



THE EDICT CLAS-ACT PROJECT¹

Introduction

“For many years, the underprivileged were exploited for the ends of medical research. In the 19th and 20th centuries, women, racial and ethnic minorities, the poor, children, those without decisional capacity, orphans and other groups were systematically forced or coerced into risky medical research either without their knowledge or informed consent.² While some of these benefitted physically from the experimental interventions, many did not, most were harmed, and all were wronged. Fortunately, codes of conduct,³ laws,⁴ and regulations⁵ were passed in the second half of the Twentieth century to help prevent these wrongs in the future.

“Unfortunately, when it comes to the inclusion of the underprivileged in beneficial clinical trials, there has been a pendulum swing in the opposite direction. While human subject protections now prevent the abuse of certain populations in medical research, these populations are now, for the most part, *under*represented in clinical trials. This contributes to health disparities by keeping the newest techniques and drugs out of the reach of disadvantaged groups, and by making approved drugs more dangerous for these populations because they may not have been tested on a sufficiently diverse participant pool to detect population-specific contraindications.”⁶

EDICT⁷

Eliminating Disparities in Clinical Trials (EDICT) is a four-year project (2005-2009) of the Chronic Disease Prevention and Control Research Center (CDRC) at Baylor College of Medicine and the Intercultural Cancer Council (ICC).^{8,9} The EDICT Project was designed to develop practical and realizable policy solutions to the problem of clinical trial disparities, through which change can occur at the federal, state, and institutional levels as well as in the public, private, and non-profit sectors. The project has two arms – policy research and field research – which provide both a theoretical and practical basis for policy recommendations.

National Standards on Culturally and Linguistically Appropriate Services (CLAS)¹⁰

The National Standards on Culturally and Linguistically Appropriate Services (CLAS) were developed by the Department of Health and Human Services (DHHS) Office of Minority Health (OMH) to help reduce health disparities as they impact racial and ethnic groups. (See Figure 1.)

The 14 standards are organized by themes: Culturally Competent Care (Standards 1-3), Language Access Services (Standards 4-7), and Organizational Supports for Cultural Competence (Standards 8-14). Within this framework, there are three types of standards of varying stringency: mandates, guidelines, and recommendations as follows:

CLAS **mandates** are current Federal requirements for all recipients of Federal funds (Standards 4, 5, 6, and 7).

CLAS **guidelines** are activities recommended by OMH for adoption as mandates by Federal, State, and national accrediting agencies (Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13).

CLAS **recommendations** are suggested by OMH for voluntary adoption by health care organizations (Standard 14).

The CLAS standards are primarily directed at health care organizations, and are intended to be integrated throughout an organization. However, individual providers are also encouraged to use the standards to make their practices more

culturally and linguistically accessible. In addition, the organizations are encouraged to implement the standards in partnership with the communities being served.

Culturally and Linguistically Appropriate Services And Clinical Trials (CLAS-ACT)¹¹

The CLAS standards were originally developed in the context of clinical care rather than research. However, the OMH has been intergrally involved with the EDICT project. Consequently, the CDRC proposed to OMH that CLAS standards be applied to eliminating disparities in clinical trials. In 2007, OMH provided initial funding to the CDRC to explore how to combine CLAS “And Clinical Trials” (CLAS-ACT).

Figure 1. National Standards on Culturally and Linguistically Appropriate Services (CLAS)⁹

Standard 1. Health care organizations should ensure that patients/consumers receive from all staff member's effective, understandable, and respectful care that is provided in a manner compatible with their cultural health beliefs and practices and preferred language.

Standard 2. Health care organizations should implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area.

Standard 3. Health care organizations should ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery.

Standard 4. Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation.

Standard 5. Health care organizations must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services.

Standard 6. Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).

Standard 7. Health care organizations must make available easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area.

Standard 8. Health care organizations should develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services.

Standard 9. Health care organizations should conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations.

Standard 10. Health care organizations should ensure that data on the individual patient's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated.

Standard 11. Health care organizations should maintain a current demographic, cultural, and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.

Standard 12. Health care organizations should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and patient/consumer involvement in designing and implementing CLAS-related activities.

Standard 13. Health care organizations should ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers.

Standard 14. Health care organizations are encouraged to regularly make available to the public information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information.

TIMELINE OF EDICT CLAS-ACT ACTIVITIES

CLAS-ACT Project Staff have worked closely with the OMH and CLAS-ACT Advisory Group since April 2007. The timeline of EDICT CLAS-ACT Project activities is as follows:

April – June, 2007

Project Staff invited selected individuals to serve on the CLAS-ACT Advisory Group, which convened in Houston, May 7, in conjunction with a regular EDICT meeting.

presentation about the project at the annual meeting of the Society of Clinical Research Associates (SoCRA) in Denver. The presentation audience were enthusiastic about the project and discussed ways in which CLAS standards could be formally incorporated into SoCRA initiatives.

June – September, 2007

Project Staff developed a work plan with methods and a timeline. In line with CLAS Standard 9, it was decided that a first project deliverable would be a self-assessment handbook. Both individual researchers and organizations could use the handbook to assess how well they incorporate CLAS standards into their clinical trials. Project Staff then develop a first draft of the CLAS-ACT Self Assessment Handbook.

October 2007 – February 2008

Project Staff revised the Self Assessment Handbook based on the Advisory Group's feedback and ongoing consultation with OMH.

March 2008

Project Staff distributed the next draft of the Self Assessment Handbook to the Advisory Committee and OMH for review.

September, 2007

On September 18, during the EDICT fall conference, the Advisory Committee met in Houston. They reviewed the first draft of the CLAS-ACT Self Assessment Handbook and provided feedback to the Project Staff. Project Staff also made a

April, 2008

The EDICT CLAS-ACT Project and Self Assessment Handbook were announced nationally in Washington, D.C., at a press conference and at the 11th Biennial Symposium on Minorities, the Medically Underserved & Cancer.

FOR MORE INFORMATION:

The CLAS-ACT Self Assessment Handbook and other resources for culturally and linguistically appropriate services can be found at the CLAS-ACT Website (<http://www.bcm.edu/edict/clas-act>).

For more information about the EDICT CLAS-ACT Project, contact:

Larry Laufman, Ed.D.
EDICT CLAS-ACT Project Director
Tel: 713.798.5387
E-mail: llaufman@bcm.edu

References:

1. The EDICT CLAS-ACT Project is funded under Cooperative Agreement Number MPCMP051006-03 from the U.S. Department of Health and Human Services Office of Minority Health to the Baylor College of Medicine Chronic Disease Prevention and Control Research Center.
2. Lederer, Susan D. *Subjected to Science: Human Experimentation in America before the Second World War* Baltimore: Johns Hopkins Press, 1995.
3. National Institutes of Health, "Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research," 59 FED. REG. 14,508, (1994).
4. Food and Drug Administration Modernization Act of 1997. Available at: <http://www.fda.gov/cder/guidance/105-115.htm>. Accessed 8/25/2006.
5. Centers for Disease Control and Prevention, "Policy on the Inclusion of Women and Racial and Ethnic Minorities in Externally Awarded Research," 60 FED. REG. 47, 947 (1995).
6. Eliminating Disparities In Clinical Trials: Executive Summary. Available online at: http://www.bcm.edu/edict/PDF/Policy_Primer_Intro.pdf
7. Eliminating Disparities in Clinical Trials (EDICT). Accessible online at: <http://www.bcm.edu/edict/home.html>
8. Chronic Disease Prevention and Control Research Center at Baylor College of Medicine. Accessible on line at: <http://www.bcm.edu/cdrc/>
9. Intercultural Cancer Council. Accessible online at: <http://iccnetwork.org/>
10. National Standards on Culturally and Linguistically Appropriate Services (CLAS). US Department of Health and Human Services Office of Minority Health. Available online at: <http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15>
11. CLAS-ACT Project. Accessible online at: <http://www.bcm.edu/edict/clas-act>