Case Study: Data-driven Diversity Assessments at a Medical Device Company

Boston Scientific utilizes data to systematically prioritize racial and ethnic diversity in cardiovascular treatment and clinical trials

Summary

Through their health equity initiative, *Close the Gap*, Boston Scientific developed straightforward data-based tools to call attention to demographic disparities in cardiovascular treatment and clinical research. At partner hospitals, the company used a novel application on a mobile Salesforce® platform to highlight demographic subgroups being missed in cardiovascular treatment. At selected clinical study sites, the initiative collected demographic data, actively monitoring disparities in study enrollment on their 'Catalyst Clinical Trial Scorecard.' Boston Scientific's data-based tools for combatting disparities demonstrate a tangible approach for sponsor companies to contribute to diverse representation in clinical research and care.

Background: Close the gap

Close the Gap is Boston Scientific's health equity initiative created to eliminate disparities in care across the United States.[1] *Close the Gap* focuses on awareness, advocacy and education in order to help close the proverbial gap in treatment between White men and other underserved demographic communities.[2]

The *Close the Gap* initiative was established in 2004, at a time when cardiovascular disease in women was gaining widespread attention. Although implantable cardioverter defibrillators (ICDs) had been recently approved for primary prevention of sudden cardiac death (SCD) in high risk heart failure patients, women and ethnic minorities at-risk for SCD were more than 60% less likely to receive ICDs than their White male counterparts. Boston Scientific, in conjunction with other advocacy organizations,

> Dr. Paul Underwood, Boston Scientific Interventional Cardiology Medical Director noted, "the disconnect between the burden of illness observed in the community and who is actually being treated in the hospital **makes obvious that some of the people needing treatment are being missed.**"[4]

acted on the disturbing emerging trend.[3] Since its inception, the initiative has expanded to include other therapeutic areas such as coronary artery disease, atrial fibrillation, and, recently, colon cancer.

[1] Close the Gap. Boston Scientific. Available at https://www.knowyourhealth.com/en-US/About-Close-the-Gap.html

[2] Mezu U, Halder I, London B, Saba S. Women and minorities are less likely to receive an implantable cardioverter defibrillator for primary prevention of sudden cardiac death. Europace. 2012 Mar 1;14(3):341-4.

[3] Gauri AJ, Davis A, Hong T, Burke MC, Knight BP. Disparities in the use of primary prevention and defibrillator therapy among blacks and women. The American Journal of Medicine. 2006 Feb 1;119(2):167-e17.

For Boston Scientific, the ICD implant disparity became apparent with the observation that the number of patient defibrillator implants was not consistent with number of patients known to have heart failure with indications for the device. Further analysis revealed that minority patients were being underserved. The company quickly recognized that bridging this gap demanded social equity and access to care, as well as physician awareness of the new indication and the referral pathway for a device implant.

Boston Scientific responded to this treatment disparity by creating the awareness-raising and education-oriented *Close the Gap* initiative. The initiative networks client hospitals with
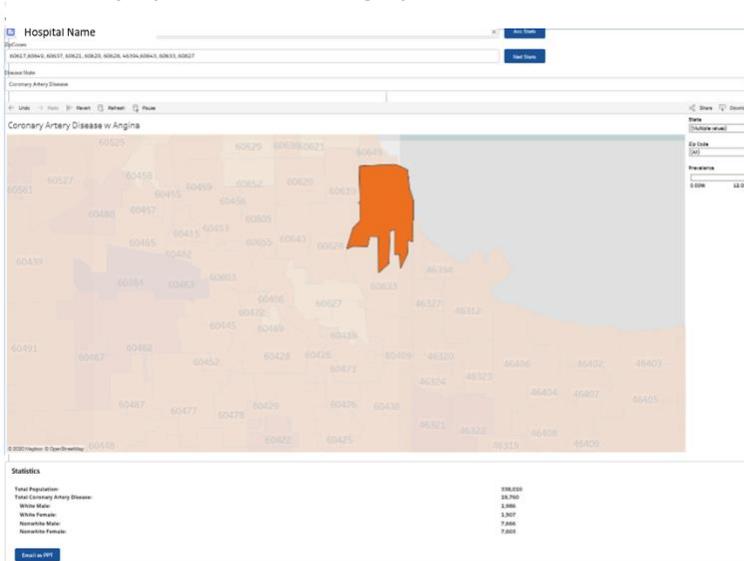
Dr. Underwood explained that after using the app to inform sites of their current performance, "hospitals would be encouraged…to **establish a task force** to understand better where some of the demographic gaps are and then develop a plan that would help mitigate some of the identified barriers to care."[4]

In cardiology, "providers generally know that disparities exist, but not in **their clinics** or **their practices.**"[5]

community partners and professional/patient advocacy organizations to spread awareness regarding demographic disparities in cardiovascular care. The initiative also links the providers' understanding of disparities with the provider's experience. Often, hospitals don't address disparities in a meaningful way; although 'community engagement' activities are common, they are often not targeted and limited in scope leading to ineffective impact on treatment disparities in the long term.

Figure 1: Hospital service area coronary disease burden visualization on the mobile app, indicating number of cases by zip code and demographic

Quantifying treatment inequities: Disparity Index mobile application
The Boston Scientific *Close the Gap* Disparity Index mobile app was designed to initiate conversations around health disparities between Boston Scientific's local sales teams and partner hospitals. Using a mobile app, hospitals can be provided with a graphic analysis of their clinical coverage regarding treatment access for patients within their service area.

How it works: Claims data from partnering hospitals is collected to calculate treatment rates by demographic group in the therapeutic area of interest.

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[4] Dr. Paul Underwood. Close the Gap. [Personal interview, 8 August] Telephone; 2019 (unpublished).

[5] Lurie N, Fremont A, Jain AK, Taylor SL, McLaughlin R, Peterson E, Kong BW, Ferguson Jr TB. Racial and ethnic disparities in care: the perspectives of cardiologists. Circulation. 2005 Mar 15;111(10):1264-9.
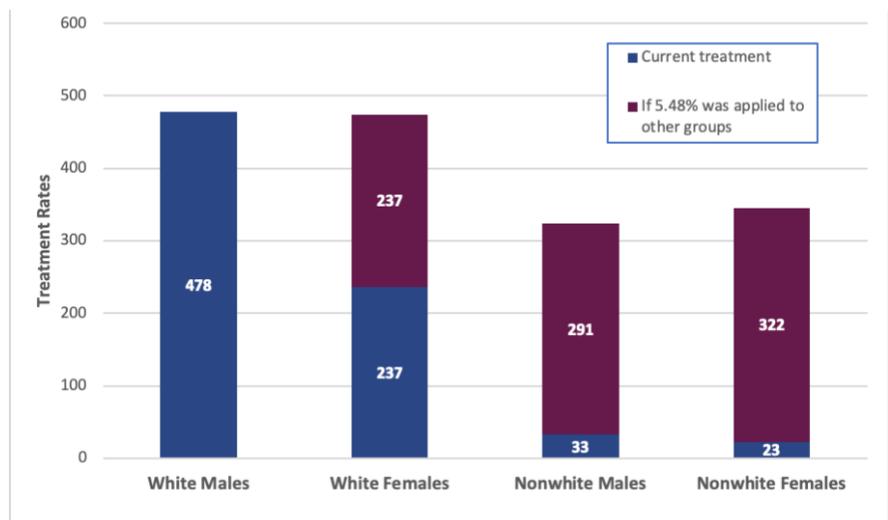
The claims data is matched to publicly available census data at the zip code-level to project disease prevalence by demographic subgroup (see Figure 1). A customizable hospital service area map is created using zip codes derived from the hospital's community health needs assessment (CHNA). The CHNA is a publicly accessible document dictated by the Affordable Care Act to accompany an Implementation Plan for hospitals to maintain their non-profit tax status. Using matched data, visualizations can be generated on the app, presenting scenarios of selected disease states by demographic subgroup within the hospital's service area (see Figure 1).

These visualizations can help hospitals understand their patients' demographics and the quantitative impact on disease burden in order to facilitate establishing long term goals and monitoring metrics.

These matched data also enable hospitals to quantify the treatment disparities in a given disease. By comparing treatment rates of patients at the hospital to cases present in the hospital's catchment area by demographic, the *Close the Gap* Disparity Index app effectively quantifies and visualizes the facility-level demographic 'gap' in treatment for certain therapeutic areas (see Figure 2). The *Close the Gap* team is constantly identifying additional spaces where health and treatment inequities exist.

Figure 2: PCI treatment rates in select groups

'Gaps' figure on the mobile app, indicating treatment disparities at the hospital for Percutaneous Coronary Intervention (PCI) in particular demographic subgroups. Data was derived from 2016 Medicare data to estimate the number of individuals who were diagnosed with disease in the selected catchment area.
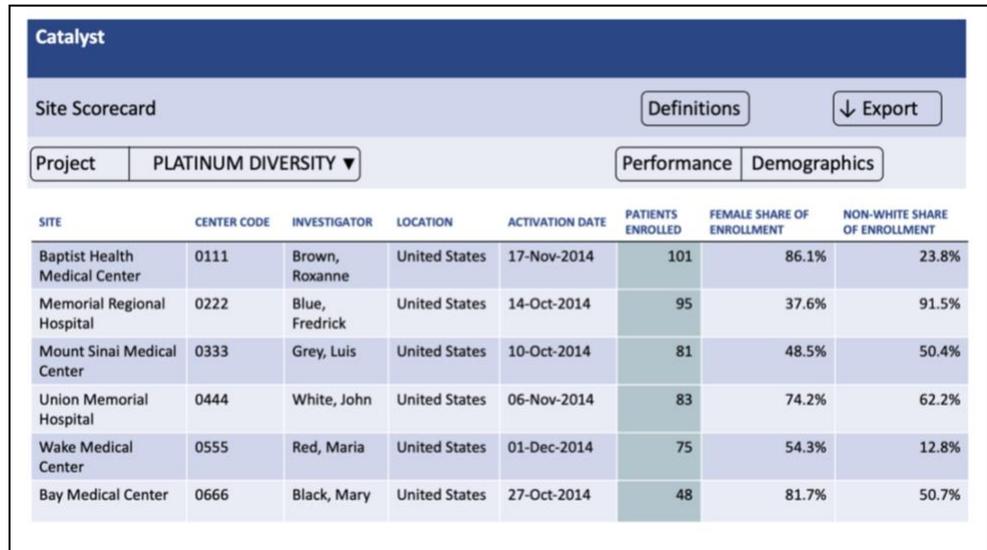
The next data update of the Index will include diabetes, prostate cancer and benign prostate hyperplasia.

In addition to providing a quantitative snapshot for the hospital, the Boston Scientific initiative then encourages the hospital to form an internal hospital-based task force to identify specific groups that are undertreated within their service area and address their unique barriers to care. While not a central focus of the task force, *Close the Gap* can maintain relationships with the task forces to share data in addition to patient and physician educational resources relating to cardiovascular treatment and outcome disparities. As a result, groups such as African Americans, who already carry a higher baseline burden of heart failure,[6] began receiving the care they needed.

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[6] Carnethon MR, Pu J, Howard G, Albert MA, Anderson CA, Bertoni AG, Mujahid MS, Palaniappan L, Taylor Jr HA, Willis M, Yancy CW. Cardiovascular health in African Americans: a scientific statement from the American Heart Association. Circulation. 2017 Nov 21;136(21):e393-423.

Monitoring diverse enrollment: Clinical Site Scorecard
In addition to using demographic data to highlight cardiovascular treatment disparities at a given hospital, Boston Scientific also uses demographic data to promote diverse enrollment in their clinical studies.

By utilizing real time enrollment demographic data from all clinical sites, project teams can develop a 'Clinical Site Scorecard' for each investigative site. The dashboard displays demographic data by gender and race. By collecting the data in real-time, enrollment of diverse populations can be actively monitored in conjunction with other trial performance indicators such as query response time and protocol compliance.

Figure 3: Boston Scientific 'Catalyst Clinical Site Scorecard' quantifying enrollment demographics of any clinical trial in real-time

The dashboard and scorecard ensure the aggregate population being enrolled in the study is representative of the population most likely to use the study device (see Figure 3).[7]

> "If in a certain disease state, half the affected people will be women, you should expect half the subjects in the clinical trial to be women. But in reality, it's often more complex…"[8]

By mapping the demographic pages from the electronic case report forms through a centrally accessible Catalyst dashboard, clinical trial project teams can develop a real-time Clinical Site Scorecard to understand the demographic composition of the patients sampled in the study. These data are used to assure sites are enrolling patients reflective of their clinical practice and the disease prevalence in the hospital's patient community. Manual combination of real-time enrollment data with investigative site catchment area data enables assessment of the clinical site's ability to match the available treatment with the disease prevalence demographics in the hospital service area community (See Figure 4).

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[7] Data in Figure 3 have been modified to protect identity of sites and investigators.
[8] Dr. Paul Underwood. Close the Gap. [Personal interview, 8 August] Telephone; 2019 (unpublished).

The combined data are then used internally by clinical project teams and the *Close the Gap* team to drive diverse enrollment in their clinical program.
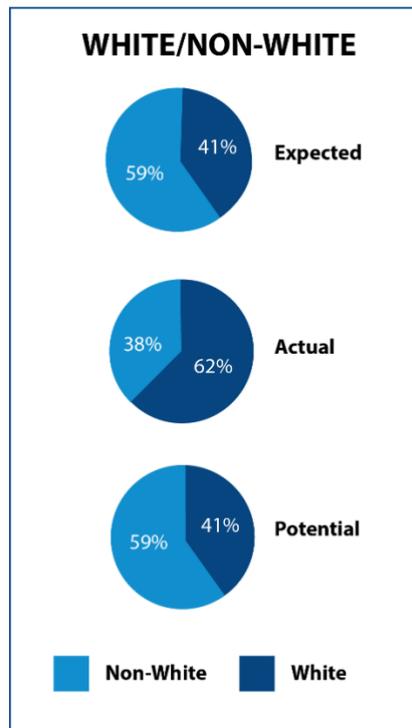
Close the Gap's data driven quantification and visualization of demographic data enables Boston Scientific clinical project teams to monitor site performance and understand the diversity of a clinical study population in aggregate and in real-time. The tools have also been used to support recommendations during clinical study site selection.

Figure 4: Example of Clinical Site Scorecard

WHITE/NON-WHITE

Expected: 41% White, 59% Non-White
Actual: 62% White, 38% Non-White
Potential: 41% White, 59% Non-White

Non-White / White

Combined data from a hypothetical trial's 'Clinical Site Scorecard' by race (white, non-white) 'Expected' represents the hospital treatment rate at the clinical site; 'Actual' represents the real-time enrollment demographics seen on the Catalyst dashboard; 'Potential' represents is the demographic prevalence in the hospital service area.

Scaling up and next steps

In conversation around the future of the *Close the Gap* Disparity Index mobile application and the Catalyst Clinical Site Scorecard, Underwood noted many opportunities to scale the tools within Boston Scientific:

- **Expand data areas to include more therapeutic areas** – currently only available for a limited number of cardiovascular conditions
- **Expand demographic subgroups** - currently only provides male/female and white/non-white data
- **Increase interoperability of data –** complete migration from iPad to Salesforce® application platform
- **Catchment area discrepancies** – target geocoding to more accurately reflect catchment area geography and demographics
- **Census-based data limiting targeted catchment areas –** current data sources exclude 'Federal' populations such as Veterans Administration, American Indian reservations, and prisons
- **Incorporating other important data elements–** such as comorbidities and age
- **Broadening clinical scorecard functionality –** to assist clinical sites to use current enrollment data to promote diverse study enrollment
- **Automate linking demographic enrollment data to hospital/clinical site service area –** currently combined data is created manually for visualization; automation would provide real-time comparisons useful for sites

Points to consider

- Clinical project teams should think critically about the data they have available to them to gain actionable insight and, optimally, use an approach as highlighted in this case study.
- Real-time monitoring of clinical trial enrollment and utilization of clinical trial scorecards enable an understanding of the diversity present across a trial population
  - Real-time monitoring helps to ensure that the intended distribution of enrolled populations is on target.
  - Real-time monitoring may be particularly useful for adaptive clinical trials.
- Quantitative assessment of treatment disparities and clinical trial diversity are necessary components to ensure clinical trial data are generalizable to the entire population.
  - Clinical sites ideally would have the capacity to generate actionable data that promotes health equity and diverse participation in clinical studies. Site metrics enable them to inform sponsors/CROs of their capacity for diverse subject enrollment.
  - These data can assist sites to perform feasibility assessments focused on diversity (i.e., assessments that target treatment rates in specified subgroups).