

Reaching Populations Labeled “Hard-To-Reach.”

By Linda Burhansstipanov, MSPH, DrPH, CHES; and Linda U. Krebs, RN, PhD, AOCN

People of all cultures want to live beyond a cancer diagnosis. If a clinical trial (CT) might help them, they will want information about the CT. The purpose of this opinion piece is to share experiences we have had implementing “Clinical Trials Education for Native Americans (CTENA)” – a population typically referred to as “hard to reach.”

Native Americans and other underserved groups can effectively be recruited and retained in CTs. In order to appropriately engage these groups, it is important to rectify some common misconceptions held by healthcare providers and/or Native patients regarding CTs. We will review these misconceptions and some recommendations for effectively recruiting underserved patients into CTs.

Brief Background

Despite recent decreases in national trends, cancer incidence and mortality continues to escalate among Native Americans (NAs).¹ (See Figure 1). Natives continue to have the poorest 5-year relative survival from “all cancers” in comparison to all other ethnicities in the US.² Since 1998, Native American Cancer Research’s (NACR) “National Native American Cancer Survivors’ Support Network”, has been collecting information from Native cancer patients. These data demonstrate that Native cancer patients are receiving neither *standard* nor *timely care* unless they have private health insurance.³ Furthermore, Indian Health Service (IHS) is under-funded by Congress, capable of supporting only 40-60% of the documented healthcare needs of Native peoples.³

Clinical Trials Curricula

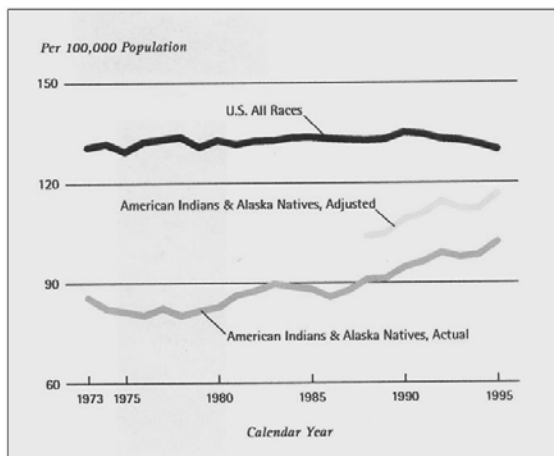
Two CT curricula offered by NACR in partnership with the University of Colorado’s Comprehensive Cancer Center and Mayo Clinic’s Native American Programs provide the basis for this opinion piece: (1) the “Colorado Culturally Competent Clinical Cancer Care Curriculum” (abbreviated as the “7Cs”) and (2) “Clinical Trials Education for Native Americans” (abbreviated as CTENA).³ These curricula were developed, implemented and evaluated with both providers and community members from 1998 through 2003.

Although the objectives addressed during the workshops differed, the overall pre-and post-workshop knowledge of the providers and communities at baseline and completion are very similar.

Between March 2004 and August 2005, 286 participants completed the 7Cs or CTENA curricula. The average pre-workshop percent correct is 58% for knowledge items and the average post-workshop percent correct is 83%, an average percent increase of 26%. In addition, when asked if they want more CT information to make an informed choice about taking part in a CT, all of the Native respondents said, “Yes.” This is a promising finding given some commonly held beliefs of Native communities regarding clinical trials, including:

- (1) Native people only receive the placebo and do not get *real* treatments;
- (2) Native people are used to test potentially hazardous treatments that would not be acceptable for white patients;
- (3) the treatments are actually to study something other than the reason for which the Native patient is seeking help;
- (4) the CTs are actually deceptive attempts to annihilate the race;
- (5) the CTs are costly and will not be covered by the Indian Health Service / Tribal and/or Urban (I/T/U) programs;
- (6) only the researchers benefit from the CTs by getting rich from patents; and
- (7) Native people are not really wanted on CTs.

IHS Age-adjusted Malignant Neoplasm Death Rates



IHS Trends, 1999, Chart 4.33, p. 116

Misconceptions and Brief Explanations

In addition to the above, there are also many misconceptions held by those responsible for supporting and conducting clinical trials. What follows is a brief synopsis of many of

these myths followed by brief explanations and/or recommendations.

Myth #1: We need to study and fund more studies on the barriers to medically under-represented populations’ participation in CTs.

While working at the NCI in the early 1990s, Burhansstipanov found more than 40 NIH-funded reports that repeatedly listed barriers to participation in CTs. Current literature cites numerous barriers for the recruitment and retention of women, minorities, and the medically underserved to cancer care trials.⁴

Given that there are few “new” barriers (e.g., Internet access, changes in healthcare system), and cancer monies have been limited in recent years, research dollars need to focus on culturally appropriate interventions designed to address the identified barriers.

Myth #2: Almost all barriers to participating in CT can be addressed by the healthcare facility providing transportation for the patient.

There are many barriers that can be more easily addressed than others. For example, for the cancer patient living in the city, travel vouchers (taxi, subway and bus fares) can be provided. However, for many of the Native patients and other underserved groups, travel barriers are broader, including travel that is more than a hundred miles one way to the nearest cancer center, high costs associated with lengthy stays far from home, financial and social costs of childcare during lengthy absences from home, and/or inability to work or participate in subsistence living responsibilities (hunting, fishing, etc.) while away from home undergoing treatment.

Myth #3: Problems of recruitment and retention of medically under-represented populations to CT can easily be addressed.

Research protocols often over-simplify the CT recruitment and retention processes. Some scientists naively believe that once they identify a precise barrier, this recognition will result in a “quick fix” to the problem. However, problems in recruitment and retention are complex, including:

- more time needed by providers to tailor information about CTs to the audience;
- time constraints placed upon providers by healthcare systems limiting adequate explanations of CTs;
- potential patient “loss” by referring providers if the patient enters a CT; and
- protocols that include only the 10-15 minutes per patient encounter typically mandated today.

Myth #4: Native communities realize they are rarely participants of CT studies and are eager to take part.

There are many reasons why Native communities are resistant to taking part in research studies. These include, but are not limited to: (1) Native people do not want to be “guinea pigs”; (2) the study findings are rarely shared with the participating Native communities; (3) the study findings rarely improve local services for the Native community; (4) the promised study benefits rarely reach the Native community; (5) insufficient access to resources to allow community members to participate in the study;⁵ and (6) a history of abuse of Native people who were included in studies without informed consent.⁶

Myth #5: AI/AN and other medically underserved communities are unlikely to adhere to the CT research protocol.

This is a common belief among many providers and health care professionals. However, once the patient understands why the protocol is so specific, minority, poor and other under-represented patients are very willing to adhere to the research regimens.

Myth #6: CTs are more costly than standard care.

It is a general belief of the healthcare community that treatment provided through a CT represents the best possible care that a

patient can receive. Contrary to common belief, participation in CTs is *not* more expensive than normal standard care.⁷

Myth #7: Sufficient monies are allocated by federal agencies for Cancer CT research.

In order to maintain an effective war on cancer, it is critical that we guarantee sustained sufficient levels of funding for cancer research. Over time, funding for cancer research, as with other issues, can be affected negatively by changes in the political climate—such as the present war overseas, bioterrorism, disaster relief—compromising our ability to sustain our progress and to continue making innovative advances. Just as with a physical war, if we do not sustain sufficient resources and reinforcements, we cannot gain new ground and we run the risk of losing territory.

Myth #8: All patients, regardless of race, poverty, and/or rural living environment are provided the same information as is an insured, educated white patient.

Many barriers exist that make Native populations less likely to consider enrollment. One of the most important is lack of information about clinical trials participation and access. Almost none (<5) of the 240 breast cancer patients in the Native Network were provided information about cancer care clinical trials. In some cases, information on the CT is not offered by providers or that when it is, the information is not provided in a manner that is culturally appropriate or at the literacy level of the patient.

Myth #9: Health literacy is rarely an issue affecting enrollment or retention in CT.

Health literacy is obviously more than one’s reading level. With respect to CTs, the consent processes must be at the appropriate reading, format, health literacy and numeric literacy levels. This affects people from all population groups.

Myth #10: The current informed consent processes are easy-to-understand by most patients.

The informed consent process was developed to ensure that patients enter a study with a clear understanding of what is expected and any associated risks. However, complex language, lengthy forms, and difficult to read font sizes can make informed consents difficult to understand. Increasing complexities added by the Health Insurance Portability and Accountability Act (HIPAA) and multiple Institutional Review Boards (IRBs) on a single CT can be a barrier to informed decision-making and discourage participation in CTs.

Myth #11: Providers are the most effective information source for CT.

Due to strict time constraints, physicians are limited to an average of 15 minutes per patient contact. This time constraint added to any cultural limitations of the provider may inhibit his/her effectiveness. It is important to have a culturally competent individual trained to work with the specific population(s) explaining the CT to potential participants. It is also critical that this be done in a manner allowing time to answer patient questions and concerns.

Myth #12: The only important measurement of success or efficiency is the number of medically under-represented people who are enrolled in CTs.

The “bottom line” for federal agencies is typically the number of people who enroll in a trial, followed by the number retained in the trial. However, there is great need to document the number of medically under-represented people who make an informed choice regarding their participation in a CT. What if the reason for refusal could be addressed with minor modifications to the protocol that would not minimize the scientific validity of the outcomes? We believe there needs to be an “interim goal” of documenting the patients who have enough *understanding* to make a fully informed decision about participation. Another “interim goal” is the number of patients who have *opportunities* to make a fully informed decision about participation. The omission of these two interim goals is probably related to the number of medically under-represented people who are not retained in a CT. We believe that there is a need for measures that document the full range of experience of individuals and providers including, but not limited to: (a) Awareness of clinical trials; (b) Decision-making determinants; and (c) Adherence to recommendations.



Conclusion

Clinical trials education needs to be offered to all people in a culturally and linguistically appropriate manner. The outcomes of CT education need to be *informed choice* by the participant not just successful “*enrollment*”, or *retention*.” After years dedicated to building trust, we are seeing more and more Natives successfully enrolled and retained in CTs. What we have learned is that under-represented populations can be recruited and retained in a clinical trial if:

- (1) the trial is explained in a relaxed manner that encourages questions;
- (2) the participant is provided with accurate information to eliminate misconceptions and to make an informed choice;
- (3) the participant is provided with culturally appropriate CT education;
- (4) the participant is encouraged to discuss the CT options with significant others (e.g., family);
- (5) the participant is provided with well-trained community navigators – preferably from a similar background – capable of explaining CTs in a culturally appropriate manner;
- (6) the participant is provided with resources that effectively address the barriers that interfere with their participation in the CT; and
- (7) the participant is allowed flexibility in the eligibility criteria.

Acknowledgments:

- “Clinical Trials Education for Colorado Providers” [PI Krebs; NCI R25 CA 82714]
- “Quality of Life: Native American Cancer Education for Survivors” [PI Burhansstipanov; Komen #POP0503920] and [#POP0202135]
- “Native American Cancer Education for Survivors” [PI: Burhansstipanov; NCI R25 CA 101938]
- Mayo Clinic’s “Spirit of E.A.G.L.E.S. SOE)” [PI: Kaur; NCI U01 CA86098];
- Mayo Clinic’s “Spirit of Eagles Community Network Programs” (PI: Kaur; U01 CA 114609)

References

1. Jemal A, Clegg LX, Ward E, Ries LAG, Wu X, Jamison PM, Wingo PA, Howe HL, Anderson RN, Edwards BK. Annual Report to the Nation on the Status of Cancer, 1975-2001, with a Special Feature Regarding Survival. *Cancer*2004;101:3-27.
2. Horm JW, Devesa SS, Burhansstipanov L. Cancer incidence, mortality, and survival among racial and ethnic minority groups in the United States. Eds. Schottenfeld D and Fraumeni, Jr. JF. *Cancer Epidemiology and Prevention*. Oxford University Press. New York. 1996.
3. Burhansstipanov L, Krebs LU, Bradley A, Gamito E Osborne K, Kaur JS . Lessons Learned while Developing “Clinical Trials Education for Native Americans” Curriculum. *Cancer Control*. September / October 2003: vol 10, No 5. 29-36.
4. For a comprehensive survey of the barriers to clinical trial accrual, see Ford JG, Howerton MW, Bolen S, Gary TL, Lai GY, Tilbourt J, Gibbons MC, Baffi C, Wilson RF, Feuerstein CJ, Tanpitukpongse P, Powe NR, Bass EB. Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials. Evidence Report/Technology Assessment No. 122 (Prepared by the Johns Hopkins University Evidence-based Practice Center) Rockville, MD. Agency for Healthcare Research and Quality. June 2005.
5. Burhansstipanov L, Christopher S, Schumacher A. Lessons Learned from Community-Based Participatory Research in Indian Country. *Cancer Control: Journal of the Moffitt Cancer Center*. November 2005; pp. 70-76.
6. American Indian Policy Review Commission’s Report on Indian Health. (1977). *American Indian Journal*, 17-23.
7. Fireman BH, Fehrenbacher L, Gruskin EP, Ray GT. Cost of care for patients in cancer clinical trials. *J Natl Cancer Inst* 2000;93:37-43.