FDA’s Strategies to Close the Health Equity Gap Among Diverse Populations - Original Research

Enhancing FDA’s Reach to Minorities and Under-Represented Groups through Training: Developing Culturally Competent Health Education Materials

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Abstract
Health communications may not reach intended populations due to cultural and language barriers. These barriers may prohibit consumers from understanding information needed to make informed health decisions. It is important to ensure everyone—especially racial and ethnic minorities and under-served and under-represented populations—has access to information on medical products. One strategy to address this issue is to develop trainings and resources to better understand how cultural competency affects the ability to communicate effectively with racial/ethnic minorities. The FDA’s Office of Minority Health & Health Equity developed a 3-module training to (1) increase staff knowledge of the role that cultural competency plays in determining health communication messages and channels and (2) provide tools to assist them in creating culturally-competent strategies and action plans. Offered on 4 occasions, the 4.5-h interactive training, grounded in adult learning and project-based learning theories, and used curricula, case studies, and multimedia to guide the discussion and group work. Participants also completed an action plan to guide their current work. Cultural competency knowledge was assessed pre- and post-training and training satisfaction was assessed post-training. Among the 53 individuals who completed the training, average knowledge increased by 13.6%. The training was a success based on anecdotal and evaluation feedback. The majority of participants indicated that they would refer their colleagues to the training and apply what they learned in their work. Participants felt the training was meaningful, applicable to their work, and provided an opportunity to learn and engage with their peers. Becoming culturally competent is a process that should be supported through ongoing training to help build a strong communications and health educator workforce with expertise in developing culturally competent messages to meet their constituents’ needs.

Keywords
health literacy, health outcomes, health promotion, underserved communities, minority health, health equity, training, cultural competency, medical decision-making, health disparities

Introduction
Building a culturally competent, diverse public health workforce is essential to closing the health equity gap experienced by many racial and ethnic minorities and under-served and under-represented groups. For many racial and ethnic minorities, health disparities continue to exist related to disease incidence, prevalence, severity, and complications. This is due, in part, to health education campaigns, materials, and resources that are not culturally or linguistically tailored to allow for better decision making, thus perpetuating the cycle of health disparities.

The nation’s demographic profile is evolving, with increases in racial, ethnic, and cultural diversity. By 2045, it is anticipated that whites will account for 49.7% of the

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population compared to 24.6% for Hispanics, 13.1% for Blacks, 7.9% for Asians, and 3.8% for multi-cultural populations. As a result, racial and ethnic minorities will account for the majority of consumers who will be making health decisions for themselves and their family members.

A key component of public health is developing health education campaigns that raise awareness about disease prevention, treatment, and management. The goal of public health communications’ campaigns is to influence a population to maintain or improve its health status. Examples of successful campaigns include Sudden Infant Death Syndrome (SIDS), 1967 to 1970 smoking counter-advertising, and Reye’s Syndrome prevention campaigns. Yet, despite the existence of health communications campaigns to address the leading causes of death and disability in the United States, racial/ethnic disparities in health outcomes continue to exist. To be effective, health education campaigns must: (1) stimulate demand for health services by the target audience; (2) reach the intended audience and communicate the desired message frequently; (3) improve the audience’s knowledge and attitudes and societal norms such that behavior change is desired, (4) communicate the behaviors that can be easily substituted; and (5) establish reasonable goals for the campaign and the audience. Health campaigns must also account for the diversity of the population’s needs, experiences, health literacy levels, and other characteristics that inform their decision to pay attention to the message, change their behavior, and make informed decisions moving forward. This requires a culturally competent health communication and promotion workforce that is equipped with the knowledge and tools to develop culturally and linguistically tailored health messages, materials, and resources for a diverse population.

The Intersection of Culture and Health

Culture is an integrated pattern of human behavior. This includes thought, communication, language, beliefs, values, norms, practices, customs, rituals, roles, and relationships. (See Figure 1). Some aspects of culture are easier to identify like a person’s race, language, or gender. Other cultural aspects are not as readily identifiable like religion, education, or beliefs, for example. Whether seen or unseen, all aspects of a person’s culture impact the way they make decisions about their health, such as engaging in the health care system or utilizing health education materials. Representation matters, and people will be drawn to and trust public health professionals, health education materials, and resources that have them in mind and where they are respected and valued. Examples of best practices leading to positive impacts on health outcomes include implementing culturally inclusive health policies, graphics, and images on health education materials like fact sheets, brochures, websites or social media that accurately represent their culture, or programs that have been culturally tailored to reflect their norms and beliefs. Ideally, the people who will ultimately use the materials would be involved in the development process, as their input is critical to better understanding the cultural values and norms that influence their decision making. When health promotion professionals acknowledge and respond to diversity in thought, values, beliefs, and behaviors, it helps to ensure that everyone can make informed health decisions.

Recognizing the influence of culture on health decisions is part of becoming culturally competent. Cultural competence in healthcare and public health involves “understanding the importance of social and cultural influences on patients’ health beliefs and behaviors; considering how these factors interact at multiple levels of the health care delivery system (eg, at the level of structural processes of care or clinical decision-making); and devising interventions that take these issues into account to assure quality health care delivery to diverse patient populations.” It also involves an understanding that low health literacy—limited capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions—contributes to racial/ethnic and other health disparities and is highly connected to culture. Most adults have issues with health literacy, and 20% of U.S. adults perform at the lowest literacy levels. However, for racial/ethnic minorities, literacy levels are much worse. For example, many Asian-Americans and Hispanics report not understanding written information, and 40% of African-Americans have difficulty reading health information. This translates into difficulty understanding, for example,
how to interpret lab values or how to take prescription medications correctly, which can lead to medication errors or decreased ability to self-manage chronic diseases.

While those who develop health communications generally recognize that culture matters, limited theory, research, and tools to guide the development, implementation, and evaluation of culturally competent health communications create challenges in effectively engaging diverse audiences with health promotion messages.\(^5\)\(^,19\) The Food and Drug Administration’s Office of Minority Health and Health Equity has begun to address this gap agency-wide through the development and implementation of a training focused on health communications.

**FDA OMHHE’s Role in Health Education**

The Food and Drug Administration’s (FDA) mission is to promote and protect the public’s health. As such, the FDA is responsible for assuring that drugs, vaccines, and other biological products and medical devices intended for human use are safe and effective.\(^20\) One of FDA’s priorities is to promote better informed decisions about FDA-regulated products because FDA’s communications may not reach diverse audiences due to language, culture, and health literacy barriers. Section 1138 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 requires FDA to ensure access to adequate information on medical products for all, with a special emphasis on under-represented subpopulations, including racial subgroups.\(^21\)

The FDA’s Office of Minority Health and Health Equity (OMHHE) strives to create a world where health equity is a reality for all and helps to advance FDA’s mission through enhanced research and communication. By doing so, OMHHE contributes to the reduction of health disparities and the advancement of health equity. OMHHE focuses its efforts around 3 key areas: diversity in clinical trials, language access/translations, and priority health topics that disproportionately affect minorities (eg, diabetes and heart disease). Part of OMHHE’s communication work is guided by FDASIA, Section 1138.\(^21\) Additionally, OMHHE supports FDA’s strategic priorities and the goals of the Department of Health and Human Services to “advance the health, safety, and well-being of the American people”.

To address FDASIA 1138, OMHHE uses 3 overarching strategies to ensure that diverse groups get the health communications they need in a manner they can use them: (1) being spokespersons for minority health, health disparities, and health equity, (2) implementing cultural and linguistically tailored health education resources, and (3) hosting trainings and educational opportunities to address minority health issues.

Little progress has been made toward developing and implementing sustainable cultural competency training programs in public health settings.\(^5\) Therefore, the public health workforce may lack the skills needed to address cultural competency issues which are sensitive, yet critical, in nature. Public health professionals need the opportunity to develop skills that allow for cultural awareness and knowledge and self-reflection, which are key to addressing the needs of diverse consumers.\(^22\) To address the inadequacy and lack of trainings available to help develop these skills within the workforce, one solution is to incorporate sustainable, low-cost cultural competency training into the institution’s curricula. Given the gap in available resources to address cultural competency at the institution level, OMHHE designed, implemented, and evaluated a cultural competency training. It was designed to continue to build the FDA workforce’s capacity to develop quality culturally-appropriate health education materials through a recognition of the importance of cultural competency, how cultural competency impacts consumers’ ability to make health decisions, and tools available for ongoing support after the training.

**Methods**

**Training Development**

The training that was developed, entitled *Communicating with Confidence: Strategies to Create Effective Communications for Diverse Audiences (CwC)*, was an in-person, group-based 4.5-h training to improve the cultural competency of FDA staff involved in the development of health education materials. Subject Matter Experts (SMEs) in the areas of curricula design, health education and communications, cultural competency, facilitation, program evaluation, adult learning worked collaboratively to design and implement the curricula and evaluation. A training framework was designed after which the content, hands-on learning tools, case studies, multi-media content, resources, action plan, and other training components were developed. All content was informed by the literature and SMEs’ prior experience and expertise. Adult learning principles and a project-based learning strategy served as the foundation for the training. Adult learning principles consider that all learners have something to offer, are purpose driven, and take an active part in learning. Project-based learning has been found to ensure active and engaged learning experiences for adult participants, and it motivates participants to obtain a deeper knowledge of the content and skills they are learning.\(^23,24\) Additionally, research indicates that people are more likely to retain the knowledge and skills gained through this approach far more readily than through traditional learning.\(^25\)

In the development of organizational leaders, project-based learning enables managers to undertake a project that allows them to quickly and effectively transfer their learning to a typical, real-world work situation, resulting in both learning and practical benefits to the organization.\(^26\)
Training Curricula

The curricula included 3 modules:

- Module 1: What is Health Literacy and Why is Cultural Competency Important?

The goals of Module 1 were to (1) understand the influence of cultural knowledge, respect, bias, and trust on targeted health literacy and communication efforts and (2) identify cultural factors that can play a role in gaining insight into developing communication strategies for target audiences. During this module, participants focused on key points like defining culture; the importance of health literacy; defining a communication strategy; the rationale and need for cultural competency; historical laws, regulations, and standards; the impact of bias; and cultural factors that influence health decisions and behaviors.

- Module 2: The Role of Cultural Competency in Determining Health Communication Sources, Messages, and Channels

The goals of Module 2 were to (1) create a culturally accurate and relevant audience profile; (2) apply cultural knowledge and insight to practices that ensure effective message delivery and dissemination, and (3) utilize a defined set of practices and processes to competently identify and address cultural factors in current and future development of targeted health communication materials and programs. Key points discussed included checking assumptions about the target audience, cultural beliefs, and strategies to develop culturally-informed health messages.

- Module 3: Creating a Culturally Competent Strategy and Plan of Action

The goals of Module 3 were to (1) utilize lessons learned regarding the importance of cultural competency and how it applies to creating effective health communications for racial/ethnic minorities and other diverse groups and (2) develop a culturally competent health communications strategy and plan for a targeted racial/ethnic minorities or other diverse groups. Participants used case studies and additional tools to develop a communications strategy and action plan.

Pilot Training

After the training was developed, it was piloted with a group of FDA employees selected by OMHHE. This multicultural group, representing various offices and centers within the agency, was tasked with critiquing the training such that improvements could be made before the training was implemented agency-wide. Once those recommended changes were incorporated into the training, participant recruitment ensued.

Recruitment

Participants were recruited via agency-wide listserv announcements, digital banners, intranet, print posters, and word of mouth. Those who were interested in attending the training were directed to an online registration form that captured basic demographic information (i.e., name, email address, phone number, office/center) and allowed them to register for 1 of 4 training sessions. Upon registering for the training, participants received an email confirming their registration and were sent a link to the pre-assessment that was to be completed prior to attending the training. Participants who did not register in advance or complete the pre-assessment prior to attending the training were provided a hard-copy version to complete upon check-in on the day of the training. Registrants received reminders about their upcoming training one-week, 3-business days, and one-business day prior to their training session.

Pre-/Post-Assessment

A 10-question pre-assessment was created to measure participants’ baseline knowledge of the concepts that would be presented during the training. The training concluded with a post-assessment that included the same 10 questions from the pre-assessment. The post-assessment measured the change in participants knowledge. Questions included in the assessments were developed to meet the cognitive learning levels of application, analyzing, and evaluation. For example, questions asked about the cultural competency continuum, strategies to develop effective health communications, and the impact of culture on health. Each correct response to the assessment questions was worth 10 points, for a total possible score of 100 points.

Training Implementation

The training was delivered on 4 occasions. Subject matter experts (SMEs) in adult education, cultural competency, and professional development implemented each of the trainings, with each session consisting of 1 trainer who delivered the content and 2 facilitators who led the various activities and provided support to participants as they worked through the activities within their assigned groups. The same mix of trainers and facilitators supported each session.

Upon completion of the training, participants were asked to complete a hard copy of the post-assessment which consisted of the same questions as the pre-assessment. Immediately following the training, participants received
an email with a link to evaluate their session. The evaluation included 6 statements to gage participants’ level of agreement on various aspects of the training. Those statements were as follows:

S1. The workshop delivered what I was promised when I registered.
S2. The topic and skills were timely and worthwhile.
S3. I will apply what I learned in my work.
S4. The trainer was knowledgeable about the workshop topic.
S5. The slides, facilitator, activities, and materials were helpful to learn and share.
S6. I would recommend this workshop to my colleagues.

A Likert scale from 1 to 5 was used, with 1 indicating “Strongly Disagree” and 5 indicating “Strongly Agree.” Participants were also asked to share what they liked most and least about their training sessions, to share any additional comments they had, and to list other training courses they’d like to see offered in the future. Participants received up to 2 reminders to complete their evaluations. All participants received a follow-up email with a certificate of completion and their pre- and post-assessment scores (if available). Additionally, continuing education units (CEUs) were offered to physicians, pharmacists, and nurses, and Certified Health Education Specialist (CHES) who completed a training.

### Results

Four trainings were held between June and July 2019. In total, 155 participants registered for the trainings. Of those, 57 participants attended one of the trainings (Table 1). Initially, each session was capped at a maximum of 20 participants to support group learning and shared dialog. However, based on low attendance for Training #1, the decision was made to allow up to 35 individuals to register for Trainings #3 and #4, as it was expected that some employees would not attend the session or communicate in advance that they would not be able to attend the session for which they registered. Training #2 was reserved for U.S. Public Health Service (PHS) Officers stationed at FDA. About 85% of the PHS Officers who registered for Training #2 attended the session. For all other training sessions, only 38% of participants who registered attended the training session. About 93% of those who attended a training completed all requirements (ie, completed pre-assessment and post-assessment).

Participants were a multi-disciplinary group consisting of scientists, communicators, public health analysts and advisors, senior leadership, and researchers. Pre- and post-assessment data was completed by 53 participants (93% completion rate). Table 2 presents the average change in knowledge among training participants. Prior to the training, the average pre-assessment score was 65.8%. After the training, the average post-assessment score was 79.4%. Based on the results from a paired t-test, the participant’s knowledge significantly increased 13.6% from pre-to post-test (P < .0001).

Of the 57 participants, 45 completed an evaluation (79% response rate). Most participants “strongly agreed” or “agreed” with each of the evaluation questions. Figure 2 presents the average scores for each of the evaluation questions. About 93% of participants indicated that they would refer their colleagues to the training, and 80% indicated that they would apply what they learned in their work.

### Table 1. Registrations, Attendance, and Completions by Session.

| Session # | Registered/ walk-ins | Waitlisted | Expected attendees | Attended | Attended different session | Completed all requirements |
|-----------|----------------------|------------|--------------------|----------|---------------------------|--------------------------|
| 1         | 22                   | 0          | 22                 | 7        | 1                         | 6                        |
| 2         | 44                   | 17         | 27                 | 23       | 1                         | 23                       |
| 3         | 35                   | 0          | 35                 | 13       | 1                         | 12                       |
| 4         | 43                   | 11         | 32                 | 14       | 0                         | 12                       |
| Totals    | 144                  | 28         | 116                | 57       | 3                         | 53                       |

### Table 2. Average Change in Knowledge among Training Participants (n=53).

| Training session # | Number of participants | Average pre-assessment score (%) | Average post-assessment score (%) | Average change in knowledge (%) |
|--------------------|------------------------|----------------------------------|-----------------------------------|--------------------------------|
| 1                  | 6                      | 65.0                             | 75.0                              | 10.0                           |
| 2                  | 23                     | 59.1                             | 73.5                              | 14.3                           |
| 3                  | 12                     | 72.5                             | 85.0                              | 12.5                           |
| 4                  | 12                     | 72.5                             | 87.5                              | 15.0                           |
| Overall average    |                        | 65.8                             | 79.4                              | 13.6                           |
When asked what they liked most about the training, their responses generally centered around the trainers, interactive learning experiences using real-world examples, engagement and open dialog with colleagues, having resources to take for future use, and learning new information. Most participants had positive feedback about the trainer and indicated they were knowledgeable, upbeat, made it easy to have deeper discussions, seamlessly integrated participant discussion into the training, and did a good job at staying on track and following the agenda. Trainers were selected for their ability to effectively lead trainings for the federal workforce, incorporate adult learning principles, and engage effectively with diverse groups. Their backgrounds included a range of skills ranging from adult education, cultural competency, psychology, instructional design, training and facilitating—all of which were well suited to lead the trainings and produce positive results in increasing participant’s knowledge.

When asked what they liked least, several commented that there was nothing they didn’t like about the workshop. Other responses centered around the short length of the training, lack of time to complete training activities (eg, case study exercise, certain discussions), and difficulty understanding the case study exercise. Additional comments were mostly positive, with several comments indicating that participants enjoyed and appreciated the workshop, approved of the trainer, thought the workshop was “very applicable” to their work, and the training could have been longer. Others shared recommendations that included the preferred placement of training materials in the participant manuals, an increased emphasis on strategies for responding to cultural insensitivity, sharing more data to support the theories and practices presented, additional activities that would allow participants to face their biases, and wanted additional trainings to be developed.

**Discussion**

Continuing to grow along the cultural competency continuum takes courage. This growth requires deep self-reflection, the ability to engage in training opportunities, and the space to nurture those learned strategies to become more sensitive, aware, and humble. It also allows for opportunities to better engage diverse communities and learn about their culture. The keys to achieving and maintaining cultural competence are ongoing learning and research that supports best practices and, most importantly, recognizing that cultural difference does not equal “less than.” As we live in a diverse, global society, we must ensure that cultural groups are highly regarded as partners if we want to make progress in achieving health equity in our lifetime.

Based on anecdotal and evaluation feedback, the training was a success. Participants felt the training was meaningful, applicable to their work, and provided a great opportunity to learn and engage with their peers. Evaluation results showed an improvement in knowledge of cultural competency. The biggest improvement in knowledge was in participants’ understanding of behaviors exhibited at various stages of the cultural competency continuum. Based on evaluation results, staff wanted additional trainings. Additionally, in follow-up conversations, participants expressed that they still use the training materials to guide their daily work and champion the training to their counterparts.

Being the first of its kind of training offered at FDA (ie, specific to health communications for diverse audiences), there were many lessons learned throughout the development and implementation phases. For instance, participants indicated that more time was needed for various discussion and training activities. Participants wanted to have deeper conversations about some topics (eg, strategies for responding to cultural insensitivities, facing and addressing one’s own bias and the bias of others, data that informs cultural competency theories), and most participants requested additional time be added to the 4.5-h training to delve deeper into these topics.

OMHHE also learned that the registration process needed to be streamlined by combining the registration and pre-assessment processes. Doing so reduces the steps and time spent to confirm an individual’s registration. Additionally, completion of the pre-assessment was a good predictor of
training attendance. Among the 51 registrants who completed the pre-assessment online prior to the training, 48 (94%) attended the training and completed all requirements (data not shown). OMHHE also learned that more detailed demographic questions could be added to the registration form to capture descriptive data of who attended the trainings which will allow for more sophisticated data analysis. Examples of demographic voluntary questions could include asking participants to specify their race/ethnicity, age, and/or gender for example. Attrition was an issue for all the trainings, so future trainings should include additional reminders. Given the level of interest, additional delivery formats should be considered such as online/web-based, or a mix of in-person and online delivery to accommodate participant schedules and those who work off-site.

Closing the health equity gap will require a multi-pronged approach, including training to build a culturally competent public health workforce. Organizations, both public and private, should consider cultural competency trainings for employees to build the workforce capacity to address the unique health needs of diverse groups. The CwC training has gained momentum. Moving forward, the goal will be to expand the trainings agency-wide to increase the number of staff trained. Individual centers and offices within FDA have requested the training and are considering including it as a training goal. Given the success of the training, OMHHE is in the process of developing additional web-based trainings to further expand upon some of the core concepts from the CwC training.

OMHHE is committed to advancing health equity and building a culturally competent workforce. By investing in these types of trainings, we are contributing to closing the health equity gap and improving health outcomes for all. Having a trained workforce that can develop culturally-tailored health education materials, resources, and programs that resonate with diverse populations will, ultimately, lead to better, more informed decision-making by consumers.

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