



# **Rationale and Design of the Persian CardioVascular Disease Registry (PCVDR): Scale-Up of Persian Registry Of CardioVascular Disease (PROVE)**

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**Abstract:** We aimed to present the methodology of a national registry entitled “Persian CardioVascular Disease Registry (PCVDR).” Persian Registry Of cardioVascular disease (PROVE) was a demonstration registry conducted in Isfahan since 2014 to test the feasibility and practicality of PCVDR in Iran. Built on that experience, the first phase of PCVDR that consist of angiography and percutaneous coronary intervention (PCI) registry at national level started in March 2017. Currently, PCVDR is in place in 19 hospitals, located in 7 provinces. Five questionnaires including basic information, angiography, and PCI techniques, discharge and follow-up were completed for registered

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**patients. Since beginning until October 7th, 2019, the number of angiography and PCI cases registered in all provinces were 37,120 and 16,277, respectively. Of all PCI cases registered, 11,846 patients (72.8%) were followed up until 12 months. We expect that this registry be expanded to cover most hospitals and centers with cardiology departments in the country. (Curr Probl Cardiol 2021;46:100577.)**

## Introduction

**A** high-quality health care for cardiovascular disease (CVD) is necessary in all countries and is consistent with standards of health care. Unfortunately, when the quality of health care for CVD in the Eastern Mediterranean countries is investigated, most often significant “gaps” in care, and unexplained variation in care delivery and outcomes, and medical errors are seen.<sup>1</sup> As such, a major focus of the current national health care debate is to find a way to improve the quality of care in order to fill these gaps, reduce inappropriate variability, and eliminate medical errors. CVD registration systems will help to improve the quality of health care for people with CVD.<sup>2</sup> Information obtained from a registry system can be used for health surveillance, prevention, quality improvement, and research. It will also constitute a basis for management and planning of health services, aimed at people with CVDs, as well as monitoring new cases and the prevalence of these diseases in the population. Inter-regional differences are very important, which reflects not only the difference in disease prevalence but in CVD risk factors like smoking, dietary patterns, level of physical activity, obesity, diabetes, arterial hypertension, and dyslipidemia.<sup>2</sup>

The urge for establishing registration systems for patients undergoing interventional cardiology dates back to 1987. At that time, the American College of Cardiology (ACC) commissioned a standardized system for recording the clinical features and outcomes of patients undergoing cardiac catheterization and percutaneous coronary intervention (PCI). Since 1998, this registry has recorded information of more than 1275 million catheterization visits, 8175 million cardiac catheterizations, and 4596 million PCI at various centers, located in different geographic areas of the United States.<sup>3</sup> Another important registry in this field is the Global Registry of Acute Coronary Events (GRACE), an international registry which covers the information of acute coronary syndromes (ACS) from 94 hospitals in 14 countries with an aim to improve the quality of care for

patients with ACS by demonstrating the differences in patient's characteristics, treatment modalities, and in-hospital and postdischarge outcomes around the world. It began in 1999 and was intended to cover approximately 10,000 patients admitted with ACS, annually.<sup>4</sup> In New York, the Department of Health designed a registration system for uniform reporting of PCI data, evaluating clinical outcomes, and publishing important information to physicians, hospitals, and the general population.<sup>5</sup> The Norwegian Institute of Public Health also launched the Norwegian Cardiovascular Disease Registry, in March 2010 with an aim of providing a tool to conduct clinical research, in order to improve the quality of health care delivery and preparing evidence-based knowledge in the field of primary and secondary prevention on cardiovascular diseases. This registry system covers stroke, myocardial infarction, peripheral vascular surgery, and angiography/PCI.<sup>6</sup>

CVD registration has started in Iran since 2002. However, these registries were local, started with ACS and stroke then expanded to other disease and although in many centers, but all in one province with much lower coverage than a national registry.<sup>7–11</sup> Therefore, The Persian CardioVascular Disease Registry (PCVDR) (available via URL:<http://pcvd.ir>) was designed by the Iranian Network of Cardiovascular Research (INCR) (available via URL:<http://ncrn.net.research.ac.ir>) which is affiliated to the ministry of health in Iran, after testing the feasibility and practicality by a demonstration study.<sup>10</sup> INCR was established in 2010 by the ministry of health and consists of presidents of CVD research centers or cardiology societies or head of cardiac divisions from different provinces in Iran. The INCR main goals were to assist research in the field of CVD management, diagnosis, prevention and control by providing technical assistance, and partial funding. A steering council that consists of all board members is the highest decision-making part of INCR, but all research proposals, tools, and even subjects of new articles using national data are discussed in a scientific committee within the formal structure of INCR. In addition, a monitoring and evaluation committee supervise the implementation of studies funded by the INCR.

This registry was developed, considering the necessity of having a national database to assess the efficacy and outcomes of various CVD interventions, to determine the costs and effectiveness of different diagnosis and treatment methods and to follow the survival and quality of life of CVD patients. In addition, we can use the results of these registries as a useful evidence for developing national guidelines on diagnosis, treatment, and prevention of CVD. In this article, we describe the rationale, design, and methodology of this national registry.

## Material and Methods

### *Demonstration Study*

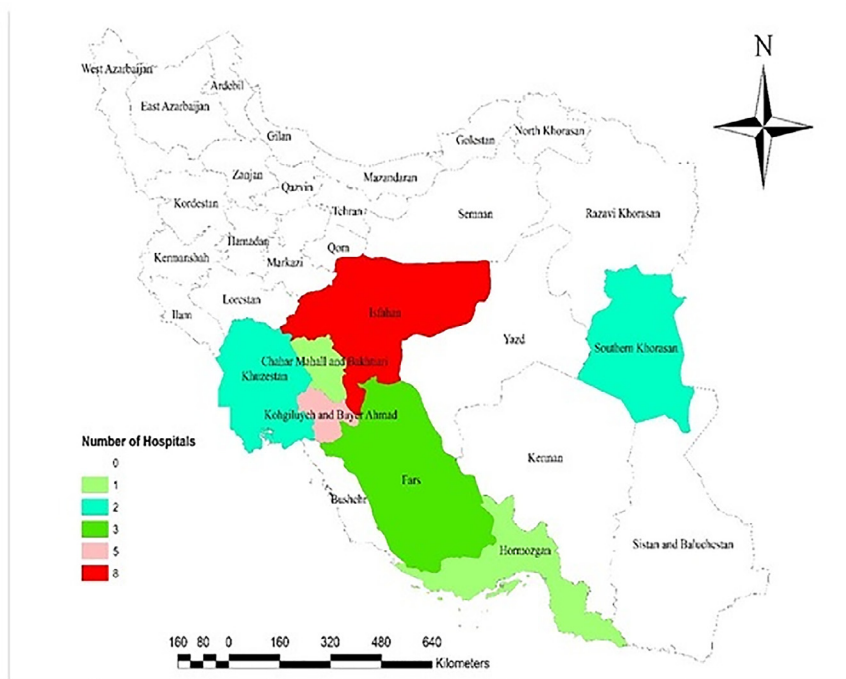
A demonstration study was run in Isfahan (one of the central provinces of Iran) to test the feasibility and practicality of a large-scale registry, before designing and launching the PCVDR. This local demonstration project named “Persian Registry Of cardioVascular disease (PROVE)” in which, different CVD types, including ST elevation myocardial infarction (STEMI), stroke, heart failure, atrial fibrillation, angiography and PCI, congenital heart disease, and chronic coronary ischemic cardiovascular disease were registered in an online database, starting from 2014 in Isfahan. More details of this study are presented elsewhere.<sup>10,12–14</sup> After completing this successful project and identifying its weaknesses and strengths, the first phase of the national implementation was designed in 2016 and implemented in March 2017 in the format of PCVDR. This phase aimed to register all cases of coronary angiography and PCI in participating centers. Registration of STEMI has started later, but we planned for other CVD disorders to be registered next phases.

### *Centers and Patients*

PCVDR started in March 2017 at the Chamran Hospital, as the largest referral hospital in Isfahan province. Request of participating in this registry from other provinces was presented by principal investigators (PI) who were usually a faculty member at that university or a research center in other provinces. This request was initially studied and discussed by the INCR board members and approved, if the 2 criteria (existence of the least needed infrastructure and a partial financial resources) were met. After this primary approval, the PI was in close contact with the INCR scientific committee members, for receiving the required training in order to guide the team of the registry in that province. The aim was to select a university referral hospitals or research centers on cardiology with an attempt to cover more Iranian geographical districts and ethnicities. Currently, PCVDR is in place in 19 hospitals located in 7 provinces. The geographical distribution of these centers throughout the country is shown in [Figure](#). All patients, undergoing angiography or PCI in these centers are enrolled in this registry.

### *Data Collection Questionnaires*

The original questionnaires validated and applied in PROVE were used for the implementation of PCVDR after few modifications. Process



**FIG.** Geographical Distribution of Centers Participating in Persian CardioVascular Disease Registry (PCVDR) in Iran 2019-2020.

of selection and validation of these questionnaires was similar to PROVE. Initially, the research team that consists of experts in Interventional Cardiology, Epidemiology, and Biostatistics have carefully studied many international registries and determined the items needed to be added to this registry. Based on the demonstration study results, each team member independently provided a list of variables that appeared to be necessary for this national registry. During multiple sessions, common items between all researchers were selected and added to the questionnaires or outcomes to follow. Therefore, our questionnaires included data on the patient's demographic status, angiography, and PCI characteristics, patient outcomes while hospitalized or after discharge and during follow-up. The follow-up questionnaire is completed only for patients undergoing PCI at 1-, 6-, and 12-month intervals, after the date of PCI. The type of the data that is recorded in each questionnaire, along with the questionnaire filling location and the responsible personnel, is summarized in [Table](#). All questionnaires are completed when the patient is in the hospital, but the follow-up forms for post-PCI cardiovascular events, are completed by a phone call. If the patient's response is positive, he or she will

be asked to provide documents and medical records of the event. The relevant documents are reviewed by the events' ascertainment committee, and approved on the basis of the consensus of these committee members on the occurrence or nonoccurrence of the CVD events in question. The process of implementation in each of 19 centers in Iran was completely monitored and evaluated by the monitoring and evaluation committee of INCR.

Since July 2019, STEMI registry has also started as part of the PCVDR after several requests by other provinces and its successful implementation in Isfahan in demonstration study. INCR decided that national implementation goes gradually and not in many provinces in short time, therefore, STEMI registry is currently active only in 3 provinces.

## *Data Management*

The management of PCVDR is similar to PROVE with nationwide extent. The registry team consists of 3 groups (1) Interventional cardiologists or fellows, cardiologists or their residents, (2) Research nurses, (3) Research assistants, who are responsible for data entry of the catheterization laboratory department, discharge, and follow-up data, respectively.

Access to the entire national data is only possible for the central data manager. The next level is the data manager of each province with access to local but not the national data. The following level is the hospital manager who has access only to his hospital data. After these 3 levels, there are system users who only have access to the data they have recorded with 24 hours' time to edit a patient's information after recording. The ability to edit after this time requires submitting a request to the hospital manager and re-editing the data within a limited time.

## *Patient Identification and Tracking*

Patients are enrolled in PCVDR based on their Iranian national code that is unique for each Iranian individual. This allows tracking them if any event happen to them, or they are hospitalized for any reason.

## *Quality Assurance and Quality Control*

Quality assurance and control processes are performed by the Quality Assurance and Quality Control subcommittee. The PROVE developed a precise protocol to ensure the quality assurance and control of this registry. Describing all the details of this protocol, goes beyond the scope of

**TABLE.** Registered data in Persian Cardiovascular Disease Registry (PCVDR), Iran, 2019

Location	Data entry of personnel	Data collection	questionnaire	Type of registered data
Catheterization laboratory	Cardiology resident's/ cardiology fellows/ Interventional Cardiologists	Baseline characteristics	General	First and last name Birth-date Gender Nationality National code Phone numbers Insurance status Education level
			History and Risk factors	Height Weight Smoking Alcohol consumption Diabetes mellitus Hypertension Dyslipidemia Chronic kidney disease Currently on dialysis History of prior MI History of prior CABG History of prior PCI Positive Family History Cerebrovascular disease Heart failure(> 14 days) Peripheral arterial disease Noncoronary heart surgery Atrial fibrillation
			Clinical presentation	Stable angina Unstable angina STEMI Non-STEMI Heart failure Peripheral vascular disease Arrhythmia

(continued)

**TABLE.** *(continued)*

Location	Data entry of personnel	Data collection	questionnaire	Type of registered data
				Valvular heart disease
				Cardiogenic shock within 24 h
				Cardiac arrest within 24 h
				Cardiomyopathy or LV Systolic dysfunction
				Asymptomatic
				Other explanations (Clinical)
				History of performed less invasive imaging studies
				History of performed invasive imaging studies
		Angiography		Cardiologist name
				Angiography date
				Angiography time
				Date entry name
				Data intendant name
				Medications
				Contrast volume
				Contrast type
				Fluorescent dose
				Fluorescent type
				Referring status (elective, urgent,...)
				Angiography type
				Angiography approach
				Done LV assessment
				Pressure data (LV, Aorta, PA, RV)
				Aorted Root
				Angiography
				Aortic diameter (mL)
		PCI		Aortic dissection
				Operator name
				Angioplasty date
				Angioplasty time
				Date entry name
				Data intendant name
				Contrast volume
				Fluorescent dose
				Fluorescent type
				Other procedure associated with PCI

*(continued)*



Location	Data entry of personnel	Data collection	questionnaire	Type of registered data
				Atrial access site Emergency of procedure Cardiogenic shock Assessed pre PCI LVEF Indication Procedure medications(24 h prior and during PCI) Important dates and times Drugs used before admission Vital signs ECG data Plan for reperfusion Echocardiography data Laboratory data
Ward	Research nurse	Discharge	STEMI	discharge date discharge time Date entry name Data intendant name Intra procedure events (arrhythmia, death, coronary spasm, dissection, bleeding, pulmonary edema, artery perforation, cardiac arrest, hematoma, successful CPR) Postprocedure events (Myocardial infarction, cardiogenic shock, heart failure, stroke, tamponade, dialysis, other events, blood transfusion, evaluation EF, other vascular events need treat) New (not planned before) intervention

(continued)

TABLE. (continued)

Location	Data entry of personnel	Data collection	questionnaire	Type of registered data
Any location	Research nurse / general physician	Follow-up		Pre-/postprocedure para-clinics (CKMB, troponin I, troponin T, creatinine, hemoglobin) Intrahospital outcome (alive, transferred, deceased) Intrahospital outcome date Intrahospital outcome time Discharge to Rehab recommendation Medications Eligible to follow Follow-up date
				Date entry name Data intendant name Follow-up type Event arise after PCI Again angiography after PCI Again angioplasty CABG after PCI Death

CABG: Coronary Artery Bypass Surgery, CKMB: Creation kinase-MB, LVEF: Left ventricular ejection fraction, MI: Myocardial Infarction, PCI: Percutaneous coronary intervention, STEMI:ST-Elevation Myocardial Infarction.

this article and has been published before.<sup>10</sup> However, here we point out to the activities that have been set up for this purpose:

Registry Quality Assurance

Designing an accurate, complete, and easy-to-use protocol that incorporates all the details of a data registration, resolving user problems, and standardization of the way that the questionnaires are filled by different users.

Conducting training sessions where the general principles of working with the online data entry system were taught in person.

Performing a pilot study on online national data entry system before the formal initiation of the work, and identify and resolve data entry problems by entering test samples into the system.

Making every effort to record the information in real time or as soon as possible, after the patient leaves the station.

### *Quality Control*

Continuous interim analysis to ensure the highest quality and the least missing data entry.

Periodic evaluation of the accuracy of the data entered, as follows: a random sample of patients enrolled by PCVDR is selected, the accuracy of basic data is examined by a telephone interview with the patients, while the accuracy of clinical data is evaluated through visiting and reviewing their hospital records, and a random sample review of their angiography and/or PCI data recorded on angiography or PCI CDs or in their related systems. If there is a significant difference between evaluation and registered results, then a third independent reviewer will be asked to collaborate. Finally, an agreement between 2 of 3 sources of data will be considered.

### *PCVDR Outputs*

Besides providing a medical report of the results to the patients, all other data will be provided to the statistics department in an excel format for further analysis.

## **Results**

Since the launch of the registry until September 14, 2019, the number of coronary angiography and PCI cases registered has been 37,120 and 16,267, respectively. Of all patients, undergoing PCI registered in the system by September 14, 2019, 11,846 patients (72.8%) were followed up.

STEMI registry started since July 2019, and is currently active in 3 provinces of Kohgiluyeh and Boyer Ahmad, Hormozgan and Chaharmahal, and Bakhtiari. The number of registered cases of STEMI in these 3 provinces is 392, 149, and 30, respectively, and 571 in total.

## **Discussion**

According to the global burden of disease reports, the prevalence of IHD in the Middle East/North Africa (MENA) region has estimated over

2000 cases per 100,000.<sup>15</sup> However, Iran as one of MENA countries has more than 9000 cases of CVD per 100,000 persons. Therefore, Iran is one of the countries with the highest CVD rate in the world based on global burden of disease data.<sup>16</sup> To the best of our knowledge, PCVDR is the first national CVD registry in Iran. PCVDR main goals are to answer questions about quality, appropriateness, efficiency of, and access to health care whether management, diagnosis or treatment like interventional cardiology in the field of CVD in Iran.

We started to register coronary angiography and PCI to be able to track patients in terms of CVD outcomes over time. This registry enable the process of tracking outcomes, side effects of medicines used or intervention techniques and devices used to assist consequent modifications and future policies that can be made in the process performing PCI, which can be considered as a postmarketing surveillance too.<sup>17</sup> Furthermore, the cost-effectiveness and safety of these procedures can be improved by designing prospective studies based on this database. On the other hand, according to Dreyer and Garner,<sup>18</sup> although registries are valuable sources of data to assess the effectiveness of therapeutic interventions over time, their role in decision-making is somewhat controversial. Analyzing and interpreting the results requires a great deal of precision. For example, treatment given to a patient who is registered in a registry system is affected by various factors, such as the severity of his/her illness, previous treatments, comorbidities, the expertise and experience of the prescribing physician, and the level of health insurance coverage. These selection biases, along with a systematic loss to follow-up, can severely influence the results of registry-based studies, especially regarding the assessment of therapeutic effects.<sup>18</sup> Therefore, in analyzing registry data, it is important to consider potential bias sources. Quantitative evaluation of the effectiveness of study results by different biases like performing sensitivity analyses can enhance the value of the findings from the registries.<sup>18</sup>

Despite the lack of national registries of different types of CVD in MENA region, it has long history in western countries. CVD registry started in 1987 in the United States by the ACC.<sup>19</sup> CathPCI Registry is part of the National Cardiovascular Data Registry which is a national program that has collected data about coronary angiography and PCI procedures in the United States. Few years later than the Society for Cardiovascular Angiography and Interventions (SCAI) joined the ACC as a partner in the CathPCI Registry. This Registry include 1577 US hospitals, several international sites and more than 12 million patients till 2013.<sup>3</sup>

Another registry with more than 25 years' history is Swedish Coronary Angiography and Angioplasty Registry which was established in 1992. Swedish Coronary Angiography and Angioplasty Registry is a national registry that collect data about all coronary angiographies and PCIs performed in Sweden. In this registry, each catheterization procedure is described with 50 angiographic and 200 PCI variables that include both demographic and procedure-related data.<sup>20</sup>

In France, the ACIRA registry is an on-going, multicenter, cohort study of patients who undergo coronary angiography or PCI in any of the catheterization laboratories. From January 2012 to June 2018 about 147,136 procedures performed on 106,005 patients have been included in the ACIRA registry.<sup>21</sup>

In Asia, PCI registration was done in some countries. The Japanese percutaneous coronary intervention (J-PCI) registry is an ongoing, multicenter registry of the Japanese Association of Cardiovascular Intervention and Therapeutics, which was designed to record clinical characteristics and outcomes of patients who undergo PCI. Since 2013, it has been incorporated into the National Clinical Data system, which is a nationwide prospective online registration system.<sup>22</sup>

In South Asia, a prospective registry study in 89 centers from 10 regions and 50 cities in India was established to document the characteristics, treatments, and outcomes of patients with acute coronary syndromes who were admitted to hospitals. PCI findings of these patients have been reported.<sup>23</sup>

The primary angioplasty registry of Kerala in India is another registry to analyze the quality and outcomes of primary PCI services in this area.<sup>24</sup>

In the MENA region, the Gulf COAST registry was established as a prospective, multinational, cohort-based study in which patients with a confirmed diagnosis of ACS from 29 hospitals in 4 Middle East Gulf countries were recruited from January 2012. Two hospitals in Bahrain; 6 hospitals in State of Kuwait (Kuwait); 12 hospitals in Oman and 9 hospitals in United Arab Emirates were involved in this registry. On-site cardiac catheterization was available in 9 of these hospitals, while another 10 were far from a cardiac catheterization laboratory about 1 hour driving.<sup>25</sup>

In Iran, PROVE registry was implemented in 2014 as a demonstration registry of different types of CVD in Isfahan, a province with 4 million populations in the central part of Iran. Based on the feasibility and practicality of PROVE, a national scale up was performed by the INCD and PCVDR was designed and implemented as a multicenter, prospective,

and nominative registry in 2017. The mission of the PCVDR is to improve the quality of cardiovascular care by providing information, knowledge and tools, and supporting researchers and policy makers to improve patient care and outcomes.

Compared with other national registries, the PCVDR had a moderate coverage until now. The number of catheterization centers connected to our registry has been 19 centers until now. This is lower than many other national registries (Australia: 34 centers,<sup>26</sup> Spain: 101 centers,<sup>27</sup> Britain: 63 centers,<sup>28</sup> and Italy: 49 centers.<sup>29</sup>) Therefore, we need to increase our efforts to add other provinces and hospitals throughout the country.

Despite the necessity of follow-up as an important component of data registry on PCI, according to Cardiology Audit and Registration Standards (CARDS),<sup>30</sup> however, only limited number of worldwide registries perform the follow up. In CathPCI Registry, the main outcome measures include quality process metrics and only in-hospital patient outcomes. However, we visited followed our patients at 1, 6, and 12 months after PCI in the study. Among all essential outcomes for follow-up after PCI that are suggested by CARD,<sup>30</sup> including survival status, angina, dyspnea, hospital readmission, stroke, myocardial infarction, repeated PCI, coronary artery bypass surgery, cardiac rehabilitation and medications, the follow-up questionnaire in our registry only lacks the status of angina and dyspnea due to difficult and nonvalid response in the phone calls follow-up, and cardiac rehabilitation due to its low frequency in Iranian patients.

Generally speaking, we can say PCVDR is methodologically comparable with other popular registries on angiography and PCI worldwide. Some examples are applying a scientific team of investigators for establishing of this registry,<sup>21</sup> using the comprehensive and detailed online questionnaires for data gathering,<sup>19</sup> periodic following up of registered patients undergoing PCI<sup>24</sup> and utilizing valid techniques for quality control of registry.<sup>31</sup>

## *Strengths and Limitations*

A considerable characteristic of this registry is planning for expansion to recruit other centers in other provinces and to cover other types of CVD similar to the process of expansion of PROVE.<sup>10</sup> The advantages of PCVDR are its accurate and high quality data, it's rapid data registration, patients being registered according to their national code, and thus, the ability to track the patient for future events or hospitalizations and to prevent the duplication of same patient registry. Being an online system, and consequently allowing timely recording of data, being sensitive to

different data linked to each other, and as a result, preventing unrealistic data inconsistencies, the conditional data saving, which is subjected to completing all the necessary fields, and allowing to make outputs of accurate and complete data that are entered. However, the most important problem in this registration system is the patient follow-up. Unfortunately, in spite of our team extensive efforts we were able to follow 72% of all patients until 12 months, and many patients were not responsive to our team phone calls for follow-ups. Therefore, it is not possible to be aware of the occurrence of CVD or other future events. Other problem is the time-consuming completion of questionnaires. Since basic patient information is also recorded in the hospital chart, linking this registry system and the patient chart through a unique national code can save users a significant amount of time. However, hospitals' administrative systems have opposed this linkage because of their commitment to maintaining patient information security. Other problem is the shortage of staff due to financial issues. The result is an increased workforce pressure on limited staff, which leads to unfinished jobs. INCR steering council is trying to alleviate the problem of workforce shortfalls by convincing policymakers to allocate dedicated funding for this important national registry. In addition, in some centers, PCI and coronary registry became as part of fellow's duties.

## **Conclusion**

PCVDR can provide accurate and precise information on CVD patients to physicians, researchers, and policy makers and take effective steps to improve the physical condition, quality of life and life expectancy of CVD patients. It can be a platform for experts to develop national guidelines and recommendations. While the current goal of PCVDR is to recognize the quality of care provided to patients undergoing coronary angiography and PCI and to serve as a platform for quality improvement, policy makers can use its results as part of broad quality programs and by investigators for cutting-edge health services research. PCVDR findings could also be used for multicenter interventional research and international collaborations.

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