



Examine the Ways in Which the Culturally and Linguistically Appropriate Services (CLAS) Standards can be Applied to Recruiting Diverse Communities to Clinical Trials

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.

Source: National Standards for Culturally and Linguistically Appropriate Services in Health Care. Executive Summary. U.S. Department of Health and Human Services, Office of Minority Health. March 2001.

What are the CLAS Standards?



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The CLAS Themes



Why is the CLAS standards important to clinical trials?

- The CLAS standards provide a systematic way to integrate culturally competent care into clinical trials
- Adoption of the CLAS standards makes it possible to:



Obtain true informed consent



Establish an intimate relationship between researcher and participant



Allow for better treatment adherence and outcomes

Case Study: Mohammad Kochi's Story

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.

Source: Worlds Apart by Grainger-Monsen, Maren, MD and Haslett, Julia.

A Four-Part Series on Cross-Cultural Healthcare by the Stanford University Center for Biomedical Ethics

ICARUS Films, 32 Court Street, 21st Floor, Brooklyn, NY 11201



Things to Consider



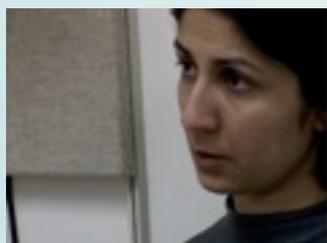
What role does language play in the development of a researcher-participant relationship?



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

It's not just good practice, **it's the law!**

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

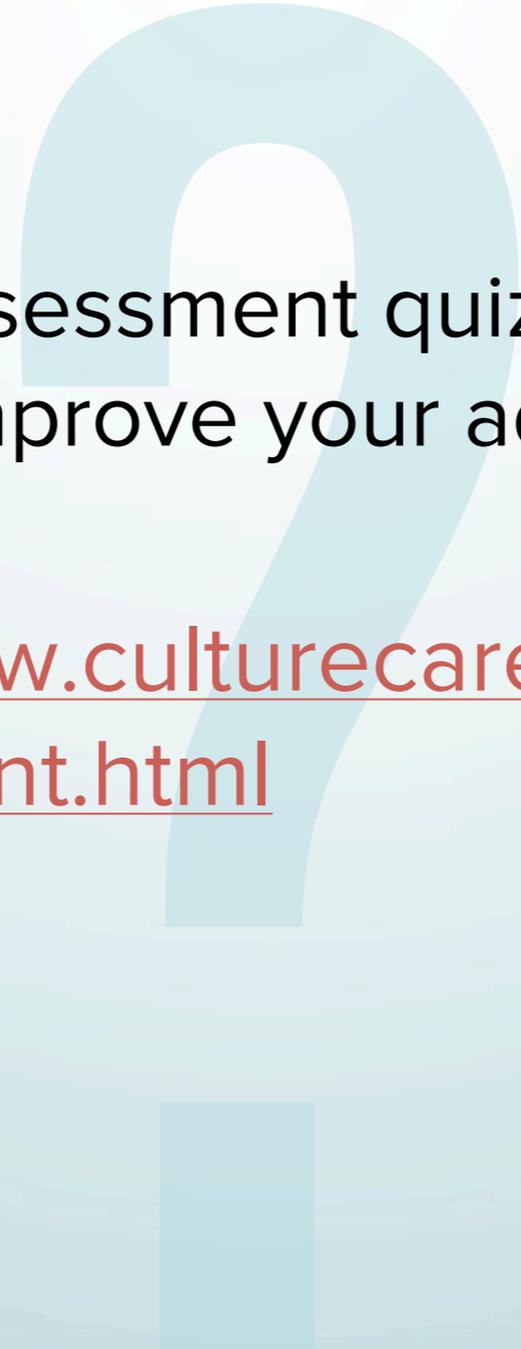


Any healthcare organization receiving federal funding is required to:

Access and assure the competence of language assistance provided to the patient

Make available easily understood patient-related materials, including signs, consent forms, medical information, etc.

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
- Link to quiz: <http://www.culturecareconnection.org/navigating/assessment.html>

In order to implement the CLAS Standards, it is crucial to:

- Recruit and train bilingual/bicultural staff
- Translate necessary research materials such as the consent forms, educational materials, and research protocols
 - Take into account the literacy rate of your target population reading level
 - **SMOG Tool** http://www.wordscount.info/wc/jsp/clear/analyze_smog.jsp
 - Engage the community in the development of research material via focus groups or community forums

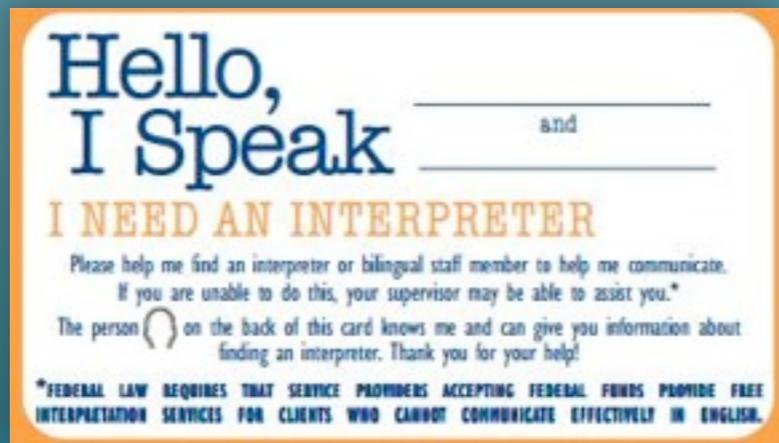
Recruitment and training of bilingual/bicultural staff



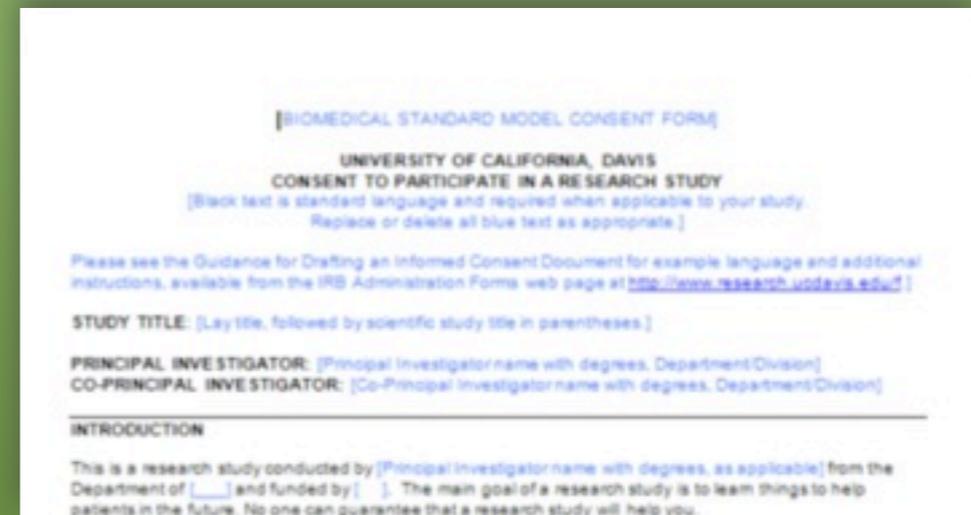
- Regularly train staff in cultural competency and CLAS standards
- Assess staff on their skills and comfort level of cultural terms/references

Translation of Necessary Materials

Usage of "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.

Case Study: Facing Growing Diversity

More Than Words: From Translation to Interpretation
<http://www.youtube.com/watch?v=kmKENXDHnGA>

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

Where can I learn more?

- The Office of Minority Health. <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>