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Design, development, and deployment of a web-based registry for cardiovascular intensive care unit (CVICU)

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A B S T R A C T

Introduction: The cardiovascular intensive care unit (CVICU) registry provides physicians with tools for monitoring, managing, and following up on patients. The CVICU registry provides researchers with the ability to analyze and evaluate integrated data patients. Our goal with this study is to explain the design, development, and deployment of a comprehensive, integrated, qualified cardiovascular intensive care unit registry, as well as to characterize individuals admitted to CVICUs.

Material and Methods: From June 2012, a cohort study of ICU admissions for adults (≥18 years) in a teaching hospital's CVICU began. The study includes retrospective collection of existing data from paper records and hospital information systems (HIS) and ongoing prospective collection using the proposed CVICU registry portal.

Results: Between June 2013 and June 2022, 2587 admissions were included, among which 1041 (40.2%) were women, 1546 (59.8%) were man, and the median age was 58 ranging from 18 to 93 years and their mean (SD) age was 56.8 (13) years. About 11.1% of the patients died in the CVICU. The primary indications for CVICU care included mechanical ventilation (29.7%), weaning time or readmission (4.9%), cardiovascular (17.4%), myocardial infarction (1.7%), diabetes (9.3%), hypertension (14.3%). Of these, about 73% had coronary artery bypass grafting (CABG), 15% valve surgery and the remains has other cardiovascular surgeries. About 39% experienced an on-pump surgery. In addition, patients had 6.4 hours weaning time after operation. The overall CVICU length of stay (LOS) rate was 3.6 days and mean predicted by APACHE IV, APACHE II, SOFA, and SAPS II were 5.67, 3.03, 4, and 4 days, respectively.

Conclusion: The use of registries equipped physicians and researchers with an integrated data pool to manage and evaluate information. Appropriate patient registries allow effective decision-making for appropriate interventions, resource allocation, and ongoing data monitoring and analysis. Ultimately, this leads to the optimal outcomes for patients. This registry aims to generate valuable knowledge about cardiovascular ICU patients in Iran and to collect accurate and qualified data.

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INTRODUCTION

A system that gathers standardized clinical data using observational techniques to obtain determined outcomes is called a patient registry. Registry individuals are patients with a particular disease, condition, or exposure. The file/files derived from the registry form the registry database [1]. Registries aggregate sets of digitized patient data and track patient characteristics over time to allow for the identification of patients with a particular symptom [2]. Clinical registries have been recognized as a significant tool for enhancing the value of healthcare by policymakers in recent years. Outcome data is now

being used to fill in evidence gaps that randomized controlled trials cannot offer [3]. In addition, clinical registry data is increasingly being used to improve learning networks and facilitate research collaborations among academic researchers, physicians, stakeholders, patient groups, and families [1].

ICU has been changed from the CCU to advanced cardiac intensive care unit [2], cardiovascular intensive care unit [2-4], or intensive cardiac care unit [5], which deals with cardiovascular diseases and responds to multiple organ failure management by multiple medical teams including various field physicians. In such circumstances, several scores for predicting the outcome of severe cases have been proposed and shifting to lifesaving for more severe cases in ICU. Cardiovascular intensive care refers to special systemic management for patients with severe cardiovascular disease (CVD), which consists of heart disease and vascular disease. CVD is one of the leading causes of death in the world. In order to prevent death due to CVDs, an intensive care unit for severe CVD patients, the so-called cardiovascular intensive care unit (CVICU), has been developed in many general hospitals [6]. The joint collection of information about intensive care patients, their treatment, and outcomes began in the 1950s with the aim of communicating and exchanging experiences [7]. From these early attempts, several initiatives to collect and analyze comprehensive sets of information from a large number of intensive care units (ICUs) emerged, with a focus initially to document and learn from daily practice. Registries then developed from collecting data from discharged patients' charts to collect more reliable data that were defined in advance.

Many national registries addressing critically ill patients have been successfully developed around the world [8-12]. For example, the Australian and New Zealand Intensive Care Society (ANZICS) Adult Patient Database (APD) is widely recognized as one of the largest intensive care units (ICU) databases, collecting more than two million patients since 1992 [13]. The Australian and New Zealand Pediatric Intensive Care Registry (ANZPICR) also successfully holds Journal Pre-Proof Journal Pre-proof 7 approximately 170,000 records of pediatric patients, collected since 1997 [13]. The Case Mix Program by the Intensive Care National Audit & Research Centre (ICNARC) in the United Kingdom has a high-quality dataset recorded from approximately 1.8 million patients for over 20 years [14]. The Japanese Intensive Care Patient Database (JIPAD) was established by the Japanese Society of Intensive Care Medicine (JSICM) to construct a high-quality ICU database as a national registry with the goal of improving the quality of care and pursuing the development of intensive care medicine in Japan [15]. The Alberta Provincial Project for Outcomes Assessment in Coronary Heart Disease (APPROACH) is a registry of prospectively collected information on all patients undergoing cardiac catheterization and any subsequent cardiac procedures including cardiac surgery in the province of Alberta, Canada. The registry captures detailed individual patient demographic, medical, angiographic, surgical, and postoperative information [16, 17]. The Critical Care Cardiology Trials Network (CCCTN) is a collaborative network of advanced CSICUs in the USA and Canada. The design and methods of the CCCTN Registry have been described in detail [18]. Data are collected with a waiver of consent due to the minimal risk associated with registry enrolment (no personal identifying health information). The International Cardiac Arrest Registry (INTCAR) is a prospectively recorded multinational registry offering detailed description of the treatment and outcomes of cardiac arrest patients with return of spontaneous circulation (ROSC). The registry is ICU-based and predominantly includes patients treated with MIH, headquartered in Lund, Sweden. Registry includes 83 participating hospitals and medical centers worldwide (73 Europe/Asia, 10 North/South/Central) [19].

The most important objectives of intensive care registries include: 1) Collect data for comparative audit, 2) Select data, provide definitions and data collection guidelines, 3) Provide mechanisms for accurate and complete data capture, 4) Maintain a customized risk adjustment model, 5) Produce timely reports and provide easy access to data, 6) Support advanced analysis of data, 7) Organize audits and coach improvement programs locally and 8) Arrange meetings for participants to discuss and develop intensive care quality [20].

The purpose of this registry is to be a reliable, valid, and timely information source for cardiovascular intensive care units (CVICUs) in Iran. The registry's aim is to identify risk factors related to ICU patients and to provide statistics to public health programs and health care professionals for use in planning and evaluation. The registry results are used to investigate the causes and prevalence of cardiovascular patients and to develop preventive strategies to decrease the occurrences of these complications. The purpose of this study is to describe the design, development and deployment of a country-wide, web-based, user-friendly and interoperable registry.

MATERIAL AND METHODS

Data capture

The cardiovascular registry was designed to capture longitudinal data. The captured data is kept to a minimum to deliver an efficient and user-friendly data collecting tool. The user must complete all the

mandatory fields/check all the mandatory boxes in order to save the entry. However, the system allows editing and/or completion of previously unanswered non-mandatory fields at the user's convenience. Data on all adults (≥18 years) admitted to ICUs except for those who die in the early hours of admission at the ICUs. In total, ۲۷8 data items from all adult patients are collected. Demographics, laboratory and all imaging data imported from Hospital Information System (HIS) by a web service. These features help to data integrity in our registry and reduces time to gathering data. A health expert, daily enters data. Responsible specialist checks data accuracy at end of working hours (Fig 1).

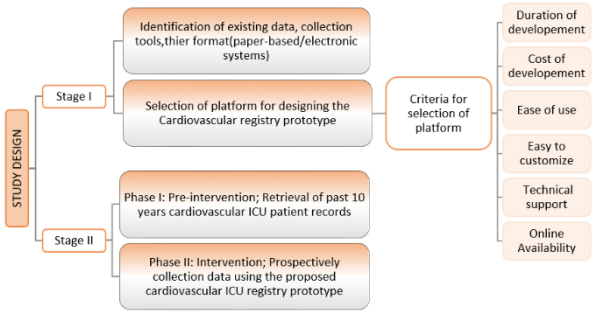

Fig 1: Study design flowchart

Registry software

The Web-based application was initially developed using Hypertext Preprocessor (PHP) as the server-side code and MySQL as the back-end database server to store the registry data. The registry is designed as a portal. It is a web-based platform that user can configure which information to display. It includes dashboard for executives and managers. A web service is added to fetch data from Hospital Information Service (HIS). For more details of patient data in the cardiovascular registry (Table 1).

Data analysis and graphical displays

Cardiovascular ICU registry is designed to be both a registry and a managing tool, data export and analysis features are very important. A dashboard that shows data summaries for the user to manage and monitor specific data, such as total patients, drugs, imaging, laboratory items, etc. Severity scores, including the Acute Physiology and Chronic Health Evaluation (APACHE) III score [21], the APACHE II score [22], the Simplified Acute Physiology Score (SAPS) II score [23], European system for cardiac operative risk evaluation (EuroScore) [24] and the Sequential Organ Failure Assessment (SOFA) score [25] within 24 hours of ICU admission are calculated. For more sophisticated analyses, physicians can export their own data on excel or csv format and analyze it.

Table 1: Capture of patient data in the cardiovascular registry

Modules	Summary
Demographics	Participants' personal and contact details. Patient registered by unique identity number.
Pre-Operative Data	Captures detailed information on clinical history, chief complaint, allergies, physical examination, vital sign
Intra-Operative Data	Operation information, Drains, intra operative events, blood products, fluids
Post-Operative Data	Weaning and intubation status, complications, scoring system
Laboratory Data	Captures detailed information on laboratory data for Complete Blood Count , Coagulation, Biochemistry, Liver Function Tests, Arterial Blood Gas, Covid-19
Imaging	Captures details of various imaging tests, such as Electrocardiogram (EKG), Echocardiography, Sonography, Chest X-ray, Angiography, CT Scan
Drugs	All kind of drug used before, intra and after operation by patient.
Discharge	date of discharge, ICU stay, outcome
Follow-up	Follow patient in different timespans

Data security and integrity

By logging-in to the application, the users understand that the information in the system is confidential and that they agree to use this information only for providing health care and research services. User logins and passwords identify each user of the application. Unique user logins are assigned for each hospital. These unique identifiers provide restricted access to various components of the CVICU registry. The users of the registry are assigned different authority levels in the current application, which can be associated with a time when they will remain valid. The users with read-only access (levels 1) cannot enter data into the system. They are only allowed to view the data. The users with write permission (all levels except level 1) can enter data into the registry. Only the administrator has full access to all the registry features including the Administrative Page. None of the users has access to the administrative functions other than administrator. User levels 1–7 can be considered as common user levels with various authorities and level 8 as the administrative position. Every hospital

has registry users with different user levels. There is no limitation on the number of users for any user level including administrator level. The browse-only user access is usually provided to researchers and hospital administrators for dashboard, browsing charts, search results, and annual reports. A patient's identifiable information is not accessible to browse-only users, but rather statistics and counts only. There is an additional user level, this registrar can access registry data of all participating hospitals and can create registrar accounts for each hospital. These registrars can then create users for their individual hospitals. The user can access the login page of the registry after a successful cookie set-up. The user must provide the exact username and password assigned to him/her by the registrar to login successfully into the registry. After a successful login, the user can use the registry features according to the defined authorization level. No users can bypass these security levels. Security checks are performed before each Web page is shown to the user. The user is redirected to a warning page with an appropriate message if he/she is not authorized to access that particular page. If, while using the application, a user exceeds his/her time limitation, then the user's session is abandoned by the application automatically. For each user session, the user ID, national code of the user, access start and end times of the session, and the PC identity, which is used for the accession, are recorded in the Logfile database table. Only the registrar can view the Logfile information periodically or as the need arises. This feature is accessible from the administrative section and enables registrars to track registry usage. Every form has been designed with various data validation checks and warnings.

Data quality

High quality data of diseases registries is considered as one of the most important elements in the establishment and maintenance of a registry [26]. Quality assurance includes quality improvement activities such as medical, clinical, and record audit and observational studies, to which the ethical principles of research apply. A physician monitors the registered data in registry every day for accuracy and validation. Formal checks do automatically by system includes Type check, format check, correctness check, uniqueness check and so on.

Web forms

This section features a sequence of web forms and functionalities that are in use by More than 3,000 patients' data have been entered and validated to be used for analysis and reporting. The users can enter a new patient by entering the National Identifier or view an existing one by entering either a National Identifier number, record number, name and etc. When the user enters the National Identifier, the application checks the existence of the record in the database. If it finds the record, then control is redirected to the patient main page. Otherwise, a blank Demographics Form for a new record entry is presented to the user.

Within the application, data recorded for each patient is divided into the following categories: demographic, Pre-Operation, Intra-Operation, Post-Operation, vital signs, imaging, laboratory data, drugs, discharge and follow-up sections (Fig 2). Data pertaining to these sections are entered into the system and can be easily updated as necessary. Data are collected by the registrar from patient charts and then entered into the system. The person who collects data and who enters it into the system can be the same or different user. Basically, nurses fill charts and specialist submit it and registrar enter it into system. Therefore, the system records the names of the data entry personnel along with the date of each entry. Because each user is associated by a national code in users' database table, the dropdown lists contain only those users who belong to a particular hospital. In the application, all related patient information can be accessed from the patient's main page. From this page, various actions, can be performed, such as viewing, updating or deleting either the entire record or individual data of a patient. The New Record button on this page allows users to add a new patient to the registry. All patient data can be updated from this page.

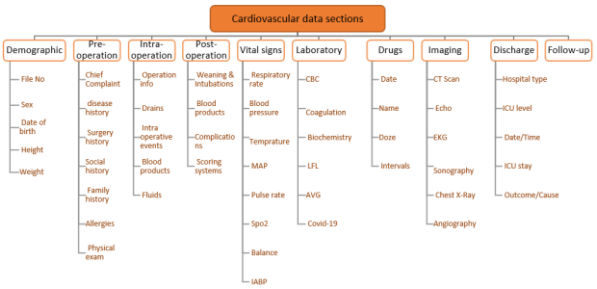

Fig 2: The structure of the cardiovascular registry prototype

Stakeholders

Stakeholders were departments or institutions involved in the care of intensive care units' patients. The involved stakeholders were the Intensive Care Units of Imamreza Hospital, Persian Cohort Research Center, Ministry of Health and Medical Education and the Department of Medical Informatics of the Mashhad University of Medical Sciences . These institutions were identified because of their history of research on medical fields.

Personnel and training

The research assistants consisted of two nursing staffs with the experience of working in the intensive care units and one physician who worked in the ICU department. They attended one-day training on ethical code of conduct and standards of practice. The

research assistants had a support group consisting of senior clinicians, data acquisition and processing team, finance, and management teams. The data collection team was coordinated and supervised closely by an Intensive care specialist with special interest in cardiovascular ICU. This ensured that data were accurately extracted, cleaned and recorded by the research assistants. Interval meetings were scheduled for feedback and needs assessment. The study however received ethical clearance from the Medical University of Mashhad while permission to carry out the study in the hospital was granted by the Office of Research and Technology of Medical University of Mashhad.

Patient follow-up

Patients will be reassessed through medical consultation and, when unable to return for reassessment, will be contacted by telephone after 90, 180 and 365 days of the initial evaluation to determine the occurrence of clinical outcomes and ICU readmissions.

Registry recruitment

Participation in the Registry is based on admission in cardiovascular ICU, and participants must provide informed written consent to participate in the Registry. The Registry currently includes individuals admitted in cardiovascular ICU. Patients with cardiovascular disease who referred to ICU from other hospital wards, are diagnosed and registered.

Ethics and governance

Ethic Committee (Mashhad University of medical science, 4010280) approval were obtained prior to recruiting patients for the Registry, and there are no costs to participants. A management committee has been established to oversee the operation of the registry and ensure appropriate access. The project investigators/institutions will permit project-related monitoring, audits, and regulatory inspections, providing direct access to source data/documents. This may include, but is not limited to, review by Ethic Committee. Data entry will occur under the supervision of the Registry Coordinator. Registry deployment The Cardiovascular Registry was deployed on June 2020 using the Registry Portal of Persian Cohort Research Center which enables the efficient customization and sustainable deployment of web-based disease and patient registries for rare and common disorders. The portal is modular in design, allowing for registries to be easily and dynamically modified, while promoting the use of data standards and common data elements. By using this portal, we were able to design an interoperable web-based Registry by data elements where appropriate, whilst also incorporating bespoke data elements, sections and forms required for the various specific cardiovascular ICU patients. This portal provides distinct levels of inbuilt security, including Secure Socket Layer security which encrypts all web traffic to and from the application, Cross-Site Request Forgery checking, and login restrictions of all views. It utilizes a role-based security model, which allows configurable permission levels for multiple levels of access, with security audit trails enabled.

RESULTS

Characteristics of ICU admissions in CVICU

There were 2587 admissions from 2013 to 2022 retrospective and is currently collected prospectively. The patient demographics are shown in Table 2. Among them 1041 (40.2%) were women, 1546(59.8%) were man, and the median age was 58 ranging from 18 to 93 years and their mean (SD) age was 56.8 (13) years. The primary indications for CVICU care included mechanical ventilation (29.7%), readmission (4.9%), cardiovascular (17.4%), myocardial infarction (1.7%), diabetes (9.3%), hypertension (14.3%). The mean predicted by APACHE IV, APACHE II, SOFA, and SAPS II were 5.67, 3.03, 4, and 4 days, respectively.

Cardiovascular ICU outcome

Of all 2587 admissions, 2300 (88.9%) were discharged alive from the cardiovascular ICU to the general wards. ICU mortality was 11.1%. The median length of ICU stay was 3.6 days in the critically ill adults. Of these, about 73% had coronary artery bypass grafting (CABG), 15% valve surgery and the remains has other cardiovascular surgeries. About 39% experienced an on-pump surgery. In addition, patients had 6.4 hours weaning time after operation. Of these admissions, 195423 laboratory data, 248,225 imaging data include EKG, CT scan, Echo, Sonogram, chest x-ray and angiography and 821,812 drugs information were registered. An overview of dashboard is shown in Figure 3. The baseline categorical characteristics, of patients admitted to the CSICU are shown in Table 3.

Table 2: Main variables included in the cardiovascular registry

Main section	Subsections	Variables	
Demographic data	Personal information	national ID First name Last name	
	Primary information	Sex Ethnicity Date of birth Age at the referral time Place of birth Marital status Job	
	Contact information	Country Phone number Mobile number Address	
	Emergency contact information	Emergency phone number1 Emergency phone number2 Relative	
	Demographic information	Height Weight BMI	
	Filing information	System record number Record number in hospital Date of record Referral patient	
	Admission information	Admission type (elective, emergency) Date of admission(Hospital) Time of admission(Hospital) Date of admission(ICU) Time of admission(ICU) Readmission ICU name Bed number First prescription date First prescription time	
Pre-operative	Chief compliant	Type of compliant Severity (1-10) Duration interval (day, month, year)	
	Disease history	Type of disease Severity (1-10) Duration interval (day, month, year)	
	Surgery history	Type of surgery Duration Severity (1-10) interval (day, month, year)	
	Family history	Relation Disease Duration interval (day, month, year) Comments	
	Social history	Type of addiction Status Duration interval (day, month, year)	
	Allergies	Drug allergy Seasonal allergy Food allergy	
	Physical examination	NYHA class (1-5)	
		Glasgow Coma Scale(GCS)	Eye opening response (1-4) Best verbal response (1-5) Best motor response (1-6)
		Pupil status	Size Symmetry Reaction to light
		Cardio sounds	Status Severity
		Organs (Upper-right)	Normality Edema Change color Temperature Cyanosis Sensitivity Clubbing
		Organs (Upper-left)	Normality Edema Change color Temperature Cyanosis Sensitivity Clubbing

Main section	Subsections	Variables	
		Organs (Lower-right)	Normality Edema Change color Temperature Cyanosis Sensitivity Clubbing
		Organs (Lower -left)	Normality Edema Change color Temperature Cyanosis Sensitivity Clubbing
		Abdomen status	
		Skin status	
		RASS	
		Respiratory sounds	
Intra-operation	Operation information	Operation type Surgical duration Surgeon Anesthesiologist Blood Group Pump status Pump time Cross clamp time Grafts Number Elective surgery Previous AF	
	Drains	Retrocardiac Pericardiac Left thoracic Right thoracic	
	Intra operative events	Event1 detail1 Event1 detail2 Event1 detail3 Event1 detail4	
	Blood products	Packed cells Fresh frozen plasma (FFP) Platelets (Plt) Fibrinogen Cryoprecipitate (Cryo)	
	Fluids	Crystalloids Colloids Total intake Drainage Urine output (UO) Albumin	
	In-operation Drugs	Drug name Doze Intervals Drug interaction	
Post-operation	Weaning & Reintubation	Weaning Weaning duration Weaning cause Reintubation Reintubation duration Reintubation cause Weaning & Reintubation Weaning & Reintubation cause	
	Blood products	Packed cells Fresh frozen plasma (FFP) Platelets (Plt)	
	Complications	Complications title Date Cause Intervention Duration Response Nurse	
	Scoring	SOFA SAPS STSS SMR SLORS EuroScore APACHE II APACHE IV	
Laboratory	CBC	WBC PMN Lymoj Plt Hb	

Main section	Subsections	Variables	
		HCT	
	Coagulation	PT PTT INR Fibrinogen D Dimer FDP	
	Biochemistry	FBS HbA1C BUN Cr Na K Cal P Mg Alb LDH	
	LFT	AST ALT ALP Bil-Total Bil-Direct	
	ABG	PH PCO2 HCO3 BE PaO2 SaO2 SvO2 FiO2	
	Covid-19	PCR Igg Igm ESR CRP	
Drugs	Drugs	Drug name Delivery Date Shape Drug code Drug unit Doze of Drug Number of requests	
Angiography	Angiography	LM 3VD Involved Vessels	
Vital signs & Monitoring	Monitoring	IABP Start date IABP End date Balance	
	Vital signs	Date RRMin RRMax TempMin TempMax SystoleMin SystoleMax DiastoleMin DiastoleMax MAPMin MAPMax SpO2Min SpO2Max PRMin PRMax	
Imaging	CT Scan	Center Date PACS Number Comment	
	ECHO	EF(%) PAP(mmHg) TAPSE Pericardial Effusion Hypokinesia RV LV Comment other findings	
	Sonography	Right Lung	A Line B Line B Line Val Air Bronchogram Shred Sign Effusion Lung Point
		Left Lung	A Line

Main section	Subsections	Variables	
			B Line B Line Val Air Bronchogram Shred Sign Effusion Lung Point
	EKG	EKG Information	Date Time Normality EKG file
		Rate & Axis	Atrial HR Ventricular HR Status Axis Degree
		Times	QT (ms) QTc (ms) QTcB (ms) QTcF (ms) QT Dispersion (ms)
		P Wave	Duration (ms) Voltage (mv) Axis Degree PR (bpm) Disorders (Y/N)
		QRS Wave	Duration (ms) Voltage (mv) Axis Degree Disorders (Y/N)
		T Wave	Duration (ms) Axis Degree Status
		ST Wave	Duration (ms) Status
		Disorders	Myocardial Infraction Angina Atrioventicular Block Bundle Branch Block(BBB) Wolff-Parkinson-White(WPW) Lown-Ganong-Levine(LGL) Discription
	Chest X-Ray	Chest X-Ray	Date Time Total Severity Lung Score Comments
		Right Lung Involved Lobes	Upper degree Middle degree Lower degree
		Right Lung Distribution	Focal (Y/N) Multifocal (Y/N) Diffuse (Y/N) Central (Y/N) Peripheral (Y/N) Anterior (Y/N) Posterior (Y/N)
		Left Lung Involved Lobes	Upper degree Middle degree Lower degree
		Left Lung Distribution	Focal (Y/N) Multifocal (Y/N) Diffuse (Y/N) Central (Y/N) Peripheral (Y/N) Anterior (Y/N) Posterior (Y/N)
		Pattern of Lesion	Pure Ground Glass Opacification (Y/N) Mixed GGO and Consolidation Consolidation (Y/N) Crazy Paving Pattern (Y/N) Vacuolar Sign (Y/N) Microvascular Dilation Inside Lesion (Y/N) Interlobular Septal Thickening (Y/N)
		Embolism	Right PA (Y/N) Left PA (Y/N) Upper (Y/N) Middle (Y/N) Lower (Y/N) Saddle (Y/N)
		Airway Findings	Airway Wall Thickening (Y/N) Traction Bronchiectasis (Y/N)

Main section	Subsections	Variables	
			Endoluminal Secretion (Y/N)
		Other findings	Air Bronchogram Sign (Y/N) Linear Opacities Combined (Y/N) Adjacent Pleural Effusion (Y/N) Pericardial Effusion (Y/N) Lymphadenopathy (Y/N) Pulmonary Emphysema (Y/N) Halo Sign (Y/N) Reverse Halo Sign (Y/N) Cardiomegaly (Y/N)
Discharge	Discharge	Hospital type Intensive care unit level Date of discharge (ICU) Time of discharge (ICU) ICU Stay Prolonged ICU Stay causes Date of discharge (Hospital) Time of discharge (Hospital) Hospital Stay Prolonged Hospital Stay causes Outcome Outcome Cause Number of ICU beds	
Follow-ups	Follow-up	28-Days Descriptions 3-Month Descriptions 6-Month Descriptions 12-Month Descriptions	

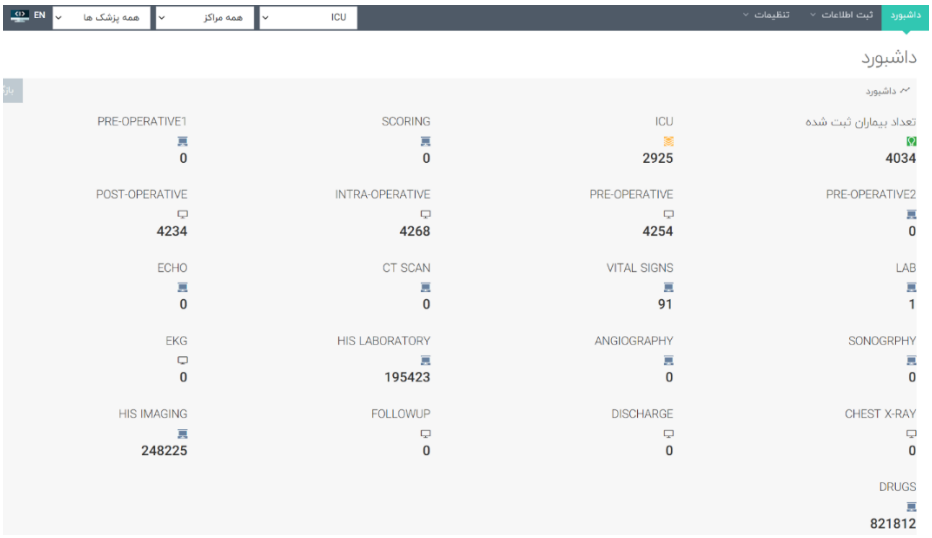

Fig 3: An overview of dashboard of the cardiovascular registry

DISCUSSION

To develop, implement, evaluate and sustain a quality improvement program in the ICU is an important and demanding undertaking. The work can be made easier by joining an intensive care registry. Mature registries have resources and knowledge that go beyond collection of well-defined data for comparative audit; they provide analyses, feedback reports, and a structure in which ICUs discover and discuss the findings in order to improve treatment and organization [20].

The CVICU registry will facilitate the efficient capture of accurate and longitudinal data. The registry will provide valuable information on cardiovascular patients, resource allocation, surgery landscape and ICU outcome, which is currently an unmet need in Iran. Furthermore, the registry will facilitate to predict patient length of stay and mortality. The use of a web-based data storage system allows the registry to extend recruitment across multiple centers in the country. The modular design and scalable nature of the framework used to deploy the CVICU registry make it easily adaptable over time, ensuring its long-term sustainability. Furthermore, the use of domain-specific ontologies adds value to data, through an integrated knowledge base that is searchable and comparable by user and by machines. In fact, by resorting to common data elements, core outcome sets, and standardized data structures, the CVICU registry can support the exchange of data across datasets, facilitating the connection to other registries at an international level. The interoperability of this registry by means of data harmonization is a key feature pointing to its utility and scalability. Another important issue of a web-

based registry is usability, i.e., the capacity of a software system to provide conditions for its users to perform the tasks satisfactorily, effectively, and efficiently.

Table 3: Baseline categorical characteristics of patients admitted to the CSICU

Characteristics		LOS ≤ **7** (N=2386)	LOS > **7** (N=201)	Total (N=2587)	P-value
		Count (Percent)	Count (Percent)	Count (Percent)	
Gender	Male	1438 (93%)	108 (7%)	1546 (59.8%)	0.042
	Female	948 (91.1%)	93 (8.9%)	1041 (40.2%)	
GCS	3	348 (90.6%)	36 (9.4%)	384 (14.9%)	0.036
	4-6	357 (93 %)	27 (7%)	384 (14.9%)	
	7-8	349 (93.8%)	23 (6.2%)	372 (14.4%)	
	9-10	656 (92%)	57 (8%)	713 (27.6%)	
	11-13	353 (92.2%)	30 (7.8%)	383 (14.8%)	
	14-15	321 (92%)	28 (8%)	349 (13.5%)	
Mortality	Yes	224 (78%)	63 (22%)	287 (11.1%)	0.000
	No	2162 (94%)	138 (6%)	2300 (88.9%)	
Mechanical Ventilation	Yes	695 (90.5%)	73 (9.5%)	768 (29.7%)	0.021
	No	1691 (93%)	128 (7%)	1819 (70.3%)	
Readmission	Yes	115 (89.8%)	13 (4.9%)	128 (4.9%)	0.190
	No	2271 (92.4%)	188 (7.6%)	2459 (95.1%)	
Emergency Surgery	Yes	140 (90.9%)	14 (9.1%)	154 (6%)	0.306
	No	2246 (92.3%)	187 (7.7%)	2433 (94 %)	
Smoker	Yes	92 (93.9%)	6 (6.1%)	98 (3.8%)	0.349
	No	2292 (92.2%)	195 (7.8%)	2487 (96.2%)	
Addiction	Yes	132 (90.4%)	14 (9.6%)	146 (5.6%)	0.241
	No	2252 (92.3%)	187 (7.7%)	2439 (94.4%)	
Cardiovascular	Yes	412 (91.4%)	39 (8.6%)	451 (17.4%)	0.250
	No	1972 (82.7%)	162 (7.6%)	2139 (82.4%)	
Myocardial Infarction	Yes	42 (1.8%)	3 (1.5%)	45 (1.7%)	0.532
	No	2342 (92.2%)	198 (7.8%)	2540 (98.3%)	
COPD	Yes	20 (95.2%)	1 (4.7%)	21 (0.8%)	0.505
	No	2364 (92.2%)	200 (7.8%)	2564 (99.2%)	
HLP	Yes	170 (91.9%)	15 (8.1%)	185 (7.2%)	0.473
	No	2214 (92.3%)	186 (7.8%)	2400 (92.8%)	
Diabetes	Yes	216 (90%)	24 (10%)	240 (9.3%)	0.113
	No	2168 (92.5%)	177 (7.5%)	2345 (90.7%)	
CVA	Yes	20 (0.8%)	3 (1.5%)	23 (0.9%)	0.263
	No	2364 (99.3%)	198 (7.7%)	2562 (99.1%)	
HTN	Yes	339 (91.6%)	31 (8.4%)	370 (14.3%)	0.263
	No	2045 (92.3%)	170 (7.7%)	2215 (85.6%)	
Pre ICULOS (Days)	1	1199 (92.4%)	98 (7.6%)	1297 (50.1%)	0.369
	2	1187 (92%)	103 (8%)	1290 (49.9%)	

Abbreviations: GCS, Glasgow Coma Scale; COPD, Chronic obstructive pulmonary disease; CVA, Cerebrovascular Accident; HLP, hypertriglyceridemia.

The CVICU registry combines a user-friendly platform and reduced load of data entry with the possibility to generate a pdf document that can be saved, thus eliminating the need for duplicate records. Additionally, there is also the possibility of hospital information system (HIS) with structured information to deliver their data directly to specific subfields of the registry, thus enabling a quick fill in process. Finally, the versatility of the platform makes it possible to serve as electronic case report form (eCRF) for upcoming observational, natural history or post-market authorization studies.

There are several strengths associated with CVICU registry. This is the first national CVICU registry in Iran. Our automated data collection system makes it possible for each participating ICU to reduce their workload and improve the completeness and validity of data. In our electronic registration system, there are very few missing data concerning patient demographics, information before CVICU admission, CVICU treatment, and the outcome because the data cannot be uploaded to the central server unless the input of all data to the input form is completed. Despite the limited staff resources and dour financial circumstances, the administration of this project has advanced smoothly thanks to the inclusion of specialists with different backgrounds and corresponding managers to participate in CVICU registry using a cost -saving software program and components developed ourselves. This database has been successfully administered thanks to the co-

operative efforts of individuals involved in the CVICU registry project.

On the other hand, several weaknesses should also be noted. First, as automated data collection systems are not used in all institutions, the workloads for data collection may differ among participating CVICUs, leading to variability in data completeness. Second, some useful data items (e.g. comorbidities such as hypertension and diabetes mellitus, and laboratory and/or physiological data beyond 24 h after ICU admission) remain uncollected at present. The data variables included in this registry should be re-evaluated to ensure their appropriateness and rearranged periodically. Finally, the numbers of participating ICUs and patients registered to the database are lower than in other national ICU databases like ANZICS CORE, ICNARC, or NICE. Although the numbers of registered admissions and participating CVICUs have been gradually increasing since the start of the project, further recruitment of new participating institutions for CVICU registry is needed.

CONCLUSION

The use of the CVICU registry, where all the data are centralized and real-time, gives physicians and other health care professionals' continuous insight information of the disease and the medical care dynamics. This helps in reporting statistics to the ministry of health and highlighting the problem areas for the action plan. This action plan may include the availability of various drugs in the dispensaries, resource allocation, preparation of national guidelines for the management of CVICU surgery, and preparation of training and educational programs for improving the lifestyle of the people. Because the CVICU registry provides valuable information about the standards of care provided for patients and according to importance of these registries in quality control and statistical assessment, providing a prediction model to predict the CVICU registry outcomes is essential.

Prediction model in this study is a prognosis model to measure the most important outcomes of CVICU registry including mortality and length of stay. The designers and programmers can apply it as a foundation for the designing, implementation and producing CVICU registry software. By developing this model, it is provided the possibility of using a standard source and reference in order to verify the implementation of a software in presenting of related services, facilitating the selection of available software on the market, and helping to improve the quality of produced applications. Also, add other ICUs such as medical intensive care unit (MICU), neonatal intensive care unit (NICU), pediatric intensive care unit (PICU), surgical intensive care unit (SICU) and trauma intensive care unit (TICU) will be considered in the future plans.

AUTHOR'S CONTRIBUTION

All authors contributed to the literature review, design, data collection and analysis, drafting the manuscript, read and approved the final manuscript.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this study.

FINANCIAL DISCLOSURE

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