Development of a Cancer Research Study in the Shanghai Textile Industry

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This article describes the development of a cancer study among Shanghai textile workers. Due to the organization of work between 1949 and the 1980s, and superior record-keeping practices, it is possible to track textile workers' job tasks and workplace exposures over virtually the entirety of their working lives. The authors' experiences utilized important relationships developed over more than ten years to access work exposures and cancer outcomes. Initial findings indicate a significantly increased risk for breast cancer for women employed in cotton, wool, mixed-fiber, and machine-maintenance sectors. This project is an example of the unique research opportunities to be found in China, and illustrates how these data sources may be lost due to ongoing changes in the Chinese economy. Key words: China; cancer research; textile industry.

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research project currently under way will examine site-specific cancer incidence in a cohort of 267,000 women employed in the textile industry over the period 1990–1999 compared with prevailing rates among Shanghai women in general. In addition, through a series of nested case–cohort analyses, the study will examine the risks of specific cancers in relation to exposures to cotton, wool, silk, and other dusts; bleaches; dyes; and other specific chemicals found in the industry.

Data collection for this occupational health research project have been completed and data analysis is under way. The first analysis of the cancer risks in this cohort included investigating associations for all major cancer sites and associations by textile sector (Wernli—in press). Cohort cancer incidence was computed based on the Shanghai Cancer Registry rates. There was no overall difference in the age-adjusted cancer incidence in the cohort compared with Shanghai women (SIR = 0.99, 95% CI = 0.95-1.05). There were small but statistically significant increased risks for breast cancer (SIR = 1.17, 95% CI = 1.11-1.23) and uterine cancer (SIR = 1.23; 95% CI = 1.06-1.41). Women working in the cotton, wool, mixed-fiber, and machine-manufacturing sectors had an increased risk of breast cancer.¹ We continue nested case–control analyses of selected cancers in this cohort using detailed employment histories and take this opportunity to share the challenges and opportunities of conducting research in China.

Assembling a cohort of women workers in a single industry that would be large enough to effectively investigate occupationally related cancers present serious challenges. To do so requires access to a very large number of women and detailed information about their individual cancer risk factors, complete and accurate surveillance of cancer incidence, detailed information about each individual work history, and complete and preferably quantitative data about workplace exposures. However, in China, we have found exactly this set of conditions among women in the textile industry in Shanghai, making it possible to investigate the occupational cancer risks for women in this industry.

Although the evidence is largely from research on male workers, the International Agency for Research on Cancer (IARC) has determined that there is limited evidence that work in the textile industry poses an increased risk of cancer.² In addition, there is limited evidence of an association of increased risk of breast cancer among women in several sectors of the industry³⁻⁵ and a deficit of lung cancer has been observed among workers exposed to cotton dust.⁶⁻⁸

The current setting provides a unique opportunity to significantly contribute to the understanding of these risks in a large and well-characterized cohort of women workers. We believe this will be the biggest cohort of women ever studied for occupational cancer. In this paper we address how this opportunity came about, and what conditions have made a study of this sort possible. We also address some of the challenges in doing occupational epidemiology research in China.

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BACKGROUND

The Shanghai Textile Industry

The textile industry in Shanghai has a long history and was once the primary industry in the city. Originally designated as a treaty port in the mid-1800s at end of the first "Opium War," Shanghai businesses focused primarily on trade in silk, tea, and opium until the late 1800s. Industrialization increased dramatically after 1895, when foreigners could legally build and operate factories. Cotton textile production was lucrative due to the access to domestic cotton, water, and cheap labor. Mills were established by the British, Germans, Americans, and Japanese, along with an equal number of Chinese factories. By 1919 more than 90,000 workers, about 6% of the population, were employed in the Shanghai cotton mills. Prior to 1920s most mill workers were men or children, but by the late 1920s most machine operators were women, as they were viewed as more stable and were willing to work for lower wages. Labor strikes were common due to poor working conditions, low wages, and other issues; these working conditions contributed to worker unrest and the strength of the growing Communist party. (For an indepth discussion of the history of women in the Shanghai textile industry, see Honig.⁹)

After World War II and the founding of the People's Republic of China (PRC), Shanghai joined the rest of the country in a rapid industrialization. The textile mills were nationalized and those shut down during the war were restarted. The Shanghai textile industry produced cotton, wool, silk, and, by the 1970s, synthetics, according to central government directives. In Shanghai the government organized an industry trade group, the Shanghai Textile Industry Bureau (STIB), that provided oversight for the production of textiles and related products starting in the 1950s. The STIB was vertically integrated and had, at one time, well over 500 factories and more than 550,000 workers producing not only textiles but also finished garments for domestic and foreign markets. In 1981 STIB factories yielded profits of about 400 million Yuan (\$48 million) and accounted for three fourths of the total exports from Shanghai. Factories affiliated with the STIB also manufactured much of the textile-production equipment, procured raw materials, and produced support products for the industry.

As part of the self-insurance system to provide health care for workers, the STIB factories each maintained a health station for routine care. In addition, there were three STIB hospitals dedicated to caring for textile industry workers. The STIB also had a textile university to train engineers and textile production professionals.

Even prior to China's recent economic policy changes, the Shanghai textile industry was undergoing considerable modification. By the mid-1990s the STIB required reform of all state-owned textile factories in order to increase efficiency and profitability. Privatization and joint ownership with foreign companies, mergers, relocations, and bankruptcies resulted in consolidation of the industry in and around Shanghai. From 1991 to 1994 the number of textile workers in the STIB decreased 25%, from about 535,000 to 400,000 (verbal communication. Dr Fan Liang Chen, STIB, 1995). By 2002 about 120 textile factories, down from 500 at the industry's peak, were still operating in Shanghai.

Chinese Organization of Work and Record-keeping Practices

Over the past 50 years the work life of the Chinese factory worker has been remarkably stable. As part of the centralized economy the government set production quotas, products, work hours, and work shifts across the entire industry. In addition, because of the requirements of the universal employment policy and housing restrictions by the central government, workers generally did not move between factories. Often within a factory workers did not move, sometimes staying in the same job for decades. Initial data on cases and controls from our current occupational study verify the limited movement within and between factories; 85% had worked in one or two factories and 63% in one or two jobs over their working lives (Table 1). Central production planning by the government also standardized work activities across plants with similar production processes; consequently, workers in the same job type

TABLE 1. Distribution of Cases and Controls (N = 7,390) in the Occupational Health Study by the Number of Factories Worked in and Total Number of Jobs Held

No. of Jobs	No. of Factories					
	1	2	3	4	В5	Total
]	2,261					2,261
2	1,480	954				2,434
3	580	358	401			1,339
4	294	89	159	202		744
В 5	223	76	63	87	163	612
Total	4,838	1,477	623	289	163	7,390

Autobobbin: a spinning mill worker loads bobbins on a rewinding machine. An example of increasing automation in spinning plants. The worker is exposed to noise and some cotton dust. (All photos in this article by occupational study staff.)



Combing: here a worker tends a modern cottoncombing machine; this is another example of increased automation. Equipment in this picture was manufactured in 2002. The worker is a study participant and is being monitored for dust exposure.



received fairly homogeneous exposures. From an occupational health standpoint, this resulted in fairly stable exposures, which could be attributed to one or two work processes and has allowed for characterization of worker-specific exposures based on job titles.

Each STIB factory keeps records using standardized hard-copy logbooks and forms. Until recently computers were not available for use by the factory administration. Records include information about materials, production, maintenance, inspections, personnel, and health. The factory health clinics maintain health records for the duration of employment and keep them on hand for one or two years after the worker leaves the factory either by changing jobs or retiring, and for up to five years after death. Human resource records often move with the employee to a new factory. Production and maintenance records are retained in the factory office or in the STIB archives even when the factory closes.



Cutting fabric: a garment factory worker cuts multiple layers of fabric on a cutting table with an electric cutter. This is an example of one of the few men working in this industry. In the textile industry men are usually engaged in maintenance activities, jobs that require heavy lifting, or management.

Hemming sleeves: a garment worker hems sleeves in a garment-assembly plant.

Record keeping by the health care system is also standardized according to local and national guidelines. In Shanghai, STIB hospital inpatient records are kept in the medical records department of the hospital, whereas outpatient records are given to the patient to take to the next clinic visit.

In China, cancer is a reportable disease, and since 1963 each hospital has reported cancer cases to the Shanghai Cancer Registry, now run by Shanghai Municipal Center for Disease Control and Prevention (CDC). In addition, the STIB maintained its own cancer registry through the STIB Station for the Prevention and Treatment of Cancer. The factory health clinics reported all deaths with cause and newly diagnosed cancer cases to the STIB registry. The factories also report to the CDC all industrial accidents, injuries, and work-related illnesses.

Work History and Exposure Data

Factory human resource records described above were invaluable in compiling work histories for the cases and controls in our occupational study. With few exceptions, hard copy of employment documents for current and retired workers could be easily retrieved. Factories that had closed or merged due to industry consolidation often maintained skeleton crews to manage pension benefits and other operations and were helpful in retrieving old employment records. In the few cases where employment records could not be found, we have been able to interview supervisors, coworkers, or family members to recreate individual work histories.

We have been able to obtain exposure data in two ways: from factory inspection records and by in-factory air sampling. China has developed several industrial



Student in roving: graduate student George Astrakianakis in rows of roving bins. Roving is part of the first stage of cotton thread spinning. Exposures include cotton dust and noise.

standards to address occupational diseases and exposures, including the Tentative Hygiene Standards for Industrial Enterprises (1956), Occupational Health Standards of Noise for Industrial Enterprises (Interim) (1980), Act of Prevention and Control of Pneumoconioses (1987), and Labor Protection Act (1991).

In Shanghai there has been a system of factory review since the 1950s, with inspections conducted by health and safety professionals from the Shanghai district-level anti-epidemic bureaus. Although the frequency of these reviews was and is variable, the information contained in the periodic reports from each factory is extraordinary by Western standards.

At each inspection, the health and safety personnel review and diagram the industrial process, list the hazardous agents to which workers may have had exposure and enumerate the workers exposed to each, and document quantitative industrial hygiene measurements for a variety of agents. The agents most commonly measured include dust, noise, and benzene and other solvents. While these data suffer from a number of common problems in industrial hygiene data, they form an unusual historical record of exposure conditions over the past several decades.

The anti-epidemic bureau, now known as the Shanghai Municipal Center for Disease Control (CDC), provides oversight for factory inspections with the STIB industrial hygienists, and often collaborates with the district CDC offices in conducting inspections. A review of a number of the factory-inspection records we have obtained indicates that the number, frequency, and extent of the factory inspections appear to have increased since the late 1980s. Records of safety and hazardous-exposure inspections are kept at the factory if the inspections revealed cause for remedial action. All inspection records are kept at the agency that performed the inspections, usually one of the 16 District CDC offices, or by the STIB industrial hygienists.

While the existence of these extensive factoryinspection records and personnel employment records are an invaluable resource for conducting epidemiologic research, access to the records and extraction of the laboriously hand-written documents into a useful database are a major challenge to the conduct of these studies.

In addition to use of existing records, our exposure assessment has required use of industrial hygiene measurements obtained with methods accepted in the West. In order to interpret the dust-exposure data from the CDC inspection reports, we conducted our own comparison of the Chinese Dust Sampler (CDS) with the Vertical Elutriator (VE), the standard method in the United States. A two-week sampling campaign covering seven processes in two factories was conducted with



Pearl Tower: recent investment designed to attract Western capital to Shanghai has produced remarkable modern cityscapes. The Pearl Tower in located in the Pudong, a redevelopment area across the river from the old city of Shanghai. This new area has attracted considerable Western investment and is the location of several international companies.

assistance from our Chinese colleagues. The data derived from this study will be used to help translate the CDS data to exposure estimates that are comparable to U.S. standards. Additionally, data collected in three of the Shanghai mills by Dr. David Christiani and colleagues over the past 20 years will be used to help validate our exposure estimates.¹¹

STUDY INFRASTRUCTURE

Study Setting: BSE Trial

In 1988 members of the Fred Hutchinson Cancer Research Center (FHCRC) in Seattle, Washington, began working with the STIB to evaluate the efficacy of breast self examinations in reducing breast cancer morbidity and mortality (Randomized Trial of Breast Self Examination in Shanghai, referred to here as the BSE Trial). This project was one of the outcomes of a scientific visitation to the FHCRC by Dr. Dao Li Gao from the STIB in the mid-1980s. The major elements and results of the BSE Trial are discussed elsewhere.^{12,13}

At the inception of the cohort, 290,000 women working in 512 factories owned or managed by the STIB were identified. Of these, 267,040 individuals were located, interviewed, and information was collected on alcohol consumption and smoking as well as a variety of risk factors for breast cancer. All data-collection forms and procedures were developed collaboratively by the Chinese and U.S.-based staff. The field staff was able to collect personal and health information from women participating in the study, often under challenging circumstances, consistently and reliably, over the ten years of follow-up of the study.

The research infrastructure developed to carry out the BSE Trial, funded by the National Cancer Institute, provided a base for several other studies conducted by the FHCRC and the STIB over the past 15 years. In addition to the occupation study, studies of nutritional factors, cell proliferation, abortion, contraceptives, gene polymorphisms, and genetic determinants of breast cancer risk have been undertaken under the umbrella of this BSE cohort. Future studies that build on the cohort and the study infrastructure include a planned investigation of electromagnetic field exposure and breast cancer.

Relationships

Relationships are very important to efficient work in China. Dr. Thomas' long relationship with Dr. Gao and the Shanghai study office during the BSE Trial has proved invaluable in assembling the necessary work teams to collect data for our occupational study. Dr. Thomas built this relationship over a long period of time with numerous personal and professional visits to Shanghai, and by invitation of Dr. Gao to the United States.

Oversight for studies done on the BSE cohort in the STIB factories is provided by a group of advisors connected with the STIB (the Leading Group) and includes three Chinese physicians who were the directors of the three STIB hospitals and the head of Public Health for the STIB. This group was set up to advise and monitor the progress of all research done with the cohort.

In addition to providing technical and logistic expertise to the research projects, Dr. Gao and members of the Leading Group have professional relationships with many of the STIB factory managers. These relationships were the key to our being able to gain access to professional staff, factories, and other resources.

Organization of Study Infrastructure in the U.S.

The Shanghai Studies Coordinating Center at FHCRC was set up at the beginning of the BSE trial. Seattle staff has included principal investigators, anthropologists, computing staff, statisticians, managers, field

Replacing bobbins: workers rapidly replace full bobbins with empty spools in cotton spinning. In most factories this is still a manual task, though some newer mills have automated this procedure. Noise levels are commonly over 100 dBA and there is some cotton dust exposure.



Weaving worker: a worker tying off warp strands in a weaving workshop with over 500 weaving frames. There is considerable noise exposure (over 105 dBA) and cotton dust exposure here. Weavers are almost universally women.



operations, and other study staff. A key part of the staff is Mandarin–English translators, who translate datacollection forms, translate questionnaire results, and facilitate numerous communications and face-to-face meetings.

All study procedures were approved by both the FHCRC and the Station for Prevention of Cancer of the STIB institutional review boards and informed consent following U.S. guidelines was obtained from all participating workers. As institutional review board (IRB) standards have changed over time, key personnel in Shanghai, including members of the STIB IRB, have received updated IRB training.

Study Organization in Shanghai

The BSE Trial was managed out of the Shanghai Studies Office housed in the Station for Prevention and Treatment of Cancer of the STIB, which is located at STIB Hospital 3, now part of the Zhong Shan Hospital Cancer Center. Dr. Gao, Director of Epidemiology for the hospital, is the principal investigator in Shanghai.



Study staff working: graduate student George Astrakianakis checks instruments at a Chinese Dust Sampler location during our project to compare the U.S. and Chinese methods for dust exposure assessment.

Dr. Gao hired an office staff of six, and a project manager, to oversee all of the field data collection, information abstraction, and computer data entry. The Shanghai Studies Office assembled a group of about 34 field workers to collect the enormous quantity of data from paper records and conduct direct interviews with the entire cohort. Many of the field workers (Chinese trained physicians and nurses) had worked in STIB hospitals, clinics, and factory clinics and had personal and professional ties with the factories. In just over one year, the field workers were able to collect work histories for 8,895 cases and controls in the occupational study.

Technical Support—The Industrial Hygienists

Industrial hygiene practice in Shanghai is carried out through the public health systems of hospitals and clinics; and industrial hygiene services to the textile industry were no exception. Each of the three major STIB hospitals had at least one industrial hygienist on staff to serve STIB factories affiliated with that hospital. All the STIB industrial hygienists were trained at the Shanghai medical school, and after graduation the government assigned them to a particular job or sector. For the occupational study, we retained three retired industrial hygienists who had worked either for the STIB or the CDC in addition to three industrial hygienists currently working for each of the STIB hospitals.

The industrial hygienists collected information about the production history of more than 500 factories that participated in the occupational study, a task that was accomplished in less than a year. They obtained historical information about production processes, raw materials, and factory-inspection air-monitoring data through interviews of plant personnel of operating factories; or retired plant engineers of closed or merged factories; or by reviewing factory-inspection reports. In cases where no other source of information was available, the industrial hygienists constructed factory profiles based on their professional knowledge of the industry and reference to STIB publications. They also assisted in developing data-collection instruments and in coding the information prior to data entry.

CHALLENGES

Distance, Time, Money, and Language

Shanghai is a rapidly developing city. Many professionals speak or understand at least some English, which facilitates discussions and collaboration. However, work, communication, and movement outside major urban areas continues to be a challenge and may impede occupational health and safety research unless competent translation is readily available. Personal relationships continue to be essential, without which access to complete information about workers or factories in China may be time-consuming, if not impossible to achieve. (For a fascinating account of recent economic and cultural reforms occurring in Shanghai in particular, see Yatsko.¹³)

Gaining access to certain inspection records, particularly records from closed factories, has proved to be challenging. However, it has been our experience that production information that can not be obtained from actual inspection records can be largely recreated through interviews with factory engineers or management personnel. Because there has been little movement of factory personnel between factories, workers with personal memories of production methods, products, work activities, and exposure controls often can be found to interview. In the long term, obtaining factory personnel records from closed or merged factories may become difficult, as the responsibility for management of retired worker pensions moves from the factories to community-based pension committees.

Economic Reform

Under Deng Xiaoping the Chinese government began moving from a centrally planned to a market economy, and by the mid-1990s considerable changes in the Shanghai textile industry began taking place. To improve competitiveness, the industry began to consolidate: some mills merged with others, some mills moved out of Shanghai, and others closed altogether.

Through this process, there has been a large disruption of the historically very stable employment and social systems. Many workers were displaced and some (though surprisingly few) personnel records were lost. The ability to track and monitor large groups of workers over time will be made more difficult by these economic and social changes. In addition, access to historical records and retired plant engineers will be hampered, reducing the likelihood of reconstructing past production operations and related exposures.

Informed Consent and IRBs

In order to conduct research on human subjects using U.S. National Institutes of Health funding, we were legally and ethically required to have our protocols reviewed by an established institutional review board (IRB), and have subjects provide informed consent. In addition to the FHCRC IRB, we established an IRB within the host institution. The STIB proved to be a willing and supportive participant in coming into compliance with Office for the Protection from Research Risks (OPPR) of the U.S. National Institutes of Health, and FHCRC personnel trained their IRB.

The nature of informed consent on the factory floor has proved challenging. Although the health risks associated with participation in our research are nil (only exposure assessment and work history review), the exercise of obtaining informed consent from workers may not have the same meaning in China that it does in the United States. Factory management may not clearly understand informed consent procedures. Often workers were assigned by their supervisors and were strongly encouraged by their peers to participate in exposure assessment conducted for research purposes. In some cases workers were willing to provide verbal consent, but were reluctant to provide a signature. In studies in which more invasive procedures or more personal information is needed, researchers should carefully review their methods of ensuring workers' rights. Also, steps to instruct and engage the factory personnel as well as study personnel in humansubjects protection will be needed to assure ethical conduct of the studies.

CONCLUSIONS

Chinese workplaces afford an important opportunity for research—in terms of the technical opportunities (exposure, stable workforce, and access to information, etc.) and the vast opportunity to improve working conditions for a large and as yet underserved workforce.¹⁴ However, the technical, logistic, and ethical obstacles to doing this work are formidable. Perhaps the key challenge is to establish long-term personal and professional relationships with partners in China. Chinese researchers are increasingly becoming equal scientific partners in planning and implementing occupational health research. Without such partnerships, it is impossible to gain useful access to Chinese workplaces.

A second challenge is the logistic difficulty of working across at least eight time zones, and in a different and difficult language. It is imperative to have staff in China associated with the project who can conduct the day-today work, after training and guidance from the researchers. However, after such lines of communication and staff resources have been established, the Chinese are exceptionally efficient at getting the work done.

Finally, the ethical problems of conducting research on workers who have a limited set of rights to privacy and access to mechanisms to induce change in a workplace in comparison with U.S. workers presents considerable challenges. As the Chinese economy develops, which it is doing at an extraordinary pace, workers may demand and gain more opportunity to protect their health and safety, along with other rights. Participation in research that addresses occupational health and safety issues should help stimulate the process of change for healthier and safer workplaces.

China represents a unique opportunity to conduct research on occupational health issues due to centrally organized work, production goals, and record-keeping practices. However, this situation is rapidly changing due to a movement to a market economy accompanied by community and work reorganization. These changes represent significant challenges to researchers interested in work exposures in China. Time is of the essence for occupational health researchers interested in engaging in research activities that only China can offer and that can produce important information for the profession and for specific research areas.

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What in the World, continued from Cover 4

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