ORIGINAL RESEARCH

Cardiovascular Disease Performance Measures in the Outpatient Setting in India: Insights From the American College of Cardiology's PINNACLE India Quality Improvement Program (PIQIP)

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***Background*—**India has a growing burden of cardiovascular disease (CVD), yet data on the quality of outpatient care for patients with coronary artery disease, heart failure, and atrial fibrillation in India are very limited. We collected data on performance measures for 68 196 unique patients from 10 Indian cardiology outpatient departments from January 1, 2011, to February 5, 2014, in the American College of Cardiology's PINNACLE (Practice Innovation and Clinical Excellence) India Quality Improvement Program (PIQIP). PIQIP is India's first national outpatient CVD quality-improvement program.

***Methods and Results*—**In the PIQIP registry, we estimated the prevalence of CVD risk factors (hypertension, diabetes, dyslipidemia, and current tobacco use) and CVD among outpatients. We examined adherence with performance measures established by the American College of Cardiology, the American Heart Association, and the American Medical Association Physician Consortium for Performance Improvement for coronary artery disease, heart failure, and atrial fibrillation. There were a total of 68 196 patients (155 953 patient encounters), with a mean age of 50.6 years (SD 18.2 years). Hypertension was present in 29.7% of patients, followed by diabetes (14.9%), current tobacco use (7.6%), and dyslipidemia (6.5%). Coronary artery disease was present in 14.8%, heart failure was noted in 4.0%, and atrial fibrillation was present in 0.5% of patients. Among eligible patients, the reported use of medications was as follows: aspirin in 48.6%, clopidogrel in 37.1%, and statin-based lipid-lowering therapy in 50.6% of patients with coronary artery disease; RAAS (renin–angiotensin–aldosterone system) antagonist in 61.9% and beta-blockers in 58.1% of patients with heart failure; and oral anticoagulants in 37.0% of patients with atrial fibrillation.

***Conclusions*—**This pilot study, initiated to improve outpatient CVD care in India, presents our preliminary results and barriers to data collection and demonstrates that such an initiative is feasible in a resource-limited environment. In addition, we attempted to outline areas for further improvement in outpatient CVD care delivery in India. **(*J Am Heart Assoc*. 2015;4:e001910 doi: 10.1161/JAHA.115.001910)**

Key Words: American College of Cardiology • India • performance measure • PINNACLE India Quality Improvement Project (PIQIP) • Practice Innovation and Clinical Excellence (PINNACLE) • quality improvement

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India is currently the second most populous country in the world, with a population of >1.2 billion.[1] Although there is a paucity of contemporary data on the prevalence of coronary artery disease (CAD) in India, various preliminary studies have reported high CAD prevalence, approaching 11% in the urban population and 7% in the rural population.[2] It has been estimated that ≈9.2 million productive years of life in India were lost to cardiovascular disease (CVD) in the year 2000, a number that is expected to rise to 18 million by 2030 (10 times the burden in the United States).[3,4] There has also been an increase in the prevalence of traditional CAD risk factors in India because of a combination of behavioral risk factors, such as tobacco use, physical inactivity, and diets low in fruit and vegetable content, paralleled by low levels of awareness and treatment and control of CAD risk factors.[5]

Although prior facility-based research on cardiovascular care in India has focused on in-hospital processes and outcome measures for stroke and myocardial infarction, for example, through the Kerala Acute Coronary Syndrome Registry,[6] data on outpatient facility-based cardiovascular care in India are limited, with no widespread mechanism to offer feedback to clinicians on their performance with outpatient CVD care. Furthermore, there are only ≈4000 cardiologists in India, and the ratio of physicians to cardiac patients is disproportionately low.[4] Popular medical care providers may see >200 patients each day.[7] Consequently, busy practitioners are too overwhelmed to report or attempt to improve the quality of outpatient CVD care.[4]

Accordingly, the American College of Cardiology (ACC), in collaboration with local Indian cardiologists interested in participating in the Practice Innovation and Clinical Excellence (PINNACLE) India Quality Improvement Program (PIQIP), began data collection on the quality of outpatient care for CVD risk factors (hypertension, diabetes mellitus, current tobacco use) and disease states (CAD, heart failure [HF], atrial fibrillation [AF]) in India for the PIQIP, an extension of the ACC's US-based PINNACLE registry.[8] The PINNACLE registry is a national prospective office-based quality-improvement program for cardiac care, designed to capture, report, and improve compliance with outpatient performance measures in the United States.[8]

Methods

Data Collection in PIQIP

We extended the PINNACLE registry to India in 2011 under PIQIP, the first outpatient CVD care data collection and reporting program implemented in the country (Figure 1). Prior to its inception, local Indian cardiologists were contacted for evaluation of the feasibility of data-collection methods (eg, paper, Web-based, tablet, and local versus cloud-based storage) and for modification of the PINNACLE data dictionary and paper data-collection form. Following establishment of data-collection methods and modification of the data-collection form to meet the requirements of the Indian cardiologists, a small-scale pilot project was conducted, including 300 unique patient visits and 6 cardiologists from the states of Bihar and Maharashtra, to assess data-capture feasibility. The PIQIP Patient Care Tool (https://ehr.pinnaclehqi.org/PIQIPHQI/login.aspx), a Web-based data-collection form, was also designed based on a 1-month field trial at Ruby Hospital in Pune, India. Academic and private cardiology practices were then invited to participate voluntarily in PIQIP. PIQIP representatives conducted site visits at each of the interested practices to install standardized equipment and resources for data acquisition, including a scanner and Android-based data-collection software. PIQIP representatives also provided training to practice personnel for initial data capture. Sites from 4 major Indian cities (Ahmedabad, Mumbai, Pune, and Hyderabad) were represented in this registry (Figure 2).

Patients evaluated in outpatient departments (OPDs) in India usually receive an OPD card that lists basic demographic information, medical conditions, laboratory data, and related prescriptions. Unlike the PINNACLE registry in the United States, for which data collection is achieved through integration with practices' electronic medical records,[8] data in PIQIP are collected primarily by trained personnel scanning each patient's OPD card and extracting the requisite information into the PIQIP Patient Care Tool and then uploading the information to a tablet computer that physicians can use to track their patients' progress on a longitudinal basis.[9] The data-entry staff held bachelor degrees in pharmacy. A 3-tiered process was instituted to ensure data integrity. Tier 1 was front-line data entry, tier 2 involved quality assurance by sampling 25% of the charts, and tier 3 involved auditing ≈5% charts.

Study Population

For the purposes of this study, we included data on patients enrolled in PIQIP from January 1, 2011, to February 5, 2014. All patients from participating cardiology OPDs were eligible for the study, with 100% sampling from each participating OPD. The final study population included 68 196 unique patients from 10 cardiology OPDs, encompassing a total of 155 953 patient encounters. For this study, risk factors and disease states were defined based on physicians' documentation. Data on medication use in different CVD states represent use of medications by unique patients at any encounter.

Statistical Analyses

In the current study, we examined the prevalence of CAD, HF, and AF for the first 68 196 patients. We also provided basic

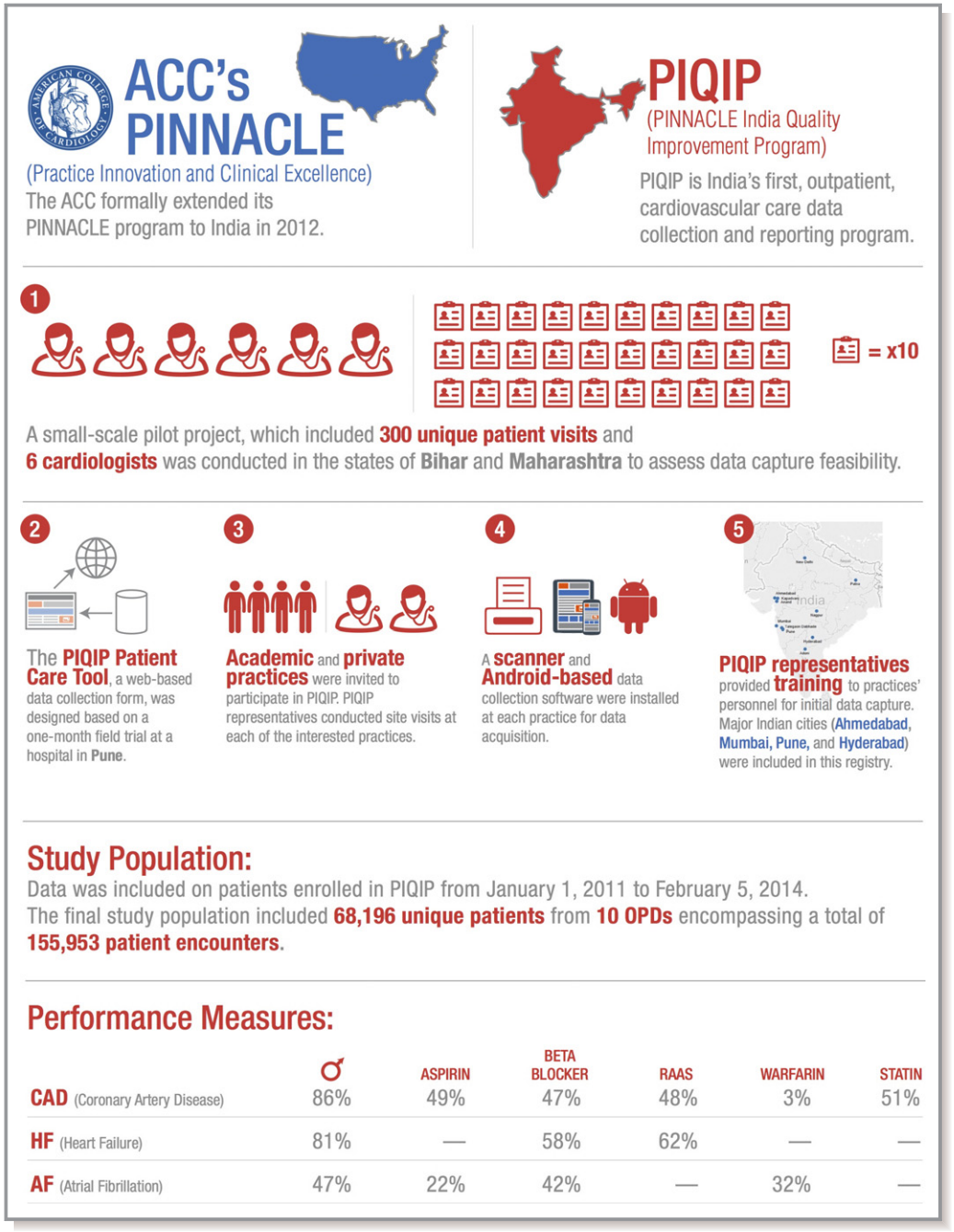

Figure 1. Infographic demonstrating, in a chronological fashion, the data-collection steps that were implemented by the American College of Cardiology for the PINNACLE India Quality Improvement Program. ACC indicates American College of Cardiology; AF, atrial fibrillation; CAD, coronary artery disease; HF, heart failure; OPD, outpatient department; PINNACLE, Practice Innovation and Clinical Excellence; RAAS, renin–angiotensin–aldosterone system.

demographic data, presence of related cardiovascular risk factors, and use of evidence-based medication for each disease condition. All analyses were conducted with SAS version 9.3 (SAS Institute).

The PINNACLE registry in the United States had a waiver of informed consent; although the PIQIP did not undergo institutional review board application in India, standard practices for data collection and patient data protection as in the United States, including handling of patient data in compliance with Health Insurance Portability and Accountability Act practices, were followed. The vendor conducting the data entry in the PIQIP was the same vendor used for the PINNACLE registry in the United States.

Figure 2. Map of India showing towns and cities where the Practice Innovation and Clinical Excellence (PINNACLE) India Quality Improvement Program was conducted at 10 different sites, including 4 major Indian cities (Ahmedabad, Mumbai, Pune, and Hyderabad).

Results

Of the 10 cardiology OPDs that participated in the study, 7 were private OPDs, 2 were run by trusts, and 1 had an academic affiliation with a medical school. Six of the 10 OPDs were based in major cities (Ahmedabad, Mumbai, Pune, and Hyderabad). Collectively, 115 cardiologists from these 10 OPDs submitted data to PIQIP.

There were a total of 68 196 unique study patients, encompassing a total of 155 953 patient encounters. The mean age of the study population was 50.6 years (SD 18.2 years). A majority of the represented population was aged <65 years (53 497 patients [78.5%]) and was male (47 697 patients [70.0%]). The mean blood pressure was 126/78 mm Hg (SD 20/11 mm Hg), and the mean body mass index was 25.8 (SD 4.8) in kg/m^2.

CAD Risk Factor Profile in PIQIP

Hypertension was the most prevalent CAD risk factor, reported in 20 268 patients (29.7%), of which 14 400 (71.0%) were men. Diabetes mellitus was reported in 10 167 patients (14.9%), of which 7675 (75.0%) were men. Current tobacco use of any type was present in 5202 patients (7.6%), of which 4163 (80.0%) were men (Table 1).

Profile of Patients With CAD and Evidence-Based Medication Use in CAD Patients

CAD was present in 10 106 patients (14.8%) who were predominantly male (8639 patients [85.5%]). The mean age of the CAD population was 58.3 years (SD 11.4 years), with a lower mean age of men represented (57.9 years [SD 11.3 years]) compared with women (60.9 years [SD 11.6 years]). Hypertension, diabetes mellitus, and current tobacco use of any type were present in 5124 (50.7%), 3327 (32.9%), and 342 (3.4%) patients with CAD, respectively.

Medication use among CAD patients is summarized in Table 2. Aspirin was prescribed for 4908 CAD patients (48.6%), clopidogrel was prescribed for 3747 (37.1%), and prasugrel was prescribed for 696 (6.9%). Similarly, beta-blocker and RAAS (renin–angiotensin–aldosterone system) antagonist (including angiotensin-converting enzyme inhibitors and angiotensin receptor blockers) therapies were prescribed in 4762 (47.1%) and 4863 (48.1%) CAD patients, respectively. The use of lipid-lowering agents was documented in 5385 CAD patients (53.3%), with 5112 (50.6%) documented as being on a statin-based therapy and 273 (2.7%) documented as receiving non–statin-based lipid-lowering therapy.

Profile of Patients With HF and Evidence-Based Medication Use in HF Patients

History of HF was present in 2752 patients (4.0%) who were predominantly male (2230 patients [81.0%]). The mean age of patients with HF was 56.9 years (SD 13.8 years).

Medication use among HF patients is summarized in Table 3. Prescription for RAAS antagonist therapy was documented in 1704 patients (61.9%), beta-blocker use was documented in 1599 (58.1%), and diuretic use was documented in 1384 (50.3%).

Profile of Patients With AF and AF Medication Use

History of AF was documented in 348 patients (0.5%). The prevalence of AF was 0.3% (163 patients) in men and 0.9% (178 patients) in women. The mean age of the study population with AF was 56.1 years (SD 14.9 years). A majority of these patients were aged <65 years (239 [68.7%]) compared with patients aged 65 to 74 years (74 [21.3%]) or ≥75 years (35 [10.0%]). Hypertension was present in 39.6% (138 patients), followed by diabetes mellitus in 16.4% (57 patients) and HF in 10% (34 patients). CHADS2 score was 0 for 179 patients (51.4%), 1 for 105 patients (30.2%), 2 for 55 patients (15.8%), 3 for 8 patients (2.3%), and 4 for 1 patient. Beta-blocker and calcium-channel antagonist use was documented in 147 (42.2%) and 26 (7.5%) patients, respectively. Similarly, use of systemic anticoagulation with oral vitamin K antagonist (warfarin) or one of the novel oral anticoagulants (dabigatran) was documented in 129 patients (37.0%), with a vast majority (112 patients, 87.0%) prescribed warfarin therapy. Antiplatelet agents concomitantly used in patients with atrial fibrillation included aspirin (77 patients [22.1%]) and clopidogrel (40 patients [11.5%]). All patients with AF who were also prescribed clopidogrel had concomitant CAD. Medication use among AF patients is summarized in Table 4.

Table 1. Prevalence of Cardiovascular Disease Risk Factors and Coronary Artery Disease, Heart Failure, and Atrial Fibrillation in the PINNACLE India Quality Improvement Program Registry

Disease State	Total Patients, % (n=68 196)	Men (n=47 697)	Women (n=20 499)
Hypertension, n (%)	20 268 (29.7)	14 400 (71)	5834 (29)
Diabetes mellitus, n (%)	10 167 (14.9)	7675 (75)	2479 (24)
Dyslipidemia, n (%)	4444 (6.5)	3095 (70)	1343 (30)
Tobacco use, n (%)	5202 (7.6)	4163 (80)	1038 (20)
CAD, n (%)	10 106 (14.8)	8639 (85.5)	1457 (14.5)
HF, n (%)	2752 (4)	2230 (81)	522 (19)
AF, n (%)	348 (0.5)	163 (47)	178 (51)

AF indicates atrial fibrillation; CAD, coronary artery disease; HF, heart failure; PINNACLE, Practice Innovation and Clinical Excellence.

Table 2. Medication Use for Coronary Artery Disease in the PINNACLE India Quality Improvement Program Registry

Medication	Patients (n=10 106)	CAD Patients, %
Aspirin	4908	48.6
Clopidogrel	3747	37.1
Prasugrel	696	6.9
Beta-blocker	4762	47.1
RAAS antagonist	4863	48.1
ACE inhibitor	3212	31.8
ARB	1651	16.3
Lipid-lowering therapy (statin-based)	5112	50.6
Lipid-lowering therapy (nonstatin)	273	2.7
Warfarin	314	3.1
Dabigatran	8	0.01

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CAD, coronary artery disease; PINNACLE, Practice Innovation And Clinical Excellence; RAAS, renin–angiotensin–aldosterone system.

Discussion

PIQIP is the first outpatient CVD-care data-collection and reporting program implemented in India. In a country with a disproportionate provider/patient ratio[10] and low levels of government funding for quality improvement, physician-driven initiatives for practice-based learning and improvement could be considered an unrealistic expectation.[4] PIQIP demonstrates the feasibility of data acquisition in this challenging environment.

In these preliminary analyses from the PIQIP registry, we examined clinical profiles of the first 68 196 CVD outpatients, encompassing 155 953 patient encounters from 10 cardiology OPDs in India. There were several important findings. Although there seemed to be a significant difference by sex among CVD encounters, with women composing only 7% and 3% of patients with CAD and HF, respectively, more data are required before a firm conclusion on gaps in access to specialty care by sex can be made. Other significant observations from our pilot study include younger mean age of the represented populations with CVD and relatively lower prescription of evidence-based medications for CAD, HF, and AF. Only a large-scale nationwide study in India with adoption of several methods to overcome the barriers that we have encountered with our data collection and use of quality-control measures to ensure data integrity can provide better evidence about cardiovascular demographics and evidence-based medication use in India. It is possible that local documentation practices could explain the lower medication prescription and prevalence of tobacco use seen in our study, especially because robust medical record keeping in India is not common. A lower prevalence of tobacco use in our cohort compared with previously published data[11] could also reflect other differences such as a higher rate of smoking cessation in patients with established CVD and variation based on the specific study population (ie, patients seeking care in cardiology OPDs in India in our study compared with the general Indian population). Nevertheless, our study shows the feasibility of initiating such a novel quality-improvement program in a resource-limited setting such as India.

Unique challenges were related to the implementation of PIQIP. A majority of the OPDs participating in the registry did not use electronic medical records. Although health information management sections of hospitals store paper charts for inpatients following hospitalization for a specific duration before records are destroyed, medical record keeping for outpatients in India is mostly nonexistent. Patients who were evaluated in the OPDs in hospitals or offsite clinics usually received an OPD card that they were responsible for and brought to their OPD visits. Each outpatient visit usually generated a new OPD card, regardless of whether the index visit was an initial or follow-up appointment. Consequently,

Table 3. Medication Use for Heart Failure in the PINNACLE India Quality Improvement Program Registry

Medication	Patients (n=2752)	HF Patients, %
RAAS antagonist	1704	61.9
ACE inhibitor	1185	43
ARB	519	18.9
Beta-blocker	1599	58.1
Diuretics	1384	50.3

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; HF, heart failure; PINNACLE, Practice Innovation and Clinical Excellence; RAAS, renin–angiotensin–aldosterone system.

Table 4. Medication Use for Atrial Fibrillation in the PINNACLE India Quality Improvement Program Registry

Medication	Patients (n=348)	AF Patients, %
Beta-blocker	147	42.2
Calcium-channel blocker	26	7.5
Oral anticoagulants	129	37
Warfarin	112	32.2
Dabigatran	17	4.8
Aspirin	77	22.1
Clopidogrel	40	11.5

AF indicates atrial fibrillation; PINNACLE, Practice Innovation and Clinical Excellence.

linking data from one visit to another was difficult, given the lack of unique identification of patients from visit to visit. Given their clinical responsibilities, including high patient volume, physicians were reluctant to change their workflow and to use the Web-based tool, adding further complexity to data acquisition; however, physicians were ready to scan prescription or OPD cards and send them to the ACC site in Pune for data entry. In addition, ancillary staff responsible for scanning prescriptions or OPD cards required repeated training to operate the software appropriately, and that put increased demand on resource availability and funding. Finally, prescriptions or OPD cards were hand-written by physicians and were not always legible, making data extraction difficult. With wider implementation of electronic medical records in India in the future, we expect some of these barriers to be less problematic. Moreover, careful resource allocation to improve documentation metrics without adversely affecting clinical work flow will be an important step to improve the quality of cardiovascular care in India.

Several strategies are being considered for the future course of the PIQIP registry: progression to a model that enables OPDs to become self-sufficient in data collection and reporting and, consequently, less dependent on ACC staff; enhanced data capture including socioeconomic variables, medication contraindication, and laboratory values; and expansion of the program to other sites across India. If feasible, to improve data integrity, we will consider additional measures in the future, such as validation for the presence of risk factors such as hypertension and diabetes by examining measured blood pressure, blood glucose (or hemoglobin A1c), and medication use for such conditions in a random sample of patients from each site. Similarly, presence of cardiac diagnoses can be validated by examining documentation of coronary angiograms or noninvasive tests for CAD, echocardiogram for HF, and electrocardiogram for atrial fibrillation in a randomly selected sample. These efforts at data collection and validation of cardiovascular risk factors and disease conditions will be coordinated closely with local cardiologists.

This study has several important limitations. First, patients were followed longitudinally only if they returned to a data-collecting OPD; in other words, longitudinal data could be collected only for patients who returned to a site that they had visited before. Second, the study relied on clinicians for data collection; therefore, the success of the program was contingent on clinicians' diligence regarding medical record documentation, which may not be complete. Contraindication to an indicated medication, for example, was not captured by the PIQIP registry but could account for the lower rate of medication prescriptions. In addition, it is possible that there was ascertainment bias related to capture of risk factors (ie, hypertension, diabetes mellitus, and current tobacco use) in this registry. Furthermore, CHADS2 score was used for nonvalvular AF, and data on etiology of AF were not available. The World Bank data from India demonstrates that the average doctor–patient interaction lasts for 3.8 minutes, in which the doctor asks 3.2 questions and performs slightly >1 physical examination procedure.[7] Traditionally, physicians in India document only the diagnosis followed by a list of prescription medications on OPD cards, unlike US office visit documentation, which comprises a detailed history and physical examination, medications, allergies, physical examination, laboratory and diagnostic data, and assessment and plan information. Although data-collection forms were designed to encourage improved documentation and capture of all key encounter variables, physicians could not be compelled to document missing diagnoses, laboratory values, or medications. Furthermore, despite the data being extracted by trained individuals, data were not reviewed later by an independent physician or research nurse. Consequently, the lower reported use of evidence-based medications in this registry could reflect the local documentation practices in India. Third, given their participation in a quality-improvement registry, the participating practices could represent highly motivated sites, and thus these data may not be generalizable to the larger Indian population with CVD. Finally, it is possible that the cost associated with medications could influence the lower prescription rate in India. Despite these limitations, the PIQIP registry collected real-world data. This approach was advantageous for the swiftness of setup and for scalability, sustainability, and cost.

Conclusion

In this first report from the PIQIP registry, we showed the feasibility of studying outpatient quality of cardiovascular care in India. In addition, this report describes several challenges unique to outpatient quality measurement in India and outlines future strategies to overcome them.

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