Fernald Medical Monitoring Program (FMMP)

The Fernald Community Cohort (FCC) consists of 9782 persons who participated in the Fernald Medical Monitoring Program (FMMP) from 1990-2008. The FMMP was a eighteen year medical surveillance program for community residents living within five miles of the former US Department of Energy uranium processing site at Fernald (near Cincinnati), Ohio. After community members became aware of the uranium releases from the Fernald plant, attorneys representing individuals (class members) who lived or worked within five miles of the Fernald uranium processing plant for two consecutive years between 1952 and 1984 filed a class action law suit. A settlement between the US Department of Energy (DOE) was reached in 1989 after a summary jury trial. The Settlement Fund provided a medical monitoring program for members of the class and an epidemiological study of the area. (Former workers at the site are enrolled in a different medical monitoring program.)

The initial comprehensive medical examinations conducted as part of the Fernald Medical Monitoring Program (FMMP) began in the autumn of 1990. The FMMP provided 9,782 initial examinations and 33,394 re-examinations. In December 1998, the FMMP changed from a three year to a two year examination cycle. All data collected from the FMMP were coded by certified medical record coders, double entered and verified into a SAS database on site of the examinations. Funding for the physical examinations and testing component of the Fernald settlement ended in November, 2008, but the data and biospecimens collected during the 18 year tenure of the FMMP continue to be available to researchers for epidemiological studies.

PURPOSES OF THE FERNALD MEDICAL MONITORING PROGRAM

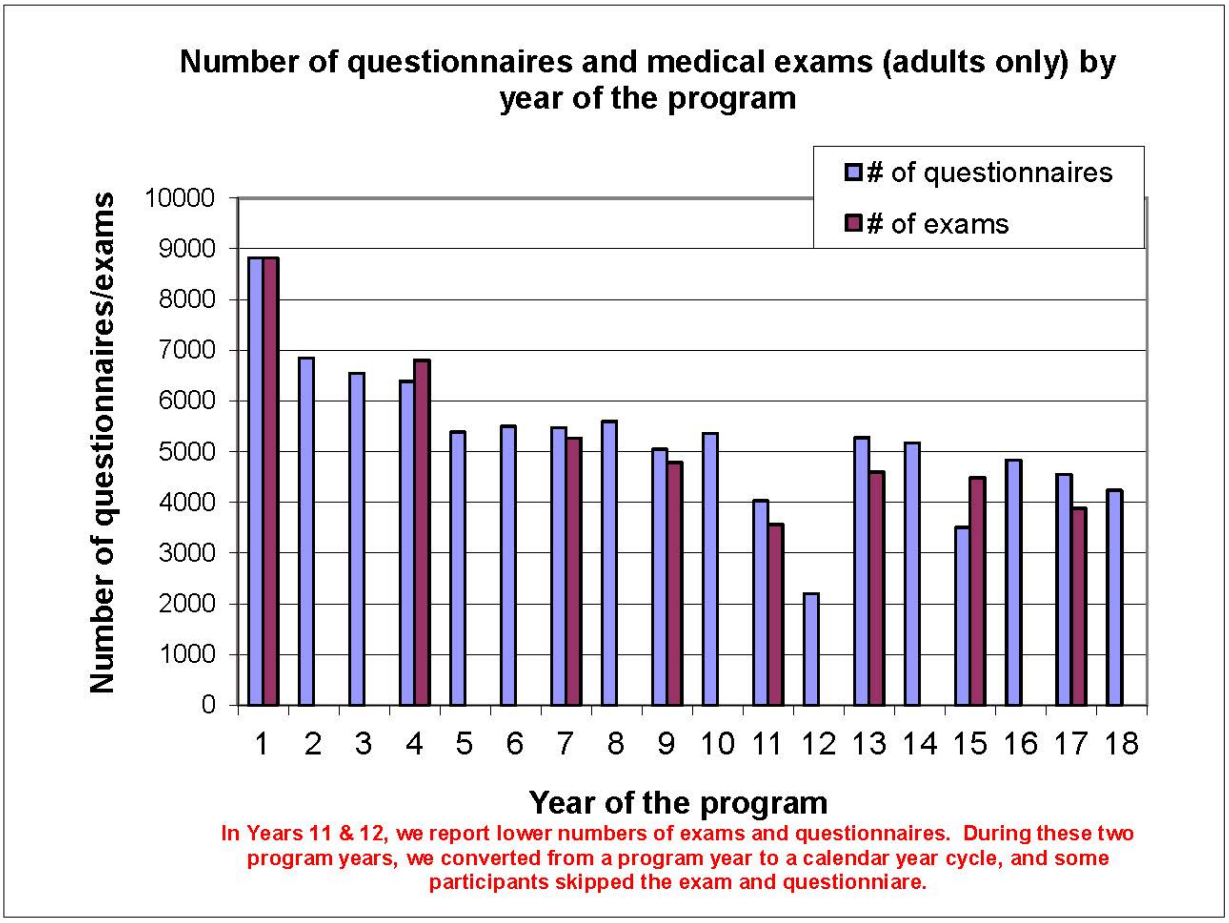
1. To provide a comprehensive evaluation of the current health of eligible class members.
2. To provide a comprehensive evaluation of risk factors for diseases which class members might develop.
3. To educate class members on how to modify their risk factors and thereby improve their health.
4. To establish a good baseline database for class members which may be useful in subsequent epidemiological studies.

SCOPE

The Fernald Medical Monitoring Program provided health screening services and benefits to eligible participants according to a pre-established protocol approved by the Fernald Settlement Fund Trustees. Each examination included many medical screening tests, but the Medical Monitoring Program did not provide additional diagnostic testing for abnormalities discovered on screening tests. The Program did not provide treatment for diseases or conditions identified. All participants were referred to their physicians for further diagnosis and treatment if necessary.

Upon entry to the FMMP all participants received a thorough medical examination and diagnostic tests including chest x-ray, electrocardiogram, pulmonary spirometry, and mammograms and cervical pap smears for female participants. Laboratory tests included the usual series for hematology, chemistry and lipid profile of blood serum, and urinalysis. At conclusion of the examination physicians recorded any new medical diagnoses apparent at the time of the examination, as well as diagnostic uncertainties requiring further diagnostic testing. Nurses employed by the program conducted participant follow-up by phone for at least six months on all those needing further testing or treatment by their usual primary care practitioner. (This follow-up

was a key to our excellent record of continuing program participation.) New diagnoses recognized through this follow up also were recorded on the medical record. Outside medical records (usually a pathology report) were obtained to validate any new diagnosis of cancer. For some cancer cases, a tumor block exists in our biospecimen archive.

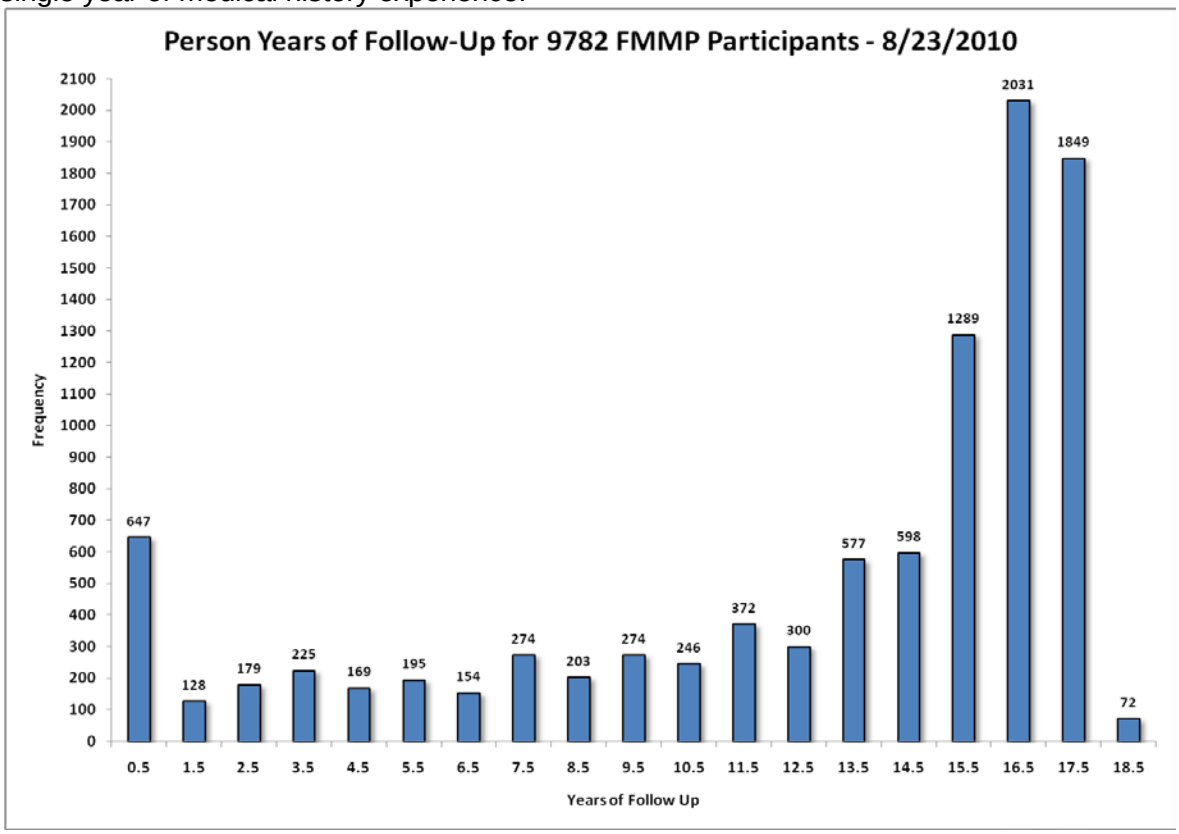


This same procedure was used at the time of the periodic medical examinations, offered every three years through 1998. In December 1998, financial analysis of monies left in the Settlement Fund indicated that re-examinations could be offered every 2 years (1999 to 2008). During the entire tenure of the program, 42,217 medical examinations of adults were conducted. (At the time of the initial exam, 994 program participants were <18 years, and considered children. As these participants reached age 18, they were included in the adult examination program.) Female participants age 40 and older were offered mammograms each year (including years when a complete medical surveillance examination is not scheduled), and men over 50 years were offered a PSA every other year.

Following the initial questionnaire, participants also were asked to complete yearly questionnaires requesting information about new medical problems and recent hospitalizations and surgeries, resulting in 94,771 completed questionnaires from adults. Yearly questionnaire return rates varied by Program year, but in 2007 were 51.6% of the original enrollees. Our yearly questionnaires were computer-generated, so that participants who missed a past questionnaire were re-issued critical data items from those missed questionnaires, greatly improving total ascertainment on any data item. Continued participation in the program at the time of re-examinations fell 23% at the

first re-exam for adults and has remained at about 50% for each examination since that time. (Some participants skipped one exam but then returned for the next one.) Only 216 participants withdrew from the Program and are no longer contacted or followed (except to obtain information when we learn of their death); 184 participants are lost to follow-up.

Questionnaire data collection was designed so that a different version of the form was sent to those who have skipped a year of questionnaire return, covering multiple years rather than a single year of medical history experience.



Overall follow-up was excellent. Follow-up time (period under observation), is considered to be the time from the first examination date until the last questionnaire or exam contact, or death. For most program participants, we have 12.5 years of follow-up. Death certificates have been obtained, or an NDI search completed, on most of the 662 participants who have died. FMMP medical records are thoroughly reviewed by both quality assurance nurses and coders after every medical examination, performing quality assurance for completeness and clarity of data.

Archived specimens:

At the first examination we obtained three 1-ml aliquots of whole blood, plasma, serum, urine and urine with buffer, or 15 aliquots per person for future analyses. Additional serum and plasma biospecimens were collected at the time of the second examination. Whole blood and serum were archived in 2006-2008. Specimens have been stored in minus 80 degree freezers. Although one of four freezers (at Holmes Hospital) failed during the July 4 weekend in 1996, and all samples in that freezer were lost, many of the plasma and serum samples were replaced when participants came for their next examination. Since 2001 specimens have been stored in six freezers at CCHM Research Lab. The status and temperature of each freezer is

continuously monitored by a central alarm system with established protocols for notification and transfer of specimens if needed. The freezers have a CO_2 back-up system and are undergo scheduled maintenance through a contract with the SoLow Company. Only a small proportion of the specimens have been used for research. We have a large inventory database of all of the biospecimens, with queries that enable us to retrieve information about biospecimens linked to a specific program participant.

During the examination program, Robert Wones, MD, was the Program Director and Susan Pinney, PhD the epidemiologist, both serving in those roles since the inception of the Program. Dr. Pinney is now the Fernald Community Cohort Director. Jeanette Buckholz, RN, MSN was the second Program Coordinator during the 18-year Program tenure and is currently the Research Coordinator. The Program required that participants sign a consent at the time of each examination, and has IRB approval (04-02-07-05-EE and 2012-3745, last approved on 1/11/2016), including approval for use of data and biospecimens for future research.