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American College of Cardiology (ACC)'s PINNACLE India Quality Improvement Program (PIQIP)—Inception, progress and future direction: A report from the PIQIP Investigators

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ABSTRACT

Cardiovascular diseases have surpassed infectious disorders to become the leading cause of morbidity and mortality in India.¹ A national-level registry comprehensively documenting the current-day prevalence of cardiovascular risk factors and disease burden among patients seeking care in the outpatient setting in India is currently non-existent. With a burgeoning urban population, the cardiovascular disease burden in India is set to skyrocket, with an estimated 18 million productive years of life lost by 2030.² While there are limited quality improvement registries in India, for example, the Kerala acute coronary syndrome and Trivandrum heart failure registries, their focus is on in-patient care quality improvement, while the vast majority of patients with cardiovascular diseases worldwide, including India, interact with the health care system in the outpatient setting.^{3,4} Recognizing this unmet need, the American College of Cardiology partnered with local stakeholders in India to establish India's first outpatient cardiovascular disease performance measurement initiative in 2011, the PINNACLE (Practice Innovation and Clinical Excellence) India Quality Improvement Program (PIQIP).⁵ This manuscript discusses the inception of the PIQIP registry, the progress it has made and challenges thus far, and its future direction and the promise it holds for cardiovascular care quality improvement in India.

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1. Introduction

Cardiovascular diseases (CVD) have become the leading cause of mortality in India, forcing local public health authorities and the World Health Organization to shift their focus and resources from infectious diseases to CVD prevention, diagnosis and treatment.¹ Reliable data on true prevalence of CVD risk factors, coronary artery disease (CAD), and heart failure (HF) in the Indian subcontinent are lacking, largely due to the absence of a national

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registry that can comprehensively account for disease burden in the Indian population. This is due to lack of federal funding to construct a national database, which can be a large undertaking given the current census of 1.2 billion people in India, and also in part due to a skewed provider:patient ratio, resulting in significant clinical burden on Indian doctors with no incentive, resources or time to invest in performance measurement and quality improvement.^{5,6} There are a few laudable examples of in-patient registries in India, for example, the Kerala acute coronary syndrome (ACS) and Trivandrum HF registries, that have focused on reporting quality metrics for in-hospital and discharge care planning.^{3,4} However, similar efforts in the outpatient setting have been lacking, with the understanding that a vast majority of patients with CVD risk factors and CAD worldwide, including India, access medical care in the outpatient clinics. In recognition of this unmet need, the American College of Cardiology, in collaboration with local stakeholders (Indian cardiologists interested in performance measurement in their outpatient clinics) established the PINNACLE (Practice Innovation and Clinical Excellence) India Quality Improvement Program (PIQIP), India's first outpatient cardiovascular performance measurement initiative.⁵

2. PIQIP—inception

PIQIP was established in 2011, following a successful pilot study initiated in 2008 that established feasibility of data collection on 300 patients in 6 cardiologists' offices in Bihar and Maharashtra.⁵ The pilot study validated the PIQIP Patient Care Tool, a web-based tool customized for data collection in cardiology outpatient departments (OPDs) in India, following a trial in a hospital in Pune, Maharashtra.⁵ Interested practices (academic and private practice with Indian cardiologists as physician champions and local stakeholders) were invited to participate and contribute their data in the PIQIP registry.⁵ Hand-written OPD cards were scanned by ACC-trained staff at each of the participating sites, and requisite information extracted into a PIQIP Patient Care Tool, the fidelity of which was validated by personnel holding bachelor degrees in pharmacology.^{6,7} A cloud-based storage application enabled downloading of data into physicians' personal computers, facilitating long-term longitudinal follow-up of patients' co-morbidities and medications.^{6–8}

The PINNACLE registry in the United States has a waiver of informed consent.⁵ Due to a lack of local standards governing patient data collection, the PIQIP did not undergo institutional review board application in India.^{6,7} Data collection was held to the standards of the Health Insurance Portability and Accountability Act practices, and the same vendor that was used for the PINNACLE registry in the United States conducted data entry in PIQIP.^{5–7} Participation in the registry was voluntary, and all patients receiving care in participating practices were eligible for entry into the registry.^{6,7}

3. PIQIP—progress

Since its inception in 2011, the PIQIP has made pivotal strides in collecting and reporting outpatient cardiovascular disease performance measurement metrics in Indians. The PIQIP now has 17 participating cardiology practices, a vast majority situated in urban centers in India (Adoni, Ahmedabad, Anand, Delhi, Hyderabad, Mumbai, Nagpur, Nashik, Patna, Pune, Talegaon) (Fig. 1), that have contributed data on >100,000 patients (321,628 patient encounters).⁹ Although the data represents a fraction of the Indian population at large, it has provided contemporary insights into the CVD burden in urban India, and prescription patterns of cardiologists taking care of patients with CAD, HF and atrial fibrillation.⁵

The first report from the PIQIP registry that described data-collection methods on 68,196 patients from 10 participating OPDs documented a CAD prevalence of 15%, with hypertension being the most common CVD risk factor present in 30% of CAD patients, followed by diabetes mellitus (15%) and tobacco use (8%).⁵ Aspirin and statin prescription documentation in patients with CAD was 49% and 51%, respectively, demonstrating low prescription of guideline-directed medical therapy, at least in part due to a lack of robust medical record-keeping in the outpatient setting in India.⁵ Similarly, in patients with HF, prescription of beta-blockers and renin-angiotensin-aldosterone system antagonists were documented in 58% and 62% patients, respectively.⁵

The second report from the PIQIP registry focused on quality of outpatient cardiovascular care in patients with HF with reduced ejection fraction (HFrEF), defined as a left ventricular ejection fraction $\leq 40\%$.⁶ Of the 75,639 patients that were then enrolled in the registry, ejection fraction was documented in 46% patients, and 21% patients had ejection fraction $\leq 40\%$.⁶ Hypertension and diabetes were the most prevalent CVD risk factors, similar to CAD patients described in the first report, present in 37% and 23% patients, respectively.⁶ A history of myocardial infarction or CAD, however, was documented in only 17% and 27% patients with HFrEF.⁶ Similar to findings in the first report, prescription of beta-blockers, renin-angiotensin-aldosterone system antagonists, and their combination were documented in only 35%, 34%, and 30% patients with HFrEF, respectively, once again demonstrating low prescription of guideline-directed medical therapy.⁶ Importantly, documentation of guideline-directed medical therapy gradually increased over time, with documentation of beta-blockers and renin-angiotensin-aldosterone system antagonists increasing from 28% each in the first study quarter (January–March 2008) to 51% and 45%, respectively, in the last study quarter (July–September 2014).⁶

Both reports also demonstrated a younger mean age of represented populations with CVD—58 years in the first report, and 56 years in the second report.^{5,6} There was also a significant difference by sex, with women composing only 7% and 3% of patients with CAD and HF, respectively, in the first report, and 23% of patients with HFrEF in the second report, thus forming the focus of the third report from the PIQIP investigators.^{5–7}

The third report from the PIQIP registry was the largest study to date examining gender differences in CVD care in the outpatient setting in India.⁷ Comprising data on 98,041 patients, the study showed that women represented 32% of the entire patient cohort. Women participants in the PIQIP registry were younger (mean age of 49 years vs. 52 years in men), had a higher prevalence of cardiovascular co-morbidities (hypertension in 62% vs. 46% in men and diabetes in 40% vs. 35% in men), and lower prescription documentation of evidence-based medications for CAD (aspirin in 38% vs. 50% in men; aspirin or thienopyridine combination in 47% vs. 57% in men; and beta-blockers in 37% vs. 48% in men) and HFrEF (beta-blockers in 31% vs. 37%; and renin-angiotensin-aldosterone system antagonists in 29% vs. 35% in men) compared with men.⁷

Several challenges were encountered in establishing and beginning data collection for the PIQIP registry. Cardiologists running busy OPDs were understandably not amenable to amend their workflow to start using the PIQIP Patient Care Tool. Scanned OPD cards were not always legible for trained personnel to extract high-fidelity data from all patient visits. In addition, with non-existent outpatient medical record-keeping in India, each patient visit generated a unique patient identification or medical record number, making data linking between visits difficult.



Fig. 1. Map of India showing towns and cities where the PINNACLE (Practice Innovation and Clinical Excellence) India Quality Improvement Program (PIQIP) is being currently conducted at 17 different sites.

4. PIQIP—future direction

In a challenging health care environment with limited resources and excessive workload on clinicians (World Bank data from Delhi, India has demonstrated a typical doctor–patient interaction lasting for 3.8 min in busy OPDs), PIQIP has successfully demonstrated the feasibility of data collection to conduct performance measurement for outpatient cardiovascular care quality improvement in India.^{5,10} Utilization of scanners and cloud-based technology for data extraction and downloading capabilities into physicians' personal computers for long-term follow-up is an example of innovation circumventing hurdles for

data collection in high-volume OPDs with no incentive, resources or time for quality improvement initiatives.⁸ As PIQIP continues its maturation into potentially a robust national-level registry, the focus will be on inclusion of larger practices, both academic and private practice, adding significantly to its patient database, and enhanced data capture to include socioeconomic variables, medication contraindication and laboratory values.⁵ Also, improvement of data integrity through validation of diagnoses in OPD cards by documenting results of noninvasive and invasive tests such as echocardiograms and angiograms will be an important step to ensure data fidelity.⁵ In the future, regular audit and feedback reports on prescription of guideline-directed medical therapy for

CAD, HF and atrial fibrillation would be important, and hopefully drive both better documentation and better quality of CVD care delivery in India.

The PIQIP registry was envisioned as the first of the global iterations of the PINNACLE registry, hoping to increase the ability of scientists and practitioners to benchmark performance and create novel scientific research across multiple countries and settings of care. PIQIP plans to grow at an increasing rate, and hopes to double the number of participating sites during each year of operation. It is also essential that a representative cross-section of care settings be obtained, and thus the outreach and enrollment efforts target both private and academic outpatient centers in equal measure. Similarly, the geographic spread across India must keep a balanced ratio of participants in both rural and urban settings, across all Indian states. The aggregate data will be made available for analysis to researchers and public health authorities, as well as the physicians and administrations of the participants themselves, in keeping with the ACC's well-tested protocols surrounding research and publications from their registry data.

A crucial next step is to identify the role of electronic health records (EHRs) in quality improvement in health care delivery in India. Under the current policies initiated by the Indian government, there is a push toward implementation of EHRs in federally-funded hospitals in India.¹¹ However, the evidence base supporting this policy change is lacking.¹² Implementation of EHRs, at least in the short-term, will augment health care costs in resource-limited settings due to allocation and training of additional personnel and resources.¹³ The data from the PIQIP registry will shed light on differences in prescription of guideline-directed medical therapy among EHR- vs. non-EHR-capable practices to evaluate for impact of EHR in prescription pattern and quality of cardiovascular care delivery in cardiology OPDs in India, impacting future health policy decisions with regard to widespread adoption and implementation of EHRs in public and private OPDs and hospitals in India.

5. Conclusion

PIQIP is a significant milestone in an effort to initiate and foster quality improvement in outpatient cardiovascular care setting in India.⁵ Its growth and sustenance are vital for cardiologists and their patients in India. It has the potential to become the leading national-level outpatient cardiovascular registry to improve CVD care delivery in India.

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Conflicts of interest

The authors have none to declare.

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