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List of Terms and Abbreviations

BD	Broncho-dilator
BMI	Body Mass Index
COPD	Chronic Obstructive Pulmonary Disease
EOHSI	Environmental and Occupational Health Sciences Institute
FDNY	Fire Department of New York
GERD	Gastro Esophageal Reflux Disease
GI	Gastro-Intestinal
LODI	Line of Duty Injury
MMTP	Medical Monitoring and Treatment Program
NYPD	New York Police Department
PAPD	Port Authority Police Department
PCB's	Polychlorinated Biphenyl's
PFT	Pulmonary Function Test
RADS	Reactive Airway Disease Syndrome
WTC	World Trade Center

Abstract

An estimated 40,000 men and women worked at Ground Zero, the former site of the World Trade Center in New York City, and at the Staten Island landfill, the principal wreckage depository. Firefighters, law enforcement officers, paramedics, construction workers, utility workers, volunteers, and others carried out rescue-and-recovery operations, restored essential services, cleaned up massive amounts of debris and, in a time period far shorter than anticipated, deconstructed and removed remains of buildings. The diverse worker and volunteer group included operating engineers, laborers, ironworkers, railway tunnel cleaners, telecommunications workers, and workers at the landfill and the Office of the Chief Medical Examiner. Many had no training in response to civil disaster. The highly diverse nature of this workforce posed unprecedented challenges for worker protection and medical follow-up.

Workers at or near the WTC site potentially sustained exposures to: 1) a range of environmental toxins, including cement and glass dust, asbestos, fiberglass, respirable and larger particulate matter-much of it highly alkaline, as well as lead and other heavy metals; PCB's, dibenzofurans, volatile organic compounds and other products of combustion; 2) psychological trauma; and 3) physical hazards including fire, collapsing buildings, falling debris, noise, and extremes of temperature.

Dust and debris gradually settled, and rains on 9/11/01 diminished the intensity of outdoor ambient dust exposure somewhat. However, rubble removal processes repeatedly re-aerosolized the dust, leading to continuing intermittent exposure for many months. Fires burned both above and underground until December 2001. Levels of certain contaminants remained high well into 2002, with spikes in both benzene and asbestos levels, for example, as late as March and May 2002 respectively.

The specific purpose of this study was to enroll and monitor the health of those individuals who sustained exposures at or near "Ground Zero" of the WTC site during rescue and recovery activities; the study has identified those with persistent WTC-related medical conditions. These clinical assessments have also served to establish "baseline" clinical status for individuals exposed at or near "Ground Zero" for purposes of comparisons with future clinical assessments for diseases with longer latency. This study also was able to provide comprehensive health monitoring and treatment services for WTC related conditions in WTC responders, assist WTC responders to secure health benefits, workers' compensation and other appropriate services, and has begun to engage in bi-directional communication of program results for aggregation and analysis and to disseminate program results to WTC responders, other relevant parties, and the general public. On a broader goal, this study has developed a comprehensive database of medical assessments for rescue, recovery, volunteer and other workers exposed to hazards of the World Trade Center site in the aftermath of September 11, 2001, so that this knowledge

will hopefully be utilized to prevent the degree of illness and injury in subsequent populations that respond to national disasters.

Highlights/Significant Findings:

Since inception, a total of 4,011 monitoring examinations have been performed at EOHSI; 1,601 of these were baseline exams (72% of cohort). On average, 80% of those monitored are referred for further diagnostic evaluation, treatment, and follow up under the treatment program for WTC related or WTC suspected conditions. The demography of our monitoring population has remained consistent through the program duration; approximately 35% work in law enforcement, e.g. NYPD, PAPD, NJ State Police, and local NJ police departments), 10% in Utilities, 5-7% are firefighters (Non-FDNY), 18% in 'Other' (entrepreneurs), and 13% work in construction. Consistently, 90-95% has their own health insurance though it cannot be determined who, of those insured, may be 'underinsured'. Results of the monitoring program portray that the majority of WTC-related suspected conditions identified are 'upper airway' (85%). Mental health conditions account for 24-38% of those identified, and gastro-intestinal issues account for 51-58%; lower airway, 8%-32%. Our monitoring program has not identified any significant number of musculoskeletal WTC related conditions (0-4%), among our responder population.

Highlights/significant findings include the following:

1. Identification of barriers to mental health care for law enforcement personnel working in New York City during the period of time prior to the inception of a WTC treatment program. Many of these obstacles to obtaining care have been minimized (though not completely resolved) by the development of a mental health provider network and treatment which does not have to navigate through the medical insurance plan from the law enforcement workplace or through workers compensation (LODI system).
2. Identification of '*aerodigestive syndrome*' along with the other clinical centers of the WTC program.
3. The paper, *Unique Features of Obstructive Sleep Apnea in World Trade Center Responders with Aerodigestive Disorders*: Journal of Occupational and Environmental Medicine, Vol 53 No9, 975-980; September 2011, established that obstructive sleep apnea and WTC responders correlated with upper respiratory diagnoses and symptoms and did not correlate with elevated BMI.
4. Another paper, *Respiratory Symptoms Were Associated with Lower Spirometry Results During the First Examination of WTC Responders*: Journal of Occupational and Environmental Medicine, 53(8):49-54, January 2011, involved investigators from the other clinical centers of excellence; it demonstrated that

symptomatic patients did not perform as well on spirometry as patients without either upper or lower respiratory symptoms. Dr. Udasin was the lead author.

5. An abstract on eosinophilic esophagitis, a case study, concerns the prevalence of eosinophilic esophagitis in responders seen at the clinic between January 2007 and October 2008. In a retrospective chart review of 45 responders seen during this time period, three biopsy proven cases of eosinophilic esophagitis were identified yielding a prevalence of 6.67% of those referred for GI symptoms. This number appears to be 13 fold higher than the usual population referred to GI clinic for these symptoms. It was presented at Digestive Disease Week, May 2009.

Translation/Impact of Findings:

1. Mental Health of New York City and Port Authority Police Officers: Through the WTC Medical Monitoring and Treatment Program, mental health assessments at the clinic with quick referral(s) to treatment without utilizing the workplace medical insurance or workers' compensation/ LODI program, in a location close to where the responder lives, has resulted with increased compliance with the mental health treatment plan and less concern/anxiety over stigmas and consequences of treatment regarding their careers. The New Jersey State Police as well as NJ Municipal police have easier access to mental health treatment without suffering the stigma and career consequences of their New York counterparts.
2. The WTC exposures have been shown to be associated with *aerodigestive* disorders; many of these conditions would not have occurred or would have been less severe if responders were trained and provided with appropriate respiratory personal protective equipment. In the event of future disasters, our research justifies the need for training and provision of such equipment. Furthermore, workers with significant respiratory problems should make best attempts to minimize exposures.
3. Obstructive sleep apnea findings suggest that this condition may be more common than previously thought in patients who are exposed to agents which cause upper and lower respiratory inflammation. Increasing awareness of this condition, early treatment, and lifestyle changes can minimize the effects of disruption of sleep and its consequences on chronic diseases.
4. Spirometry monitoring continues to be valuable in assessing the severity of respiratory symptoms.
5. Gastroenterologists should be more aware of the presence of eosinophilic esophagitis in treatment of disaster workers. This has implications in the treatment of these patients who may require other therapeutic modalities in addition to proton pump inhibitors.

Scientific Report:

The project goal was to determine whether there are persistent health effects in workers as a result of exposure to toxins and hazards at the World Trade Center or the Staten Island landfill sites during the months following the attacks on September 11, 2001. The workers who participate in the study initially had monitoring every 18 months, and this was later changed to monitoring every 12 months. The evaluation included a comprehensive medical and occupational history; physical examination with emphasis on the respiratory and ear, nose, and throat systems; mental health assessment; pulmonary function testing (spirometry) with and without bronchodilator; chest x-ray; and blood chemistry, urinalysis and complete blood count.

Aims:

1. To conduct medical evaluations of exposed workers at intervals initially of every eighteen and then every twelve months, with emphasis on the upper and lower respiratory systems. Workers who manifest ear, nose and throat symptoms or have objective abnormalities on examination will be offered more extensive diagnostic testing and may be referred for further evaluation and treatment.
2. To perform standardized mental health assessments of workers on a self-administered standard questionnaire. If a worker screens positive for any mental health disorder, further evaluation will be performed by a mental health clinician.
3. To identify, implement, evaluate, and revise as needed, appropriate protocols, procedures, and outcomes for treatment of WTC-related health conditions, using best available evidence from all relevant WTC responder clinical and research programs.
4. To assist WTC responders and their families to secure health benefits, workers' compensation and other appropriate services.
5. To engage in bi-directional communication of program results to the Data Collection Center for aggregation and analysis; and to disseminate program results to WTC responders, other relevant parties, and the general public.

Background:

In the aftermath of September 11, 2001, thousands of rescue and recovery workers joined the New York City Fire Department (FDNY) firefighters in working directly on and

adjacent to the debris pile. These operations were conducted 24 hours per day, seven days per week and exposed more than 5000 workers each day to physical and environmental hazards, both at the World Trade site in Manhattan as well as the Staten Island landfill sites where the debris was taken. Safety was of paramount concern, as workers removed over 100 million tons of debris from the 16 acre site.

In January 2003, the EOHSI Clinical Center began to see patients as part of the World Trade Center Worker and Volunteer Medical Screening Program; 364 patients were seen as part of our program between January 2003 and June 30, 2004. Our analysis of these patients indicated that greater than 40% of patients had abnormal mental health findings. Our medical findings indicated that at least two thirds of our patients had abnormal upper or lower respiratory findings.

Methodology:

- 1) This project is primarily an occupational medicine monitoring and treatment program. All examination components are routine for clinical occupational medicine monitoring exams.
- 2) All participants are administered informed consents and have all questions regarding the program answered prior to their examination.
- 3) A patient information form asks the patient's identifying information, employment status, occupation, health insurance status, and workers compensation for line of duty injury claim status. This information is required by NIOSH for reporting to Congress and will also help the program to identify additional needs of the participants. The form will not be used externally and identifying information will not be sent to NIOSH as the data will be aggregated and reported only as summary statistics.
- 4) Tests and procedures for exams include: A standardized physical examination with particular attention to the nose, throat, respiratory, GI, and neurological systems, performed by a physician; blood and urine sampling for laboratory testing, including a complete blood count, blood chemistry, and urinalysis. Also pulmonary function testing (spirometry) with bronchodilator for visit 1, (all others just have spirometry with bronchodilator at discretion of physician), a medical history and mental health interview. Chest x-rays are done every other year. The mental health procedure consists of the following: Exam 1— a self-administered mental health questionnaire; Exam 2— a self-administered mental health questionnaire and mental health interview. Exam 3— a self-administered mental health questionnaire and mental health interview if needed. All participants have the option to complete the mental health questionnaires. They can choose not to answer questions or partially answer them. They may also choose not to participate in the mental health interview.
- 5) The examinations described in the procedures will be divided into a baseline monitoring examination (visit 1) and an annual periodic exam (visit 2, 3,

etc.). The periodic exam will consist of one set of questionnaires instead of a different set for Visit 2, 3, etc.

- 6) Analysis of aggregate data to assess overall prevalence of symptoms, physical exam findings, spirometry results, radiographic findings, and laboratory results, is coordinated by the Data Coordination Center at the Mount Sinai Medical Center. Data stripped of identifiers by the DCC is provided to the funding agency, the National Institutes of Occupational Safety and Health (NIOSH).

Procedures	Initial Visit (VI)	Visit 2	Visit 3, etc (periodic)
Physical exam	Done	Done	Done
Routine Lab Work	Done	Done	Done
Chest X-ray	Done	Optional	Optional
Breathing Test	Done with medication	Done	Done
Psychological Assess	Done	Done	Done
Exposure Assessment	Done	Not Done	Not Done

Characteristics of subject population: The subject population consists of adult men and women between the ages of 18 and 85.

Inclusion and Exclusion Criteria: The populations eligible for medical screening and research protocol enrollment under this Program include members of the following groups:

1. People who worked primarily at or immediately adjacent to Ground Zero, either during or after the disaster, including firefighters from outside New York City, police officers from New York City and surrounding communities, emergency rescue workers from a variety of organizations (including emergency medical technicians and paramedics), building and construction trades workers from the New York City metropolitan area and throughout the nation, members of the press/news media, health care workers, food service workers, structural and other engineers, and a variety of other public and private sector workers.
2. People who worked in the immediate vicinity of Ground Zero restoring essential services, such as telephone service, electricity, and transportation, or performing services vital to reopening buildings in the area, including cleaning and assessing the structural integrity of nearby buildings.

Results and Discussion:

Upper Respiratory Findings: Over three fourths of our responders have upper respiratory findings including chronic rhinitis, chronic sinusitis, chronic pharyngitis, chronic laryngitis, and secondary obstructive sleep apnea which are consistent with exposures at the WTC rescue and recovery effort. Responders with recurrent symptoms were referred to Otolaryngologists who are part of the EOHSI network of providers and located in central New Jersey, North Jersey, Staten Island, and the Hudson Valley, New York area. Treatment of these conditions included medications, saline sinus wash, surgery, and treatment of acute infections.

Mental Health conditions were identified as follows: Post Traumatic Stress Disorder, Major Depression, Anxiety, and secondary substance abuse. Patients received therapy from clinical social workers and psychologists along with pharmaceutical treatment from psychiatrists. The medications for mental health treatment are much more expensive than those used to treat physical health. It is challenging to gauge improvement on these patients. We are in the process of identifying indicators in order to best assess the effectiveness of our mental health program.

At least 50% of responders in the treatment program had findings consistent with GERD. In most cases, our patients suffer from GERD along with respiratory illnesses. Many of our patients are refractory to usual doses of proton pump inhibitors. At least two of our patients were recommended to have surgical procedures to treat this difficult condition. Barrett's esophagus, a pre-cancerous condition, continues to increase in our patient population. These cases are particularly challenging as the medical literature does not clearly specify the frequency of endoscopy. The use of ablation as a treatment modality is likely to become a more frequent treatment option as this may decrease cancer rates as well as improve symptoms.

Lower respiratory illnesses (30%), are still highly prevalent in our population. While many patients have easily controlled asthma, we have a small number that require multiple therapeutic modalities and may require systemic steroids. An outcome of this management was the development of protocol to treat the chronic medical conditions which were complications of systemic steroid use. In addition to asthma!RADS/exacerbation of COPD, other lower respiratory conditions include sarcoidosis, pulmonary fibrosis, and pulmonary nodules. One of our responders has been referred to a lung transplant program.

Cough: World Trade Center Cough continues to be a challenging problem. It has been associated with upper and lower respiratory issues as well as GERD, and even with mental health.

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8. Crowley, LE, Herbert, R., Moline, JM., Shukla, G., Schechter, C., Skloot, GS., Udasin, I., Luft, BJ., Harrison, D., Shapiro, M., Wong, K., Sacks, HS., Landrigan, PJ., Teirstein, AS., Sarcoid Like Granulomatous Pulmonary Disease in World Trade Center Disaster Responders, American Journal Of Industrial Medicine. 54:175-184, 2011*
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Inclusion Enrollment Report

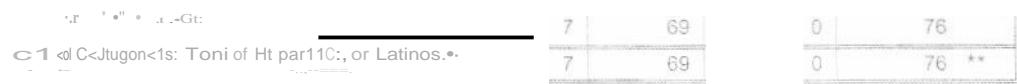
This report format should NOT be used for data collection from study participants.

Study Title: The V Trade Center Medical Monitoring and Treatment Pr
Total Enrollment: 1411
Grant Number: U10H
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Ethnic Category			Sex/Gender Unknown or Not Reported	Total
	Females	Males		
Hispanic or Latino	7	69	0	76
Non-Hispanic or Latino	90	1,245	0	1,335
Unknown (individuals not reporting ethnicity)		0		0
English Category Total 'All Subjects'	17	1,318		1,411

Racial Categories			
American Indian/Alaska Native		13	
Asian			19
Black or African American	17	17	11
Hispanic or Latino	11	11	11
White	11	11	11

PAR-e 1-tiSPACE ENROLLMENT REPORT: Number of Hispanic or Latino males, rolled to Date (Cumulative)			SIx 'G and' r Utklo.vn or
Racial Categories	Female	Males	Total
American Indian or Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Other	0	0	0
Black or African American	0	0	0
White	0	0	0



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clusion Enrollment