

EMPACT

Examine the Ways in Which the Culturally and Linguistically Ap- propriate Services (CLAS) Standards can be Applied to Re- cruiting Diverse Communities to Clinical Trials

A presentation by the EMPACT consortium

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First of all: What is CLAS?

CLAS is an expansion of The Civil Rights Act of 1964, Title VI. The 14 CLAS Standards aim to meet the increasingly diverse demographics by requiring healthcare organizations to provide culturally competent care.

The CLAS Standards

...are comprised of 14 standards and 3 themes.

The **14 standards** include:

- 4 mandates that are required by law
- 9 guidelines
- and 1 recommendation

The **3 themes** are:

- Culturally Competent Care Awareness
- Language Access Services
- and Organizational Support for Cultural Competence

And now, a closer look at the CLAS themes:

With *Culturally Competent Care Awareness*, organizations need to recruit and train staff members to provide culturally congruent and linguistically appropriate care.

Language Access Services requires health organizations to provide bilingual staff and provide interpreter services at the patient's request. In language medical materials must be readily available.

Organizational Support for Cultural Competence means healthcare organizations should integrate information about participant demographics into their medical records for future use and healthcare organizations should work towards building community networks with the population it serves.

Why are the CLAS standards important to clinical trials?

The CLAS standards provide a systematic way to integrate culturally competent care into clinical trials.

The adoption of the CLAS standards makes it possible to obtain true informed consent, establish an intimate relationship between researcher and participant, and allow for better treatment adherence and outcomes.

Now in the next case study: we will see how the CLAS Standards can be applied

Mohammad Kochi is a 63-year-old Afghanistani whose family immigrated to the United States in 1988. He is a devoted Muslim and a well-respected member of the community. He was previously diagnosed with gastric cancer and had the tumor removed via surgery. However, following surgery, his doctor recommended chemotherapy to eradicate the remaining cancerous cells. Mr. Kochi has consistently refused chemotherapy. During his visits, Mr. Kochi is accompanied by a family member or friend who serves as his translator. No hospital translator is provided.

Things to Consider:

What role does language play in the development of a researcher- participant relationship? What implications can the lack of adequate language services have on a participant's willingness to consider enrolling in a clinical trial?

Learning Points:

This video identifies the gaps in cross-cultural communication that exists in health-care today and the frustration that can result from miscommunication between researcher and participant in the absence of adequate language services:

- Mr. Kochi's family *neglected* to tell him that the surgery did not remove all of the tumor mass.
- Mr. Kochi *confused* chemotherapy treatment with "the pump" believing that it was the only treatment available.
- Dr. Fisher *did not understand* that, due to religious practices, "the pump" was not an acceptable treatment option.
- Because of this *misunderstanding*, Mr. Kochi's treatment was delayed 6-months.

Ensuring there is no miscommunication because of a language barrier is not just good practice, it's the law!

Any healthcare organization receiving federal funding is required to:

- Provide language services at no cost to patient with limited English proficiency at all visits and point of contact.
- Provide patients written and verbal notices informing them of their rights to receive language assistance services in their preferred language
- Access and assure the competence of language assistance provided to the patient
- And make available easily understood patient-related materials, including signs, consent forms, medical information, etc.

In summary, here is what you should do:

Ask yourself: How well does your current clinical trials recruitment and retention efforts adhere to CLAS standards?

Take the CLAS self-assessment quiz to identify gaps in your service and ways to improve your adherence to CLAS standards at www.culturecareconnection.org

Know, that in order to implement the CLAS standards, it is crucial to

...recruit and train bilingual/bicultural staff and translate necessary research materials such as the consent forms, educational materials, and research protocols. Please take into account the literacy rate of your target population reading level. You can use the SMOG tool found at www.wordscount.info. Also, engage the community in the development of research material via focus groups or community forums.

In the Recruitment and training of bilingual/bicultural staff

- Regularly train staff in cultural competency and CLAS standards.
- Assess staff on their skills and comfort level of cultural terms and or references.

For the Translation of Necessary Materials

- Use “I Speak” cards,
- Translate consent forms,
- Provide in-language education materials,
- Translate clinic signs.

Case Study: Facing Growing Diversity

Like other healthcare organizations, AnMed Health must face the growing diversity in the population by finding an effective and low-cost way to provide language services to its patient. This video highlights the success of their partnership with the language service provider, MedVerse, that resulted in the deployment of medical translators for patients as well as training on cultural competency for the hospital staff.

Things to Consider

What value does language interpretation add to the understanding of study protocols for non-English speaking patients?

What aspects does a language interpreting program need in order to successfully follow the CLAS standards?

Learning Points

Successful application of the CLAS standards has evidence of:

- Culturally and linguistically appropriate services being integrated into each step of the clinical trial process
- Engagement in community capacity development
- Programs that are community driven and community controlled
- Trust and communication between researcher and the targeted population

You can learn more about the CLAS standards from these resources:

- The Office of Minority Health online at <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=11>
- National Standards for Culturally and Linguistically Appropriate Services in Health Care: Executive Summary. U.S. Department of Health and Human Services, OPHS, Office of Minority Health. (2001) <http://minorityhealth.hhs.gov/assets/pdf/checked/executive.pdf>
- Betancourt JR, Green AR, Carrillo JE. (2002) Cultural Competence in Health Care: Emerging Frameworks and Practical Approaches. The Commonwealth Fund. www.cmwf.org.
- Vigil A, Hotrum K, Rodriguez D, Sutin J, Armitage K. Culturally and Linguistically Appropriate Services (CLAS) Toolkit. Department of Health, New Mexico. <http://nmdohcc.org/files/DR-CLAS%20instrument%20final%208-18-09.pdf>

This presentation has been brought to you by EMPACT, enhancing minority participation in clinical trials.