IMPLEMENTATION OF A PILOT PROJECT PROGRAM TO EXPAND RESEARCH ON ALCOHOL USE DISORDERS IN AMERICAN INDIAN AND ALASKA NATIVE COMMUNITIES

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ABSTRACT

Pilot project programs offer early-stage and other investigators support to pursue emerging research areas, explore new methodologies, gain experience as principal investigators, and collect pilot data needed to pursue larger extramural research funding, such as from the National Institutes of Health. Pilot project programs may be particularly important to early-stage investigators from underrepresented backgrounds, who must overcome unique challenges to launching careers in community-based participatory research. This paper describes the structure, function, and impact of the Native Center for Alcohol Research and Education (NCARE) Pilot Project Core. **Methods**: During four calls for applications from 2018 to 2021, research investigators interested in conducting alcohol use disorder research in partnership with Tribal communities were recruited, with a focus on early-stage and American Indian and Alaska Native investigators. Eligible investigators were required to submit letters of intent prior to preparing full applications, which underwent a rigorous review process. **Results**: Eight pilot projects were awarded. Of the eight pilot project investigators, seven were early-stage scholars, seven were female, and four identified as American Indian or Alaska Native. The funded projects included two primary areas of research, epidemiological studies and intervention projects. Once funded, the Pilot Project Core assisted pilot project investigators with securing approvals for their research studies, responding to methodological and analysis questions, and mentoring and monitoring their progress. At the time of writing this paper, three pilot project investigators have completed their pilot projects, three investigators are currently collecting data, and one is in the

analysis phase. One pilot project investigator did not complete their project due to COVID-19 restrictions early in the pandemic. The pilot project investigators submitted 36 grant proposals for independent external funding and received 25 grants after funding of their pilot project; four were directly related to pilot project grants. Additionally, four peer-reviewed manuscripts resulting from Pilot Project Core support were published. **Conclusions**: Despite challenges related to the COVID-19 pandemic the pilot project funding through NCARE provided eight pilot grants, half of which identified as AI/AN and most of which led directly to multiple grants and papers. The NCARE pilot program provides a model for other similar programs seeking to support early-stage investigators who identify as AI/AN or other groups underrepresented in science.

Keywords:

Pilot projects; training programs; substance use disorders; American Indian and Alaska Native communities

BACKGROUND

Recently, the National Institutes of Health (NIH) has introduced a variety of initiatives focused on increasing the diversity of the scientific workforce (National Institutes of Health, 2022). These efforts include the funding of research investigators through programs such as diversity supplements and other training awards designed to attract scholars from groups underrepresented in science. NIH has also prioritized research that seeks to improve health equity and addresses the complexities of social determinants of health, which in turn mandates a range of opinions and perspectives (S. A. Blanchard et al., 2019; Daley et al., 2009; Hemming et al., 2019; Polite et al., 2017). Investigators from groups underrepresented in science are often highly motivated to address health outcomes that directly impact their communities and may actively engage them in integrating cultural practices into public health prevention programs and interventions (Gibbs & Griffin, 2013; Mahoney et. al, 2008; Pedersen et al., 2016). However, compared to their white peers, investigators from groups underrepresented in science are less likely to be awarded federal funding (Ginther et al., 2011) and, if not funded, less likely to reapply (Tabak & Collins, 2011).

Early-stage investigators often face a catch-22: funding bodies want to see the results of preliminary studies before providing financial support; yet, such support is needed to conduct preliminary studies (Crist et al., 2004). Although some institutions offer a modest level of funding for early-stage research, the scope of current programs is limited by significant constraints and by insufficient funds in relation to need. Shortcomings include: restrictions on funding to members of specific departments, schools, centers, or programs; inadequate funding for high-risk but potentially high-impact projects; meager support for training; an absence of frameworks for sharing core resources essential to developing innovative research; and limited incentives for cross-disciplinary collaborations or networks (Buchwald & Dick, 2011; Hall et al., 2018; Morozumi et al., 2020; Nearing et al., 2015; Vizueta et al., 2020).

Pilot projects provide valuable opportunities for early-stage investigators to advance their research objectives and can serve as the impetus for future funding. Pilot projects can seed emerging research areas, explore new methodologies, and pursue new regional and national collaborations that might evolve and produce independently-funded research or demonstration projects. Pilot project data are also crucial for obtaining funding from the NIH, industry partners, and private foundations. Therefore, institutional support for pilot projects is vital, particularly for diverse faculty, such as American Indian and Alaska Native (AI/AN) investigators, engaged in health equity research (Ginther et al., 2011). Additionally, prior pilot project programs supporting research on the topic of social determinants of health in AI/AN populations have shown preliminary success in addressing health disparities (Becker et al., 2018).

The overall objective of the Washington State University Native Center for Alcohol Research and Education (NCARE),

a Comprehensive Alcohol Research Center (P60) funded by the National Institute on Alcohol Use and Alcoholism (NIAAA), is to develop and implement innovative community-engaged alcohol use disorder (AUD) prevention and treatment research that positively impacts AI/AN people across the lifespan. The NCARE Pilot Project Core was designed to support pilot projects that rigorously examine practices, treatments, educational efforts, and policies that can affect sustained, widespread reductions in AUD-related health disparities experienced by AI/AN populations and offer logistical and scientific resources to investigators. In this paper, we describe the NCARE Pilot Project Core, its initial outcomes, and lessons learned. The Core offers a model that might be replicated to increase the diversity of the scientific workforce and facilitate new research efforts to improve AUD prevention and treatment in AI/AN and other underserved communities. We hope that this approach will foster an ecosystem of innovative and rigorous research to reduce AUD and related health disparities in AI/AN communities.

METHODS

We conducted four calls for applications during the five years of NCARE funding. Each call involved the recruitment of pilot project investigators, the submission of applications, peer review and scoring of applications, funding decisions, and evaluation of other support needs and professional development. Information on the process for pilot project investigator recruitment, application review, and outcomes was gathered to evaluate the NCARE Pilot Project Core (see Figure 1 for a step-by-step illustration of the application submission and review process).

Description of Funding and Eligibility

Pilot project applicants could request up to $40,000 for 12 to 24 months of funding; indirect costs were not provided and funding for the investigator's effort in excess of 15% required approval from Pilot Core leadership. While pilot project proposals were being developed, the applicants were able to request ethical, statistical, and data management support, including from the Pilot Project Core Leader, who is an investigator with expertise in AUD treatment and experience partnering with AI/AN communities. Support could include discussing pilot project proposal concepts and community partnerships, reviewing draft Specific Aims, and consulting with the Research Methods Core on methods and statistical design.

The proposed pilot project research was required to address AUDs and related health inequities in AI/AN communities; both community-based and secondary analysis studies were permitted. Other eligibility criteria included holding a doctoral degree in social, behavioral, or health sciences or a similar field. Pilot project principal investigators either could not have received an NIH R01 level grant, or if they had received an R01 or similar grant, they could not have conducted research focused on AUDs in AI/AN communities. These eligibility criteria favored early-stage investigators. AI/AN investigators who met eligibility criteria were strongly encouraged to apply. During the COVID-19 pandemic, potential applicants were asked to consider telemedicine/telehealth interventions, virtual data collection methods, and/or secondary data analyses.

Recruitment

NCARE solicited pilot grant applications four times total and advertised funding opportunities to all NCARE-affiliated investigators and partners, as well as through presentations and webinar announcements, email listservs, and social media posts. The call for applications was sent out three times over three months to allow for wide distribution and time for applicants to formulate an idea and submit their letter of intent (LOI). The announcement promoted innovative research projects to reduce the burden of AUDs and related health inequities in AI/AN communities that were likely to lead to future external funding. After the start of the COVID pandemic, recruitment materials included updated relevant considerations (e.g., telemedicine, virtual collection, and secondary analysis). Recipients were asked to widely distribute the call for applications to their networks. All information was also posted on the NCARE website.

Review Process for NCARE Pilot Project Core Proposals

The review process consisted of two levels. First, interested investigators were required to submit an LOI that included a list of potential co-investigators and community partners who would assist in the completion of the project; the intended community, Tribe, or setting of the proposed project; and a 500-word abstract that included a background, specific aims, and data analysis plan. The NCARE Pilot Project Core lead, an investigator with expertise in AUDs, and an AI/AN research organization leader reviewed the submitted LOIs for scientific merit and programmatic priorities. Applicants were contacted to clarify questions brought up during the initial review; applicants whose LOI was accepted were invited to submit a full pilot project grant application and sent detailed instructions describing grant formatting, content requirements, and the submission process. Full applications followed an NIH-style format consisting of a detailed budget; a budget justification, including personnel, travel, and equipment requests; a one-page specific aims; and a six-page research strategy comprised of significance, innovation, and approach. A full application also included a statement of future directions and career plans, biosketches from the pilot project principal investigator and key personnel, letters of support and collaboration, and Tribal resolutions or similar documents of support from Tribal partners.

Full pilot project grant applications were reviewed by the NCARE Pilot Project Core Review Committee, which functioned like an NIH grant review panel. The Committee was composed of multidisciplinary investigators who were experts in AUDs, AI/AN health, and/or research methods with experience in NIH-style grant reviews. Reviewers included NCARE faculty, as well as external faculty with relevant experience. The chair was a senior investigator with expertise in AUD research who headed a large pilot project program at a partnering university, followed by a senior investigator with expertise in AUD research with extensive NIH grant reviewing experience. After the first grant cycle, we also invited funded pilot project investigators to serve as reviewers. Three individuals reviewed each application. The review team included a Research Methods Core member, an expert in the field, and a funded pilot project principal investigator (following the first call for applications). Also, the Pilot Project Core Review Committee included a member from each of the NCARE cores, who gave extensive feedback during the review process, particularly members of the Research Methods Core.

Evaluation, Scoring, and Funding of Pilot Project Applications

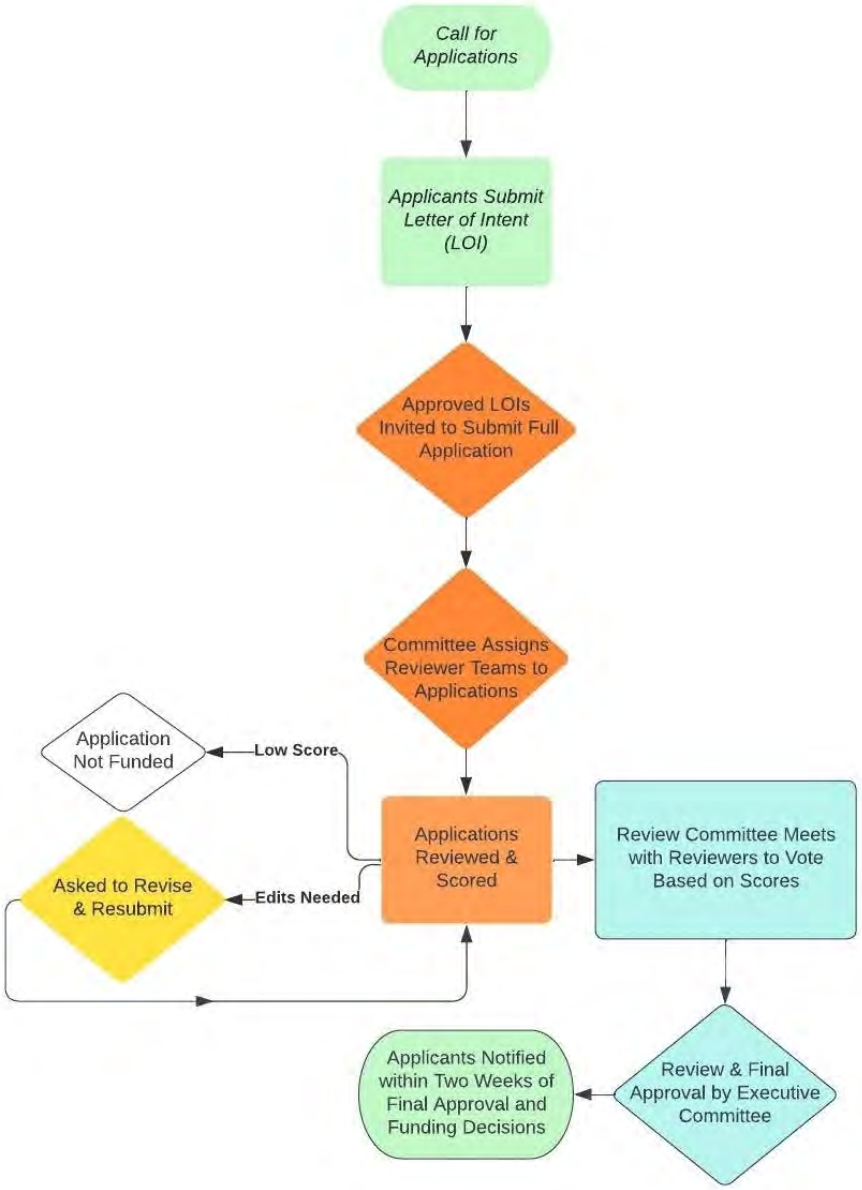
Reviewers evaluated grant applications based on relevance to AUD research and implications for AI/AN health equity, as well as typical NIH review criteria of significance, innovation, approach, environment, and the qualifications of the research team. They also evaluated the likelihood that the grant proposal would result in useful outcomes and that the results could be disseminated and eventually used to obtain additional research funding. Each reviewer provided written feedback and suggestions to the applicant based on the above criteria and then assigned scores for each criterion with an overall score based on the standard NIH scoring system (from a high of one to a low of nine). Additional considerations included: assurance of the project's feasibility for completion with available resources within the grant's maximum period of 24 months; that it complied with NIH and U.S. Food and Drug Administration guidelines; and its compatibility with the priorities, goals, and interests of NCARE.

Summaries were compiled from each review team and initial scores were tallied. The Pilot Project Core Review Committee discussed and scored applications in a follow-up meeting with all reviewers present. Reviewers could change their scores during their respective team's discussion of the application. Final scores were averaged and multiplied by 10 per NIH scoring standards. Like the NIH council review process, each application was then presented to the NCARE leadership team for final decisions, and recommendations were sent to NIAAA for funding the most meritorious applications.

Eligible applicants could resubmit in subsequent calls for applications, and those whose applications had

weaknesses that could be improved upon were strongly encouraged to reapply for funding and offered the full range of NCARE services. Those encouraged to reapply were provided with detailed reviewer comments, offered an opportunity to review comments with the Pilot Project Core Co-Leader, and offered the opportunity to receive feedback on their revised application from the Pilot Project Core Co-Lead. Relevant IRB and Tribal approvals were required.

Figure 1: NCARE Pilot Project Application and Review Process



RESULTS

Table 1 below details the total number of LOIs that were submitted, the number of full proposals submitted, and the number of pilot projects funded each year. There were three LOIs rejected prior to review because of ineligibility (in one, the PI did not have a terminal degree; in the second, the proposed project was not focused on an AI/AN

population; and in the third, the applicant was from an institution that was not eligible to receive an NIH grant). After review of full applications, some investigators were asked to revise their full application and resubmit. Of those investigators who were selected to submit a full application, six did not do so, resulting in the discrepancy between the number of LOIs invited to submit full applications and the number of full applications subsequently received. Funded projects that involved clinical trials or 'greater than minimal risk to human subjects' designations required prior approval by NIAAA before initiation, as stipulated by the RFA.

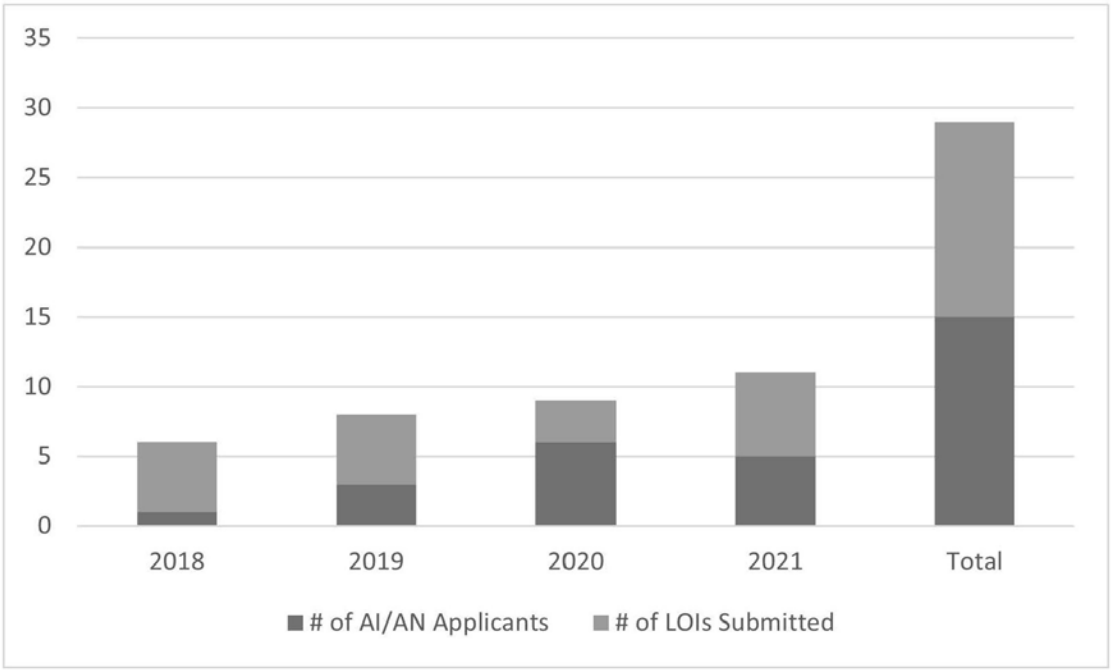
Table 1: Data on Pilot Grants Submissions*

Grant Submission Year	LOIs Submitted	LOIs Invited for Application	Applications Submitted	Awarded Projects
2018	6 (1)	6 (1)	5 (1)	3 (1)
2019	8 (3)	7 (3)	3 (2)	1 (0)
2020	9 (6)	8 (5)	7 (5)	3 (2)
2021	6 (5)	5 (4)	4 (3)	1 (1)
TOTAL	29 (15)	26 (13)	20 (11)	8 (4)

**Data in parenthesis indicates self-identified AI/AN investigators out of the total number provided*

Figure 2 visually describes the number of AI/AN investigators who submitted LOIs out of the total number of LOIs. Of the eight pilot project grants awarded, seven came from early-stage investigators (e.g., Assistant Professor or Research Fellow) and seven were from female investigators. Four funded pilot project investigators (50%) identified as AI/AN.

Figure 2: Data on AI/AN Applicants and Total Number of Applicants



The topics of the funded pilot projects encompassed primarily epidemiological studies (i.e., secondary data analyses and/or data collection related to AUD) and intervention projects (i.e., development of intervention or prevention programs on AUD). As shown in Table 2, pilot project topics represented the spectrum of AUD-focused research, from alcohol abstinence to reduction of risky drinking to developing and validating culturally relevant measures. Pilot projects included men and women, a range of ages, including children and adolescents, and featured sites across the country. Some data in this table are incomplete (e.g., number of grants and publications) because projects are not yet completed.

Table 2: Funded Pilot Project Titles

Epidemiological Studies
Exploring Alcohol Use and Pregnancy Among American Indian and Alaska Native Women
Re-Centering Measures for Alcohol Misuse Among American Indian and Alaska Native Communities
Assessment Of Alcohol Use, Mental Health Risks, And COVID-19 Experiences Among Native Americans Living Along the Eastern and Southern Seaboard of The U.S.
Relationship Of Food Security and Alcohol Use Among American Indian and Alaska Native Parents of Young Children
Exploring The Impact of the COVID-19 Pandemic on AUD Among Native American Young Adults
Intervention Projects
Real-Time Breathalyzer Monitoring and Contingency Management for Alcohol Use in American Indian Women
Pathways To Recovery Among Urban Alaska Native and American Indian People with Long-Term Abstinence from Alcohol
Feasibility And Impact of Distance American Indian Peer Recovery Coaches

At the time of writing this paper, three pilot project investigators have completed their pilot projects, three are currently collecting data, and one pilot project is in the analysis phase. Project timelines were frequently delayed due to the cascading effects of the COVID-19 pandemic on partner Tribal communities, site staffing issues, disparities in technological access/usability, and changes to virtual intervention formats. One pilot project investigator did not complete their project due to restrictions early in the COVID-19 pandemic. The pilot project investigators submitted 36 grant proposals for independent external funding and received 25 grants after funding of their pilot project; four were directly related to pilot project grants using the data and skills acquired from the NCARE Pilot Project Core experience. Four peer-reviewed publications have resulted from pilot project data, and six of the eight pilot project investigators have served as a reviewer for another NCARE pilot project applicant.

In the submission process, few direct requests were received from pilot project investigators for specific NCARE core support. Once funded, informal contacts with Pilot Project Core staff and pilot project investigators occurred frequently, including correspondence and questions via email unless phone was requested. Existing mentoring relationships appeared important to the pilot project investigators, as they indicated they were collaborating closely with a current mentor at their own institution on questions such as data analysis. During the COVID-19 pandemic, the pilot project investigators worked closely with the NCARE Pilot Grant administrative team to adjust timetables and additionally with the Research Methods Core to discuss potential changes in sample size or data collection procedures.

DISCUSSION

Our preliminary data from the NCARE Pilot Project Core shows initial and promising successes from our pilot project investigators. As noted in previous papers, pilot projects are an important first step in providing support for diverse faculty, as well as for understanding different health disparities that are under-researched (Becker et al., 2018; S. A. Blanchard et al., 2019; Cruz et al., 2020; Daley et al., 2009; Harawa et al., 2017). The NCARE Pilot Project Core was able to provide substantial pilot project funding to often underserved early-stage investigators, specifically AI/AN scientists who are consistently among the most underrepresented minority groups in health research (Buchwald & Dick, 2011) and of NIH-funded awardees (Ginther et al., 2011). While the long-term impact of the present study is yet to be explored, we know from other analyses of pilot project programs that an increase in small grant funding shows great promise in providing future opportunities for external grant funding and other training for culturally diverse investigators (R. D. Blanchard et al., 2019; S. A. Blanchard et al., 2019; Buchwald & Dick, 2011). For example, a pilot project funding program for early-stage investigators, similar to NCARE where many of the investigators were racial or ethnic minorities, led to five of the seven funded faculty later obtaining independent extramural funding totaling $4.7 million (Daley et al., 2009). In addition to providing funding for early-stage investigators, these pilot projects provide early-stage investigators the resources to develop collaborative community partnerships, which is often a resource-heavy undertaking (Cruz et al., 2020).

While the NCARE Pilot Project Core showed preliminary accomplishments, some lessons learned can be considered for future programs. First, the number of applications to the NCARE Pilot Project Core were fewer than anticipated. The reasons remain unclear but might include competing programs and diminished demand; the COVID pandemic and its role in hindering recruitment; or a need for other recruiting techniques to reach audiences that we did not use. Future pilot project programs should collect more specific data on the recruitment and application process, including more data from people interested in the opportunity who do not subsequently apply to identify barriers to applying, as well as collecting more data on interactions with different cores to see how these could be better promoted and used. In our NCARE Pilot Project Core, it is unclear if the requirements for applying, modeled after the NIH application and review process, were too stringent for the funding offered.

There are additional challenges in these types of pilot projects that should be considered. We found this in the NCARE Pilot Project Core, where some early-stage investigators needed assistance from the Research Methods Core, but others seemed to get most of their help from their own internal and existing mentors. Having a clear understanding of the number of mentors available to early-stage investigators, and coordinating their activities as they apply for pilot project funding is critical for their long-term success (Cruz et al., 2020). Other pilot project programs have explored the promise of group mentoring, where a cohort of scholars receives mentoring in different topics in a group setting (Buchwald & Dick, 2011; Harawa et al., 2017; Manson et al., 2006). However, researchers also recognize the vital importance of individual mentoring (Manson et al., 2006). Harawa et al. (2017) conclude that an individualized mentoring approach may be warranted, as "...important predictors of success...likely vary across scholars' backgrounds," meaning that pilot project and mentoring programs can better and more precisely focus training strategies.

Of additional note is how the success of these pilot project programs is evaluated. Traditionally, metrics for success evaluate research productivity, such as peer-reviewed publications and receipt of research funding (Harawa et al., 2017). Indeed, we provide the results of some of these metrics in our Results section. However, success can and should be measured in additional ways when focusing on community-engaged research. For example, other programs have also included the development of pilot project ideas that directly engage community partners; increased opportunities to develop strong professional networks; and encouraging alternative ways of disseminating materials, such as lay publications, presentations, and social media dissemination efforts that are designed for community audiences within their evaluation measurements (Buchwald & Dick, 2011; Harawa et al., 2017; Manson et al., 2006). Outside of traditional

academia, community organizing activities and the development of curricula or trainings that influence health-related behaviors and healthcare practices are also important measures. Additionally, Harawa et al. (2017) describe informal or "invisible skills" that are critical to career success, such as work-life balance, which could be included in training programs and eventually evaluated. Finally, subsequent to receipt of their NCARE funding our early stage investigators submitted and were awarded 36 and 25 grants, respectively, suggesting they may have gained valuable skills in moving through the Pilot Project Core process.

Therefore, how we view the "success" of pilot project grantees should be adapted to the wants and needs of the community when tracking the long-term impact of these programs. While pilot project grant programs may not fully address the unique needs of minority investigators (Buchwald & Dick, 2011), they are important first steps in both training and addressing health equity and promoting community-engaged research projects (Harawa et al., 2017; Manson & Buchwald, 2007; Manson et al., 2006). Our NCARE Pilot Project Core has shown preliminary success both in supporting diverse early-stage investigators and developing a greater understanding of the epidemiology of and potential for culturally informed interventions to address AUDs and related health inequities with Tribal communities.

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