

Disparities in PH

This spring, Dr Arunabh Talwar, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Northwell Health; Dr Vinicio de Jesus Perez, Stanford University; Dr Patricia George, National Jewish Health; Juliana Liu, Stanford Health Care; and Dr Elizabeth Joseloff, Vice President, Quality Care & Research, Pulmonary Hypertension Association (PHA), gathered to discuss real world experiences in dealing with health disparities and what the PHA can do to address them.

Dr Talwar: We are here because we are on a crossroad journey with PHA, trying to see how we can help further with the management of our patients. In the last 5 years or so, the issues of diversity and access to health care have come to our attention, and this has become even more important after COVID-19 epidemic. If one was to look at health disparity and access to health care, I would think of it in terms of 5 subsections.

The first is problem identification and then problem analysis. Based on these two subsections, most organizations will then develop an action plan. We'll call that stage plan development. The most difficult part of this process is the next stage, plan implementation. Then comes the time for the organizations to do an impact assessment. If I was to put this process back from the prism of PHA, and particularly focusing on pulmonary arterial hypertension (PAH) and a bigger broad spectrum of cardiovascular diseases, I think we are still at a stage of problem identification. That's why it's more important for us to explore the issues associated with diversity and access to health care. Only by recognizing the problems first can the organizations like PHA come up with an action plan. The purpose of this meeting is to get everybody's thoughts on this, as to where PHA should be moving in terms of providing information and guidance to the health care providers about issues of diversity, socioeconomic, and health care delivery. We also need to examine what we can learn from other patient advocacy organizations about these issues to help provide optimum care to the patients. I'd like to ask Vinicio as to what do you think we have learned from the PHA registry (PHAR)?

Dr de Jesus Perez: Our most recent study published in the *Annals of ATS* this past month used PHAR data to look at clinical characteristics of Hispanics compared to non-Hispanic whites. Interestingly, we found that Hispanics appeared to have an advantage over non-Hispanic whites in terms of morbidity and mortality. While [it] would be very easy to conclude that the benefit seen in Hispanics could be attributed to the level of care and resources available to these patients, we found that the socioeconomic status and health insurance coverage was lower compared to non-Hispanic whites. While we can't fully explain the discrepancies between socioeconomic status and clinical characteristics, these findings emphasize the existence of disparities based on race and ethnicity that likely has an impact on health care outcomes and quality of life for these patients. How other contributors of health disparities such as mental health, addiction, education, and geographic location influence PH clinical outcomes in Hispanics and other race/ethnic groups remains to be fully studied.

Dr Talwar: Vinicio, do you think the PHAR captured enough Hispanic population data to come to this generalization, or you do think this population is still underrepresented in that registry?

Dr de Jesus Perez: While the PHAR has helped us start to answer some of the burning questions surrounding health disparities in PH, we still need to carry out more studies in larger and more diverse populations. That's something that Patty just pointed out in her recent paper on *CHEST*. In that paper, her group documented that there is a significant underrepresentation of ra-

cial-ethnic groups in not only registries but also clinical trials. This observation emphasizes a major gap in our clinical data that could be adversely impacting how reliable the data from registries and clinical trials represents our patient population.

Dr George: It's interesting because, when we speak about race in medicine, that it is a social construct rather than a genetic construct, some will argue we shouldn't even mention race in trials and may argue that we should be race-blind in terms of enrolling people into clinical trials and perhaps even registries. My concern here is that, if we are in fact blind to race or other social identifiers, we may blind ourselves to biases in trial and registry enrollment, which will unfairly bias our impressions of prevalence of PH among different racial and ethnic groups.

In our field, there are numerous major clinical trials where race was not reported. I think that reporting this is important to make sure that there is equitable access to these pivotal clinical trials and therapies, and of course, lack of diversity in our trials and registries may also affect the generalizability of the results, a significant issue when we don't see the trials and registries reflect the actual prevalence of the disease.

Dr Talwar: Patricia, let me ask you. Race is at some level considered as a sociopolitical construct. Social scientists have argued that it may not be well reflective of genetics. Still, it has been proven in other chronic diseases that race, health literacy, socioeconomic status do play a significant role in terms of access to health care. The point of it is that, in other cardiovascular diseases like hypertension, there is some men-

tion of race-based treatment protocols. Should PHA be looking into a little bit more detail? What should we be doing in terms of making sure that the clinical trials that are done have adequate representation of the minorities?

Dr George: I would definitely argue against race-based treatment paradigms, as there are no data to support this, and race is a social construct. I do think that accounting for race and other social determinants of health in our enrollment would help us make sure that we [reach] a representative population of people that suffer from this disease.

What can PHA do? I think it starts with a multiplatform strategy that would have to be required to improve enrollment into clinical trials. This first comes from improving access to care for socially disadvantaged groups, so that people get to the PH specialist. To do this, we need to continue to work to improve educational practices aimed at frontline health care providers, who first see these patients early in their disease. We also need to make sure we as health care workers continuously address our own inherent biases and make early and accurate diagnoses and establish treatment plans in an equitable manner. Are there differences in how we treat patients even when they get the right diagnosis? Are people making biased subconscious determinations and prescribing less than standard of care to certain patient populations? If so, why and how can we correct it? In this space, PHA could collaborate with other patient advocacy organizations to provide workshops on implicit bias training in health care workers.

In addition to educating health care providers about PH and inherent bias, we need to also reach out into communities to bring disease awareness about PH and that, with PH and other diseases, it is important to get to the doctor to seek help for symptoms such as shortness of breath with exertion, fatigue, and unexplained symptoms. One way PHA might get involved would be to partner with local medical centers or practices and reach out to disadvantaged communities, with events such as local community health fairs to provide

cardiovascular and pulmonary health screening.

Speaking more from a socioeconomic angle, in addition to education of physicians and communities, we need to also make sure that socioeconomically disadvantaged people have the ability to get to the doctor. Do they have health care insurance and access? Does the system allow them to take a day off from work? Does the person have transportation to get to the doctor in a timely manner? We need to also make sure the system allows people to get to a doctor. PHA has an excellent track record in lobbying our representatives in government, so I think contributing our voice to these issues and supporting universal health care and access to health care would be powerful.

Once we have the proper diagnosis and treatment plans, a huge issue is paying for those medications. Especially this last year, I think a lot of us and a lot of our patients struggled with the new patient assistance programs, and there was a lot of stress around getting copays covered. Imagine a person who is socially disadvantaged without somebody truly advocating for them and not in a PH specialist's practice, where people are fully versed on prior authorization and the assistance programs, how will they be able to afford the PH medications? PHA could help by analyzing this issue and by advocating for the simplification of medication prior authorizations and copay assistance programs.

Juliana: From the perspective of access to therapy, when I started in PH almost 20 years ago, it was actually "easier" to get PH drugs. First, there weren't that many options, and the insurance companies weren't really dictating treatments. PH was construed as a rare disease with rare treatment options. Now there are significant barriers such as step therapy requirements or formulary restrictions that are different for every insurance plan. That is not only difficult for people with adequate insurance to navigate, let alone people with Medicaid type of insurance, etc.

As an example, in the state of California, where we are, as of this year, they launched a new Medicaid central in-

surance clearing house system in which only sildenafil is on the covered drug list. Everything else needs to escalate to an appeal type of process. So for all PH patients on Medi-Cal, they had to redo all prior medications authorizations, resulting in severe therapy disruption.

There was a lot of excitement when generics came to play, that the cost of therapy will go down, but what we found is the opposite for PH treatments. Generics don't necessarily drive the cost down. In fact, it makes it even more difficult for patients to access therapy because previously available grant programs or therapy access programs have been shut down because manufacturers cannot give copay assistance cards, etc., for patients who are on government-based insurance, for example.

The most frustrating aspect of this is that the rules of medication access are not necessarily based on scientific nor standards of treatment. It's not necessarily based on things that are best for the patient or what the clinician recommends for the patient. It's really driven either by policy or financial factors. If there's anything that the PHA can do to help us, it is to collectively speak to lawmakers and other stakeholders to change that. The prohibitive cost of therapeutics is a national discourse going on that certainly touches on PH patients as well. If there's a way in which we can move the needle on that, it would be helpful for our patients. It really is a shame that, for our patients, securing access to therapy is a full-time job every year as insurance formulary rules change and they need to struggle to access foundation funds to pay for life-sustaining therapy.

When the PH care centers (PHCC) initiative came onboard, we talked about, won't it be great if there are certain accredited centers in which, perhaps if you are a patient who gets seen there, then there's an assumption that the treatment is adequate, and therefore, the insurance can move quickly. In fact, that's how it operates in other counties. This is not necessarily because we want to exclude patients out, by no means, but it's simply a balance to control the cost of therapeutics but, at the same time, give adequate care without needless bureaucratic redundancies. What we have

right now is not doing either. What the pandemic has taught the general public, if anything, is how fragmented the US health care system is, and because there are no consistent rules, and every jurisdiction and insurance has its own standards, the prescriber has to navigate through the extremely complicated and inefficient administrative hurdles just to get a patient started or maintained on therapy.

One successful initiative that the PHA was able to advocate for was the centralization of one REMS program for ambrisentan. When generic ambrisentan came online, they set up 2 REMS programs for the drugs. That meant that, depending on your pharmacy and which generic product you were receiving, you had to enroll in one REMS program versus another. That also meant, if your pharmacy stocked another type of ambrisentan, you had to enroll in the other REMS program. As you can imagine, this caused needless delay in therapy. Through the advocacy work of the PHA, Dr Sager and myself, we spoke to the REMS program; we were able to convince the drug manufacturers to disband one of the programs and merge into one entity.

Something that the PHA can do and has successfully done is to partner with us as clinicians to provide a collective voice on behalf of the patients.

Dr Talwar: From listening to both Patricia and Juliana, PHA does try to make its voice heard both at the local and federal policy level. We need to argue for proper access to care for minorities, for ethnic minorities, or people who have low socioeconomic status, which correlates at some level with health insurance as well. PHA obviously needs to focus more on health education, both for the patients as well as for the providers.

Let me ask Elizabeth and Vinicio, what about PHAR? What have they taught us? Where are we moving with this? Secondly, what can we learn from other organizations, like Cystic Fibrosis (CF) Foundation, Pulmonary Fibrosis Foundation, and other patient advocacy organizations, that we can take from them and probably incorporate into PHA's efforts?

Dr de Jesus Perez: The PHAR is certainly a very unique and powerful resource that was designed to capture race, ethnicity, socioeconomic status, and other information missing from previous registries. I would love to hear from Elizabeth since she worked with the CF Foundation and can certainly provide a very important perspective of this.

Dr Joseloff: Sure. I'm happy to talk. The PHAR is now reaching a substantial enrollment number. We're approaching 2000 patients enrolled. We have 11 publications now. The science is coming out that will support data behind these types of studies. There's more information to come in that regard.

If you look at other more mature registries, there are a number of publications and papers that can be used to support these types of studies that can be used to support basic knowledge, patient education, understanding in the community, and also to support advocacy. That's where PHA is heading. We want to be able to leverage with the care centers and the registry to be able to help so that there aren't these disparities and challenges that continue for the PH patient populations.

With our advocacy work at PHA, this is on our radar too, with making sure that we keep everyone in mind and advocate for all patients with PH.

Dr Talwar: I'm hearing that maybe PHA needs to collaborate more with other such organizations to learn from them and share their experience to see where we are. Listen, all these diseases at one time were considered rare. I'm so impressed with CF Foundation, the way they advocate for their patients, how they support their centers, and even help collect data. I think that's amazing and maybe something that we can learn from them as well.

Dr Joseloff: PHA is partnering with the CF Foundation and organizations on advocacy work. Many disease foundations and associations [are] working together as partners for advocacy. That's already ongoing.

Dr George: That's so key because, while we are in one rare disease space, by

partnering with other organizations, we bring greater numbers to these important core issues. There is definitely power in numbers, and I'm glad PHA is doing this.

Dr Talwar: One of the things that always has intrigued me as a PHA member is that PHA focuses more on the PHA physicians per se, but the problem starts with the primary care physicians. There is a big gap in timely referral from primary care physicians to the specialist centers. At times patients who don't speak English, either because they are minorities or they have other socioeconomic problems, cannot get to their primary care physicians, or often they cannot explain their symptoms. I feel there is a delay by the time the patient is referred to a proper PH center for care.

What should PHA be doing, Vinicio, so that we can target this particular problem? Is there something that we can come up with in terms of guidelines, or what we have done up until now? Has there been any introspection?

Dr de Jesus Perez: I cannot speak for PHA, of course, but what I can say is that this is an important problem, and it goes beyond the health disparities aspect. As we all know, many patients, including patients who do not necessarily fall in the bracket of being underserved, get lost in the system for a long time before the diagnosis is suspected. You reported a couple of years that, when these patients finally reach you, they are in a much worse functional class. [I] think, when it comes specifically to addressing health disparities, there are several avenues.

I think insurance plays a key role in financial support, access to centers as well as resources to connect the patient with the practitioner through interpreter services, through matching with providers who are from the same race, ethnicity, religious background, sexual preference, any of these factors because they do play a key role in how patients see us and the trust that they put on us.

With regards to what PHA can do, reaching out and educating the medical community is a major step. Maybe

working with professional societies like the American Medical Association and American Family Medicine could help add PH as part of the educational curriculum for general practitioners and specialists. Also, promoting the implicit bias training for professionals, which can certainly go a long way in mitigating some of these initial additives that we bring with us into a patient encounter can help mitigate mistrust and improve communication between patients and providers.

Dr Joseloff: I would say this is definitely an area of development. Incorporating diversity, inclusion, and equity is definitely an area of focus for PHA. We want to keep diversity, equity, and inclusion in the forefront of all aspects of what we do. That's one of the areas for the care centers that we're focusing on this year, to target outreach to new PH care centers in geographical areas that maybe have gaps in access to PHCCs. That will help us make sure that PH patients get seen by expert health care providers and get the right treatments as early as possible.

Dr Talwar: That brings me to a different issue altogether, which I think is tied to long-term access to care. There are PH centers all across the country. I also look at so many pulmonary training programs. Not every pulmonary training program has the kind of capacity to train fellows in PH. I feel that the PHA physicians, with the backing of the PHA, should make a push to argue for further training in PH for all trainees in pulmonary fellowship. If extensive PH management experience is not available in a particular training program, some facilitation should be made so that trainees can rotate through a program where this kind of experience is available. Vinicio, what do you think?

Dr de Jesus Perez: If I may point out, besides physicians, there's of course nurse practitioners (NPs) and other health professionals who are essential in managing this patient population. I would love to hear from Juliana, who has been working in this field for more than 20 years, what her thoughts are regard-

ing educating nurses, caregivers, and physician assistants (PAs). What do you think? Do you think this is a legitimate goal that we should prioritize?

Juliana: Thank you, Vinicio. In terms of training the nonphysician provider, I think the challenge is that there are so many different pathways into becoming either a PA or a NP. Usually, their training is very diverse, not necessarily as standardized as medical training. Any specialization comes from where you end up working.

That being said, I think PAs, NPs are more attuned to dealing with some of these general health issues that affect health care that may not be so pathobiologically focused. Their training includes ways to see the whole patient and bring in issues pertaining to socioeconomic status, cultural background, etc. Not to say physicians aren't, but there's a strong emphasis at least in the nursing tradition to look at that.

It's impossible to train all these non-physician providers about PH, but if we can develop a really great digitally accessible curriculum that can be promulgated to these PA or NP societies, for example, can be a great start. Really, they are the frontlines to see and identify the high-risk patient and then refer them to a tertiary center.

They're not going to supplant the role of the PH center, but we really need more hands and feet out there in the community. That might be a good avenue to spread the knowledge, to help us really widen the catchment of these high-risk patients.

Regarding nurses, I often tell people, once they're diagnosed, actually, the nurse's job just starts. It's, how do we ensure that the patients continue on their therapy and do well? I have patients who've been on epoprostenol almost 20 years, and they're doing really well. Why? Because, honestly, the nurse was there to call the patient and make sure every line infection doesn't evolve into sepsis. There needs to be more focus in the PHA in supporting the nonphysician provider and also to bridge the gap between those patients who have difficulty accessing tertiary care centers.

We really need to think of our model of care, not just physician-patient but really to broaden the scope of care through not just nurses but even trained community health educators to help patients understand their disease. They can help improve health literacy, even understand things like insurance access or how to take basic health steps to improve one's overall health or food choices. Much of the guidance around food and things are very mainstream American cultural focus. How do you incorporate dietary recommendations that are ethnically mindful that incorporate traditions from other cultures?

Patients who might not come from the majority culture, sometimes they will just defer to the physician and not ask questions. Even having culturally diverse and meaningful patient education tools builds trust because it signifies to the patient that we hear them and want to try to help.

In California, there is a significant Asian population. We have never had any PH material in different Asian languages. I know that the PHA has a memorandum of understanding with a lot of the international PH groups. We don't have to recreate the wheel. There's a lot of culturally appropriate material that was actually generated overseas that we can incorporate. Leveraging the vast network is something that the PHA can definitely tap into and in turn result in more culturally relevant and pertinent materials.

Dr Talwar: Yes. I would call it as transdisciplinary training and education, which incorporate nurses, PAs, NPs, and physicians. We need to make an effort that enough teaching about PH is provided during training period as well. We need to make sure that PH as a differential diagnosis exists in the mind of health care providers when patients present with all kinds of symptoms.

Patients don't read textbooks, so they present with all kinds of different complaints. If this disease is not on our radar, we are unlikely to think of it, even as our sixth, seventh, or eighth differential diagnosis. That's where I think perhaps things start falling through the cracks.

I think, Juliana, you were right in pointing out, initial screening place right now is done in primary care practices much more by NPs and PAs. We have to think of that territory as well. I have to take them along with us as we move in terms of treatment and other management issues. Hopefully that will then result in early diagnosis and improved outcomes down the line.

Dr George: First off, I'm loving hearing what all you have to say. These are really important points that you bring up. If I were to utilize an organization like PHA in trying to educate people who are on the front line, that's what we're talking about; they don't have to treat PH, but they have to send them to the experts. You have to at least have it on a differential. I would think about, again, partnering with other advocacy organizations in rare diseases.

It's one thing to go out there and educate the world about PH, but in a busy primary care practice, it's hard. Our traditional venues have been in pulmonary medicine and in cardiology. Will it be seen by the frontline physicians? What if you'd have at American College of Physicians national meeting or joint sessions with the American Academy of Family Physicians, for example. There could be a rare disease panel, a "zebra panel," if you will, or an unexplained dyspnea panel, "When shortness of breath is not asthma or COPD," but you actually get representation from different rare diseases to flesh out that differential.

Dr Joseloff: PHA is hosting annually an Associated Diseases Summit. We bring 10 or so organizations of associated diseases together, and we talk about common issues and how we can work together. This is [a] relevant topic to bring to the summit for discussion. I will share this with my colleagues at PHA.

PHA has exhibit booths at other organizations' conferences for awareness and outreach. We'll be having at the PHA 2022 Conference in June a [Pulmonary Vascular Research Institute] and PHA joint session on beyond group 1 PH. This is an example of when we're working together with other organizations.

Dr George: That is super. It would also be amazing to generate a summary article from the Associated Disease Summit and consider getting it cross-published into multiple journals and different specialties.

Dr Joseloff: That's a great idea. Thank you.

Dr George: One other barrier to care I also wanted to mention before our time is up is challenges with telehealth and access to care, highlighted by the COVID-19 pandemic. We work with people from across state lines, and one might think that telehealth is a great option. However, I cannot conduct a telehealth visit with someone across state lines. I can see them in Colorado, where I'm licensed, but I cannot see them if they are sitting in their home in Wyoming or another state. Additionally, there are a lot of issues with telehealth and access to care. Many people even in large cities do not have broadband. They may not have a device that can connect.

PHA could help greatly by advocating with the government for the ability to treat people across state lines, especially when there are no PH specialists in a state or region. Additionally, advocating for expansion of universal broadband, an infrastructure issue, would help us reach more of our patients as well.

Dr Talwar: These are important issues and something very granular. Patients who come from a poor socioeconomic background, they may not have the capability of doing video. They may be able to do telephone. It's very simple. I have seen it in my practice time and again. It's very much correlated with health literacy, socioeconomic status, and to their ethnicity.

In the remaining few minutes, I just want to get everybody's opinion on some other issues. There is some data maybe that—if you look at the subsets of PAH, maybe the collagen vascular disease is more common in the African American, maybe portopulmonary is more common in the Hispanic population. How should that be addressed or put together so that a little bit more resources are put there so that patients with that kind of ethnic

minority are able to get equal access to care, Patricia?

Dr George: I have a quick question regarding these statements. Whenever I see this racial prevalence of a subtype of PAH, my larger concern is, are we underdiagnosing the denominator (PAH) in certain patient populations? For example, are we making a connective tissue disease (CTD) diagnosis and then doing appropriate screening (which is excellent), yet missing the diagnosis in the non-CTD PAH subtypes?

Dr Talwar: Absolutely.

Dr George: It may be that only when some people have scleroderma or portal hypertension is PH considered. I think that is more likely than some sort of biologic reason. So maybe that changes how we discuss this issue.

Dr Talwar: It's an access-to-care issue at a much broader level. That's what I believe. That's why I said before that we should educate our providers, including the bigger territory of primary care providers who are the first gateway for these patients. Let's go through one by one and say, what's the most important thing on your mind that we should be doing for next 1 to 4 years in terms of bridging the gap of access to care? Vinicio, let's start with you.

Dr de Jesus Perez: Education. I think we have to be very aggressive about reaching out and educating. I think we know the problem is there. I'm sure that, from the perspective of the primary care providers, there's no problem. They're not aware of it. Again, there's the implicit bias aspect that is playing a major role. I think we just really need to reach out and be aggressive about making sure that the community's educated.

I like Patty's idea that maybe we should start interacting with medical societies so that we can be part of those discussions, give presentations, etc.

Dr Talwar: Juliana?

Juliana: I would say also we could focus on empowering the current providers

and reaching out to different groups' needs. Along with educating providers, we need to create culturally meaningful educational materials, for example, not just in Spanish, but other major languages.

Even in our support group structure, I know that PHA does an excellent job in having demographic-specific groups like the young generation support group. Maybe there is a way to further develop language-based support groups. I think that would be huge. That would be really great to support the patients that are already diagnosed.

Dr Talwar: Patricia?

Dr George: I think those are excellent points. I echo what Vinicio is saying in expanding education, but I think it goes beyond education. I think there's this system problem in US health care that disadvantages people being diagnosed appropriately when they have rare diseases. The problem begins with having 20 minutes to see a new patient and 10 minutes for a follow-up visit. If a

health care provider is trying to manage diabetes, hypertension, and social issues like the patient just lost their job (and insurance) and cannot get a ride to clinic, how are they supposed to remember and even think and have time for the doorknob moment when they're leaving the room; then the patient says, "You know what? By the way, when I go up the stairs, I'm a little more short of breath." It is easy to see how someone might have to say, "Okay, here is an inhaler, and I'll see you in 6 months."

It may not always be that health care workers are ill-informed or ill-educated; they are having to take on bigger issues. If I were an advocacy organization like PHA, I'd partner with others and actually discuss this health care system issue as being one of the contributors to delayed diagnosis and delayed therapies in rare diseases.

Dr Talwar: Elizabeth?

Dr Joseloff: These are fabulous ideas and definitely information that will help PHA as we start to grow and expand to

make sure that we are addressing these disparities and eliminating the barriers down the road. PHA now has a very extensive accredited care center program network. Continuing to reach out to other PH care centers, we can work towards all PH patients are getting the appropriate care, the highest standard of PH care in the near future.

Dr Talwar: I echo everything that you all have said. I think reducing disparities in a rare disease process like PAH requires a multilevel and a multicolaborative approach. Mind you, PHA has a very important role to play. PHA is a bridge between the patient, health care providers, both PA, NPs, nurses, and physicians. We need to be able to identify the barriers to access to health care, both at individual and community level. We need to lobby for it so that we can provide it with more resources, and if need be, financial efforts so that everybody and anybody in this country who has PH is able to get optimum care without consideration for gender, sex, race, socioeconomic status. Thank you.