

**Addressing Unmet Needs in Diverse Populations:
Therapeutic, Aesthetic, and Investigational Approaches**

Hema A. Sundaram, MD, interviewed by Alyx Cali Rosen, MD

ALYX CALI ROSEN, MD: Hi. This is Alyx Rosen from *Dialogues in Dermatology*. And I'm here with Hema Sundaram. And today, we are going to talk about Addressing Unmet Needs in Diverse Populations: From a Therapeutic, Aesthetic, and Investigational Approach. Thank you for being here today.

HEMA A. SUNDARAM, MD: Thank you, Alyx, it's really a pleasure.

ALYX CALI ROSEN, MD: So I had the wonderful opportunity attending your lecture the other day. And there were so many amazing pearls and topics that you addressed from this overall category of addressing these unmet needs. But you approached it from two different ways of a clinical and investigational standpoint. Can you tell me a little bit about what you mean about the unmet needs of the diverse populations from a clinical standpoint?

HEMA A. SUNDARAM, MD: Thank you, Alyx, and absolutely. Well, we know that there are inequities across the board in dermatology, both from a therapeutic and from an aesthetic perspective. And we do have some publications on this topic. Really, this whole session came about because of some observations I'd made in my own clinic that made me want to look for data that would provide an evidence-based framework for what I was observing experientially.—

--And I did find some evidence, but I was even more struck by how big the evidence gaps still are. So, for instance, we know that patients in minority groups, by which we mean minority with respect to skin type, ethnicity, and/or culture have a lack of access to healthcare in general. There are social determinants of their health status. And often, they are cared for by health systems that have limited resources and time.—

--And as a result, they cannot experience provision of high quality healthcare. One thing that came out of the literature that I reviewed which was very positive and encouraging is that we as dermatologists can be the primary agents of change. And I also delved a little bit into the whole issue of cultural competence and how important cultural competence is in improving healthcare quality.—

--If we fail to understand and manage social and cultural differences, this can have significant health consequences. And there are some publications that document this currently. The early conceptual models of cultural competence focused on the interpersonal relationships between healthcare providers and their patients. But that whole concept has been expanded now also to incorporate consideration of how the healthcare system as a whole treats patients.—

--So we now have a much more integrative view of what cultural competence really is. And the key techniques that I can identify for us as dermatologists that can help us to achieve cultural competence and, in turn, lead to us being able to achieve better and safer outcomes for our patients include interpreter services, training and recruitment and retention policies, coordinating with traditional healers where this is appropriate, and the use of community health workers.—

--We can also foster culturally competent health promotion, including through family and community members of our patients. We can become more immersed into other cultures. And we can also have administrative and organizational accommodations for our patients of different ethnicities, skin types, and cultures.

ALYX CALI ROSEN, MD: Those are all really wonderful considerations. And I'm curious how you even started to think about all of these unmet needs within the population?

HEMA A. SUNDARAM, MD: Well, Alyx, it really all started with my experiences as a clinical investigator, both on the aesthetic and the therapeutic side of dermatology. Because if we don't

have the data from studies for our diverse patient populations, we cannot adopt an evidence-based approach in the way we are managing and treating those patients. So we know across the board in medicine that there are challenges with recruitment and retention of diverse study subjects.

ALYX CALI ROSEN, MD: So when you started to become involved with all of these investigations and clinical trials, what did you find?

HEMA A. SUNDARAM, MD: So what I started to find is that there were challenges with recruitment and retention of diverse study subjects in dermatology trials. And we know this already from other arenas of medicine, such as oncology, where we see these same barriers for patients with cancer entering into clinical studies. There's underrepresentation of racial and ethnic minorities in clinical trials. And the reason this is so very important is that it jeopardizes our ability to assess the safety and efficacy of new therapies and devices.—

--If we don't have the research data, we cannot translate from that into evidence-based practice that reflects our entire patient population who are eligible to be treated. And this is a significant contributor to the clinical challenges we find with diverse patients.

ALYX CALI ROSEN, MD: Can you expand a little bit on some of those challenges?

HEMA A. SUNDARAM, MD: Yes, absolutely, Alyx. First of all, we can look at the challenges on an individual level. There's lack of awareness of appropriate clinical trials, both by healthcare professionals and by patients themselves. There are comorbidities that can exclude minority patients from participating in trials. And then there can be patient concerns about the cost of participation, both from the perspective of lost work time and also from the perspective that transportation to and from the study site may not be so easy for them.

ALYX CALI ROSEN, MD: What are the negative outcomes of some of these disparities?

HEMA A. SUNDARAM, MD: Well, on an individual level, we see patient concerns also about being experimented on or serving as guinea pigs. There are language barriers. Sometimes it's not possible for regulatory organizations and study sponsors to be able to translate consent forms and required study paperwork, in order to be inclusive of all minority patients. And unfortunately, there has been documented the perception amongst healthcare providers that minority patients may be less compliant with clinical trial requirements and so they are less likely to be recruited.—

--We can also look at system level barriers. Inadequate infrastructure and resources at clinics and hospitals that are serving minority patients. And a lack of access to up-to-date literature and data regarding optimal treatment protocols.

ALYX CALI ROSEN, MD: I think one of the biggest things you've talked about was the language barrier. Can you talk a little bit more about the language barrier, because that seems like such a simple solution. With translators these days being very readily available, that that's still a limitation, it's quite unfortunate.

HEMA A. SUNDARAM, MD: Yes, absolutely. Language barriers are still a limitation in terms of recruiting and retaining study patients, because it isn't always the case that the nuances can be well translated. And patients also when they are going through a third party, so to speak, to communicate with a clinical investigator, may feel inhibited themselves to express their concerns and their questions. And instead of being able to do that, they may end up simply being noncompliant.

ALYX CALI ROSEN, MD: A very interesting perspective that seems like there could be a simple solution. What are your thoughts on how some of these unmet needs and these barriers could be improved upon?

HEMA A. SUNDARAM, MD: Well, one thing that I have been focusing very much on is on the development of study tools for diverse patient populations. And the reason for that is that much of our data pertains to Caucasian patients. And often, we don't even realize that we have that subliminal bias in every aspect of our clinical trials. So it all begins with facial cannons, which are the typical measurements of different types of faces.—

--So we've had Caucasian facial cannons since antiquity, since the time of the ancient Greeks and probably even before then. But it's only recently that there have been publications on facial cannons for African-American, Asian, Latino, Caribbean, and Indian populations. So we're getting there but we still have a way to go. Most of these cannons relate to rhinoplasty, because that is the most commonly sought procedure by minority patients.—

--We don't have cannons that really relate to injectables. And this is one of the projects that I'm working on. I'm also looking at how we integrate facial cannons and ideals of beauty with cultural considerations for different groups of patients. And also the fact that we have tended to fall into the trap of what I call ethnic homogenization, which is to perceive minority populations mistakenly as uniform populations. For instance, to talk about the African population, the Latin American, or the Asian population without realizing that there is significant morphotypic variations within these groups of patients.

ALYX CALI ROSEN, MD: Can you expand on those morphologic differences a little bit?

HEMA A. SUNDARAM, MD: Yes, absolutely. And I can give you the example of Asian facial morphotyping, which is something that I have taken quite an interest in. I was involved in the publication of a paper in 2016 in *Plastic and Reconstructive Surgery Global Open*, which we're very proud to say won a best paper award. And the reason that I started developing a Pan-Asian facial morphotyping was that most of our publications on Asian patients focused very much on the northern Asian or the Korean facial morphotype.—

--But when we start to look at patients in southeast Asia or even in the middle regions, such as certain parts of China, we see quite different facial morphotypes. And the morphotype that we observe very much guides the type of strategy that we would be using, for instance, for injectables treatment.

--Whereas the patient from Korea and other northeast regions with a typical morphotype from there could benefit from higher dose toxin to the masseters and would not have so much need for filler to the nose for aesthetic balance, because their nose is already quite high-arched. We can now look at southeast Asian faces and see that the needs are completely different. These faces already tend to have a taper from the upper and the middle two-thirds going down to the lower one-third, and so may not have so much need of toxin to the masseters.—

--However, there is a need for filler to the nose, or a perceived need by patients, in order to give the impression that the nose is narrower and higher.

ALYX CALI ROSEN, MD: When we talk about clinical trials and investigational research, what are the consequences of not incorporating minority populations into our investigational trials and research studies?

HEMA A. SUNDARAM, MD: Well, the consequences are quite profound. If we don't have an appropriate representation of different populations in our study subjects, then we're not going to be able to translate that research into clinical reality for those patients. And so they lose out in the end, because we cannot apply evidence-based practice to them without the necessary data.—

--It's now mandated the US FDA studies should include a certain proportion of patients with skin types 4 to 6. However, one experience I've had is that in many studies, there is a preponderance of skin type 4 and not so many of skin type 5 and 6. So again, we don't have the

full database that we really need. It's extremely important that we consider the needs of all patients within these different populations, because although we refer to them as minority populations, the reality is that by the year 2050, more than 50 percent of patients in the United States are going to have skin types 4 or above.

ALYX CALI ROSEN, MD: From your perspective, what are the best assessment tools that we could use to evaluate this diverse patient population?

HEMA A. SUNDARAM, MD: What we really need are ethically-appropriate tools of assessment. And another facet of that that I've been performing research into is strategies for comprehensive dynamic assessment of patients from different ethnicities and of different skin types. It's very important to include dynamic assessment across the board for skin types 1 to 6. We know that this is the key really to achieving optimal and most natural looking aesthetic results.—

--But when we come to skin types 3 and above, it becomes even more important because these patients, due to differences in their anatomy, for instance in the amount of fat that they have in their facial fat compartments and also how much is distributed above and below the muscle. Due to those differences, they may not manifest the signs of aging that we are used to seeing in the Caucasian face when they are at rest. It's only when they animate that we start to see differences between say a 25-year-old skin type 5 lady and a 50-year-old skin type 5 lady.—

--So I've been working on a set of dynamic assessment tools, which will provide comprehensive evaluation for the perioral region and the lips. And I've also been working on a scale, which will be validated looking specifically at Middle Eastern populations in the perioral region. And I think through looking at these different parameters and these different methods of assessment, we can get a much better understanding of how we can be serving these populations in terms of optimizing their treatment and avoiding complications.

ALYX CALI ROSEN, MD: I can imagine that those tools will be incredibly useful, both from a clinical and aesthetic standpoint with regard to clinical trials, not just within your patient population, but across the country and really worldwide.

HEMA A. SUNDARAM, MD: Yes, that would really be my hope, that the development of these tools can be of value to clinicians, not only in our country but throughout the world. And we need also at the same time development of tools in parallel for therapeutic concerns, as well. And this is something that we're also looking into for conditions such as psoriasis and vitiligo and hyperpigmentation.

ALYX CALI ROSEN, MD: I'd like to end by taking advantage of having an expert in the field of treating patients of very diverse backgrounds and see if you would maybe share with the audience a few of your top three tips, tricks, or pearls that you would like the audience to know and to incorporate possibly into their diverse patient population, as well?

HEMA A. SUNDARAM, MD: The first tip that I would give would be to assess all patients on an individualized basis. Yes, of course we're aware that patients fall within certain groups with respect to ethnicity or race or skin type. But above and beyond that, each patient has an individual morphotype. And when we are seeking to rejuvenate patients, for instance, what we need to consider is the congenital baseline for them as an individual, and the age-related disharmonies that are superimposed on that baseline.—

--And sometimes there are trauma-related disharmonies, as well. So the idea for every face is to harmonize by modulating the congenital baseline, as appropriate, and by correcting any age or trauma-related disharmonies. The second tip I would give relates actually to therapeutic dermatology and a concern that is very prominent amongst patients of diverse ethnicities and skin types. And this is hyperpigmentation, melasma.—

--And we need to be aware of the value of multimodal therapy here. There are some new therapies that are coming to prominence. We have relied previously on hydroquinone but that can be quite a challenge for patients of color. I find in my experience it isn't always the most effective therapy. And even if it is, there's quite a high incidence of rebound hyperpigmentation after discontinuing the therapy and that can occur sometimes within months or even weeks of discontinuation.—

--So now we have a full spectrum of other modalities to address different stages of the melanogenesis pathway. And through addressing different stages, we can get synergistic benefits for these patients. The third tip that I would give is to be aware that skin conditions can present quite differently in patients of color. And I'll give the example first of all of skin cancer, which does have a significant incidence in non-white patients, ranging from 1 to 2% in African-Americans to 4 to 5% in Latin Americans.—

--There's increased morbidity and mortality in these populations. And one reason for that is that there can be atypical presentations. There's also a lack of skin cancer prevention and screening programs in these populations. Another example we can look at is psoriasis. We are now seeing the development of some scales for assessment of psoriasis in skin of color. And this is much needed, because again it can be difficult to assess the extent and the severity of psoriasis against the backdrop of pigmented skin.

ALYX CALI ROSEN, MD: This has been a wonderful *Dialogues* and I am so happy that we got to sit here and discuss some of the unmet needs within diverse populations. Is there any final advice that you want to leave our *Dialogues* community with?

HEMA A. SUNDARAM, MD: The final thought I would like to leave us all with is that we need consensus between like-minded clinicians within our field, in order to identify and analyze these unmet needs and to propose solutions. Once we have those solutions, we can move to

implementing them in pilot programs. And then through analyzing the results from these pilot programs, we can finalize guidelines which will assist clinicians in practice and, in turn, help their patients.

ALYX CALI ROSEN, MD: Excellent. Thank you so much for being here today on another episode of *Dialogues in Dermatology*. It was wonderful having you here.

HEMA A. SUNDARAM, MD: Thank you so much, Alyx, it was a pleasure.

Commentary

Author: Harrison Nguyen, MD, MBA, MPH, DTM&H

Health disparities are costly. In one analysis, an estimated 30.6% of direct medical expenditures for ethnic minorities were attributable to excess costs arising from health inequities, and if these disparities had been eliminated over a three year period, approximately \$230 billion in direct medical care expenditures and \$1 trillion in indirect costs could have been saved [1]. Disparities also have a significant consequence on clinical outcomes, and emerging studies have demonstrated that a lack of attention to integrating the health needs of minorities as early as the clinical development phase can have a major downstream impact on patients from minority backgrounds [2]. In this episode of *Dialogues in Dermatology*, Dr. Hema Sundaram and Dr. Alyx Rosen discuss an evidence-based framework for approaching the unmet needs of diverse populations in dermatology.

In this Dialogue, Dr. Sundaram touches upon several systemic barriers to providing equitable health care for patients from minority backgrounds. In the clinical setting, barriers include inadequate access to interpreter services, lack of training of providers and ancillary support staff in cultural competence, and insufficient attention to health promotion through family and community members of patients. These factors, in addition to other basic socioeconomic barriers like ability to pay for services, result in wide health disparities. In dermatology, it is important to consider underlying differences in the incidence or prevalence of dermatologic conditions, such as atopic dermatitis, psoriasis, and melanoma, across racial/ethnic groups that would impact whether certain demographics would seek care from a dermatologist. Some demographics, as Dr. Sundaram mentions, turn to traditional healers, and it may be important to consider collaborating with these healers to improve access to and efficacy of care.

Dr. Sundaram further elaborates that the problem can begin as early as the clinical trial phase, when studies often fail to recruit diverse patient populations [3]. The etiologies of this problem are multifactorial and range from language barriers to provider concerns that minority patients are less compliant. Furthermore, with previous instances such as the Tuskegee Experiment in which minorities have been unethically treated in historic studies, patients from diverse backgrounds are still skeptical to enroll in contemporary clinical trials. As Dr. Sundaram notes, even with regulation mandating studies to include Fitzpatrick skin types 4 to 6, there is still a major preponderance towards skin type 4.

Similar to the etiologies, the solution to bridging the gap must be multifactorial. Developing administrative and organizational accommodations for patients of different ethnicities, skin types, and cultures is critical,

and Dr. Sundaram also recommends approaching patients on an individualized basis, specifically considering how skin conditions may present differently in patients of color and which patients may be particularly susceptible to hyperpigmentation. Finally, development of ethically appropriate study tools for diverse populations will be paramount to creating equity in clinical studies. One example that Dr. Sundaram points to in her own investigative work is developing facial cannons for profiles from diverse cultures. Overall, gaps in care for patients of all backgrounds are prominent in dermatology, and an understanding of the etiologies and development of targeted solutions are essential to ultimately closing these gaps.

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