LEADERSHIP FORUM

DISPARITIES: ACTIVATING THE RIGHT STRATEGY
FINDING CURES FOR ALL

During the past year, the topic of disparities has elevated in importance for nonprofit leaders. During the HBS Kraft Leadership Forum on December 16, 2020, we heard discussions around two major issues related to disparities:

1 **Enrolling representative patient populations in clinical trials and patient registries.** Enrolling representative populations is hard. It requires building trust and forming partnerships with culturally aware community-based organizations, health systems, and academic medical centers.

2 **Leveraging patient data to better understand disparities and gaps.** Just enrolling a representative population is only part of the challenge. Once an organization has robust data, it must analyze its data to understand where disparities exist, why these disparities exist, and what can be done to alleviate these disparities.

HBS Kraft Accelerator Background

In 2016, the Kraft family made a donation to Harvard Business School focused on precision medicine, and Kathy Giusti and Richard Hamermesh became co-leaders of the HBS Kraft Precision Medicine Accelerator. Over the next four years they brought to HBS over 300 of the most innovative leaders from across the precision medicine ecosystem. Giusti and Hamermesh published multiple articles in places such as the *Harvard Business Review*, shared best practices, and have curated everything in the HBS Kraft Accelerator Playbook for Cures.

HBS Kraft Accelerator Leadership Forum

During the COVID-19 pandemic — where many nonprofits experienced revenue declines of 40% or more — and in anticipation of the post-COVID world, Giusti and Hamermesh decided to create the HBS Kraft Accelerator Leadership Forum. The purpose of these intimate meetings of C-level nonprofit leaders is to focus on the most significant challenges they are facing, to share solutions and best practices, and to hear from leaders in the space.

In the first meeting of the Leadership Forum in October 2020, participants were in agreement that among all of the challenges they currently face, no issue is more important than addressing disparities.

Leadership Forum — 12/16/20 — Disparities

A survey among Leadership Forum participants identified different ways that nonprofits CEOs are thinking about disparities.

- Some are focused on **understanding the registry space** and getting engagement of the entire patient population in registries.

- Others whose organizations have robust registries are looking at disparities from a **data and analytics perspective**.

- Some are looking at disparities as an **access** issue, in getting access to care.

- For others, disparities is largely a **policy issue**.

Based on input from Leadership Forum participants, Giusti and Hamermesh identified and interviewed more than 30 experts on disparities, including direct-to-consumer experts, experts on registries, and experts at health systems, academic medical centers (AMCs), and within communities. Among the key findings from these interviews is that events in 2020 have shined a light on disparities, which nonprofits need to act upon in 2021 and beyond.

This meeting provided the opportunity to hear and learn from several experts.

The title of this meeting was *Disparities: Activating the Right Strategy — Finding Cures for All*. The title was chosen intentionally based on the learning over the past four years that one of the key success factors for nonprofits — which is often overlooked — is to set the strategy upfront.

The urgent response to today's situation — Solving for disparities in COVID development
Diane Montross, Senior Director of Patient Recruitment & Retention, Moderna

Diane Montross led patient recruitment for Moderna's Phase 3 COVID study, known as COVE. She had been told that recruitment for this study would not be an issue, as people were lining up to participate. But early on it became apparent there was a gap in enrollment around minority groups. Montross shared five lessons learned from her experience.

1. **Define your enrollment goals up front.** Moderna had made assumptions that its sites would enroll a diverse population but had never explicitly defined its enrollment goals.

2. **Communicate these goals to everyone involved in a study and hold people accountable for achieving these goals.**

3. **Make sure recruitment materials are inclusive and appropriate.** Moderna's recruitment materials had been developed without its full audience in mind. To improve minority recruitment, Moderna had to redo its materials. Just including a photo of an African American or an Asian person is not adequate. Get input from experts who understand these groups.

4. **Build trust among diverse minority populations.** Building trust must happen at the community level, which doesn't occur overnight. Organizations that already have diverse databases or registries, such as Clinical Connection, CenterWatch, and TrialScope, can help streamline this process.

5. **Be transparent.** Moderna's transparency was groundbreaking. The company published its full trial protocol on the company's corporate site, along with weekly enrollment updates broken out by race and ethnicity. Moderna was applauded for this level of transparency and competitors followed suit.

Moderna was also transparent in its communication with each site. Twice weekly the company sent a report to each site showing race, age, and gender information for enrollees, along with county-level census data to show the site how it was performing based on its location. Any gaps were called out.

> **"THERE'S MUCH MORE AWARENESS OF CLINICAL RESEARCH THAN THERE'S EVER BEEN . . . AND THERE'S A LOT OF GREAT OPPORTUNITIES TO CONTINUE TO EDUCATE AND INFORM PEOPLE ABOUT THE IMPORTANCE OF HAVING STUDIES THAT ARE REPRESENTATIVE OF THOSE THAT ARE IMPACTED THE MOST."**
> DIANE MONTROSS, MODERNA

Going broader — Understanding, awareness and education
Leonardo Seoane, SVP & Chief Academic Officer, Ochsner Health

Ochsner is a hybrid. It is the largest health system in Louisiana with about 40 hospitals and clinics that provide care to roughly one million individuals. Ochnsner has a clinical research arm, a data science research arm, and medical education programs. Ochsner is an Independent Academic Medical Center. There is an organization the Alliance for Independent Academic Medical Centers that represents organizations like Ochsner. For years Ochsner has been working to improve African American participation in clinical trials. Lessons from Ochsner's experience include:

1. **Have an attitude of deep humility.** Ochsner doesn't go to the community with pre-formed solutions. The organization has a sense of humility, and listens carefully to the solutions desired in the community.

2. **Build trust in the community.** Steps that Ochsner has taken include forming a diverse Community Research Advisory Board, recruiting diverse public advocates as spokespeople in the community, investing to build 10 community health centers in disadvantaged neighborhoods, and launching the Institute for Health Equity.

3. **Form partnerships.** Ochsner has partnered with Xavier University, a local HBCU, to start a joint physician assistant program. Ochsner's attitude and actions have provided "street cred" in the community. This credibility had to be earned, as Ochsner historically was not always seen as a partner in New Orleans' diverse communities.

4. **Secure additional resources.** For studies on COVID-19 vaccines, Ochsner was selected as a site, based on its history of minority recruitment for studies. But for these COVID studies, the large pharmaceutical companies didn't provide any additional resources to assist with recruitment of diverse populations, and the recruitment materials were inappropriate. Ochsner had to do develop its own materials and plan to engage diverse populations. This involved going into communities, partnering with the two local HBCUs, and enlisting influencers like the presidents of these HBCUs. Lack of additional resources is frustrating and highlights the need for adequate resources. It shows the lack of understanding by some of the trust and the partnerships that need to be established in order to do what it takes for minority recruitment.

5. **Complete the last mile.** Give the community feedback on the results of the trial, whether these results are positive or negative, and demonstrate the impact on improving patient care.

> "WHEN YOU'RE DEALING WITH RECRUITING MINORITIES, IT'S GOING TO REQUIRE EXTRA RESOURCES. YOU CAN'T TREAT THEM THE SAME AS YOU WOULD TREAT A SITE TO RECRUIT MIDDLE- UPPER-CLASS WHITE PATIENTS."
> LEONARDO SEOANE, OCHSNER HEALTH

Starting earlier: Continuous engagement
Casimir ("Caz") Starsiak, Head of Project Baseline, Verily

Verily is a health and life sciences company that was spun out of Google. Seven years ago it was a team of about 10 people, which has grown to about 1,000 people. One of Verily's largest programs is Project Baseline, which includes the Baseline Health Study and the Baseline Community.

With Project Baseline, Verily is seeking to use modern technology and approaches to change research and evidence generation. Two important aspects of Project Baseline are trying to:

1. **Build a community that enables people to easily contribute to research and receive value back.** In building the Baseline Community, representative participation has always been a goal and emphasizing diversity is a priority. But since the Baseline Community is open to all comers, representation can fluctuate. The Baseline Health Study was designed match the census in terms of demographics, age, race, and ethnicity. With the Health Study, Verily has used priority scheduling to ensure the observational trial matched the census.

   Building a community is hard and takes time, empathy, humility, and partnerships. One of Verily's major partnerships is with the American Heart Association. Together the partners have worked to increase participation of women and women of color. Verily has also partnered with health systems, advocacy groups, and influencers.

   Verily emphasizes returning value to participants perceive value from their experience of participating and don't feel like a guinea pig. Value is provided by crafting lay summaries of research and easy-to-understand infographics.

2. **Use the company's clinical trials platform to make research more patient centric and data rich.** Verily has adopted Google's user-centered design principles, which is about incorporating the patient voice into the trial design process. User-centered design is incorporated into areas such as digital ads, study materials, and trial workflow. Verily is also focused on decentralized trials that can be administered while participants are at home and trials in multiple languages targeting sixth-grade literacy levels.

In addition to hearing about efforts to address disparities in clinical trials (Moderna), in the delivery of care at a health system (Ochsner), and in providing a platform for registries and clinical trials (Verily), this meeting featured a community perspective and two case studies.

Perspective from the Community

CEO Silas Buchanan explained how the Institute for eHealth Equity works with underserved communities of color, raising their literacy around adopting and utilizing technology to improve their health outcomes. It is also important to work with creators and innovators of health tech solutions to ensure that solutions are developed in culturally appropriate ways, which is often not the case.

Some organizations try to go directly into communities. But product developers can benefit by working with the right "trust brokers," since the messenger can be as important as the message.

> **"There's an advantage to invest in that middleware piece that has some cultural understanding."**
> SILAS BUCHANAN

Faith-based organizations can be important messengers. Buchanan has worked the AME Church, which is the largest mainline historically Black denomination in the world, with 2,000 congregations and about two million members. The idea has been for these congregations to have dedicated health ministers who are often doctors or nurses (often retired), who are embedded in the congregation. Almost 40% of congregations now have health ministries. This provides a culturally appropriate platform to gather data about patients with specific diseases and to provide information and assistance to patients.

Buchanan is now working on both a secular and a non-secular social network consisting of faith-based organizations along with barber shops, nail salons, and corner stores. The intent is to find ways to strengthen communities on an ongoing basis, not just when there is an urgent need, and to share data with communities to improve health outcomes. The goal is to form partnerships that become clinical trial resource centers and these centers can become embedded as part of the clinical trial process.

CASE STUDY

Case Study: Cystic Fibrosis Foundation (CFF)

CFF CEO Mike Boyle shared three learnings on disparities gleaned during the past year.

1 Right data and right questions. CFF has a registry that includes demographic data, started in the early 1970s, on 90% of the CF patients in the US. But CFF hadn't looked in-depth at this data to better understand disparities. That changed in 2020 as CFF looked more rigorously at that data in its registry. Through this analysis, CFF found:

— A 14% participation rate in clinical trials among patients with CF, but only a 3% participation rate among African Americans and Hispanics.

— 2X higher mortality rates among African Americans and Hispanics over age 18.

CFF has been transparent in calling attention to this data at its international CF meetings, which has lit a fire in the scientific and care community.

> **"One of the lessons for us was that we are collecting the right data, but let's really look at this data to understand and quantify some of the disparities to give us a target. In-depth understanding is essential if we are to develop the right strategy to deliver on our mission to serve all people with CF."**
> MIKE BOYLE

2 Understand the basis for these disparities. The prevailing assumption was that differences in outcomes were due to socioeconomic differences. As background, 90% of people with CF can benefit from drugs that have been developed. But among the 10% who don't respond to these drugs, 40% are African American or Hispanic. The reason for disparity isn't just socioeconomic — it's also genetic.

3 Cycle of trust. Despite previous efforts to enlist minorities in trials, only 3% of African Americans and Hispanics participate in trials. CF is perceived as a white person's disease and CFF is perceived as focused on the white community. To address this, CFF is working to build a cycle of trust by identifying brand partners and giving a greater voice to people of color.

CASE STUDY

Case Study: The Multiple Myeloma Research Foundation (MMRF)

CEO Mike Andreini said that multiple myeloma is unfortunately one of the most cited diseases when evaluating health disparities. African Americans are disproportionately affected by myeloma and suffer from mortality rates twice those of whites. Moreover, African Americans are often underrepresented in patient registries and clinical trials.

In the MMRF's largest historical registry, the CoMMpass Study, the MMRF was successful in that 17% of trial participants were African American. As a result, the MMRF generated insights that advanced the discussion of health disparities in the myeloma community. These insights include:

- African Americans have **less access to standard therapy** (autologous stem cell transplant and triplet therapy) compared to whites.

- African Americans have **lower incidence of high-risk cytogenetics** compared to whites.

These findings contributed to other published research suggesting that disparities in outcomes seen in African Americans are most likely driven by access issues rather than genetic or biological differences. New research even suggests that African Americans may have better outcomes than whites when all patients have equal access to treatment.

More data is now needed to validate these hypotheses, which the MMRF hopes to do in its new CureCloud registry. Enrolling a representative patient population is critical to doing so.

Strategies the MMRF is focusing on include:

- **Going directly to patients (DTP)** in outreach and marketing.

- **Lowering barriers to participation** through at-home genomic testing and electronic health record retrieval.

- **Building partnerships with community health systems, AMCs, and professional association**s that have boots on the ground in areas where they can reach underserved populations.

Conclusion

The presentations from different participants in the ecosystem showed that considering and working to address disparities is now squarely on everyone's radar. For nonprofit organizations, the presentations highlighted different paths in creating more representative participation clinical trials and patient registries, and showed the importance of mining the patient data that is collected from different sources to identify gaps and opportunities.

It is important for each nonprofit to understand the issues and the landscape to map out the organization's strategy for addressing disparities.