

Case Study Topic

- 1. Cultural Differences and Effective Collaboration**
- 2. Academic Health Centers and Community Clinicians -Barriers In Forming Partnerships**
- 3. Community Reluctance to Participate in Clinical Research Activity**

Case Study Topic

Cultural Differences and Effective Collaboration: Two contrasting stories of collaborations involving minority communities in Seattle.

Research question

1. The Kame Project is a study set in the Japanese American community of King County Washington. The study had its origins when a member of our Alzheimer's research community had a sabbatical at the Tokyo Metropolitan Geriatrics Institute in the Early 1980s. This led to interest in developing migration studies of populations in Japan, Honolulu and a US population. Eventually an RFA was issued and a team from Seattle decided to apply. Prior to this decision there had been 3 meetings of UW investigators, community representatives and on two occasions collaborators from Japan and Honolulu.

There had been other studies in this community of Diabetes and vascular diseases. However, when the dementia research group approached the community with the idea that we needed to perform a census, we were told by other investigators that given the experience of so many persons from this age group with selective service registration and the subsequent forced movement of Japanese American families into secure camps in California and the Pacific Northwest, they expected there would be a natural reluctance to being "counted" and singled out for enrollment in a research study aimed to determine prevalence and ultimately incidence rates and risk factors for dementia and Alzheimer's disease. This was confirmed when we spoke with Japanese American colleagues, community leaders and informal conversations with neighbors. With this in mind we formed a community advisory board before even submitting a grant, discussed the best approach to developing the project, and committed to working with a community advisory board consisting of clergy, community leaders, social workers and others who appreciated the potential for medical research to provide general good and also were sensitive to cultural values, including the heterogeneity across generations and experiences, of the Japanese American community.

In our grant, we spent considerable time explaining our approach and outlining the pre-work we had done with the community and had a specific work plan to partner with the community in the research project through the community advisory board, and through our intention to hire a staff that would be by design 50% of Japanese American or mixed Asian background.

When the project was funded, we celebrated with the entire community, began to serve on other community boards, and were able to recruit a competent staff which also had strong roots in the community. We met quarterly with the "CAB" (community advisory board), developed a culturally appropriate name (Kame – the turtle which is a symbol of aging), a logo designed by a local artist. The project endured for 11 years and has since been succeeded after a several year hiatus with a research team aiming to study both Japanese and Chinese American Seniors. For the investigators, staff and community the whole project was a great experience – scientifically, personally and for the cultural lessons we learned from the work we did together. On occasion we had to either abandon well intentioned plans, spend more time explaining them and/or develop more detailed communication plans to ensure we had support for studies which initially we were told "wouldn't fly". We were not independent scientists but ended up feeling we had a genuine partnership with the community through the CAB. At the end of the study, the PI wrote a summary of every paper, abstract and a general synopsis of what we had learned from the Kame project and placed this in the context of advances in the emerging science related to late life dementias

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and migration studies of other chronic diseases. We also commissioned a lithograph and sent this as a gift with the report to all participants.

2. At about the same time, there was great interest in the transplant community about the availability of organs for minority persons suffering from end stage heart, kidney and liver diseases. There was also a program project from NHLBI which was designed to develop bone marrow donor registries for persons who would be candidates for bone marrow transplantation. An grant or contract was developed by a well known cardiac surgeon purporting to work with African American churches to encourage donor registration through driver's licenses and enrollment in the developing Bone Marrow Donor Registry at the Puget Sound Blood Center. The grant or contract proposal was written with a short timeline and some last minute endorsement by one or two African American clergy – albeit without a great deal of advance planning. After a rocky start, I think it is fair to say, that the program was not the least bit successful. In fact, there were official community protests against the high handed tactics of the busy surgeon and the lack of connectedness with the Blood Center team that was mounting the Bone marrow donor registry. At least one lawsuit as well as other protests were lodged against the investigative team – who had only the best interests of the community and the best of intentions. The project was abandoned and persons at the university and in the community quietly practiced damage control and fence mending. It is possible that some of the problems spilled over into a conflict between the African American community and the obstetrics services leading to a major effort to address cultural differences and “institutional racism” concerns which ultimately did result in an improvement in relations.

Case Study Topic

**Academic Health Centers and Community Clinicians -
Barriers in Forming Partnerships: Research priorities
versus clinical care priorities.**

Center for Disease Control and Prevention: Contract number 200-94-0839
Evaluation of Clinical laboratory Tests in the Diagnosis and Treatment of Urinary Tract Infections

Research question

Microbiologic testing in the primary care office substantially decreased following the introduction of Federal CLIA legislation in 1995. Within a few years, 80% of primary care practices found themselves unable to perform microbiologic tests in practice laboratories. Among the most frequently missed procedures was urine culture and sensitivity testing used in the diagnoses of urinary tract infections (UTI). Following CLIA, most practices sent their urine cultures to an outside laboratory for calibrated loop inoculum culture and Kirby-Bauer sensitivity training. The purpose of the proposed study was to determine whether alternative laboratory methods, specifically a low complexity test known as dip inoculum and direct sensitivity training, could be used in place of the highly complex test of calibrated loop and Kirby-Bauer testing. If dip inoculum techniques performed as well in the primary care practice as calibrated loop and Kirby-Bauer techniques did in the laboratory, primary care providers could again offer a rapid, low cost alternative for UTI diagnosis while maintaining a "low complexity" laboratory.

The study was conceived of at the Center for Disease Control and Prevention (CDC) by a young clinical investigator interested the potential for practice-based research, and a subcontract was awarded to a large national contract research organization (CRO) to provide support. Four Practice Based Research Networks (PBRNs) of primary care clinicians agreed to participate, and met at the CDC to initiate the study. Unfortunately, within a few weeks of the meeting the CDC investigator died unexpectedly. While the CDC looked for another suitable lead, responsibility for the study moved to the contracted CRO. A senior investigator with 20 years of experience in public health epidemiology was selected from the CRO to lead the study along with a seasoned research coordinator with 15 years of experience in laboratory technology. Following the death of the CDC investigator 3 of the 4 participating networks dropped out. Our network did not.

The study design seemed straightforward. All clinicians in participating primary care practices who saw patients with urinary tract infections would be involved in enrolling patients. Nurses would initially screen suspected UTI patients based on presenting complaint, complete a one page data collection form, and consent the patient. Next, the treating clinician would make a final determination of the patient's eligibility based on explicit criteria, record an assessment on a data collection form, return the form to the nurses station, and have the patient added onto the study log.

Next the patient's urine specimen would be randomized in the laboratory to one of two treatment groups. In the first treatment group the urine specimen would be sent to the central lab where a calibrated loop culture and Kirby Bauer test would be performed and the results faxed back to the clinic. In the second treatment group the specimen would be divided in two aliquots, one for the local clinic where dip inoculum testing would occur, and the second for the central laboratory where calibrated loop and Kirby-Bauer testing would occur. In this group the clinician would treat the patient based on the dip inoculum, and would not receive the results of the central laboratory testing.

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After four weeks the CRO would send the patient a follow up form which the patient would return to the clinic. The clinic would complete additional follow up information, and return it to the CRO. The clinic would be reimbursed \$20 for each consented patient, and \$20 for each followup. The CRO would provide all testing material, training, and postage.

Before long, the study began to run into serious problems.

- 1) Practice laboratory personnel quickly determined that the dip inoculum test being used did not have an existing CLIA complexity certification. In order to perform experimental techniques, the clinic was required to have a high complexity laboratory with a pathologist as the laboratory director. From over 100 clinics in the network, only three were identified with the necessary laboratory and staff certification. All three volunteered.
- 2) A letter was sent from the CRO to all staff at the participating clinics announcing arranged training dates. The project coordinator and a CRO staff member scheduled a meeting with each clinic - from 6 to 7:30 AM for all clinical providers, from 8:00 AM to 10 AM for nursing and research staff, and from 10:30AM to 12:00 PM for laboratory and other personnel. A 42 page manual of operations was sent to a designated volunteer staff member with forms for: 1) re-ordering expendable supplies, 2) equipment temperature log, 3) media shipment inspection log, 4) quality control log, 5) enrollment log, 6) test requisition forms, 7) and three different laboratory reporting forms for urine testing results based on the participant's randomization status. All physicians were provided with a nine page set of detailed instructions. Medical assistants were given a 14 page set of instructions detailing procedures for rooming patients with potential symptoms of urinary tract infection.. Another clinic dropped out, leaving two.
- 3) A 31 page contract was sent to each remaining clinic from the CRO confirming participation in the study and requiring monthly reports, weekly updates of recruitment, and compliance with Federal Acquisition Regulations. The PBRN decided to pay the clinics and began sending cans of popcorn.
- 4) Recruitment began in December, and averaged 14 patients per month from each clinic. This was fewer than expected, and the study was already behind schedule. The screening and recruitment logs demonstrated that apparently all eligible patients agreed to participate in the study. However it was noted that some patients were being treated over the telephone without coming in to the clinic. Since the study intended to capture all eligible patients, a meeting of participants was arranged to address the potential impact of this issue on the clinical findings. The PI offered creative methods of randomizing the telephone calls when patients called in with symptoms of urinary tract infection. He wanted all patients to drop off urine samples at the clinic before initiating treatment. The clinicians were concerned about the additional effort involved in capturing and randomizing after hours calls, the difficulty of having staff appropriately triage UTI symptoms, and potential medical and social problems associated with delaying treatment. The PI believed that failure to include all potentially eligible patients in the study could produce serious biases. He suggested that the practices should stop providing antibiotics over the phone (a questionable practice anyway) and instead have the patients come to the clinic for evaluation. The clinicians were convinced that the practice of providing antibiotics over the phone was not only safe, but was the most cost effective strategy for providing care and was endorsed by some existing guidelines. Unfortunately both participating clinics were unable to come to an agreement with the Principal Investigator. The following month the study was canceled, having recruited 118 patients.

The project officer subsequently appointed by CDC wrote a very kind letter pointing out that "the successful execution of practice-based research requires striking a very delicate balance between the scientific demands of the research and the clinical and pragmatic demands of a busy practice."

Case Study Topic

**Community Reluctance to Participate in
Clinical Research Activity**

Research question

Many of the communities that RIOS Net works in are minority and/or underserved. Early in the network's operations, focus groups were conducted in these communities to discuss views about health research of the type the network might do in their communities. The following are excerpts from some of the transcripts of those focus groups:

"Well, the community can be labeled defective in some way if they have a higher rate of a disease and that's a big concern in Indian communities, especially the Navajo tribe as a whole and in individual Pueblos. They don't want to see the name of their tribe on the front page of the paper again saying they have more of something bad which leads to more discrimination against them."

"People say, 'we're going to be studied? We've been studied over and over and over again and then how is it going to benefit us, you know?'"

"If people know that we have a high incidence of diabetes or something else, that could skyrocket health insurance costs or workforce issues and now they're going to be out of work more because of this. I could see that being an impact when the community is looking to bring in a new manufacturer or something along those lines. I know they look at those sorts of things nowadays when they look at communities."

"Who is it going to benefit, you know? Is it really going to benefit the Hispanic culture? Is it going to benefit white people? Who is it really going to benefit?"

"What I've seen is [that] research groups will make every effort to obtain permission. They'll do anything to get it and once they do it, they look at the results and they'll say, 'Here. Here are the results.' And they won't explain in detail. They won't come back and tell the community. They won't come back and go to the councilmen who gave them approval and explain in detail to where they would understand. Not to where the researchers would understand, but to where the community members would understand."

"I think it would be something that would affect us emotionally because we are already discriminated against in communities and if you add to that an illness I think it would affect us."

"I've had a lot of bad experiences. Some of the concerns I have are you don't ever hear back or that they do a research study and they say, 'Okay. This is the results. See you later.' You know there's not a next step. There's no 'Let's help design some interventions to deal with what the results of this health survey were.' You know, 'Let's help the community build the capacity to deal with what this condition or concern is that was researched.'"

"How is this information passed on? Where does that information go? How is it disseminated? Where does this information go is my question?"