery	Accurate: Surgery date Inaccurate: Different date Omitted: No mention of surgery date recorded
Grade (Bloom-Richardson grading)	Grade of breast cancer	Accurate: Grade 1/2/3 Inaccurate: Incorrect / non-similar record to manual finding Omitted: No mention of grade of breast cancer
Estrogen receptor (ER)	ER status	Accurate: Positive / Negative Inaccurate: Incorrect / non-similar record to manual finding Omitted: No mention of ER status
Progesterone receptor (PR)	PR status	Accurate: Positive / Negative Inaccurate: Incorrect / non-similar record to manual finding Omitted: No mention of ER status
Human epidermal growth factor receptor 2 (HER2)	HER2 status	Accurate: 0 / 1+ / 2+ / 3+ Inaccurate: Incorrect / non-similar record to manual finding Omitted: No mention of HER2 status

Based on this scoring, an assessment of clinical information was captured by i-Pesakit© Breast Cancer Module system after its first full year of implementation. The objective of this evaluation is to test the accuracy of clinical data documented by the new breast cancer module system versus UMMC's legacy manual transcription system.

To test the system's efficiency in establishing capture of newly diagnosed cases, a demographic pie chart and frequency summary chart were plotted to compare the frequencies of new breast cancer cases captured by i-Pesakit© Breast Cancer Module and the manual legacy data from February 2016 to December 2017 throughout the first two years of implementation.

3.4.3.3 Supportive feedback mechanism

In getting rapid and accurate feedbacks from first-hand users, there are three main mechanisms of communication to provide an on-going technical assistance. The first mechanism is via public talks at the hospital under the E-health initiative ("University of Malaya e-health initiative: Where medicine meets ICT," 2017) started by the hospital. Second approach is by engaging faculty members and hospital EMR committee which includes the IT management team in the hospital and finally frequent communication with the breast care nurses who provide direct feedbacks from doctors who use the system on-site. These methods will create understanding among involved parties on how the implementation process is progressing, as well as recognizing strategies to improve the system.

From time to time adjustments are made by the programmers based on feedbacks given by users and stakeholders. However, in order to expedite the process of correcting bugs or errors, more programmers can be recruited, or students can be engaged in the development team.

3.4.4 Phase Four: Improving future applications

3.4.4.1 Learning from experience

Through this exercise, we have a designed plan, which is generic to be implemented in other departments in the hospital. It is good that the foundation used in the Breast Cancer Module is the hospital's existing EMR system, hence the upper layer design workflow can be reused to match the requirements in the other departments such as Radiology and Pathology. Continuous efforts are under way in maintaining and improving the Surgery, Oncology and Pharmacy modules using the feedback form provided to end users. The model derived from the experience of design and implementation of the module has taught the importance of incorporating a platform for research that has access to both confidential data and editing capabilities, as working on cancer would need identifiers and communication with other bodies.

As aforementioned, the model is in line with the standards laid out by the Clinical Data Interchange Standards Consortium (Clinical Data Interchange Standards Consortium, n.d.) The CDISC standard has also been applied in prominent research on EMR (Hudson et al., 2018; Kuchinke et al., 2009; Noumeir, 2008).

3.5 Conclusion

I-Pesakit© Breast Cancer Module was developed based on the Quality Implementation Workflow conceptual model (Meyers et al., 2012) as a guide in implementing innovations of the breast cancer module. It provides overview of ideas of implementation framework which assists system designers and developers to adopt the steps in previous successful framework that implemented similar projects, which covers the pre- , during, and post-implementation phases. These steps were implemented according to the UMMC setting suitability.

CHAPTER 4: RESULTS

4.1 Overview

This chapter presents the findings of this study, where outputs of i-Pesakit© Breast Cancer Module development and implementation are demonstrated. The first section describes the system content features of the seven main breast cancer clinical templates, while the second part focuses on the auto-populated mechanism for national cancer registry reporting and system outputs for secondary data use. In this study, a prototype module that consolidates clinical data from Surgery, Oncology and the Pharmacy department is successfully developed. The i-Pesakit© Breast Cancer Module is used widely in clinics, wards, as well as diagnostic and treatment multidisciplinary meetings with Radiology and Oncology departments in discussing breast cancer diagnosis and treatment plans. Other usages and outputs of the system are also explained in this chapter. The system has gone live at the Surgery Department since February 2016 and throughout this period up to today, many milestones were achieved while improvisation of system is made from time to time in enhancing the breast cancer module system interoperability.

4.2 System Content Features and Implementation into Clinical Workflow

Effective clinical documentation is an indispensable part of breast cancer management. With the abundance of electronic medical information overtime, the system interoperability functions and usability structures of EMR have become a crucial issue. Complicated EMR structures may be a hindrance to end-users in completing electronic clinical workflow tasks. In i-Pesakit© Breast Cancer Module, system structure and content strategy are in-line with the manual clinical workflow sequence, so clinicians could accurately transcribe, retrieve, organize and mine pertinent clinical data accordingly during clinic sessions, multidisciplinary team meetings as well as secondary use.

Diagrams of i-Pesakit© Breast Cancer Module outputs in UMMC Surgery and Oncology departments are presented in Figure 4.1 to Figure 4.11. The main sections of the system consist of UMMC EMR Dashboard, templates of First Visit, Diagnostic MDT with Radiology, Treatment MDT with Oncology, Relapse MDT, Results Clinic, Follow-up Visit, Relapse, and Breast Cancer Chemotherapy e-Prescription. As demonstrated in these figures, the specialized system functional design and structure for each clinical form template are in line with the clinical workflow routine sequence.

The two menu top bars, patients' details summary and allergies information are constantly visible across the screen regardless of which clinical template clinicians are working on. The upper bar shows different segments of i-Pesakit© which include outpatient and inpatient information, patient search, clinic protocols and reports retrieval functions. The second bar is an array of menu for the searched patient which contains information of clinical overview, notes, charts and results, e-documents, e-prescription and clinical procedure orders systems.

I-Pesakit© Breast Cancer Module is an embedded module within the EMR. A mix of different types of questionnaires are used such as multiple-choice questions, radio-button answer options, textboxes, checkboxes, dates selections and digital drawings. Users are navigated to the breast cancer module from EMR dashboard by selecting the *Surgery* heading from the list of clinical departments, which then immediately displays a series of surgical template options displayed as subheadings. The i-Pesakit© Breast Cancer Module is executed via *Breast Surgery Unit* subheading shown in Figure 4.1. The drop-box menu selection of breast cancer module section is available on the right of the screen and a clinical record summary is displayed on the left side in Figure 4.2, and are available at every stage of the breast cancer module template.

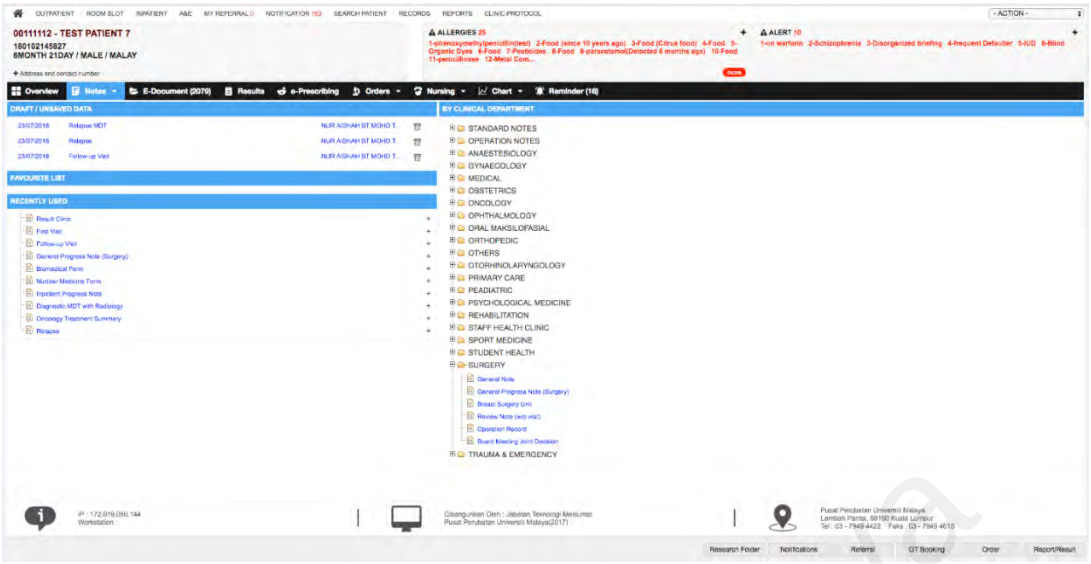


Figure 4.1: UMMC i-Pesakit© electronic medical record dashboard

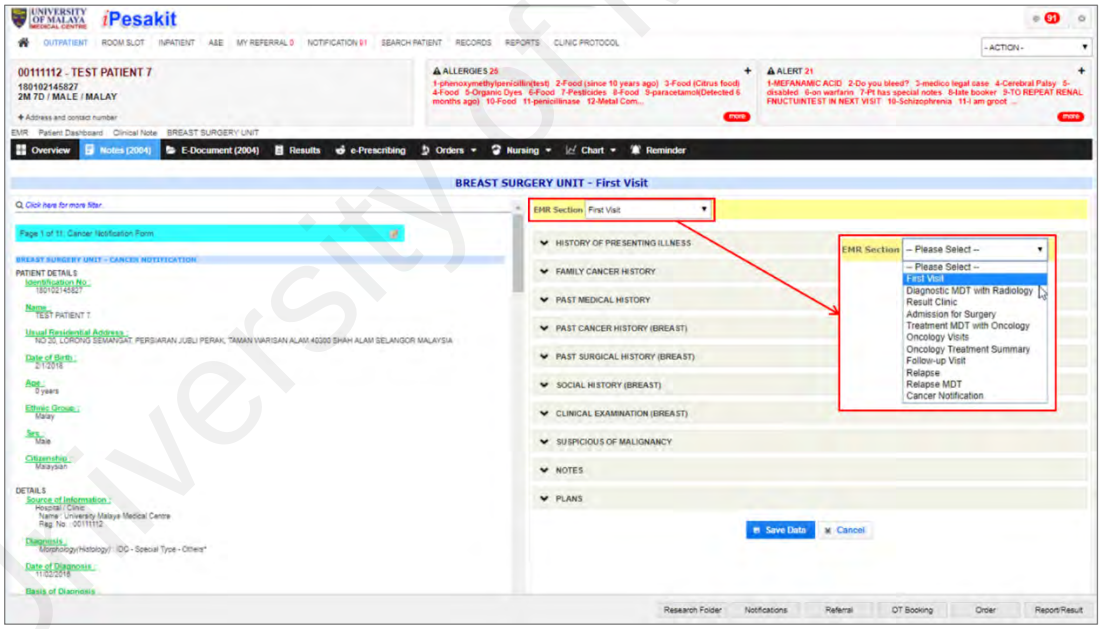


Figure 4.2: i-Pesakit© Breast Cancer Module First Visit template

Upon each new case registration at Breast Surgery Clinic, the First Visit form template (Figure 4.2) is used by clinicians to asses patient's past medical and present illness backgrounds as well as previous cancer, surgical, and gynecology histories. Breast clinical examination results are transcribed, and suspicion of malignancy are recorded as well and these medical inputs are transcribed at clinical point-of-care. Clinicians can also type additional free text in the text box at the bottom of the page under the Notes or Plans tabs. An automatic display summary is available on the left window when clinicians save the clinical inputs, which improves usability and data accessibility for clinicians to review these notes during the next follow-up clinic visits. The most suitable format in the First Visit template is multiple choice question with radio-button answer options due to the large number of questions to go through during the clinic visit (Figure 4.3).

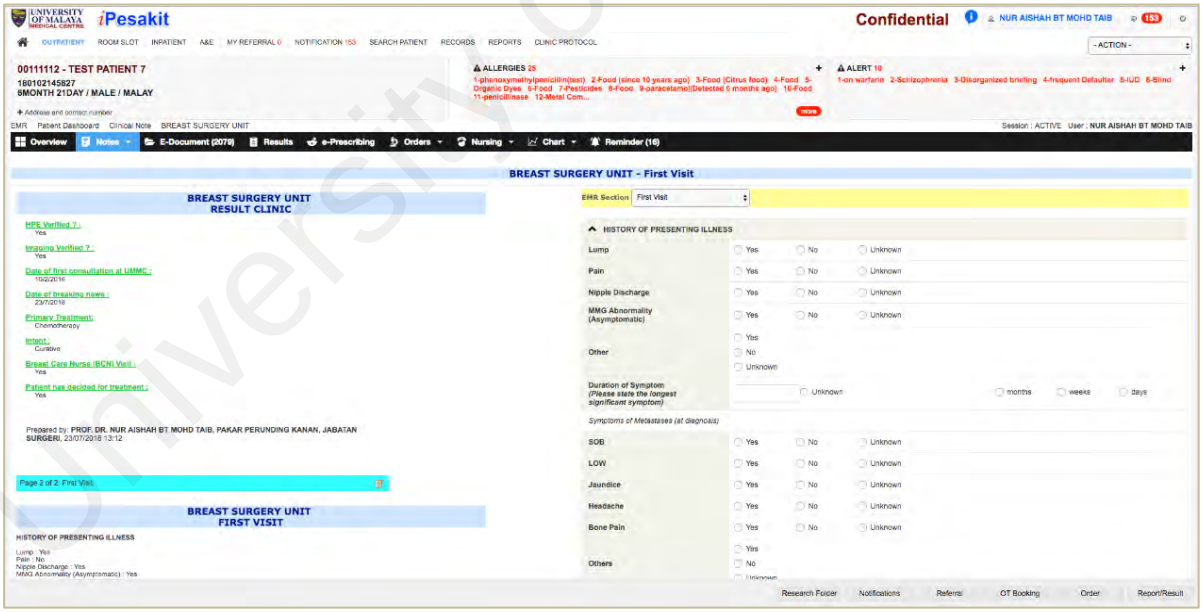


Figure 4.3: Multiple-choice questions with radio-button answer options for First Visit section template

This newly implemented system supports basic and advanced functions which allow multidisciplinary users to experience the interoperability system between clinical departments. Multidisciplinary care is regarded as the most ideal practice in breast cancer management, where the patients are formally reviewed by a specialist team. The breast cancer team involves surgeons, radiologists, oncologists, pathologists, breast care nurses as well as pharmacists.

Diagnostic MDT meeting with Radiology template from the breast cancer module is used during the weekly diagnostic MDT meeting, as presented in Figure 4.4. The beginning of the page, an auto-generated first visit review is displayed from patient's previous visit, as clinicians' reference to discuss breast cancer diagnosis, imaging and biopsy examinations results during the meeting. These inputs are transcribed into the system in real-time by a designated MDT member, and the digital template arrangement is in line with the actual meeting discussion sequence. The main component of the template, which is the breast cancer diagnosis are as characterized in Table 4.1. Imaging examinations include mammogram, breast ultrasound, axillary ultrasound (US), CT scan and bone scan; while biopsy examinations include fine-needle aspiration cytology (FNAC), core biopsy, excision biopsy, stereo biopsy, ultrasound guided biopsy, and hookwire localization excision biopsy (HWLB).

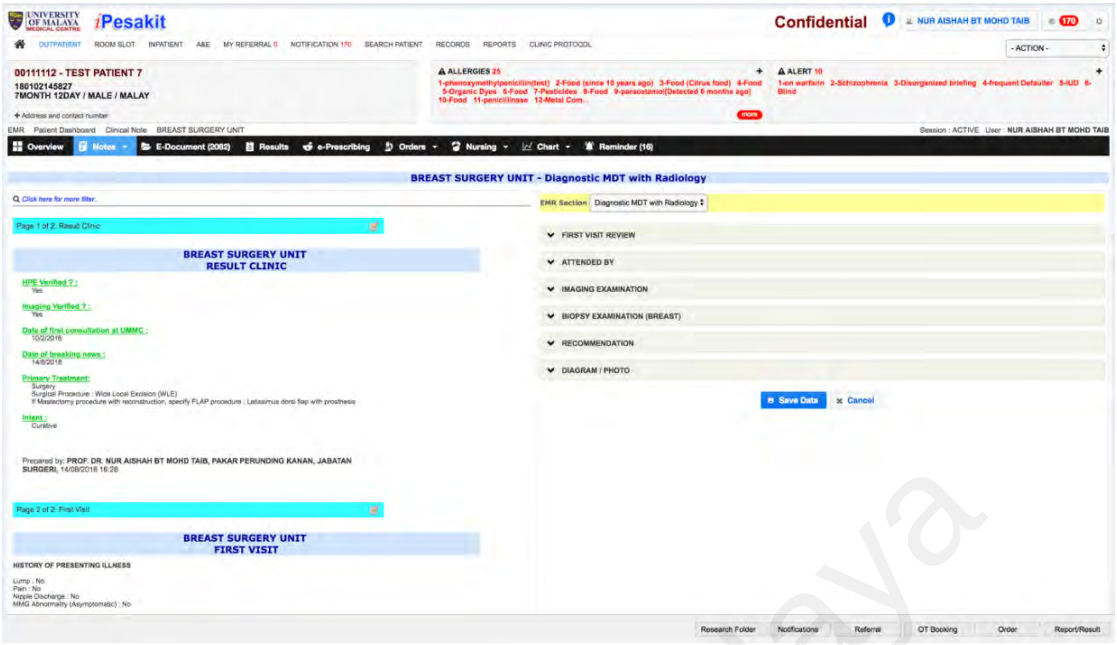


Figure 4.4: i-Pesakit© Breast Cancer Module Diagnostic MDT with Radiology template

Table 4.1: Breast cancer diagnosis details in Diagnostic MDT meeting with Radiology template

Imaging examination	**Details**
1. Mammogram	- Date of examination - Type - Size in cm - Breast density score
2. Breast ultrasound	- Bi-RADS - Breast percent density - Multifocal - Multicentric
3. Axillary ultrasound (US)	- Date of examination - Axillary lymph nodes involved / suspicious - LN FNAC details
4. CT Scan	- Date of examination - Scan findings
5. Bone scan	
Biopsy examination	**Details**
1. FNAC	- Date of examination - Biopsy location
2. Core biopsy	
3. Excision biopsy	
4. Stereo biopsy	
5. Ultrasound guided biopsy	
6. Hookwire localization excision biopsy (HWLB)	

The next significant feature of i-Pesakit© Breast Cancer Module is the ability to browse clinical notes, lab reports, and treatment plans with tabs in current window, specific data editing roles for clinicians and nurses, as well as data sharing between related clinical departments. More importantly, it implements the point-of-care data collection method which increases the efficiency of clinical workflow. Not only this approach is suitable during clinic visits, it is highly useful in the treatment and relapse MDT meeting with Oncology as shown in Figure 4.5 and Figure 4.6.

Overall, findings from these meeting observations confirmed the importance of breast cancer module system in discussing treatment options. The use of the system impacted interactions in meetings and stimulates interdisciplinary team discussions, through projection of Treatment and Relapse MDT with Oncology template forms onto a screen and entering real-time clinical data. The treatment MDT components consist of breast cancer surgery details, histopathology, metastasis, staging information and recommended treatments; while relapse MDT section includes treatment intent details.

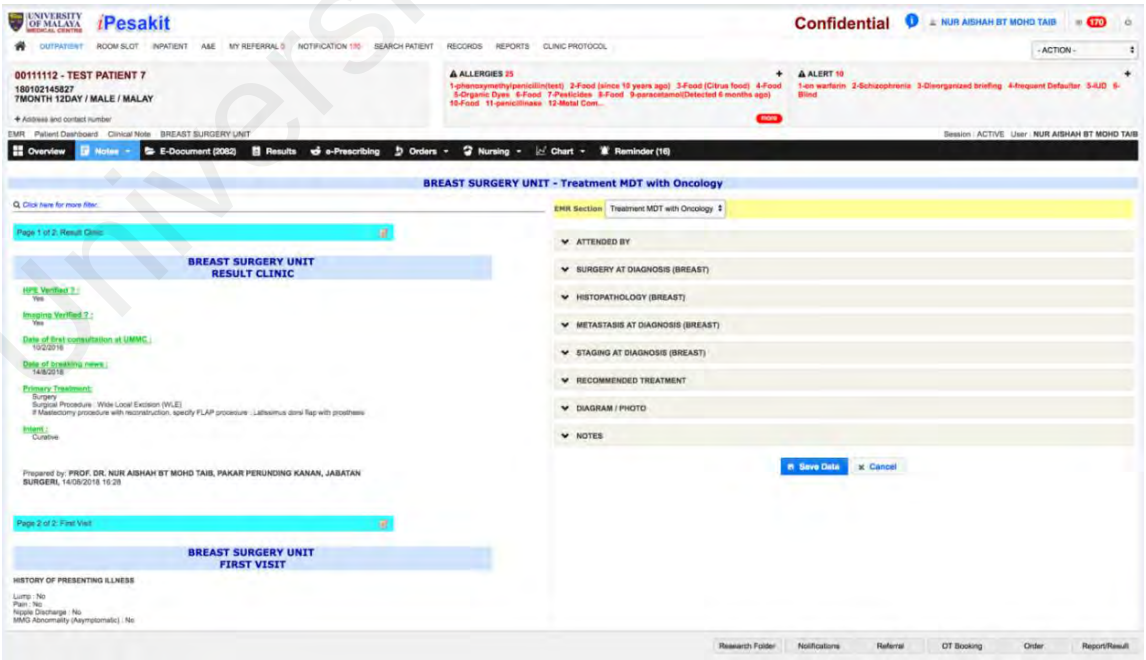


Figure 4.5: Treatment MDT with Oncology template

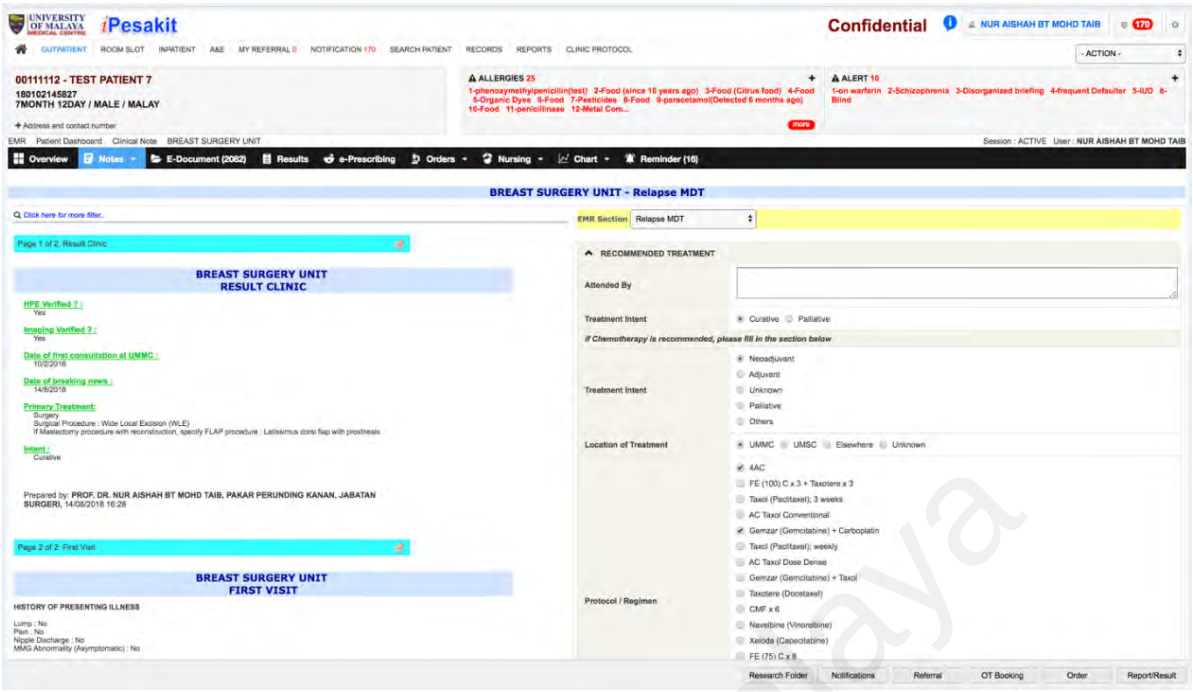


Figure 4.6: Relapse MDT template

The straightforward user content strategy and structure design by coordinating with the digital workflow system in Figure 4.7 provides an overview of the Results Clinic section layout which combines Yes/No, dates, free text, check-boxes, and multiple-choice questions types in a single template. Templates for Follow-up Visits and Relapse also implemented this similar design approach as shown in Figure 4.8 and Figure 4.9.

At the beginning of the page of the Results Clinic template, an auto-generated review from the previous diagnostic MDT is displayed for clinicians' references. Each clinical template is unique on its own and it follows through from one treatment stage to another. However, due to the intermediate level of usage among users, there is a lack of continuity of data flow. Conducting periodic user training would be useful and creating a cancer journey icon will provide an effective system guideline solution. This breast cancer module implementation has successfully developed a plan to help redirect electronic clinical workflow at the point-of-care to enhance effectiveness in the use of the EMR structured clinical documentation. Through these favorable outcomes, it may be implemented in other clinical departments of the breast cancer group as well in the future.

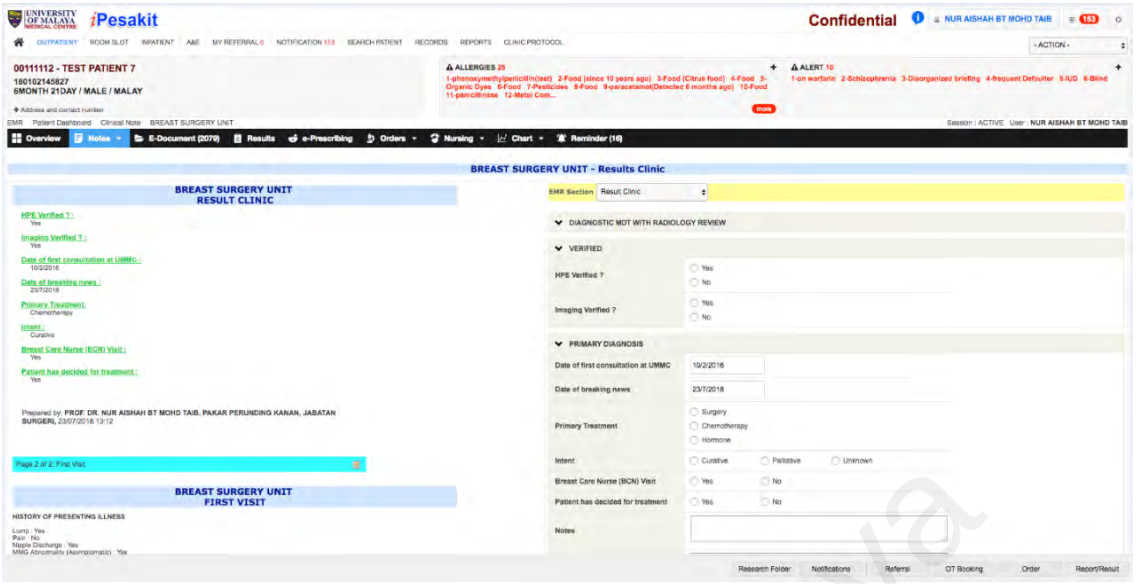


Figure 4.7: i-Pesakit© Breast Cancer Module Results Clinic template

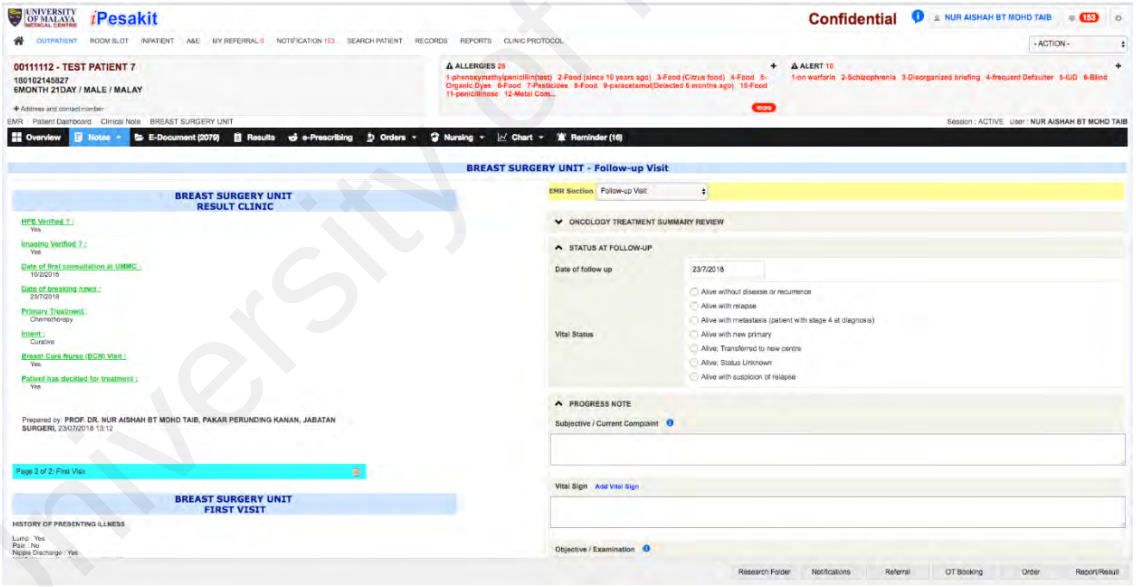


Figure 4.8: i-Pesakit© Breast Cancer Module Follow-up Visit template

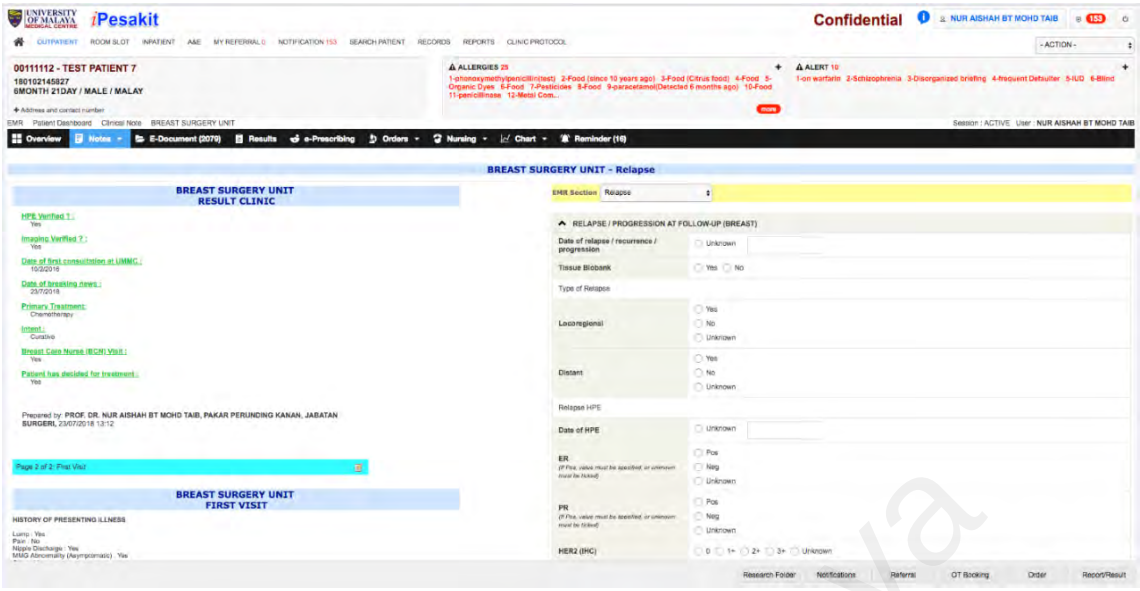


Figure 4.9: i-Pesakit© Breast Cancer Module Relapse template

Another system content feature of the i-Pesakit© Breast Cancer Module is the electronic chemotherapy prescription for breast cancer patients, as shown in Figure 4.10 and Figure 4.11. Prescribers can view patients' medical records and treatment plans from the i-Pesakit© Breast Cancer Module and new chemotherapy regime orders are sent through online. A two-layer security is implemented, where two oncology nurses double check the prescription before prescription is forwarded to the pharmacy department for chemotherapy drug dispensing. The main components of the electronic prescribing chemotherapy module are chemotherapy regime, cycle interval and date (Figure 4.10). Through this e-prescribing platform, oncologists may easily incorporate the practice into their clinical oncology routines as the electronic workflow design is similar to the manual workflow. These chemotherapy summaries will be reflected in the i-Pesakit© Breast Cancer Module oncology summary review (Figure 4.11).

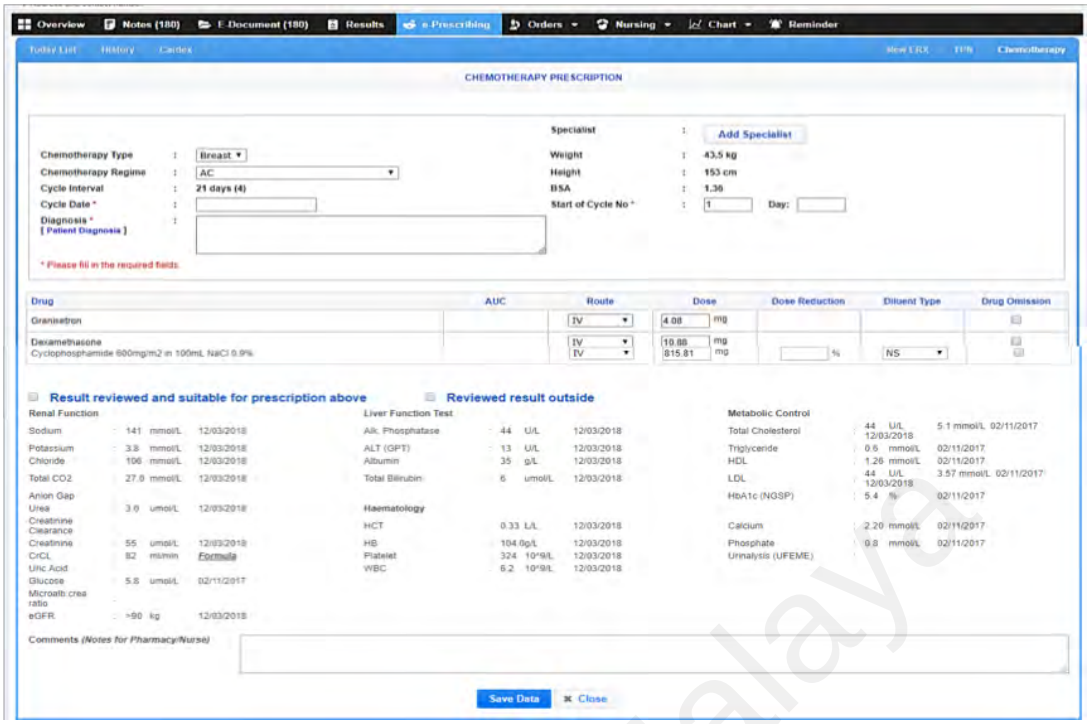


Figure 4.10: i-Pesakit© Breast Cancer Chemotherapy e-prescription

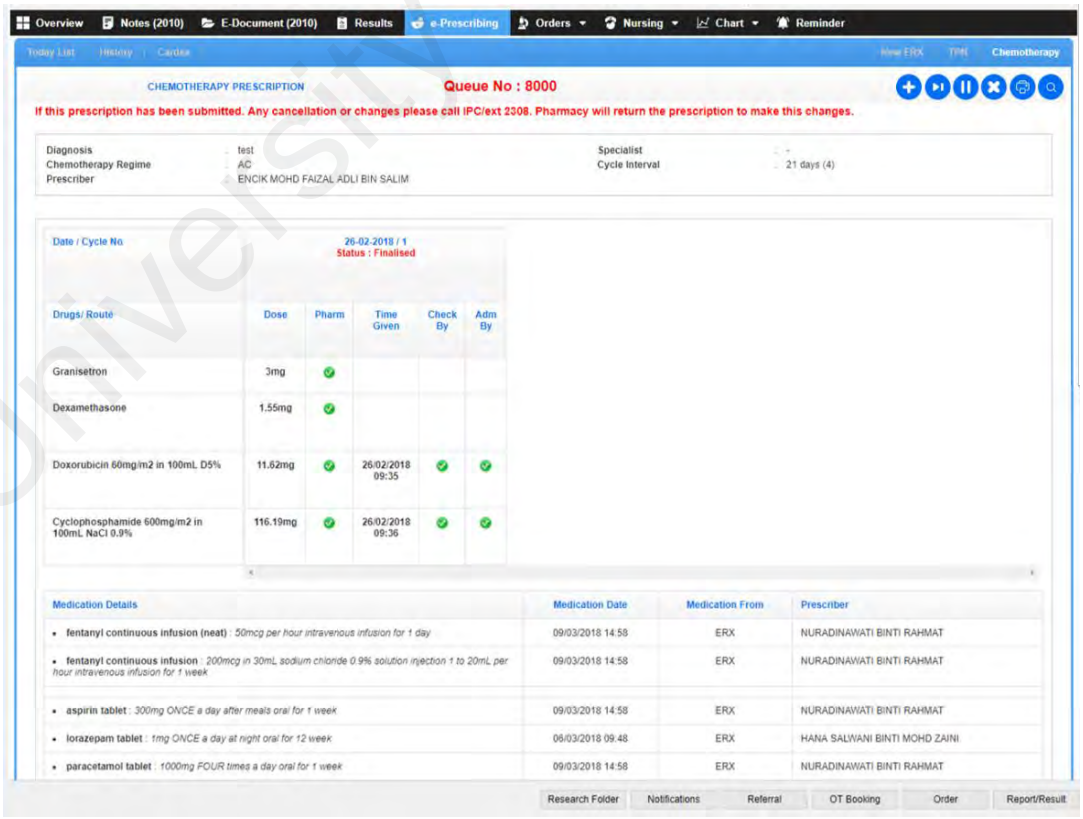


Figure 4.11: i-Pesakit© Breast Cancer Chemotherapy e-prescription summary

The integration of chemotherapy prescription into the UMMC EMR system infrastructure permits real-time access to patient information, including treatment parameters, and documentation of chemotherapy administration sequence. The electronic chemotherapy prescribing template is electronically linked to pharmacy and nursing systems, which allows electronic validation process in nursing workflow. Completed chemotherapy prescriptions are immediately sent to the pharmacy department for validation and preparation of chemotherapy. Overall, this online prescribing system involves multidisciplinary teams of oncologists, nurses, and pharmacists with rounds of evaluation and validation before dispensing chemotherapy.

4.3 Secondary Use of i-Pesakit© Breast Cancer Module

In addition to i-Pesakit© Breast Cancer Module's primary purpose in clinical workflow, it serves as the main data capture points for secondary data use. Data mining, analytical modules and machine learning techniques in prediction works, especially in breast cancer recurrence and survivorship studies are important as they guide national cancer control policy. Clinical data contained in or derived from the breast cancer module are used for various purposes. There is a wide range of secondary uses of the data: clinical audit and clinical governance; support of survivorship cohort studies; clinical registry reporting; audits against national standards; national statistics; and measuring quality performance for future services planning.

4.3.1 Auto-populated National Cancer Registry reporting

As the primary use is to support patient care, it is also important in generating registry reports for the Malaysian National Cancer Registry reporting. Automating this data extraction process reduces human resources and produces more accurate form of reporting. What stands out in this function is that manual transcription process can be reduced through this automatic data capture workflow as shown in Figure 4.12.

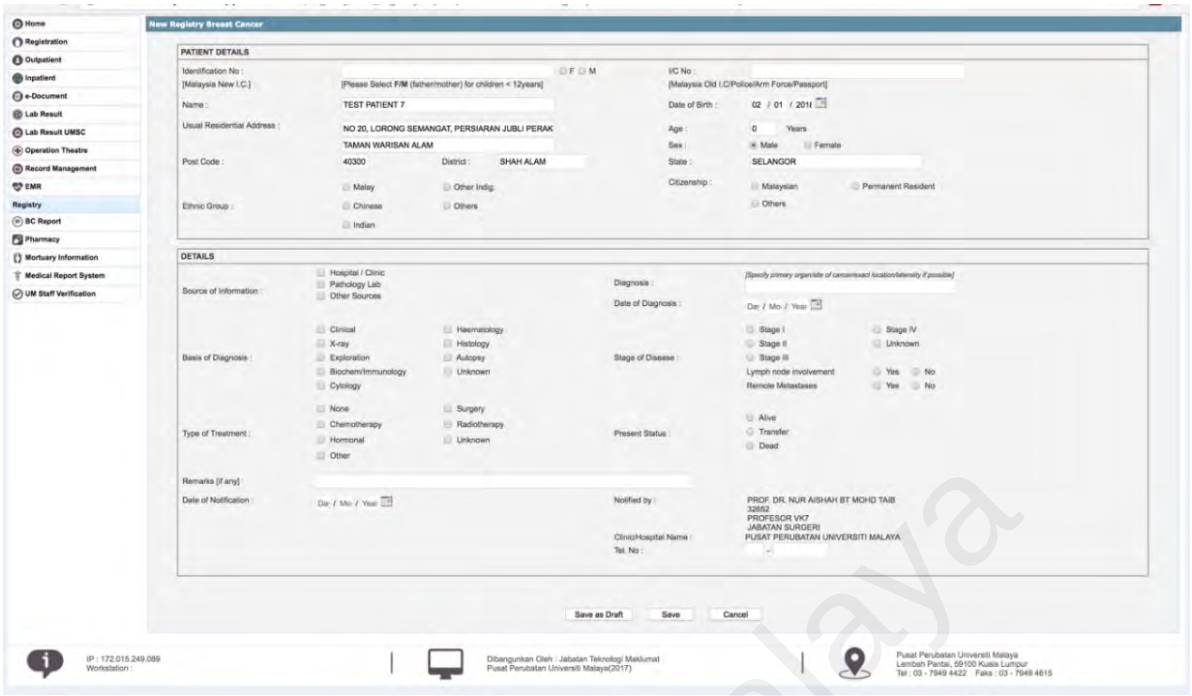


Figure 4.12: Breast cancer registry form for national cancer registry reporting

Clinicians however can update these forms from time to time at different stages of diagnosis and treatment level until the form is complete. The final output of auto-populated Cancer Notification Form in

Figure 4.13 shows the finalized and validated version which is ready for submission for reporting to the ministry. It is in a flexible format where forms may be sent through the backend or can be saved in PDF format. The authorized person for this form is the responsible clinician attending to the case, and the signed name display is subject to the last clinician who saves the record.

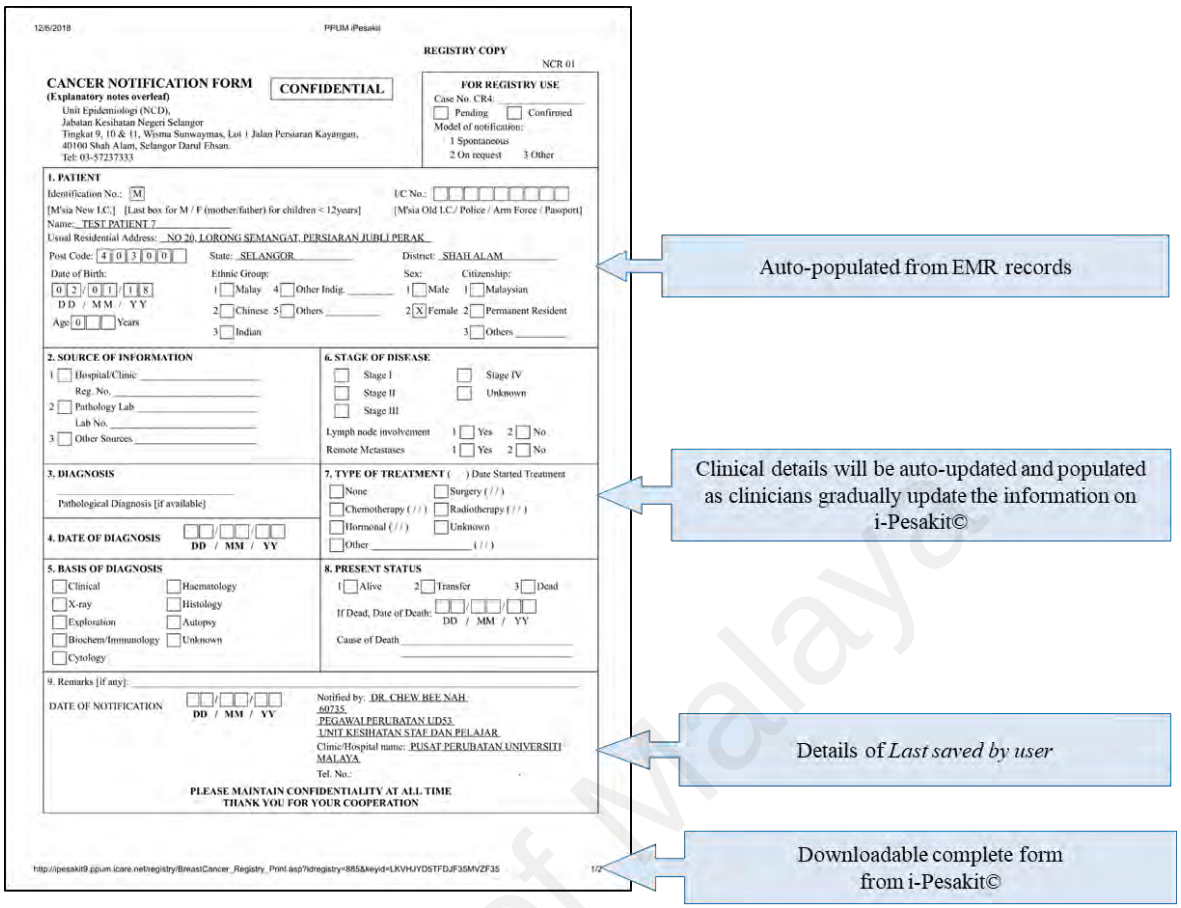


Figure 4.13: Auto-populated Cancer Notification Form output for national cancer registry reporting

4.3.2 Extracting i-Pesakit© Breast Cancer Module data for clinical research

Customized clinical data can be exported from the breast cancer module to a spreadsheet format to facilitate breast cancer research in achieving an overall meaningful use in EMR. This function however is restricted to only the team leader and members of breast cancer research group approved by the research ethics committee. An example of extracted data in Microsoft Excel format for secondary use is as shown below in Figure 4.14. Each table records are categorized monthly according to template sections of the module. It is an automatically generated content and the first step to data mining applied in the EMR data set for knowledge discovery in future researches. However, currently these data extracted are a mixed of patients with cancer and benign breast diseases because the Follow-up template is also used by medical officers and surgeons for all types

of cases. Future enhancement will be done by refining the data extraction algorithm to specifically capture newly diagnosed breast cancer cases as a preparation of an effective data mining application.

RECORD OF FOLLOW UP VISITS
JULY 2017

NAME	RN	DOB	STATUS AT FOLLOW-UP: Date of f/up	STATUS AT FOLLOW-UP: Vital Status	PROGRESS NOTE: Subjective / Current Complaint	PROGRESS NOTE: Vital Sign	PROGRESS NOTE: Objective / Examination	PROGRESS NOTE: Assessment / Investigation	PROGRESS NOTE: Treatment / Medication	PROGRESS NOTE: Diagnosis	PROGRESS NOTE: Plan	PROGRESS NOTE: Notes
################	#%$&*^!	12/06/1972	03/07/2017		review wound postop day5 no haematoma				chloramphenicol 1% eye ointment : affected eye(s) topically Apply THREE		- cmc ointment (LA) PRN	
################	#%$&*^!	11/03/1956	05/07/2017		Left breast cancer 2000 Left MAC Completed chemo, radiotherapy and tamoxifen-5 years			Mammogram			TCA 1 year MMG in 2019 BSE	
################	#%$&*^!	17/09/1951	05/07/2017	Alive without disease or recurrence	65yo/C/F - left breast carcinoma, pT1N0M0, triple negative post BCS+AD in 2004 Chemo adjuvant FEC X 6 and radiotherapy to breast recurrence in 2008 (localised disease), simple mastectomy done HPE: IDC, triple negative refused 2nd line chemo					left breast CA	- TCA 1 year - MMG next year	
################	#%$&*^!	30/09/1979	05/07/2017	Alive without disease or recurrence	left breast cancer done left MAC in 2011 had neoadjuvant chemo, then adjuvant RT ER/PR negative. no lump felt coping well not keen for recon wearing prosthetic breast no family history of cancer 3 children		no lump felt right breast left mastectomy no nodules felt no lymph nodes felt	Mammogram			see back in 1 year with mammogram	
################	#%$&*^!	10/06/1960	05/07/2017		left breast cancer-MAC 1999 colon cancer-panproctocolectomy in H pantai in 2015 thyroid cancer done total thyroidetomy in TUng Shin Hosp in 2010 colonoscope Aug 2016-normal		no breast lump no recurrence	Mammogram		liver metastasis for investigations	for CT TAP early appt. TCA after CT	
################	#%$&*^!	19/01/1993	05/07/2017		excision biopsy of bilateral breast fibroadenoma in 2016 c/o drastically increasing new right breast lump 2/12		right breast lump 4x4cm mobile	Ultrasound		TRO phyllodes	core biopsy done	
################	#%$&*^!	24/11/1963	05/07/2017	Alive without	53yo/C/F			Others [ ] Mam		right breast CA	- TCA 6/12	

Figure 4.14: Automatically generated content in Microsoft Excel format of benign and breast cancer cases in University Malaya Medical Centre

4.4 i-Pesakit© Breast Cancer Module System Usability

From February 2016 through July 2018, a total of 15,935 clinical data were recorded in the breast cancer module system. Figure 4.15 shows the number and type of i-Pesakit© Breast Cancer Module notes generated during this interval.

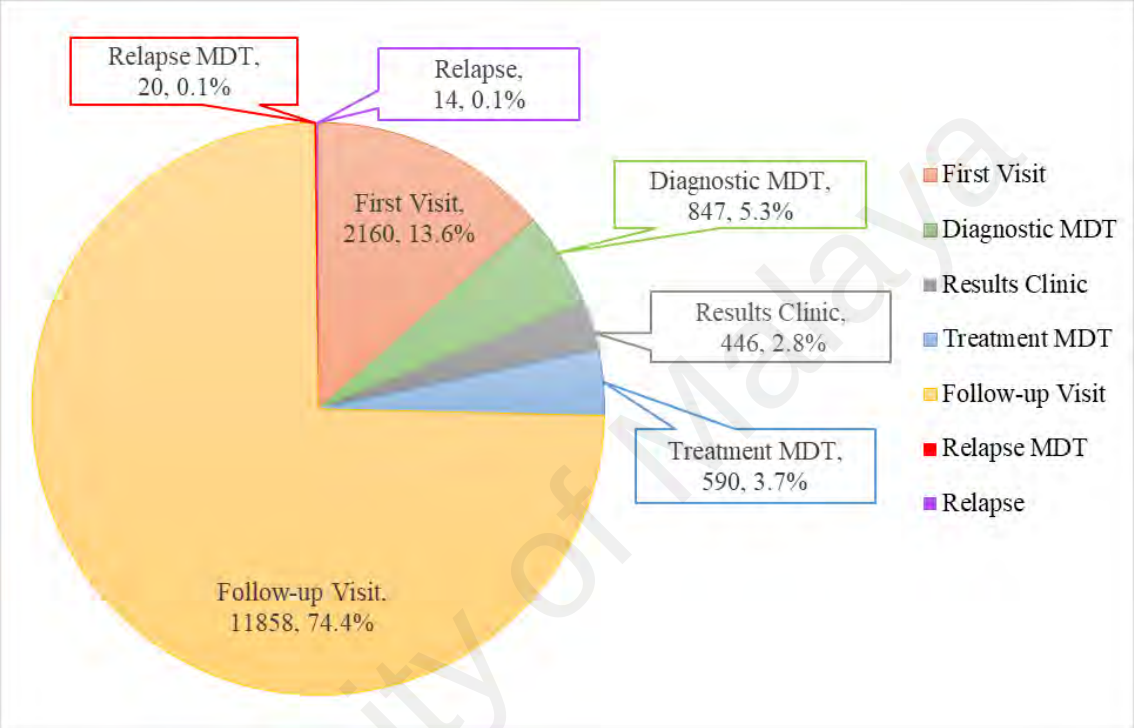
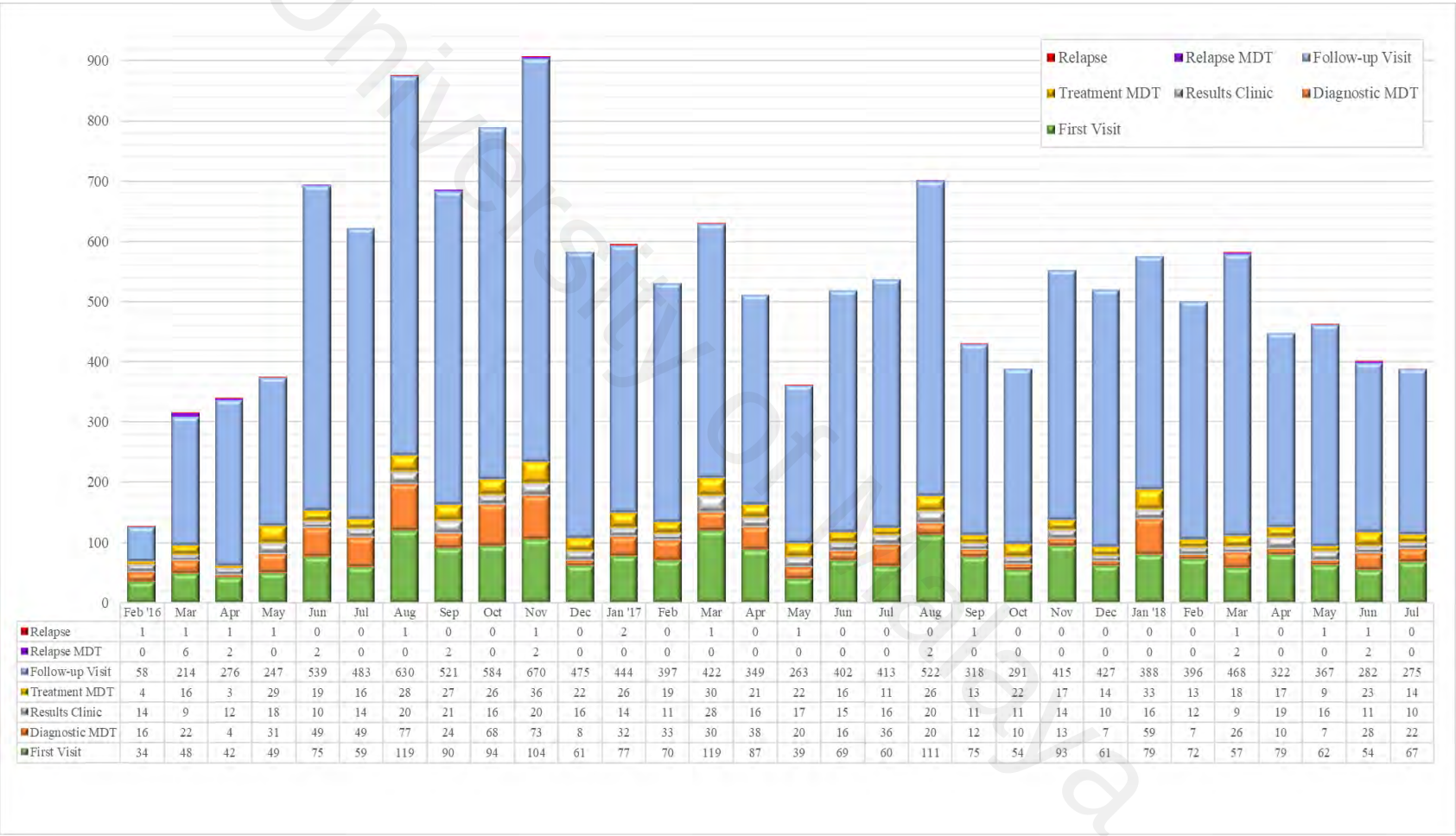


Figure 4.15: Quantity and type of clinical notes generated in i-Pesakit© Breast Cancer Module from February '16 to July '18

Over the course of 30 months of implementation since February 2016, follow-up visits and first-visit clinics accounted the majority of generated notes at 11,858 and 2160, respectively. The least common notes generated were relapse (14) and relapse MDT (14) which only indicated 0.1% of system use fraction. Other returned system usage yielded 5.3% (847) diagnostic MDT, 2.8% (446) results clinic and 3.7% (590) treatment MDT clinical records.

Figure 4.16 shows the total clinical notes per month fluctuates but displayed gradual increment since February 2016, rise to a high point and peaked in November 2016 with 906 data points, but drops sharply the month after with only 582 data points. The overall contour shows fluctuating but steady ascend and decline, terrace and undulating patterns with some combinations of irregular intervals. It demonstrates the monthly trend of total clinical notes generated in UMMC i-Pesakit© Breast Cancer Module since February 2016 to July 2018. The graph reveals that the follow-up visit template is the most-frequently used proforma throughout the implementation period covering 74.4% of the system module use frequency, with 11,858 follow-up visits records of benign and cancer patients since February 2016. The relapse and relapse MDT templates remained the lowest proportion of usage with approximately zero to three transcriptions in most months, only reaching 0.1% of clinical notes generated. However, six relapse MDT clinical notes were generated in March 2016 and this was the highest recorded throughout the implementation period.



	Feb '16	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan '17	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan '18	Feb	Mar	Apr	May	Jun	Jul
Relapse	1	1	1	1	0	0	1	0	0	1	0	2	0	1	0	1	0	0	0	1	0	0	0	0	0	1	0	1	1	0
Relapse MDT	0	6	2	0	2	0	0	2	0	2	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	2	0	0	2	0
Follow-up Visit	58	214	276	247	539	483	630	521	584	670	475	444	397	422	349	263	402	413	522	318	291	415	427	388	396	468	322	367	282	275
Treatment MDT	4	16	3	29	19	16	28	27	26	36	22	26	19	30	21	22	16	11	26	13	22	17	14	33	13	18	17	9	23	14
Results Clinic	14	9	12	18	10	14	20	21	16	20	16	14	11	28	16	17	15	16	20	11	11	14	10	16	12	9	19	16	11	10
Diagnostic MDT	16	22	4	31	49	49	77	24	68	73	8	32	33	30	38	20	16	36	20	12	10	13	7	59	7	26	10	7	28	22
First Visit	34	48	42	49	75	59	119	90	94	104	61	77	70	119	87	39	69	60	111	75	54	93	61	79	72	57	79	62	54	67

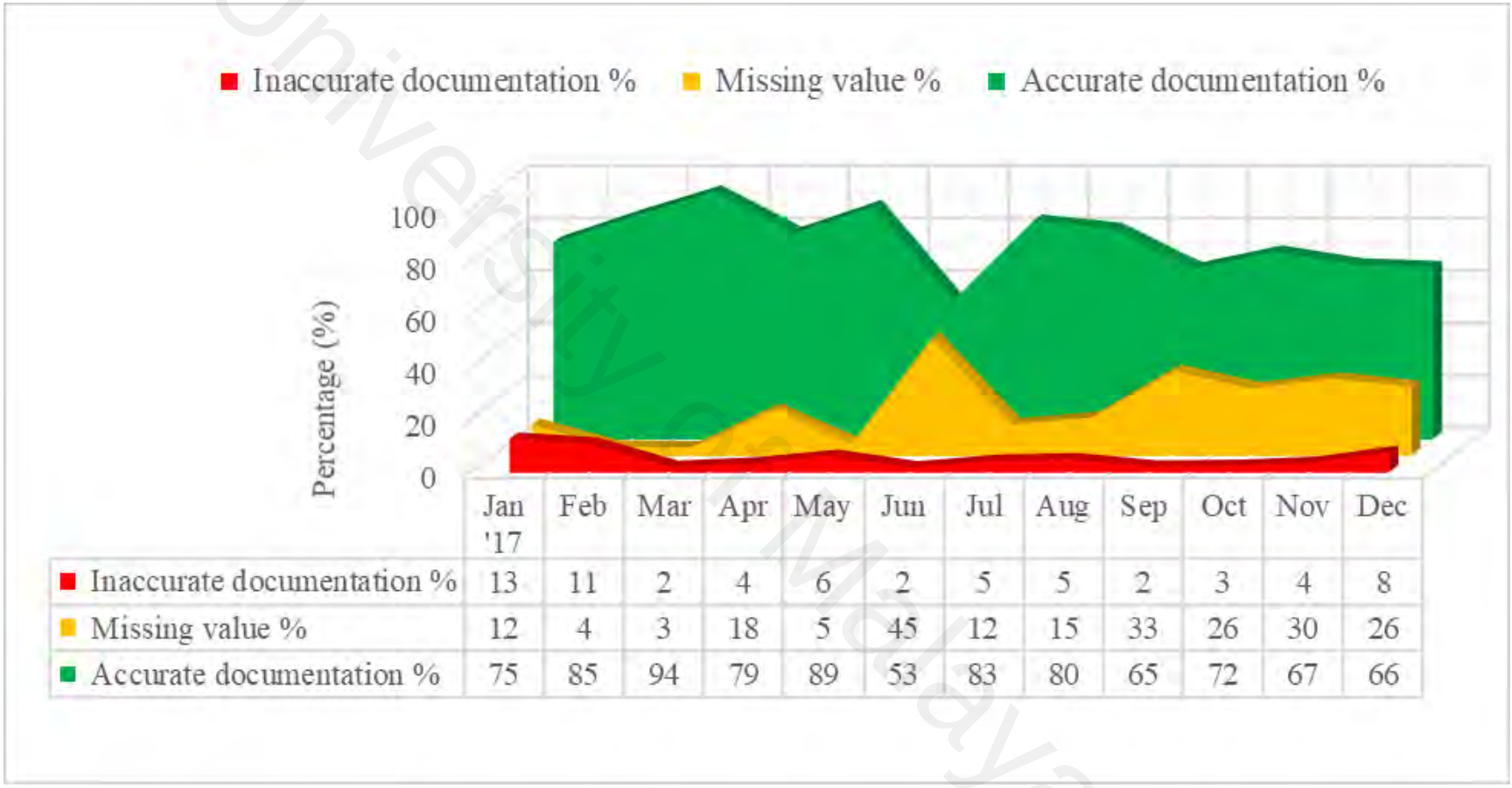
Figure 4.16: Monthly usage breakdown of UMMC i-Pesakit© Breast Cancer Module in the Department of Surgery

4.5 i-Pesakit© Breast Cancer Module System Evaluation

A total of 193 of breast cancer module EMR charts were audited within the time frame of 1 January 2017 to 31 December 2017. 1158 data fields from six variables (type and date of breast surgery, grade of breast cancer, ER, PR and HER2 statuses) were reviewed retrospectively to test the new system's efficiency in comparison to the previous manual transcription process. Descriptive statistical analysis was performed to evaluate and compare the frequency of accuracies, inaccuracies and missing values for the mentioned variables in these two systems.

4.5.1 Accuracy of clinical data

Figure 4.17 shows monthly distribution of overall system accuracy trends of generated clinical notes in i-Pesakit© Breast Cancer Module in 2017. Of the 1158 electronic breast cancer module information fields reviewed, 872 (75.3%) were accurate, 61 (5.3%) were inaccurate and 225 (19.4%) were absent values. Throughout the implementation of electronic transcription system, there is a high average of 75.6% documentation accuracy with a score of 94% accuracy in March 2017, and low average of 5.4% inaccurate clinical documents with minimum score of 2% inaccuracy recorded within the system. However, the mean percentage of missing values in the breast cancer module is reported to be 19%, which is a surprising outcome. Closer inspection of Table 4.2 compares accuracy patterns of clinical notes generated in i-Pesakit© Breast Cancer Module and manual Excel transcription.



	Jan '17	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Inaccurate documentation %	13	11	2	4	6	2	5	5	2	3	4	8
Missing value %	12	4	3	18	5	45	12	15	33	26	30	26
Accurate documentation %	75	85	94	79	89	53	83	80	65	72	67	66

Figure 4.17: Percentage of accuracy trends in i-Pesakit© Breast Cancer Module documentation workflow

Table 4.2: Comparison of accuracies, inaccuracies, and missing values in factors that affect breast cancer prognosis and treatment variables in manual data transcription versus i-Pesakit© Breast Cancer Module

	Manual Clinical Data Transcription		**I-Pesakit© Breast Cancer Module**	
	(n = 1158)	**n (%)**	**(n = 1158)**	**n (%)**
Accurate documentation	**863**	**74.5**	**872**	**75.3**
Date of Surgery	131	68	134	69
Type of Surgery	156	81	154	80
Grade	130	67	132	68
ER Status	155	80	153	79
PR Status	152	79	155	80
HER2 Status	139	72	144	75
Inaccurate documentation	**71**	**6.1**	**61**	**5.3**
Date of Surgery	26	13	22	11
Type of Surgery	8	4	3	2
Grade	17	9	13	7
ER Status	4	2	4	2
PR Status	4	2	6	3
HER2 Status	12	6	13	7
Clinical data not documented	**224**	**19.3**	**225**	**19.4**
Date of Surgery	36	19	37	19
Type of Surgery	29	15	36	19
Grade	46	24	48	25
ER Status	34	18	36	19
PR Status	37	19	32	17
HER2 Status	42	22	36	19

Figure 4.18 presents a bar chart of system performance comparison, with each segment representing an information field. These diagrams are descriptive analysis demonstrating the frequency of accuracies, inaccuracies and missing values for variable fields of factors that affect breast cancer prognosis and treatment. Accurate, inaccurate and missing values are found in all breast cancer module and manual data transcription variables. The breast cancer module and manual transcribed records show a marginal difference of accurate data (75.3% versus 74.5%), where highest value was recorded in type of surgery and ER status variables. Inaccurate data records were found higher in manual proformas compared to the electronic i-Pesakit© Breast Cancer Module (6.1% versus 5.3%). The date of surgery information has the highest frequency of inaccurate data in both workflow systems with the record 13% in breast cancer module and 11% in manual transcription record. However, total of missing values is similar between paper charts and electronic breast cancer module, at 19.3% and 19.4% respectively.

Interestingly, the frequency of undocumented clinical data in manual paper proformas and i-Pesakit© Breast Cancer Module system was found to be more than three times higher than the inaccurate information fields; with 225 data in the electronic record and 224 in the manual legacy data.

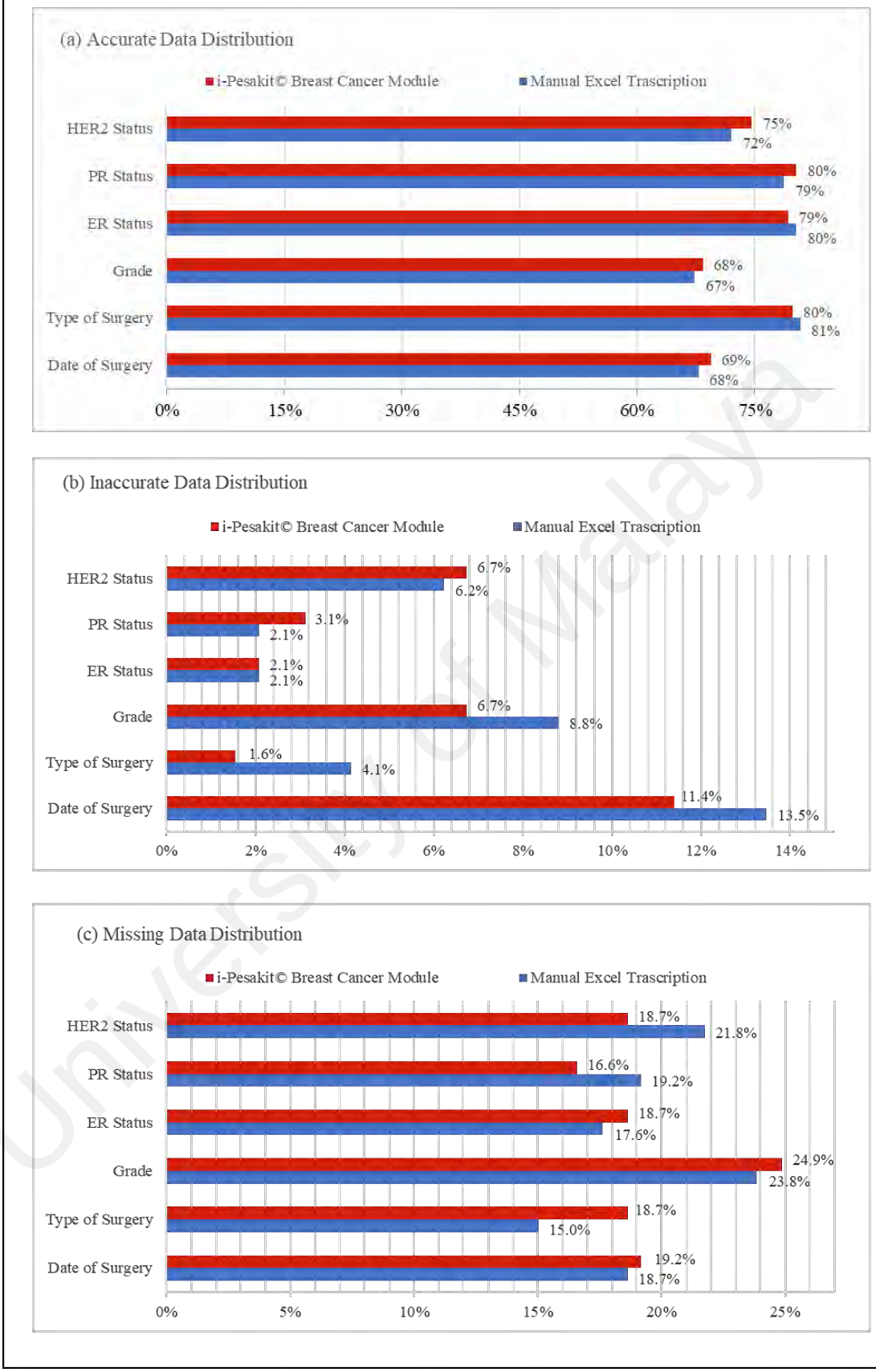


Figure 4.18: Percentage of clinical data documented through comparison of clinical data (a) accuracy (b) inaccuracy and (c) missing data distributions between the manual and electronic i-Pesakit© Breast Cancer Module workflows

4.5.2 Newly diagnosed breast cancer incidences captured by i-Pesakit© Breast Cancer Module

From February 2016 through July 2018, a total of 353 unique episodes of breast cancer incidences were recorded in the breast cancer module system as presented in Figure 4.19. It presents trends for breast cancer incidence rates since February 2016, when i-Pesakit© Breast Cancer Module was implemented. Incidence rates of breast cancer fluctuates but slightly descends in the first two months in February 2016, rises steadily until May 2016 before dropping sharply the following month. These counts fluctuate, peaking in March 2017 at identifying 28 breast cancer incidences that month. The system assessment concludes that the new digital data management system captures an average of 58.8% newly diagnosed breast cancer yearly, with 60.1% (170 new cases) during first year and 57.5% (183 new cases) in second year of implementation.

After reaching the peak of 38 incidences in November 2016, breast cancer rates dropped sharply (nearly 26.7%) and stabilized between end of 2016 to early 2017. Incidence rates rose again in the latter of 2017, with an increment of 22.6% within the first three months of the year. It is recorded that breast cancer rates increased by 26.9%. in the course of the first two years of system implementation.

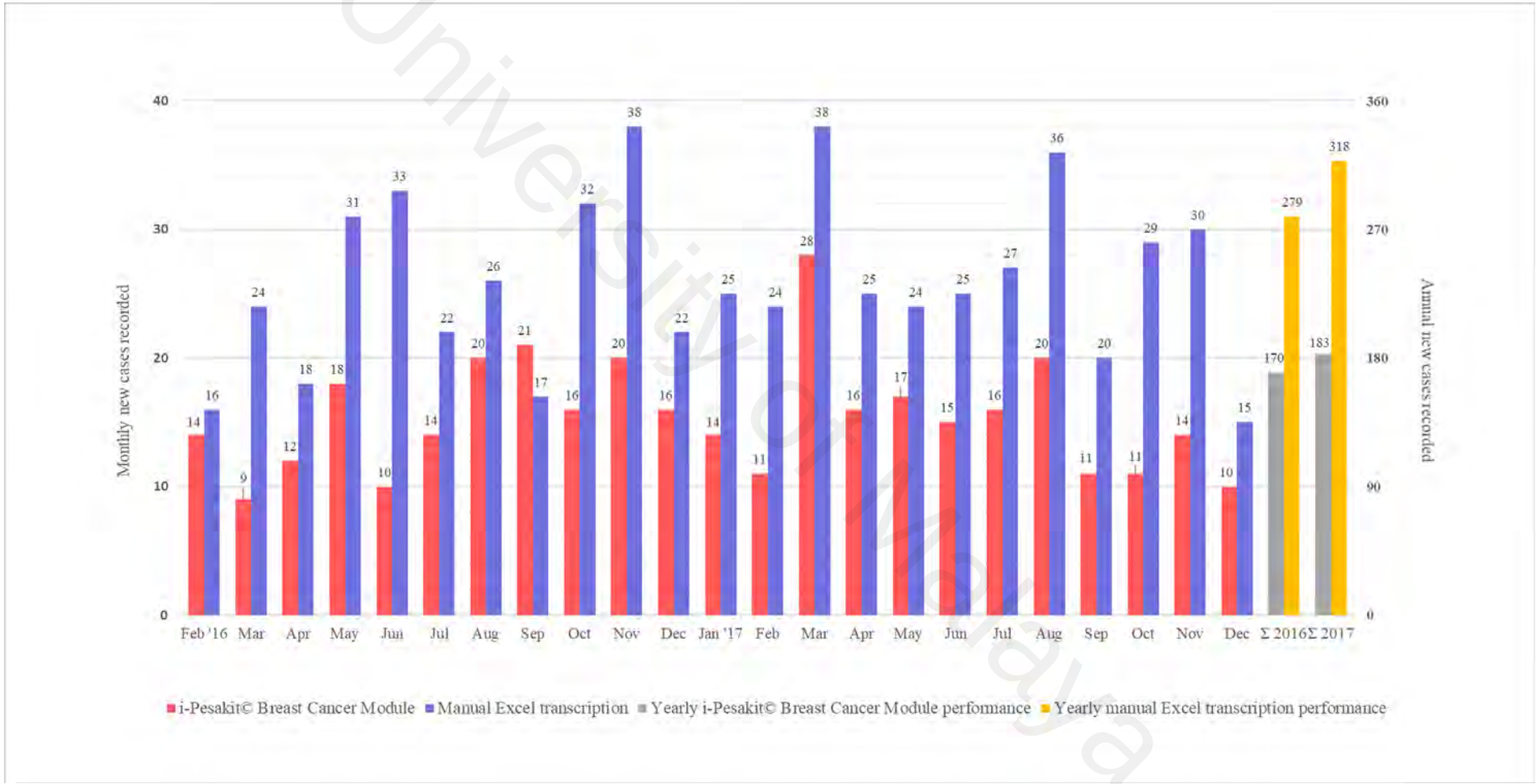


Figure 4.19: Normalized histogram that compares newly diagnosed breast cancer incidences captured by i-Pesakit© Breast Cancer Module and manual clinical workflow systems

Figure 4.20 presents the variations in breast cancer incidence reported in University Malaya Medical Centre by nationality. Although the overall incidence rate for breast cancer in UMMC are Malaysians, the pie chart shows rates that they are foreign patients from Indonesia (2.4%), Myanmar (0.3%) Philippines (0.3%) Brunei (0.3%) treated here in the medical centre.Figure **4.21** shows breast cancer incidence and death rates by race and ethnicity during implementation period since February 2016 to December 2017. Incidence rates for breast cancer in UMMC are highest among Chinese with 159 incidences (47%), followed by Malay with 108 cases (32%) compared to women inn other racial and ethnic groups. Indian women and other races have the lowest incidence, with (58) 17% and (12) 4% incidences respectively.

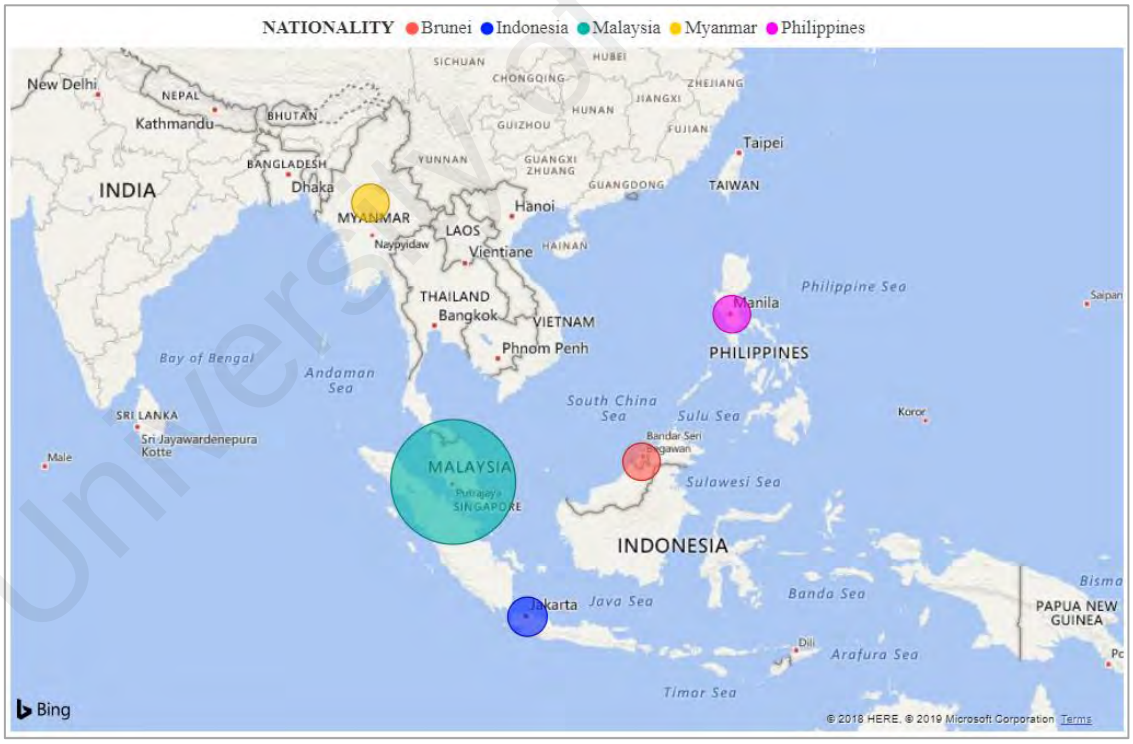


Figure 4.20: University Malaya Medical Centre breast cancer patients' demographics

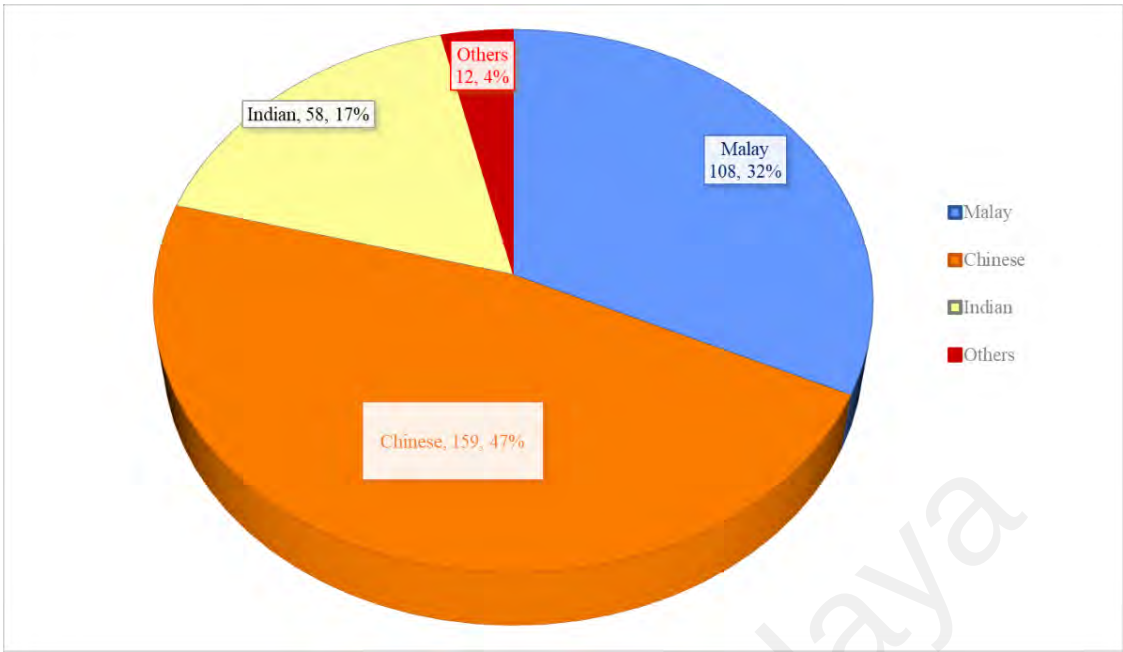


Figure 4.21: Reported newly diagnosed breast cancer cases in 2017 at University Malaya Medical Centre by nationality and races (n= 337), where the Malays, Chinese and Indians are Malaysians while Others are foreigners. Data source from manual breast cancer cases transcription data

4.6 System Usability Test Survey and Evaluation Results

A variety of perspectives were expressed during the usability survey conducted at the Department of surgery on 18 July 2017; eighteen months post-system implementation. From these diagrams below (Figure 4.22), positive feedbacks were given by surgeons, surgical registrars, and senior medical officers where 98.34% of them use the system frequently in their clinical workflow routine.

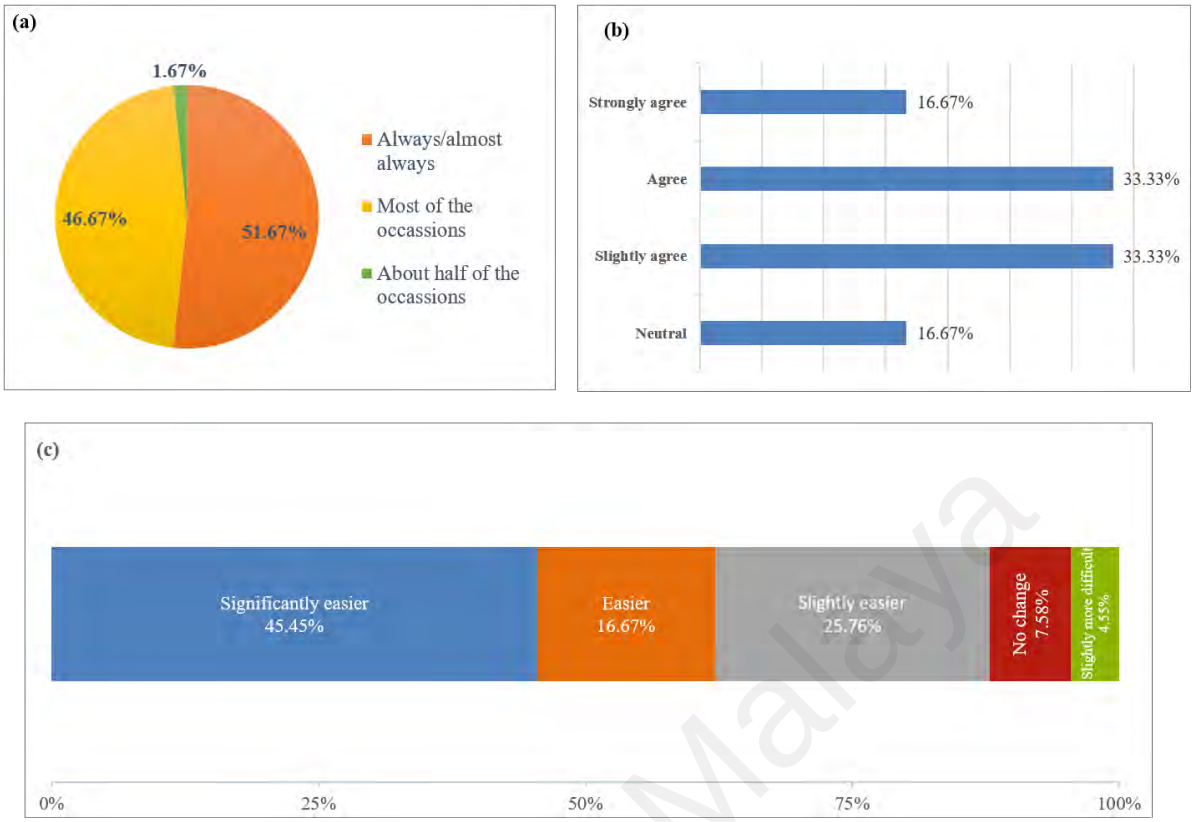


Figure 4.22: System usability survey in measuring clinicians' perceptions of the system (a) Usage of i-Pesakit© Breast Cancer Module in clinical work (b) Is this system worth the time and effort to be used? (c) Effect on clinical workflow by using the breast cancer module among clinicians

Over half of those surveyed indicated that using the breast cancer module system has made their workflow smoother as well as easier, while 7.58% of them experience no change in convenience and 4.55% find the system complicated. However, 83.33% of clinicians agree that the breast cancer module is worth the time and effort to be used. More user training is required, to familiarize them with the system in order to achieve maximum benefit of the system, where clinical workflow is more structured with structured mineable data.

All participating clinicians showed interest in using the emerging breast cancer module technology in their clinical workflow routine. The general impression they had was the electronic medical record is a digital form of clinical notes. They acknowledged this technology system is a useful tool for both clinicians as well as patients. They expressed preference of a user-friendly, clear and concise system, accessible from portable devices, supports accuracy of free text and structured documentations, and permits data exchange for clinical research and audit. They perceived that free text inputs are useful based on their previous manual transcription experience with structured clinical paper-based proformas. They commented that a combination of free text with structured questionnaires brings the freedom in generating accurate and individualized clinical notes. Among other benefits, materials (clinical paper proformas) and time savings were also emphasized by the participants.

However, among the negative feedbacks received by participants were the inability to access information from other settings because of dependence on the Local Area Network internet connection on fixed desktops. Limited time spent onsite to transcribe patient data during clinical encounter was a hindrance that affects the doctor-patient interaction. Cross-sharing of information and data sharing were among the features they wanted to see for comprehensive breast cancer data management system. When asked, "What could be done to improve clinical practice's efficiency and patientcare?" they expressed interest in tools to assist clinical decision-making as a primary use, and support data exchange and sharing for research and audit purposes as secondary uses. Other responses by participants are summarized in Table 4.3.

Table 4.3: Survey transcript review among participants on their comments as users of the system

Feedback and suggestions by respondents on i-Pesakit© Breast Cancer Module
1. *"System features are great and increases efficiency. However, there are two possible drawbacks:* *(a) Over-dependent on the system (less of communication skills / history taking)* *(b) Less eye-contact with patient, less of human factor"* *-Senior medical officer, 34 years old*
2. *"Hope the system can be used as a source for research and clinical audit."* *- Breast surgeon, 42 years old*
3. *"Too many attributes to fill up." -Senior medical officer, 33 years old*
4. *"There are a lot of particulars to type which sometimes may be time consuming."* *-Senior medical officer, 35 years old*
5. *"Certain answer columns overlap; hence we are unable to choose more than one option in some questions. Suggestion: Have a separate Left and Right Breast side that allows multiple answer inputs." -Surgeon, 37 years old*
6. *"I am still doing my own method that I learnt initially. There must be a fast-efficient way of bypassing certain things and getting straight to the point. Whenever I could not find the data field I am looking for, I will use the text box to type in my clinical notes to save time ." -Breast surgeon, 42 years old*

The Evaluation of UMMC i-Pesakit© Breast Cancer Module Questionnaires address evaluation of the overall system as well as the detailed scenario assessment. The series of four questionnaires rely measures satisfaction of front-end users with the new digital workflow system implemented in the department. Although the sample size was small, it represented the total user diversity in a one-day clinic setting; surgeons, registrars and senior medical officers. The focus group response in the survey is summarized in Table 4.4.

Table 4.4: i-Pesakit© Breast Cancer Module evaluation survey summary

Question / Response	Never/almost never 1	Seldom 2	About half of the occassions 3	Most of the occassions 4	Always / almost always 5	Mean ($\bar{x}$)	Standard deviation (sd)	95% Confidence interval
Usage of i-Pesakit Breast Cancer Module for clinical tasks in the hospital								
Q1. Seek out specific information from patients record	-	-	-	50%	50%	4.5	0.55	(4.06 , 4.94)
Q2. Follow the results of a particular test or investigation over time	-	-	-	50%	50%	4.5	0.55	(4.06 , 4.94)
Q3. Obtain results from new test or investigations	-	-	-	50%	50%	4.5	0.55	(4.06 , 4.94)
Q4. Enter and update clinical notes	-	-	-	33.3%	66.7%	4.7	0.52	(4.25 , 5.00)
Q5. Obtain information on investigation or treatment procedures	-	-	-	33.3%	66.7%	4.7	0.52	(4.25 , 5.00)
Q6. Display data summary and review of specific information	-	-	-	33.3%	66.7%	4.7	0.52	(4.25 , 5.00)
Q7. Patients' test results are stored in a structured manner for easy review and determine appropriate plan of care	-	-	-	50%	50%	4.5	0.55	(4.06 , 4.94)
Q8. Use during multidisciplinary team (MDT) meeting	-	-	-	33.3%	66.7%	4.7	0.52	(4.25 , 5.00)
Q9. Usage of paper-based medical record as information source in daily clinical work	33.3%	16.7%	33.3%	16.7%	-	2.3	1.21	(1.36 , 3.30)
Q10. Usage of i-Pesakit Breast Cancer Module as information source in daily clinical work	-	-	16.7%	50%	33.3%	4.2	0.75	(3.56 , 4.77)
Q11. Availability of relevant information needed to determine appropriate plan of care within i-Pesakit© Breast Cancer Module	-	-	-	16.7%	83.3%	4.2	0.41	(3.84 , 4.49)
User's satisfaction in using i-Pesakit Breast Cancer Module								
Q1. Content								
a. System providing precise information	-	-	-	83.33%	16.67%	4.2	0.41	(3.84, 4.49)
b. Information content meeting user's needs	-	-	-	100%	-	4.0	0.00	-
c. Feeling confident when using the system while seeing patients	-	-	-	83.33%	16.67%	4.2	0.41	(3.84, 4.49)
d. System providing sufficient information	-	-	-	83.33%	16.67%	4.2	0.41	(3.84, 4.49)
Q2. Accuracy								
a. Frequency of times system is accurate	-	-	-	66.67%	33.33%	4.3	0.52	(3.92 , 4.75)
b. Overall satisfaction with system accuracy	-	-	-	66.67%	33.33%	4.3	0.52	(3.92 , 4.75)
Q3. Format								
a. Output is presented in a useful format	-	-	33.33%	50%	16.67%	3.8	0.75	(3.23 , 4.44)
b. Clear information presentation	-	-	-	83.33%	16.67%	4.2	0.41	(3.84, 4.49)
Q4. Ease of use								
a. User-friendliness	-	-	66.67%	16.67%	16.67%	3.5	0.84	(2.83 , 4.17)
b. Concise and responsive user interface	-	-	50.00%	50.0%	-	3.5	0.55	(3.06 , 3.94)
Q5. Timeliness								
a. Getting the information needed in time	-	-	-	100.0%	-	4.0	0.00	-
b. System roviding up-to-date information	-	-	16.67%	50.0%	33.33%	4.2	0.75	(3.56 , 4.77)

In the i-Pesakit© Breast Cancer Module system usability and performance evaluation, confidence intervals were used to determine the reliability of the observed sample mean responses and provides a range of values for the estimated population parameter. Table 4.4 summarizes 23 questions from the questionnaire with percentage of respondents for each response on a 5-point Likert scale, the mean, standard deviation and confidence interval (CI). In the first section, the usability mean score for Questions 4,5,6 and 8 was 4.7 (95% CI = 4.25,5) on a 5-point Likert scale ranging from 1 to 5, which describes the usability of transcribing, retrieving data and usage during MDT meetings. The information in the table above summarizes the total scores given a mean and standard deviation from 2.3 (1.21) to 4.7 (0.52). On average, for most questions, the ratings were "Most of the occasions" to "Always/almost always" , indicating that a majority of the system users reported favorable levels of satisfaction with i-Pesakit© Breast Cancer Module use compared with the paper-based system.

4.7 Conclusion

I-Pesakit© Breast Cancer Module is in operation at the Department of Surgery UMMC, where it has proven to be stable and reliable. This electronic breast cancer management system has achieved our initial outline; by being widely accessible on web-based system from either Windows or Mac platforms, standardized structure across breast cancer multidisciplinary domains (surgery, oncology, radiology, pathology, pharmacy) as a data model for other future disease-specific system in the hospital, which uses point-of-care systems to support clinical routines and MDT meetings, and is easy to learn and use. The accomplishment of the breast cancer module within the EMR will bridge the gap between clinical care and medical informatics research in the future. With the additional UMMC biobank facilities and research questions, future bioinformatics research can be conveniently performed.

CHAPTER 5: DISCUSSION AND CONCLUSION

5.1 Overview

This chapter discusses the study findings presented in the previous chapter. The purpose of this work is to implement an electronic structured clinical documentation system called i-Pesakit© Breast Cancer Module which is embedded in University Malaya Medical Centre's EMR to help redirect workflow at the point of care to enhance effectiveness in the use of EMR for patientcare and future clinical research. The first section discusses about the main study findings of the deployed system and the evaluation of usability and effectiveness of i-Pesakit© Breast Cancer Module. System strength, challenges and limitations throughout the implementation process are justified, and suggestions on improving the electronic clinical practice workflow as well as future research implementation suggestions are explained in the later part of this chapter.

5.1.1 Quality Implementation Framework

The deployment of EMR in hospitals improves patientcare, enables automatic reporting and fosters research through affiliations with external institutions and establishing potential research collaborations. In this study, the i-Pesakit© Breast Cancer Module was developed following the steps of the Quality Implementation Framework (QIF). The QIF technique was adopted because it synthesizes existing models with structured guidelines in system implementation to improve patientcare and provides direction towards secondary data use in reporting and research activities, which is in line with the hospital's vision in upgrading healthcare. A top-down approach and applied research techniques are used as foundation to improve clinical service and research standards. Phase 1 of the QIF confirmed the need to engage clinicians and planning real-time workflows. Stakeholders' involvements, especially clinical champions are critical to the success of these implementation efforts. Prior work on implementation of clinical information systems provides broad guidance to inform effective engagement strategies.

Phase 2 focuses on the structural and functional features on implementation. In this phase, understanding the multidisciplinary breast cancer clinical workflow is crucial in designing a practical system for users, as well as planning strategies in enhancing the system during the testing phase. Phase 3 deals with the support strategies during implementation. In this phase, direct engagement with stakeholders is carried out from time to time, in monitoring and evaluating the system efficiency and receiving feedbacks from users to improve the system functions. Finally, in Phase 4, suggestions are proposed to improve future application through retrospective system analysis based on feedbacks and suggestions by users. The implementation framework using the QIF steps provides the team a clear path to developing a breast cancer reporting system which incorporates both clinical and research needs for clinical and research activities. In this study, the QIF provided a clear guideline in proposing and developing an EMR for a middle-income country scenario and a multidisciplinary clinical setting such as breast cancer workflow. In summary, by adopting the QIF framework, we managed to build a successful EMR model by engaging stakeholders and following the clinical workflows very closely to ensure usability and accuracy of data captured, complying to Personal Data Protection Act (PDPA) and proposing a secondary data use strategy for clinical research and registry reporting.

5.1.2 i-Pesakit© Breast Cancer Module

Breast cancer has a structured, predictable workflow from patient's first visit consultation to treatment delivery and follow-up sessions, but the tools to support this workflow documentation using the existing EMR is limited. As introduced in Chapter 1, redundancy of work between manual and digital transcription process and lack of interoperability between these systems result in the aggregation of inefficient work process and the loss of time (Pasalic et al., 2018). Therefore, i-Pesakit© Breast Cancer Module system was implemented within the EMR based on a point-of-care (POC) system which supports the multidisciplinary breast cancer electronic clinical workflow. This approach inscribed a real-time pattern of use which maximizes system operation and improve outcomes (Nierenberg, 2018). The use of EMRs with timely access at the point of care may be a challenging form of data entry but is the critical success of implementation and the ultimate goal which implementers and policy makers are striving for (Safdari et al., 2015).

The National Strategic Plan for Cancer Control Programme Malaysia 2016-2020 (Ministry of Health Malaysia, 2017a) highlighted their policy of improving cancer surveillance through strengthening of comprehensive cancer data and information systems through the National Cancer Registry (NCR) and Patient Registry Information System (PRIS). In this study, i-Pesakit© Breast Cancer Module functions as a structured breast cancer clinical documentation system embedded within the UMMC EMR which supports breast cancer registry reporting, through automatic data mapping from the i-Pesakit© Breast Cancer Module as data source.

A similar study was reported by Pasalic *et al.* (2018) where Texas MD Anderson Cancer Center uses a web-based radiation oncology system called Brocade (Pan et al., 2017). Like i-Pesakit© Breast Cancer Module, Brocade was developed internally and applies the same concept. However, there is a small difference between these two systems. Brocade operates as an intermediary system between an oncology data management software called MOSAIQ, and the EMR called EPIC (Figure 2.2), while the i-Pesakit© Breast Cancer Module is implemented within the UMMC EMR environment as shown in Figure 3.8. Another comparable electronic breast cancer module is ARIA by Boston Medical Center (Russo, 2016; Varian Medical Systems, 2012). It is a radiation oncology system which is externally linked to the hospital's EMR, and functions as an analytics resource system at the University of Michigan (Pan et al., 2017). Different from i-Pesakit© Breast Cancer Module which is developed internally by UMMC, ARIA is a commercially available software by Varian Medical Systems, Palo Alto but not widely used (Varian Medical Systems, 2012). An interface link is built between ARIA and the EMR as a measurement so data can be safely imported automatically to the EMR and making these radiation oncology data available real-time on EMR interface. On the other hand, i-Pesakit© Breast Cancer Module supports interdisciplinary data exchange between clinical departments involved in breast cancer patientcare.

Through these comparisons of systems in advanced countries with i-Pesakit© Breast Cancer Module, we have the advantage of customizing our system according to the clinicians' needs as it was developed in-house within our local EMR. This clinical data management workflow is cost-effective as it does not require system purchase and upgrade from third party. Flexibility of design and implementation plus interoperability of system are achievable through this approach. The i-Pesakit© Breast Cancer Module is a governance operating model of electronic clinical workflow at the point-of-care to enhance effectiveness in the use of the EMR structured clinical documentation. Through

these favorable outcomes, it may be implemented in other clinical departments of the breast cancer group as well in the future.

5.1.3 Evaluation of i-Pesakit© Breast Cancer Module deployment in Department of Surgery, UMMC

The i-Pesakit© Breast Cancer Module was tested rigorously by a group of users (clinicians within the department of surgery). As presented in Results (Chapter 4), in general, clinicians spoke favorably about the i-Pesakit© Breast Cancer Module system. They believed that the system has improved the quality and clarity of documentation. However, some clinicians described the system as complex and too complicated. They had difficulty at the beginning especially during the familiarization of system flow. While some feel the system features have improved work efficiency, they also experience some drawbacks such as the point-of-care (POC) data entry resulted in lack of time for eye contact and less clinician-patient communication. This may reduce the effectiveness to build a rapport with patients as clinicians are more focused on the notes in the system as compared to patient consultation. POC may improve data accuracy, however it may be lacking in its completeness of data for clinical research (Boardman, 2017; Ellsworth et al., 2015; Majeed et al., 2008). System quality audit of data accuracy and completeness needs to be done in maintaining the clinical data integrity in ensuring a certain level of quality (Gliklich et al., 2014).

5.2 Strength and Uniqueness of i-Pesakit© Breast Cancer Module

Through a great teamwork collaboration with the multidisciplinary team of UMMC clinical professionals and technical experts, the implementation of i-Pesakit© Breast Cancer Module has demonstrate more structured workflow and improved clinical data quality which are mineable for secondary use. Clinicians now have migrated from manual

to digital clinical workflow practice, and the association with information technology system has facilitated that transformation.

5.2.1 Availability of clinical champions and technical support

The highlight of the i-Pesakit© Breast Cancer Module is that it was developed in-house with close supervision by clinical and research experts in the hospital using electronic forms embedded within the EMR system as the opportunity presented during the transitioning between paper based to EMR in UMMC. This study adds on to the existing literature applying the dimensions to analyze participation of stakeholders in a breast cancer interdisciplinary work setting. Good communication and teamwork were found to be an important contributing factor to the success system implementation. This multidisciplinary collaboration between surgery and oncology departments enhanced clinical workflows and POC data capture, impacts clinical decision making for clinicians, for hospital performance audits and research use (Mohd Nor et al., 2019). The completion of the UMMC i-Pesakit© Breast Cancer Module requires consolidating multidisciplinary data from various clinical departments and these suggestions are proposed in the system implementation future works.

5.2.2 Users acceptance and efficiency enhancement in clinical practice processes

The interesting aspect of the i-Pesakit© Breast Cancer Module is the straightforward user content strategy and structure design by coordinating the electronic workflow system with the actual clinical workflow sequence to ensure accurate information entry and ease of use. The next significant feature of i-Pesakit© Breast Cancer Module is the ability to browse clinical notes, lab reports, and treatment plans with tabs in current window, specific data editing roles for clinicians and nurses, as well as data sharing between related clinical departments. The i-Pesakit© Breast Cancer Module allows clinicians to have better access to comprehensive patient histories and clinical notes, through a structured

documentation format. Not only this approach is suitable during clinic visits, it is useful during Treatment and Relapse MDT meetings with Oncologists as shown in Figures 4.5 and 4.6.

Overall, outcomes from these MDT meeting observations confirmed the importance of the i-Pesakit© Breast Cancer Module in discussing treatment options. The use of the system impacted interactions in meetings and stimulates interdisciplinary team discussions, through projection of Treatment and Relapse MDT with Oncology template forms onto a screen during discussion and entering real-time clinical data. Efficient use of the EMR can promote effective communication, clinician-patient interaction, and improve the process of documenting patient care. The result can lead to improved patient outcomes and improved clinical workflow.

5.2.3 Perceived improvements in data quality

Implementing a well-structured clinical data management system is an important measurement in producing mineable data for primary and secondary data use. Good quality data improves research outcome. Despite these known EMR benefits, reuse of these data has been limited by a number of factors, including concerns about the quality of the data and their suitability for research (Weiskopf & Weng, 2013). In this study, we have developed a systematic implementation of approaches that has proven to be as accurate as the manual legacy data management system as presented in Figures 4.17, 4.18 and Table 4.2. Clinicians felt that the system implementation has improved the quality of their records: where clinical charts and system user interface are better organized, and they were able to find data quickly. Overall, users expressed ambivalence about the new system; while some of the promised benefits were starting to be realized, there was a feeling that the implementation was much more difficult to grasp than anticipated.

5.3 Challenges in Implementing EMR in a Middle-income Country

The proposal in this study is in line with global efforts in digitizing data and clinical workflows (Armstrong, 2017; Gheorghiu & Hagens, 2016; Kostera & Briseno, 2018; B. Lau, 2017), by paying close attention towards the challenges faced in a middle-income country setting (Bigdeli et al., 2013; Mohd Nor et al., 2019). Many efforts were attempted to improve the dire situation of poor records management in Malaysia, however, there are some challenges faced which hinders the success. One of the main challenge is lack of funding in supporting medical research costs. In Malaysia, technology is available and has been incorporated into private sectors such as banking and commerce at an accelerated pace. However, as a middle-income country, funding in medical and healthcare focusing on research-based activities is restrained. According to the Malaysian National Budget, price allocation for medical research is barely USD358m (Government of Malaysia, 2017), which is less than 10% as compared to other developed countries such as USD380m in Singapore and USD32.3b in the USA (Department of Health and Human Services, 2017; Singapore Ministry of Finance, 2017).

Another challenge faced is the issue of data confidentiality (Laws of Malaysia, 2010). A governance framework needs to be established to comply with the Personal Data Protection Act 2010, where the framework must provide data protection of personal information by ensuring secured data sharing in clinical work and research. This includes assuring the system meets the security standards, privacy protection and infrastructure readiness. In this study, workflow factors that contribute to patient data privacy in accordance to the Personal Data Protection Act 2010 and Malaysia Health Care Act and the National Archive of Malaysia Act were incorporated early during the planning process to ensure sustainability and compliance (Laws of Malaysia, 2010) through direct engagement with the Medical Records department. However, reaching agreement in finalizing the governance policy matters pertaining to data policy and confidentiality with

the hospital management and medical records department took months and was time consuming as it goes through different levels of meeting with the stakeholders. Models of governance is managed by Clinical Investigating Centre (CIC) , a committee within hospitals to address issues brought about by projects like this which is a point of integrated network between clinical workflow and research. The roles of CIC go beyond liaising with Medical Ethics Committee to ensure safe clinical workflow and ethical standards are met (University of Malaya, 2019).

5.4 Limitations

Although the acceptance of most users was positive; however, some stated that they only felt adequately prepared. Additional time training may be helpful for users having difficulty using the system. Through the on-site observation, some were frustrated due to several aspects of the i-Pesakit© Breast Cancer Module including readability of the screen interface. There may be a need to address these concerns with the system development team as well as the evaluation and quality assurance team (breast care nurse) regarding the need to improve ease of use and utility of i-Pesakit© Breast Cancer Module. The i-Pesakit© Breast Cancer Module prototype system implementation across the departments contain limitations that restrain the smoothness of implementation which need to be acknowledged. The primary limitation is related to the lack of compatibility and high complexity of system, doctor-patient interaction which affects work quality, technology barriers especially in system interoperability of specialized system features and inaccuracies in data capture.

5.4.1 Lack of compatibility and high complexity

Some users perceived that the i-Pesakit© Breast Cancer Module system as complex, difficult to use, inflexible, and less compatible with their current needs. The top comments given were:

"When we need to include multiple inputs to the system, there is not much of flexibility. It only allows us to put in one answer."

"When you enter the medications details, options are limited and constraint to a few choices."

"Too many particulars need to be filled up, it is very time-consuming searching for the options."

"The interface layout can sometimes be confusing, we sometimes key in free text inputs to speed up our work in the busy clinic."

The complexity and usability problem issues result in clinicians having to spend more time and effort to master clinical system workflow, which they see it as a burden. Some senior clinicians considered i-Pesakit© Breast Cancer Module to be challenging to use because of the lengthy questions and multiplicity of templates, options and navigational aids. This was felt due to system interface issues, lack of familiarity when using the system. The most affected group of users facing difficulties are the senior clinicians who concluded that they may have insufficient technical skills in using i-Pesakit© Breast Cancer Module, and that this results in resistance. Furthermore, quick typing skills are needed to transcribe patient medical information, notes and prescriptions into the i-Pesakit© Breast Cancer Module, and some clinicians are frustrated with it as it is time-consuming. This lack of skills hinders the wide adoption of i-Pesakit© Breast Cancer Module. Several clinicians mentioned the decrease in efficiency due to technological barriers such as lack of system interoperability. Some external materials such as referral letters and outside test results need to be scanned in; hence the system may overlook these inputs as a newly diagnosed breast cancer incidence. This drawback affects the data quality, especially in audit and quality measurement.

Deploying i-Pesakit© Breast Cancer Module system means switching from manual data management and transcription to electronic-based systems. Some clinicians were initially reluctant to switch workflow patterns as they are comfortable with the current state of manual clinical data transcription. From the usability survey conducted, results show that those who are unwilling to try out the new system are skeptical about claims that digital structured clinical documentation can successfully improve the quality of clinical practice, which creates individual resistance to adopt i-Pesakit© Breast Cancer Module.

5.4.2 Inaccuracies in data capture

Erroneous user input is due to lack of experience dealing with the breast cancer module. High turnover of medical officers occurs within the department once in every three months. Figure 4.18 and Table 4.2 reported the inaccuracy of clinical inputs where there are mistakes of information being reflected in the breast cancer module.

We found low capture of new cases – reiteration of pages, to include capture of new incident cases during first visit and after a diagnosis . Clinical visit templates were not correctly picked by users, as data collection is dependent on using the designated result clinic template for new cases data capture. Hence, we reviewed the users' clinical workflow and found that we missed out some new cases that were diagnosed from outside UMMC. The i-Pesakit© Breast Cancer Module system has been enhanced to capture new cases during the first visit. The system has been updated to include registry reporting form template at designated clinical templates to enable gradual data collection.

The electronic chemotherapy automated reporting also needed revival and revamp as only prescribed data were available, however actual doses administered was not captured as the nurses were not able to change their workflows in documenting manually. Hence, careful usability needs to be considered for successful implementation. Currently nursing

workflows are being studied to find the best solution to document administration of chemotherapy.

5.4.3 Lack of doctor-patient interaction affects work quality

A fluent patientcare workflow is a priority to the work of clinicians. The usability test conducted was to test the ease-of-use and convenience of the system. It was found that allthough most participants' experiences lead to increased digital workflow convenience, the senior clinicians perceived the time taken when using the system is longer. In some scenarios, clinicians find it more convenient and efficient to use paper-based records during the clinical encounter .With many data fields to fill in the digital form, they find the system module lengthy to use and would slow down their workflow. Clinicians have to turn to the computer to complete the electronic clinical templates during patient encounter and become over-dependent on the system, with less eye-contact with the patient that affects communication skills and history-taking. Though it was thought that the i-Pesakit© Breast Cancer Module would eventually lead to increased efficiency, there is a small fraction of clinicians experiencing time lag between each patient queue because it takes longer time to see a patienefficiet. It is important to curb this issue as the ability to communicate effectively with patients can contribute significantly to improved patient outcomes. However, other clinicians argue that mastering the i-Pesakit© Breast Cancer Module system will help them to work more efficiently.

5.5 Future Works: Improving Electronic Clinical Practice Workflow Through Implementation Suggestions

The advancement in technology has changed how stakeholders operate in a healthcare institution. To be successful, healthcare professionals must work together interdisciplinary to keep up with the progress of technology, maintain quality, control cost, and implement the best digital clinical workflow practice. Since the i-Pesakit©

Breast Cancer Module has gone live since February 2016, many lessons were learnt from the experience and improvement suggestions were made to enhance the current system.

5.5.1 i-Pesakit© Breast Cancer Module workflow guideline poster

A workflow poster diagram was designed and displayed in the clinic as shown in Figure 5.1. These step-by-step instructions assist users in categorizing patients' types between newly diagnosed, follow-up or recurrence breast cancer cases. The following visual guideline has been prepared as an effective way to assist in i-Pesakit© Breast Cancer Module sequence in clinics.

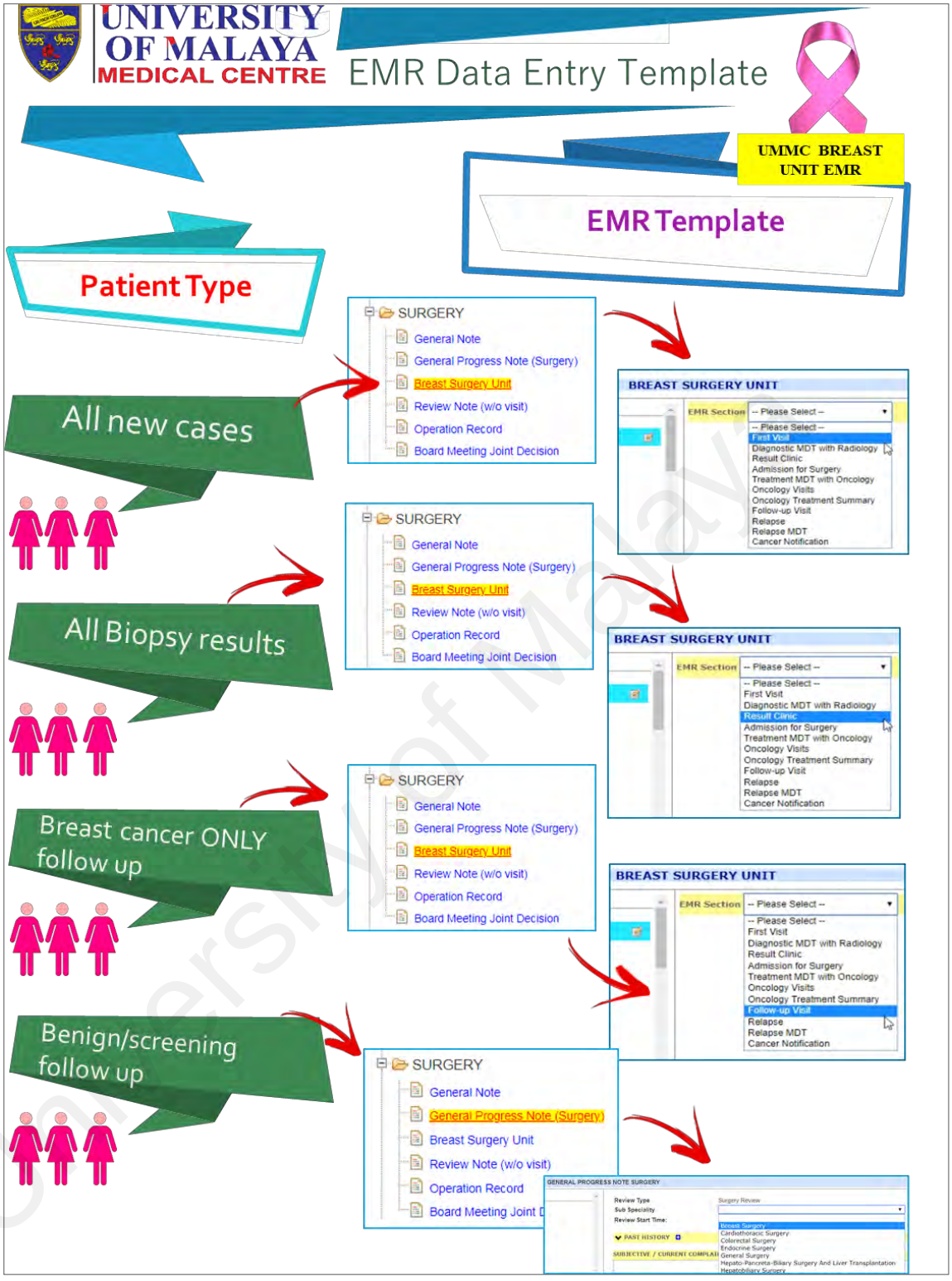


Figure 5.1: Digital workflow poster display of i-Pesakit© Breast Cancer Module at UMMC breast surgery clinics

5.5.2 National Cancer Registry form pop-up

The data source of capturing newly diagnosed breast cancer cases are from first visit, results clinic, and follow-up visit patients who are alive with a new primary cancer. Additionally, this information may also be captured from wards discharge summary as well as at the oncology clinic visit. A solution is proposed in ensuring clinical data are accurately recorded as mentioned in Chapter Section 5.4.2. Due to the missed new cases diagnosed outside UMMC captured by the system, a technical work flow design is prepared to include registry reporting form template on selected clinical templates to enable gradual data collection; namely First Visit and Results Clinic templates. Figure 5.2 illustrates the build-in system which prompts the Cancer Registry Form to pop-up at multiple stages of the module system. This form should appear at the first visit and results clinic sessions to allow timely data capture, particularly for those diagnosed outside UMMC. Some patients may come for a "first visit" in UMMC as a follow up appointment from a different hospital, also some may have done biopsy and mammogram examinations outside UMMC and brings the reports for review at UMMC. Thus the NCR pop up would be able to document these incidences hence provide a solution for capturing details of newly diagnosed cases outside UMMC. The workflow also functions as a guideline to ensure the correct templates are used at the right time. A similar technical function of template NCR form pop-up on i-Pesakit© Breast Cancer Module will be implemented in the wards discharge summary, oncology clinic department documentation within the EMR to expand the scope of data capture of new cases.

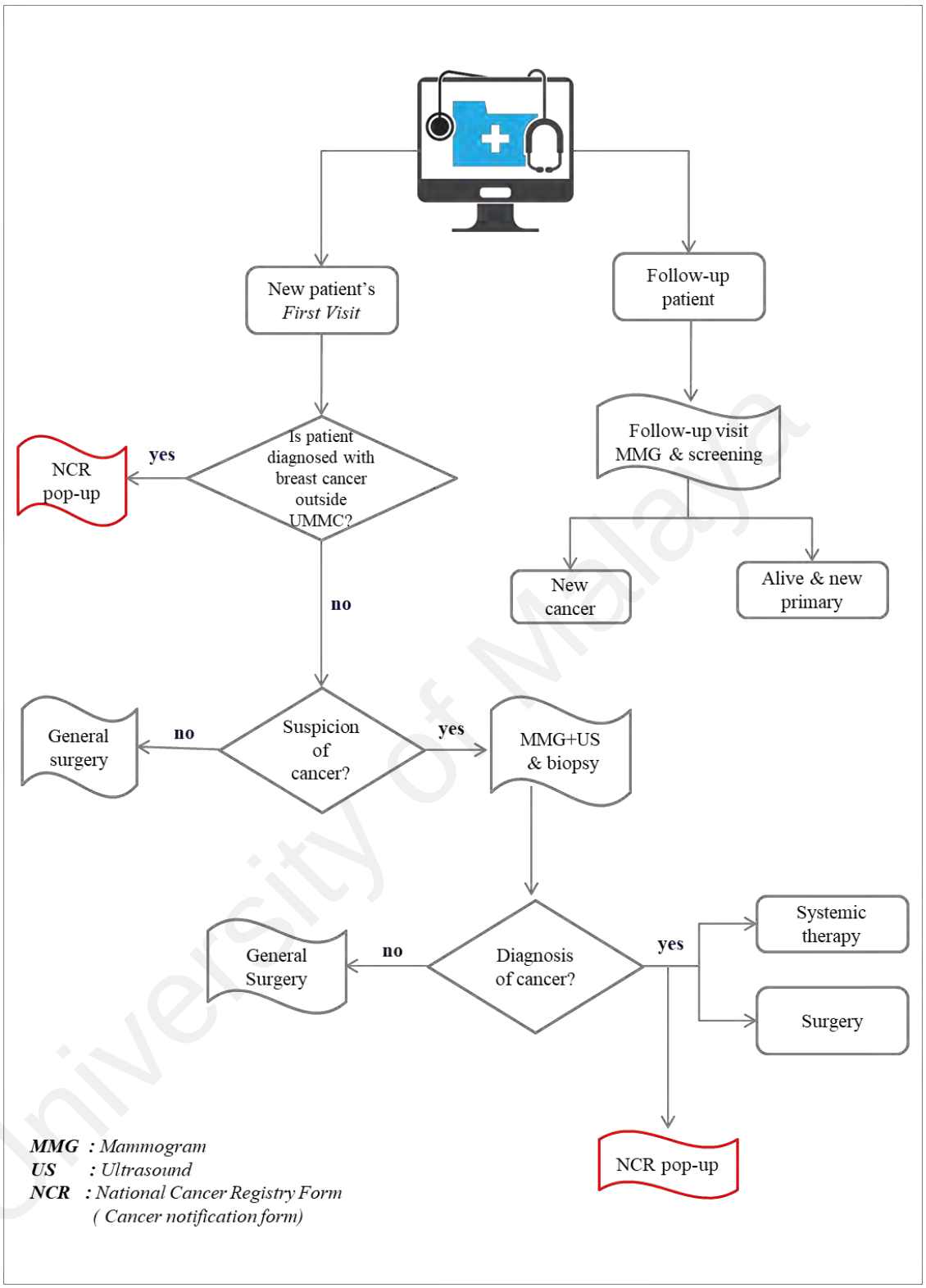


Figure 5.2: Cancer notification form pop-up flowchart

5.5.3 Integrating other related departments: Pathology and Radiology

Through this implementation, we have a design plan which is generic to be implemented in other departments in the hospital. It is good that the foundation used in the i-Pesakit© Breast Cancer Module is the hospital's existing EMR system, hence we can reuse our upper layer design workflow to match the requirements in the other departments such as Radiology and Pathology. Continuous efforts are under way in maintaining and improving the Surgery, Oncology and Pharmacy modules using the feedback form provided to end users. Future work in incorporating other disciplines into the i-Pesakit© Breast Cancer Module will allow other data sources from oncology, radiology, pathology and pharmacy to be integrated to improve the completion and accuracy of the data reported into the existing audit and research forms. Outcome research in oncology requires accurate clinical and follow-up data. In view of future developments in bioinformatics, research organization readiness to produce accurate clinical and follow-up data is crucial. Additionally, we would like to incorporate the National Cancer Registry form workflow of other clinical units managing cancer sites and consolidate these data that can be managed as UMMC cancer registry in the future.

5.5.4 Automated measurement and improvement of outcomes

As the electronic clinical data increases and the burden of breast cancer rises, there is a critical need to implement quality metrics that measure and benchmark the breast cancer care. Such metrics can be used to drive quality improvement, and accountability for population-based outcomes. The main approaches of the solution proposed are clinical audits and measuring the hospital's patientcare performance using healthcare quality metrics. As the ICD coding system in TNM staging undergoes a new version in the future (for example, ICD-11), the transition process involves the previous ICD concept to be extended through 1-to-1 mapping to support compatible integrated access to clinical legacy data (Hernandez-Ibarburu et al., 2019; Monestime et al., 2019).

5.5.5 Clinical audit and reporting

As the use of EMR expands, there is an opportunity to use the patient data from EMR for other purposes. The EMR is a resourceful source of data in performing clinical audit. Currently, bi-annual process has been done manually by clinicians in charge. There is a window of opportunity in utilizing the EMR system for this purpose. The ability to produce reports on breast cancer outcomes in Malaysia to be used by stakeholders such as clinicians, researchers, and the government is essential for research, hospital performance for policymakers to track outcomes and provide direction in cancer control. This is also a time effective approach while producing new knowledge through systematic data capture design, data mining and analysis, enhancing research and development in the medical and health sciences domain.

5.5.5.1 Quality measurement

The key domains and individual metrics have been identified after feedback from the clinical champions. Through series of discussion conducted, agreement on a set of measures and guidance on how the clinical data should be automatically mapped from the system and reported. A developed series of breast cancer care quality metrics across the i-Pesakit© EMR were identified. This future system function systematically evaluates breast cancer care for patients such as time taken to diagnosis and time taken to surgery. At this current state, engaging stakeholders from diverse clinical departments to guide the implementation and dissemination of this project is still ongoing.

In expanding the scope of study in measuring the work efficiency among clinicians, the next step is to capture the time taken to fill up the electronic module compared to time taken previously to fill up manual sheets, as the main impact of EMR would be clinic time as clinical text takes time.

5.5.5.2 Ongoing user training

i-Pesakit© Breast Cancer Module user training was offered prior to EMR start-up, but there were no formal sessions scheduled once implementation has started. Users recognized their need for on-going training in the breast cancer module system use, as well as beginner's trainings for clinicians who newly joins the department, as the turn-over rate of medical officers are high; every three months once.

Some clinicians perceived a need for proper system usability training and are reluctant to use i-Pesakit© Breast Cancer Module without it. Therefore, breast care nurses will be assigned to coordinate on-site training within the practice and system use. Some clinicians reported a lack of access to technical support, so breast care nurses will also be responsible to as the intermediary team between clinicians and system development team for fast-response in solving technical issues at the clinic. This would be a practical solution to curb the technical support issues on-site. Relying on the breast care nurses may not be feasible due to the busy routines in a day's clinic, hence training for each new posters is another way to ease the burden in monitoring the system performance review.

5.5.6 Clinical research implementation suggestions

I-Pesakit© is a rich source of data for different types of clinical breast cancer research, such as cohort studies, assessments of the meaningful use of EMR and producing meaningful oncology outcomes. This benefit can be achieved through the establishment of research knowledgebase (i-Research) which opens up opportunities to external research collaborations in the future. The model (Figure 3.6) derived from the experience of design and implementation of the module has taught the importance of incorporating a platform for research that has access to both confidential data and editing capabilities, as working on cancer would need identifiers and communication with other bodies. As aforementioned, the model is in line with the standards laid out by the Clinical Data

Interchange Standards Consortium (Clinical Data Interchange Standards Consortium, n.d.) The CDISC standard has also been applied in prominent research on EMR (Hudson et al., 2018; Kuchinke et al., 2009; Noumeir, 2008).

Future work will also include a research module (i-Research) where primary clinical data will be de-identified and used for research-based activities. We propose mirroring of i-Pesakit© to produce the i-Research module as presented in (Figure 3.8), where different levels of access and permissions are granted for clinicians and researchers. The deployment of EMR in hospitals enables electronic reporting and fosters research by establishing affiliations with other institutions and potential external collaborations. It provides a carefully controlled research environment for clinicians and scientists to conduct safe and high-quality clinical research through the compliance of the Malaysian ICH Good Clinical Practice and is acceptable by the international regulatory authorities.

5.5.7 Data science reshaping healthcare

The health care system is rapidly producing a large amount of data, driven by record keeping, registry reporting, compliance and regulatory requirements, and patientcare (Bhatt et al., 2017). Being able consolidate high volume of structured clinical data and further make sense of it is the key objective for data scientists and machine learning experts. It also has a high potential to revolutionize healthcare and there are many significant ways data science is advancing the medical industry. Interdisciplinary approach is the way forward. Clinicians, bioinformaticians as well as information technology experts must work together in achieving its premium clinical informatics benefits. This approach may bridge the gap between healthcare delivery and population health for meaningful use (Wyber et al., 2015). It opens opportunities to improve the infrastructure of operations to create a safer and higher-quality healthcare delivery, and

gradually changing the mindset of stakeholders from skepticism to understanding the usefulness of health information technology in simplifying tasks.

It is widely believed that EMRs improve clinical decision-making (Ben-Assuli et al., 2015). Data science may potentially increase accuracy of diagnosis through deep learning algorithms which reads imaging data, analyze and cross-checking the results with actual clinical notes and laboratory reports (AltexSoft, 2018). Friedman *et al.* (2015) discussed about turning cancer patientcare into precision medicine, where clinicians are able to define specific symptoms of the disease, taking into account the individual condition of the patient, medical history, and genetic information in order to tailor the treatment accordingly and increase the chances for positive outcomes. More importantly, this would also be useful in disease prevention, early detection, and treatment (Friedman et al., 2015; Shieh et al., 2017).

5.6 Conclusion

This thesis contributes to health informatics research in developing countries mainly in three ways. Firstly, it contributes to the understanding of breast cancer clinical data management in a middle-income country setting such as University Malaya Medical Centre where the importance of implementing a digital workflow is acknowledged. Secondly, it contributes to the understanding of expanding the EMR scope beyond clinical usage for quality measurement, audits, national registry reporting and high-quality research in producing oncology outcomes. Thirdly, it provides understanding of impact in migrating to an interdisciplinary digital clinical workflow.

We have successfully implemented a client-web-based i-Pesakit© Breast Cancer Module system for breast cancer interdisciplinary clinical care, by adopting the Quality Implementation Framework, using structured data entry to improve the ease of clinical documentation, and simultaneously populate the system module and EMR to facilitate

outcomes reporting. The pilot disease cohort for this system is UMMC breast cancer surgery, oncology and pharmacy services. Based on the initial implementation impact in terms of efficiency gains, these outputs are significant in providing a governance model and proof-of-concept for other breast cancer multidisciplinary disciplines such as Radiology and Pathology to complete the breast cancer module that can then be used for other cancer sites.

The ultimate goal of this study is to merge both electronic clinical and research workflow concepts into a single automatic system to provide optimum benefits to healthcare providers and researchers. This is done by making the EMR as data source for patientcare and secondary data use with multilevel user access and system security. Linking electronic medical records and state registry data enables outcomes research and consolidating these records with National Registration Department mortality data improves health services research.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

PUBLICATIONS

1. **Mohd Nor, N. A.,** Taib, N. A., Saad, M., Zaini, H. S., Ahmad, Z., Ahmad, Y., & Dhillon, S. K. (2019). Development of electronic medical records for clinical and research purposes: The breast cancer module using an implementation framework in a middle income country-Malaysia. *BMC Bioinformatics*, *19*(13), Article #402.

PAPERS PRESENTED

1. **Nor, N. A. M.,** Taib, N. A., Saad, M., Zaini, H. S., Ahmad, Z., Ahmad, Y., & Dhillon, S. K. (2018). Development of electronic medical records for clinical and research purposes : The breast cancer module using an implementation framework in a middle-income country- Malaysia. Paper presented at the 17th International Conference of Bioinformatics (InCoB 2018), 26-28 September 2018, New Delhi, India.

2. **Nor, N. A. M.,** Taib, N. A., Dhillon, S. K. (2017). Breast Cancer Data Integration : Multidisciplinary point-of-care data capture for innovative healthcare. Paper presented the 4th UM eHealth Journal Club, 13 March 2017, University of Malaya, Kuala Lumpur.

3. **Nor, N. A. M.,** Taib, N. A., Dhillon, S. K. (2016). Expanding the scope of electronic medical records for breast cancer clinical research and secondary data use. Paper presented the 11th International Conference on Healthcare and Biological Research (ICHBR), 21-22 February 2016, Dubai, United Arab Emirates.

4. **Nor, N. A. M.,** Taib, N. A., Dhillon, S. K. (2015). Establishing breast cancer research knowledgebase: A computational approach using UMMC clinical records. Paper presented the 20th Biological Sciences Graduate Congress (20th BSGC), 9-11 December 2015, Bangkok, Thailand.