CODIQ-My

TECHNICAL REPORT

COVID-19 **Di**gital **Q**uarantine & Home Monitoring
(CODIQ-My)

RESEARCH TITLE:

Asymptomatic COVID-19 Quarantine Digital Solution: A Proof-of-Concept Study

RESEARCH CODE: NMRR-20-2761-57684

In collaboration with

DHRi Digital Health Research & Innovation
NIH Institut Kesihatan Negara National Institutes of Health
ICR Ministry of Health Malaysia Research that matters to patients
Kementerian Kesihatan Malaysia
CREST Collaborative Research in Engineering, Science & Technology Catalyst for Malaysia's E&E
infront
ProvenPac
BioCare
Respiree Remote Patient Monitoring System
HAYYSOFT SYSTEMS
Microsoft

ASYMPTOMATIC COVID-19 QUARANTINE DIGITAL SOLUTION: A PROOF-OF-CONCEPT STUDY (NMRR-20-2761-57684)

Version Number: DHRi/CODIQ-My-V1.0 / 2022
Date Release: 11th January 2022

Editorial Team

Dr Mohan Dass Pathmanathan
Fatin Norsahida binti Giman
Digital Health Research and Innovation (DHRi),
Institute for Clinical Research (ICR),
National Institutes of Health (NIH),
Ministry of Health, Malaysia.

Any enquiries or comments on this report should be directed to:

Dr. Mohan Dass Pathmanathan
Digital Health Research and Innovation (DHRi),
Institute for Clinical Research (ICR),
National Institutes of Health (NIH),
Ministry of Health,
Jalan Setia Murni U13/52 Seksyen U13, Setia Alam,
40170 Shah Alam, Selangor

Email : drmohandass@moh.gov.my
Tel : +60333628628

Published by:
Digital Health Research and Innovation (DHRi),
Institute for Clinical Research,
Ministry of Health, Malaysia.
http://dhri.crc.gov.my/

FOREWORD

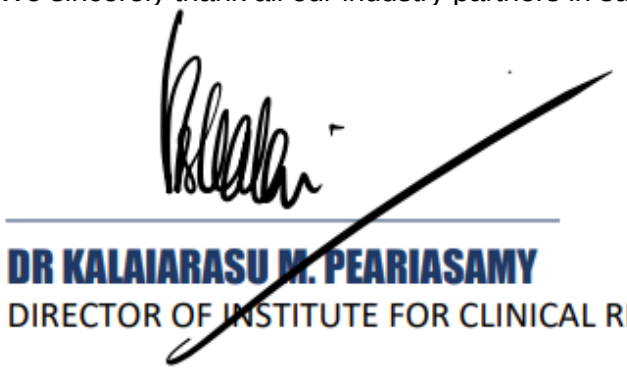
The COVID-19 Digital Quarantine & Home Monitoring (CODIQ-My) solution is one of the several digital health innovations developed and undergoing clinical trials by the Digital Health Research & Innovation Unit (DHRi), Institute for Clinical Research. This solution was developed with local and international healthcare industry partners and scientists. Now with this solution, healthcare providers can remotely monitor patients using technologies such as the internet of things (IoT) and artificial intelligence (AI) using a user-friendly mobile application connected to a wearable biosensor for remote monitoring by the healthcare providers.

In COVID-19 mitigation strategies, we need a robust and validated solution that integrates risk stratification and patient safety while being quarantined at home. This technical report covers the device trial conducted by DHRi on the feasibility and functionality of CODIQ-My at PKRC MAEPS.

We see opportunities that can leverage data analytics and machine learning for other similar healthcare applications to enable the healthcare system to be more resilient. DHRi is now working towards enhancing this platform for future needs of such a solution in the management of other infectious diseases and non-communicable diseases.

ICR believes that through CODIQ-My initiative we can enhance our clinical trial ecosystem with our industry partners where the direction ahead is driven by digital health technologies.

We sincerely thank all our industry partners in supporting this initiative.



DR KALAIARASU M. PEARIASAMY
DIRECTOR OF INSTITUTE FOR CLINICAL RESEARCH (ICR)

ACKNOWLEDGEMENT

We wish to thank YBhg. Datuk Dr. Noor Hisham bin Abdullah, Director General of Health and Dr. Hishamshah bin Mohd Ibrahim, the Deputy Director General of Health (Research & Technical Support) for their guidance. This study was conducted with funding from the Ministry of Health Malaysia and the authors would like to express their gratitude to the Ministry for this financial support.

We also wish to extend our sincere gratitude and appreciation to Dr. Kalaiarasu M. Peariasamy, Director, Institute for Clinical Research for his guidance and support. The project team was led by Dr. Mohan Dass Pathmanathan from Digital Health Research and Innovation (DHRi), Institute for Clinical Research. Our acknowledgement also goes to all the team members: Dr. Mohd Aizuddin Abd Rahman, Dr. Wong Xin Ci, Dr. Kuan Pei Xuan, Mr. William Law Kian Boon, Dr. Shahabuddin Ibrahim and Dr. Marzilawati Abd Rahman for their time, effort and contribution spent on this report. We also want to thank all collaborators who have assisted in the implementation of the study. Gratitude to the reviewers of this technical report, for their assistance in completing this technical report.

We have the utmost gratitude to all those who have contributed their expertise either directly or indirectly in ensuring the success of this technical report. Last but not least, our sincere appreciation to all who had participated in the study. Their contributions in the study would assist the Ministry of Health in improving health services in Malaysia.

DISCLAIMER

Any recommendations, suggestions or opinions contained in this publication do not necessarily represent the policy or views of the Ministry of Health Malaysia. No person should act on the basis of the contents of this publication without first obtaining specific, independent professional advice.

Digital Health Research & Innovation Unit, Institute for Clinical Research, National Institutes of Health will not be liable for any loss, damage, cost or expense incurred or arisen by reason of any person using or relying on the information in this publication.

LIST OF INVESTIGATORS

National Institutes of Health (NIH)

Dr. Kalaiarasu M. Peariasamy
Dr. Mohan Dass Pathmanathan
Dr. Mohd Aizuddin Abd Rahman
Dr. Wong Xin Ci
Dr. Kuan Pei Xuan
Mr. William Law Kian Boon

Putrajaya Presint 18 Health Clinic

Dr. Rozita Binti Zakaria

Kelana Jaya Health Clinic

Dr. Nik Mazlina Binti Mohammad

Bahagian Pembangunan Kesihatan Keluarga (BPKK)

Dr. Fatanah Binti Ismail

Malaysia Agro Exposition Park Serdang (MAEPS) - Low Risk COVID-19 Quarantine & Treatment Centre

Dr. Shahabuddin Ibrahim
Dr. Marzilawati Abd Rahman

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CDC	Centre for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
CPRC	Crisis Preparedness and Response Centre
ILKKM	Institut Latihan Kementerian Kesihatan Malaysia
NIH	National Institutes of Health
MOH	Ministry of Health, Malaysia
IoMT	Internet-of-Medical-Things
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
rRT-PCR	Real-time reverse transcriptase–polymerase chain reaction
UKA	Unit Kesihatan Awam
URTI	Upper respiratory tract infection
SpO_2	Oxygen saturation
CNS	Central Nervous System
GI effects	Gastrointestinal effects
AI	Artificial Intelligence
MAMPU	Malaysian Administrative Modernisation and Management Planning Unit

CASE DEFINITIONS

Confirmed COVID-19[2]**:** Positive result on high-throughput sequencing or real-time reverse transcriptase–polymerase chain reaction (rRT-PCR) assay of nasal and pharyngeal swab specimens.

Asymptomatic COVID-19[2]**:** Patients with positive rRT-PCR for SARS-CoV-2 and devoid of any symptoms that would indicate SARS-CoV-2 infection throughout the course of infection until negative rRT-PCR is obtained at day 10 from admission.

Pre-symptomatic COVID-19[2]**:** Positive rRT-PCR for SARS-CoV-2 and lack symptoms indicating SARS-CoV-2 during hospital admission, however develop symptoms later.

Symptomatic COVID-19[2]**:** Positive rRT-PCR for SARS-CoV-2 patients who develop symptoms characteristic of COVID-19 prior or at the time of hospital admission.

Person-under-investigation for COVID-19 (PUI) [2]**:** Acute respiratory infection (sudden onset of respiratory infection with at least one of: shortness of breath, cough or sore throat) with or without fever

AND

Travelled to / resided in foreign country within 14 days before the onset of illness OR
Close contact in 14 days before illness onset with a confirmed case of COVID-19 OR
Attended an event associated with known COVID-19 outbreak

Table 1. COVID-19 diagnosis based on clinical stages[2]

	Clinical Stage	Clinical characteristics
1	**Asymptomatic**	• Only RT-PCR test positive • No clinical symptoms • No chest imaging findings
2	**Symptomatic without pneumonia**	• Upper respiratory tract infection (URTI) symptoms (e.g., pharyngeal congestion, sore throat, cough or fever) for a period less than 7 days • No chest imaging findings
3	**Pneumonia without hypoxia**	• URTI symptoms with others like vomiting, diarrhoea, abdominal pain, myalgia, loss of smell/ taste • Signs of increased work of breathing and increased respiratory rate, but no hypoxemia • Involvement of lungs as evident by chest imaging
4	**Pneumonia with hypoxia requiring oxygen supplementation therapy**	• Tachypnoea* with hypoxemia (SpO_2<95% on room air) • CNS effect: Lethargy, decreased level of consciousness, seizure • GI effects: Dehydration, difficulty feeding, raised liver enzymes • Myocardial effect: Raised Creatinine Kinase, Troponin • Involvement of lungs as evident by chest imaging
5	**Critically ill**	Rapid disease progression with: • Respiratory failure requiring mechanical ventilation (acute respiratory distress syndrome (ARDS)) • Persistent hypoxemia • Septic shock • Organ failure requiring invasive monitoring and mechanical ventilation

EXECUTIVE SUMMARY

INTRODUCTION

Malaysia has implemented home quarantine for asymptomatic COVID-19 patients in response to an overwhelming number of positive cases[3]. However, monitoring of warning signs is crucial as these patients may experience silent hypoxia at home[4]. The study aims to assess the functionality and usability of a newly developed home quarantine digital solution called CODIQ-My.

METHODOLOGY

The CODIQ-My consists of a wearable biosensor, a mobile application and a centralized monitoring dashboard for health officers. Important vital signs (body temperature, oxygen saturation and pulse rate) were captured by the wearable biosensor remotely which is then transmitted to the centralized monitoring dashboard via the paired mobile application. Moreover, geofencing enables monitoring of quarantine compliance. The patient is required to fill in a self-reported survey on their symptoms twice daily for three days consecutively. Notifications and alerts are incorporated within the system enhancing the monitoring activity by health care professionals.

RESULTS

A total of 71 COVID-19 patients from a designated quarantine centre were recruited into the study. Among them, 8 (11.0 %) patients failed to use the CODIQ-My due to technical issues. During the study period, 1525 (99.0%) check-in attempts were performed and recorded 3838 (84.0%) vital readings successfully. A total of 1172 alerts were triggered, with 560 (48.0%) for vital signs monitoring, 262 (22.0%) for user photo mis-match, 144 (12.0%) for quarantine breach, 90 (8%) for operational problems, and 113 (10.0%) for symptom checker.

CONCLUSION

CODIQ-My is a secure and robust system for safe home quarantine. The system helps to enhance patient management especially during the major outbreaks like COVID-19 and its ability to detect alerts and analyse disease patterns will assist the health care provider to provide a fast and targeted treatment plan.

1. INTRODUCTION

A study in Malaysia demonstrated that 95% of COVID-19 cases were mild with 3.5% of these patients progressed to severe disease[1]. The same study revealed that the milder cases did not require active treatments which supports the established guidelines by the Ministry of Health in treating COVID-19 patients[1,2]. Thus, Malaysia implemented home quarantine for COVID-19 patients who are asymptomatic or with mild symptoms in response to the upsurge in the daily confirmed cases[3]. Nevertheless, monitoring of both symptoms and vital signs while in quarantine is important as these patients are at risk of sudden deterioration caused by silent hypoxia[4].

However, emerging evidence shows a drop in patient oxygen saturation, increased respiratory rate and fever may predict worsening disease stage in COVID-19 patients thus a regular real-time monitoring of these parameters may alert the health care practitioner to any changes in the patient's health status[1,5,6]. Therefore, the availability of biosensor technology and mobile application under an integrated alert system will be beneficial in making remote monitoring feasible[7,8].

To address the problems faced by the Ministry of Health Malaysia (MOH) in managing the COVID-19 pandemic, the Institute for Clinical Research (ICR), NIH worked together with several stakeholders to develop a digital solution, CODIQ-My in enhancing the way in managing home quarantined patients. This R&D (Research & Development) was in collaboration with:

1. Collaborative Research in Engineering, Science & Technology (CREST)
2. Infront Consulting Malaysia
3. ProvenPac Sdn. Bhd.
4. Yuno Solutions Sdn. Bhd.
5. Biocare Group (M) Sdn. Bhd.
6. Respiree Pte. Ltd.

7. Bysol International Sdn.Bhd
8. Hayysoft Systems Pte. Ltd
9. Microsoft Malaysia

CODIQ-My, which incorporates the internet-of-medical-things (IoMT) and artificial intelligence (AI) aimed to assist the healthcare professionals to monitor the quarantined patients safely in real-time.

This solution uses a biosensor to measure important vital parameters such as temperature, heart rate and oxygen saturation level. The mobile application (currently developed for Android OS (Operating System)) with inbuilt identity verification using AI and location-based technology will transmit the acquired information from both biosensor and mobile application to data centre hosted in NIH. For the purpose of automation and machine learning processing, cloud computing is utilized and presented on a web application allowing the healthcare providers to monitor these patients both individually and regionally (Figure 1). A robust architecture using API was developed using best practices in cybersecurity and abiding to the MOH ICT ver 5.0 regulation.

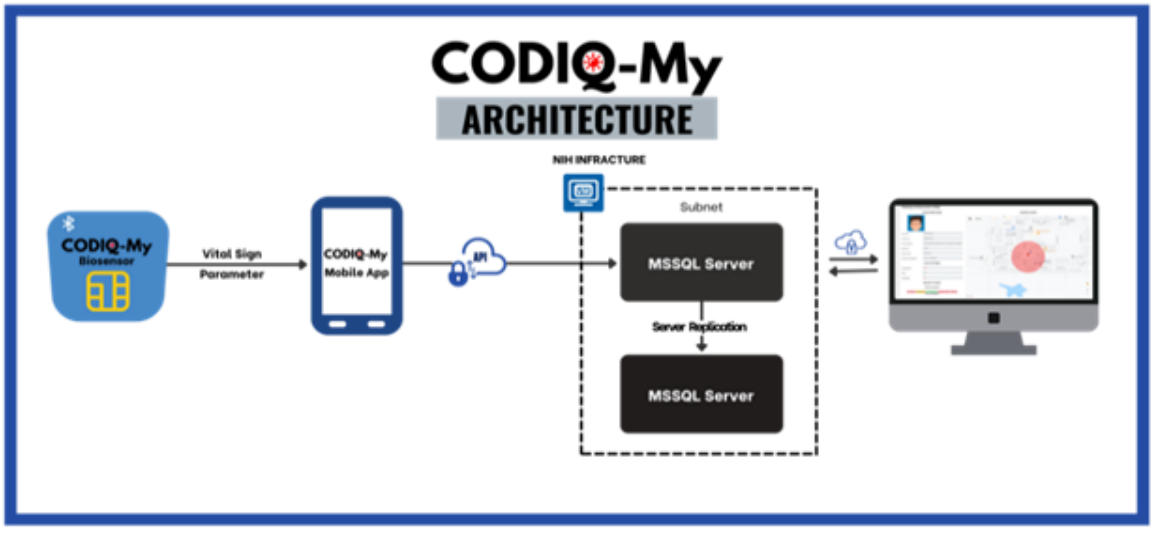


Figure 1: CODIQ-My architecture demonstrating the end-to-end process

2. PURPOSE OF PROOF-OF-CONCEPT

This proof-of-concept (POC) observational study aimed to assess the feasibility of CODIQ-My solution to monitor COVID-19 patients remotely. Apart from functionality and usability of the solution, this study is to assess feasibility of various wearable biosensors to be incorporated into the system.

The goal of this solution is to enhance monitoring of home quarantine patients remotely. This solution may be a method to decongest the already overwhelmed health facilities apart from being cost-effective.

3. METHODOLOGY

This study was conducted in accordance with the “Malaysian Guidelines for Good Clinical Practice” and registered with the National Medical Research Register (NMRR-20-2761-57684) and approved by the Medical Research and Ethics Committee, Ministry of Health, Malaysia (KKM/NIHSEC/P21-135(8)).

This proof-of-concept study involved 71 patients asymptomatic rRT-PCR positive COVID-19 patients from the low risk COVID-19 quarantine & treatment centre – MAEPS. Patients who fulfilled the inclusion and exclusion criteria will be recruited for the study after signing the informed consent.

For the purpose of this POC, three different wearable devices with biosensors from various vendors were used. These devices applied various method to obtain the acquired information and those wearables were:

1. ProvenPac Beta (CQ01)
    - Automated measurements of vital signs through placement of the biosensor either on the forehead or index finger. Patients were needed to check in to the customed mobile application in order to measure the vital signs.

2. Respiree (CQ02)
    - Automated measurements of vital signs through placement of the biosensor either or the chest and finger.

3. Blueguard (CQ03)
    - Automated measurements of vital signs through continuous placement of the biosensor on the wrist.

The CODIQ-My mobile application was downloaded in candidate patients' mobile phones using APK (Android Application Package). Patients were then required to register themselves to the system, where their demographic information obtained and were trained on the use of the solution (both biosensor and mobile application). Each patient was required to login through the mobile application two times a day for three days consecutively, where they will be required to verify identification through facial recognition technology. This was followed by measurement of vital signs either through placement of the biosensor on the forehead/index finger, or on chest/finger, or continuous placement on the wrist depending on the device used. Subsequently, these patients would fill in a short survey on their experienced symptoms.

Data acquired were then analysed for these purposes:

1. to assess the feasibility of the biosensors in measuring the vital signs.
2. to assess the functionality of the system to demonstrate alerts on patients' risk of deterioration.

Descriptive analysis including frequencies and percentages will be used for statistical analysis on utilization and response of the solution. Every single successful check-in attempt that was recorded into the system was analysed as one data point. Only the data from patients who successfully enrolled into the system was used for the analysis purposes. Data acquisition complied with the Personal Data Protection Act 2010. The collected data was stored in the National Institutes of Health (NIH) Data Centre, which abides to the data security regulations by MAMPU.

4. RESULTS

A. Study Cohort

A total of 71 COVID-19 patients out of 240 screened were enrolled into the POC study. Among them, 63.9% (N=63) successfully monitored using the CODIQ-My system. Eight patients were considered as drop-out due to no check-in activity recorded in the system. Data from 63 patients were analysed to assess the functionality of the system. The analysis cohort consisted of 32 (51%) female and 31 (49%) male patients with median age of 33 years old, ranging from 18 to 59 years old.

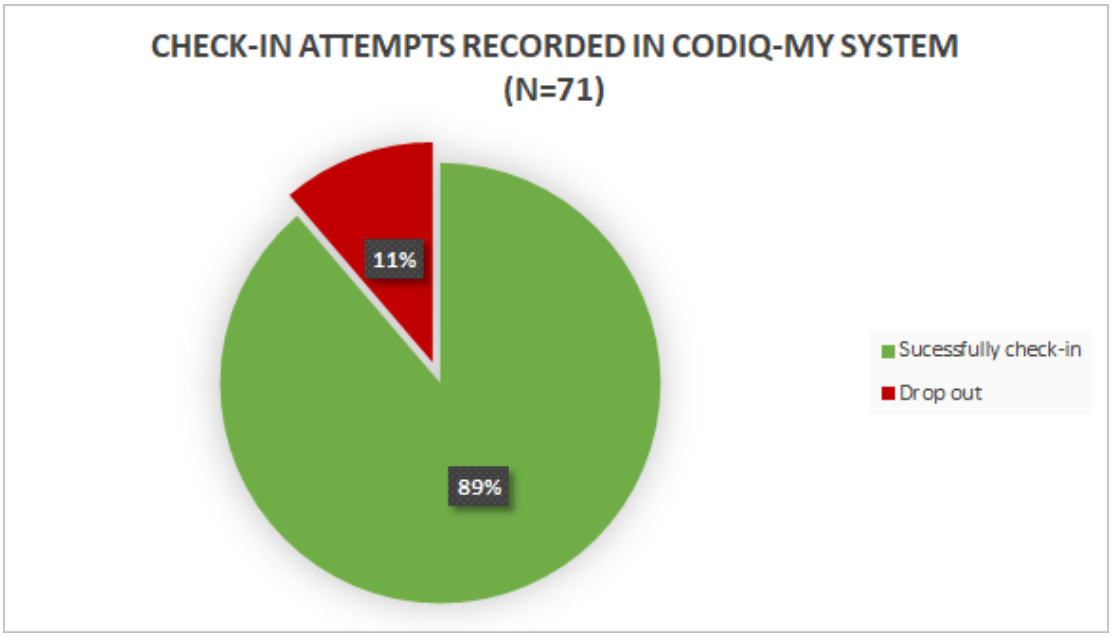


Figure 2. Analysis on check-in attempts into CODIQ-My system during the study period.

B. Patient compliance

Patient's compliance in using CODIQ-My mobile application were analysed where 70% (n=44) of patients were able to check-in at least twice for 3 consecutive days while the rest 30% of patients were unable to commit due to reasons such as incomplete training, biosensor failure and other personal reasons.

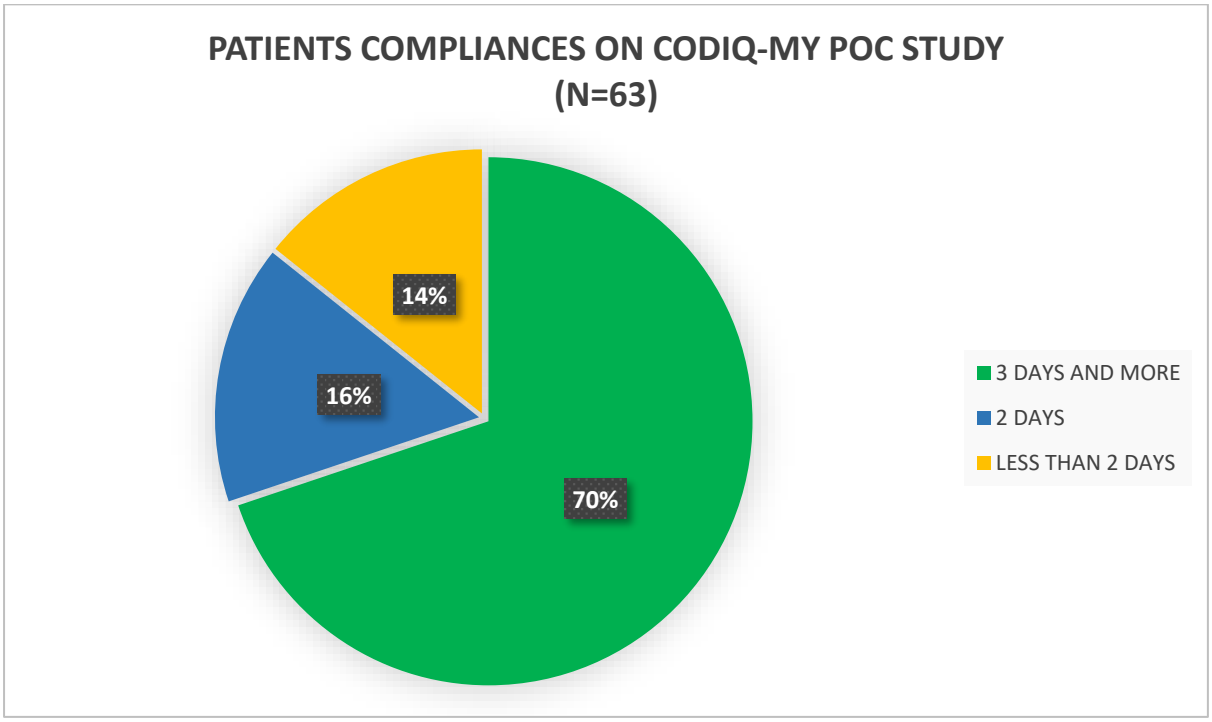


Figure 3. Analysis on patients' compliances in using CODIQ-My mobile application during the study period.

C. Data capture rate

During the study period, 1525 (99.0%) check-in attempts were performed and recorded. CODIQ-My solution demonstrated a data capture rate of 84% in overall vital signs monitoring using multiple biosensors (CQ01, CQ02, and CQ03). However, it is to note that recording of data using CQ01 is only done upon placing the sensor on the body part upon request, whereas CQ02 and CQ03 are using an automated system to record the vital signs. CQ02 and CQ03 are highly dependent on the connectivity of the biosensor to the gateway and internet. Data capture performance for individual vital signs categories were then analysed where 85% of patients' temperature managed to be captured and 83% for patient's SpO_2 and heart rate respectively.

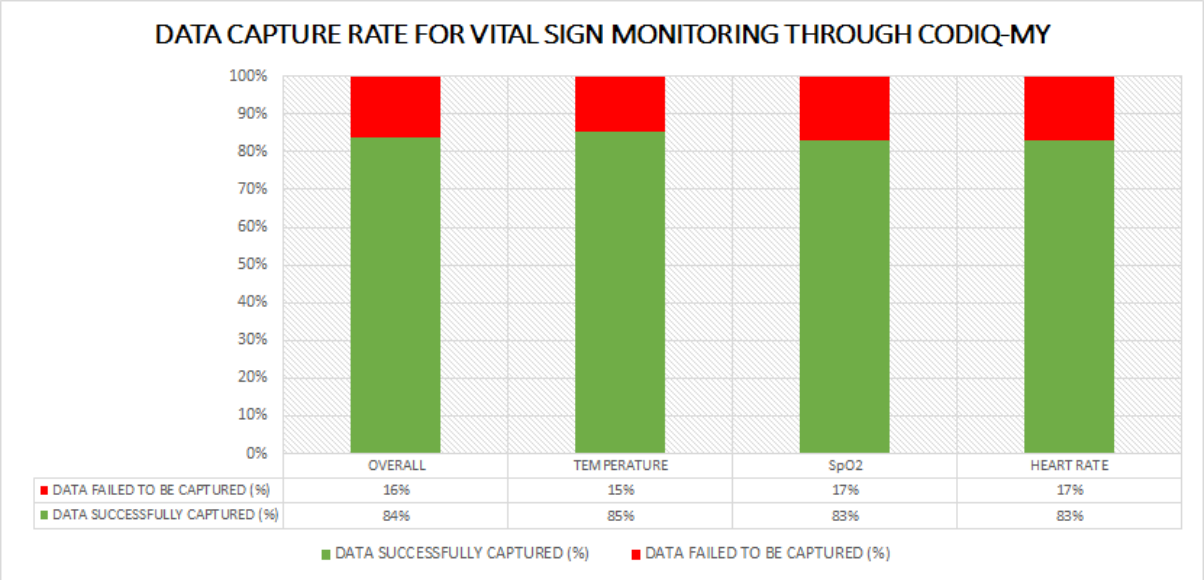


Figure 4. Analysis on data capture rate on vital signs monitoring which includes all biosensors used during the study period.

D. Triggering alerts

i. CODIQ-My performances in triggering alerts related to mobile application usage

The performance of CODIQ-My in triggering alerts related to the mobile application was assessed where 144 alerts triggered for quarantine breached, 262 for photo mismatch and 113 for symptom checker were managed to be triggered.

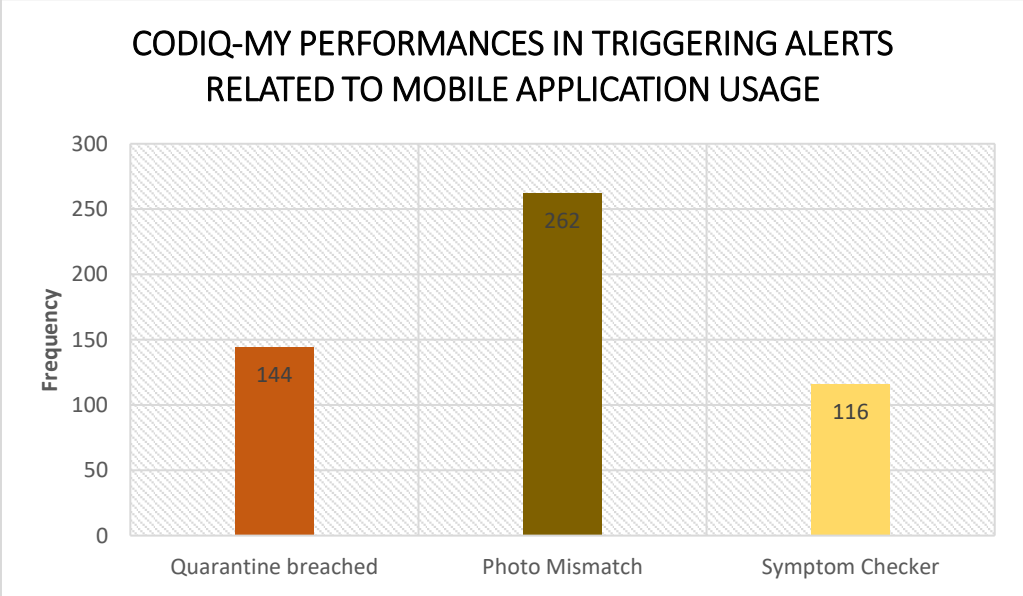


Figure 5. Analysis on CODIQ-My performances in triggering alerts related to geolocation, identity and symptom checker.

ii. CODIQ-My performances in triggering alerts on symptom checker

CODIQ-My is able to trigger various alerts related to different levels of symptoms based on the self-reporting questionnaires filled by the patients. Only data from 50 patients selected for assessing CQ01 and CQ02 were included whereas 13 patients selected for CQ03 were excluded from this analysis since patients were using the vendor's mobile application instead of the developed CODIQ-My mobile application.

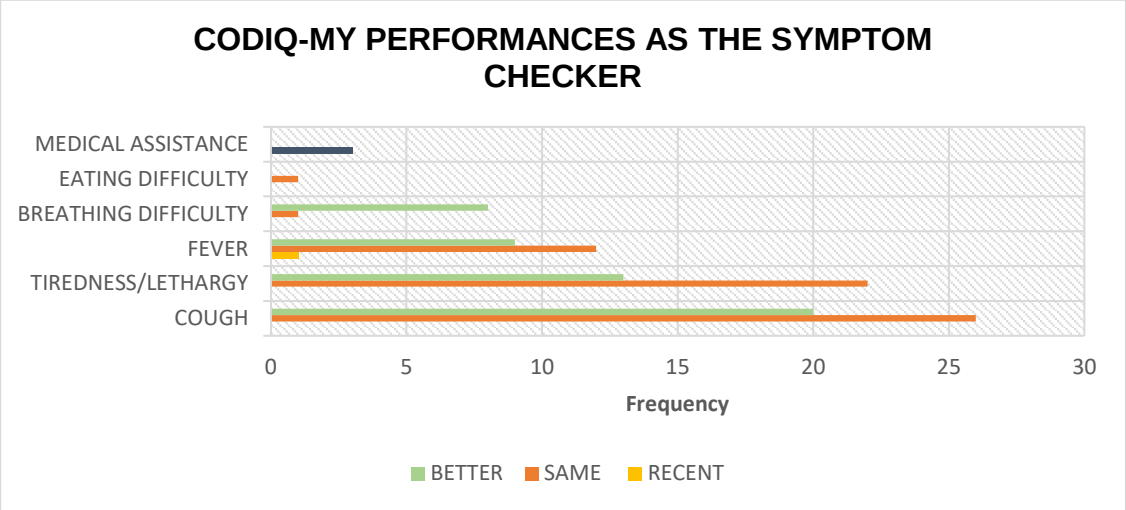


Figure 6. Analysis on CODIQ-My performances in monitoring different levels of patient's symptoms during the study period. Only 50 patients were selected for this analysis (CQ01 and CQ02).

iii. CODIQ-My performances in triggering alerts related to operational issues (CQ01 only)

Additional analysis was performed for CQ01 to assess the capability of the system in triggering alerts related to the operational issues. CODIQ-My system managed to trigger 7.7% alerts on biosensor failure and 2.9% alerts on check-in failure out of 456 alerts triggered related to CQ01.

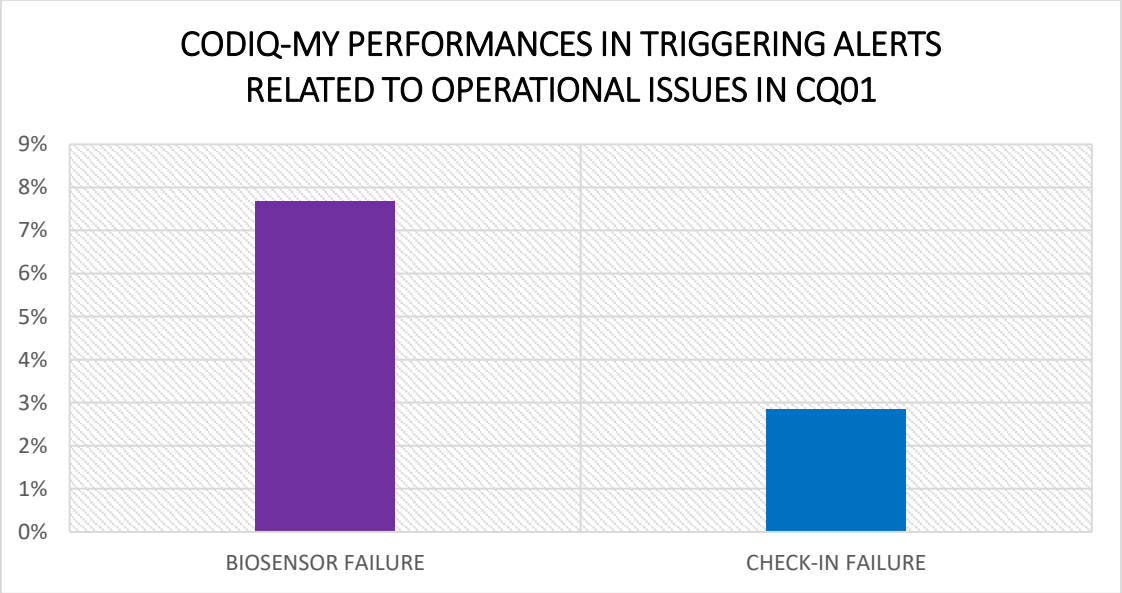


Figure 7. Analysis on CODIQ-My performances in triggering alerts on operational issues such as check-in failure and biosensor failure for patients selected for CQ01 assessment.

iv. CODIQ-My performances in triggering alerts on vital sign monitoring

Last but not least, CODIQ-My performance in vital sign monitoring was then assessed by analysing the performance in triggering alerts related to changes in patient's vital signs. 58% alerts on abnormal SpO_2, 40% on abnormal temperature and 2% on abnormal heart rate were also managed to be triggered by the system and these data show a huge potential on CODIQ-My in monitoring asymptomatic COVID-19 patients.

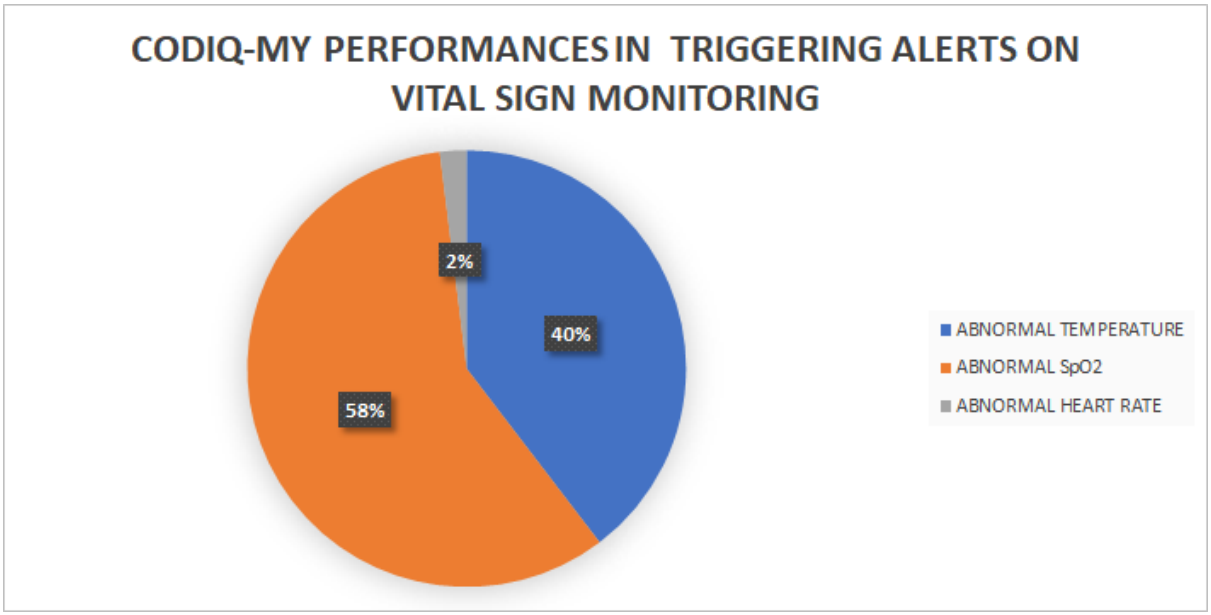


Figure 8. Analysis on CODIQ-My performances in vital signs monitoring to observe the feasibility of the solution in triggering alerts related to abnormal vital signs.

Overall, the CODIQ-My solution is able to achieve a high data capture rate (84%) and is able to trigger various customized alerts.

5. CONCLUSION

Emerging technology can facilitate pandemic response in ways that are difficult to achieve conventionally. The availability of validated biosensors and artificial intelligence algorithms made it possible to enhance patient management especially during the major outbreaks like COVID-19[9].

Our study indicated that CODIQ-My solution is a secure and robust system with an ability to detect warning signs in quarantine patients remotely. This can help in reducing the risks of silent hypoxia for individuals that need to do self-quarantine at home. Patients can be remotely monitored in a consistent manner using the provided biosensors and self-reported symptoms during the quarantined period. Subsequently, the health care providers can monitor these patients in real-time to provide fast and targeted treatment plans apart from monitoring the physical movements of these patients with its geofencing ability.

To conclude, CODIQ-My is a feasible digital solution for safe home quarantine. Its ability to detect red flags and disease patterns, assists the health care provider to provide a fast and targeted treatment plan.

6. FUTURE DEVELOPMENT

Further investigations are planned to validate the biosensor performance by comparing its performances against the standard clinical parameter tools and to upgrade the performances of the system.

The system can then be applicable to the public where patients and healthcare workers are able to use this robust secure system to enhance patient cases while reducing the burden on the health facilities. Developments of the system can be done to increase its functionality to work against different biosensors which are applicable for other diseases, mainly the non-communicable diseases such as hypertension, diabetes and stroke.

7. REFERENCES

1. Sim, B. L., Chidambaram, S. K., Wong, X. C., Pathmanathan, M. D., Peariasamy, K. M., Hor, C. P., Chua, H. J., & Goh, P. P. (2020). Clinical characteristics and risk factors for severe COVID-19 infections in Malaysia: A nationwide observational study. *The Lancet Regional Health - Western Pacific*, *4*, 100055. https://doi.org/10.1016/j.lanwpc.2020.100055

2. *CLINICAL MANAGEMENT OF CONFIRMED COVID-19 CASE IN ADULT AND PAEDIATRIC*. (2021, August 13). Retrieved November 1, 2021, from https://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm/ANNEX_2e_CLINICAL_MANAGEMENT_OF_CONFIRMED_COVID-19_CASE_IN_ADULT_AND_PAEDIATRIC_13082021.pdf

3. *Malaysia orders covid-19 patients with mild or no symptoms to be treated at home*. The Straits Times. Retrieved November 1, 2021, from https://www.straitstimes.com/asia/se-asia/malaysia-orders-covid-19-patients-with-mild-or-no-symptoms-to-be-treated-at-home

4. *COVID-19: Home quarantine patients need to monitor for happy hypoxia*. Astroawani.com. (n.d.). Retrieved November 1, 2021, from https://www.astroawani.com/berita-malaysia/covid19-home-quarantine-patients-need-monitor-happy-hypoxia-310912

5. Inada-Kim, M., Chmiel, F. P., Boniface, M. J., Pocock, H., Black, J. J., & Deakin, C. D. (2020). Validation of home oxygen saturations as a marker of clinical deterioration in patients with suspected COVID-19. https://doi.org/10.1101/2020.11.06.20225938

6. Zhou, C., Huang, Z., Tan, W., Li, X., Yin, W., Xiao, Y., Tao, Z., Geng, S., & Hu, Y. (2020). Predictive factors of severe coronavirus disease 2019 in previously Healthy Young Adults: A single-center, Retrospective Study. *Respiratory Research*, *21*(1). https://doi.org/10.1186/s12931-020-01412-1

7. Patel, S., Nanda, R., Sahoo, S., & Mohapatra, E. (2016). Biosensors in health care: The milestones achieved in their development towards lab-on-chip-analysis. *Biochemistry Research International*, *2016*, 1–12. https://doi.org/10.1155/2016/3130469

8. Yilmaz, T., Foster, R., & Hao, Y. (2010). Detecting vital signs with wearable wireless sensors. *Sensors*, *10*(12), 10837–10862. https://doi.org/10.3390/s101210837

9. Lazarus, J. V., Ratzan, S. C., Palayew, A., Gostin, L. O., Larson, H. J., Rabin, K., Kimball, S., & El-Mohandes, A. (2020). A global survey of potential acceptance of a COVID-19 vaccine. *Nature Medicine*, *27*(2), 225–228. https://doi.org/10.1038/s41591-020-1124-9

8. APPENDICES

Annex 1: CODIQ-My MREC approval

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(*MEDICAL RESEARCH & ETHICS COMMITTEE*)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Kompleks Institut Kesihatan Negara (NIH)
No.1, Jalan Setia Murni U13/52,
Seksyen U13 Bandar Setia Alam,
40170 Shah Alam, Selangor. Tel.: +(6)03-33628888/ 33628205

Ref. : KKM/NIHSEC/P21-135(8)
Date : **26-January-2021**

DR. KALAIARASU PEARIASAMY
NATIONAL INSTITUTES OF HEALTH (NIH)

DR. MOHAN DASS PATHMANATHAN
NATIONAL INSTITUTES OF HEALTH (NIH)

Dear Dato'/ Dr/ Sir/ Madam,

LETTER OF ETHICAL APPROVAL:

NMRR-20-2761-57684 (IIR)
ASYMPTOMATIC COVID-19 QUARANTINE DIGITAL SOLUTION: A PROOF OF CONCEPT STUDY (CODIQ-My)

This letter is made in reference to the matter above.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator/ Hospital Director and all relevant heads of departments /units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations including the Access to the Biological and Benefit Sharing Act 2017.

3. The investigators and sites involved in this study are:

Institut Latihan Kementerian Kesihatan Malaysia (ILKKM) Sungai Buloh, Selangor
Dr. Kalaiarasu Peariasamy (Principal / Coordinating Investigator)
Dr. Mohan Dass Pathmanathan (Principal / Coordinating Investigator)
Dr. Fatanah Ismail
Dr. Kuan Pei Xuan
Dr. Mohd Aizuddin Bin Abdul Rahman
Dr. Nik Mazlina Mohammad
Dr. Rozita Zakaria
Dr. Wong Xin Ci
Law Kian Boon

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Cover letter to MREC (Version 1, dated 16-12-2020)
2. Declaration of Conflict of Interest (COI) (Version 1, dated 16-12-2020)
3. Protocol (Version 2, dated 18-01-2021)
4. English: Patient Information Sheet/ Informed Consent Form (Version 1, dated 16-12-2020)

…/2-

Ref : KKM/NIHSEC/P21-135(8)

5. Malay: Patient Information Sheet/ Informed Consent Form (Version 1, dated 16-12-2020)
6. Questionnaire (Version 1, dated 16-12-2020)
7. Data Collection Form (Version 1, dated 16-12-2020)
8. IA-HOD-IA, CV and GCP Certification of:
    - Dr. Kalaiarasu Peariasamy
    - Dr. Mohan Dass Pathmanathan
9. CV and GCP Certification of:
    - Dr. Kuan Pei Xuan
    - Dr. Mohd Aizuddin Bin Abdul Rahman
    - Dr. Rozita Zakaria
    - Dr. Wong Xin Ci
    - Law Kian Boon
10. CV of:
    - Dr. Nik Mazlina Mohammad
    - Dr. Fatanah Ismail

5. Please note that the approval is valid until **25-January-2022**.The following are to be reported upon receiving ethical approval. Required forms can be obtained from the National Medical Research Registry (NMRR) website.

i. **Continuing Review Form** has to be submitted to MREC within 2 months (60 days) prior to the expiry of ethical approval.
ii. **Study Final Report** upon study completion to the MREC.
iii. Ethical approval is required in the case of **amendments**/ **changes** to the **study documents**/ **study sites**/ **study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.
iv. **Applicable for Clinical interventional Studies only:** Report occurrences of **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** and **Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.

6. There will be **100 subjects**/ **patients**/ **respondents** targeted to be enrolled in this study within Malaysia.

7. Please take note that the reference number of this letter must be stated in all future correspondence related to this study to facilitate the administrative processes.

Project Sites:
INSTITUT LATIHAN KEMENTERIAN KESIHATAN MALAYSIA (ILKKM) SUNGAI BULOH

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Disapproved

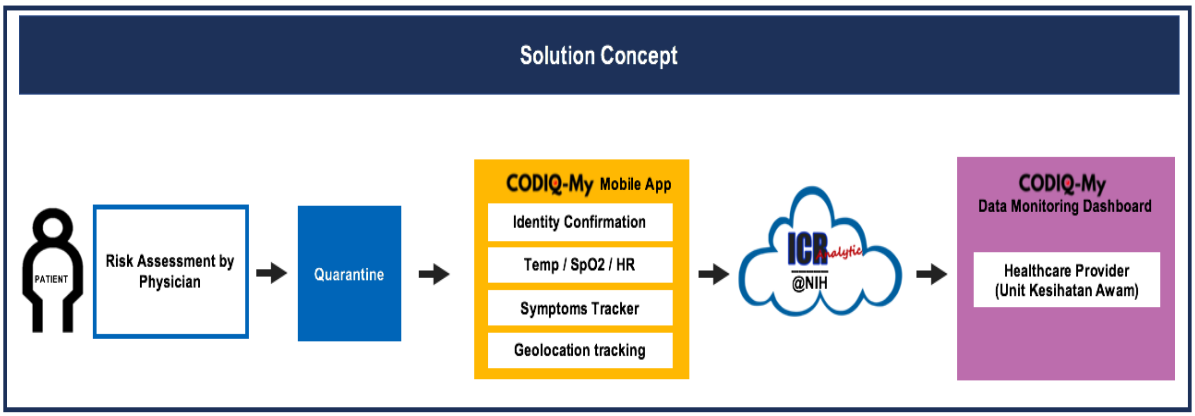
Date of Approval : **26-January-2021**

.....
DR. HJH SALINA BINTI ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
(MMC No: 27117)

CM\MREC_Share\Approval 2020\Expedited by Primary Reviewer\January 2021\57684

-2-

Annex 2: CODIQ-My Solution Technical Workflow



Annex 3: Photos taken from the POC Study

NOTES

DIGITAL HEALTH RESEARCH & INNOVATION UNIT,
INSTITUTE FOR CLINICAL RESEARCH

BLOK B4, NATIONAL INSTITUTE OF HEALTH (NIH),
NO.1, JALAN SETIA MURNI U13/52, SEKSYEN U13, SETIA ALAM
40170 SHAH ALAM, SELANGOR DARUL EHSAN

http://dhri.crc.gov.my/

TECHNICAL REPORT

COVID-19 Digital Quarantine & Home Monitoring Solution (CODIQ-My)