Title: Communicating results of a dietary exposure study following consumption of traditionally smoked salmon

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Running Title: Culturally appropriate data disclosure

Abstract

One expectation of community-based participatory research (CBPR) is participant access to study results. However, reporting experimental data produced by studies involving biological measurements in the absence of clinical relevance can be challenging to scientists and participants. We applied best practices in data sharing to report the results of a study designed to explore polycyclic aromatic hydrocarbons (PAHs) absorption, metabolism, and excretion following consumption of traditionally-smoked salmon by members of the Confederated Tribes of the Umatilla Indian Reservation (CTUIR). A dietary exposure study was developed, wherein 9 Tribal members consumed 50 grams of traditionally-smoked salmon and provided repeated urine samples over 24 hours. During recruitment, participants requested access to their data following analysis. Disclosing data is an important element of community-based participatory research, and must be treated with the same rigor as that given to the data analysis. The field of data disclosure is relatively new, but when handled correctly can improve education within the community, reduce distrust and enhance environmental health literacy. Using the results from this study, we suggest mechanisms for sharing data with a Tribal community.

Introduction

Within a community based participatory research (CBPR) framework, there is an expectation that data will be shared with participants and the community [1]. There is a secondary expectation that data will be presented in an informative and easy to understand format. Yet, sharing environmental or biomedical data with participants can be challenging to researchers because it requires communication of nuanced toxicological, biological, and chemical details. Furthermore, studies are often conducted to learn new information and/or when human health effects are unknown or unclear [1-5].

Data sharing is even more important when collaborating with Native American communities, as there have been several unfortunate incidents where researchers have misused Tribal data [6]. For example, in 1989 the Havasupai Tribe reached out to an anthropologist at Arizona State University to investigate a genetic link to diabetes within the tribe [7]. The Havasupai contributed biological samples with the belief that the samples would be used exclusively for diabetes research. Unfortunately, the samples were also analyzed to evaluate schizophrenia, inbreeding, and migration theories without consent of the Havasupai [8]. Situations such as these have created mistrust between scientists and Native Americans, which creates a barrier to further scientific endeavors. One approach to overcoming this barrier is developing a Material Data Sharing Agreement (MDSA) between Tribes and scientists. The MDSA specifies the research projects, limits use of data to the those projects, and requires Tribal approval for all additional proposed uses of the data [9]. The benefit of a MDSA is three-fold. First, and most importantly, a MDSA recognizes and respects tribal sovereignty, a key principle in conducting CBPR with tribal communities [10, 11] which has the added benefit of building cultural capacity within the researchers and scientific capacity within Tribes. Secondly, this approach helps prevent harmful miscommunications [6] and; thirdly, potential participants are made aware of how the samples will be treated and returned .

In addition to an MDSA, CBPR guidelines speak of having a ‘gate-keeper’, an individual who works with Western researchers to build cultural capacity and ensure that research projects are conducted in a culturally appropriate manner [10]. This gatekeeper insures that the interpretation of any study respects Tribal customs and practices. This is particularly important in environmental health studies because Native American lifestyles are closely entwined with their natural environment and traditional cultural practices, which creates complex exposure pathways that are not well described and often overlooked by environmental managers [12-16].

A Tribal-University partnership

The Confederated Tribes of the Umatilla Indian Reservation (CTUIR) is a union of the Cayuse, Umatilla and Walla Walla tribes, located in Pendleton, OR [17]. CTUIR is governed by the Board of Trustees, which oversees all CTUIR organizations, including the Department of Science and Engineering (DOSE). DOSE personnel began working with Oregon State University (OSU) faculty in 2003 to evaluate tribal exposure scenarios funded by a US Environmental Protection Agency (EPA) Science to Achieve Results (STAR) grant. The tribal-university partnership continued to develop with expanded scientific studies within the Community Engagement Core of the EPA/National Institute of Environmental Health Sciences (NIEHS) Superfund Center at OSU (Table 1). The partnership has previously been described as unique in its approach to address environmental concerns while simultaneously expanding scientific and cultural capacity [18].

Of particular interest to DOSE and CTUIR were research projects designed to evaluate the implications of a polluted environment on the traditional foods consumed by the tribe [19]. Studies of indigenous health, as well as interviews with tribal members, reveal the necessity of evaluating risk assessments within the context of a holistic understanding of health [12-15, 20, 21]. Tribal communities often evaluate health and risk as the comprehensive whole of their eco-cultural system, which encompasses the community, the environment, natural and cultural resources [22]. As such, traditional risk assessments are often inadequate, as they may underestimate consumption rates or may not reflect tribal practices, tribal health co-risk factors or the eco-cultural system [14, 16, 22]. For example, many indigenous peoples living along major waterways have very high fish consumption rates. The CTUIR Reservation lies next to the Columbia River and its tributaries and the average CTUIR subsistence fish consumption rate for adults is estimated to be 540 grams per day [12]. The EPA typically assigns a default fish consumption rate of 17.5 grams per day [23], but EPA Region 10 now proposes a more protective rate of 175 grams per day, as used by the state of Oregon [24, 25]. Since intake rates strongly influence the quantification of human health risk, Tribal populations are concerned that any dietary exposure study in a traditional food will lead risk managers to recommending reduction in intake as the primary way of reducing individual risk without taking into consideration the cultural significance of traditional food for Native Americans [13, 15, 16]. Traditional foods represent the complex interconnectedness of cultural and traditional practices, ceremony, knowledge transmission and nutrition [20, 26]. Therefore, a stipulation in the CTUIR-OSU MDSA stated that any recommendations developed to reduce risk posed by environmental chemicals would focus on improving health without adversely affecting cultural practices.

Community-Based Participatory Research to Evaluate Dietary PAH Exposure

Previously, DOSE and OSU measured PAHs in salmon before and after, hot smoking, and in the urine of the individuals who smoked the salmon. For this project, analytical chemists at OSU developed an improved analytical method to measure 32 PAHs [27, 28]. The study found the smoking process increased the concentration of 21 different PAH compounds at levels significantly higher (30-40x) than those found in commercial cold smoked salmon [29]. However, very little is known about the absorption, metabolism, and excretion of the different PAHs found in the traditionally-smoked salmon. A secondary study was designed to collect information that would begin to address concerns raised by Tribal members. All aspects of the study were jointly designed by the research teams at CTUIR-DOSE and OSU-SRP. Considerations for reporting and sharing data were enumerated in the MDSA that has been the foundation of the CTUIR-OSU partnership. This research was approved by the OSU Institutional Review Board, the Northwest Portland Area Indian Health Board Institutional Review Board and the CTUIR Health Commission.

As previously described [30], DOSE recruited 9 adult non-smoking CTUIR tribal members through convenience techniques, via word-of-mouth. The language to describe the study was drafted in collaboration between DOSE and OSU:

> The Department of Science and Engineering (DOSE) has partnered with the Superfund Research Program (SRP) at Oregon State University to measure how our bodies eliminate residues that can attach to food when it is smoked. This study will focus on residues called polycyclic aromatic hydrocarbons (PAHs), which are produced by burning wood and other materials. This study will identify those residues, and how much of these residues are absorbed in the body….Participants will be asked to eat traditionally smoked salmon and provide urine samples to help researchers understand how the residues produced during smoking events are processed by the body.

Participants were enrolled and provided informed consent at a 1-hour meeting hosted by DOSE and OSU researchers. At the meeting, participants received an informational handout and letter detailing the study. All participants were asked to maintain a low-PAH diet 48 hours prior to beginning the study. A low-PAH lunch was served [31]and meals were provided while the scientific and cultural importance of the research were discussed. An OSU project coordinator explained the MDSA and explained that all samples and data belonged to CTUIR. Following informed consent, participants then completed a survey to evaluate non-dietary PAH exposures. Two days after the enrollment meeting, participants arrived at a tribally-owned restaurant and provided a baseline urine sample, as previously described [30]. Each participant consumed 50g of traditionally smoked salmon and provided 4 additional urine samples over the next 24 hours. A DOSE technician collected the samples and provided each participant with a $25 gift card. Samples were returned to OSU for analysis. Analytical chemists at OSU designed an improved method for measuring urinary PAHs for this project and all samples were analyzed for 19 PAHs and 33 hydroxylated-PAHs (OH-PAHs), the metabolism product of PAHs [28, 30].

Disclosing Data to a Tribal Community

While it was originally planned to share aggregated data with the community, the participants specifically requested to see their data in addition to aggregated data. Considerable research supports disclosure of biomedical data to participants. The very nature of CBPR can support data disclosure [32], as do the ethical principles of clinical medicine [33, 34], and the ability to improve education on the research [35, 36]. There are associated risks, such as participants feeling their expectations were not met, or participants feeling concern/fear when they receive their results. In addition, even when interventions are possible, participants may not have the ability to make changes to reduce their risk. However, these risks must be balanced with the benefits and expectations of the study. Here, we describe the process by which data were compiled and disclosed to participants and how published best practices were modified for use within a tribal community. Reports were designed to combine graphs and text with data placed in the context of the study population, and accompanied by annotated graphical legends [3].

Many report-back styles focus on the individual exposure, whereas tribal communities prefer that research and data are discussed within the context of the community [37]. Additionally, the novelty of this study limited options for appropriate comparison groups. Following analysis and scientific peer review of the results [30], the data were used to create relevant reports that interpreted the toxicological and biological results within the cultural framework of CTUIR members. This meant that reports described the benefits of salmon consumption, the recognition of salmon as a culturally important species to CTUIR, and highlighted the main findings from the study rather than conclusions specific to the individual's data. The report was created through an iterative process between public health, chemists, epidemiologists, toxicologists and community engagement specialists.

The data disclosure was prefaced by a cover letter, which stated the study rationale and the cultural context for the research. Also included was a previously published newsletter which also described the rationale for the metabolism study and background information on the partnership and previous research studies. The cover letter read:

> By eating a single, small serving of traditionally smoked salmon of 50 grams, and providing five urine samples over a 24-hour period, you provided data that helps us to learn how people absorb and eliminate polycyclic aromatic hydrocarbons (PAHs). We know that people are exposed to PAHs when they eat traditionally smoked salmon. During the smoking process, PAHs are emitted from the wood-burning fire and are absorbed by the fish. People can metabolize PAHs. This process occurs in the liver where enzymes add an oxygen molecule to their chemical structure. These PAH metabolites are called hydroxylated PAHs which are abbreviated to OH-PAHs. OH-PAHs are more soluble than PAHs which means they dissolve more easily in liquids. This helps our bodies eliminate PAHs in urine and feces.

The second page provided bulleted conclusions from the study which directed the reader to the page with the relevant data.:

- After eating 50-grams of traditionally smoked salmon, the amount of PAHs in urine increased. This indicates that even small amounts of PAHs that are present in the smoked salmon are being absorbed by the body.
- The absorbed PAHs were quickly metabolized to improve their excretion in urine. As seen on page 3, the concentration of PAH metabolites (OH-PAHs) peaked at approximately 3 hours and the concentration of un-metabolized PAHs peaked at 6-hours.
- Depending on the individual, the peak levels of PAHs and OH-PAHs occurred at different times. This indicates that metabolism of PAHs is complicated and involves many biological processes which likely differ between individuals.
- After 24 hours the concentration of PAHs and their metabolites returned almost to baseline levels. This indicates that the body was able to eliminate almost all of the PAHs it absorbed from the 50-grams of traditionally smoked salmon within one day.
- Participants who drank more water had faster elimination of PAHs and their metabolites in their urine. This suggests that people should drink more water when eating traditionally-smoked foods to improve elimination of PAHs in urine.
- Salmon is a nutritious food. In order to continue enjoying the health benefits and the cultural heritage associated with salmon, while also limiting exposure to PAHs, we recommend that people rotate eating fresh, frozen, canned, and dried salmon with

> smoked salmon. Children and pregnant women may also want to limit how much smoked salmon they eat and enjoy salmon prepared in other ways.

While the report highlighted key findings, results were not presented in terms of human health risk, although many data disclosure mechanisms use this as a way to provide context for the data [3]. Instead, the focus was to help participants understand the results, and to hear suggestions for reducing potential risk. This is an approach previously used with pesticide risk assessments [38]. The study was not designed to evaluate human health given the small sample size (n=9), but rather to evaluate the absorption, metabolism, and excretion of PAHs following ingestion. For these reasons, the chemical concentrations of each individual PAH or OH-PAH were not included, but were available to participants upon request.

A graphical legend designed to build graph literacy and enhance understanding of the data accompanied all data presentations (Figure 1). Aggregate data from the study were presented in two forms. The first graph showed the average PAH and OH-PAH concentrations in urine over time (Figure 2A). The second graph showed the data from all 9 participants, with the individual's data highlighted (Figure 2B). Descriptive text accompanied the data:

> The top graph is a template, explaining how the graph is designed for the PAH and OH-PAH sums. Next, we show the average response for all nine individuals for total PAH and total OH-PAH at each of the five time points. This information shows us how average PAH and OH-PAH chemical concentrations changed over time for this group of people.

Your individual results are shown in orange and the results from the other participants are shown in black. If you would like to see your individual results for each chemical measured, please contact us. These graphs show how people have slightly different PAH absorption, metabolism, and excretion. Yet, despite these differences everyone's PAH and OH-PAH levels return nearly to baseline levels within 24 hours.

Finally, basic information on PAHs was provided, along with the rationale used by DOSE to evaluate exposures to PAHs:

The Department of Science and Engineering and other scientists, consider several factors when determining the potential for PAHs to impact people's health. These include:

- Identifying and measuring specific PAH compounds in air, water, soil and food.
- Measuring the amount of contact a person has with specific PAH compounds in their environment and diet.
- Learning about the toxicity of each PAH compound.

Reports were returned to participants and contact information for the OSU coordinator was provided.

Summary of data disclosure recommendations

A comprehensive handbook details many best practices in reporting data, including placing participant levels in context to national averages, supplying individualized recommendations to each study participant, and providing suggested alternatives to reduce exposure [3]. These were three recommendations that were specifically altered when preparing the CTUIR reports.

Provide appropriate context for the results. The first peer-reviewed publication that reported the concentration of PAHs in the urine of people who smoked salmon did include a comparison to NHANES [30], but for the personal reports it was deemed inappropriate, as the NHANES data are not reflective of the unique exposures sustained by Tribal populations, nor are they reflective of purposeful dietary challenges, i.e. sampling following ingestion of smoked salmon [12-15]. The results were, therefore, presented within the context of the study population.

Use a community, not individual, context. Individual results were not tabulated or presented in descriptive text to make any conclusions about the individual's sample. The goal of the report was to present data within a community framework, rather than an individual framework and focusing on the individual's sample detracted from that viewpoint.

Recognize the cultural framework. When working with tribally-important foods, the significance of the data goes beyond that of a risk assessment. Data presentation and associated recommendations should account for the cultural significance of traditional foods for Native Americans, which goes beyond that of nutrition [20]. Here, the focus of the report was on understanding the data and options for reducing exposure if a participant felt it was necessary.

Conclusions

Sharing data from environmental studies that explore novel environmental health concerns within a specific cultural framework helps build scientific and cultural capacity in both Tribal and University partners. An MDSA and collaboration helps create transparency and establishes clear boundaries for all study parameters. Using the results from a novel dietary exposure study, we illustrated several best practices for sharing data with a Tribal community. The reports were designed to be respectful of the importance of salmon as both a nutritional and cultural element.

Most importantly, the data were reported back at the request of the study participants. This is an important element of CBPR, and must be treated with the same rigor as that given to the data analysis. The field of data disclosure is relatively new, but when handled correctly can improve education within the community, reduce distrust and enhance environmental health literacy [36, 39].

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Author Disclosure Statement

The authors have no conflicts of interest or financial ties to disclose.

Tables

Date	Event
2003	*Awarded*: EPA-STAR grant –JI-R831046 (2003-2007) Regional Tribal Exposure Scenarios Based on Major Ecological Zones and Traditional Subsistence Lifestyles
2006	Memorandum of Understanding between OSU, CTUIR/DOSE signed
2008	*Publication*: Harper, B.L., et al., Traditional tribal subsistence exposure scenario and risk assessment guidance manual. EPA-Star-J1-R831046. Richland, WA. 2008 [15]
2009	*Awarded*: NIEHS Superfund Research Program – P42ESO16465; Tribal-University Evaluation of Chemical Exposures to Improve Community Health, PAHs: New Technologies and Emerging Health Risks.
2010	*Project*: Ambient air quality study *Project*: Smoked Salmon Inhalation study (air and urine samples collected)
2011	*Publication*: Forsberg, N.D., G.R. Wilson, and K.A. Anderson, Determination of parent and substituted polycyclic aromatic hydrocarbons in high-fat salmon using a modified QuEChERS extraction, dispersive SPE and GC-MS. J Agric Food Chem, 2011. 59(15): p. 8108-16 [27] *Publication*: Harding, A., et al., Conducting research with tribal communities: sovereignty, ethics and data-sharing issues. Environmental Health Perspectives, September, 2011: p. 11-24 [9] *Outreach*: Personal air monitor training video created. <http://superfund.oregonstate.edu/main_news> *Outreach*: CTUIR-OSU Partnership Newsletter
2012	*Project*: (Passive Sampler Device) PSD deployed in Nixya'awii Governance Center *Project:* Evaluation of PAH in traditionally prepared salmon *Publication*: Harper, B., et al., Subsistence exposure scenarios for tribal applications. Human and Ecological Risk Assessment: An International Journal, 2012. 18: p. 810-831. [14] *Publication*: Forsberg, N.D., et al., Effect of Native American fish smoking methods on dietary exposure to polycyclic aromatic hydrocarbons and possible risks to human health. Journal of agricultural and food chemistry, 2012. 60: p. 6899-6906. [29] *Outreach*: CTUIR-OSU Partnership Newsletter
2013	*Publication*: Schure, M.B., et al., Perceptions of the Environment and Health Among Members of the Confederated Tribes of the Umatilla Indian Reservation. Environmental Justice, 2013. 6: p. 115-120 [19]
2014	*Renewed*: NIEHS Superfund Research Program – P42ESO16465 *Project*: Smoked Salmon Ingestion study *Outreach*: CTUIR-OSU Partnership Newsletter
2015	*Publication*: Motorykin, O., et al., Determination of parent and hydroxy PAHs in personal PM(2).(5) and urine samples collected during Native American fish smoking activities. Sci Total Environ, 2015. 505: p. 694-703. [28] *Publication*: Motorykin, O., et al., Metabolism and excretion rates of parent and hydroxy-PAHs in urine collected after consumption of traditionally smoked salmon for Native American volunteers. Science of The Total Environment, 2015. 514: p. 170-177 [30] *Publication*: Lafontaine, S., et al., Relative Influence of Trans-Pacific and Regional Atmospheric Transport of PAHs in the Pacific Northwest, U.S. Environ Sci Technol, 2015 [40] *Project*: Smoked salmon reports returned

Table 1. Timeline of CTUIR-OSU Partnership and Products

Figures Legends

Figure 1. A graphical legend was provided to illustrate how the data was graphed and to aid interpretation of results.

Figure 2. Example of how aggregate results were presented. (A) Example graph showing sum PAH concentration over the 24-hour study period. Sum OH-PAHs were also presented in the same format. (B) The orange line depicts the individual's results; the black lines represent the results of the other 8 participants. Sum OH-PAHs were presented in the same format.

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