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Reality Versus Grant Application Research "Plans"

Linda Burhansstipanov
Native American Cancer Initiatives

Linda U. Krebs
Native American Cancer Initiatives

Daniel Petereit
Rapid City Regional Hospital

Mark Dignan
University of Kentucky

Sheikh Iqbal Ahamed
Marquette University, sheikh.ahamed@marquette.edu

See next page for additional authors

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Authors
Linda Burhansstipanov, Linda U. Krebs, Daniel Petereit, Mark Dignan, Sheikh Iqbal Ahamed, Michele Sargent, Krisin Cina, Kimberly Crawford, Doris Thibeault, Simone Bordeaux, Shalini Kanekar, Golam Mushih Tanimul Ahsan, Drew Williams, and Ivor D. Addo

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Linda Burhansstipanov
Native American Cancer Initiatives, Pine, CO
Linda U. Krebs
Native American Cancer Initiatives, Pine, CO
Daniel Petereit
Rapid City Regional Hospital, Rapid City, SD
Mark B. Dignan
Southeastern Program Evaluation Inc., Lexington, KY
Sheikh Iqbal Ahamed
Marquette University, Milwaukee, WI
Michele Sargent
Avera Health, Rapid City, SD

Kristin Cina
Rapid City Regional Hospital, Rapid City, SD
Kimberly Crawford
Rapid City Regional Hospital, Rapid City, SD
Doris Thibeault
Rapid City Regional Hospital, Rapid City, SD
Simone Bordeaux
Rapid City Regional Hospital, Rapid City, SD
Shalini Kanekar
Rapid City Regional Hospital, Rapid City, SD
Golam Mushih Tanimul Ahsan
Marquette University, Milwaukee, WI
Drew Williams
Marquette University, Milwaukee, WI
Ivor Addo
Marquette University, Milwaukee, WI

Abstract

This article describes the implementation of the American Indian mHealth Smoking Dependence Study focusing on the differences between what was written in the grant application compared to what happened in reality. The study was designed to evaluate a multicomponent intervention involving 256 participants randomly assigned to one of 15 groups. Participants received either a minimal or an intense level of four intervention components: (1) nicotine replacement therapy, (2) precessation counseling, (3) cessation counseling, and (4) mHealth text messaging. The project team met via biweekly webinars as well as one to two in-person meetings per year throughout the study. The project team openly shared progress and challenges and collaborated to find proactive solutions to address challenges as compared to what was planned in the original grant application. The project team used multiple strategies to overcome unanticipated intervention issues: (1) cell phone challenges, (2) making difficult staffing decisions, (3) survey lessons, (4) nicotine replacement therapy, (5) mHealth text messages, (6) motivational interviewing counseling sessions, and (7) use of e-cigarettes. Smoking cessation studies should be designed based on the grant plans. However, on the ground reality issues needed to be addressed to assure the scientific rigor and innovativeness of this study.

Keywords

Native American/American Indian, minority health, health disparities, cessation, tobacco prevention and control, Internet/electronic interventions, technology, health education, cultural competence

Introduction

This article reflects “research to practice” mission of *Health Promotion Practice*. Regardless of how diligent a research team may be when writing a grant application, by the time the grant is awarded (typically more than 1 year following submission), several changes commonly need to be integrated into

the planned research protocol to successfully carry out the project. This article describes implementation of the American Indian mHealth Smoking Dependence Study (PQ4; RFA CA-11-011 NCI Provocative Questions), focusing on the differences between what was written in the grant application compared to what happened during implementation. It provides insights into ways the project team modified strategies to yield successful outcomes by maintaining flexibility and retaining scientific rigor even when the implementation plan deviated from the original proposal. The purpose of this article is to fill a gap in the literature related to how grant protocols must evolve to best accomplish study aims while maintaining ethical and scientific standards.

Background

Lung cancer is a particularly important public health issue among American Indians (AIs) due to higher prevalence of daily cigarette use, which is nearly double that of non-Hispanic Whites (Cobb, Espey, & King, 2014). Similarly, the decline in tobacco use reported for most racial/ethnic groups is not observed among AIs (Centers for Disease and Prevention, 2012; Plescia, Henley, Pate, Underwood, & Rhodes, 2014). AIs also have significantly higher mortality rates and die more rapidly from lung cancer than do non-Hispanic Whites (White et al., 2014). Of importance, AIs also have statistically significant regional differences in cancer mortality rates, with deaths from lung cancer posing a major problem for AIs living in the Northern Plains (Espey et al., 2014).

In 2011, the National Cancer Institute developed the Provocative Questions (PQs) Initiative and released a series of Requests for Applications to support new research projects designed to use sound, innovative strategies to solve specific problems and paradoxes in cancer research. The study described in this article was designed to address PQ4: Why don't more people alter behaviors known to increase the risk of cancers? and to specifically answer the research question, "Why don't Northern Plains American Indians alter tobacco use behaviors known to increase the risk of cancer?" The study was based on the theory of planned behavior (Ahsan et al., 2013; Ajzen, 1985; Hukkelberg, Hagtvet, & Kovac, 2014; Quinn et al., 2011) and used the phase-based framework for smoking cessation that divides the cessation process into four discrete phases: (1) motivation, (2) precessation, (3) cessation, and (4) maintenance, to guide the intervention (Baker et al., 2011; Collins et al., 2011).

The project setting was a cancer institute based in the northern plains that is the primary treatment site for AIs with lung cancer living in South Dakota. The project team members from this cancer institute included the principal investigator and project coordinator as well as three community research representatives (CRRs) who work in Rapid City or on the Pine Ridge or Rosebud Reservations. The team also included two researchers from a Colorado community-based, AI nonprofit organization that provides cancer-related interventions within indigenous communities; the director of a Wisconsin-based computer science laboratory well known for designing mHealth programs specifically for poor and underserved communities; and a well-established statistician with an evaluation corporation based in Kentucky. Each setting had a community advisory committee that provided guidance throughout the first 18 months of the study. Additionally, two series of usability tests were conducted in each of the three project settings: one on survey items and the other on text messages to ensure materials were culturally congruent with the cultural beliefs and norms of the AIs residing in the study settings.

The project was designed to evaluate a multicomponent intervention involving 256 participants randomly assigned to one of 15 groups (at least 16 participants in each group). Participants received either a minimal (M) or an intense (I) level of the four intervention components: (1) nicotine replacement therapy (M = 1 NRT product; I = 2 NRT products), (2) precessation counseling (M = 2 counseling sessions; I = 3 counseling sessions), (3) cessation counseling (M = quit date counseling plus 2 additional counseling sessions; M = quit date counseling plus three additional sessions), and (4) mHealth (M = 2 mHealth text messages daily; I = 4 mHealth text messages daily; see Table 1).

Table 1 Experimental Design Used to Investigate the Four Components of Phase-Based Framework

Group	Component 1: Precessation and Cessation Nictoine Patch and/or Oral NRT	Component 2: Precessation Counseling (Phone and m-Health)	Component 3: Cessation In-Person Counseling	Component 4: m-Health Text Messaging (Query and 2-4 Culturally and Phase Tailored)	All Groups[a]: Maintenance Medication for 16 Weeks
1	Intense	Intense	Intense	Intense	
2	Intense	Intense	Intense	Minimal	
3	Intense	Intense	Minimal	Minimal	
4	Intense	Intense	Minimal	Intense	
5	Intense	Minimal	Intense	Intense	
6	Intense	Minimal	Intense	Minimal	
7	Intense	Minimal	Minimal	Intense	
8	Intense	Minimal	Minimal	Minimal	
9	Minimal	Intense	Intense	Intense	
10	Minimal	Intense	Intense	Minimal	
11	Minimal	Intense	Minimal	Minimal	
12	Minimal	Intense	Minimal	Intense	
13	Minimal	Minimal	Intense	Intense	
14	Minimal	Minimal	Minimal	Intense	
15	Minimal	Minimal	Minimal	Minimal	

NOTE: NRT= nicotine replacement therapy. There were 16+ participants per group, 256 participants recruited.
[a] All groups because research shows maintenance medication is recommended for all cessation participants.

To be eligible, participants had to be AI, smoke daily, be at least 18 years old, and live in one of the three South Dakota study sites. They also needed to be willing to (1) stop smoking within 3 months from date of recruitment, (2) complete carbon monoxide tests, (3) use a nicotine alternative (patch, gum, and/or lozenge), (4) take part in motivational counseling sessions, (5) receive and respond to daily mHealth text messages about smoking cessation, and (6) meet with the CRRs up to 11 times (surveys, carbon monoxide tests, counseling) during the study. Those with a previous or current diagnosis of cancer could enroll. Individuals were excluded from participation if pregnant, enrolled in another smoking cessation program or study, using or planning to use any smoking cessation prescription medication, using or planning to use e-cigarettes, or during a quit attempt.

The study used iPads for the informed consent process and data collection. The iPads include tailored information for each study visit including schedules, protocols for counseling sessions, survey items, and process interactions. mHealth (mobile health) text messages, transmitted through study-provided cell phones, delivered health-related smoking cessation information up to four times daily to study participants.

The project team used biweekly calls/webinars and one to two in-person meetings each year to review study progress and to discuss challenges and identify solutions to project-related problems occurring during meeting intervals. These helped identify innovative strategies to address tobacco cessation within a population well-known for excessive tobacco use. The sessions also were a significant component of the process evaluation that allowed the team to recognize issues and make proactive changes in a timely manner.

A total of 256 individuals were recruited to the study; 21 were cancer survivors. While currently in the final data analysis phase, carrying out the study provided many lessons on how plans made during the initial application had to be altered or adapted to meet the realities of study settings, populations, protocols, staff, and other unforeseen events that affect day-to-day study conduct.

Results: Required Project Alterations

Cell Phone Challenges

Loss of Phones Purchased for Participants

To facilitate effective participation in the study, the project provided cell phones to all participants. All phones were basic phones that included unlimited talk and text but could not access the Internet. Despite signing a contract and receiving specific instructions for responsible use, 45 phones (20%) were replaced, significantly higher than the 5% to 10% estimated. The CRRs confirmed that many were lost, others loaned to family members, several reportedly run over by vehicles, a few dropped in toilets, and a few broken while used as hammers to knock on a door or loosen a stuck item. Due to a decrease in phone price from $60 at grant submission to $35 during implementation, replacements did not adversely affect the study budget.

To prevent similar losses, the project team discussed steps to increase users' behaviors to keep the phones safe and functional. At each participant visit, the CRRs inquired how the phone was working, asked to see the phone to assess for loss or damage, and discussed its safe and appropriate use. Unfortunately, this did not significantly reduce cell phone loss or damage. To encourage greater personal accountability for cell phone safety and functionality and to minimize cell phone loss or damage in future studies, the project team recommends using the participants' personal phone and will provide a small monthly incentive to partially pay participants' phone bill.

Improper Use of Phone and Service Fees

Based on numerous conversations with phone company representatives, the team estimated a $20 per month service charge for each deployed phone. Because the intervention had staged recruitment, the maximum number of phones in use at any one time was expected to be 120 for $2,400 in monthly service costs. However, for at least 4 months, the total monthly bill was as high as $9,000. This deviation

occurred for several reasons (1) the discounted service cost negotiated with the phone company was not honored; (2) there were many over charges and duplicate charges for activating individual phones; and (3) there was heavy use of 411 (information) calls at $1.99 for each call (a few participants generated almost $400 *each* in 411 calls over a 1-month period) and high numbers of collect calls. Attempts to resolve service plan issues were not successful. The CRRs repeatedly reminded participants that the phone was for study purposes only and could not be used for 411 or collect calls. Unfortunately, blocking select services/features was not feasible for the types of phone purchased for this study. Gradually, with continued reminders, only a few continued to abuse the phones and monthly bills decreased, but they never became as low as originally estimated. Excessive phone charges were eventually offset using institutional funds.

Participant Misrepresentation of Tobacco Use for Access to Study Phone

The word that phones and phone services were being provided by a study spread quickly in the study settings. Some community members called the CRRs and wanted the phone, even though they did not smoke. A few nonsmokers exposed themselves to smoke (visiting a casino where smoking is permitted) so that the carbon monoxide test given at baseline would lead the CRR to conclude they were smokers. Such attempts were caught by the CRRs during screening or when other community members shared that "so-and-so" was not an actual smoker. If the phone had been provided, the CRR immediately stopped the phone service and collected the phone.

Study Phones Versus Smartphones

The number of individuals who had personal smart phones increased throughout recruitment. The majority would have preferred their own devices rather than downgrading to the study phone or having to carry two phones. The original study protocol allowed for partial reimbursement of personal phone service, but auditors for the primary grant recipient would not allow this. Participants ended up carrying their personal phones along with the study phone; while this was cumbersome, compliance was good.

Making Difficult Staffing Decisions

It became apparent after the application was funded that the original consultant hired during grant writing had provided insufficient guidance for several aspects of the study including the content and overall number of survey items and their frequency of assessment. Insufficient depth and breadth of survey items could have affected the overall quality and outcome of the project. Thus, the difficult decision to replace the original consultant with a new, more receptive and culturally aware replacement needed to be considered. For this study, the principal investigator took the lead, and while the discussion was difficult and awkward, the project team was unanimous that a replacement be identified and recruited. This proved to be important for the scientific rigor of the study as the replacement provided invaluable guidance on improving the survey items and frequency of repetition to track behavioral changes. These improvements directly affected the study protocol and research design. Similarly, project team members noted improved responsiveness and overall working relationships with the new consultant. Although it is awkward to replace a consultant on a study, when the person is not a good fit with the rest of the team, it is essential for both the short-term working relationships and the long-term rigor of the study to "bite the bullet" and replace the consultant with another professional who is more proactive, meshes well with the team, and can provide guidance that maintains scientific rigor.

Survey Lessons

Once a new tobacco cessation consultant was added to the project, the project team learned that the survey items proposed in the grant application were insufficient to measure intervention components and cessation experiences or to document theory of planned behavior factors. It is challenging to evaluate the adequacy of the survey designed during the proposal phase as it relies heavily on the expertise of the "smoking cessation expert." After the launch of the study, a new "expert" replaced the original consultant, and the survey was redesigned with input from the community advisory committees and the community usability tests. Total survey items were expanded from ~80 items to 367 items with subsets of items repeated at specific intervals. This resulted in a much more robust and rigorous survey design and implementation process that ensured theory of planned behavior components were assessed and challenges to tobacco cessation were assessed. The project team increased the survey's scientific quality so that outcomes could be effectively measured while ensuring the study captures data to facilitate reproducibility.

Nicotine Replacement Therapy

Unanticipated Changes in Access to NRT

One of the key intervention components was access to NRT at no cost to participants. Shortly before the onset of the intervention phase, one key Indian Health Service (IHS) clinic announced it would no longer provide NRT patches. The principal investigator met with IHS leadership and negotiated an alternative plan to support and provide NRT patches for study participants. If the IHS leadership had not agreed, alternatives included writing small grants or requesting a supplement, both of which would have taken significant time without any guarantee of success.

Allergic Reactions to the Patch or Dislike of the Other Products

Beginning as early as the usability tests, participants reported previous or current experiences with allergic reactions to the patch and/or dissatisfaction with the taste or flavor of the other NRT products. Because use of the patches and NRT products was a key intervention component, the project team decided that people who could not tolerate the NRT would have an additional code to allow their data to be analyzed separately; they were encouraged to continue the study without NRT.

mHealth Text Messaging

Video Messaging

When the phones were purchased, the project team was told the phone plan could support video as well as text messaging. However, the phone company refused to support this service once the intervention was initiated. The project team had videotaped northern plains AI smokers and captured video vignettes for inclusion in the intense mHealth intervention component. These videos were uploaded to a Web page open to the public (but not promoted to people outside the study during the intervention) and occasionally incorporated into an in-person counseling session by one of the CRRs. Future mHealth applications will support both text and culturally tailored video messaging.

Ability to Customize and Individualize Text Messages

Because the intervention period was 18 months and the intense group would read four messages a day, at the time of study design the project team identified numerous types of messages that could be delivered to reduce the amount of duplication. About half of the messages were focused on AI culture and/or traditional beliefs and quotes, while the other half related to tips, strategies, and other topics

related to smoking cessation. What was unknown during grant planning was the app designers' ability to create specific tailored personal messages for an individual participant. During discussions with community advisory committee members and usability test participants, the possibility of having very individualized text messages was raised. The suggestion was presented to the app designers who created the programming to allow this new option. This allowed Participant No. 44 to create a personal message (e.g., Stop Smoking so that you can be healthy to take part in Mary's Sun Dance ceremony), which the app designers then made available for that specific individual. The message was designed to appear more frequently than were other mHealth messages. Although available, few participants took advantage of this personalization feature; the project team does not know why.

Demand for the App From Other Regions of Indian Country

Informal "word of mouth" communication rapidly spread the word of the existence of the culturally tailored mHealth tobacco cessation program. The project team started receiving requests to use the app before the intervention even started. Similar requests for the app occur every time project team members share information about the project. This demand for an untested app was not anticipated. The reality is that AI community members are desperate for such technological programs. Once the app is deemed "effective" and the intervention completed, the project team plans to expand the app for use with different devices (Android, iPhone, iPad, Tablets) and promote its availability.

Motivational Interviewing Counseling Sessions

The original grant application proposed using existing session outlines from organizations such as American Legacy, American Cancer Society, or Livestrong and modify these for cultural relevance. However, available resources lacked sufficient detail and content and did not include required cues for motivational interviewing to meet the needs of the study population. Thus, significantly more additions to the outlines were required than the originally expected cultural modifications. The new session outlines were based on the Mayo Clinic motivational interview counseling training, information and resources provided by a local addiction counselor, and culturally modified content based on concepts from the originally identified organizations. The CRRs (who took the lead), project team, and community advisory committee members successfully expanded the detail and integrated AI-relevant issues throughout the pre- and postcessation counseling sessions. The team plans to share tailored/customized counseling outlines on their respective websites as free downloads when the study is completed.

Use of E-Cigarettes

At the time of writing the grant, there was limited information on the use and safety of e-cigarettes. Thus, there was no mention of e-cigarette use in the eligibility criteria for the study. At the time of implementation, e-cigarette use was significant throughout the United States, and the project team needed to decide whether to allow it. Due to unknown health risks, the project team decided to amend the exclusion criteria to include use or planned use of e-cigarettes.

Conclusions

The American Indian mHealth Smoking Dependence Study (PQ4) included over 6 months of intensive planning using multiple consultants. However, even with this detailed planning, multiple changes needed to be made to the study protocol prior to and during implementation. This is common for most intervention studies and has been true for all studies conducted by this project team.

This article summarizes the changes that were made from what was initially written in the grant application for the American Indian mHealth Smoking Dependence Study, PQ4, compared to what happened during implementation of this smoking cessation intervention study. Seven areas were described (1) cell phone challenges, (2) managing difficult staffing decisions, (3) survey lessons, (4) nicotine replacement therapy, (5) mHealth text messaging, (6) motivational interviewing counseling sessions, and (7) use of e-cigarettes. The changes depicted were necessary to carry out the study in a scientifically rigorous and culturally appropriate manner. Without these changes, project implementation would not have been successful.

Recommendations Related to This Study That Affect Future Studies for This Project Team (and Possibly Other Project Teams)

Study Cell Phones and Phone Service Plans

For all future studies requiring a cell phone, eligibility criteria will include having access to a cell phone that meets the minimum requirement for proposed study interventions. This will reduce the excessive cell phone losses/damages and service fees incurred in this study. Rather than paying for phone service, each participant will receive a monthly incentive fee for participating in the intervention(s). The incentive can be used to partially offset monthly phone service charges; however, participants will be responsible for their own phones, call plans, and service plans.

Cell Phone Requirements

Requirements for study cell phones will need to be simple enough to ensure that potential participants are not deemed ineligible simply because of an inadequate cell phone type. This will require evaluation of cell phone types and available service plans within study areas to ensure adequate sample sizes without unduly preventing some otherwise eligible individuals to participate. With advancing technology, newer phones can do more while remaining relatively inexpensive. As apps and programs are developed for study purposes, multiple platforms may be required to ensure that participants can access all study intervention materials while retaining their own phones and service plans.

Altering Grant Staff Composition

Difficult staffing decisions often cannot be anticipated until in the midst of grant activities, whether during grant proposal development or during implementation of the funded study. With a diverse project team from multiple settings and organizations, it is imperative that the team work well together, respecting individual contributions and prior experiences, being open to varying opinions, and being able to come to consensus for the “good of the grant.” Sometimes that means replacing a team member who is not a good fit regardless of timing within the grant trajectory. Clear roles, work expectations, and timing of deliverables at the onset of developing the grant proposal can mitigate some staffing difficulties, but when an individual clearly is not beneficial to the team, making the decision to replace the individual needs to be done as quickly and respectfully as possible.

Adaptation of Current Materials for Intervention Use

Even though initial evaluation of available materials for the motivational interviewing counseling session outlines appeared adequate, the project team was disappointed with the lack of detail, content, and cues found during in-depth evaluation of each resource. Thus, while the original plan was simply to culturally modify current materials for the intended study population, considerably more time and resources were required to compete this task than specified in the original grant protocol and budget.

For future studies, the team will conduct more in-depth evaluations during project planning as well as allocate more time and resources for similar adaptations throughout the development and implementation phases of the funded study.

Use of E-Cigarettes

Based on health and scientific findings, should the project team conduct future smoking cessation studies, use of e-cigarettes will continue to be prohibited.

Recommendations Beyond Those Limited to This Study

This article used examples from the American Indian mHealth Smoking Dependence Study (PQ4) to assist readers in understanding changes that may need to be made within a study protocol to ensure its proper and ethical implementation and completion while retaining its scientific rigor. Through examining these changes, two additional recommendations relevant to all grantees became apparent.

Prior Approval for Protocol Changes

Investigators need to understand that they can make changes/improvements from what was specified in the original grant submission; however, they cannot do so unilaterally. Obviously, there is a need to find the balance between the original research plan and changes that improve scientific rigor (i.e., it is never an option to sacrifice rigor). Some protocol changes will require approval from the funding institution while others will not. Prior approval generally depends on the extensiveness, depth, and/or breadth of the proposed change(s). New researchers may believe they must retain the initial protocol regardless of innovations and local events that occur from the time of submission to the initiation of the grant. However, the goal is to complete the project using scientific rigor and ethical research practices and should not be looked on as inappropriate. Significant changes should be discussed with the funding agency project officer and made only with appropriate approvals. This process was followed by the project team for this study that resulted in the changes identified above and successful implementation of the American Indian mHealth Smoking Dependence Study (PQ4).

Report and Publish Rationale for Changes

The project team recommends that investigators include specifics about changes made to protocol design and implementation and the rationale for these changes in grant reports and in publications. Such information helps other researchers who plan to build on published protocols, and studies the time, money, resources, and frustrations that can occur from not knowing/understanding the actual path followed from development through implementation. Peer-reviewed publications need to be willing to publish studies that are not successful and address changes that were implemented to help future researchers avoid going down a path that required significant modification to reach its end point. With these additions to both final grant reports and publications, future researchers will be able to more accurately build on previous research moving science further and faster.

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