

Methodology

The study methodology is a qualitatively-based design using semi-structured, key-informant interviews. All interviews were conducted by a qualitative Research Associate (RA1). A second Research Associate (RA2) was present at each interview along with the RA1. The Principal Investigator (PI) provided oversight of the methodology to ensure its accuracy. The RA1 was trained in qualitative methodologies and has utilized these skills in domestic and international settings while adhering to all Institutional Review Board (IRB) standards.

Literature and policy reviews were conducted. Reports, journal articles, newspaper articles, and various other types of publications were collected and analyzed to help provide a foundation and rationale on which the interviews were based. An advisory committee composed of five experts with extensive experience working with government scientists provided insights and guidance to the project.

Interview Guide

An interview guide (see Appendix A) was developed and revised using feedback from the advisory committee members and two informational interviews conducted with leaders in the field of science and government. The RA1 used these interviews to discuss the proposed research and the questions being developed for the semi-structured, key-informant interviews. Feedback and advice from these interviews assisted with the development of the interview guide.

Three pilot interviews were conducted using this interview guide in May 2008. Additional feedback from these interviews helped refine the interview guide and provided the interviewer with a better understanding of what was feasible and necessary to ask during each interview.

Participant Recruitment

Hundreds of potential subjects were asked to participate in the study with the expectation that approximately 50 would be willing and able to participate. Within the project's available budget and

timeframe, 37 participants were secured for interviews. Five sampling strategies from qualitative inquiry were used to recruit interview participants. These strategies were Snowball or Chain, Criterion, Opportunistic, Combination or Mixed, and Convenience.²⁵

Interview recruitment began once IRB approval was received in May 2008, and continued through November 2008. (See Appendix B for IRB approval information.) Pilot interviews were conducted in May 2008, and the remaining interviews began in June 2008 and continued through January 2009.

The research team recruited participants who held advanced degrees and had at least five years of experience working in a scientific capacity for a federal agency that focuses on health or the environment. The criterion of working for a health or environment agency was broadened to include persons whose agencies may not have this focus, but whose work was related to health or the environment. For example, a participant from the Department of Housing and Urban Development (HUD) worked on lead and asbestos exposures in federal housing. Therefore, it was a health and environment topic that was being addressed even though the agency's mission is not primarily health or the environment. All participants met all of these criteria, with the exception of three who had worked fewer than five years for the government. There were no inclusion or exclusion criteria based upon gender, race/ethnicity, age, risk factors, or prevalence/incidence.

Recruitment information was disseminated on numerous listservs (American Public Health Association, environmental and occupational health, federal, universities, local, etc.), and research team members distributed recruitment flyers at several conferences (e.g., American Public Health Association annual meeting and the Center for Science in the Public Interest's conference on scientific integrity.) Members of the research team also participated in meetings to inform colleagues of the work and to recruit participants, including meeting with the Department of Professional Employees at AFL-CIO and presenting at the "Representing Professionals in Science, Engineering,

and Technology” conference at Harvard University Law School.²⁶ After conducting 25 interviews, the assistance of participants was solicited to recruit additional participants, and this yielded an additional 12 interviews.

Subjects were given the option to sign a consent form or not, since such records could compromise confidentiality; instead, interview participation was considered consent. All research documents and audio tapes containing identifiable information (e.g., agency name or subject title) were kept in a secure location only accessible to the research team, and will be destroyed.

Interview Participants

From May 2008 through January 2009, 37 in-depth, semi-structured, key-informant interviews were conducted with individuals who worked for, or had previously worked for, 13 different federal agencies. Several interviewees had work experience at multiple agencies, which resulted in a total of 55 agency work experiences. Participants described experiences at the following agencies:

Agencies of the Department of Health and Human Services:

- Centers for Disease Control and Prevention (CDC), including the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Toxic Substances and Disease Registry (ATSDR)
- Food and Drug Administration (FDA), including the Center for Drug Evaluation and Research (CDER) and the National Center for Toxicological Research (NCTR)
- National Institutes of Health (NIH)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Other agencies:

- US Consumer Product Safety Commission (CPSC)
- US Department of Agriculture (USDA)

- US Department of Commerce, including the National Institute of Standards and Technology (NIST)
- US Department of Defense (DOD)
- US Department of Housing and Urban Development (HUD)
- US Department of Labor, including the Occupational Safety and Health Administration (OSHA)
- US Department of Veterans Affairs, including the Veterans Health Administration (VHA)
- US Environmental Protection Agency (EPA)

Several of these participants were members of the Public Health Service (PHS) Commissioned Corps, and were also able to comment on their experience of working for federal agencies while serving as PHS members.

Interview Data Analysis

Data was collected via audio tapes of interviews and via handwritten/typed notes taken during the interviews by RA2. After each interview was conducted, field notes were typed and reviewed to identify any items in need of clarification. The audio tapes were transcribed, and the transcribers signed confidentiality statements and adhered to all IRB regulations. Audio tapes, transcripts, and notes were used during the issue-focused,²⁷ open-coding analysis, which provided a means by which to organize and interpret collected data.

The analysis of the qualitative data involved creating data categories based on general themes and subcategories, also known as ‘codes,’ into which each piece of data was assigned. In order to reduce the possibility of bias when conducting the qualitative data analysis, the research team worked together to code two interviews. Using the principle of Grounded Theory, under which the data drives the analysis, the team read through the interviews and identified the themes, or codes, that emerged. Then, to determine the validity of the themes identified by the entire team, two of the team members conducted analysis separately and then compared their coded data

to determine whether two different researchers would come to the same conclusions regarding code assignment. Based on this process, the team members determined that the themes were accurate. Once this process was completed, RA1 conducted the analysis of the interviews, applying agreed-upon codes to every statement made in the interviews, then sorting the statements into theme-based documents, and finally synthesizing the data to be used in writing the report.

Qualitative research is “a broad approach to the study of social phenomena ... [drawing on] multiple methods of inquiry,” including structured interviews and analysis of documents and materials.⁹ Qualitative research also has limitations. One of these is funding, which determines the amount of time a researcher can devote to a project. Ultimately, qualitative researchers aim to reach the point of data saturation; however, a researcher is never absolutely certain that it has been attained. Qualitative research does not employ nor aspire to have a representative sample; rather, validity and reliability are achieved by rigorous application of field methods and analysis, especially recruitment for the characteristics being researched.

Additional Research: Policy Review

To supplement the data collected through interviews, the research team also reviewed policies regarding the practice of science from science-based federal agencies that focus on health or the environment. The team began by contacting health- and environment-focused agencies to request policies regarding the work of agency scientists, and received a few responses referencing online agency resources. In one case, a response from the Department of Labor indicated that policies from the Mine Safety and Health Administration (MSHA) were posted on the agency’s intranet, but not on the website accessible to the public.

The team then searched online for policies from health- and environment-focused agencies regarding procedures for research, publication, and communication with

the media and the public by scientists employed at federal agencies. Relevant policies were found regarding at least one of these activities from the following agencies and centers:

- Center for Drug Evaluation and Research (a center of the US Food and Drug Administration)
- Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health
- National Institutes of Health
- US Department of Agriculture, including Agricultural Research Service and Food Safety and Inspection Service
- US Department of the Interior, including the US Geological Survey
- US Environmental Protection Agency

Follow-up Survey

To investigate effects that a new administration might be having on scientists’ views of the topics covered during the interviews, an online follow-up survey was conducted during July and August 2009, approximately six months after the Obama administration began.

The questions addressed workplace supportiveness, access to data, research review process, publication/review clearance process, access to media, access to meetings/conferences, ability and willingness to provide feedback, and overall work environment.

The research team utilized an online survey service called Zoomerang²⁸ to disseminate, collect, and analyze the anonymous survey. Only the RA1 had access to the survey online, and results, once downloaded, became available only to the research team. These results will also be destroyed.