QATAR UNIVERSITY

COLLEGE OF HEALTH SCIENCES

USABILITY TESTING OF THE INTERNATIONAL CARDIAC REHABILITATION REGISTRY

BY

HANA JIHAD ABUKHADIJAH

A Thesis Submitted to

the College of Health Sciences

in Partial Fulfillment of the Requirements for the degree of

Masters of Science in Health Sciences

June 2022

COMMITTEE PAGE

The members of the Committee approve the Thesis of
Hana Abu-Khadijah defended on 09/05/2022.

_____

Dr. Karam Adawi
Thesis Supervisor

_____

Prof. Sherry Grace
Thesis Co-supervisor

Approved:

_____

Dr. Hanan Abdul Rahim, Dean, College of Health Science

ABSTRACT

ABU KHADIJAH, HANA, J., Masters of Science:June: 2022, Health Sciences

Title: Usability Testing of the International Cardiac Rehabilitation Registry

Supervisor of Thesis: Dr. Karam, I, Adawi.

Background: Cardiac rehabilitation (CR) is a comprehensive model of secondary preventive care for cardiovascular diseases (CVDs). However, there is a wide variety of implementation characteristics globally, specifically in low-and-middle-income countries. Thus, the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) was urged to develop a CR registry to establish the quality of CR services in such settings.

Aim: To explore the usability of the newly developed International Cardiac Rehabilitation Registry (ICRR) in the World Health Organization's six-designated regions of the world to ensure the applicability and optimal utility of the registry before its launch.

Methods: This was a mixed methods study comprised of Think-Aloud method to elicit feedback on the ICRR while end-users were entering patient data, followed by semi-structured interviews and SUS survey. The Unified Theory of Acceptance and Use of Technology 2 framework (UTAUT 2) informed the analysis. During the interview, participants were asked to log in to the ICRR demonstration site and share their screen and enter the patient's data anonymously while thinking and talking aloud. Notes including facial expressions and gestures ideas raised by the participants were taken. After that, a semi-structured interviews were conducted to explore the topic in depth.. Interviews were transcribed verbatim, thematic analysis was undertaken to categorize the content using NVIVO software. Finally, participants were asked to fill out the

System Usability scale survey (SUS), which provides a global measure of system satisfaction. SUS score was calculated based on Brooke's standard scoring method.

Results: Four major themes emerged from the interviews and Think-Aloud method: (1) ease of approvals, adoption, and implementation; (2) benefits for programs, (3) variables and their definitions, as well as (4) patient report & follow-up assessment. Based on participant feedback and utterances, suggestions for changes to the ICRR were implemented, including changes to the program survey, on-boarding processes, navigational instructions, inclusion of program logos, direction on handling unavailable data, and optimizing data completeness, as well as policies for program certification. System usability score (SUS) was (83.75) indicating that the registry was "excellent" and rated as class "A" technology.

Conclusions: Results of this study proved that ICRR is relevant, user-friendly with high end-user satisfaction, and showed high perceived usefulness to support CR service quality. The usability of the ICRR was enhanced based on participants' feedback. The ICRR is ready for the next stage, which is the pilot testing before the final launch.

Keywords: Cardiac Rehabilitation, Cardiovascular Diseases, Registries, Low and Middle-income Countries, Quality of Health Care, User-centered design

DEDICATION

All praise to Allah, who guided me and gave me the strength and patience throughout this journey.
To my parents, my brothers, my sisters, my husband, my loving kids and all my friends

who supported me throughout my journey.

ACKNOWLEDGMENTS

I would like to express my sincere gratitude to Dr. Karam Adawi, who has been an idyllic advisor, and thesis supervisor, offering guidance, and inspiration blended with her visionary ideas and rich experience. I'm proud of and grateful to my time working with her. I would like also to extend my sincere gratitude to Professor Sherry Grace for her support and guidance. Finally, I would like to acknowledge the support of Qatar University for providing all the needs and funds to achieve the requirements of this study.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

1.1 Background

Globally, a total of 41 million individuals die each year due to non-communicable diseases (NCDs), which account for 71% of total deaths (1, 2). NCDs are a major contributor to disease morbidity as well. For example, 1.43 billion Disability-adjusted life years (DALYs) were lost in 2019 (3). Between 2011 and 2025, the cumulative economic loss due to NCDs in low-and middle-income countries is estimated at US $7 trillion, if no action is taken (4). Using existing cost-effective interventions, such as establishing clinical registries to monitor the quality of cardiac rehabilitation (CR) services in low-resource settings, is imperative to achieve the 30% reduction in premature mortality of NCDs by 2025 (5, 6).

Cardiovascular diseases (CVDs) account for most NCDs fatalities (2). CVDs are the leading cause of mortality and a significant contributor to the burden of the disease globally, with rising incidence in low- and middle-income countries (LMICs) (7, 8). CVDs account for over 80% of deaths in low-and-middle-income countries (9). Thus, public health programs and policy development are most needed in these countries. CVD prevalence has almost doubled from 271 million in 1990 to 523 million in 2019 (5); this is mainly due to advancements in screening and associated risk factor control as well as acute treatments, such that most cardiac patients survive upon initial diagnosis, but then live with CVD chronically at an increased risk of mortality and further morbidity (10). CR is a comprehensive model of secondary preventive care to mitigate this burden (11-16). A multidisciplinary team delivers CR core components, including risk factor assessment and control, structured exercise, patient education, and psychosocial counseling. Participation in CR reduces cardiovascular mortality and hospitalization by 20% (11) and improves the quality of life (17); CR benefits are also robustly established in LMICs (18). However, CR programs in low-resource

settings (i.e., LMICs or a high-income country but with limited financial and/or healthcare resources) (19) are less comprehensive, and inadequate if they exist (13, 15, 20). Thus, there is grossly insufficient CR capacity, particularly in LMICs.

Clinical registries support care quality. They are widely used in health care processes (21-23). For example, their data are used to support quality improvement projects (24-31), monitor compliance with clinical practice guidelines (29, 32, 33), meet standards (32, 34, 35); and to reduce care delivery costs (36, 37). Unfortunately, there are few CR registries, most of which do not apply to LMICs, as identified in a recent systematic review (38) . There is a need to develop a cardiac rehabilitation registry that supports the quality of CR services provided by programs in LMICs. Thus, the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) recently developed a registry specific to low-resource settings, and is leading the way in supporting the development of new high-quality programs as well as improving the quality of services of existing ones (21-23, 39).

1.2. Study Aim

The aim of this mixed methods study was to explore the usability of the newly developed International Cardiac Rehabilitation Registry for low resource settings to ensure applicability and optimal utility, and hence ultimate uptake to establish and standardize the quality of CR services.

1.3 Study Objectives

The objectives of the usability study were:

Objective 1: To explore the perception of the CR staff regarding usefulness of the registry in improving CR service quality.

Objective 2: To identify challenges and facilitators to use and adopt the registry by the CR staff

Objective 3: To explore the insights of the CR staff regarding the ICRR structure, design, data dictionary, program survey, and patient reports to enhance ICRR utility before its launch.

Objective 4: To assess the usability of the ICRR quantitatively using the SUS survey.

1.4 Research Question

The study was conducted to answer the following research questions:

1. How do CR staff perceive the ICRR in terms of usefulness or burden?

2. What are the perceived challenges and facilitators to use and adopt the registry by the CR staff?

3. What are the perceived areas of improvement in the ICRR structure, design, and data to enhance the registry by the CR staff?

4. To what extent are the CR staff satisfied with the newly developed registry?

.

CHAPTER 2: LITERATURE REVIEW

This chapter is presented in six sections: the first section addresses the burden of CVDs globally, and in LMICs. The second section highlights the cardiac rehabilitation program's core components, and its effectiveness in reducing mortality and morbidity on a global level. The third section introduces clinical registries and how it is distinct from electronic medical records, followed by shedding the light on the effect of CVD registries in improving healthcare quality and patient health outcomes. Finally, the fourth section in this chapter introduces the International Cardiac Rehabilitation Registry (ICRR) development based on best practices and guidelines.

2.1 Burden of Cardiovascular Diseases

Cardiovascular disease patterns have important implications for health care management and public health policy formulation (40). CVD cases nearly doubled from 271 million to 523 million between 1990 and 2019 (5). Globally, CVD prevalence is projected to increase significantly due to population growth and aging in the coming years, especially the proportion of elderly is expected to increase twofold between 2019 and 2050 (5). Similarly, CVD deaths increased from 12.1 million to 18.6 million between 1990 and 2019. Additionally, projections showed that CVDs would contribute to over 23.6 million deaths in 2030 worldwide (41). Stroke and ischemic heart disease (IHD) are the most prominent CVDs and the leading cause of death and disability (5). Four of five deaths from CVDs are due to stroke and heart attack.

CVDs are a considerable burden in terms of morbidity. Disability-Adjusted Life Years (DALYs) is a global scale for measuring disease burden. The number of DALYs is a measure of the total burden of disease that results from disabilities and premature deaths. One DALY is equivalent to one lost year of healthy life. Throughout the period 1990 to 2019, the global trend of

CVDs DALYs increased steadily from 279.84 million to 393.11 DALYs (3).

2.1.1 CVD Burden in Low-Income and Middle-Income Countries

Non-communicable diseases are the leading cause of nearly half the disease burden and mortality in LMICs (42). Between 2006 and 2015, half of NCDs mortality was attributed to CVDs. NCDs are projected to increase by 17% in the next ten years and by 27% within the African region (43). Currently, CVDs account for over 80% of deaths in LMICs (41). As mentioned previously, CVD deaths raised from 12.1 million to 18.6 million globally between 1990 and 2019 (5). However, between 1990 and 2017, there was a dramatic heterogeneity in death rate trends between high-income countries (HICs) and LMICs. For example, between 1990 and 2017, death rates decreased in HICs from 271.8 per 100, 000 to 128.5 per 100,000, while there was a slight change in death rates in the same period for LMICs, i.e. from 368.2 to 316.9 per 100,1000 (44). This heterogeneity in death rates between LMICs and HICs is mainly driven by CVD management, including advanced technology, resources availability in HICs, and differences in competing health priorities by geographical area (10–12). According to the World Health Organization's (WHO) risk stratification, CVD risk thresholds eligibility for intensive intervention are 20%, 30%, and 40% for high-resource settings, medium-resource settings, and low-resource settings, respectively. This high threshold level for low-resource settings compared to high-resource settings would deny most people at risk the opportunity to delay or prevent CVD events. If the risk threshold for intervention is decreased, the number of individuals eligible to benefit will increase. Resource availability allows for expansion to include people at moderate risk of CVDs in the coming 9 to 10 years in the eligible population for CVDs mitigation strategies. However, unfortunately, this may not be feasible in LMIC due to scarce resources and competing health priorities (45-47). The risk factors in these countries are high fasting plasma glucose, high systolic

blood pressure, unhealthy eating patterns, high low-density lipoprotein levels, and poor air quality. Globally, the total DALYs caused by CVDs increased steadily from 279.84 million in 1990 to 393.11 million in 2019 (3). Therefore, cost-effective strategies, policies, and public health program development, such as cardiac rehabilitation programs, are most needed to mitigate the CVDs burden in the LMICs. These programs should offer quality services to get the utmost benefits to patients.

2.2 Cardiac Rehabilitation

Cardiac rehabilitation is a comprehensive secondary prevention program for patients with cardiovascular diseases (48, 49). The American College of Cardiology and the American Heart Association (AHA) recommended CR as a Class 1 for treating patients with coronary artery disease and chronic heart failure (22, 50-54). Despite being recommended in clinical practice guidelines internationally, a recent global cardiac rehabilitation survey showed that only 111 countries offer CR services out of 203 countries (54.6 %) (20). Moreover, based on available data, i.e., only for ischemic heart disease (IHD), it has been estimated that there are 20,279,651 incident cases of IHD globally yearly. However, the CR global study indicated that- in countries with existing CR services- the absolute CR density was one spot per 11 IHD cases, while globally, it was one spot per 12 IHD cases (20, 55). Moreover, CR services are underutilized, not standardized, and quality improvement methods and outcomes are rarely published (13, 38, 49). Eligible patients in most need for CR do not receive it or will not derive the utmost benefit from it (20, 48, 56).

2.2.1 CR Core Components

CR is a multi-component complex intervention. Patients' benefits vary greatly depending on the nature and quality of CR services provided (49). Thus, the AHA and the American Association of Cardiovascular and Pulmonary Rehabilitation identified six core components that all cardiac

rehabilitation/secondary prevention programs should contain to enhance CVD risk reduction, reduce disability, and promote a healthy and active lifestyle for patients with CVDs (50). CR components are: baseline patient assessment, nutritional counseling, risk factors management (weight, blood pressure, lipid, diabetes, and tobacco cessation), psychosocial management, physical activity counseling, and exercise training. In low-resource settings, models of delivery of these core components have been suggested based on resource availability (13, 57). Thus, the International Cardiac Rehabilitation Registry (ICRR) aims to provide further quality data and future recommendations once launched to optimize the delivery of all CR components in low-resource settings effectively.

2.2.2 Cardiac Rehabilitation Benefits

There is compelling evidence that cardiac rehabilitation decreases the risk of all-cause and cardiac-related mortality and considerably enhances health-related quality of life (56, 58). About half of the reduction in mortality attained by exercise-based CR can be credited to reducing risk factors, such as smoking (12). A systematic review of 47 randomized controlled studies including 10,794 patients comparing exercise-based cardiac rehabilitation to usual care showed that overall mortality and cardiovascular mortality risks were reduced by 13 % and 26%, respectively, in patients randomized to CR (14). Moreover, the systematic review showed that hospital admissions rates decreased by 31% (14). It was evident that health-related quality of life was significantly higher with exercise-based cardiac rehabilitation than the usual care, as reported in seven out of 10 trials (14).

In another systematic review and meta-analysis, of a total of 63 randomized controlled studies and 14,486 participants, the overall study results indicated that CR reduced cardiovascular mortality

by 26% (RR: 0.74; 95%CI: 0.64 to 0.86) as well as hospital admissions by 18% (RR: 0.82; 95%CI: 0.70 to 0.96). Fourteen out of twenty studies reported improved health-related quality of life scores (11).

2.3 Clinical Registries

2.3.1 What is a Clinical Registry?

Clinical registries are observational databases that focus on clinical conditions, procedures, therapies, or populations. It collects data systematically for scientific, clinical, or policy purposes (36). A clinical registry is essential in assessing the impact of healthcare delivery and treatment models on health outcomes through monitoring disease and capturing real-world data [1–3]. The use of clinical registries has become increasingly popular in quality improvement projects for improving healthcare processes (24-31), following clinical practice guidelines (29, 32, 33) and meeting standards (32, 34, 35); and reducing care delivery costs (36, 37). Registries generally provide hospitals and clinicians with information about clinical care, adherence to evidence-based guidelines, and patient-reported outcomes. Registries play a critical role in medical research; they are excellent platforms for randomized clinical trials because they reduce the time and cost associated with prospective data collection.

Moreover, by collecting real-world data within registries, researchers generate research hypotheses (59, 60) and can conduct descriptive studies and health service research (61), and incorporate genomic, biomarker, and imaging data with clinical registry data, which can improve research opportunities (61, 62). Researchers can use registry data to answer questions that are not feasible or ethical to address with randomized controlled trials (63). In general, clinical registries serve as a surveillance health system to assess healthcare effectiveness and safety, support and measure the effectiveness of quality improvement, evaluate factors influencing prognosis and

quality of life, improve patient care experience, and patient outcomes for a variety of conditions, such as CVDs (22).

2.3.2 Registries and Electronic Health Records (EHR)

There is a belief that EHR data could replace registries as the primary source of clinical data in real-world settings, but there are essential differences between them that could affect how they are used for evidence generation, public reporting, and quality improvement (64). For example, a trained abstractor enters data from the clinical record into dedicated clinical registries according to specific definitions (5–7, 10, 57) ensures the reliability and validity of registry information. Physicians and other clinical team members enter patient care data into EHRs for purposes of assessment and diagnosis rather than for purposes of analysis and reporting. Clinicians may not document their clinical interventions and assessments in standardized ways due to the workload and overwhelming demand on healthcare services (64, 65); because of this lack of standardization, it would be more challenging to compare compliance to guidelines between different providers or settings or use these data for benchmarking in national and international comparisons (64).

2.3.3 CVD Registries Impact on the Quality of Care and Patient Outcomes

Clinical registries generally have positive impacts on healthcare outcomes and processes. A recent systematic review evaluating the impact of registries on health outcomes supports this conclusion (66). In all 17 studies that were identified in the review, only two focused on cardiac diseases specifically, stroke care. Sixteen studies reported positive results after implementing a registry. The impact of the registries was measured in various ways, including changes in processes, quality of care, treatment outcomes, survival rates, and compliance with guidelines. The two registries assessing stroke care were established to improve stroke care quality in USA and Germany in 1999

and 2001, respectively. The stroke registry in Germany included 70 hospitals (67), several quality indicators were developed to measure the impact of the registry on patient outcomes and quality of care. The study results indicated that the rate of admissions within 3 hours of stroke onset increased significantly from 28.2% to 34.6% between 2001 and 2006, accompanied by proper use of emergency medical services. The duration of hospitalization was reduced by two days for ischemic stroke and by 2.5 days for transient ischemic stroke. Discharge to patients' homes, nursing homes, and rehabilitation facilities increased significantly and reached proportion of 36.2%, 6.5%, and 40.0%, respectively (67).

Regarding the registry impact on health service usage, it was evident that participation in the registry in 2006 was associated with reduced time loss due to contacting general practitioners instead of medical emergency services; further, stroke management aided by clinical imaging and treatment has improved significantly. Finally, even though improving patient quality of care directly impacts patient outcomes, these were not assessed (68). Another study reported the impact of a stroke registry established in USA in 1999 (Ethos registry) which included 86 hospitals (69). The impact on health service usage was described, but the impact on the process of care was either not measured or not reported. Three targeted quality improvements were developed to measure the impact of the registry. The study results indicated that stroke optimal treatment rates have significantly improved during the first three months of participation in the registry and continued to improve with a longer duration of participation. Treatment rates for antithrombotic medication use within 48 hours were 92.5%, 84.6% for antithrombotic medications at discharge. Finally, 77.1% for deep vein thrombosis prophylaxis (69).

2.4 CR Registries

Based on clinical guidelines, such as the European, American, and Australian, audit and evaluation are core components of cardiac rehabilitation registries used to characterize the quality of care, service delivery, and patient outcomes (38) . Globally, only eight active CR registries exist (38). These are national CR registries, i.e., serving only their own CR programs, of Austria, Japan, Denmark, Germany, Mexico, China, the United States of America (USA), and the United Kingdom (UK) (38) . There were two CR registries but are no longer functioning: Canada National CR registry (in the process of being re-initiated), and the International European Cardiac Rehabilitation Registry, which includes 69 centers in 12 European countries (EuroCaReD). Three studies were derived the EuroCaReD to provide insights on CR service provision and outcomes across Europe (70-72). These registry-based studies revealed some gaps in the CR service delivery and clinical practices. For example, the study by Benz et al. (2017) showed that Europe has different program designs, indications, clinical characteristics of patients, and poor adherence to the recommended guidelines (70). It was clear that there was an underrepresentation of women in CR programs (76% of patients were male). The indication for CR varies among countries. The predominant indication was acute coronary syndrome in Switzerland (79%), Portugal (62%), and Germany (61%); elective percutaneous coronary intervention in Spain (32%), Austria (36%), and Greece (37%); coronary artery bypass graft surgery in Russia and Croatia (36%). Minority of patients presented with chronic heart failure (4%). There were various CR delivery models, i.e. durations ranged from 3 to 24 weeks with a total number of sessions between 30 and 196 sessions. Ultimately, patients' CV risk profiles had only modest improvements with higher rates of exercise capacity among young patients and those who were employed. Overall, the data from the international registry showed that there was a country-specific CR effect. Documentation of CR

results in Europe was not sufficient due to incomplete electronic case report form (70).

The second study demonstrated improvement in CVD risk factors, including blood pressure, low-density lipoprotein, body mass index, and fasting glucose among patients enrolled in the program compared to non-enrollee. However, this registry-based study underlined gaps in program completion with 70% of patients (72).

In the third study, researchers assessed predictors of dropping-out from different CR programs in the 12 European countries (71). The study showed a high percentage of patients dropped off the program for unspecified reasons of program interruption, which highlights the need for further research and investigations. Other drop-out related factors were recurrence of events and comorbidities, while the dropout rate was not influenced by age, gender, or initiating event. This indicates that these subgroups need special attention in CR programs (71). In summary, these results from the International European Cardiac Rehabilitation Registry underline the importance of registries in revealing gaps in clinical practices and priority areas to improve services. However, the European registry only served CR programs in Europe. Apparently, there is a need to establish a CR registry to monitor the quality of CR services and adherence to evidence-based guidelines, especially in LMICs or low resources settings where there is a rising incidence of CVDs (7).

2.4.1 Development of the International Cardiac Rehabilitation Registry (ICRR)

Rationale: There is only one CR registry, Chinese, in LMICs, where CVDs are most prevalent with 80% of total CVD death taking place in these countries (38) . In response to the lack of CR registries in LMICs and to the request of members, the International Council for Cardiovascular Prevention and Rehabilitation (ICCPR) has developed a health services registry, namely the International Cardiac Rehabilitation Registry (ICRR) for CR programs in low-resource settings (19). The registry aims to determine the quality and effectiveness of CR delivery in low-resource

settings; describe care patterns, variations in treatment, and outcomes; provide evidence for advocacy and policy; and conduct research. Moreover, the ICRR may support standardization and optimization of CR delivery internationally.

The registry was developed based on best practices in registry development and operation, and usability tested based on the Unified Theory of Acceptance and Use of Technology 2 (UTAUT 2) (59), which was covered in the next section (73). Generally, before the final launch of the registry, it goes through several tests to ensure optimal utility.

Registry Development: Initially, a review of best practices in registry development was carried out; results of Medline search, policy-type papers, and grey literature were considered. Therefore, development of the ICRR comprised of 5 steps (Figure 1) (39), which was finalized based on evidence-based guidelines and best practices for developing clinical registries (21, 59, 64, 74-77), namely, the Agency for Healthcare Research and Quality (AHRQ) Registry User's Guide (64) and Mandavia et al. (75). These steps include: planning, governance, dataset, mitigating challenges, and registry initiation.

Figure 1. Five-Step registry development process with ICRR activities

In the planning phase, funding of the registry was secured through a collaboration by Qatar and York Universities, the International Research Collaboration Co-Fund (IRCC # 2005); the registry infrastructure was set, i.e. software hosted by Dendrite and all issues related to security/privacy as well as registry scope/protocol and inclusion/exclusion criteria. Dendrite has implemented over 170 major national/international registries and is an approved registry supplier. Dendrite's information security arrangements are regularly (every 12 months) assessed and certified by the UK Department of Health to ensure Dendrite's compliance with the strict information governance/security (Data Security and Protection Toolkit) requirements. Dendrite has successfully passed all assessments. The latest Dendrite's certification shows 'Standards Exceeded' – this is formally published on the Data Security and Protection Toolkit website:

https://www.dsptoolkit.nhs.uk/OrganisationSearch?searchValue=8HJ38. Dendrite code is: 8HJ38 Dendrite's systems and processes are also regularly certified by CyberEssentials. Registry data will be stored in perpetuity.

This phase involved setting the registry objectives, where input for ICRR objectives, mentioned above, was solicited and approved by the ICCPR Executive. As soon as the registry objectives are in place, the second step is establishing an ICRR governance committee to ensure sustainability and goal achievement through and day-to-day management of the registry. The governance included executive committees and a steering committee with sub-committees comprised of CR experts from all regions of the globe (Figure 2, see https://globalcardiacrehab.com/ICRR-Governance).

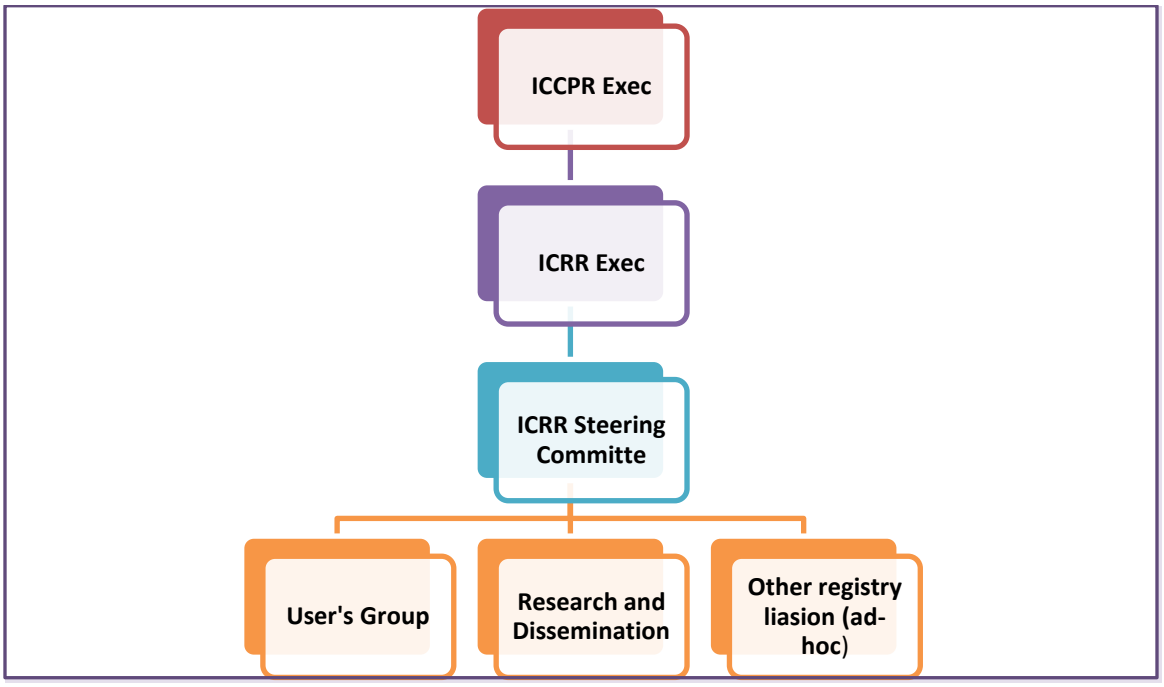


Figure 2. Organization chart of the international cardiac rehabilitation registry (ICRR)

Dataset and variable selection presented the third step of the ICRR development. ICRR variable selection followed a rigorous, stepwise approach. It is based on recommendations by Core Outcome Set-STAndards for Development (COS-STAD) (78), and considered AHRQ Outcome Measures Framework (i.e., characteristics, treatment, and outcome domains) (64). First, data dictionaries of all existing CR registries were obtained and reviewed for common data elements and core outcome sets. Second, twenty-one purposively-identified stakeholders and experts served on a Delphi panel to rate the variables from other registry sets. The panelists were asked to add variables, perceived importance, to the list and to provide input on each variable definition to finalize. They rated variables to be used as indicators for benchmarking in registry dashboards and for patient lay summary. Eventually, the final list was publicly available for comments, all comments were integrated, as appropriate, in the final version of the variable list. The final list included a set of 29 variables: 12 program reported and 17 patient-reported variables (Appendix A), see here https://globalcardiacrehab.com/resources/Documents/ICRR%20Data%20Dictionary_v8-3clean3.pdf).

The fourth step is anticipating and mitigating challenges through usability testing; one needs to be aware of cross-cutting challenges, such as completing data and reaching consensus on data requirements, data governance, and legal factors before launching the registry, which is the last step. Usability testing is the scope of this study and methods were described in details in Chapter 3. Usability testing of the ICRR was informed by the Unified Theory of Acceptance and Use of Technology 2 (UTAUT 2) in Chapter 3.

2.5 ICRR Usability

Usability is a key characteristic of software quality. The software quality model consists of six dimensions, namely functionality, portability, maintenance, efficiency, reliability, and usability (79). Different standards and researchers have different definitions of usability in the literature. According to the International Organization for Standardization ISO 9241-11, usability is defined as the capability of a product to assist a user with achieving a specific objective with efficiency, effectiveness, and satisfaction in a defined context (80). Software usability contributes directly or indirectly to software quality issues. These often lead to poor efficiency and ineffectiveness. As a result, many users may find it difficult to use specific software, which affects its acceptance by end-users and ultimately its successful implementation. While the number of eHealth apps has grown exponentially, the number of studies that report the results of usability testing on these apps has not increased at the same rate. Only a few digital health applications published their usability evaluation results. (81). The results of a scoping review for 133 studies reported the most common methods were used for usability testing for eHealth applications (websites, PC software, smartphone and tablet applications), in decreasing order of frequency as the following: questionnaires (n=105), task completion (n=57), 'Think Aloud' (n=45), interviews (n=37), heuristic testing (n=18) and focus groups (n=13) (See Figure 3) (81). Further iterations of the app were reported in a minority of the studies (n = 41). The most ten health conditions or diseases were evaluated for usability were: mental health (n = 12), cancer (n = 10), nutrition (n = 10), child health (n = 9), diabetes (n = 9), telemedicine (n = 8), cardiovascular disease (n = 6), human immunodeficiency virus (n = 4), health information systems (n = 4) and smoking (n = 4).

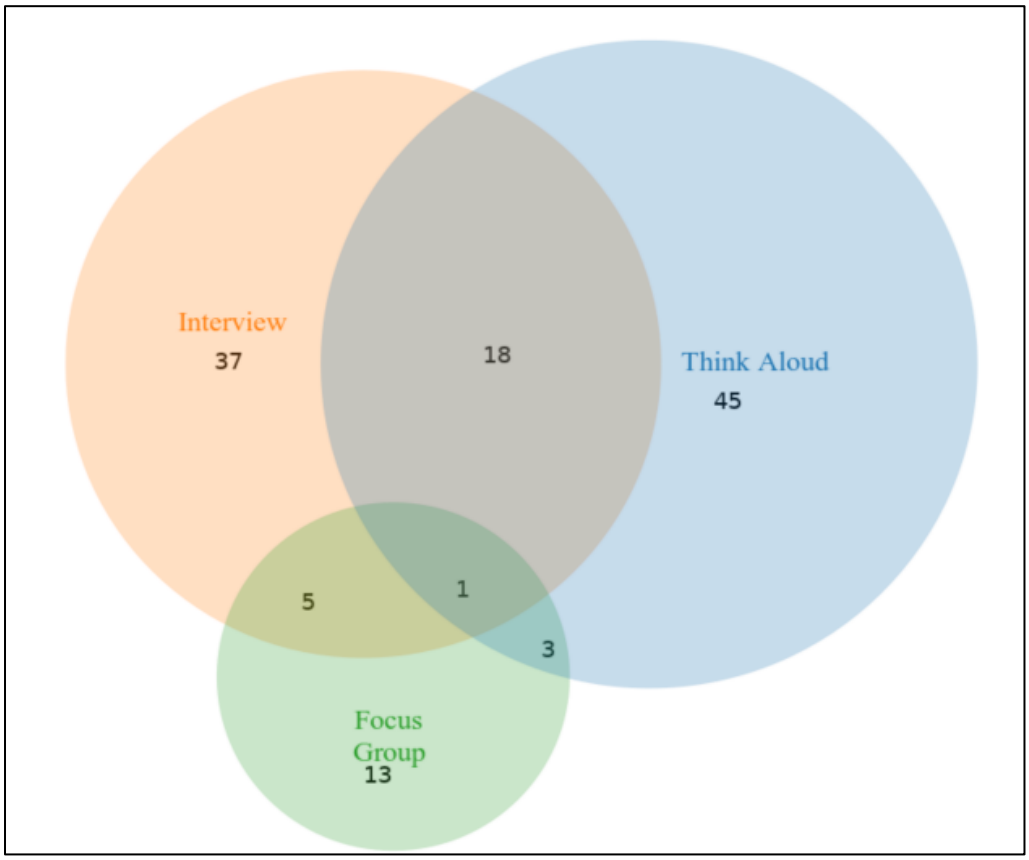


Figure 3. Qualitative methods of testing.

According to the review the most common form of evaluating usability in eHealth applications is a questionnaire, which provides an overall measure but does not identify specific problems. The System Usability Scale (SUS) was the most frequently used questionnaire (n=44). Overall successful implementation of any eHealth app depends on its acceptance and usability. Thus, used a mixed-methods design comprising Think-Aloud, semi-structured interviews and SUS to test and explore in-depth the usability of the ICRR to ensure the applicability, optimal utility and successful implementation of the registry before its launch.

2.6 System Usability Scale (SUS): Evaluation of users' experience and system usability

User Experience (UX) is currently a key factor in establishing the quality of a product or service (82). User Experience is defined by the ISO 9241-11 (83) as a person's perceptions and responses resulting from the use and/or anticipated use of a product. Among the methods to evaluate UX is the standardized questionnaires, in which end-users describe their perception regarding aspects such as whether the product is easy to use, clear, confusing, or original, among others. A systematic review including 553 studies revealed the most standardized questionnaires used to evaluate user experience: AttrakDiff, UEQ, and meCUE. 38.5% of the studies reviewed used the standardized UX evaluation questionnaires as the only evaluation method, while the 61.5% of the remaining primary studies (340 studies) used between one and five complementary methods, among which is the SUS usability questionnaire, which stood out and reported in 120 studies analyzed. SUS is a valid and reliable instrument to measure perceived usability. It has been shown to effectively distinguish between unusable and usable systems even with very small sample sizes of 8-12 users with less effort and less expense (84). It correlates highly with other questionnaire-based measurements of usability (concurrent validity) (85). The items selected for the SUS were those that provided the strongest discrimination between the systems. In the original paper by Brooke (1996), he reported strong correlations among the selected items (absolute values of r ranged from 0.7 to 0.9), but he did not report any measures of reliability or validity. SUS yields a single number representing a composite measure of the overall usability of the ICRR. It is short; consists only of ten items on a five-point Likert scale from 1-5 (strongly disagree to strongly agree). The scale alternates between positive items. e.g., "I thought ICRR was easy to use", and negative items, e.g. "I found ICRR unnecessarily complex" (86).

CHAPTER 3: METHODS

3.1 Theoretical Framework:

Our theoretical framework is based on the combination of the Unified Theory of Acceptance and Use of Technology (UTAUT2) and the International Organization for Standardization (ISO) for assessing usability based on software quality, specifically ISO 9126. UTAUT 2 (Appendix B) is a robust framework which contributed to understanding a critical research area in information systems, specifically evaluating users' acceptance of technology (87). This area of research proved to be remarkably important because using technology to improve productivity requires individuals' acceptance and adoption. In this context, several competing models rooted in different sciences such as psychology and sociology have been developed, each with a different set of acceptance determinants (88). The theory has been applied in numerous research field and proved to be very useful in understanding the determinants of adopting new technology (89-91). In this study, the interview guide (Appendix C) and subsequent analysis were based on UTAUT2 (73, 87, 92), which was consolidated from eight models. The eight models explained only between 17 and 53 percent of the variation in user intentions to use new technology. In contrast, the UTAUT and its extension UTAUT2 (Appendix B) significantly improved this to explain 70 percent of the variation in behavioural intention and 50 percent of the variation in technology use (73, 87, 92). Based on the UTAUT framework, an individual's intention to use technology is influenced by four fundamental constructs: performance expectancy (individuals' beliefs that using the system will improve their job performance), effort expectancy (how easy a system is to use), social influence (how much the social network appreciates the use of technology), and facilitating conditions (organizational and

technical infrastructure in place to support the use of the system). The extension of UTAUT to UTAUT2 added more constructs to the framework, such as hedonic motivation construct (level of enjoyment), price value constructs (trade-off between perceived benefits and monetary costs), and habit construct (length of time that passes since the first technology usage) (92), these constructs are moderated by individual differences, such as age, gender, and experience. Similar to what previous research has revealed, it is worth noting that *a subset* of these constructs was adopted in our usability tests, based on the nature of the study (93).

ISO and the International Electrotechnical Commission (IEC) have developed several standards for assessment of usability of a software (80). Namely, ISO/IEC 2501n was used to inform the qualitative analysis along with the UTAUT2. The ISO/IEC 2501n is a model with 6 elements: appropriateness recognizability (users' ability to determine whether a product or system is suitable for their needs), learnability (the extent to which a product or system can be used by specified users to meet specified goals, including effectiveness, efficiency, freedom from risk, and satisfaction in a particular context), operability (measure of how easy it is to operate and control a product or system), user error protection (system's ability to prevent users from making errors), user interface aesthetics (product or system attributes that increase the user's satisfaction and pleasure), and accessibility (the extent to which a system or product can be used by people with the broadest range of characteristics and capabilities to accomplish a targeted objectinve within a specified context) (80).

3.2 Methods

This mixed-methods study was conducted between 5 May and 4 September 2021 among CR staff from LMICs. We employed three methods to achieve the study objectives: Think-Aloud Method, semi-structured interview and the SUS quantitative survey. Think-Aloud methods are considered

the "gold standard" for usability testing (94). It is an observational technique in which participants verbalize their thoughts when performing tasks, used to elicit insights into their thought processes that would not be obtained by only observation (95). We reported the participants' verbalized thoughts, facial expressions, and gestures while using the registry. The Think-Aloud technique allowed us to discover how users feel about the ICRR design, particularly their misconceptions and challenges, which led to actionable redesign recommendations, followed by implementation to enhance the registry. When users misinterpreted design elements, we documented them to change the registry (96). The semi-structured interview consisted of questions derived from concepts of UTAUT2 (73, 87, 92). The interview included 15 questions that speak to five of the UTAUT2 concepts as described in Table 1.

Table 1. The link Between UTAUT2 Concepts and the Interview Questions

UTAUT2 Concepts	Related Question
Facilitating conditions	Questions: 1, 4, 5, 7, 8, 11, 15
Effort expectancy	Questions: 2, 3, 6-8, 10, 15
Performance expectancy	Questions: 8, 9, 13
Social influence	Question: 12
Price value	Question: 13, 14

The third method is the System Usability Survey, composed of 10 items (Appendix D). It was used to measure the overall participants' satisfaction on the use of the ICRR among participants and challenges faced. More details about the SUS survey are presented below under "Measures" section. This study was reported in concordance with the Consolidated Criteria for Reporting Qualitative research (COREQ). COREQ checklist covers the reporting of qualitative studies utilizing interviews, it was developed to ensure that focus groups and interviews are reported explicitly and comprehensively, COREQ consists of 32 criteria, each accompanied by a description (Appendix E).

3.3 Participants

CR staff working at a CR program meeting inclusion criterion: (a) programs had to be offering Phase II (i.e., post-acute, outpatient); (b) programs in a low resource setting as defined above. Exclusion criteria were: (a) inability to read and communicate in English and (b) residing in a country which already has a CR registry or where one is in development (38). For instance, given the European Association of Preventive Cardiology plans to develop a registry, no participants were sought from that region. Previous research suggests that 85% of usability problems can be discovered by four or five participants, while 100% can be discovered by 15 users (82, 97, 98). Therefore, we initially aimed for 15 interviews, interviews were continued until similar themes emerged indicating saturation with 12 participants.

3.4 Recruitment

Potential participants were recruited through the ICCPR's network (~60 council/friend member associations and the ICCPR's program email distribution list). CR programs were contacted via email and social media, where they were informed about the study and invited to participate. CR staff were selected purposively to meet the above inclusion/exclusion criteria, i.e. present CR programs in LMICs/low resource settings from all the WHO's regions, but Europe, as well as from diverse healthcare disciplines (e.g., physician, physiotherapist). The word interviewee or participant in the study refers to CR program's staff who consented to take part in the study. Participants were directed to ICRR's website to read the information about joining the ICRR (https://globalcardiacrehab.com/ICRR_sites). Then, informed consent was sent to their emails and they were asked to review and sign before the interview, or they could discuss the contents at the outset of the interview and sign before it began (i.e., written consent). Copies of relevant registry

materials (e.g., data dictionary, information on navigating ICRR's ancillary features such as outcome dashboards and data export) as well as a login to the ICRR demonstration ("demo") site were provided to participants, and told to familiarize themselves before the usability test. Participants were asked to share a copy of the patient information letter and consent form with some patients as well as the variables /survey for the patient report, and the patient lay summary. The aim was to obtain some input from patients to share with the research team during the interview of the usability test. Participants were asked to be ready to enter the data of a patient, who has completed their program, during the test, ensuring they do not reveal the identity of the patient, and complete a program survey detailing the structural aspects of their program such as the number of prescribed sessions and duration, on which registry post-test assessment timing is based. Finally, a copy of the interview guide (Appendix C) was provided where participants were interested.

3.5 Data collection

At the beginning of the interviews, we asked participants to open their webcameras to facilitate the interviewers' observation during data entry (Appendix C). We reminded all participants not to respond in a socially desirable manner to reduce self-report bias. Basically, social desirability refers to research participants' tendency to provide answers to surveys and experiments to appear more attractive.

Then, we asked the participants to log in to the ICRR demo site (Figure 4; see https://demo.e-dendrite.com/icrr/;) and share their screen, as well as to have their data dictionary readily accessible. After that, we instructed the participants to enter pre and post-program data on the graduated patient (patients who completed CR program), whom they had pre-identified, while thinking and talking aloud. During data entry, we noted and documented the interviewee's thoughts

spoken out loud to enhance data collection. Notes included aspects of the context of the test, facial expressions, and gestures that would not be recorded, and some ideas raised by the participants in the process were noted as well.

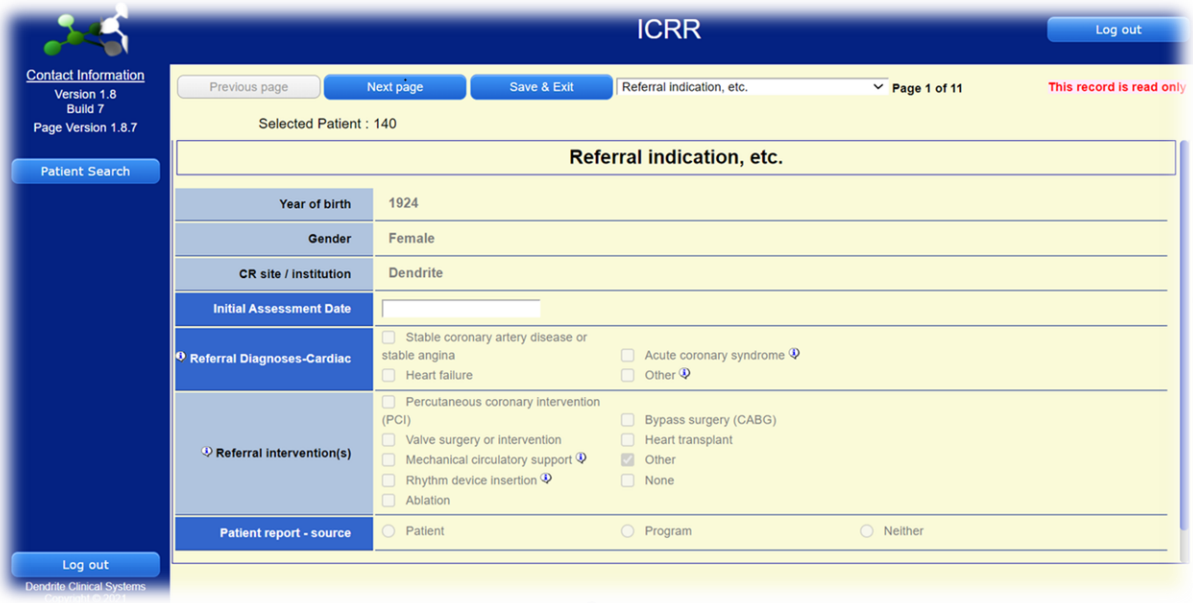


Figure 4. Screenshot of the international Cardiac Rehabilitaion registry: patient data entry interface.

Afterwards, a semi-structured interview was conducted to explore the topic in depth. The interview guide (Appendix C) and subsequent analysis were based on concepts of UTAUT2 (73, 87, 92). Interviews with CR staff were conducted in a private and quiet environment, through video conferencing platform using a computer and lasted on average 60 minutes.

Finally, email invitations were sent to participants from Research Electronic Data Capture REDCap to complete the System Usability Scale to assess participants acceptance of the ICRR (Appendix E, also see Figure 5 for summary) (86). REDCap is a web-based tool developed by Vanderbilt University for collecting data for clinical research and for creating databases and projects, REDCap provides a secure environment for research teams to collect and store highly

sensitive data (86, 99).

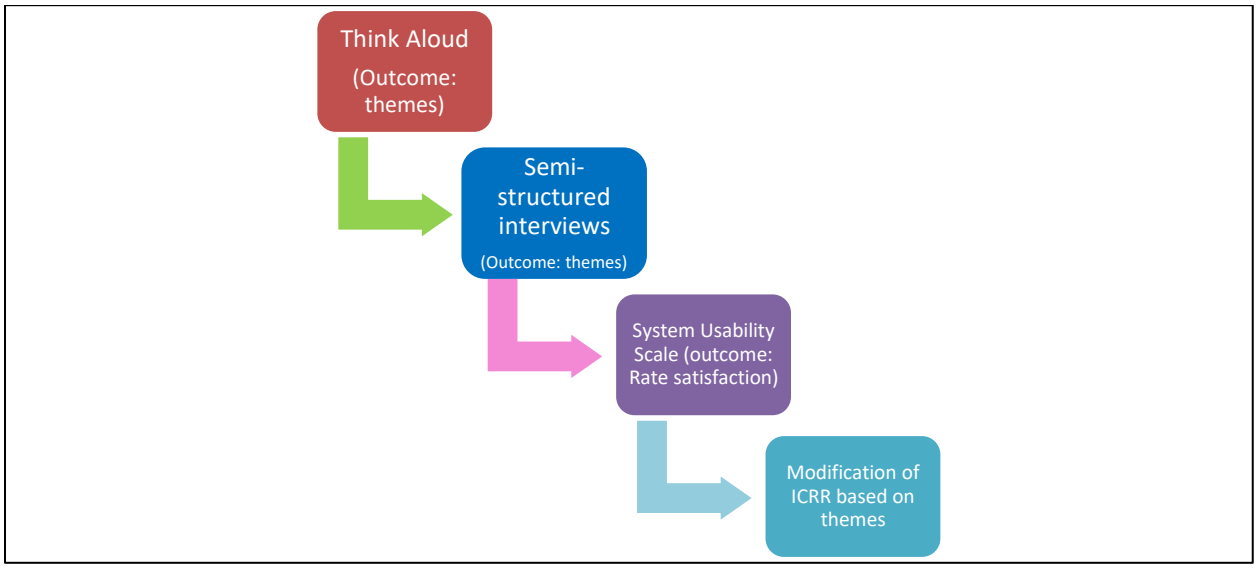


Figure 5. A summary of the methods used for this mixed-methods study.

Observing participants while entering the data provided a rich understanding of the participants' experience in their natural environment, and better insight about challenges they faced during data entry, through their spoken thoughts and facial expression. We conducted the interviews until similar themes emerged indicating saturation, which means no further data collection or analysis is needed.

3.6 Measures

The instructions for the Think-Aloud segment of the usability test were standardized (Appendix D). The interview guide (Appendix D) was developed based on previous knowledge (100, 101) and informed by UTAUT2 theory (73); the interview questions aimed to invite variation on the following parameters: registry adoption (e.g., effort expectancy for approvals, patient consent), perceived ease of use/operability, system characteristics such as variables and patient report, as well as perceived usefulness of ICRR output to support quality improvement and other program

needs. We strived to ask open ended questions to understand participants' point of views about the challenges and facilitators of adopting and using the registry.

For the quantitative part, the SUS survey was emailed to participants (85, 86, 102-105), and asked to rate the usability of the ICRR. The SUS is used by the ISO 9241-11 (86, 103, 104). It consists of 10 items, each rated on a five-point Likert scale from 1-5 ("strongly disagree" to "strongly agree"). The scale integrates positive and negatively-framed items to account for biases resulting from the respondent's potential lack of attention while completing it (86). A total score was calculated using Brooke's standard scoring method (86); each item contributes to the final score with a range of 0-4, with 4 being the most positive. For positively worded items (1, 3, 5, 7, and 9) the score contribution for each item is the user's response for that item minus 1, while for negatively worded items (2, 4, 6, 8, and 10) the score contribution for each item is 5 minus the user's response. Then, the total score is multiplied by 2.5 to obtain the overall value of SUS on a scale from 0-100 (this scale score should not be interpreted as percentages) (106). A SUS score above 68 is considered above average and a score below 68 is below average (107). However, the best way to interpret score is to convert it to letter-grades (from A+ to F) based on percentile ranks (105). An A+ grade corresponds to an average SUS score of 84.1-100 as described in Table 2. The SUS is a valid and reliable instrument to measure perceived usability. It has been shown to effectively distinguish between unusable and usable systems even with small sample sizes of 8-12 (84). It correlates highly with other questionnaire-based instruments of usability (85).

Table 2. SUS Scoring Numeric and Alphabetical System

Grade	SUS	Percentile Range	Adjective	Acceptable
A+	84.1-100	96-100	Best imaginable	Acceptable
A	80.8-84.0	90-95	Excellent	Acceptable
A-	78.9-80.7	85-89		Acceptable
B+	77.2-78.8	80-84		Acceptable
B	74.1-77.1	70-79		Acceptable
B-	72.6-74.0	65-69		Acceptable
C+	71.1-72.5	60-64	Good	Acceptable
C	65.0-71.0	41-59		Marginal
C-	62.7-64.9	35-40		Marginal
D	51.7-62.6	15-34	ok	Marginal

Source: UIUX Trend. Measuring and Interpreting System Usability Scale (SUS) 2021 [https://uiuxtrend.com/measuring-system-usability-scale-sus/]

3.7 Data Analysis

Interview analysis was concurrent with data collection. Recorded interviews were transcribed verbatim, behavioral observations and participant comments from the Think-Aloud method, including facial or verbal expressions as participants navigated ICRR screens, were considered. Transcribed interviews were analyzed using thematic analysis NVIVO 1.5.1 software (108). Thematic analysis was undertaken in several steps to categorize contents allowing training and calibration sessions, the coding and grouping process was conducted by another researcher along with me, the first author, to ensure soundness and trustworthiness. The inter-rater reliability is expected to be high with coding discrepancies in three occasions, where a discussion was carried out and a consensus reached. Data analysis started with reading the interview transcripts and field notes several times line-by-line in order to gain an overall understanding and identify essential codes. Meaningful codes were derived through open coding, then these codes were sorted into groups through axial coding based on the study's objective, axial coding was done by grouping

similar codes into subcategories and then further combined into one main category in relation to the study objectives. Finally, each category was unified around one major category, which represented the study's resulting themes (Figure 6 & Figure 7).Emerging themes were supported by meaningful quotations (verbatim, except for some minor edits, which were made to increase clarity in the case where the respondent's first language was other than English). Themes with sub-themes were then shared with all interviewees to inquire whether they resonated, and request any input to ensure credibility (i.e., member checking) (109).

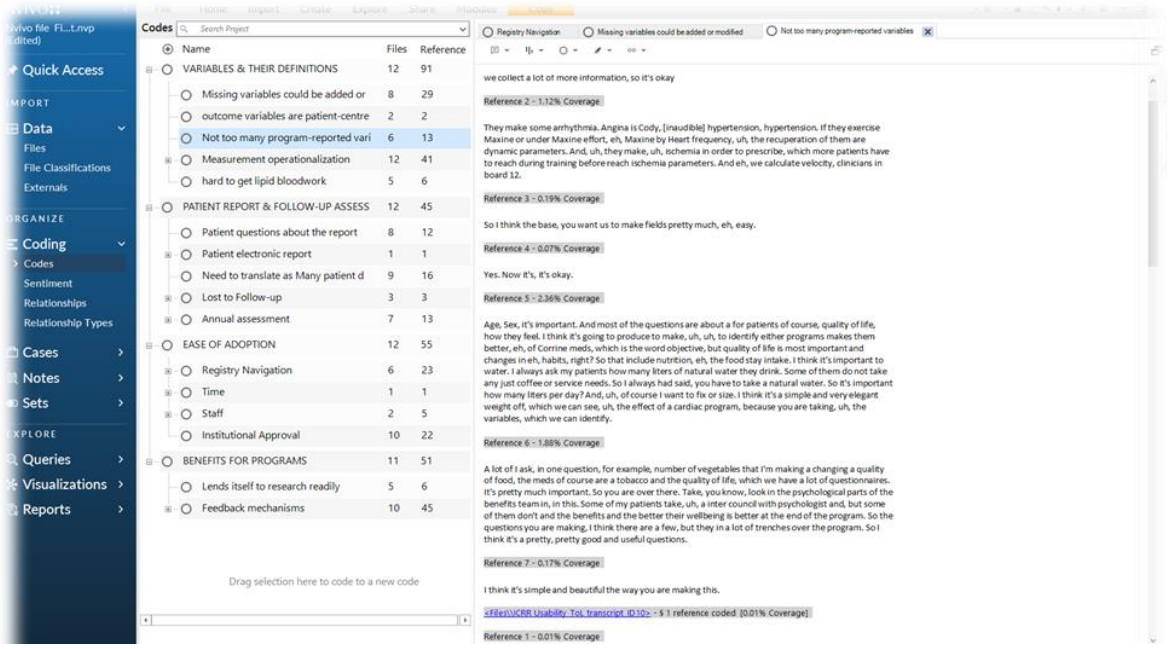


Figure 6. Screenshot of codes using NVIVO (1)

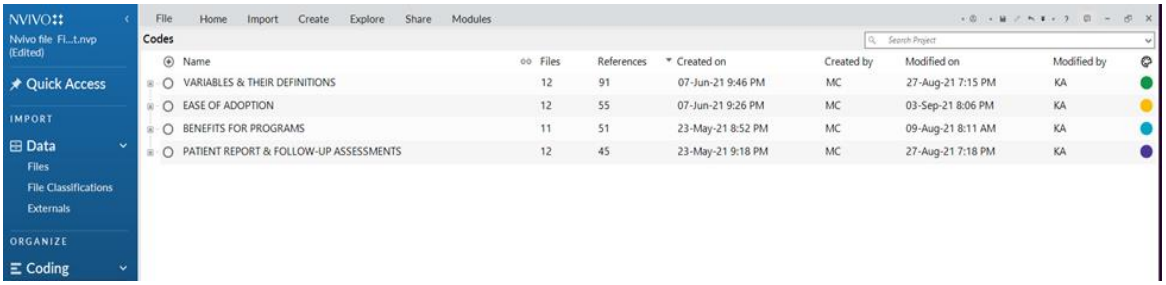


Figure 7. Screenshot of codes using NVIVO (2)

3.8 Ethical Approval

The study was approved by Qatar and York Universities Office of Research Ethics (e2020-147; Toronto, Canada; QU-IRB 1518-EA/21; Doha, Qatar) (Appendix F & Appendix G).

CHAPTER 4: RESULTS

Sixteen CR staff expressed interest in participating. As shown in Table 3, ultimately, we conducted 12 interviews before saturation was achieved. CR staff had various disciplines from in all the WHO's regions but Europe (67% female). The four who were not interviewed were from Latin America, which was already well-represented in the sample. Participants worked in both privately and publicly funded programs. One was from a rural area. The tests and interviews combined averaged one hour in duration.

Table 3. Characteristics of the Interviewees

ID#	Sex	Discipline	WHO's Region[1]
1	F	Kinesiology (program manager)	Region of Americas
2	M	Cardiology	Region of Americas
3	F	Cardiology	Region of Americas
4	F	Kinesiology	Region of Americas
5	F	Physiotherapy (with Ph.D.)	Region of Americas
6	F	Physiotherapy (Ph.D. student)	South-East Asia
7	M	Physiotherapy (with Ph.D.)	Region of Americas
8	F	Nursing	Eastern Mediterranean
9	M	Physiatry (physical medicine and rehabilitation)	Eastern Mediterranean
10	F	Cardiology	Western Pacific
11	F	Physiatry (physical medicine and rehabilitation)	Western Pacific
12	M	Kinesiology (program director)	African Region

[1] WHO: World Health Organization

4.1 Usability Tests: Think -Aloud

Overall, participants were readily able to navigate the demo registry to enter the pre and post-program data. It was evident that most of the variables were assessed in their routine practice and definitions were consistent with their practice, such as tobacco use, blood pressure, body mass index, functional capacity, quality of life, work status, and education level. Participants used different functional capacity tests at their programs, but the data dictionary (the relevant excerpt of which is available in the registry screen in an information bubble provides information on how to convert the various measures to metabolic equivalents of task (METs); several participants successfully converted values during the usability test (ID5, ID6).

Based on participants' spoken thoughts and utterances, suggestions for changes to the ICRR were raised, shown in Table 4. For instance, with the registry itself, some software glitches were identified (could not edit participant email for patient-reported outcomes; ID3), the definitions of some variables required clarification (e.g., years of education, ID12; referral diagnoses cardiac only and other diagnoses to be reported elsewhere, ID1), the response options or ranges on some variables required modification (e.g., the maximum number of sessions, ID12; entering multiple referral interventions, ID12), and the addition of an optional variable pre and post-program was suggested (e.g., blood glucose, ID6). All of these suggestions were implemented.

Table 4. Results of Think-Aloud Technique and Semi-Structured Interviews with the Main ICRR Changes Made, with Supporting Quotes as Appropriate

	Registry Interface Changes	Supporting Quote(s)	Theme/Subtheme*	Usability Theoretical Construct
1	When entering the wrong patient phone number on page 1, keep getting an error when trying to edit it; prevents you from entering the correct value or making it blank (rectified)	Ooh! I keep getting an error	Registry navigation / usability	Effort expectancy (Ease of use)
2	Added site-specific name and/or logo to patient report emails /texts & lay summary	"Could you brand with your own stuff?" (ID1)	Patient electronic report	Facilitating conditions
3	Need to specify years of schooling starts from grade 1; added to data dictionary and "i" bubble in registry interface	"Yeah, searching for how many years that patient does formal schooling, So I want to say at least five, at least. Well..." (ID12) "No, no, this is from first ever grade". (Interviewer)	Measurement operationalization	Learnability
4	Added a blank variable with free-text to pre- and post-program report pages, so sites can add data they wish (e.g., blood glucose)	"Oh, what about those sugar levels? What is the reason why that wasn't looked at? The sugar level is one the values that gets collected very frequently in our center, and we believe that if that's under control and the disease, a major part of the disease is under control." (ID11)	Variables missing / could be added	System characteristics
5	Increased maximum number of supervised sessions from 150 to 199 (had inserted minimum and maximum for all continuous variables to minimize data entry errors)	"You will be surprised with this patient because he is a champ. He's now coming for a whole year five times a week; every single day he is coming" (ID12)	Variables and their definitions	System characteristics
6	Added further navigational instructions regarding moving through registry pages, and exiting (including before all data entered for a patient) to data dictionary	"The drop-down options on the top right through which you select the various pages, I didn't figure out in the beginning; I just tended to select the option "save and next" to get to the next page. So initially, when I tried the registry, I completed only five pages, but then I saw two remaining pages." (ID 6) "Initially, I got confused between the pre and the post [assessments], because I hadn't gone to all the pages. So initially, when I was filling in data, I was not sure which to put in. But then once I figured out the pages from the drop-down options, I realized which page I had to navigate to" (ID 6)	Easy to navigate data entry screens how to save and exit to come back later	Operability

	Registry Interface Changes	Supporting Quote(s)	Theme/subtheme*	Usability Theoretical construct
7	Added to data dictionary to ask patients to get blood pressure with available automated device at follow-up assessments, if possible, if patient cannot come in and to mitigate attrition bias	"So, we have both, face-to-face exercise and then we also just recently added the online for patients who couldn't come face-to-face; like they had like some conflicts at work. But since then, since COVID, we started also a home program .... There are patients who have BP [blood pressure] monitors at home, so we get this information". (ID6)	Loss to follow-up	Effort Expectancy
8	Concern about benchmarking against all programs in registry dashboards. For example, how urban programs are being compared to rural programs and how these results are aggregated in the registry dashboard. Change: we Made note in the registry ancillary features file about how they are benchmarked against all programs, but the ICRR could give them information about the average patient and program characteristics of participating sites to which they are being compared, and that they should interpret the dashboards with knowledge of their local program. The research sub-committee will do adjusted analysis, considering other factors (e.g., region, whether programs are academic, disease severity)	"So, the only concern is that when it comes to all sites, it will be comprised of sites that are rural and urban. For example, if the majority of programs participating in the registry are from urban settings, probably. Gives us a different picture for quality. If I say maybe if the graph could be split between the two. Yeah, then your rural programs could always compare themselves with other rural programs. I understand then whether they are performing adequately" (ID6)	Theme 2: benefits for the program. Subtheme: feedback mechanisms	Performance Expectancy

* Refer to Figure 8: Emerged themes/subthemes

1

4.2 Usability Themes

Four major themes emerged from the interviews, as shown in Figure 8,also refer to screenshot of NVIVO analysis (Appendix H) . Exemplary quotes are shared for each below, with some text added in square brackets in some instances to provide context of interviewer question for clarity. Themes 2, 3 and 4 helped to understand our first objective: to explore CR staff perception of the usefulness of the registry to support CR services' quality. While all themes contributed to understand our second objective: to explore in-depth CR staff's challenges and facilitators to use and adopt the registry. Theme 3 and 4 helped to understand our third objective: To utilize CR staff's feedback to enhance the ICRR structure, design, and improve all related materials e.g., data dictionary, program survey, and patient's reports (Figure 9).

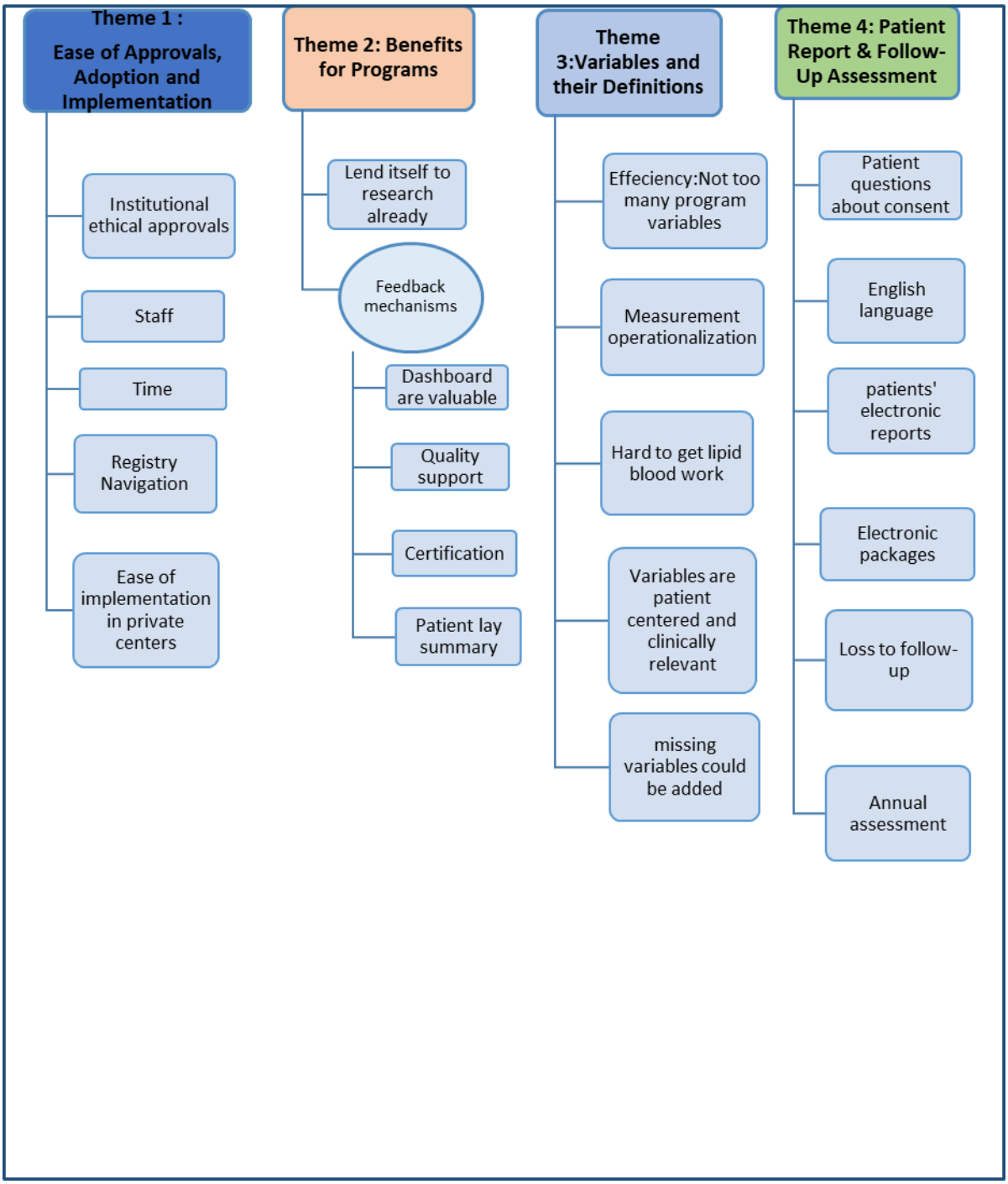


Figure 8. Emerged themes/subthemes.

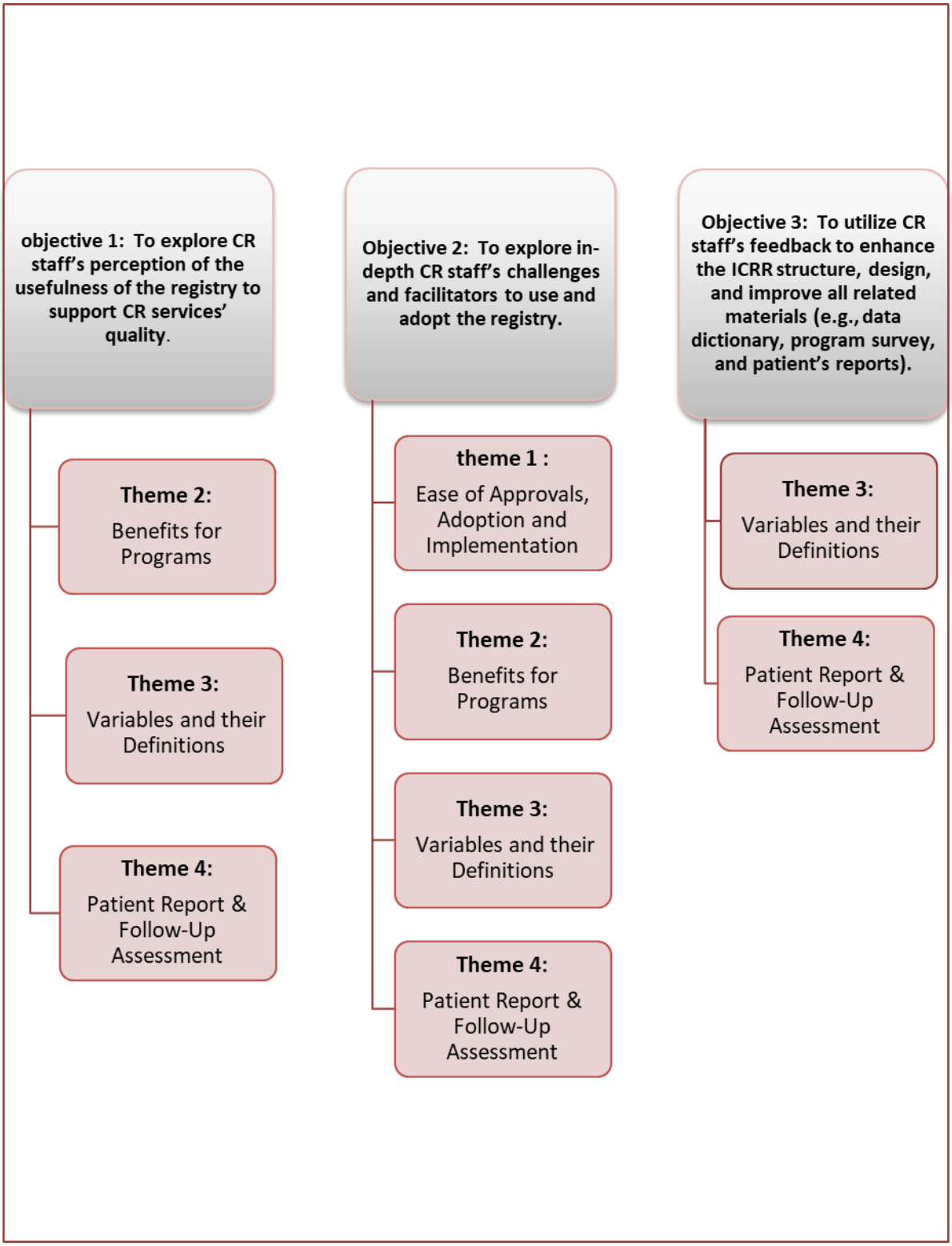


Figure 9. Study's objective and contributing themes.

4.2.1 Theme 1: Ease of Approvals, Adoption and Implementation

This theme comprised 5 sub-themes, with the first 3 regarding approvals, staff and time relating to the usability theoretical constructs of facilitating conditions and effort expectancy of the UTAUT 2 framework. The subthemes of registry navigation and application to private as well as public centers relate to the usability theoretical constructs of perceived ease of use and operability.

ICRR on-boarding involves securing institutional signature on a site agreement as well as research ethics approvals. Most participants perceived they could secure these approvals, but noted the time required for the latter. Participants at privately-funded programs sometimes did not have a research ethics board associated with their institution, so they stated they would need to reach out to collaborators to secure approval elsewhere and it would cost. Programs had someone on staff with the necessary institutional appointments to be eligible to apply for ethics approval.

> *"I have two centres here. One mine, it's a private centre, so I have no problem to install these kinds of registry in my program. And I have another workplace that's an institution, it's a hospital. And there is of course, an ethical committee and investigation committee. And of course, I have to propose to that committee." (ID2)*

> *"I mean if the program director doesn't have an academic appointment, he wouldn't be able to apply for ethics. So, I'd have to get our medical director to do it I think because he's an appointed professor overseeing students. I mean you'd have to have someone with an academic affiliation." (ID1)*

Participants talked about which staff would enter data in the ICRR, and how they would carve out time to do so from their full clinical schedules. Most programs were small with few team members. Some of the physician participants wanted to enter the data solely to ensure it was of the utmost completeness and quality. Ideas to ensure data entry feasibility included engaging trainees and administrative staff, as well as exploiting the patient report feature.

"I must be honest here. This is probably my major problem, it's time". (ID12)

"Yes, we have a lot of work, but because it's pretty important, all the data I collect it's by me personally. The administrative staff will take care about all this administrative stuff." (ID3)

"I was thinking about this [using a trainee to enter the data] when I read the questions and well, I think we can find a way to do that because we're really interested. I think it's a good idea. It's an excellent idea. We have to promote this." (ID2)

On a related note, to the above, participants discussed the need for time to adopt and make optimal use of the registry. They recognized the amount of time would be needed for approvals as outlined above but found the registry so easy to use they thought the on-boarding process would not be time-prohibitive. They did raise about the time to enter the data in terms of duplication with their data collection requirements at their institution (e.g., MS Excel, electronic health records, paper charts which they often showed with pride); they commented that there would need to be a real champion

dedicated to the value of the registry to ensure the variables were entered. They did appreciate the lay discharge summary feature, which they perceived rendered the effort to enter the data worthwhile.

"We should improve our health information system because we use paper." (ID9)

"Yes. Here we have maybe a little problem because we have a lot of work and also, we have our own database in which we are making the registry of all the variables on our patients. And that of course is a lot of work. There's just me and maybe one or two cardiologists that could be doing it." (ID2)

"There are two cardiologists. There are two physical therapists; I have one specialist that maybe could also help me in this." (ID2)

"Having something like this, like, the amount of time would take me to input the data would save me the amount of time that it's going to take me to write the report." (ID1)

Participants verbally reported the ease of using the software, logging in, navigating and exiting the patient data entry area of the registry made it seem the ICRR would be quite seamless to adopt. No matter the region, all participants were able to access the patient lay summary, download an outcome dashboard figure, as well as export their entered data.

"It was easy actually to enter the data and to get in, to log in. And it's actually short, you know, the time you spend. and so, it's okay." (ID8)

"Yes, I can [export the entered data and download the patient lay summary]." (ID5)

Finally, participants, including those worked at private and publicly-funded centers, perceived the registry would work well in both contexts, although motivations for adoption may be different. Participants from privately-funded programs were particularly interested in the program certification option leveraging data entered into the ICRR (https://globalcardiacrehab.com/Program-Certification).

"So, it will be nice to participate in this program. I think it's very important to be a member of this project, and we should start working from now to prepare our submission to the ethical committee." (ID9)

Overall, most participants perceived they could secure the ethical approvals, but noted the time required to secure them. Participants perceived ICRR easy to use in terms of using the software, logging in, navigating and exiting, which made ICRR seamless to adopt, but they did raise some concerns regarding the time to enter the data, and the need to dedicate a real champion for data entry. They did appreciate the lay discharge summary feature, which they perceived rendered the effort to enter the data worthwhile.

4.2.2 Theme 2: Benefits for Programs

This theme comprised 2 subthemes. The first around research utility relates to the theoretical construct of Performance Expectancy and perceived usefulness. Similarly, the other subtheme was around the utility of the many ICRR feedback mechanisms, and related to the usability theoretical constructs of output quality, performance expectancy. Interviewees raised many benefits of participating in the registry, which would outweigh or at least balance the downside of time required to get approvals and enter data for each patient. Participants working at academic centers noted how readily the registry lends itself to research. They wanted to know how contributing programs could be involved in research and how their participation would be recognized. They were pleased with the ready ability to download their own site data at any time for research or other purposes.

"So, once we use this registry, this is kind of a database for research." (ID2)

"I think for us low- and middle-income countries or developing countries, it's important to participate in this registry. To compare our program, and our results of this program with the other countries, and to improve our program and develop our rehabilitation." (ID9)

"All the information we have already entered in the database I think will be used and analysed. It's simple. It's the most important things and it's a great initiative." (ID3)

Participants noted four in-built feedback mechanisms they perceived as major benefits

of the registry. First, they could see how they could use the outcome dashboards to fulfill reporting requirements in their institution. Although the variables were not exactly consistent with what was required, it was perceived they would complement them nicely. Participants did express desire, but for some other comparisons for the outcomes other than the two available; they requested to compare to only other programs in their region rather than all programs in the registry, and where applicable to compare to only programs outside of urban and/or academic centers.

> *"So, I think it's good. It's useful. I mean, the amount of time that you spent entering the data that's how much information that it gives you back. Right. I think it's good. Yeah. I think you're a really nice fit." (ID8)*

> *"I wouldn't want us to be lumped in with [city], I'd want to know how we do compared to some of their community programs, and I would really be interested in knowing how rural versus urban sites are doing."* (ID1)

> *"We were wondering about region, doing it by region" (ID5)*

Second, they appreciated the planned quality improvement supports to be provided by ICRR's user committee (see: https://globalcardiacrehab.com/resources/Documents/ICRR_QI%20plan_v1-2.pdf). They reported they wanted to do more quality improvement but had limited time, and would appreciate the tools and resources provided. Third, they did want to take advantage of the program certification possibility for programs participating in the registry. While they perceived the cost as reasonable but suggested a sliding scale

based on country income classification (which was implemented), they did ponder whether ICCPR would be known to patients and their institution.

"If we're going to do quality improvement, like what are we going to do with it, and generating those tools for people that maybe don't have the same knowledge. Here a lot of people that work in cardiac rehab are clinicians, so helping us and supporting us in that way would be useful." (ID1)

"I don't think $500 over the course of three years is unrealistic." (ID1)

" I don't think anybody would really care or know what it means to be certified by ICCPR."(ID1)

"I think this is interesting that you can help us, and then I do agree you may want to charge. I think that would really help." (ID10)

The final in-built benefit participants raised was the lay discharge summary, as it quantifies for patients how they have improved and encourages further self-management post-program. Respondents did suggest having more figures or images rather than text.

"This is actually good because it shows the improvement for the patient and what s/he needs to continue or what s/he needs to improve." (ID8)

"I would say yes, this would be amazing. It'd be cool to have a print-out with visuals. I'm meeting too many patients who don't

really read all right, so the graphs could show them how they've done." (ID1)

Overall, interviewees perceived the built-in feedback mechanism and benefits of participating in the registry outweigh or balance the downside of time required to get approvals and enter data for each patient. Benefits such as the patient lay discharge summary, which quantifies changes/improvement pre- to post-program on specific key indicators and encourages further self-management post-program. The other feedback mechanism is the dashboard summary, which fulfill reporting requirements in their institution. Moreover, they appreciated the quality improvement supports, which is planned to be provided by ICRR's User Committee. Participants perceived the cost of program certification reasonable, but suggested a sliding scale based on country income classification. Finally, participants appreciated how readily the registry lends itself to research.

4.2.3 Theme 3: Variables and their Definitions

This theme consisted of 5 sub-themes, namely: number of variables, measurement operationalization, difficulty securing lipid bloodwork, the patient-centered and clinically relevant nature of the outcome variables, and missing variables or could be added. These sub-themes speak to the usability theoretical constructs of learnability, performance expectancy efficiency, system characteristics and satisfaction.

Interviewees were very pleased with the low number of program-reported variables and found the variable definitions or operationalization as clear and not complex.

"I like to comment that I like the registry because it was so quick. We don't want random information getting filled up. So that was a

very good thing about the registry. I like it was really short and sweet with important details, very precise. Like what are the points, and you just look for that. So that was a very nice thing about the registry: necessary information and no extra details". (ID6)

They were also satisfied with the clarity regarding units of measurement, for example for the variables around servings of fruit and vegetables as well as years of schooling. For low-density lipoprotein (LDL), the two major units used internationally were available, so it was easy for all participants to enter this data after specifying units.

When discussing concordance between variables in ICRR's data dictionary and their practice, participants reported the pre-program and clinical variables were routinely collected. Many variables were operationalized exactly the same way in their practice (e.g., METs, blood pressure, body mass index, program completion). On the other hand, programs reported they were not assessing or were assessing differently some of the patient-reported variables such as socioeconomic status, medication adherence, and social support.

"I don't ask people directly about further medication. But, I have had people bring it up when I asked them what their concerns are." (ID1)

One variable was commonly not assessed, namely LDL (ID1, ID3, ID5, ID6, ID10)

"We try to collect cholesterol, LDL, HDL [high-density lipoprotein], saliva, serum. Um, much of them we don't have because they come to us, we set up their program, and they go back to the cardiologists not us". (ID3)

Finally, we asked the interviewees about variables that they think are missing or need to be modified; suggestions included adding maintenance program participation and blood glucose (there were few).

Overall, patients were satisfied with the number of variables and clarity regarding units of measurement. Some participants suggested to add maintenance program participation and blood glucose.

4.2.4 Theme 4: Patient Report & Follow-Up Assessment

This final theme, with 6 sub-themes, addressed the issues of securing informed consent from patients to participate in the registry, language, facilitating their provision of data, and post-program retention and annually thereafter. These related to Performance Expectancy and facilitating conditions.

Participants did invite some patients to review the ICRR information sheet and consent form. The only question they reported patients raised was about where data were stored, and whether it was outside of the country. Overall, they reported patients surveyed found the documents clear, they were willing to participate, and to provide their email address for sending surveys.

> "I think it is very understandable for the patient." *(ID2)"I gave it to three people. The only question that came up was on the second page in the last paragraph, the second last line, it says 'data may be subject to access by third parties as a result of security legislation now in place in many countries'. So the patient was asking is this data available outside of [country]." (ID1)*

> *"You sent me a consent form for patients, and I asked at least one patient. He said he was willing to participate. In that consent form,*

it was said there, you have to provide your email address, and he was willing to provide it." (ID8)

There was a major issue of language, however. ICRR materials are only available in English at this time. Some sites will have to translate the consent information so patients can provide informed consent. The sites would not be able to take advantage of patient report, which significantly reduces the number of variables that programs need to enter for each patient, unless they translated the surveys and gave them to participants on paper; they identified that this raises questions of the validity of the translations, particularly as they did not have funding for professional translation, and only three of ICRR's items are validated and have available translations (e.g., depressive symptoms). Participants stated they would interpret the items in their consultations with patients to enter the data themselves.

"I think, unfortunately, English is not our first language or not our mother tongue. So, we must interview the patient because maybe only 20% can understand the questions and answer fully. So what we would try to do is to interview the patient, and we will do program-reported data. So, we will ask the medical officer to interview patients, and then he will enter the data into the system. It's very hard for a patient to complete the questionnaire." (ID4)

"We have more patients who are [language] speaking and others we have, [language] speaking. So, maybe like half, at least half of them only would know like perfect English. But I asked one, [language speaker] and one [language speaker] too. If they would understand, they understood, but they really would have wanted it

to be in there, translated in their own language they said, especially if they didn't have a college degree or they hadn't gotten to university." (ID8)

Again, when they were planning to take advantage of the patient report surveys, they reported most patients do have personal devices to receive and respond to the surveys, but some older patients did not. Moreover, they wanted to know if the surveys could be sent via WhatsApp, as it's the most commonly-used communication means used by and with their patients. Many programs sent their intake packages to patients electronically, so they perceived it would be very easy to send the registry consent form and assessments (another sub-theme).

"Maybe some patients because they are very aged and I think it, maybe for them, it's going to be very difficult to get a smartphone, to introduce the information there. We are going to find it really difficult." (ID2)

"We do have intake packages that we send out. We have them fill that before they bring it in. We send our intake packages out by email. If you have a template, rather than email it, I could slip it in their package." (ID1)

"We have to use the smartphone to keep in contact with the patient, and we ask always if the patient prefers to use WhatsApp, email or text message. I think that most patients use WhatsApp, but always you have a patient that doesn't have it." (ID5)

"It's 50/50 to be honest. I mean we have one group that's educated - very well educated-, and then we have another group of patients who are probably not well-educated, but the caregivers are okay. They help us out with all this information with the patient. This information gets collected, sometimes through the caregiver more than the patient." (ID12)

They also raised concerns about patient retention post-program, which could lead to attrition bias in the data. They experience quite high loss to follow-up in their low-resource settings, as patients often have to pay out-of-pocket for services. Patients dropout for various clinical and non-clinical reasons. They identified some factors which may support their ability to get follow-up data. They reported they find it easier to contact patients given ubiquity of personal smartphones. In many countries, it is now possible to port phone numbers to different carriers, so they can often still contact patients a year later. Moreover, many of their institutions now have electronic health records, where patient contact information is regularly updated.

"I think that now is a little easier than before. Because when you want to change your company of cell phone, you keep it your own number. And another way is that we always try to ask for a family member number. Or may be you would have two numbers of contact." (ID5)

"Most of my patients go back to their cardiologist, so I lose them." (ID3)

"They don't come for a follow-up visit. Usually, it's medical and they'll just call, and they'll leave a message." (ID1)

"What happens is that it's difficult to get them back. The patients are coming from various other districts and far off places, so they prefer-- to be honest-- lesser number of sessions." (ID6)

Some sites had maintenance programs, so perceived they could quite easily collect annual follow-up data as well. Many participants talked about how they wanted to do annual assessments to properly evaluate their services, and participating in the registry would support this at last. Programs have been calling patients already in their hybrid models, and now with the COVID-19 pandemic; the patients are quite used to and receptive to calls.

"Yeah, because our program, there's the maintenance program built right into it." (ID1)

"So, we can make of course a good registry of the follow-up at a year. I think we can do that." (ID2)

"That was an issue initially because we wanted to have long-term data. So, we ended up with just a one year "yes or no" whether the patient is still alive, and more or less the well-being at the end of a year. So, our registry is going to go on for at least a year" (ID10, Hybrid Model)

Overall, contacted patients found the documents clear, and they were willing to participate, and provide their email address for sending surveys. Surveys could be sent via WhatsApp as well, as it's the most commonly used communication means by staff

with their patients. Participants raised concerns about patient retention post-program, which could lead to attrition bias in the data, as patients dropout for various clinical and non-clinical reasons, but since they have now electronic health records, patient contact information is regularly updated and can be contacted for follow-up.

4.3 Usability Ratings and Other ICRR Changes Considered Based on Findings

The results of the user satisfaction survey using SUS instrument is presented in Figure 10. The mean SUS score was 83.75 (standard deviation 9.83), demonstrating "excellent" perceived usability of the ICRR (105). This SUS score corresponds to a percentile from 90-95%, and is considered a letter-grade A (85).

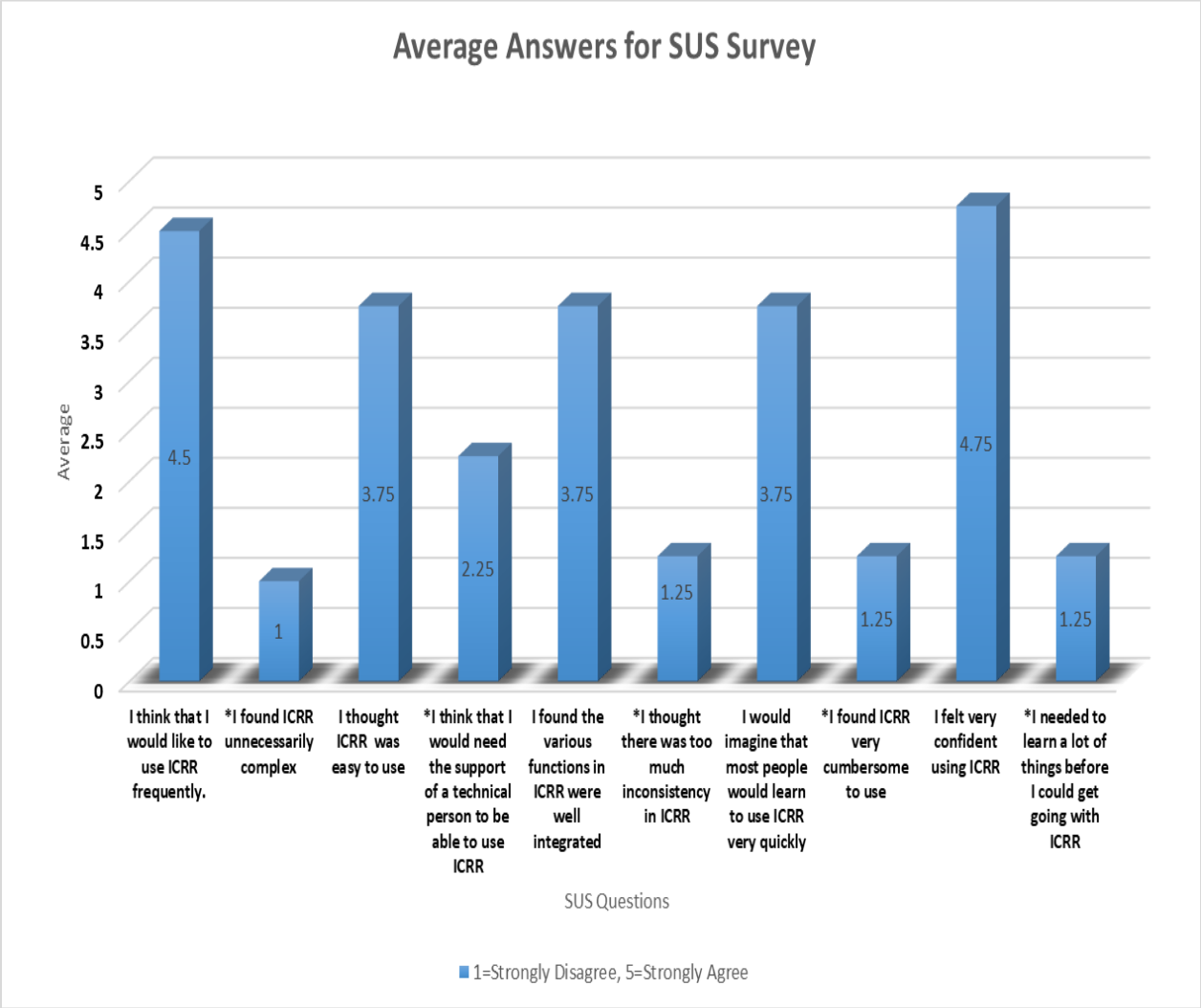


Figure 10. ICRR usability rating

Regarding non-entry usability issues identified, utterances identified the need to make some changes to other ICRR elements, of which many are shown in Table 4. For instance, the ICRR program survey (e.g., some programs prescribe a variable number of sessions to each patient, ID2; clarity around delivery of alternative models, ID6). Moreover, there was lack of clarity on patient inclusion criteria, as participants had not read the full protocol on ICRR's website (e.g., exclusion of primary prevention patients, ID1); an on-boarding meeting agenda was created where it will be confirmed this has been reviewed and understood. Utterances related to navigating through registry

screens, knowing which ones pertained to pre and post-program data, as well as how to exit a patient record (ID6); this detail was added to the data dictionary, and a training manual with annotated screenshots was developed for on-boarding programs. Participants inquired about adding their CR program name and/or logo to the email or texts sent to consenting patients with the survey link (ID8), which has been implemented by the software company Dendrite.

Participants were unclear what to do when they did not have data for a particular variable (e.g., lipids, ID6); instructions were added to the data dictionary preamble. For example, two programs assessed two variables (i.e., functional capacity and body mass index) at one point only (i.e., pre-program only not at post). Nevertheless, participants spontaneously reported willingness to start collecting these variables to improve their program.

> *"The post-exercise peak METs, usually we do not assess it regularly. But now we are starting a post-program exercise stress test to evaluate the effectiveness of the program". (ID11)*

They raised about getting post-program data from patients who do not return, and stated how they try to get it through alternate means (e.g., phone administration of Duke Activity Status Index for functional capacity, automated blood pressure monitor from pharmacy, ID6); some of these suggestions were added to the data dictionary for other programs to consider, where valid data could be collected.

> *"For many patients in our history, we can't find LDL lipids, body mass index, blood pressure or METS in our documents, because we have paper. And often we don't have access to patients at the end of the program. They go home, and we can't keep contact with the*

patient. But we hope to improve the system by the end of the year."

(ID9)

"There are patients who have BP [blood pressure] monitors at

home, so we get this information". (ID6)

Some issues identified could not be addressed, such as potentially sending out patient surveys via WhatsApp (ID3, ID5). Participants stated they did not measure some of the variables (e.g., social support) and suggested alternate variables; these were considered but ultimately we remained true to the final variable list as established through the modified Delphi process (39).

Finally, as outlined under theme two on benefits (above), the discussion on research opportunities for participating sites resulted in modifying the Data Access & Dissemination policy by the steering committee. Programs in good standing in terms of data quality and having a minimum amount of data entered would be recognized on all publications stemming from the registry as an "ICRR collaborator" (https://globalcardiacrehab.com/ICRR-Governance). Moreover, sliding scale for program certification cost was suggested and approved later, i.e. certification cost of programs in LMICs would be lower than that in HICs cost.

CHAPTER 5: DISCUSSION

The aim of this study was to explore the usability of the ICRR in all WHO six-designated regions of the world to ensure its successful implementation before its launch. We used Think Aloud technique, semi-structured interviews, and SUS survey to achieve our objectives.

Usability testing is an economical way to improve a system before launch. Studies found that a single cycle of evaluation reduces usability problems by tenfold (97, 110). The use of the Think Aloud technique and semi-structured interviews provided an in depth understanding of the participants' responses and feelings on how the registry could be further improved.

To date, there have been scarce studies on usability testing of registries or other electronic Health applications such as websites, PC software, smartphone, and tablet applications. A scoping review revealed that out of 325,000 digital e-health apps reported in 2017 only six studies addressing CVDs digital health applications published their usability evaluation results (111-116). Moreover implementation of some of the existing registries such as the British registry (The National Audit of Cardiac Rehabilitation, NACR registry) (117), and the Danish registry (The Danish Cardiac Rehabilitation Database, DCRD) (118) did not receive much attention (100, 101). Both are national quality registries which did not report any usability testing before launch, perhaps due to the comparable context of the participating programs being within the same country. Only two studies explored factors related to facilitators and barriers to registries after the implementation not during the developing stage as the scope of our study. The scarcity of studies on usability testing of registries, warrants future research on this area. In concordance with our results, some of the themes/subthemes that emerged in our study were similar to those emerged in a study explored cardiac

rehabilitation nurse leads' perceptions on these two NACR and DCRD registries (100). The five themes emerged in the study were: accessibility, reliability, usefulness, relevance, and attitudes towards public reporting. Furthermore, our findings are similar to those in another qualitative study in the same countries highlighted CR registry adoption and implementation issues (101); some of our themes were similar to their themes: data entry process, registry quality, resources and management support, quality improvement and the wider healthcare context.

The themes emerged in our study were supported by the findings of a systematic review, as discussed below, addressing barriers and enablers of implementing and maintaining a registry (38), the study revealed that establishing and maintaining CR registries is challenging. Moreover, the maintenance of registries requires ongoing funding, which is often reported as limited. For example, both the European and Canadian registries are no longer working due to funding shortages. In addition, the presence of registries does not always guarantee quality improvement, but rather a comprehensive approach is required that entails the successful implementation of data registries, continuous quality assurance of the data, and transparent and timely feedback (38, 100). Thus, the aim of this usability study is to ensure the utmost quality output of the ICRR registry and its successful implementation.

Theme 1: Ease of Approvals, Adoption, and Implementation

These themes helped to understand our first objective; to explore in-depth CR staff's challenges and facilitators to use and adopt the registry. Most participants perceived that they could secure the ethical approvals, but noted the time required to secure them. This result is similar to the findings of a systematic review revealed that establishing and maintaining CR registries is challenging (38). Barriers and recruitment of sites was

hindered by administrative obstacles including collecting signatures on a site agreement, ensuring privacy standards, and a lack of human resources (38). Even though working with the registries was described as challenging and time-consuming, only a few Danish and English sites received additional resources to complete the task. Mostly, it was reported that the time to complete registry tasks was taken from the time dedicated to patients. Another option was to register only the minimum number of variables, though some found this unsatisfactory, as they thought the output data would be more interesting if all the fields were included (119).

Participants perceived ICRR as easy to use in terms of using the software, logging in, navigating, and exiting, which made ICRR seamless to adopt, but they did raise some concerns regarding the time to enter the data, and the need to dedicate a real champion for data entry. This result is similar to the finding of another study, in both British and Danish registries. The process of collecting and entering data was perceived as an extra burden and cumbersome that must be incorporated into everyday practice (100). In the Danish registry, the tasks of data collection and data entry were an individual responsibility. In many cases, management does not formally appoint someone to enter the data. Staff members who were most interested in participating stepped up to lead or coordinate. In few sites, both in England and Denmark, entry of data was left to the administrative staff or to a few clinicians, rather than all team members. Moreover, several data quality issues in registries were reported as well, including incomplete data submissions and time delays with reporting (38). Similarly, data entry was a concern for DCRD registry; so, it has been linked to a national patient registry. However, some of the captured data were not updated as pointed out by the nurses, due to a time lag in

the registries.

In line with our results, the study also found that both NACR and DHRD registries were easy to enter and navigate and users described that the user-friendliness of the NACR had improved a lot over the years (119).

In our study, CR staff revealed that they can secure all necessary support as they have a trust that participation in the registry will impact the quality of CR services. This was concordant with NACR nurses who had a high degree of trust in data, while DCRD nurses were demotivated and lacked training and managerial support, leading to a low degree of trust (100).

Theme 2: Benefits for Programs

This theme helped to explore participants' in-depth perception of the usefulness of the registry, challenges and facilitators to use and adopt the registry. Overall, Interviewees perceived the built-in feedback mechanism and benefits of participating in the registry outweigh or balance the downside of time required to get approvals and enter data for each patient. Benefits including the lay discharge summary which quantifies patient performance pre to post program, and encourages further self-management post-program. The CR staff underlined the importance of the outcome dashboards in fulfilling reporting requirements in their institutions. Moreover, they appreciated the quality improvement supports, which is planned to be provided by ICRR's User Committee. These results are in concordance with other findings of the Denmark and Britain registries supporting the idea of a registry as a tool to improve the quality of CR services for patient's benefit (100, 101).

Participants perceived program certification as rewarding and the cost reasonable, but suggested a sliding scale based on country income classification. Similarly,

participating sites in NACR reported that CR program certification is valued high (101). Finally, participants appreciated how readily the registry lends itself to research. These results were similar to findings from UK, where nurses were positive towards the usefulness of feedback data (100). In addition, some perceived that benchmarking was useful because of the learning potential from other programs. Although the Danish nurses had not seen much feedback data, they were positive towards the concept of a cardiac rehabilitation registry and expressed hope that it would be useful in the future as a tool for quality improvement (100). Few nurses, however, had a vague understanding of the purpose of the registry.

Theme 3: Variables and their Definitions

Overall, participants were satisfied with the number of variables and clarity regarding units of measurement. Some participants suggested to add maintenance program participation and blood glucose variables. In contrast to other registries, our study solicited the feedback on each variable's operationalization during the development stage before the registry's launch. However, nurses from both the Britain and Danish registries perceived ambiguity in some variables (100, 101). This may indicate that even with expert users, it is important to continuously educate and discuss the variables to obtain reliable data. More focus on registry implementation in cardiac rehabilitation has been recommended (22, 118). Danish nurses believed that some psychosocial aspects were missing since DCRD data do not assess the complexity of the patients

Theme 4: Patient Report & Follow-Up Assessment

Overall, according to CR participants, patients' feedback was positive. They found the documents clear, and they were willing to participate, and provide their email address

for sending surveys. Surveys could be sent via WhatsApp as well, as it's the most used communication means used by and with their patients. Participants also raised concerns about patient retention post-program, which could lead to attrition bias in the data, as patient's dropout for various clinical and non-clinical reasons, but since they have now electronic health records, patient contact information is regularly updated and can be contacted for follow-up. The UK nurses perceived that feedback data were easily obtainable through *websites* (100).

In summary, 4 themes emerged in the study: "Ease of Approvals, Adoption, and Implementation", "Benefits for Programs", "Variables and their Definitions", and "Patient Report & Follow-Up Assessment". This knowledge will contribute to an integrated knowledge translation plan for future registries by emphasizing the need to account for various factors highlighted in this study when planning for future registries to maximize their utility and successful implementation.

5.1 Study Implications

The implications of this study in terms of critical revisions, based on the obtained themes to optimize the utility of the ICRR, have been identified. Accordingly, the ICRR has been amended after receiving ethics approval, and therefore, the ICRR was launched in October 2021. In future, the obtained themes and sub-themes can be considered when developing a cardiac rehab registry as a tool to improve the quality of the services provided, specially there is a growing focus on this area with the support of the WHO (120). The ICRR team is now embarking on field or pilot testing. This will allow the team to test the real-world on-boarding standard operating procedure developed, which may demonstrate ICRR has even greater learnability. It will also enable a real-world test of ICRR use in context, including a test of the patient consent

rate to contribute data and retention for follow-up assessments. Indeed, herein the annual follow-up assessment was only discussed in interviews, not truly tested in practice. This will test data quality, and ICRR data quality assurance processes. Finally, the ICRR team will check whether CR programs are eager to undergo the effort to translate some of the materials, and to take part in the certification program.

5.2 Strength and Limitations

5.2.1 Strengths

This is the first cardiac rehabilitation registry to serve programs in low recourse settings, specifically in LMICs. To the best of our knowledge, this is the first study to conduct usability testing of a cardiac rehabilitation registry in the six regions of the WHO. Therefore, the study fills a gap in the literature related to conducting usability testing, and it could be used as a guide, with adjustments as appropriate, for future cardiac rehabilitation registries. Another strength is that the study recruited CR staff from all the WHO's regions, where the registry is supposed to serve, but Europe which is developing its European CR registry. This mix of CR staff from the different WHO's region ensures getting a wide variety and range of information that can increase the transferability of the obtained results.

Third, this is an implementation study, findings had been already implemented to optimize the utility of the registry and would have a great impact on the cardiac health of a large population in different regions. The fourth strength of the study is the comprehensive approach used in assessing usability of the registry as perceived by its users. We employed three methods consisting of Think Aloud, semi-structured interviews, and the quantitative SUS survey to receive as much constructive feedback as possible to ensure the utmost utility of the registry. This improves credibility and

consequently trustworthiness of the study's findings. Moreover for this study, there were 2 coders (HA and another researcher), who were well trained before starting data collection; i.e. both coders were given same text to code, the process was reiterated so both had similar codes, a discussion was carried out if there was any discrepancy (121). All themes with sub-themes were shared with all interviewees to inquire whether they resonated and request any input to ensure trustworthiness.

5.2.2 Limitations:

The study has some limitations that caution is warranted in interpreting these results. First, limitation pertains to generalizability; the study comprised a convenience sample of CR staff which could not represent CR programs in all low resource settings/LMICs, although purposive sampling was used to include CR staff from low resource settings who could represent the 6 WHO's region. For example, there was only one country from African region while most countries of this region are classified as LMICs. Results may not be relevant in CR settings with no access to technology, and where English is not used, especially resources devoted for the registry are scarce to be deployed for translation. Second, the use of purposive sampling may have introduced selection bias among participants.

5.3 Conclusion

This study provides insights into the facilitators and barriers underlying the implementation of the ICRR among a purposive sampling of CR specialists.

The results of this study demonstrated the usability of the ICRR registry by the CR staff in terms of performance expectancy, effort expectancy, available resources to support its implementation including joining the registry at no cost (in concordance with UTAUT 2 constructs). These results were supported by a SUS survey with a score of

83.75. This result indicates that the usability of the system was above average and perceived as an excellent system by CR staff. Finally, CR staff feedback enabled us to improve the usability of ICRR registry to be deployed in clinical settings on a global level.

The study has for the first time presented a usability test of a CR registry prior to launch. Four themes have emerged: 1) Ease of Approvals, Adoption and Implementation, 2) Benefits for Programs, 3) Variables and their Definitions 4) Patient Report & Follow-Up Assessment. Most participants perceived they could secure the approvals, but noted the time required for these approvals. Interviewees raised several benefits of participating in the registry, which would outweigh or at least balance the downside of time required to get approvals and enter data for each patient. With regards to registry variables patients were satisfied with the number of variables and clarity regarding units of measurement. Some participants suggested to include maintenance program participation. The patient feedback on the registry documents, obtained by their CR staff, was positive; the consent form was clear and the patient lay summary had useful information on the progress of the patient in the program.

Several changes were made to the registry interface as well as supporting materials and policies to enhance usability, which was ultimately rated as excellent. In conclusion, the ICRR was established as easy to use, relevant, efficient, with easy learnability, operability, perceived usefulness, positive perceptions of output quality, and high end-user satisfaction, by CR staff from low-resource settings. The next research step in registry development as outlined above is determining the feasibility of the ICRR through pilot testing. This is indeed an ongoing study. For future cardiac rehab registry designs, and may be other types of registries as they share generally same broad

structure and processes, themes and sub-themes illustrated above are recommended to be considered. This study provides valuable information for policy makers in understanding the adoption challenges of registries. The study could be a practical guidance for the successful implementation of registries. The next study is pilot testing of the registry, which has been initiated. It is hoped with favorable pilot-testing, the ICRR can serve as a mechanism for programs in these settings where CR is needed most to test and improve their quality of CR delivery, ultimately improving patient outcomes.

REFERENCES

1. Global Alliance for Chronic Diseases. NCD facts and figures. 2022.

2. World Health Organization. Noncommunicable diseases 2021 [Available from: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.

3. Max Roser and Hannah Ritchie. Burden of Disease Published online at OurWorldInData.org2021 [Available from: https://ourworldindata.org/burden-of-disease.

4. World Health Organization. GLOBAL NCD TARGET:REDUCING PREMATURE DEATHS FROM NCDS. 2016.

5. Roth GA, Mensah GA, Johnson CO, Addolorato G, Ammirati E, Baddour LM, et al. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update From the GBD 2019 Study. J Am Coll Cardiol. 2020;76(25):2982-3021.

6. Bennett JE, Kontis V, Mathers CD, Guillot M, Rehm J, Chalkidou K, et al. NCD Countdown 2030: pathways to achieving Sustainable Development Goal target 3.4. The Lancet. 2020;396(10255):918-34.

7. Roth GA, Johnson C, Abajobir A, Abd-Allah F, Abera SF, Abyu G, et al. Global, Regional, and National Burden of Cardiovascular Diseases for 10 Causes, 1990 to 2015. J Am Coll Cardiol. 2017;70(1):1-25.

8. Budreviciute A, Damiati S, Sabir DK, Onder K, Schuller-Goetzburg P, Plakys G, et al. Management and Prevention Strategies for Non-communicable Diseases (NCDs) and Their Risk Factors. Front Public Health. 2020;8:574111.

9. World Health Organization. Cardiovascular diseases (CVDs) 2021 [Available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds).

10. Jernberg T, Hasvold P, Henriksson M, Hjelm H, Thuresson M, Janzon M. Cardiovascular risk in post-myocardial infarction patients: nationwide real world data demonstrate the importance of a long-term perspective. Eur Heart J. 2015;36(19):1163-70.

11. Anderson L, Oldridge N, Thompson DR, Zwisler AD, Rees K, Martin N, et al. Exercise-Based Cardiac Rehabilitation for Coronary Heart Disease: Cochrane Systematic Review and Meta-Analysis. J Am Coll Cardiol. 2016;67(1):1-12.

12. Bellmann B, Lin T, Greissinger K, Rottner L, Rillig A, Zimmerling S. The Beneficial Effects of Cardiac Rehabilitation. Cardiol Ther. 2020;9(1):35-44.

13. Grace SL, Turk-Adawi KI, Contractor A, Atrey A, Campbell N, Derman W, et al. Cardiac rehabilitation delivery model for low-resource settings. Heart. 2016;102(18):1449-55.

14. Heran BS, Chen JM, Ebrahim S, Moxham T, Oldridge N, Rees K, et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2011(7):CD001800.

15. Pesah E, Turk-Adawi K, Supervia M, Lopez-Jimenez F, Britto R, Ding R, et al. Cardiac rehabilitation delivery in low/middle-income countries. Heart. 2019;105(23):1806-12.

16. Wenger NK. Current status of cardiac rehabilitation. J Am Coll Cardiol. 2008;51(17):1619-31.

17. Francis T, Kabboul N, Rac V, Mitsakakis N, Pechlivanoglou P, Bielecki J, et al. The Effect of Cardiac Rehabilitation on Health-Related Quality of Life in Patients With Coronary Artery Disease: A Meta-analysis. Can J Cardiol. 2019;35(3):352-64.

18. Mamataz T, Uddin J, Ibn Alam S, Taylor RS, Pakosh M, Grace SL, et al. Effects of cardiac rehabilitation in low-and middle-income countries: A systematic review and meta-analysis of randomised controlled trials. Prog Cardiovasc Dis. 2021/07/17 ed2022. p. 119-74.

19. van Zyl C, Badenhorst M, Hanekom S, Heine M. Unravelling 'low-resource settings': a systematic scoping review with qualitative content analysis. BMJ Glob Health. 2021;6(6):e005190.

20. Turk-Adawi K, Supervia M, Lopez-Jimenez F, Pesah E, Ding R, Britto RR, et al. Cardiac Rehabilitation Availability and Density around the Globe. EClinicalMedicine. 2019;13:31-45.

21. Australian Commission on Safety and Quality in Health Care. Framework for Australian clinical quality registries, Sydney. ACSQHC,March 2014 [Available from: https://www.safetyandquality.gov.au/sites/default/files/migrated/Framework-for-Australian-Clinical-Quality-Registries.pdf.

22. Bhatt DL, Drozda JP, Jr., Shahian DM, Chan PS, Fonarow GC, Heidenreich PA, et al. ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and The Society of Thoracic Surgeons. J Am Coll Cardiol. 2015;66(20):2230-45.

23. Nelson EC, Dixon-Woods M, Batalden PB, Homa K, Van Citters AD, Morgan TS, et al. Patient focused registries can improve health, care, and science. BMJ. 2016;354:i3319.

24. Peterson ED, Shah BR, Parsons L, Pollack CV, Jr., French WJ, Canto JG, et al. Trends in quality of care for patients with acute myocardial infarction in the National Registry of Myocardial Infarction from 1990 to 2006. Am Heart J. 2008;156(6):1045-55.

25. Lim TO, Goh A, Lim YN, Morad Z. Review article: Use of renal registry data for research, health-care planning and quality improvement: what can we learn from registry data in the Asia-Pacific region? Nephrology (Carlton). 2008;13(8):745-52.

26. Schechter MS, Fink AK, Homa K, Goss CH. The Cystic Fibrosis Foundation Patient Registry as a tool for use in quality improvement. BMJ Qual Saf. 2014;23 Suppl 1(Suppl 1):i9-14.

27. Peterson ED, Roe MT, Mulgund J, DeLong ER, Lytle BL, Brindis RG, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. JAMA. 2006;295(16):1912-20.

28. Hoekstra JW, Pollack CV, Jr., Roe MT, Peterson ED, Brindis R, Harrington RA, et al. Improving the care of patients with non-ST-elevation acute coronary syndromes in the emergency department: the CRUSADE initiative. Acad Emerg Med. 2002;9(11):1146-55.

29. Centers for Disease C, Prevention. Use of a registry to improve acute stroke care--seven

states, 2005-2009. MMWR Morb Mortal Wkly Rep. 2011;60(7):206-10.

30. California Acute Stroke Pilot Registry I. Prioritizing interventions to improve rates of thrombolysis for ischemic stroke. Neurology. 2005;64(4):654-9.

31. Lundstrom M, Barry P, Brocato L, Fitzpatrick C, Henry Y, Rosen P, et al. European registry for quality improvement in cataract surgery. Int J Health Care Qual Assur. 2014;27(2):140-51.

32. Fonarow GC, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, et al. Improving evidence-based care for heart failure in outpatient cardiology practices: primary results of the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF). Circulation. 2010;122(6):585-96.

33. Carlhed R, Bojestig M, Wallentin L, Lindstrom G, Peterson A, Aberg C, et al. Improved adherence to Swedish national guidelines for acute myocardial infarction: the Quality Improvement in Coronary Care (QUICC) study. Am Heart J. 2006;152(6):1175-81.

34. Barron HV, Bowlby LJ, Breen T, Rogers WJ, Canto JG, Zhang Y, et al. Use of reperfusion therapy for acute myocardial infarction in the United States: data from the National Registry of Myocardial Infarction 2. Circulation. 1998;97(12):1150-6.

35. Gibson CM, Pride YB, Frederick PD, Pollack CV, Jr., Canto JG, Tiefenbrunn AJ, et al. Trends in reperfusion strategies, door-to-needle and door-to-balloon times, and in-hospital mortality among patients with ST-segment elevation myocardial infarction enrolled in the National Registry of Myocardial Infarction from 1990 to 2006. Am Heart J. 2008;156(6):1035-44.

36. McNeil JJ, Evans SM, Johnson NP, Cameron PA. Clinical-quality registries: their role in quality improvement. Med J Aust. 2010;192(5):244-5.

37. Larsson S, Lawyer P, Garellick G, Lindahl B, Lundström M. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. Health Affairs. 2012;31(1):220-7.

38. Poffley A, Thomas E, Grace SL, Neubeck L, Gallagher R, Niebauer J, et al. A systematic review of cardiac rehabilitation registries. Eur J Prev Cardiol. 2017;24(15):1596-609.

39. Chowdhury MI, Turk-Adawi K, Babu AS, de Melo Ghisi GL, Seron P, Yeo TJ, et al. Development of the International Cardiac Rehabilitation Registry Including Variable Selection and Definition Process. Glob Heart. 2022;17(1):1.

40. Roth GA, Forouzanfar MH, Moran AE, Barber R, Nguyen G, Feigin VL, et al. Demographic and epidemiologic drivers of global cardiovascular mortality. N Engl J Med. 2015;372(14):1333-41.

41. World Health Organization. About cardiovascular diseases 2021 [Available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds).

42. Alan D Lopez CDM, Majid Ezzati, Dean T Jamison, and Christopher JL Murray., editor. Global Burden of Disease and Risk Factors,. Washington (DC): The International Bank for Reconstruction and Development / The World Bank;Co-published by Oxford University Press, New York.

; 2006.

43. Islam SM, Purnat TD, Phuong NT, Mwingira U, Schacht K, Froschl G. Non-communicable diseases (NCDs) in developing countries: a symposium report. Global Health. 2014;10:81.

44. Institute for Health Metrics and Evaluation (IHME). Findings from the Global Burden of Disease Study 2017. Seattle, WA:IHME,; 2018.

45. Lima de Melo Ghisi G, Pesah E, Turk-Adawi K, Supervia M, Lopez Jimenez F, Grace SL. Cardiac Rehabilitation Models around the Globe. J Clin Med. 2018;7(9).

46. Moghei M, Pesah E, Turk-Adawi K, Supervia M, Jimenez FL, Schraa E, et al. Funding sources and costs to deliver cardiac rehabilitation around the globe: Drivers and barriers. Int J Cardiol. 2019;276:278-86.

47. Jagannathan R, Patel SA, Ali MK, Narayan KMV. Global Updates on Cardiovascular Disease Mortality Trends and Attribution of Traditional Risk Factors. Current diabetes reports. 2019;19(7):44.

48. Bethell H, Lewin R, Evans J, Turner S, Allender S, Petersen S. Outpatient cardiac rehabilitation attendance in England: variability by region and clinical characteristics. J Cardiopulm Rehabil Prev. 2008;28(6):386-91.

49. Supervia M, Turk-Adawi K, Lopez-Jimenez F, Pesah E, Ding R, Britto RR, et al. Nature of Cardiac Rehabilitation Around the Globe. EClinicalMedicine. 2019;13:46-56.

50. Balady GJ, Williams MA, Ades PA, Bittner V, Comoss P, Foody JM, et al. Core components of cardiac rehabilitation/secondary prevention programs: 2007 update: a scientific statement from the American Heart Association Exercise, Cardiac Rehabilitation, and Prevention Committee, the Council on Clinical Cardiology; the Councils on Cardiovascular Nursing, Epidemiology and Prevention, and Nutrition, Physical Activity, and Metabolism; and the American Association of Cardiovascular and Pulmonary Rehabilitation. Circulation. 2007;115(20):2675-82.

51. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE, Jr., Drazner MH, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;62(16):e147-239.

52. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP, 3rd, Guyton RA, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63(22):e57-185.

53. Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Circulation. 2011;124(23):2574-609.

54. Hillis LD, Smith PK, Anderson JL, Bittl JA, Bridges CR, Byrne JG, et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on

Practice Guidelines. Circulation. 2011;124(23):2610-42.

55. Turk-Adawi K, Sarrafzadegan N, Grace SL. Global availability of cardiac rehabilitation. Nature Reviews Cardiology. 2014;11(10):586-96.

56. Turk-Adawi KI, Grace SL. Narrative review comparing the benefits of and participation in cardiac rehabilitation in high-, middle- and low-income countries. Heart Lung Circ. 2015;24(5):510-20.

57. Grace SL, Turk-Adawi KI, Contractor A, Atrey A, Campbell NR, Derman W, et al. Cardiac Rehabilitation Delivery Model for Low-Resource Settings: An International Council of Cardiovascular Prevention and Rehabilitation Consensus Statement. Prog Cardiovasc Dis. 2016;59(3):303-22.

58. Sumner J, Harrison A, Doherty P. The effectiveness of modern cardiac rehabilitation: A systematic review of recent observational studies in non-attenders versus attenders. PLoS One. 2017;12(5):e0177658.

59. Gitt AK, Bueno H, Danchin N, Fox K, Hochadel M, Kearney P, et al. The role of cardiac registries in evidence-based medicine. Eur Heart J. 2010;31(5):525-9.

60. Granger CB, Gersh BJ. Clinical trials and registries in cardiovascular disease: competitive or complementary? Eur Heart J. 2010;31(5):520-1.

61. Hickey GL, Grant SW, Cosgriff R, Dimarakis I, Pagano D, Kappetein AP, et al. Clinical registries: governance, management, analysis and applications. Eur J Cardiothorac Surg. 2013;44(4):605-14.

62. Bufalino VJ, Masoudi FA, Stranne SK, Horton K, Albert NM, Beam C, et al. The American Heart Association's recommendations for expanding the applications of existing and future clinical registries: a policy statement from the American Heart Association. Circulation. 2011;123(19):2167-79.

63. French WJ, Reddy VS, Barron HV. Transforming quality of care and improving outcomes after acute MI: lessons from the National Registry of Myocardial Infarction. JAMA. 2012;308(8):771-2.

64. AHRQ. Registries for Evaluating Patient Outcomes: A User's Guide: 4th Edition. September 21, 2020.

65. Scholte M, van Dulmen SA, Neeleman-Van der Steen CW, van der Wees PJ, Nijhuis-van der Sanden MW, Braspenning J. Data extraction from electronic health records (EHRs) for quality measurement of the physical therapy process: comparison between EHR data and survey data. BMC Med Inform Decis Mak. 2016;16(1):141.

66. Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM. Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS One. 2017;12(9):e0183667.

67. Grau AJ, Eicke M, Biegler MK, Faldum A, Bamberg C, Haass A, et al. Quality monitoring of acute stroke care in Rhineland-Palatinate, Germany, 2001-2006. Stroke. 2010;41(7):1495-500.

68. Turk-Adawi K, Sarrafzadegan N, Grace SL. Global availability of cardiac

rehabilitation. Nat Rev Cardiol. 2014;11(10):586-96.

69. Hills NK, Johnston SC. Duration of hospital participation in a nationwide stroke registry is associated with improved quality of care. BMC Neurol. 2006;6(1):20.

70. Benzer W, Rauch B, Schmid JP, Zwisler AD, Dendale P, Davos CH, et al. Exercise-based cardiac rehabilitation in twelve European countries results of the European cardiac rehabilitation registry. Int J Cardiol. 2017;228:58-67.

71. cardiology NMoP. Predictors of drop-out from cardiac rehabilitation programs in Europe 2012 [Available from: http://www.cardioprevent.ru/en/projects/eurocared/.

72. Pogosova N-G, Benzer W, Rauch B, Ad.Zwister, et.al EK. Clinical and psychosocial outcomes after cardiac rehabilitation in Europe: results from the European Cardiac Rehabilitation Database2012.

73. Venkatesh V, Thong J, Xu X. Unified Theory of Acceptance and Use of Technology: A Synthesis and the Road Ahead. Journal of the Association for Information Systems. 2016;17(5):328-76.

74. AHRQ Methods for Effective Health Care. In: th, Gliklich RE, Leavy MB, Dreyer NA, editors. Registries for Evaluating Patient Outcomes: A User's Guide. AHRQ Methods for Effective Health Care. Rockville (MD): Agency for Healthcare Research and Quality (US) ©2020 United States Government, as represented by the Secretary of the Department of Health and Human Services, by assignment.; 2020.

75. Mandavia R, Knight A, Carter AW, Toal C, Mossialos E, Littlejohns P, et al. What are the requirements for developing a successful national registry of auditory implants? A qualitative study. BMJ Open. 2018;8(9):e021720.

76. Australian Commission on Safety and Quality in Health Care. Logical Design Australian Clinical Quality Registries. Sydney. 2012.

77. Care ACoSaQiH. Prioritised list of clinical domains for clinical quality registry development – Final report. Sydney; 2016.

78. Kirkham JJ, Davis K, Altman DG, Blazeby JM, Clarke M, Tunis S, et al. Core Outcome Set-STAndards for Development: The COS-STAD recommendations. PLoS Med. 2017;14(11):e1002447.

79. Paz F, Pow-Sang JA. A Systematic Mapping Review of Usability Evaluation Methods for Software Development Process. International Journal of Software Engineering and Its Applications. 2016;10(1):165-78.

80. ISO/IEC. ISO/IEC 25010:2011(en)Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — System and software quality models. 2011.

81. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: A scoping review. Int J Med Inform. 2019;126:95-104.

82. Marcus A. Design, User Experience, and Usability: User Experience Design for Everyday Life Applications and Services: Third International Conference, DUXU 2014, Held as Part of HCI International 2014, Heraklion, Crete, Greece, June 22-27, 2014, Proceedings,

Part III: Springer; 2014.

83. (ISO) ISO. ISO DIS 9241-210:2010. Ergonomics of Human-System Interaction; Geneva, Switzerland2010 [

84. Tullis TS, Stetson JN, editors. A Comparison of Questionnaires for Assessing Website Usability2004.

85. Jeff Sauro P. Measuring Usability with the System Usability Scale (SUS) 2011 [Available from: https://measuringu.com/sus/.

86. Brooke J. System Usability Scale (SUS)-A quick and dirty usability scale: CRC Press; 1996.

87. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. Institutions & Transition Economics: Microeconomic Issues eJournal. 2003.

88. Davis FD. Perceived Usefulness, Perceived Ease of Use, and User Acceptance of Information Technology. MIS Quarterly. 1989;13(3):319.

89. Eckhardt A, Laumer S, Weitzel T. Who Influences Whom? Analyzing Workplace Referents' Social Influence on it Adoption and Non-Adoption. Journal of Information Technology. 2009;24(1):11-24.

90. Welch R, Alade T, Nichol L. Using the Unified Theory of Acceptance and Use of Technology (Utaut) Model to Determine Factors Affecting Mobile Learning Adoption in the Workplace: A Study of the Science Museum Group. Iadis International Journal on Computer Science and Information Systems. 2020;15(1):85-98.

91. Verhoeven JC, Heerwegh D, De Wit K. Information and communication technologies in the life of university freshmen: An analysis of change. Computers & Education. 2010;55(1):53-66.

92. Venkatesh, Thong, Xu. Consumer Acceptance and Use of Information Technology: Extending the Unified Theory of Acceptance and Use of Technology. MIS Quarterly. 2012;36(1):157.

93. Venkatesh, Thong, Xu. Consumer Acceptance and Use of Information Technology: Extending the Unified Theory of Acceptance and Use of Technology. MIS Quarterly. 2012;36(1):157-78.

94. Hornbæk K. Dogmas in the assessment of usability evaluation methods. Behaviour & Information Technology. 2010;29(1):97-111.

95. Ericsson ASHA. Protocol analysis : verbal reports as data. 1993.

96. Zhang L, Gallagher R, Lowres N, Orchard J, Freedman SB, Neubeck L. Using the 'Think Aloud' Technique to Explore Quality of Life Issues During Standard Quality-of-Life Questionnaires in Patients With Atrial Fibrillation. Heart Lung Circ. 2017;26(2):150-6.

97. Nielsen J. Usability Engineering: Morgan Kaufmann Publishers Inc.; 1994.

98. Virzi RA. Refining the Test Phase of Usability Evaluation: How Many Subjects Is

Enough? Human Factors: The Journal of the Human Factors and Ergonomics Society. 2016;34(4):457-68.

99. Patridge EF, Bardyn TP. Research Electronic Data Capture (REDCap). Journal of the Medical Library Association. 2018;106(1):142-4.

100. Helmark C, Egholm CL, Kousgaard MB, Zwisler A-D, Doherty P. Nurses' perceptions of feedback from cardiac rehabilitation registries: a qualitative study across the UK and Denmark. 2019;14(5):1-13.

101. Egholm CL, Helmark C, Doherty P, Nilsen P, Zwisler AD, Bunkenborg G. "Struggling with practices" - a qualitative study of factors influencing the implementation of clinical quality registries for cardiac rehabilitation in England and Denmark. BMC Health Serv Res. 2019;19(1):102.

102. Brooke J. SUS: a retrospective. Journal of Usability Studies. 2013;8:29-40.

103. Rubin J, Chisnell D. Handbook of usability testing: how to plan, design and conduct effective tests: John Wiley & Sons; 2008.

104. Peres SC, Pham T, Phillips R. Validation of the System Usability Scale (SUS). Proceedings of the Human Factors and Ergonomics Society Annual Meeting. 2013;57(1):192-6.

105. UIUX Trend. Measuring and Interpreting System Usability Scale (SUS) 2021 [Available from: https://uiuxtrend.com/measuring-system-usability-scale-sus/.

106. Will T.
User Experience Research Articles :SUS Calculator 2021 [Available from: https://uiuxtrend.com/sus-calculator/.

107. Jeff Sauro. 5 Ways to Interpret a SUS Score 2018 [Available from: https://measuringu.com/interpret-sus-score/.

108. Quality Systems Regulation International (QSR). NVIVO 2021 [Available from: https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/about/nvivo.

109. Hashimov E. Qualitative Data Analysis: A Methods Sourcebook and The Coding Manual for Qualitative Researchers. Technical Communication Quarterly. 2014;24(1):109-12.

110. Stinson JN, Jibb LA, Nguyen C, Nathan PC, Maloney AM, Dupuis LL, et al. Development and testing of a multidimensional iPhone pain assessment application for adolescents with cancer. J Med Internet Res. 2013;15(3):e51.

111. Alnosayan N, Chatterjee S, Alluhaidan A, Lee E, Houston Feenstra L. Design and Usability of a Heart Failure mHealth System: A Pilot Study. JMIR Hum Factors. 2017;4(1):e9.

112. Athilingam P, Labrador MA, Remo EF, Mack L, San Juan AB, Elliott AF. Features and usability assessment of a patient-centered mobile application (HeartMapp) for self-management of heart failure. Appl Nurs Res. 2016;32:156-63.

113. Carrera A, Pifarre M, Vilaplana J, Cuadrado J, Solsona S, Mateo J, et al. BPcontrol. A Mobile App to Monitor Hypertensive Patients. Appl Clin Inform. 2016;7(4):1120-34.

114. Desteghe L, Kluts K, Vijgen J, Koopman P, Dilling-Boer D, Schurmans J, et al. The Health Buddies App as a Novel Tool to Improve Adherence and Knowledge in Atrial Fibrillation Patients: A Pilot Study. JMIR Mhealth Uhealth. 2017;5(7):e98.

115. Johnston N, Bodegard J, Jerstrom S, Akesson J, Brorsson H, Alfredsson J, et al. Effects of interactive patient smartphone support app on drug adherence and lifestyle changes in myocardial infarction patients: A randomized study. Am Heart J. 2016;178:85-94.

116. Radhakrishnan K, Toprac P, O'Hair M, Bias R, Mackert M, Xie B, et al. Perceptions of Older Adults with Heart Failure on Playing an Interactive Digital e-Health Game (IDEG) for Learning About Heart Failure (HF): Prototype Development and Usability Testing. Stud Health Technol Inform. 2016;225:1026-7.

117. Doherty P PC, Onion N, Harrison A. . The National Audit of Cardiac Rehabilitation (NACR): Annual Statistical Report 2017.: British Heart Foundation.; 2017.

118. Zwisler AD, Rossau HK, Nakano A, Foghmar S, Eichhorst R, Prescott E, et al. The Danish Cardiac Rehabilitation Database. Clin Epidemiol. 2016;8:451-6.

119. Egholm CL, Helmark C, Doherty P, Nilsen P, Zwisler A-D, Bunkenborg G. "Struggling with practices" - a qualitative study of factors influencing the implementation of clinical quality registries for cardiac rehabilitation in England and Denmark. 2019;19(1):1-13.

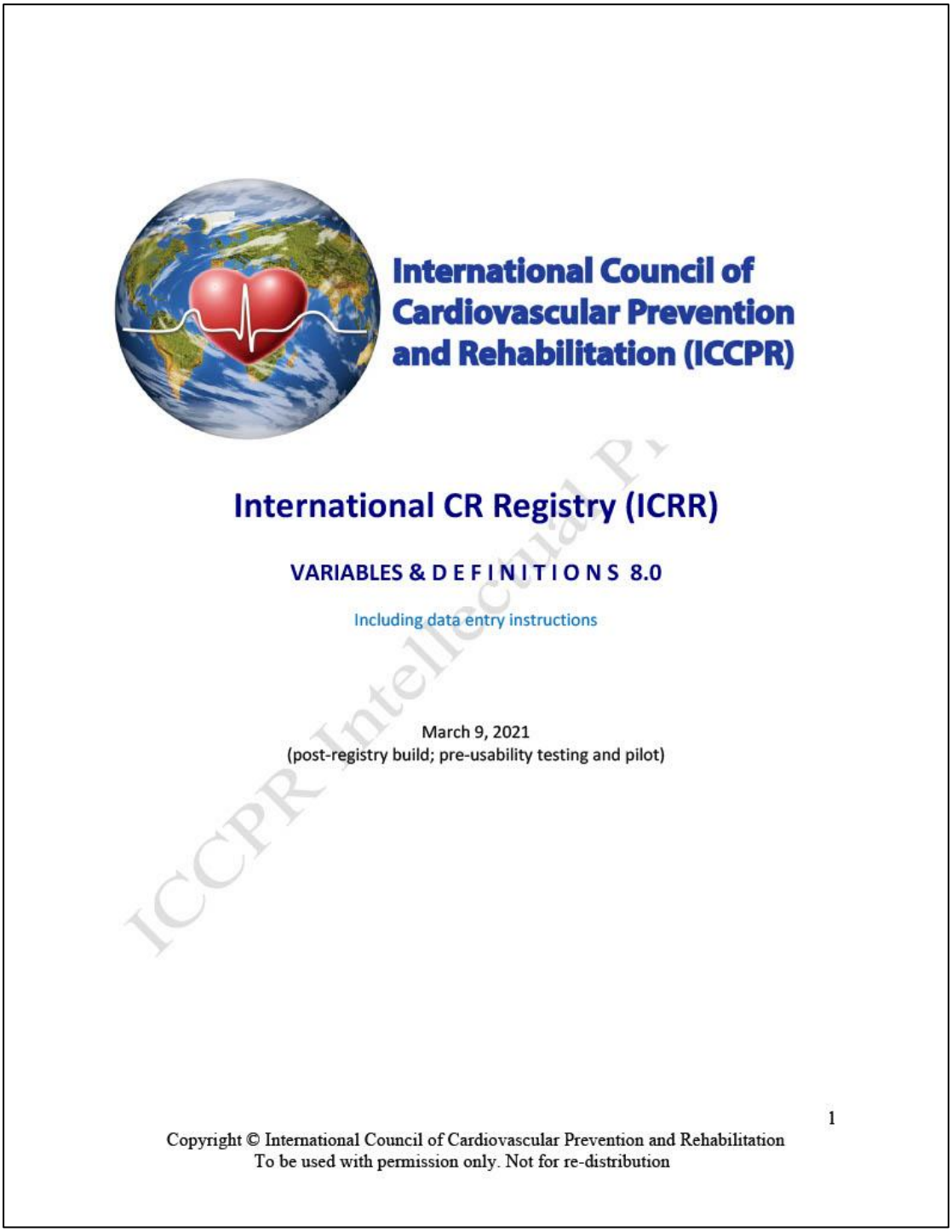
120. Organization WH. package of-interventions for rehabilitation. 2022.

121. Güss CD. What Is Going Through Your Mind? Thinking Aloud as a Method in Cross-Cultural Psychology. 2018.

APPENDICES

Appendix A: International Cardiac Rehab Registry (ICRR) Data Dictionary

https://globalcardiacrehab.com/resources/Documents/ICRR%20Data%20Dictionary_v8-3clean3.pdf



International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

International CR Registry (ICRR)

VARIABLES & DEFINITIONS 8.0

Including data entry instructions

March 9, 2021
(post-registry build; pre-usability testing and pilot)

1

INSTRUCTIONS / INFORMATION BEFORE YOU BEGIN

For any questions, or access to the registry / logins, contact iccpr.icrr@gmail.com. From the main menu, select "enter clinical data" (blue rectangle) to get started. You will see your roster of patients there on your "my patients" screen, or can "add new patient" (top left, green rectangle). (Please note if you wish to delete a patient, we will need to contact Dendrite to do so [this is to prevent accidental deletion of data]).

We have purchased 5 licenses, and therefore 5 users across all sites can be in the registry at any one time. If you can't get on, check back a bit later. We are hoping this is sufficient given this is international, and hence sites will be in different time zones. If you often cannot get in, please email us so we can explore a solution.

Please note that all referred patients should be entered in ICRR if possible, so that we can assess the proportion of referred patients enrolling (CR quality indicator). For those patients who do not enroll, please complete all available information from their referral form. It is hoped that gender, year of birth, referral diagnosis / procedure could be completed.

Only the gender and year of birth variables are mandatory, but of course we encourage as complete data provision as possible to optimize the utility of the ICRR. See the dashboard document for information on how to see data completeness.

All continuous values have minimum and maximum values to prevent data entry errors. Many variables have a blue "i" in a white bubble; hover over it to see the definitions from this document on screen.

Variables are all available in the registry on specific pages, by assessment point. When you are in a record for a patient, you can skip to any page at any time, using the white rectangle drop-down menu in the top middle of any registry page. We have specified below in the table of contents on which registry page you can find the variables, and it is also shown in orange font below.

Timing of assessment (pre-program, post/progress or annual) of the below variables is shown in yellow highlight in the ensuing data dictionary. There is also information regarding when / how assessments stop if patients are unfortunately too ill or die.

Source of information is shown in blue font (program, and potentially patient). Note for patient-reported variables, follow what you have approved with your local ethics board. If patients do not have proficiency in English, you may ask the questions of the patient directly in-person, on the phone or video call if that is approved at your institution, and enter responses directly into the registry. If patients have English-language proficiency but do not have technology skills or access, ICRR can provide you paper versions of the items at each assessment point for their completion, and then someone from your program with an approved ICRR login can enter the data. Just ask!

Table of Contents:

d. Patient-reported (or program entry if not possible) variables *pre*-program start on p.11
e. Patient-reported clinical variables *pre and post* (even if they didn't finish)-program start on p.13
f. Other patient-reported (or program entry if not possible) variables post-program start on p.15
g. *Program* and patient-reported (or program entry if not possible) variables assessed *annually* start on p. 16 and 17, respectively

PROGRAM-REPORTED VARIABLES

PRE-PROGRAM/INTAKE ONLY

These variables are all found on page 1 of the registry.

1. **Year of Birth**
   Indicate the patient's year of birth (or best estimate if patient does not know and it is not recorded). This variable is mandatory
   Data Entry: 4 digits

2. **Gender**
   Select the patient's sex. This variable is mandatory.
   Data Entry: Choices available are (choose 1):
   - ☐ Male
   - ☐ Female
   - ☐ Other /unknown

3. **Referral Diagnoses**
   The referral diagnosis refers to the most recent diagnosis preceding the patient's referral to cardiac rehabilitation. There may be more than one possible referral diagnosis reported if the second occurred within the same hospitalization period. DO NOT report historical diagnoses

   Data Entry: Choices available are (select all that apply):
   - ☐ Stable coronary artery disease or stable angina
   - ☐ Acute coronary syndrome (ACS; e.g., myocardial infarction)
   - ☐ Heart failure
   - ☐ Other (e.g., arrhythmia, valvular disease)

4. **Referral Intervention(s)**
   Report cardiac interventions or procedures preceding the patient's referral to cardiac rehabilitation (no longer than 1 month). There may be more than one possible referral procedure reported if the second occurred within the same hospitalization period (check all that apply). DO NOT report interventions in the past, as they cannot be reliably captured in all patients.

   Data Entry: check all that apply
   - o Percutaneous coronary intervention (PCI)
   - o Bypass surgery (CABG)
   - o Valve surgery or intervention
   - o Heart transplant
   - o Mechanical circulatory support (e.g., VAD)
   - o Rhythm Device insertion (e.g. CRT, ICD, pacemaker)
   - o Ablation
   - o Other
   - o None

5. Initial assessment date

Enter the date the patient had their initial visit with the CR program for assessment of risk, history, etc. This could be in-person or remote.

Note: this date will be used to determine when to trigger follow-up assessments of patients, based on duration of your program as denoted in the program survey.

Note 2: If no initial assessment do not enter a date. Even if patients do not enrol, if they are open to completion of patient-reported surveys for comparative purposes and this is approved through your local ethics board, please denote that by providing their contact information in the designated spot.

Data Entry: Enter a date. DD/MMM/YYYY

0. Patient data source

- ☐ Patient (if this is selected, you will be prompted to provide mobile # and/or email address)
- ☐ Program is entering patient-reported data (ie., you will ask the questions of the patient)
- ☐ Neither (i.e., no patient-reported data will be provided)

IF NEITHER IS SELECTED
The patient-related pages of the registry will not be available to complete.

If this was an error and you wish to enter patient data, change your selection. Then you have to click either "Next Page" or "Save & Exit" before the drop-down list at the top of the page is re-populated with the patient-related pages.

IF PATIENT IS SELECTED:
Please note that texts cost the ICRR, so we prefer email, and the registry is set up to contact patients via email first. If there is no response after a week or 2, a text will be sent.

When entering a mobile number, it should be in this format: + CCC NNNNNNN, as follows:
It is necessary to prefix it with a "+" denoting it's an international number.
"CCC" is the international dialling code for the country (as many digits as required).
"NNNNNNN" is the number including any area code. We haven't constrained the number of digits, as the number template differs from country to country.
There should be no prefixed "0" or "1".

Once patient contact information is entered, the patient-reported survey for pre-program will be sent by the registry to the patient by the next day. It will come from: icrr@e-dendrite.com

on behalf of DCS Intellect Web <noreply@e-dendrite.com>. The subject line will read "Cardiac Rehab Registry". Perhaps inform your patient to watch for it.

This will no longer be available 14 days from initial assessment date as it is assumed health behaviour would have changed from baseline. If no initial assessment date is entered, the registry will work from the first date you entered any data on the patient.

Note you can see a log of when correspondence is sent to patients, and if they respond, including dates, by clicking the blue rectangle named "pt report log" from the main menu.

Also note that if the patient is providing data, the post-program survey will not be sent to patients if you specify "death" as cause of premature program termination on page 5 of the registry (program conclusion) for variable 7. The annual surveys will not be sent if you specify "patient died" or "patient to ill to complete further assessments" on any annual follow-up (page 9 or the registry, variable 27). This information is also outlined with the variables below for clarity.

Patients may also request to stop contributing data at any time and/or to withdraw previous data. ICRR has a process in place to enact this, which involves removing any email or text # from this variable. Patients can request this at any time at: https://globalcardiacrehab.com/ICRR-for-Patients. We will be in touch as needed if we receive any such requests, and request you contact us if you receive such requests.

If the patient is alive and has not requested to stop receiving surveys to you or to ICRR between now and the end of when their program would be done (according to the timing provided for your program duration), they will receive the post-program survey at the above contact information. See below for more information.

PROGRAM-REPORTED VARIABLES
POST-PROGRAM ONLY (PROGRESS)

You informed ICRR of the number of weeks duration of your program in the initial program survey. Your site is set up so the post-program assessment will be due the specified number of weeks from the initial assessment date (if no initial assessment date is provided. On the patient search / "my patients" listing page, the "post-program assessment status" column will show as "assessment due" when it is the time to complete this assessment. When data are entered, it will show in green as "up-to-date".

These variables are all found on page 5 of the registry. This section should be completed for ALL patients who enrolled, *regardless of whether they did not complete the program*.

6. **Supervised Exercise Sessions Completed**
   Enter the total number of supervised (on-site, but could be remote if the full session is supervised in real-time remotely) exercise classes completed by the patient during their rehab program (we have the number prescribed from your completed program survey; this can be used to assess program adherence). Do not count days the patient exercises independently at home as that is captured elsewhere. Alternatively, click the box if the patient is in an unsupervised program.
   Even if the patient dropped out (which will be captured in the next variable), please report # attended.

   Data Entry: click one of the 2 buttons
   If you select "supervised exercise", then a box will appear to enter the # of sessions
   Or select "patient enrolled in solely home-based program, where exercise classes are not remotely monitored in real-time"... but technology may be used (this is captured also in patient-reported items); this is basically "not applicable"

7. **Premature Program Termination / Program Completion**

   Premature termination refers to the instance where patients do not complete their prescribed exercise sessions or other core components of the program. To complete the CR program a patient must have attended at least some of the CR intervention components AND also have completed a formal re-assessment by the CR team at the conclusion of the CR intervention.

   Indicate the reason for premature termination of the patient's cardiac rehab program, if applicable. For example, a cardiac clinical event or procedure could be having bypass surgery or experiencing heart failure decompensation or exacerbation so having to stop coming. A non-cardiac clinical event or procedure could be contracting an infectious condition or cancer for example.

   Data Entry: click one of the 2 buttons; more options appear if you click the first:

- ☐ Premature program termination (i.e., patient did not complete post-program assessment), for the following reason (select 1):
    - ☐ Lost to follow-up or unknown / Patient dropout for non-clinical reasons
    - ☐ Return to work
    - ☐ Clinical issue – Cardiovascular (non-fatal)
    - ☐ Clinical issue – Non cardiovascular (non-fatal)
    - ☐ Death (*note: once this is selected, this record will be denoted as complete*)
    - ☐ other
- ☐ Program completion (i.e., patient engaged in interventions and had post-program re-assessment)

PROGRAM-REPORTED VARIABLES

PRE/INTAKE AND POST-PROGRAM (OBJECTIVE CLINICAL OUTCOMES)

For each, try to get information from maximum 3 months prior to initial assessment to max two weeks after initial assessment; for post-program, the test should be done +/- 3 weeks from discharge assessment date.

Even if the patient does not complete the program, try to get the values from whatever source you can.

These variables are all found on page 2 (pre-program) and 6 (post-program) of the registry.

8. **Lipids: Low-Density Lipoprotein (LDL-C)**

   Data Source: Lab report

   Data Entry: select units (mmol/L or mg/dL). Enter value obtained for LDL to 1 decimal place
   ☐ Unknown (If there are no values within the time window above; or, the patient did not have any repeat lipid test done at discharge, for example)

9. **Body mass index**

   Enter the patient's BMI.
   Data Source: Direct measurement of height (m) and weight (kg) at the intake and discharge assessment. You can use an online calculator to compute if it is easier (e.g., https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm)

   Data entry: Enter value obtained from kg/m^2 to 1 decimal place if possible

10. **Systolic and**
11. **diastolic blood pressure (BP; mmHg)**

2009 Canadian Hypertension Education Program (CHEP) Recommended Technique for Measuring Blood Pressure

Place the cuff so that the lower edge is 3 cm above the elbow crease and the bladder is centered over the brachial artery. **The patient should be resting comfortably for 5 minutes in the seated position with back support.** The arm should be bare and supported with the antecubital fossa at heart level, as a lower position will result in an erroneously higher SBP and DBP. **There should be no talking, and patients' legs should not be crossed. At least three measurements should be taken in the same arm with the patient in the same position. The first reading should be discarded and the latter two averaged.**

CHEP Recommendations for accurate measurement of blood pressure:
https://guidelines.hypertension.ca/diagnosis-assessment/measuring-blood-pressure/

Enter the patient's systolic blood pressure (mmHg) and the patient's diastolic blood pressure (mmHg). BP assessement should be undertaken manually or with a validated automated device only (e.g., see:

http://www.dableducational.org/sphygmomanometers/recommended_cat.html).

Data Source: Direct measurement at the assessment.

Data entry: Enter value obtained from patient's SBP and DBP.

12. **Peak METs**

Indicate the peak metabolic equivalents of task (METs) achieved during a functional / exercise capacity test or assessment (e.g., GXT, ISWT, 6MWT) in the space provided (we will know the type of test from your program survey responses). The METs can be estimated from standard equations using speed and grade, or can be calculated from the direct measurement of oxygen consumption using gas analysis.

DASI can also be used; DASI is converted to METS by dividing the total score by 3.5.
Conversion table for 6MWT (issues if have to use shorter than 30 m passage) to METs:
https://iacpr.net/resources/Documents/6MWT%20Distance%20Conversion%20Table%20.pdf
Conversion for watts to METs: https://exrx.net/Calculators/CycleMETs
Ideas on conversion of Incremental Shuttle Walk Test to METs (see Table 2 in particular):
https://bjsm.bmj.com/content/42/1/36.long (see also:
https://journals.lww.com/jcrjournal/Fulltext/2019/05000/Validity_of_the_Incremental_Shuttle_Walk_Test_to.13.aspx)

Data Source: Exercise stress test or other functional assessment.
Data Entry: Enter the numeric value of the peak METs as indicated by the exercise test report to the nearest 1/10 of a MET (i.e. 5.4 METs).

PATIENT-REPORTED OUTCOMES (if willing, and sufficient English language capacity, or staff administer)

PRE-PROGRAM/INTAKE only (send after receipt of referral and before first exercise session, after information about registry received by patient):

These variables are all found on page 3 of the registry.

13. **Do you have someone in your life who you feel supports you emotionally and with your health?**
    - ☐ Definitely
    - ☐ Most of the time
    - ☐ Some of the time
    - ☐ Rarely
    - ☐ No I do not

14. **For how many years did you do formal schooling / education?**

    _____ years

15. **Has a doctor ever told you that you have any of the following health conditions? (check all that apply)**
    - ☐ Stroke / transient ischemic attack
    - ☐ Peripheral vascular disease / claudication
    - ☐ Diabetes
    - ☐ Liver disease
    - ☐ Kidney disease
    - ☐ Lung disease (e.g., COPD, Asthma)
    - ☐ Osteoporosis
    - ☐ Cancer
    - ☐ Human immunodeficiency virus / AIDS
    - ☐ Movement disorder (e.g., parkinson's, tremor)
    - ☐ Musculoskeletal issues (e.g., arthritis, hip or knee replacement)
    - ☐ Cognitive issues (e.g., brain injury, cognitive impairment)
    - ☐ Mental health problems, including sleep issues (e.g., depression, anxiety)
    - ☐ Sexual issues (e.g., erectile dysfunction)
    - ☐ Other (please specify: _____)
    - ☐ None of the listed options

16. **How much do you worry about having enough money to meet your basic needs, including health and health care?**
    - ☐ Not at all
    - ☐ I sometimes worry about this
    - ☐ I often worry about this

17. Do you have to pay for heart pills or medicines out of your own pocket?

- ☐ Yes, I have to pay for any medicine I take out of my own pocket, or some of the cost
- ☐ No, I have work benefits, or the government or some other source pays for all my heart medicine

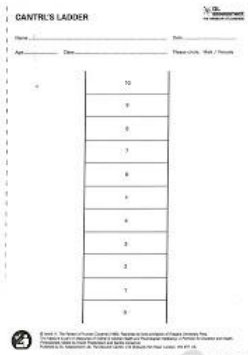
PRE/INTAKE, POST-PROGRAM (administered when program would have been done for all patients [which each program provided in the initial program survey], regardless of whether or not the patient completed the program; if program has no end date, send 4 months from pre-program assessment), and EACH YEAR FROM INITIAL PRE-ASSESSMENT:

These variables are all found on page 4 (pre-program), 7 (post-program/progress), and 10 (first annual) of the registry.

Subsequent annual follow-ups are generated automatically by the registry. They will appear on the main patient search / "my patients" page in the follow-up column as "assessment due" at the applicable number of years from the initial assessment date.

18. My Quality of Life

Assume that this ladder is a way of picturing your life. The top of the ladder represents the best possible life for you. The bottom step of the ladder represents the worst possible life for you.
Circle the number that shows where on the ladder you feel you are right now.



Validated measure: Cantril's ladder of life
Data Entry: value between 0 (worst possible life) and 10 (best possible life)

19. Depressive symptoms (validated measure: PHQ-2):

Over the past 2 weeks, how often have you been bothered by any of the following problems?

a) **Little interest or pleasure in doing things**
b) **Feeling down, depressed or hopeless**

Response options are: not at all (0), several days (1), more than half the days (2), nearly every day (3).

20. **In the last month, how many servings of fruit and vegetables did you have in an <u>average</u> day?** (e.g., here are some examples of one serving: 125 mL [½ cup] fresh, frozen or canned vegetables or fruit; 250 mL [1 cup] leafy green vegetables such as lettuce, which is about the size of your fist; 1 small piece of fruit or vegetable such as an apple, guava, nectarine, orange, peach, pear,

large carrot or celery stalk; 60 mL [1/4 cup] of dried fruit such as raisins; or small 125mL glass of pure fruit juice [sugary drinks with fruity taste should not be counted]).

_____ servings /day

21. In the last month, how many minutes per week on average were you physically active to the point of being at least slightly short of breath?

_____ minutes / week

22. Do you use any form of tobacco? (e.g., smoking, vaping etc; select 1)

☐ Never = no history of using any form of tobacco
☐ Current = use of any form of tobacco within the last month
☐ Former = use of any form of tobacco more than one month ago

23. It is hard to remember to take your pills all the time if you take them. Over the last month, how often do you think you have taken your heart pills as directed by your doctor? (select 1)

☐ All the time
☐ Most of the time
☐ Some of the time
☐ Rarely
☐ Never

Note: this is scored as 1 "never" to 5 "all the time". The mean is shown in the dashboards (see separate file on reviewing reporting dashboards)

24. What is your current work status? (select 1)

☐ I work full or part-time for pay (includes self-employment)
☐ I am on disability (sick leave) or modified duties at work
☐ I am retired
☐ I have not been employed, or have been working without formal pay (e.g., household management)
☐ Other (e.g., can't work due to health)

POST-PROGRAM ONLY (PROGRESS):

These variables are all found on page 8 of the registry.
Again, these should be administered even if the patient did not complete the program if possible.

25. Please check whether you feel you are fully informed about each of the following ways to control your heart disease (answer yes or no for each):

		Yes	No
a	I know that my primary care or other healthcare provider was informed about what happened for me in cardiac rehab or I informed him/her (leave blank if you do not have a healthcare provider)	☐	☐
b	I understand what heart pills I should be taking	☐	☐
c	I know how to manage my stress	☐	☐
d	I know how much I should be exercising and at what intensity, so I can stay active	☐	☐
e	I know how to follow a heart-healthy diet	☐	☐
f	I know my blood pressure level and how to control it	☐	☐
g	I know my cholesterol level and how to control it	☐	☐
h	I know what to do if I have chest pain	☐	☐
i	I have been supported to get back to the life roles that are important to me (e.g., relationships, domestic duties, driving)	☐	☐

26. Did you do any part of your cardiac rehab **online or via phone**? (does not include scheduling sessions or appointments)
    - ☐ Yes
    - ☐ No

Each Year Post-Initial Assessment Date

Annual follow-ups consist of 1 program-reported variable (vital status; p. 9 or registry) and several patient-reported variables if they are willing (or the program may enter the information directly on behalf of the patient, depending on your arrangement; pages 10 and 11 of registry).

Note: death during the program is denoted through the 'premature program completion" variable #7. This will result in no more annual assessments (program or patient report) being triggered, and the patient record will be complete.

If you have learned your patient has died or is too ill to complete annual assessments, you can denote this in the registry at any time after the post-program assessment. For the first year, go into the record by clicking on the right record the main "my patients" page (you can do a search by year of birth, gender and initial assessment date, or registry ID from your excel file), and go to p. 9 of of 11 from the registry page dropdown in the top middle (white rectangle) called "program report of vital status – annual". Click <save & exit>.
For subsequent years, you can also denote this before the annual follow-up from the main "my patients" page, under the column at the far right "annual follow-ups from 2nd year"; select "patient died" or "patient to ill…." as applicable.

Once the patient is denoted as dead, the record is complete. If the patient is to ill to complete annual assessments, we would appreciate if you could still denote when the patient dies in the registry, by going to "my patients" / patient search page, under the column at the far right "annual follow-ups from 2nd year" and select a new patient follow-up from the dropdown menu, and then select "patient died".

If you simply want to stop annual follow-ups by patients based on patient request, please remove their contact information from page 1 in the registry; we would appreciate if you could still collect vital status annually until the patient has died and record it in the registry; The date of next annual assessment shall appear when due.

Subsequent annual follow-ups are generated automatically by the registry. They will appear on the main patient search / "my patients" page in the follow-up column as "assessment due" at the applicable number of years from the initial assessment date.

Program-Reported
The patient row will show in the colour yellow when this is due.
This program-reported variable for the first year is found on page 9 of the registry. For subsequent years, this will be found on main "my patients" page, under the column at the far right "annual follow-ups from 2nd year".

27. Vital Status

Data Source: call to patient's home / family members to check in about annual ability to complete assessment.
Suggested talking points: "Hello. This is [data steward] calling from [cardiac rehab program name]. Is this [patient's name]?" (if becomes apparent patient has passed, denote and offer condolences; No further follow-up.)
If patient doing patient report: "I am calling to check in as it has been one year since you started your rehab program with us. Thank you again for taking part in the registry. You will be receiving a survey with 2 questions and I hope you can fill it out" (if patient provides valid reason why they cannot complete further assessment, denote so that survey no longer sent, or confirm patient alive). You should continue however to track vital status annually until patient expiry where possible.
In registry, update patient contact email or mobile if it has changed

Please note that in the registry, on the main page you can see when the next annual follow-up is due for each patient on the right.

- ☐ patient died (*note: once this is selected, this record will be denoted as complete*)
- ☐ patient alive
- ☐ patient too ill to complete any further assessments (e.g., moved to nursing facility, dementia, palliative, disabling stroke; *note selecting this will cease further emails/texts to patients reporting data*)
- ☐ Could or did not confirm

Patient-Reported

These variables are found on page 11 of the registry (for the first year); subsequent years will appear on the "patient search/ my patients" page when they are due under "annual follow-ups from 2nd year". See above how to cease follow-ups due to patient death, illness or request.

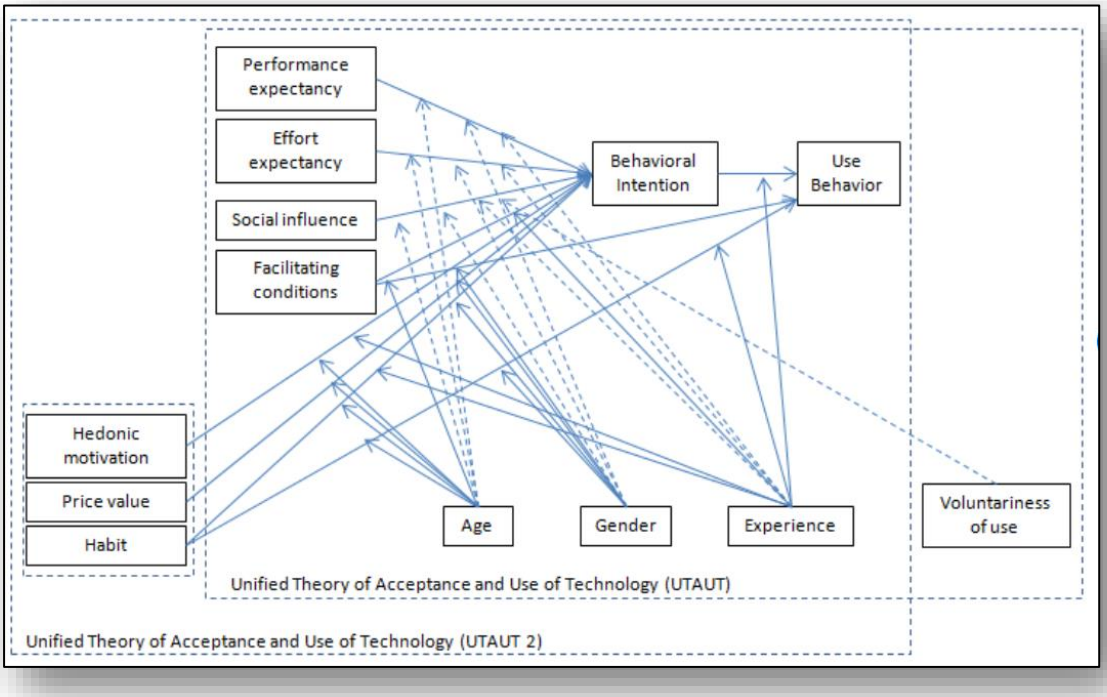
28. How often have you felt short of breath, dizziness or had chest pain on average in the past month?
    - ❑ Never
    - ❑ Rarely
    - ❑ Sometimes
    - ❑ Often
    - ❑ Always

29. Have you been hospitalized or had another heart or other health problem in the past year?
    - ☐ *Yes*
    - ☐ No

    29b. If yes, was it (check yes or no for each):
    - ☐ A heart attack

- ☐ A stroke or mini-stroke ("brain attack"; transient ischemic attack)
- ☐ I went to the emergency department for a heart problem (e.g., chest pain, heart failure)
- ☐ I stayed in the hospital overnight for a heart problem
- ☐ I had a heart procedure (e.g., bypass surgery, stent, rhythm device inserted like a pacemaker)
- ☐ I went to the hospital for a reason other than my heart
- ☐ I had another new health diagnosis (e.g., kidney problems, diabetes, cancer, cognitive impairment) by my doctor
- ☐ I think I am sick, but have not seen a doctor
- ☐ Other

Appendix B: Unified theory of acceptance and use of TECHNOLOGY (UTAUT 2 vs. UTAUT)



Appendix C: Think Aloud Protocol and Semi-Structured Interview Guide

PREAMBLE

"Hello. My name is Hana abukhadijah; I am a trained master student at Qatar university My supervisor is Dr. Karam Adawi, Assistant Professor of Public Health at Qatar university. Dr. Karam Turk-Adawi and Dr. Sherry Grace are Co-LPIs on this study.

As you know, under the auspices of the International Council of Cardiovascular Prevention and Rehabilitation we are developing an International Cardiac Rehab Registry (or ICRR). We developed the registry data dictionary with input from experts such as you from around the world, which forms the basis for the registry template to which you have been given access. Your input will help us improve and finalize the registry before we launch it. We want to make sure it is as useful for cardiac rehab staff as possible.

Did you have any questions about the consent form before we start?

IF YES (as applicable, here are some answers):

The study has been approved by York University and Qatar University.

Our session will take about 60 minutes.

If there are any questions that you do not wish to answer, you do not have to do so; however please try to answer and be as open as possible.

Data storage: Video-recordings will be kept safely on a secure university server until they are coded for changes to be made to the registry, then they will be destroyed. Interview audio-recordings, notes and transcripts of the interview will contain no

information that would allow you to be linked to specific statements. These willbe stored securelyusing a research number only.

IF SIGNED ICF NOT RECEIVED YET: If you feel willing to undertake the interview can you please sign and email me back the consent form? [GET BEFORE START INTERVIEWING]

May I begin the recording of the discussion to facilitate its' recollection? [ONLY DO THIS IF THEY CHECKED THE BOX AT BOTTOM OF ICF]

Thank you for agreeing to help us. We will do 2 things: (1) you will enter data of a patient into the registry based on the data dictionary (pre-program and post), and (2) answer a few questions at the end. This should take around 1 hour.

ICRR defines "low-resource" as: program is in a low or middle-income country according to World Bank, or setting within a higher-income country where there is under-development of CR related to financial resources, lack of healthcare system resources, lack of patient and provider awareness, and/or patient disadvantage [e.g., limited social resources, geographic barriers]. Before we start, can you please tell us what country/region of the world you practice in? in what ways is your setting "low-resource" when it comes to CR?

Think Aloud Protocol

Can you get the data dictionary handy?

And open the patient's data you will enter.

Ok, then can you go to the ICRR demo website.

IF AN ISSUE: Please ensure I do not see the patient's name as outlined in the email we sent arranging this interview. Do you have electronic patient records there or a mix of electronic records and hard charts? If electronic, do you have a 2nd screen? Please only show the registry when you screen share.

Ok, please share your screen showing the registry, and log in now.
Soon I will ask you to try to navigate the registry to enter data for a graduated patient, and complete pages 1 to 8 as possible (for 3, 4, 7 and 8, just enter some random values as these are for patient report).
Please put the initial assessment date as at least one month ago.
On page 1 for the source variable, enter "program".

As you do this, we would ask you think out loud. By that, I mean while you are going entering each variable and navigating screens, I want you to state what you're thinking as you go along. For instance, if the content is unclear or needed information is missing, please say those things out loud. Please be forthright so we get the most input we can to improve it.

We would like to test the registry under real-world circumstance, so we will pretend that you are on your own, but I can help if you are stuck as all new users will get initial training. I will be making notes as you go along.

Do you have any questions before we begin? Ok, please and get started.

…

Semi-Structured Interview Guide

Thank you. Your insights have been very helpful. Now we will have a discussion. Remember, we want you to be as critical as possible so we can optimize the utility of the ICRR to you, and reduce program hurdles to using it fully.

1. What questions or comments do you have about the registry before I ask mine?

2. With registries, there are ethical and data sharing considerations. We have ethics protocols and a draft site agreement to share with interested sites as a start, and the registry meets rigorous international security and privacy regulations.
    a. If you were to become a participating site, what do you think would be the process to get approval to adopt the registry at your program?
        i. PROBES: What barriers do you foresee?
    b. If you wanted to join the registry (which we will get to later), how can we best support CR staff such as yourself to adopt the CR registry?
3. Now let's take a look at the data dictionary [show on screen] and talk about the variables for the program to enter:
    a. Were the variables available for you to extract?
        i. Which ones were not? i.e, your program doesn't collect them
            1. [Write down specific variable #s from data dictionary]
            2. Would you be able to get patients to provide the additional data?
                a. Process logistics
                b. Patient willingness
    b. Were there some variables you collect, but measure in a different way, so you would need to change your practices or not provide data for that variable?
        i. [Write down specific variable #s from data dictionary, and how they assess differently]
    c. Any definitions that were unclear?
        i. [Write down specific variable #s from data dictionary, and how unclear]
    d. How was the number of variables – too long?
        i. Any that seem extraneous?
4. Now I would like to ask you some technical questions
    a. How did you find the process of logging in?
    b. navigating the screens?
    c. Flow / placement of variables make sense? Efficient?

    d. Were there any variables for which you had difficulty entering the data?
    e. Any restrictions on ranges etc. that are problematic?
    f. Easy to save the data?
    g. Do the "my patients" screen columns and color coding make sense? Why or why not? How could this be improved?
5. Here are again the patient information letter and consent form we suggest programs use. Do you think your program would be able to distribute this to all new patients?
    a. PROBES: if yes, in what mode? (electronic, mail, in person?)
    b. Do you foresee any issues with this?
        i. PROBES: institutional approvals, research ethics boards, program's ability to distribute to every patient

    c. Based on your experience sharing the information letter and consent form with a few patients [if they were able to], did they seem [or would they be] willing for their data to be used?
        i. Why or why not?
        ii. Did they seem willing to provide their contact information and some data directly?
6. How feasible and acceptable do you foresee it to get approval from your institution and for your program to arrange that patients directly report some data?
    a. SHARE ON SCREEN THE INTERFACE FOR PATIENT ENTRY: https://rs2.e-dendrite.com/csp/icrr/PROMS/QuestionnaireIntake.csp?zkey=MTI1IDEyOCAzOTUyMzkwNjIxMTU0OTMwNSAx
        i. PROBES: Have a look at the data dictionary and where the variables for patients to enter are found (starting on pages 11 and 13).
    b. Do you think patients could understand those questions?
        i. are your patients sufficiently literate? Are they proficient in English?
    c. Do most of your patients have a smartphone or other technological device, through which they could provide their data?
    d. Did your patients seem willing to provide their email address or mobile number so they could provide data?
7. How and when do you do your post-program assessments?
    a. Do you think you can engage patients, even those that drop-out to potentially provide data directly via text/email post-program?
    b. Would you be willing to call patients at 1 year to ascertain mortality?
8. On p. 5 of the registry website (program conclusion) there is the patient lay summary. Please navigate there and open it up (hit "download"). Take a moment to review (pause). Hopefully you may have been able to share this with a patient beforehand too.
    a. Do you think you could get approval to use this at your program? Why or why not?
    b. Do you think the information would be useful to you and /or your patients? Why or why not?

    c. Do you have any suggestions on how we could improve it?
9. Now let's have a look at the 2 dashboards. Navigate to the main menu, and select the blue rectangle marked "dashboards". Then click "generate dashboard"
    a. First the patient-related outcomes.
        i. Does this dashboard make intuitive sense to you?
        ii. How is the layout?
        iii. suggestions for improvement?
            1. PROBES: mean change as indicators
    b. Second, the program-related outcomes.
        i. Does this dashboard make intuitive sense to you?
        ii. How is the layout?
        iii. suggestions for improvement?
    c. Are the comparisons useful? (i.e., change over time, to other programs)
    d. Try right-clicking on the hamburger in the top right of one of the graphs. Can you download the graph alright?
    e. Using the information:
        i. Do you think you will be able to use this information to report to managers, administrators and policy-makers? How?
        ii. Do you think your program staff will be able to use and apply the information to consider ways to improve program quality?
            1. If not, why not?
        iii. Is there different information you would need?
10. The registry has a user-subcommittee with a mandate to support on-boarding of new sites and quality improvement activities. What kind of engagement and support would you want from the user committee?
    a. Would you want your program to be recognized if it was "high-performing" in comparison to other programs? Why or why not?
11. Try navigating to the main menu and click on "export my data"
    a. Does that feature work okay for you? Easy to use? Anything we could improve?
12. Overall, based on your experience with the registry, given there is no cost to participate, that on average with experience it requires 10 minutes to enter data for a patient with pre and post-program data, and given the information for sites shown on our website (https://globalcardiacrehab.com/ICRR_sites) do you think your program would be interested in contributing data?
        i. PROBE: why or why not?
        ii. What would be the barriers and facilitators to being a contributing site?
    b. Who do you think would enter the data?
        i. PROBE: profession; how many
        ii. PROBE: do they have time
    c. Do you have any feedback for us on our website regarding information on joining, etc?
13. Would your program be interested in arranging electronic upload of data, given it is also free?
    a. You create batch files, but issue is you need to collect the same variables as are collected and defined in the registry.
        i. Do you collect a lot of the variables we collect in the registry electronically routinely now? Which ones?

14. We are planning a program certification through the registry. It would involve evaluating some responses to the survey programs complete before joining the registry (e.g., emergency policies, staff training, multidisciplinary team), evaluating patient outcome data from the registry, and a virtual site visit. This will help us pay for the registry maintenance.
    a. Is this something your program would be interested in? why or why not?
        i. Do you think other programs would be interested?
    b. We are considering charging $500USD to be certified for 3 years. Would this be feasible for your program?
        i. If not, how much would be?
15. Lastly, is there anything else we should consider to ensure the registry is as usable as possible for CR programs in low-resource settings around the world?
    a. What other suggestions do you have for us to improve the registry?

OK, we're finished with the interview questions.

Finally, if you don't mind, I will arrange an email now to you from REDCap with a link to a brief survey to rate the usability of the ICRR. Would you mind completing 10 quick ratings in the next couple of days? If so, do you have a pen handy to write down your participant number? To keep things confidential, at the top where you are directed to enter your participant ID, please enter [#]. If you forget, just email us.

Thank you so much for your time. Your input was invaluable.

Appendix D: System Usability Scale Survey

PARTICIPANT NAME: _____ DATE: _____

System Usability Scale

For each of the following statements, please mark one box that best describes your reactions to ICRR today.

		Strongly disagree				Strongly agree
1.	I think that I would like to use ICRR frequently.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2.	I found ICRR unnecessarily complex.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3.	I thought ICRR was easy to use.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4.	I think that I would need the support of a technical person to be able to use ICRR.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5.	I found the various functions in ICRR were well integrated.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6.	I thought there was too much inconsistency in ICRR.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7.	I would imagine that most people would learn to use ICRR very quickly.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8.	I found ICRR very cumbersome (awkward) to use.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9.	I felt very confident using ICRR.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10.	I needed to learn a lot of things before I could get going with ICRR.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments (optional):

Appendix E: COREQ Checklist (COnsolidated criteria for REporting Qualitative research)

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

		analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Methods
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	Methods
Sample size	12	How many participants were in the study?	Methods
Non-participation	13	How many people refused to participate or dropped out? Reasons?	Results
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	Methods
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	NA
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	Methods/Result
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Methods
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	NA
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	Methods
Field notes	20	Were field notes made during and/or after the interview or focus group?	Methods
Duration	21	What was the duration of the inter views or focus group?	Results
Data saturation	22	Was data saturation discussed?	Methods

Transcripts returned	23	Were transcripts returned to participants for comment and/or	NA

Topic	Item No.		Reported on Page No.
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	Methods
Description of the coding tree	25	Did authors provide a description of the coding tree?	Results
Derivation of themes	26	Were themes identified in advance or derived from the data?	Methods
Software	27	What software, if applicable, was used to manage the data?	Methods
Participant checking	28	Did participants provide feedback on the findings?	Methods
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Results
Data and findings consistent	30	Was there consistency between the data presented and the findings?	Results
Clarity of major themes	31	Were major themes clearly presented in the findings?	Results
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	Results

Appendix F: Ethical Approval- Canada

YORK
UNIVERSITÉ
UNIVERSITY

Certificate #:	**e2020-147**
Initial Approval:	**05/28/20-05/28/21**
Amendments:	
Renewals:	**05/03/21 - 05/03/22**
Current Approval Period:	**05/03/21 - 05/03/22**

OFFICE OF RESEARCH ETHICS (ORE)
309 York Lanes

4700 Keele St.
Toronto ON
Canada M3J 1P3
Tel 416 736 5914
Fax 416 736-5512
www.research.yorku.ca

ETHICS RENEWAL

To: **Professor Sherry Grace**
Department of Kinesiology and Health Science
Faculty of Health
sgrace@yorku.ca

From: Alison M. Collins-Mrakas, Sr. Manager and Policy Advisor, Research Ethics
(on behalf of Veronika Jamnik, Chair, Human Participants Review Committee)

Date: Monday, May 3, 2021

Title: **Development and Pilot of the International Cardiac Rehab Registry**

Risk Level: ☒ Minimal Risk ☐ More than Minimal Risk

Level of Review: ☒ Delegated Review ☐ Full Committee Review

I am writing to inform you that this research project, **"Development and Pilot of the International Cardiac Rehab Registry"** has received ethics review and renewal by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines.

Note that renewal is granted for one year. Ongoing research – research that extends beyond one year – must be renewed prior to the expiry date.

Any changes to the approved protocol must be reviewed and approved through the amendment process by submission of an amendment application to the HPRC prior to its implementation.

Any adverse or unanticipated events in the research should be reported to the Office of Research ethics (ore@yorku.ca) as soon as possible.

For further information on researcher responsibilities as it pertains to this approved research ethics protocol, please refer to the attached document, **"RESEARCH ETHICS: PROCEDURES to ENSURE ONGOING COMPLIANCE".**

Please note that prior to commencing any research activities, researchers are advised to review the latest updates on research involving human participants at: *https://www.yorku.ca/research/researchers-faqs/*

Should you have any questions, please feel free to contact me at: 416-736-5914 or via email at: acollins@yorku.ca.

Yours sincerely,

Alison M. Collins-Mrakas M.Sc., LLM
Sr. Manager and Policy Advisor,
Office of Research Ethics

RESEARCH ETHICS: PROCEDURES to ENSURE ONGOING COMPLIANCE

Upon receipt of an ethics approval certificate, researchers are reminded that they are required to ensure that the following measures are undertaken so as to ensure on-going compliance with Senate and TCPS ethics guidelines:

1. **RENEWALS:** Research Ethics Approval certificates are subject to annual renewal. **Failure to renew an ethics approval certificate or** (to notify ORE that no further research involving human participants will be undertaken) will result in the **closure of the protocol.** No further research activities may be undertaken until such time as a new protocol has been reviewed and approved. Further, it **may result in suspension of research cost fund and/or access to related research funds may be suspended/withheld.**

2. **AMENDMENTS:** Amendments must be reviewed and approved **PRIOR** to undertaking/making the proposed amendments to an approved ethics protocol;

3. **END OF PROJECT**: ORE must be notified when a project is complete; Failure to submit an "End of Project Report" **may result in suspension of research cost fund and access to research funds may be suspended/withheld.**

4. **ADVERSE EVENTS**: Adverse events must be reported to ORE as soon as possible;

5. **AUDIT:**
    a. More than minimal risk research may be subject to an audit as per TCPS guidelines;
    b. A spot sample of minimal risk research may be subject to an audit as per TCPS guidelines.

FORMS: As per the above, the following forms relating to on-going research ethics compliance are available on the Research website:

a) Renewal
b) Amendment
c) End of Project
d) Adverse Event

Appendix G: Ethical Approval- Qatar University

Qatar University Institutional Review Board **QU-IRB**

QU-IRB Registration: IRB-QU-2020-006, QU-IRB, Assurance: IRB-A-QU-2019-0009

DATE:	April 6, 2021
TO:	Karam Adawi
FROM:	Qatar University Institutional Review Board (QU-IRB)
PROJECT TITLE:	1718430-1 Development of Qatar National Cardiac Rehabilitation Registry
QU-IRB REFERENCE #:	QU-IRB 1518-EA/21
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
REVIEW TYPE:	Expedited Review
DECISION DATE:	April 6, 2021
REVIEW CATEGORY:	Expedited review category # 4&7

Thank you for your submission of New Project materials for this project. The Qatar University Institutional Review Board (QU-IRB) has APPROVED your submission. This approval is based on an appropriate risk/ benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review according to Qatar Ministry of Public Health (MoPH) regulations. This project has been determined to be a MINIMAL RISK project.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Qatar MoPH regulations require that each participant receives a copy of the consent document.

Please note that Expedited Review approvals are valid for a period of one year and renewal should be sought prior to to ensure timely processing and continuity. Moreover, any changes/modifications to the original submitted protocol should be reported to the committee to seek approval prior to continuation.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

Documents Reviewed:

- Application Form - QU-IRB Brief Application Form_clean.pdf (UPLOADED: 03/13/2021)
- Consent Form - ResearchConsentForm_Eng_V1.pdf (UPLOADED: 03/13/2021)
- Data Collection - DataCollectionSheet_Eng.pdf (UPLOADED: 03/13/2021)
- Letter - MRC approval letter_Qatar Registry.pdf (UPLOADED: 03/13/2021)
- Other - ResearchInfoSheet_Eng_V0.doc (UPLOADED: 03/13/2021)

- Protocol - MRC-02-20-459_ResearchProtocol_V1 (1).pdf (UPLOADED: 03/13/2021)
- Questionnaire/Survey - intreview and think aloud guide.pdf (UPLOADED: 03/13/2021)

If you have any questions, please contact QU-IRB at 4403 5307 or qu-irb@qu.edu.qa. Please include your project title and reference number in all correspondence with this committee.

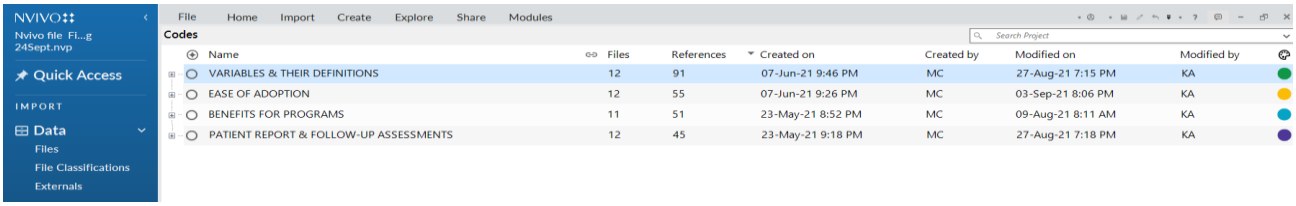
Best wishes,

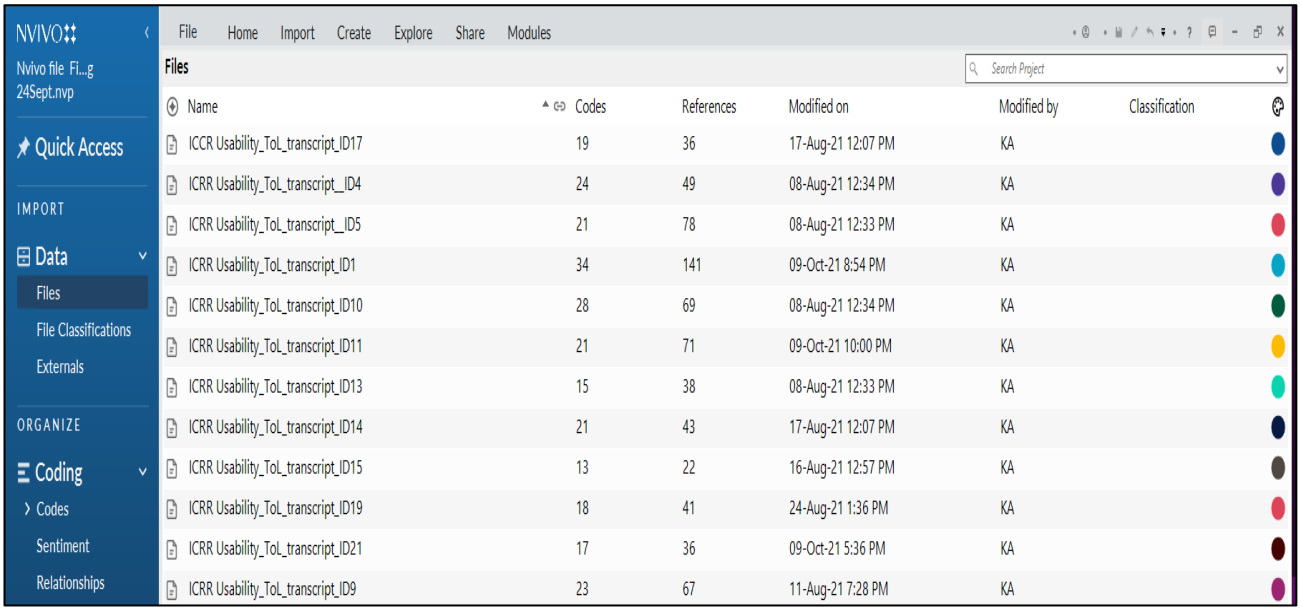
Dr. Ahmed Awaisu
Chairperson, QU-IRB

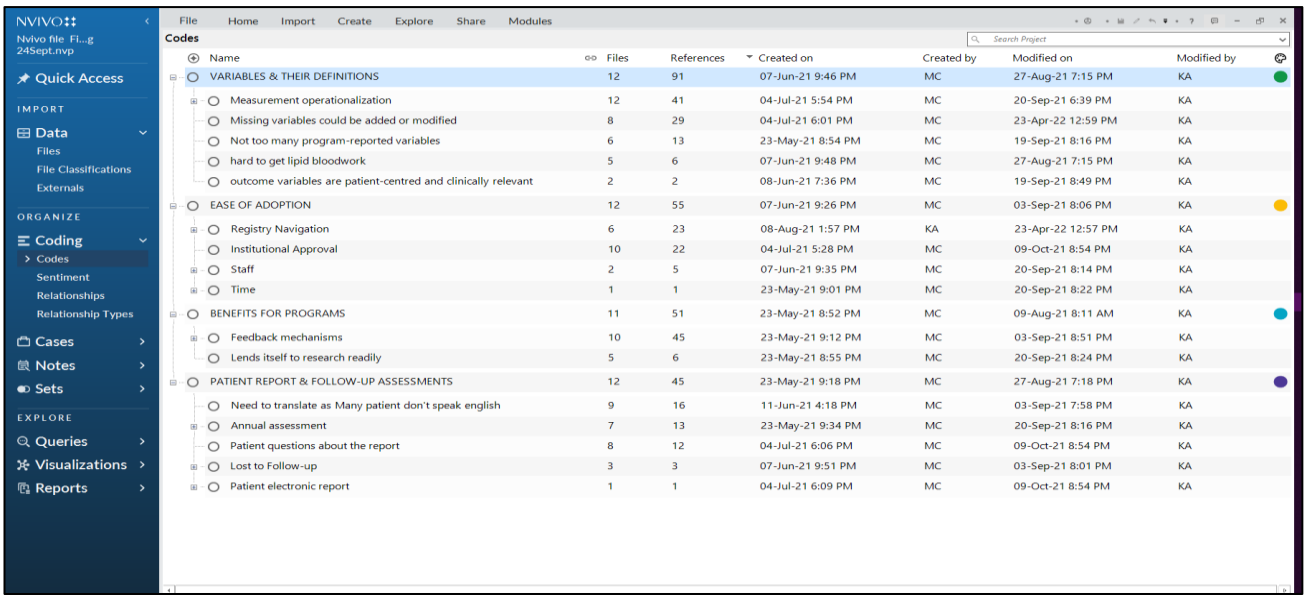
جامعة قطر
QATAR UNIVERSITY
Institutional Review Board
(IRB)
Office Of Academic Research

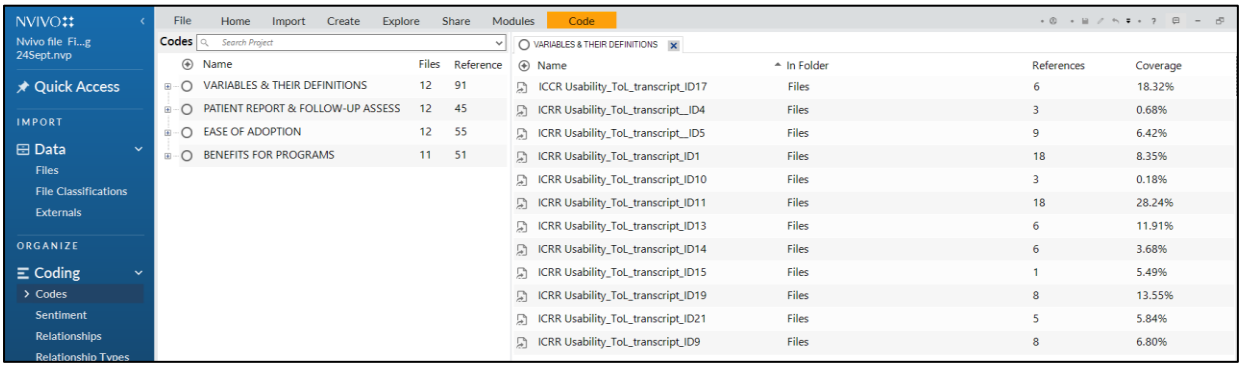
This letter has been issued in accordance with all applicable regulations, and a copy is retained within Qatar University's records.

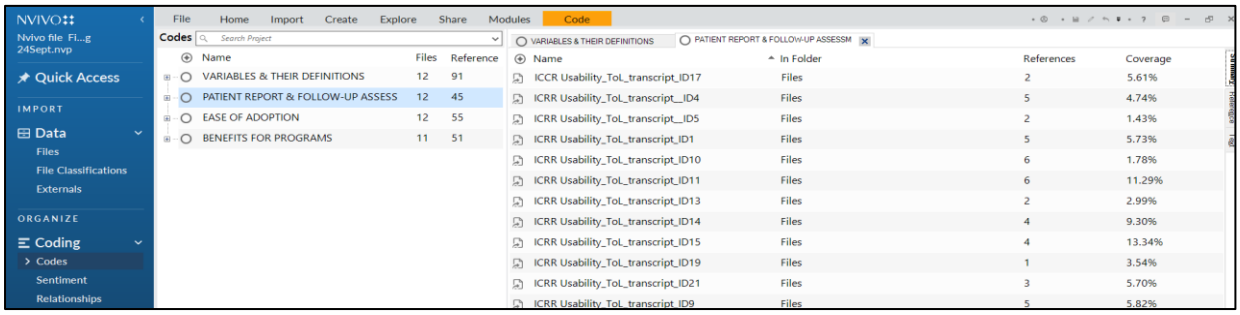
Appendix H: NVIVO Screenshots

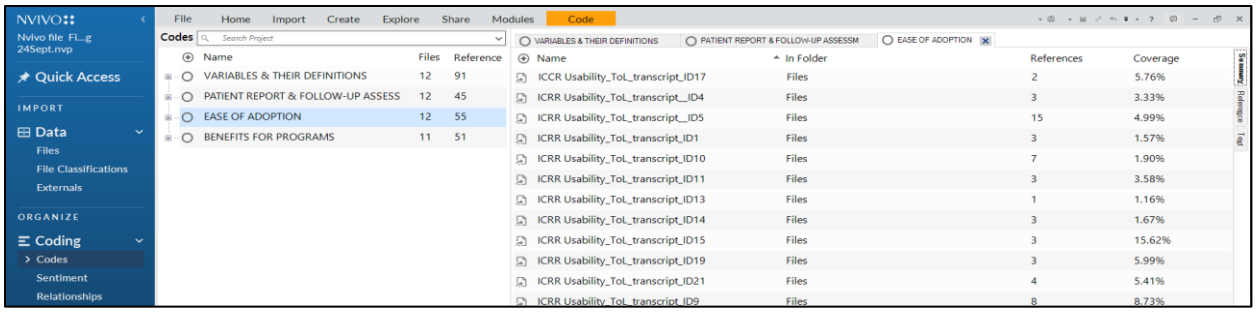


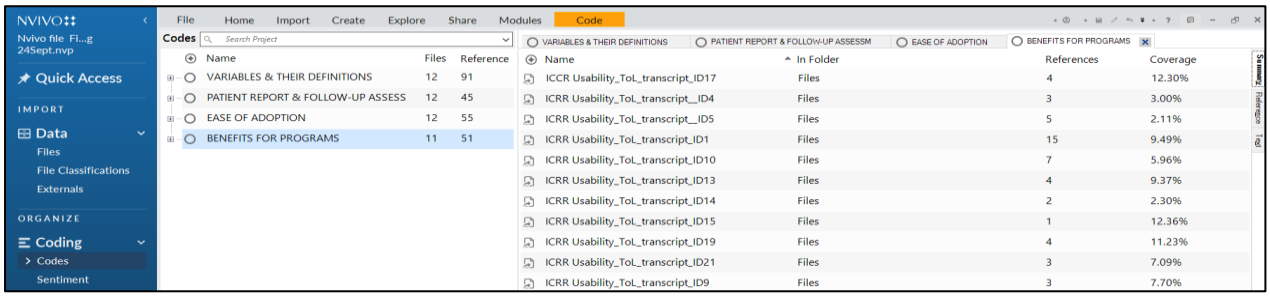





NVIVO
Nvivo file Fi...g 24Sept.nvp
Quick Access
IMPORT
Data
Files
File Classifications
Externals
ORGANIZE
Coding
Codes
Sentiment
Relationships
Relationship Types
File Home Import Create Explore Share Modules Code
Codes
Search Project
VARIABLES & THEIR DEFINITIONS
Name Files Reference
VARIABLES & THEIR DEFINITIONS 12 91
PATIENT REPORT & FOLLOW-UP ASSESS 12 45
EASE OF ADOPTION 12 55
BENEFITS FOR PROGRAMS 11 51
Name In Folder References Coverage
ICCR Usability_ToL_transcript_ID17 Files 6 18.32%
ICRR Usability_ToL_transcript__ID4 Files 3 0.68%
ICRR Usability_ToL_transcript__ID5 Files 9 6.42%
ICRR Usability_ToL_transcript_ID1 Files 18 8.35%
ICRR Usability_ToL_transcript_ID10 Files 3 0.18%
ICRR Usability_ToL_transcript_ID11 Files 18 28.24%
ICRR Usability_ToL_transcript_ID13 Files 6 11.91%
ICRR Usability_ToL_transcript_ID14 Files 6 3.68%
ICRR Usability_ToL_transcript_ID15 Files 1 5.49%
ICRR Usability_ToL_transcript_ID19 Files 8 13.55%
ICRR Usability_ToL_transcript_ID21 Files 5 5.84%
ICRR Usability_ToL_transcript_ID9 Files 8 6.80%


NVIVO
Nvivo file Fi...g 24Sept.nvp
Quick Access
IMPORT
Data
Files
File Classifications
Externals
ORGANIZE
Coding
Codes
Sentiment
Relationships
File Home Import Create Explore Share Modules Code
Codes
Search Project
VARIABLES & THEIR DEFINITIONS
PATIENT REPORT & FOLLOW-UP ASSESSM
Name Files Reference
VARIABLES & THEIR DEFINITIONS 12 91
PATIENT REPORT & FOLLOW-UP ASSESS 12 45
EASE OF ADOPTION 12 55
BENEFITS FOR PROGRAMS 11 51
Name In Folder References Coverage
ICCR Usability_ToL_transcript_ID17 Files 2 5.61%
ICRR Usability_ToL_transcript__ID4 Files 5 4.74%
ICRR Usability_ToL_transcript__ID5 Files 2 1.43%
ICRR Usability_ToL_transcript_ID1 Files 5 5.73%
ICRR Usability_ToL_transcript_ID10 Files 6 1.78%
ICRR Usability_ToL_transcript_ID11 Files 6 11.29%
ICRR Usability_ToL_transcript_ID13 Files 2 2.99%
ICRR Usability_ToL_transcript_ID14 Files 4 9.30%
ICRR Usability_ToL_transcript_ID15 Files 4 13.34%
ICRR Usability_ToL_transcript_ID19 Files 1 3.54%
ICRR Usability_ToL_transcript_ID21 Files 3 5.70%
ICRR Usability_ToL_transcript_ID9 Files 5 5.82%


NVIVO
Nvivo file Fi...g 24Sept.nvp
Quick Access
IMPORT
Data
Files
File Classifications
Externals
ORGANIZE
Coding
Codes
Sentiment
Relationships
File Home Import Create Explore Share Modules Code
Codes
Search Project
VARIABLES & THEIR DEFINITIONS
PATIENT REPORT & FOLLOW-UP ASSESSM
EASE OF ADOPTION
Name Files Reference
VARIABLES & THEIR DEFINITIONS 12 91
PATIENT REPORT & FOLLOW-UP ASSESS 12 45
EASE OF ADOPTION 12 55
BENEFITS FOR PROGRAMS 11 51
Name In Folder References Coverage
ICCR Usability_ToL_transcript_ID17 Files 2 5.76%
ICRR Usability_ToL_transcript__ID4 Files 3 3.33%
ICRR Usability_ToL_transcript__ID5 Files 15 4.99%
ICRR Usability_ToL_transcript_ID1 Files 3 1.57%
ICRR Usability_ToL_transcript_ID10 Files 7 1.90%
ICRR Usability_ToL_transcript_ID11 Files 3 3.58%
ICRR Usability_ToL_transcript_ID13 Files 1 1.16%
ICRR Usability_ToL_transcript_ID14 Files 3 1.67%
ICRR Usability_ToL_transcript_ID15 Files 3 15.62%
ICRR Usability_ToL_transcript_ID19 Files 3 5.99%
ICRR Usability_ToL_transcript_ID21 Files 4 5.41%
ICRR Usability_ToL_transcript_ID9 Files 8 8.73%


NVIVO
Nvivo file Fi...g 24Sept.nvp
Quick Access
IMPORT
Data
Files
File Classifications
Externals
ORGANIZE
Coding
Codes
Sentiment
File Home Import Create Explore Share Modules Code
Codes
Search Project
VARIABLES & THEIR DEFINITIONS
PATIENT REPORT & FOLLOW-UP ASSESSM
EASE OF ADOPTION
BENEFITS FOR PROGRAMS
Name Files Reference
VARIABLES & THEIR DEFINITIONS 12 91
PATIENT REPORT & FOLLOW-UP ASSESS 12 45
EASE OF ADOPTION 12 55
BENEFITS FOR PROGRAMS 11 51
Name In Folder References Coverage
ICCR Usability_ToL_transcript_ID17 Files 4 12.30%
ICRR Usability_ToL_transcript__ID4 Files 3 3.00%
ICRR Usability_ToL_transcript__ID5 Files 5 2.11%
ICRR Usability_ToL_transcript_ID1 Files 15 9.49%
ICRR Usability_ToL_transcript_ID10 Files 7 5.96%
ICRR Usability_ToL_transcript_ID13 Files 4 9.37%
ICRR Usability_ToL_transcript_ID14 Files 2 2.30%
ICRR Usability_ToL_transcript_ID15 Files 1 12.36%
ICRR Usability_ToL_transcript_ID19 Files 4 11.23%
ICRR Usability_ToL_transcript_ID21 Files 3 7.09%
ICRR Usability_ToL_transcript_ID9 Files 3 7.70%