

Generic Clearance for CDC/ATSDR

Formative Research and Tool Development

Title: Formative Research to Inform an Intervention to Improve the Early Detection and Surveillance of Pneumoconiosis in U.S. Coal Miners

Supporting Statement A

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Supporting Statement A

Goal of the study: The study involves conducting formative research to support the development of a quantitative data collection instrument and to help NIOSH researchers identify priority areas for an intervention to increase coal miners' participation in voluntary pneumoconiosis (also known as "black

conduct formative research to design a quantitative data collection instrument that will support future work to develop of a theory-based intervention to increase mineworker participation in NIOSH CWHSP. An effective intervention could result in improved understanding of the recent disease trends and increased prevention efforts.

NIOSH Coal Workers' Health Surveillance Program

Medical surveillance is a tool that supports secondary prevention or early detection [6]. While terms such as medical surveillance and occupational health surveillance have various definitions and interpretations based on the context, typically surveillance programs have three major functions. According to Gulumian and colleagues these functions include monitoring disease, notifying the public, and conducting research to inform public policy [7].

¹ Long-tenured miners have worked in coal mining for at least 25 years [3].

The NIOSH Coal Workers' Health Surveillance Program was established by the 1969 Coal Act [8, 9]. Aligning with Gulumian and colleagues' [7] characterization of medical surveillance, the NIOSH CWHSP monitors CWP and silicosis (henceforth referred to as pneumoconiosis), notifies the public about disease trends, and conducts research to inform public policy. In addition, the NIOSH CWHSP offers a training and certification program for physicians [9]. Mine companies are also required to maintain a pneumoconiosis screening plan for their workers through the NIOSH CWHSP [9].

NIOSH CWHSP monitors pneumoconiosis through voluntary screenings for surface, underground, and contract mineworkers conducted at approved clinics [9]. Additionally, NIOSH CWHSP offers mobile units through its Enhanced Coal Workers' Health Surveillance Program (ECWHSP) [10]. These units travel to and near mine sites to provide free and convenient screening options.

Screenings offered through the NIOSH ECWHSP include spirometry (i.e., breathing test), work history questionnaire, chest radiograph, respiratory assessment, and a blood pressure screening [10]. Despite the availability of these screenings, NIOSH estimates that annual participation in the program has only been between 30% and 40% over the last few decades [11]. These figures raise important questions about factors that influence mineworkers to participate in voluntary pneumoconiosis screenings.

Justification for the Study

Stakeholders, researchers, and policymakers continue to identify medical surveillance as an important focus area in efforts to address the increased prevalence of CWP. In 2018, the National Academy of Science (NAS) put forth a recommendation for NIOSH to "elucidate factors that act as disincentives for participation in the voluntary portions of the NIOSH occupational health surveillance programs and in the MSHA Part 90 Program, with the goal of addressing those disincentives (p. 105)" [12]. Further, the NAS identified that "research and development efforts are needed for better understanding of relationships between miners' exposures and disease, including studying effects of changes in mining practices, improving monitoring approaches, and increasing participation in medical surveillance programs (p. 7)" [12].

Additionally, in November of 2018, the CDC issued a request for information seeking factors that pose barriers to mineworkers' participation in NIOSH CWHSP screenings. More recently, the Education and Labor Committee of the U.S. House of Representatives' Committee held a hearing on the resurgence of black lung disease [13]. In his written testimony, Bruce Watzman, a retired National Mining Association executive, stated that "the one-third participation in NIOSH's x-ray surveillance program across the entirety of the workforce does not provide a realistic appraisal of disease frequency across the workforce (p. 5)" [14]. These recommendations and statements underscore the need for research that systematically explores factors that influence mineworker participation.

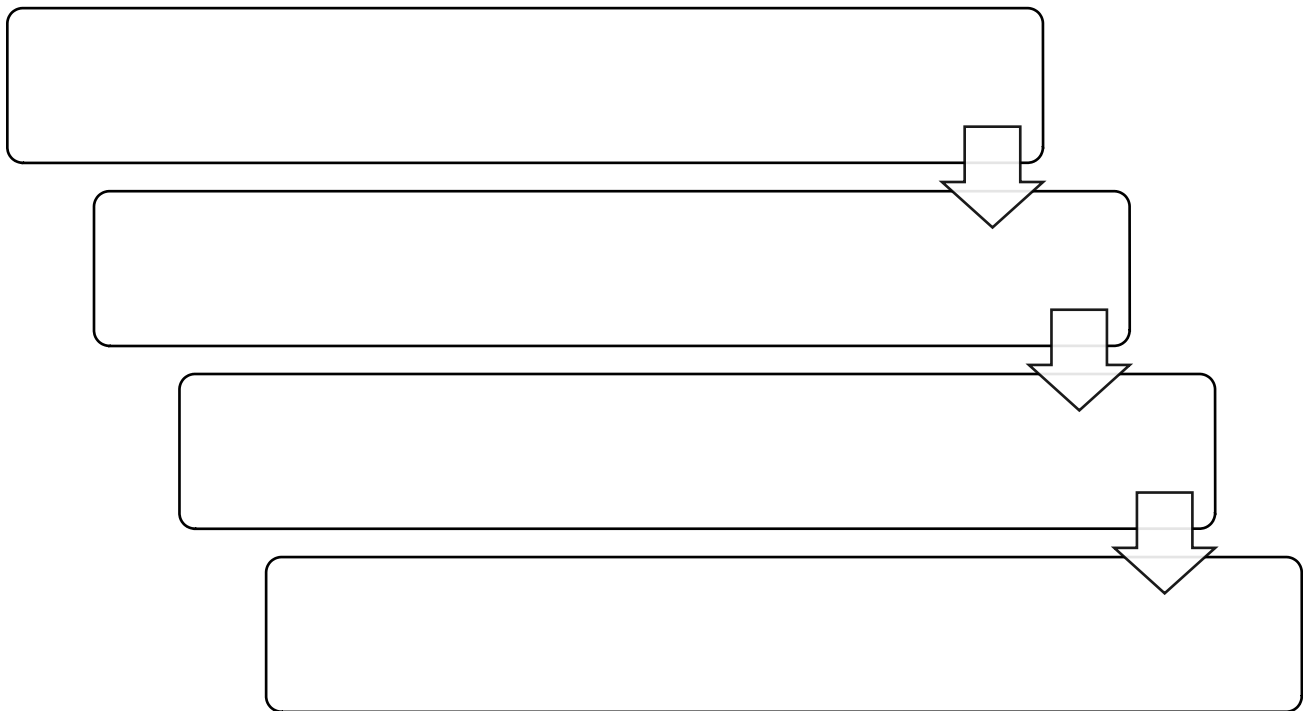
NIOSH is currently well-positioned to address this gap. In 1995, NIOSH published recommendations based on its research to inform regulatory decisions on mine dust standards [15]. Additionally, the NIOSH Mining Research Program has established relationships in the mining sector and a history of conducting research investigating CWP, primary prevention, and dust control [16, 17, 18].

2. Purpose and Use of Information Collection

The primary purpose of this study is to conduct formative research that will be used to develop a questionnaire for the next phase of the research project. The formative research will include conducting elicitation interviews with mineworkers and facilitating focus groups with mining stakeholders. Results from these data collection efforts will inform which constructs (e.g., attitudes, norms, perceived control, and self-efficacy) are measured through a survey during the next research phase and help researchers to establish priority areas for a future intervention.

Further, this study is the initial phase for an intervention development project that includes four phases. In Phase 1 (i.e., the current study), researchers will conduct elicitation interviews with coal miners to identify behavioral, normative, efficacy, and control beliefs related to pneumoconiosis screenings. In Phase 2, researchers will develop and distribute questionnaires to measure specific constructs identified in the elicitation interviews. Results from the questionnaire will be used to determine the attitudes and beliefs that will be targeted through an intervention to increase screenings. The intervention will be developed and piloted in Phase 3. In Phase 4, the intervention will be implemented and evaluated. Figure 1 outlines the phases and major research activities.

Figure 1. Phases for Intervention Development



The study will be guided by the integrative model of behavioral prediction [19, 20] and will follow the methodological approach used and recommended by Montano and Kasprzyk [21]. According to Montano and Kasprzyk [21], it is essential for researchers to conduct elicitation interviews with the target population for projects that apply the integrative model.

Researchers will collect qualitative data from the elicitation interviews. During elicitation interviews, researchers use open-ended questions to elicit information about the behaviors, norms, efficacy beliefs, and control beliefs of a population. During the interview, each subject will participate in an interview

(see Attachment B) and complete a demographic survey (see Attachments C). Data will be collected once from each participant.

Data collected from this study is essential to developing a theory-based intervention. Theoretical frameworks have been found to support intervention design and implementation [22], enhance construct validity [23], and allow for strong causal inference and practical outcomes [24]. Without the results from this data collection, NIOSH researchers will not be able to develop a questionnaire that measures beliefs and attitudes that are relevant to the target population or identify the beliefs and attitudes that need to be targeted in an intervention. Regarding the application of the integrative model, Montano and Kasprzyk [21] state that “one must go to the population to identify salient behavioral, normative, efficacy, and control beliefs associated with the behavior (p. 80).” The current project is a necessary step for NIOSH researchers to develop a data collection instrument and establish priorities for a future intervention to increase voluntary pneumoconiosis screenings among coal miners.

In addition, this study allows researchers to gather stakeholder input. Past research has identified the importance of formative research and stakeholder participation in intervention development. Formative research and stakeholder participation can facilitate collaboration, project acceptance, and aid in the development of culturally appropriate programs [25]. Formative research has also supported researchers in identifying key barriers to the desired behavior and tailoring interventions to meet the needs of the target audience [26]. Aligning with previous findings, the current study will help NIOSH researchers develop an effective intervention that incorporates stakeholder concerns and addresses the needs of coal miners.

3. Use of Information Technology and Burden Reduction

Data will be collected through semi-structured interviews, focus groups, and demographic surveys. The following outlines the data collection processes.

Data Collection Process for Interviews

- (1) Participants will be recruited at mining events using a convenience sampling approach (i.e., word of mouth) (see Attachment F) and will have the option to select an interview time from a list of options provided on an interview sign-up sheet (see Attachment G).
- (2) Each participant will be asked to complete a demographic survey (see Attachment C)
- (3) The researcher will conduct an interview guided by the established protocol (see Attachment B)

Data Collection Process for Focus Groups

- (1) Participants will be recruited at mining event following a presentation on pneumoconiosis and barriers to secondary prevention and surveillance (see Attachment H)
- (2) Each participant will be asked to complete a demographic survey (Attachment E)
- (3) The researcher will conduct a focus group guided by the established protocol (Attachment D)

4. Efforts to Identify Duplication and Use of Similar Information

The lead investigator for this study conducted a qualitative literature review to identify potential barriers to mineworkers' participation in black lung screenings. Literature was identified by searching key words such as “black lung screening” and “health screenings”. The literature search returned limited results and revealed a major research gap. However, results from the literature review were analyzed to identify

four potential barriers that may require further exploration and validation: (1) employment trends, (2) individual beliefs and attitudes, (3) black lung compensation, benefits, and policies, and (4) fear of job loss or employer retaliation.

While the literature review helped NIOSH researchers to understand some potential barriers, it did not fulfill the need to conduct elicitation interviews for two main reasons. First, due to the limited research on this topic, studies included in the literature review did not solely focus on mineworkers. For example, Shriver and Bodenhamer [27] conducted in-depth interviews with 35 black lung advocates. The advocates included mining stakeholders who served in various job roles such as clinicians, attorneys, miners, and federal employees. Findings from other studies were based on existing literature or secondary data sources [28] or explored factors that influenced prevention behaviors for other health conditions [29].

Second, the studies included in the literature review did not primarily focus on black lung screenings. For example, Reynolds and colleagues [28] aimed to characterize mineworkers' participation in the Part 90 Program. Moreover, Part 90 is a program that allows miners diagnosed with pneumoconiosis to transfer to jobs that reduce their exposure to coal mine dust [28]. While this study offers valuable information, it does not explore mineworkers' beliefs and attitudes relative to voluntary screenings.

To develop a theory-based intervention, researchers need a systematic data collection focused on the mineworkers (i.e., the target audience for the intervention). Due to limited empirical findings in this area, it is necessary for NIOSH researchers to follow the guidelines prescribed for application of the integrative model of behavioral prediction [19,20].

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Currently, there are few research findings on mineworkers' attitudes and beliefs relative to voluntary black lung screening. This data is necessary for the next phases of this project. If this data collection is not conducted, researchers will not be able to design an effective survey instrument or develop a future intervention that is supported by theory. More specifically, researchers will not have the data necessary to develop a survey instrument that will adequately measure constructs for the integrative model of behavioral prediction [19, 20]. Data from the survey will be used to develop an intervention to increase the number of mineworkers who participate in voluntary medical surveillance and early detection programs (i.e., get voluntary black lung screenings). In addition, researchers will not be able to capture the perspectives of stakeholders. As previously stated, formative research and stakeholder insights aid researchers to develop interventions that are collaborative, culturally appropriate, and more widely accepted [25].

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This request did not involve consultation outside of CDC.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

NIOSH's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. The proposed study does not involve the collection of personally identifiable information or sensitive data. Participants will not be required to use their names during the focus group or interview. Researchers will also not require participants to include any personally identifiable information on the interview sign-up sheet (see Attachment G) or demographic surveys (see Attachments C and E).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The NIOSH IRB has issued an exempt determination for research activities included in this study. The NIOSH IRB determination is included as Attachment I.

Sensitive Questions

This data collection does not require participants to answer questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. The proposed research study involves conducting one-time, semi-structured interviews with a maximum of 50 mineworkers, and up to seven, one-time focus groups with a maximum of 63 mining stakeholders. All participants will be recruited from mining events such as mine health and safety conferences and mine rescue competitions. The total estimated annualized burden hours for interviews and focus groups was calculated at 124 hours. The following section provides a detailed overview of data collection activities, timeframes and burden hours.

Interviews. The total burden to conduct interviews with 50 participants was calculated at 64 hours. First, the researcher will read a recruitment script and informed consent form to the potential participant.

Second, the participant would select a time slot from the interview sign-up sheet, which will take approximately 2 minutes with a total burden of 2 hours. During the interview, the participants will complete a demographic survey in approximately 5 minutes, which was estimated at 4 burden hours. Finally, the researcher will conduct a 45- to 60-minute interview with each participant, which was estimated at 50 burden hours.

Focus Groups. The total burden to complete the focus group recruitment process with 63 participants was calculated at 79 hours. First, researchers will read the recruitment script and informed consent form. Second, participants will complete the demographic survey in about 5 minutes—estimated at 5 burden hours. Finally, researcher will conduct a 30- to 60-minute focus group that was calculated at 63 burden hours.

Table 1. Estimated Annualized Burden Hours

Types of Respondents	Form Name	No. of Respondents	Average Burden per Response (in hours)	Total Burden (in hours)
Coal miners	INT Sign-Up Sheet	50	2/60	2
Coal miners	INT Demographic Survey	50	5/60	4
Coal miners	INT Protocol	50	1	50
Stakeholders	FG Demographic Survey	63	5/60	5
Stakeholders	FG Protocol	63	1	63
Total				124

INT = interview; FG = focus group

12b. As previously stated, study participants will be recruited from mining events that focus primarily on health and safety topics. These events often attract sector regulators, mining engineers, health and safety specialists, and mine trainers. Researchers will recruit coal miners and mining stakeholders from these mining event.

Coal miners will be recruited to participate in the interviews. Many of these individuals hold job titles such as trainer or engineer. According to the Bureau of Labor Statistics, coal mining training and development specialists and engineers reported mean hourly wages of \$38.91 and \$42.62 respectively [30]. The average of these figures was calculated for an estimated wage of \$40.77 for coal miners.

Researchers will also recruit mining sector stakeholders. Stakeholders include individuals who work in or support the mining sector. These individuals may be employed by mining companies, industry associations, regulatory agencies, labor unions, suppliers, manufacturers, or academic institutions [31]. Mining events often attract stakeholders who work in occupational health and safety. According to the Bureau of Labor and Statistics, the mean hourly wage for Occupational Health, Safety Specialist and Technicians in mining was \$34.82 [30]. This average was used to represent the average wage for a mining stakeholder in this study.

The total annualized burden costs are \$4,652 .

Table 2. Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate ^[30]	Total Respondent Costs
Coal miners	INT Sign-Up Sheet	50	2/60	2	\$40.77	\$82
Coal miners	INT Demographic Survey	50	5/60	4	\$40.77	\$163
Coal miners	INT Protocol	50	1	50	\$40.77	\$2,039
Stakeholders	FG Demographic Survey	63	5/60	5	\$34.82	\$174
Stakeholders	FG Protocol	63	1	63	\$34.82	\$2,194
Total	--	--	--	--	--	\$4652

**INT = interview; **FG = focus group*

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

This data collection does not involve other annual cost burdens to respondents or record keepers.

14. Annualized Cost to the Government

Data will be collected over a 12-month period. The estimated annualized cost to the Federal Government over the 12-month data collection period was \$24,695.50. Hourly rates for CDC/NIOSH employees were obtained from the 2019 General Schedule Pay Table [32].

Table 3. Annualized Costs to the Government

Personnel	Hours	Hourly Rate ^[32]	Data Collection, Analysis, and Writing Costs	Travel Costs	Total
Mining Engineer (GS 9-1)	50	\$21.31	\$1,065.50	N/A	\$1,065.50
Behavioral Research Scientist (GS 12-1)	400	\$30.90	\$12,360.00	\$5,000	\$17,360.00
Behavioral Research Scientist (GS 12-1)	50	\$30.90	\$1,545.00	N/A	\$1,545.00
Lead Behavioral Research Scientist (GS 14-1)	50	\$43.42	\$2,171.00	N/A	\$2,171.00
Branch Chief/Behavioral Research Scientist (GS 15-1)	50	\$51.08	\$2,554.00	N/A	\$2,554.00
Total Cost	600	N/A	\$19,695.50	\$5,000	\$24,695.50

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

All activities for the project are expected to be completed within 12 months. One year of clearance is being requested for research activities. Table 3 outlines the project schedule.

Table 3. Project Timeline

Project Time Schedule	
Activity	Time Schedule
Data collection/Conduct interviews and focus groups	1-9 months after OMB approval
Data analysis/Coding and descriptive statistics	2-10 months after OMB approval (ongoing process)
Reporting and synthesis for the next phase of the study	11 months after OMB approval

17. Reason(s) Display of OMB Expiration is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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