THE INTEGRATION OF BIOMEDICAL TESTING AND LABORATORY PRACTICES FOR A REFERRAL SYSTEM DEVELOPMENT

NURUL NABILAH BINTI SAFFINYE

SULTAN IDRIS EDUCATION UNIVERSITY

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ABSTRACT

This study aimed to explore the current laboratory practices in managing biomedical testing services in Malaysia and to develop a laboratory referral system prototype. This study is divided into two phases: i) a need analysis of biomedical testing services offered and current laboratory practices, and ii) prototype development of a laboratory referral system. The responses of 24 ISO15189 accredited laboratories were obtained through the WHO Laboratory Quality Stepwise Implementation questionnaire. The laboratory referral system framework was designed based on the responses obtained in the first phase using the IBM Garage methodology to centralise the laboratory workflow using a digital platform. A laboratory referral system prototype was developed using a Rapid Application Development method and validated through user acceptance testing. Our findings revealed nine categories of biomedical testing services offered by participating laboratories. Most laboratories face challenges in catering to the growing demands of biomedical testing due to i) financial constraints, ii) limited technical expertise, and iii) a lack of special equipment and facilities. Furthermore, none of the laboratories had a standard digital procedure for tracking and recording special biomedical tests, in which half of the laboratories manually recorded information in a logbook. User acceptance testing of the laboratory referral system prototype developed in this study showed that the prototype's technical aspects were efficient (95%) and the content aspects were user-friendly (94%). This study provides an overview of laboratory practices and the current management of biomedical testing services in Malaysia. The prototype laboratory referral system developed in this study helps mitigate the challenges faced by laboratories in handling biomedical practices more efficiently. The study emphasised the benefits of integrating digitalisation in laboratory practices. The implementation of digitalisation in laboratory workflows has the potential to improve the efficiency and coordination of laboratory services in Malaysia.

INTEGRASI UJIAN BIOPERUBATAN DAN AMALAN MAKMAL DALAM PEMBANGUNAN SISTEM RUJUKAN MAKMAL

ABSTRAK

Kajian ini bertujuan untuk meneroka amalan semasa makmal dalam menguruskan perkhidmatan ujian bioperubatan di Malaysia dan membangunkan prototaip sistem rujukan makmal. Kajian ini dibahagikan kepada dua fasa: i) analisis keperluan bagi perkhidmatan ujian bioperubatan yang ditawarkan dan amalan semasa makmal, dan ii) pembangunan prototaip sistem rujukan makmal. Maklum balas dari 24 makmal dengan akreditasi ISO15189 diperolehi melalui instrumen WHO *Laboratory Quality Stepwise Implementation*. Rangka kerja sistem rujukan makmal telah dibina berdasarkan maklum balas yang diperolehi dalam fasa pertama menggunakan metodologi IBM *Garage* untuk memusatkan proses kerja makmal menggunakan platform digital. Satu prototaip sistem rujukan makmal telah dibangunkan menggunakan kaedah *Rapid Application Development* dan disahkan melalui ujian penerimaan pengguna. Penemuan kajian mendedahkan bahawa sembilan kategori perkhidmatan ujian bioperubatan ditawarkan oleh makmal yang mengambil bahagian dalam kajian ini. Kebanyakan makmal menghadapi cabaran dalam memenuhi permintaan ujian bioperubatan yang semakin meningkat disebabkan oleh, i) kekangan kewangan, ii) kepakaran teknikal yang terhad, dan iii) kekurangan peralatan khas dan kemudahan. Di samping itu, tiada makmal yang mempunyai prosedur digital standard untuk mengesan dan merekod ujian bioperubatan khas, di mana separuh daripada makmal merekodkan maklumat dalam buku log secara manual. Keputusan ujian penerimaan pengguna terhadap prototaip sistem rujukan makmal yang telah dibangunkan dalam kajian ini menunjukkan bahawa aspek teknikal prototaip adalah cekap (95%) dan aspek kandungan adalah mesra pengguna (94%). Kajian ini memberikan gambaran keseluruhan amalan makmal dan pengurusan semasa bagi perkhidmatan ujian bioperubatan di Malaysia. Prototaip sistem rujukan makmal yang telah dibangunkan dalam kajian ini dapat membantu mengurangkan cabaran yang dihadapi oleh makmal dalam mengendalikan amalan bioperubatan dengan lebih cekap. Kajian ini telah menekankan manfaat pengintegrasian digital dalam amalan makmal. Pelaksanaan pendigitalan dalam proses kerja makmal berpotensi menambah baik kecekapan, dan koordinasi perkhidmatan makmal di Malaysia.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AI	Artificial Intelligence
BTRIS	Biomedical Translational Research Information System
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CKI	Cohen's Kappa Index
COVID-19	Coronavirus Disease 2019
CVI	Content Validity Index
DOSM	Department of Statistics Malaysia
EHR	Electronic Health Records
EMR	Electronic Medical Records
HKL	Hospital Kuala Lumpur
HWP	Health White Paper
KKM	Kementerian Kesihatan Malaysia
LQSI	Laboratory Quality Stepwise Implementation
MOH	Ministry of Health Malaysia
NCD	Non-communicable Diseases

NHMS	National Health and Morbidity Survey
NIH	National Institutes of Health
NKEA	National Key Economic Areas
PeKa B40	Skim Peduli Kesihatan Kumpulan B40
RAD	Rapid Application Development
RCPA	Royal College of Pathologists of Australasia
TAT	Turnaround Time
UAT	User Acceptance Testing
UML	Unified Modeling Language
VBA	Visual Basic Analysis
WHO	World Health Organization

APPENDIX LIST

CHAPTER 1

INTRODUCTION

1.1 Research Background

The World Health Organization (WHO) defines primary healthcare as a societal approach to health and well-being centred on the needs and priorities of individuals, families, and communities. Primary healthcare ensures that people receive comprehensive care, from promotion and prevention to treatment, rehabilitation, and palliative care, as closely as possible to their daily environment (WHO, 2021; Safurah et al., 2013). Access to healthcare is a basic human right, and the coronavirus disease (COVID-19) outbreak has challenged the current healthcare system and affected the provision of public primary care (Holladay, 2020; Kaos et al., 2021).

One of the most recent and essential developments in the healthcare world is the use of artificial intelligence (AI) to predict future disease probabilities, so that healthcare professionals and patients can proactively initiate lifestyle changes. The use of artificial intelligence to identify patients at risk of disease relies heavily on medical data produced by medical testing laboratories. However, the accuracy of AI-based disease prediction models depends heavily on the quality and quantity of the medical data produced by medical laboratories (Kumar et al., 2022). Therefore, medical laboratories must keep up with the growing demand for tests which may effect the effectiveness of AI-based disease prediction models.

Medical laboratories are under heavy pressure owing to the growing demand for higher and more complex test requirements, which results in an increasing number of laboratories outsourcing testing to fill gaps in service coverage (WHO, 2021; Giorgia, 2021). For example, the impact of the COVID-19 pandemic has affected medical testing laboratories worldwide. Business valuations for medical testing laboratories have soared to levels that no one in the healthcare world has ever imagined (Chriscaden, 2020; Holladay, 2020). In Malaysia, biomedical testing laboratories are under heavy pressure to carry out a large number of COVID-19 laboratory tests every day, as the country struggles through the outbreak (Zakiah, 2021; Tan, 2021; Koh, 2021). Laboratory tests are becoming increasingly important in medical practice, from screening and diagnosing medical conditions to choosing the appropriate therapy to treat the disease (WHO, 2021; Chriscaden, 2020; Alshieban et al., 2015).

Healthcare in Malaysia is largely administered by the public sector where all government hospitals and clinics operate as the main source of care (Safurah et al., 2013). As with any health system, the goal is to provide social protection to citizens with universal coverage and quality healthcare. One of the main challenges in Malaysia is the continuation of healthcare provision that is accessible to all communities, especially when the cost of healthcare provision is increasing (Onn, 2015; Chan et al., 2014). Primary healthcare, as the closest to the community, started in 1956 as a three-level healthcare model consisting of a primary health centre, a minor health centre, and midwifery clinic. To increase efficiency, this model was later developed into a two-level system in 1970, as what we have today, which consists of Health Clinics and Community Clinics (Safurah et al., 2013). In addition, the Malaysian health system is heavily subsidised by the Ministry of Health Malaysia (MOH), which acts as a funder, provider, and regulator. In an effort to maintain and upgrade this health system, the MOH has implemented digital healthcare transformation (Koh, 2020; Nurafifah, 2020).

Malaysia is accelerating digital healthcare transformation initiatives to meet public care needs and treatment demands (Onn, 2015). Cost reduction and increased effectiveness are the main advantages of the digital revolution in healthcare. In 2020, the Ministry of Health Malaysia emphasised the importance of transitioning the healthcare system today, focusing on high-impact initiatives for the public good, reasonable costs, and excellent results in embracing Malaysia 5.0 mission (Nurafifah, 2020; Arumugam, 2020). In support of this initiative, this study aimed to develop a digital laboratory referral system that can improve laboratory services in Malaysia. The referral system was designed based on a framework obtained by probing the challenges

faced by local laboratories in managing outsourced laboratory testing and the current practices in handling biomedical testing in Malaysia.

This study is divided into two phases: i) a need analysis of the category of biomedical testing services offered and the current laboratory practices in Malaysia and ii) prototype development of a laboratory referral system based on the designed framework. In the first phase, the instrument used a questionnaire was administered to 24 laboratory practitioners in Malaysia to ensure that the study was in accordance with the best laboratory standards. A literature review is conducted to provide an overview of this study. The second phase of the study involved the prototype development of a laboratory referral system based on the designed framework. The findings of the questionnaire data analysis and literature reviews were used in the designation of the laboratory referral system framework, which consists of two steps: 1) modelling the framework through Unified Modeling Language (UML), and 2) modelling the framework through the IBM Garage methodology. This research prototype was developed using Rapid Application Development (RAD) method and Visual Basic Analysis (VBA) programming language.

1.2 Problem Statement

Malaysia's healthcare service accessibility is limited, and many clinical testing services are unavailable outside of cities (Laura, 2019; CDC, 2018). Additionally, biomedical laboratory testing results play a significant role for healthcare providers. According to

the U.S. Department of Health and Human Services, 14 billion laboratory tests are ordered annually, and 70% of medical decisions depend on laboratory results (CDC, 2018). The demand for healthcare is expected to increase due to demographic changes such as population aging, increased life expectancy, and the spread of non-communicable diseases (Code, 2020; Rasiah et al., 2017). According to the Department of Statistics Malaysia, the aging population is expected to increase by 40% over the next 30 years, and the increased demand for treatment presents additional challenges to the system (DOSM, 2023). Therefore, hospitals are increasingly relying on technology to supplement their services. The Health White Paper (HWP) strategy from the Ministry of Health Malaysia sets out a holistic proposal for systemic and structural reforms of the Malaysian health system to respond to the nation's health challenges (KKM, 2023).

The NSP-NCD 2016-2025, the National Strategic Plan for Non-Communicable Disease developed by the Department of Prevention and Control, Ministry of Health Malaysia, addresses the non-communicable diseases (NCDs), which have emerged as the foremost cause of mortality and morbidity among the adult population in Malaysia (KKM, 2023; KKM, 2016). Digital health tools play an important role, as they encompass exercise monitors, fitness watches, sleep monitors, and applications that monitor individuals' lifestyles and NCD risk factors (WHO, 2023; Monaco et al., 2021). Furthermore, the increase in laboratory testing in Malaysia is likely to reduce the prevalence of NCDs. Notably, the PeKa B40 effort, a Ministry of Health initiative, intends to sustain low-income groups' healthcare needs by focusing on NCD laboratory testing (KKM, 2023). According to the Malaysian National Health and Morbidity Survey (NHMS), chronic diseases have been on the rise since 2011. Based on 2019

data, one in every five adults had diabetes, three in every ten adults had hypertension, and four in every ten adults had high cholesterol (NIH, 2020). These figures are among the highest in Asia, and making Malaysia one of the region's least healthy countries (KKM, 2023).

In addition, a significant challenge for Malaysia's healthcare system is poor collaboration between the private and government sectors (KKM, 2023; Hamzi et al., 2020; Rasiah et al., 2017). According to the Health White Paper by the Ministry of Health (KKM, 2023), establishing public-private partnerships is the key to enhancing the transformation of healthcare service delivery in Malaysia. It is imperative to ensure more efficient and effective utilisation of resources across both public and private sectors. One of the critical aspects of achieving this goal is the sharing of patient records across various facilities and providers. To achieve this goal, initiatives to pilot and scale up electronic medical records (EMR) are of utmost importance (KKM, 2023). In 2020, the world was confronted with the coronavirus disease COVID-19 pandemic. During the battle against the pandemic in Malaysia, Dr. Subramaniam Muniandy, the President of the Malaysian Medical Association (MMA) at that time, highlighted the labourious and inefficient MOH e-notification system and the Public Health Laboratory Information System (SIMKA) for public-private sector COVID-19 case reporting. The MMA proposed the MOH to simplify and integrate the two systems to expedite the reporting of COVID-19 test results (NST, 2021).

Furthermore, the use of technology in healthcare is essential. According to the Ministry of Health Malaysia, the effects of the COVID-19 pandemic and global digitisation trends have changed attitudes and accelerated the adoption of policies that enable businesses to work (Amanda, 2020). The impact of the pandemic on healthcare information technology (telehealth, cloud computing, artificial intelligence, analytics, IoT, e-prescriptions) in Malaysia and worldwide (Amanda, 2020; Salway et al., 2020; Ye et al., 2020). This digitisation trend allows medical practitioners to assess and diagnose patients, prescribe medications and treatments, and monitor fluctuations in their medical condition through remote consultations. The recent COVID-19 pandemic has provided an excellent opportunity for telehealth solutions to minimise exposure to social distancing (Serbulova et al., 2020; Salway et al., 2020; Ye et al., 2020). This research project provides a unique opportunity to accelerate the digital transformation in Malaysian healthcare by examining outsourcing practices for laboratory testing.

1.3 Research Objectives

This study had three main objectives:

a. To investigate the category of biomedical testing services offered and the current laboratory practices for handling biomedical testing in Malaysia.
b. To propose a laboratory referral system framework that enhances current laboratory practices in Malaysia.
c. To develop a prototype laboratory referral system based on the designed framework.

1.4 Research Questions

a. What are the categories of biomedical testing services provided and what are the current laboratory practices for handling biomedical testing services in Malaysia?
b. What is the appropriate framework for a laboratory referral system to enhance the current practices in Malaysia?
c. How can a referral laboratory system be developed based on the designed framework?

1.5 Research Overview

This study was divided into two main phases. In the first phase (Phase 1), a need analysis was conducted to identify the categories of biomedical testing services offered and current laboratory practices in Malaysia. The findings of the first phase were employed in the second phase (Phase 2) to further construct the laboratory referral system framework. This was followed by the development of a laboratory referral system prototype to facilitate future app development for real users. A literature review was conducted to provide an overview of this study.

The first research objective was achieved in Phase 1, in which an interview with a guided questionnaire was conducted to understand the challenges faced by laboratories in managing testing services. The questionnaire (guided questions) was divided into three parts. The first part consisted of questions about the respondents'

demographic information. The second part contained questions regarding the respondents' laboratory information and the category of biomedical testing services offered. The third part contained questions about their experience with laboratory test-outsourcing services. The first phase involved the participation of experienced laboratory practitioners from 24 laboratories in Malaysia, to ensure that the study results were in accordance with the best laboratory standards.

The second objective was achieved through Phase 2, based on the outcomes of Phase 1. The second phase of the study was the prototype development of a laboratory referral system based on the designed framework. The findings of the questionnaire data analysis and literature reviews were used in the designation of the laboratory referral system framework, which consists of two steps: 1) modelling the framework through Unified Modeling Language (UML), and 2) modelling the framework through the IBM Garage methodology. After modelling the referral system framework through UML Diagrams, IBM Garage methodology was used to detail each component, process, and interaction flow between elements included in the referral system framework. A framework was built using IBM Garage methodology, which is a visual representation of the actual structure or concept of this study.

The third objective was achieved in Phase 2 which was to develop a laboratory referral system prototype based on a designed framework with three components: role, experience, and implementation. The role component refers to functions served by the user. The experience component refers to the user experience. The implementation component is a functional component. This research prototype was developed using the

Rapid Application Development (RAD) method and validated through user acceptance testing (UAT). The UAT results indicate that the prototype technical aspects are efficient, and the prototype content aspects are user-friendly. The Visual Basic Analysis (VBA) programming language was used to create a prototype page and function. Prototype development has gained insights and suggestions from experienced laboratory practitioners to ensure that the workflow of the testing process, from creating a new order to reporting results is correct and follows the best standard.

1.6 Research Significance

As information technology progresses rapidly worldwide, finding and receiving information has become more manageable. The COVID-19 pandemic has added to the urgency to move forward with technology that enables flexibility and accessibility for biomedical testing laboratories. The digital laboratory referral system prototype developed in this study could be a platform that offers flexibility in handling biomedical testing and further improves the healthcare industry.

Malaysia's healthcare service accessibility is limited, and many clinical testing services are inaccessible outside of major cities (Laura, 2020; CDC, 2018; Rasiah et al., 2017). Biomedical laboratory test results play a significant role in the healthcare setting. It is estimated that up to 70% of all healthcare decisions on diagnosis and treatment are based on test results from biomedical laboratories (WHO, 2021; Avril, 2021; CDC, 2018). The importance of selecting a biomedical laboratory for outsourcing needs and

ensuring an efficient and error-free workflow cannot be understood (Weinstein et al., 2019; Mrak et al., 2018; Bennett et al., 2013; Tony et al., 2013). The laboratory referral system prototype proposed in this study can bridge the gap in the availability of clinical testing services in Malaysia and enhance the workflow involved in outsourcing biomedical laboratory tests.

Furthermore, an efficient timeframe is crucial for healthcare delivery systems (Amanda, 2019; Pan et al., 2015). An efficient and effective laboratory test outsourcing process between laboratories will benefit patients through fast-tracking diagnosis (Standley et al., 2019). A faster and high-quality laboratory test will ensure faster treatment delivery. Simultaneously, laboratories can save time in managing laboratory samples, reduce operation costs, and improve the quality of services offered. The healthcare industry will benefit from this system's positive network and environment to provide the world's best patient care.

In Malaysia, the Ministry of Health partnered with a local telemedicine company to develop a virtual health consultancy platform, called DoctorOnCall (Jotham, 2020). During the pandemic, the Ministry of Health Malaysia has made significant progress in digital healthcare transformation via the MySejahtera mobile application and adoption of telemedicine, whereby the user can use it for contact tracing, booking of virtual health consultations, or even registering for vaccination. The digital vaccine passport is another example of digital innovation in Malaysia's healthcare for domestic travel (Abdali et al., 2021; Kaos et al., 2021)

1.7 Research Limitation

The limitation of this study is the selection of respondents involved in the study are based on volunteering basis. Respondents who participated in this research were individuals with experience in the healthcare field, such as laboratory technical staff affiliated with laboratories in Malaysia, including the private and public sectors. Only accredited biomedical laboratories were selected to participate in the study as references for the development of referral systems. These laboratories were also found to have best industry practices that are equivalent to internationally recognised quality standards; the laboratories involved have been accredited to the ISO 15189 quality standard. To develop a referral system, it is important to eliminate any prejudice or contradictions in standard practice information obtained in the laboratory.

Moreover, resources for journal articles related to the research focus are limited especially from the perspective of the Malaysian context. Targeted questionnaires were used as a primary reference to build an understanding of the referral system framework. Furthermore, a literature review and document analysis accessible from other countries were also used as references. All these references have been used as a guide to determine the current state of other established systems, other laboratory practices, problems or issues, emerging trends, and new approaches currently in use.

1.8 Research Findings Summary

Phase 1 revealed that nine categories of routine biomedical and special testing services are offered in Malaysia, either in-house or outsourced (biochemistry, haematology, serology, microbiology, histology, cytology, molecular, genomics, toxicology, and drug). The analysis of the data showed that most laboratories faced challenges in catering to the growing demands for biomedical testing because of i) financial constraints, ii) limited technical expertise, and iii) a lack of special equipment and facilities to conduct such esoteric and complex biomedical laboratory tests in-house. The growing demand for complex testing puts biomedical laboratories under heavy pressure, especially during the COVID-19 pandemic, leading to an increase in collaboration and bridging of service gaps betweem laboratories. There are numerous reasons for pursuing collaboration practices, including i) time factors (TAT), ii) customer services, iii) quality assurance (ISO 15189 accreditation or College American Pathologists (CAP) accreditation), iv) handling patient data protection (PDPA), and v) service coverage. In addition, most laboratories did not have a standard procedure for tracking and recording special or esoteric tests, and half of the respondents were recorded manually in a logbook.

Phase 2 invloved the development of a laboratory referral system based on the designed framework. The findings of the questionnaire data analysis and literature review were used to design a laboratory referral system framework. This research prototype was developed using the Rapid Application Development (RAD) method and validated through user acceptance testing. The user acceptance testing results show that

the prototype technical aspects of each page are efficient and the prototype content aspects are user-friendly. Additionally, the Visual Basic Analysis (VBA) programming language was used to create a prototype page and function. The development of this research prototype has gained insights and suggestions from experienced laboratory practitioners to ensure that the workflow of the testing process, from creating a new order to reporting results is correct and follows the best standard.