



WHITEPAPER

Comparing Registry and Electronic Health Record (EHR) Data for Real-World Evidence Generation: Heart Failure as a Case Study

Mac Bonafede
Nam Nguyen

INTRODUCTION

Heart failure is becoming an increasingly heavy health burden worldwide, affecting an estimated 23 million people. Classification of heart failure patients depends primarily on the degree of left ventricular systolic dysfunction, which is measured via echocardiography.

Once heart failure patients have been identified, many researchers examine the relationship between heart failure and other factors, such as obesity, as measured by body mass index (BMI). As a result, studying and generating real-world evidence (RWE) related to patients with heart failure requires data not commonly found in administrative claims data.

In this white paper, we compare and contrast the view of heart failure patients as seen from the perspectives of two large, but distinct, sources of real-world data, both of which contain data points needed for studies of heart failure, such as left ventricular ejection fraction (LVEF) and BMI:

THE PINNACLE REGISTRY
Cardiology's largest outpatient quality improvement registry

PRACTICE FUSION
An industry leading, cloud based ambulatory EHR

We cover the differences between these two data sources in terms of collection and content as well as the implications of these differences, both for identifying key patient populations for assisting understanding of heart failure management and for potential recruitment for observational research or clinical trials.

THE TWO DATA SOURCES

For the purposes of this white paper, we limited both data sources to data collected between 2015 and 2020.

The PINNACLE Registry

The PINNACLE Registry was founded in 2008 by the American College of Cardiology (ACC). In 2020, Veradigm partnered with the ACC to manage the Registry.

Currently, the PINNACLE Registry is owned and operated by Veradigm, in partnership with the ACC. This Registry captures data on coronary artery disease, hypertension, heart failure, and atrial fibrillation. For the selected period, the PINNACLE Registry includes data from 4,000 participating sites and 16.5 million patients.

Sites that sign up to participate in the Registry transmit their patients' EHR data into the Registry in a HIPAA-compliant, secure manner. From there, the data from each site is mapped to assess 24 cardiovascular-related Quality Payment Program measures.

THE CAPTURED DATA INCLUDES:

- Basic demographic information
- Presence of cardiovascular conditions and comorbidities
- Cardiac events such as myocardial infarction, percutaneous coronary intervention, hemorrhage, and other medical events with dates
- Exams, labs, and medications

The Registry data is refreshed quarterly, and sites are provided with the 24 Quality Payment Program measure reports. This allows each site to compare its performance against its peers as well as see how it is doing over time. Sites are also able to report directly to their Quality Payment Program through the Registry.

The top specialties represented in the PINNACLE Registry are cardiology, family medicine, and internal medicine. More small and medium practices are represented than larger practices.

Practice Fusion EHR

In contrast, the Practice Fusion dataset provides data from a large, cloud based EHR that includes both primary care providers and specialists in all 50 U.S. states. Unlike the PINNACLE Registry, most of these sites are small, primary care practices. For the past year, Practice Fusion included over 48 million patients, which corresponds to more than 123 thousand providers in over 62 thousand practices. Also, unlike the PINNACLE Registry, the Practice Fusion Research Database is refreshed weekly, making it extremely timely.

PRACTICE FUSION'S DATA INCLUDES:

- Patient demographics
- Provider specialties, geography, practice links
- Visits, vitals, encounter events, problem lists
- Medical histories
- Diagnoses
- Prescription(s)
- Lab(s)
- Insurance information
- Last data refresh data

Because Practice Fusion is owned and operated by Veradigm, we have HIPAA-compliant, secure access to all the EHR data for Practice Fusion patients, including physician notes and other free text. Veradigm does not offer the unstructured data outright but provides data enrichment services in a HIPAA-compliant way through Natural Language Processing (NLP), enabling clients to access data in unstructured sources.

LVEF AND BMI

For the purposes of this heart failure case study, Veradigm’s data enrichment services, using Natural Language Processing and other data mining techniques, were critical because they made the measured LVEF values available for use. Health care providers do not always document important observations such as LVEF in a structured way in the EHR. Our analysis revealed that, in structured fields, the Practice Fusion data contained fewer than 5,000 LVEF values. However, after our data enrichment services, we were able to extract approximately 3.5 million additional data points from semi-structured text.

PATIENT SELECTION

The PINNACLE Registry had a substantially higher proportion of patients with readily available LVEF data—41.3% had available LVEF between 2016 and 2019—than the Practice Fusion EHR, in which approximately 1 in 20 patients diagnosed with heart failure had useable LVEF data during this period (Table 1). This difference makes sense when considering that LVEF data was primarily extracted from physician notes in the Practice Fusion EHR using NLP.

For this case study, we required a valid BMI measurement so we could use this number as another way to categorize patients and their cardiovascular risk. This requirement caused a relative drop of about 15% in patients available for analysis for both data sources.

The two cohorts we examined for this case study were similar in terms of demographic characteristics (Table 2), with a few notable exceptions:

- ✓ The Practice Fusion EHR patients appeared to be slightly older; however, the age of the PINNACLE Registry patients needed to be artificially truncated at age 80 to fit within de-identification requirements. This makes the two cohorts more similar in age than shown here.
- ✓ Just under 50% of patients were female, which is surprising as the heightened inclusion of males in heart failure clinical research is well-documented.
- ✓ Race and ethnicity were not required fields for either data source, but the Practice Fusion EHR did capture a larger relative proportion of non-white patients. This feature has important implications for using these data sources in clinical trials or for prospective observational research.

TABLE 1 | Patient Selection for Each Data Source

	PINNACLE		PRACTICE FUSION	
	N	%	N	%
PATIENTS WITH HEART FAILURE				
Patients with ≥1 diagnosis for heart failure: 2015-2020	812,431	100%	645,243	100%
With a Left Ventricular Ejection Fraction between 01/01/2016 and 12/31/2019 (Index date = first LVEF date)	335,593	41.3%	36,209	5.6%
Body mass index (BMI) measurement within 365 days of index date ¹	283,119	34.8%	31,749	4.9%
LVEF STRATA				
Patients with index LVEF ≥ 50	149,439	52.8%	16,123	50.8%
Patients with index LVEF 40-49	46,061	16.3%	4,922	15.5%
Patients with index LVEF < 40	87,619	30.9%	10,704	33.7%



FOR MORE INFORMATION
VISIT US ONLINE

veradigm.com   