Silicosis Prevalence and Related Knowledge, Attitudes and Practices Among Rural Mine Workers in Rwanda

A Study Supported by Partners in Health/Inshuti Mu Buzima Non-Communicable Disease Programs

RNEC Approval 4/11/2022

NCT05538299

Project Summary:

Silicosis is the most prevalent occupational lung disease in low- and middle-income countries (LMICs) with "tens of millions" estimated to suffer from the disease according to the World Health Organization (WHO). To date, there is little published data on silicosis in LMICs and the burden of silicosis in Rwanda has not been well-defined. Silicosis among local mine workers is a common reason for hospitalization and death at Rwinkwavu District Hospital, located in Rwanda's Kayonza District.

The objectives of this study are:

1. To assess the prevalence of silicosis among workers in four mines located in the Kayonza District of Rwanda
2. To adapt a validated screening tool testing in Dutch construction workers for Rwandan miners
3. To implement an occupational health education program and assess the change of before and after intervention that target towards proper use of PPE and individual risk assessment in mine workers using knowledge-attitudes-practice tool

Investigators:

Name	***Relevant Title and Institution***	***Location***	***Research Role***
Peter Barebwanuwe, MPH	Director of Social and Community Medicine , PIH	*Rwanda*	General project oversight, study design, results interpretation, manuscript writing and review.
Samuel Hatfield, MD	Internal Medicine Doctor	*Rwanda and USA*	General project oversight, study design, results interpretation, manuscript writing and review.
Daniel Mays, MD MSc	Internal Medicine Doctor	*Rwanda and USA*	General project oversight, study design, results interpretation, manuscript writing and review.
Vincent K. Cubaka, MD	Director of Research and Training, PIH	*Rwanda*	General project oversight, study design, results interpretation, manuscript writing and review
Alphonse Nshimyiryo	Data analyst, PIH	*Rwanda*	Support study design, data management, analysis, interpretation, manuscript writing.
Wellars Dusingizimana, MD	Internal Medicine Doctor, RDH	*Rwanda*	General project oversight, study design, results interpretation, manuscript writing and review.

Evgeniya Krapivinsky, MD	Assistant Professor, Medicine, UCSF	*USA*	Study design, data interpretation, manuscript review, dissemination
Esperence Uwayitu, MD	Director General, RDH	*Rwanda*	Study design, data interpretation, manuscript review, dissemination
Ainé Niyonkuru, MD	Clinical Director, RDH	*Rwanda*	Data collection, data analysis, results interpretation, manuscript writing and review
Egide Mpanumusingo, MD	District Program Director, PIH	*Rwanda*	Study design, tools development, data analysis, results interpretation, manuscript review, dissemination
Paul Sonenthal, MD	Associate Director, Inpatient Medicine and Critical Care, PIH Instructor in Medicine, Harvard Medical School and Associate Physician, Division of Pulmonary & Critical Care Medicine, Brigham & Women's Hospital	*USA*	Study design, tools development, data analysis, results interpretation, manuscript review, dissemination
Mr. Tharcisse Basigayabo	Coordinator of exploitation and exploration.	*Rwanda*	Study design, results interpretation, manuscript review
Jean Nepomuscene Renzaho	Social and Community Medicine Manager, PIH	*Rwanda*	Data collection, data analysis, results interpretation, manuscript writing and review
Symaque Dusabeyezu, MPH	Manager of NCD, PIH	*Rwanda*	Data collection, data analysis, results interpretation, manuscript writing and review
Loise Mwihaki Ng'ang'a	NCD Research Manager, PIH	*Rwanda*	Support study design, data management, analysis, interpretation, manuscript writing
Richard Nduwayezu, MD	Head of Primary Health Care Department, UR	*Rwanda*	Study design, data interpretation, manuscript review, dissemination
Jean Claude Byiringiro, MD	School of Medicine and Pharmacy Dean, UR	*Rwanda*	Study design, data interpretation, manuscript review, dissemination
Fredelick Kateera, MD	Chief Medical Officer, PIH	*Rwanda*	Study design, data interpretation, manuscript review, dissemination
Mr. Adrien Habineza	Associate Director of Training, PIH	*Rwanda*	Tools development, Data collection, results interpretation, manuscript writing and dissemination

Stella Savarimurtha, MD	Fellow, Pulmonary Medicine, Yale University	*USA*	Implementation, data interpretation, study execution
Akiiki Florence Bitalabeho, MD	Director of Community Based Education, PIH	*Rwanda*	Study design, data interpretation, manuscript review, dissemination
Mr. Innocent Kamali	Associate Director of NCD, PIH	*Rwanda*	General project oversight, study design, results interpretation, manuscript
Mr. Aphrodis Ndayisaba	Associate Director of Quality Improvement, PIH	*Rwanda*	Data collection, results interpretation, manuscript writing and dissemination

Research site: Rwinkwavu District Hospital

Study subjects: Mine workers and supervisors at three Kayonza District mining sites (Rwinkwavu, Murama, Ruramira, and mwili sectors)

Sponsor: Partners in Health / Inshuti Mu Buzima

Main Departments: Department of Research and training, PIH

Department of Internal Medicine, RDH

Department for Non-Communicable Diseases, RDH

Department of Medical Imaging, RDH

Department for Integrated Non-Communicable Diseases, PIH

Department of Primary Health Care, School of Medicine and Pharmacy, University of Rwanda

Background

Silicosis, a form of occupational pneumoconiosis, is a chronic, incurable lung disease caused by inhaling silica dust that leads to lung inflammation and the formation of irreversible fibrosis. In many cases, silicosis results in premature cardiopulmonary failure and death. Silicon dioxide, commonly called “silica,” is the most abundant mineral on earth. Silica dust, or respirable crystalline silica (RCS), consists of tiny particles less than 10 micrometers in diameter and is commonly generated, or entrained into the air, during mining operations and a variety of other industries (Fig. 1).

Figure 1 - Occupations with high exposure to respirable crystalline silica

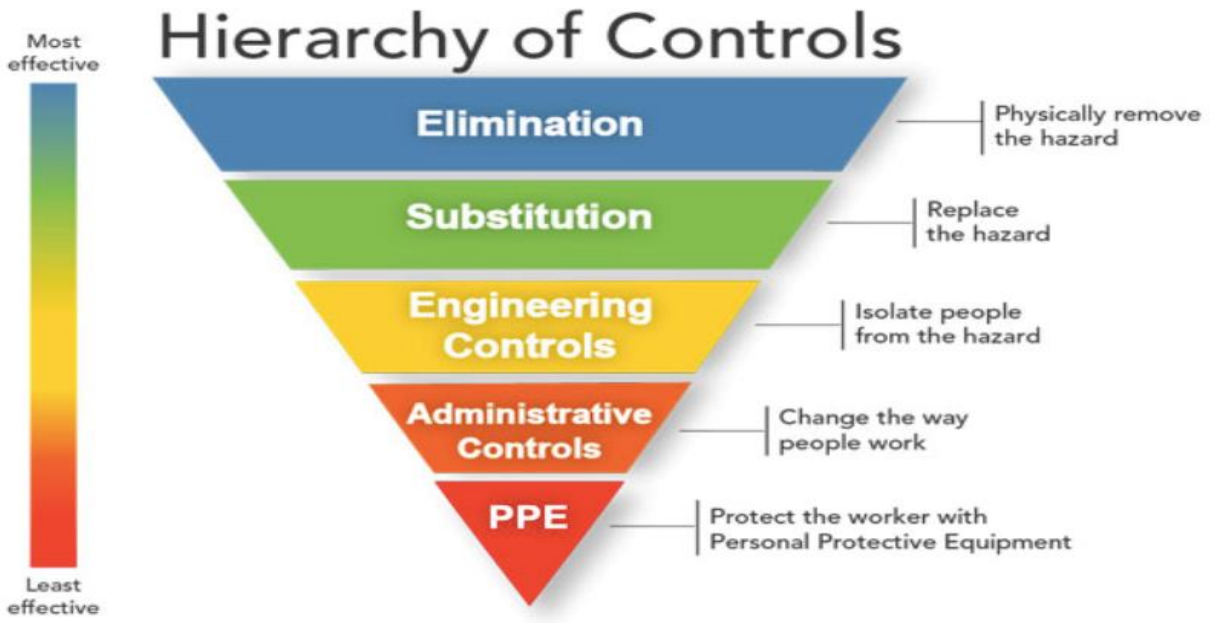
Source: Leung et al. Lancet 2012; 379: 2008–18

- Construction (including sandblasting, drilling, tunneling and demolition)
- Mining and quarrying
- Hydraulic fracturing
- Foundries
- Pottery and jewelry-making
- Stone-cutting

The current global prevalence of silicosis is not well defined, as surveillance is poor or absent in many LMICs. The WHO estimates “tens of millions of workers” suffer from silicosis worldwide. The burden is particularly severe in LMICs, with data suggesting 30-50% of workers in high-risk sectors eventually develop silicosis. The burden of silicosis in Rwanda is not well defined. In years past, silicosis has been on the agendas of the International Labour Organization (ILO) and WHO, and today the disease remains an urgent public health issue for people who work in mining and other high-risk industries. One study of South African gold miners found more than 25% had silicosis on autopsy with prevalence rates increasing significantly from 1975 and 2007, particularly among Black miners. A recent survey of underground miners in Brazil identified silicosis prevalence rates as high as 37%.

Silicosis is deadly, but it is also preventable. In recent decades, incidence rates have declined in some countries after the institution of effective occupational health measures. Eliminating the medical and socioeconomic toll of silicosis requires primary prevention through a hierarchy of controls as shown in Fig. 2 and early detection and mitigation through screening and surveillance. Mining operations will always encounter silica dust and this hazard cannot be substituted. Therefore, the most effective and practical approach to silicosis prevention in mining operations involves *engineering controls*, which isolate workers from RCS. Commonly used engineering controls in mining include ventilation systems, enclosed cabs or booths with air filtration, and water spray and other wetting systems to reduce dust entrainment. Administrative controls, such as hazard education, worker hygiene and job rotation, along with personal protective equipment (PPE) such as air filtration masks supplement the protective effect of engineering controls, however they are somewhat less effective. Administrative controls and PPE also depend on the behavior of each individual worker, and are therefore less reliable. Primary prevention through dust control along with early detection of disease, health education, and strong regulatory oversight, are consistent with joint ILO/WHO Global Programme for the Elimination of Silicosis (GPES).

Figure 2 – Hierarchy of controls in occupational health

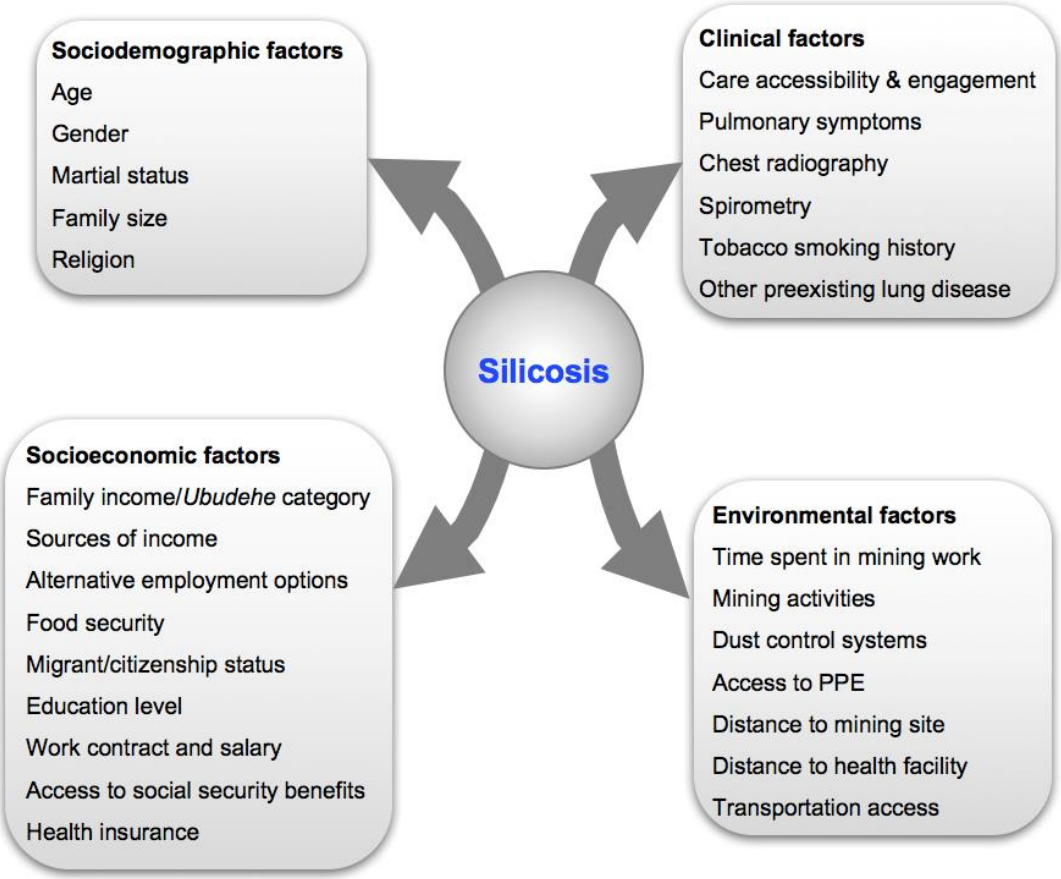


Source: United States National Institute for Occupational Safety and Health (NIOSH)

Silicosis is an insidious disease, commonly taking years to develop into clinically identifiable signs or symptoms. In the absence of regular screening and surveillance, the diagnosis of silicosis is usually not made until an extensive level of irreversible lung damage and significant physical debility have already occurred. Among workers exposed to RCS, chest radiography, commonly referred to as Chest X-ray, is among the most important clinical tools for identifying silicosis, along with spirometry, which carefully measures airflow dynamics during breathing, and symptom checklists.

Recurrent exposure to RCS is the single most important risk factor for developing silicosis. Both disease risk and severity increase proportionally with the total cumulative amount of inhaled RCS over person's lifetime. Other factors associated with silicosis are well-documented, including tobacco smoking, older age, limited education, migrant status, and delays in medical care. An array of additional factors, from individual education and income levels to political economy in poor communities, shape how silicosis arises and makes an impact both in the individual and collective, fractal life of each person living with silicosis. We have developed a biosocial conceptual framework for understanding silicosis, specifically as it manifests in Rwanda.

Figure 3 – Biosocial conceptual framework for silicosis in Rwanda



Based on the clinical experience of the authors and their network, silicosis morbidity and mortality have been consistently encountered among Rwandans with dust and mining exposure, however Rwanda currently lacks an existing body of data on current silicosis prevalence and a surveillance system for ongoing monitoring and interventions. According to the WHO, disease surveillance programs should include periodic identification and collection of health information, evaluation and interpretation of the information, and reporting and interventions for the purpose of prevention. The goal of surveillance is to monitor the trends in disease incidence over time across a particular domain, define the magnitude or relative magnitude of a problem and target and evaluate interventions. Here, we propose a study of silicosis-related data from mine workers in Rwanda's Eastern Province through the development of a silicosis surveillance and health education program at Rwinkwavu District Hospital.

Study Goal and Objectives

1. To assess the prevalence of silicosis among workers in four mines located in the Kayonza District of Rwanda
2. To adapt a validated screening tool testing in Dutch construction workers for Rwandan miners

3. To implement an occupational health education program and assess the change of before and after intervention that target towards proper use of PPE and individual risk assessment in mine workers using knowledge-attitudes-practice tool

Methodology:

Study setting:

This study will be conducted in four sectors (Rwinkwavu, Murama, Ruramira, and Mwiri) of Kayonza district in eastern Rwanda. There are 9 [Migera, Gihinga, Nyarunazi, Gahengeli, Gashushyi, Rutonde, Raveri, Bugambira, Rukira] mining sites in Rwinkwavu, Murama, Ruramira and Mwiri, and all mining activities in these sites are supervised by Wolfram Mining and Processing LTD. All these sectors are located in the Rwinkwavu District Hospital catchment area.

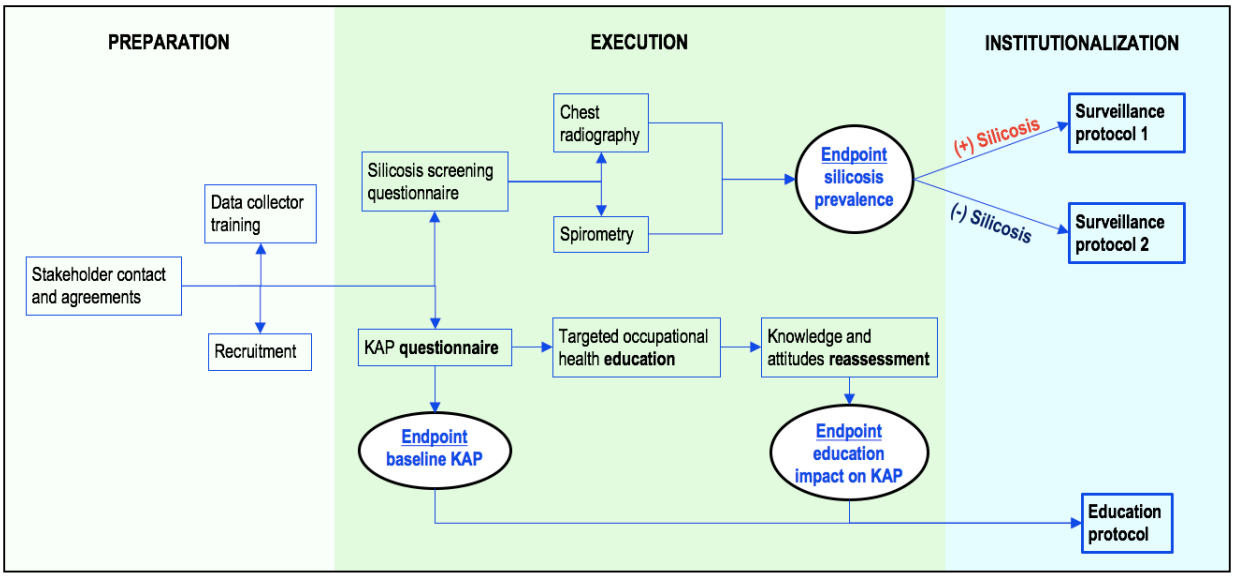
Study design:

This will be a combination of a cross-sectional study to determine the prevalence of silicosis and a pre- and post-design to assess the silicosis-related knowledge, attitudes and practices (KAP) among mining workers before and after the implementation of a health education program.

The study design will be cross-sectional study and is further detailed in Figure 4. There are three main objectives: silicosis prevalence; baseline silicosis-related knowledge, attitudes and practices (KAP); and the impact of occupational health education. A team of clinical and public health professionals affiliated with Partners In Health/Inshuti Mu Buzima and Rwinkwavu District Hospital will carry out the study with data collection assistance from trained fourth-year medical students from the University of Rwanda during their social medicine rotation. The preparation phase will involve contacting and establishing agreements with stakeholders from key organizations including Rwinkwavu District Hospital, Wolfram Mining and Processing Ltd., University of Rwanda and Partners in Health/Inshuti Mu Buzima. This phase will involve training medical student data collectors and recruiting study subjects. The study execution phase will firstly consist of a cross-sectional analysis of silicosis prevalence, adapting a validated silicosis questionnaire screening tool to the target study population and performing spirometry and chest radiography to all targeted miners [Suarthana, Eva, et al. "A Simple Diagnostic Model for Ruling Out Pneumoconiosis among Construction Workers." Occupational and Environmental Medicine, JSTOR]. This screening tool for ruling out occupational pneumoconioses, and silicosis specifically, was developed by researchers in the Netherlands. We will adapt and validate the use of this screening tool to Rwandan mine workers by comparing the screening results with objective spirometry and chest radiograph findings on all subjects who have spent at least one cumulative year working directly with mining products. Secondly, the execution phase will involve an analysis of existing silicosis-related KAP and the delivery of targeted occupational health education to study subjects followed by a reassessment of knowledge and attitudes. We will perform initial education program and KAP survey at the time of questionnaire based screening with re-assessment at 2-week time point. There are approximately 995 mine workers in the cachement are of this study and our goal is to try and involve all of these stakeholders. Baseline KAP survey will be done prior to our health education program on PPE, environmental

controls and personal safety assessment and deployment of the screening questionnaire. Silicosis related KAP data will be collected by skilled data collectors after a two week training program.

Figure 4 – Study roadmap



KAP: knowledge, attitudes and practices

Study population:

All eligible mine workers in Kayonza District in four sectors including: Rwinkwavu, Murama, Ruramira, and Mwiri sectors, located in the Rwinkwavu DH catchment area will be included in the study. Those miners with potential risk for RCS exposure, including those who handle mining either underground or above ground will be included. People who work in WOLFRAM administration (office) and never directly touch mines will not be included.

Study sample:

For the aim to determine the prevalence of silicosis, we used the single population proportion formula to calculate the required sample size. With the existing literature that silicosis prevalence among high-risk populations in LMICs may range between 30-50% [Trapido, A.S. *et al* (1998) Prevalence of occupational lung disease in a random sample of former mineworkers, Libode District, Eastern Cape Province, South Africa. American Journal of Industrial Medicine, Antão VC, Pinheiro GA, et al., High prevalence of silicosis among stone carvers in Brazil. Am J Ind Med. 2004], we used the most conservative estimate of 50% for a maximum sample size, with a level of confidence of 95%, 0.8 power and a level of precision of +/- 10% - a sample of 189 individuals will be required. For the silicosis-related KAP part of this study, we also used the most conservative estimate of 50%, a 95% confidence level, and a 0.8 power to detect a 20% difference from pre- to post-intervention. This gave us a required total sample size of 186 individuals (a minimum sample of 93 individuals will be required for the pre- and post-survey),

however the required sample size would increase to 224 individuals (112 individuals in each survey) after accounting for a 20% non-response rate. We estimate our study sample to be around 995 mine workers, so we will have ample participants to conduct our study. Our goal is to sample the complete mining population so as to obtain accurate prevalence of the full cohort of miners within the RDH catchment area, which may also allow us to detect asymptomatic disease in certain miners, and to enroll these patients in future surveillance programs

Recruitment of study participants and consent to participate

Participants will be recruited from the mining and processing company Wolfram Mining and Processing Ltd., which operates in Rwinkwavu, Murama, Mwili, and Rurambira sectors. Inclusion criteria for all three study objectives, including silicosis screening, KAP assessment and education programs are: adult residents of Kayonza District aged 18 years or older who regularly (at least once per week) works in direct physical proximity with mining products in operations managed by Wolfram Ltd. at the present time or those who regularly worked in such mining operations for at least one cumulative year within the last 10 years. Exclusion criteria include those who have a significant impairment in speech or hearing due to the limited availability of adequate accessibility provisions for such study subjects, or other physical or medical disability that may limit involvement. Patients who are illiterate may still participate in the study with help from data collectors who can help study candidates complete forms and assessments. Recruitment procedures will be proposed to the managers of Wolfram Ltd. and finalized through consensus. We will propose that those who meet inclusion criteria be informed of the opportunity to receive a free medical screening and important information on staying healthy while working in the mining industry. Mine workers who accept to be a part of study, will avail him/herself two half days. Workers are in the mine in two possible shifts, typical shifts are from 6am-2pm (One site has a night shift from 4pm-early am). We plan to perform screening and education from 2-4pm at each site for workers who agree to participate so that all miners have access to the program. All relevant ethical information, including the risks and benefits of study participation will be provided to each prospective study subject in an informed consent document that will be made available in written and oral form in both Kinyarwanda and English.

Data collection

Questionnaire data will be collected by trained data collectors and supervised by faculty and other health professionals including Internal Medicine Doctors, and trained healthcare professionals. Data will be collected across two visits, two to four weeks apart. At the first visit, each mine worker and supervisor at mining site will privately undergo a guided oral and structured questionnaire on demographic, socio-economic, and KAP related to silicosis and mining data will be collected. Each participant will be reassured and reminded that individual responses are confidential, inaccessible by the Wolfram Ltd. Company and will be anonymized prior to publication. Mine workers will also undergo an oral and structured questionnaire-based screening for silicosis symptoms. All subjects will then be assembled in small groups to receive targeted health education. At the second visit, mine workers and mining site supervisors will

undergo structured interview for retention of health education by fulfilling a repeat KAP questionnaire, identical to the original. Data collected will include percentage of questions answered correctly, and will be further analyzed based on content areas. Mine workers who have worked in mining for at least one cumulative year will also undergo chest radiography and spirometry performed by trained clinical staff at Rwinkwavu District Hospital during their first visit with results interpreted by physician specialists. All questionnaire responses will be documented by data collectors and entered into a computerized database as the questionnaire is being performed. Data will be stored digitally on password-protected hard drives, tablets, and secure cloud servers.

The published sensitivity and specificity of the silicosis screening questionnaire will be reassessed in this study population by comparing the questionnaire results to chest radiography and spirometry findings from each subject.

Pilot Study

Questionnaires and other study tools will be pre-tested in a pilot study conducted over the course of two days among 20 mine workers in Rwamagana District. We preferred to not use people under study area for avoiding any familiarity of tools before execution of the study which can be transmitted among miners which could tamper results. Feedback will be requested from these participants. Data collection and other tools will be adjusted and improved following the feedback and observations from the pilot study. In addition to sharpening the study methods, this pilot study will allow the study team to review pilot data to determine its accuracy and decide whether a retraining session will be necessary.

Data management, interpretation and analysis

All data of this study will be recorded and stored in REDCap before they will be exported into Stata v15.1 (Stata Corp, College Station, TX, USA) for analysis. Only the study team will have access to raw data and de-identified data will be kept in the analyzable dataset. We will use frequencies and percentages to summarize categorical data and median and interquartile ranges for continuous data. The pre-education KAP questionnaire responses will be compared to post-education responses and analyzed for statistically significant changes in KAP.

Institutionalized linkage to care and follow-up

For two years subsequent to this study, all mine workers who participate in this study along with local mine workers who do not participate will be provided with annual follow-up visits at Rwinkwavu District Hospital and those who were screened positive for silicosis will be seen every six months (or at internal medicine physicians discretion) depending on disease severity as an establishment of surveillance program for miners and Rwinkwavu District Hospital. Further program institutionalization will occur at the discretion of the Rwinkwavu District Hospital Director General and the Ministry of Health.

Expected Outcome

We expect to have a robust understanding of the prevalence of silicosis among Rwandan mine workers along with an understanding of their KAP related to this disease. We expect to see the change of before and after an educational program on silicosis-related KAP. The long-term impact of this study will be to support the institutionalization of a permanent silicosis surveillance and prevention program at Rwinkwavu District Hospital. This will be achieved by first establishing prevalence of silicosis among miners in Kayonza district, and enrollment of miners into a protocolized surveillance program to prevent disease progression and identify/prevent new cases. By further extension, this study is intended to bolster efforts to prevent silicosis through health education and policy change and identify and manage the disease at early stages through universal screening and prompt referral for further medical evaluation and care. Ultimately, impact of surveillance program will be measured by new incidence of silicosis in our study population against average case rates in the general population, as well as retention rates in surveillance protocols.

Dissemination of Results and Publication

We anticipate that the results of the study will be relevant to the larger medical, research, and mining community and will be of particular interest to those clinicians who are practicing in LMICs as well as areas with high prevalence of silicosis and other occupational pneumoconioses. We aim to publish this study in a peer-reviewed journal focused on occupational health, public health, global health or respiratory disease. Lead authors will be those who have contributed most significantly to the successful conceptualization and execution of the project.

Implications for practice, public health and policy

This study will help all stakeholders in mining-related policy formation, decision making, and interventions to eliminate silicosis among miners. These data will inform mining-related occupational health policies in Rwanda and elsewhere. These data will serve as a model for other health facilities and health systems to institutionalize silicosis education and surveillance. The information gleaned and delivered in this study will inform individual health care providers, hospitals and mining company employees and stakeholders regarding the nature of silicosis in Rwanda and mechanisms to prevent, identify, mitigate and ultimately eliminate the disease from this population.

Duration

Duration of project, including recruitment, deliver health education, screening, data collection, data analysis, and manuscript preparation, is expected to take 1 year.

Phase one: January 2022 – September 2022: preparation time. Designing study tools, collecting study approvals, contacting stakeholders, and testing study tools.

Phase two: October 2022-January 2023: implementation time. Training, collection, managing, analysis of data, and educating subjects on KAP.

Phase three: February – July 2023: Dissemination phase.

Anticipated Problems

We anticipate potential conflicts of interest between the hospital and the mining company and potentially losing subjects to follow-up. Also, difficulty in obtaining desired clinical data. The study team will do our best to limit anticipated errors

Ethical review and board approval

Approval from IMB Research committee and ethical clearance from RNEC will be requested along with a formal authorizing letter will be presented to Rwinkwavu District Hospital, Partners in Health (PIH) leadership, and local and mining company leaders for obtaining approval. During the recruitment stage, it will be declared to each stakeholder and prospective participant that, beyond the direct benefits of free medical screening and education, no study subject will be compensated or receive any other benefits in return for participation. There will be no penalty for declining to participate and participants may withdraw from the study any time without penalty.
Participants' **privacy and confidentiality** will be considered by using both people initials/ IDs for research reason and names for clinical/ treatment purpose. Privacy at health mining site and hospital will be ensured by identifying the private room/ place before starting screening and data collection. This means that the PI will visit screening site and district hospital prior to screening and the data collection for prior place setting and ensure privacy for screening and interviewees. In order to ensure the confidentiality, the study team explained the interviewees that nobody will be shared the information; only study team will share for research purpose. There will be **no risks** to the participants in this study, this means the study doesn't aim to harm the people and patients but to inform decision makers for preventing silicosis at early stage for risky people/ miners and improving health care. Also, the participants will be informed that there is **no compensation**/ **direct benefit** from participating in this study. The benefit of this study is to ensure effective silicosis prevention and improve quality of life for people tested silicosis positive. The researchers will request participants' consent to participate. Those who are able to read will be given consent form and read for themselves and those who weren't able to read researcher or data collector read for them. Researcher/ data collector and people will sign consent form. Data collectors were trained on research ethics prior to data collection and also training will be conducted for allowing them being familiar to study tools and ensure ethic consideration. Data will be both collectors will be fourth year medical students who will collect data during screening and hired qualified study coordinator.

See also attached for both English and Kinyarwanda versions of the consent form and questionnaire.

Budget: detailed in below table

#	Item	Frequency	Cost	Times/ month	Total
1	Research coordinator salary, half-time	1	400,000	12	4,800,000

2	Research coordinator airtime	1	15,000	12	180,000
3	Focal people's airtime	4	12,500	12	600,000
4	Projects updates meeting	1	250,000	4	1,000,000
5	Travel fee	1	30,000	6	180,000
6	Printings	1	25,000	12	300,000
9	CXR-cost	900	6,528	1	5,875,200
10	Dissemination fee	1	4,000,000	1	4,000,000
Total					**16,935,200**

Collaborators

Tentatively, recruitment will be limited to WOLFRAM-Miners leadership Rwinkwavu District Hospital, Partners In Health, and University of Rwanda, School of Medicine and pharmacy-Department of primary health care staff.

Investigators:

Project Management

Anticipated team roles include but not limited to project overall management, team coordination, data collection, data management, data analysis, data interpretation, and dissemination of results.

Project team:

Peter Barebwanuwe, MPH

Samuel Hatfield, MD

Vincent K. Cubaka, MD

Danny Mays, MD

Jean Nepomuscene Renzaho, MPH

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