

Cultural Considerations in the Conduct of Clinical Research: The Guam Experience

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Abstract

Cultural sensitivity provides one of the foundations for a successful clinical research within tribal communities. Researchers involved in the efforts that cross paths with cultural practices of human subjects must be aware of the potential impact as well as the challenges these will pose to the clinical research process. These were some of the insights gained from the research experience of the biomedical research team from University of Guam (UOGCRC) and the University of Hawai'i (UHCC) after conducting a study in Guam which aimed to describe the betel nut chewing practices of its indigents and identify specific biomarkers that occur in the saliva of humans after betel nut (BN) mastication.

An island in the western Pacific Ocean, Guam is home to a diverse society that reflects the blend of the culture of its original Chamorro inhabitants, and the political, economic and socio-cultural influences from the European, American, Asian, and other Micronesian peoples who have either occupied, visited and immigrated to the island since the 16th century. Betel chewing is an integral part of socializing in Guam and approximately 11% of the population chew betel nut on a regular basis. It is a social activity that imbues the spirit of familial goodwill even to strangers. The indigent people in Guam often offer the hard, mature nut at community celebrations and fellowships such as fiestas. However, the International Agency for Research on Cancer has deemed betel nut chewing (with or without tobacco) carcinogenic to humans. Epidemiological and animal data have suggested strong associations between betel nut consumption and oral mucosal diseases such as leukoplakia, oral and nasopharyngeal cancer, and oral sub-mucous fibrosis.

This paper looked into the cultural realities in Guam, its impact to the conduct of clinical research and the insights gained by the researchers from the process. Knowing the core elements of the culture in Guam was integral in the conduct of the clinical research that revolves around a very culturally-related practice which is the betel nut chewing. Seven cultural values were considered dominant and interrelated with the betel nut chewing practices in Guam: the importance of communal relationships; respect for familial and kinship influence especially authority; reciprocity; cultural practices and beliefs such as binge drinking and fluidity of time, language barriers; and the often paralyzing fear of social stigmatization. Researchers were reminded from the experience to be constantly mindful in approaching their work in order to guard against cross-cultural misunderstandings and/or misinterpretations.

Introduction

Cultural competence provides one of the foundations for a successful clinical research within tribal communities [1]. Researchers involved in the efforts that cross paths with cultural practices of human subjects must be aware of the potential impact as well as the challenges these will pose to the research process. According to Huang, Yates and Prior [2], culture, which refers to practiced values, beliefs, and ways of life, influences behavioral practices of certain groups in a society.

These cultural considerations were some of the insights gained by the researchers of University of Guam (UOGCRC) and the University of Hawai'i (UHCC) after conducting a study in Guam focused on describing the betel nut chewing practices of the islanders and identifying the specific biomarkers that occur in the saliva of humans after betel nut (BN) mastication [3]. Moreover, the study intended to develop a program for the cessation of the betel nut chewing practice which is considered a health hazard practice by the International Agency for Research on Cancer. Betel nut chewing practice is an integral part of socializing in Guam and Micronesia [4]. Thereby, any studies related to this practice are highly linked to culture.

Guam and the Betel Nut Chewing Practice

Guam, an island in the western Pacific Ocean, is home to a diverse society that reflects the culture of its original Chamorro inhabitants,

Publication History:

Received: February 08, 2016

Accepted: July 23, 2016

Published: July 25, 2016

Keywords:

Culture, Guam, Chamorro, clinical research, betel nut chewing

and the political, economic and socio-cultural influences from the European, American, Asian, and other Micronesian peoples who have either occupied, visited and immigrated to the island since the 16th century [5]. However, even in the face of acculturation, there are still cultural traditions and practices that remain in the Guam culture. One of these practices is the habit of masticating betel nut. According to Oakley, Demaine and Warnakulasuriya [6], betel nut chewing can be traced all the way back to the old traditions of the Chamorro people when it was very common. Approximately 11% of the population chews BN on a regular basis [7]. It is a social activity that imbues the spirit of familial goodwill even to strangers [8]. The people in Guam often offer the hard, mature nut at community celebrations and fellowships such as fiestas. It is a social activity that imbues the spirit of familial goodwill even to strangers [8].

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Citation: Mendez AJ, Arat-Cabading LC (2016) Cultural Considerations in the Conduct of Clinical Research: The Guam Experience. Int J Nurs Clin Pract 3: 188. doi: <http://dx.doi.org/10.15344/2394-4978/2016/188>

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The International Agency for Research on Cancer has deemed betel nut chewing (with or without tobacco) carcinogenic to humans. Epidemiological and animal data have suggested strong associations between betel nut consumption and oral mucosal diseases such as leukoplakia, oral and nasopharyngeal cancer, and oral submucous fibrosis [7,9].

Cultural Realities in Research: The Guamanian Context

In the conduct of clinical research in Guam, several cultural values that were interrelated with the betel nut chewing practices were encountered by the research team. Most of these variables were identified during the implementation phase, such as during the recruitment and screening of study participants, the conduct of the face to face interview, and the gathering of saliva samples. These cultural variables affected the clinical research process making it inevitable for the researchers to understand and address these cultural realities.

Cultural traits and values identified and considered dominant were categorized into common themes. Seven (7) cultural traits were then identified which are: (1) the importance of communal relationships; (2) respect for familial and kinship influence especially authority; (3) reciprocity; (4) cultural practices and beliefs such as binge drinking and (5) fluidity of time, (6) language barriers; and (7) the often paralyzing fear of social stigmatization.

Communal relationships

Central to the tribal culture in Guam is the great value they place for communal relationships. Historian Lawrence Cunningham [10] wrote, "Inafa'maolek, or interdependence, is the key or central value, in the Chamorro culture. Inafa'maolek depends on a spirit of cooperation. It is a powerful concern for mutuality rather than individualism." Thus, similar to most cultures in the Pacific, the Guam indigents have a collectivistic orientation or a great sense of belongingness to family, kin, church and community groups.

This relational culture was very much apparent during the recruitment and data gathering stages of the study. Researchers noted that when they first advertise the need for voluntary subjects, no one from the target population responded to the heavy distribution of flyers in villages, stores, workplaces and apartment complexes. Responses were only received at a positive rate when they were able to establish relationships with "one of their own" (Micronesian) and the recruitment was headed by these individuals. Hence, word of mouth and face to face interaction with the target population were more effective mechanisms.

Respect for familial and kinship influence especially authority

In a similar way, the participants were more cooperative when they identified with the one who was taking the lead in the study. It was critical that the research was endorsed by an individual from the same communal group since this gave the participants impetus to become more open and participative to the process. When the participants became comfortable, misgivings about participating in the research activities were limited. This strengthened the collaborative nature of the study and maximized inclusivity in the process. However, on another hand, this meant that the study participants hastily complied (without asking questions)

with the entire process. Such immense confidence and trust in authority and kin creates the possibility of the study participants becoming susceptible to misinformation, manipulation and abuse.

To avoid this, the researchers made an effort to explicate the need for the participants to become informed of the nature, purpose and methodology of the study. The principal investigator (researcher) read and clarified page by page the content of the consent form. The form explicitly described the nature of the proposed research, procedures involved, potential benefits, foreseeable risks, and a description on the confidentiality measure and consent for collection of their saliva during the study. The informed consent form also emphasized that study participation was voluntary and that refusal to participate was possible at any time without loss of any associated benefits [3]. Furthermore, study participants were allowed to discuss the study with their family, friends and healthcare provider before deciding on participating in the clinical research.

Reciprocity

Another fundamental value within the culture in Guam that is related to inafa'maolek, is that of reciprocity. Reciprocity is regarded to be an essential part of Pacific cultures. It is associated with the "exchange of goods, service, trust, loyalty, and social good will" [11]. In Guam, it manifests the value of mutuality within the family and community which is associated with strengthening and maintaining integrity among them [12]. Reciprocity in the study was apparent in the building of trust of the researchers with the volunteers. This confidence-building was a necessary aspect because participation was voluntary and immediate compensation was absent. Not only did this process showed appreciation for their time and effort exerted in the study, it also helped attract more participants.

Moreover, as a manifestation of reciprocity, the study must also be relevant to the community. In line with the fact that some members of the community may hold uncertainties about participating in the research, the researchers made an effort to show how the research study could bring about positive results that will directly affect them. Once the participants were confident of the good nature of the research's goals, they were able to fully commit to the activities. Nurturing and sustaining trust among each other is part of the process of creating a meaningful engagement with communities. At a deeper level, it sets the space for the subjects themselves to have a sense of mutual ownership of the study.

Cultural practices and beliefs such as binge drinking

An underlying factor that influenced this attitude is their habit of binge drinking. It is common knowledge, and all study participants admitted themselves, that drinking heavily during weekends and the days leading to the weekend is a common practice in Guam. This habit greatly affected the scheduled time of the screening, as well as the trial days of the research. For example, in the selection stage where researchers and participants agreed to meet from 8:00 am - 12:00 noon on a Saturday, none of the participants showed up for the activity because they were either still intoxicated or suffering from the delayed after effects of heavy drinking the night before. For this reason, the researchers decided to conduct the research activities only during afternoons to allow the study subjects to recuperate and become physically present in the meetings and trials.

Fluidity of time

One other critical aspect in Guam culture that led to some adjustments to the conduct of the study was their concept of time. For Pacific islanders, their concept of time is much more flexible and subjective [13]. The same is true for the study participants. This sense of the fluidity of time caused some difficulties in the implementation of some of the research activities especially during the screening stage of eligible subjects. For instance, when both the investigators and participants agreed to meet on a specific time to conduct an activity relevant to the study, most participants never arrived at the expected time of the meeting, some were at least an hour late. Because of this, the initial stages of the study took longer than expected. Their commitment to honoring mutually-arranged schedules was inconsistent despite pronouncing to be present for meetings and activities and being constantly reminded by their leaders.

In addressing this cultural constraint, Holkup, et al. [1] recommended that the researchers approach the process from a stance of frequent and thoughtful self-reflection and self-critique in order to guard against cross-cultural misunderstandings and/or misinterpretations. Marshall & Batten, [14] emphasized that flexibility, adaptability and respect on the part of the researchers must be consistently practiced. Thereby, in this situation, the researchers did some process adjustments like making follow up the participants through individual phone calls and even going to great lengths by sending vehicles to transport them from their place of origin to the study sites.

Language barriers

Communication nuances were also a challenge to the participation of study subjects particularly in the screening process. Sharma [15] explains it succinctly, "language barriers prevent true exchange of ideas, especially with respect to case studies research across cultures." Research studies commonly require participants to fill out various types of study forms such as the informed consent and health assessment questionnaires. Furthermore, the challenge presented by the differences of language was apparent when the researchers asked the study volunteers to read and sign the informed consent form. Those who were not fluent in the English language rashly gave their consent and signed the form for fear of being discovered as illiterate.

Recognizing this barrier, the researchers ensured that the various forms used in the study were linguistically validated and culturally adapted to ensure accuracy of information. Inaccuracies can result in changing the outcome of a study, or even cause the study to be invalidated. To ensure success, the translation of the research study documents were performed by experts who were native speakers, familiar with the culture, and have a background in research. The researchers also discovered that by explaining the materials and procedures during the screening until the trial stage verbally in the language of the study volunteers, they were able to overcome the challenge.

Paralyzing fear of social stigmatization

Fear was also noted to be another consideration in the conduct of the study. In Guam, identified areca nut chewers are defamed by outsiders as "islanders." This term was used often to degrade natives in the island as uneducated, poor and/or dependent to the support from the U.S. government to Guam. During the recruitment phase,

flyer distribution and identification of areca chewers, the researchers discovered that the target populations (Micronesians) were afraid of admitting that they were areca chewers for fear of the social stigma that accompanies being labeled as such. In the study, the participants initially denied this fact about them but later admitted the truth. When asked about the rationale behind the hesitation when giving up this information, most of them stated that not only were they sensitive of the stereotype, they were also apprehensive that the researchers would ask them to stop the practice.

The researchers noted that the participants, in fact, did not want this habit to be stopped despite knowing the high correlation between mastication of areca nut and serious medical illnesses such as cancer. This interesting knowledge confirms the basic notion that in order to have a better grasp of the cultural values that have had an impact on clinical research, it is helpful for the researcher to understand primarily the core elements of the culture of the participants. It is relevant to design the research process in the context of existing cultural values to safeguard the participants from discrimination, coercion, and manipulation and to facilitate the success of the research as well. Understanding cultural factors prevented the researchers from overlooking other aspects of local life (such as their fear of social stigmatization) that impacted recruitment of study participants.

Conclusion

It is apparent that the cultural diversity of a community necessitates adjustments in how clinical research is designed and conducted. There are cultural norms that must be considered in research especially when centering on certain indigenous communities as research participants. Researchers are increasingly required to have the ability to better understand the potential role of cultural differences among population groups, how such differences may impact their research study design, analysis and interpretation, and consequently how best to engage diverse populations in research. In recognizing and adhering to what is culturally appropriate in various phases of the study, outcomes of the research process is highly improved particularly the level of participation from the subjects both qualitatively (confidence in the researchers and the process) and quantitatively (turnout and punctuality). As Holkup, et al. suggested, when negotiating between diverse cultures, taking the time and making the effort to build rapport and establishing trusting relationships between the research team and the community is critical to addressing these cultural challenges.

Competing Interests

The authors declare that they have no competing interests

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