Final Progress Report Cover Page

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Project Title	World Trade Center Non-Responder Program
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Co-Investigators	Not Applicable
Project Director and Sponsors	Terry Miles Executive Director World Trade Center Environmental Health Center
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List of Terms and Abbreviations

- Chest X-ray (CXR)
- Collaborative Institutional Training Initiative (CITI)
- Community Advisory Committee (CAC)
- Continuing Medical Education (CME)
- Health Insurance Portability and Accountability Act (HIPAA)
- Motivational Interviewing (MI)
- New York City (NYC) Department of Health and Mental Hygiene (DOHMH)
- National Institute of Occupational Safety and Health (NIOSH)
- New York City (NYC) Health and Hospitals Corporation (HHC)
- Treatment Referral Program (TRP)
- World Trade Center Environmental Health Center (WTC EHC)

Abstract

The New York City Health and Hospitals Corporation (HHC) received NIOSH funding to provide screening, monitoring, and clinical services to a group of individuals experiencing health symptoms because of exposures to the World Trade Center disaster. Characterized as "Non-Responders," this group included local residents, workers, and students as well as clean-up workers. The main difference between "Non-Responders" and "Responders" is their exposures generally resulted not from their job responsibilities, but from their presence in the disaster area due to living, working, attending school, or transiting the area at the time. This include exposures from the collapsing buildings (dust cloud), as well as chronic exposures that resulted from resuspended dust and fumes, and gasses from the prolonged fires that community members were exposed to as they returned to their work or homes, or participated in clean-up activities. "Non-Responders" also differ from "Responders" with the inclusion of pediatric patients and in that around half of the patients were women.

These services were offered at three HHC sites: Bellevue Hospital Center, which originated health care for uninsured community residents affected by the disaster; Gouverneur Healthcare Services, which is located in Lower Manhattan amid the affected neighborhoods; and Elmhurst Hospital Center, where many clean-up workers lived.

As of the project end date, the WTC EHC had treated 5,820 individuals with symptoms related to WTC exposures, including 89 pediatric patients. The majority of treated health problems included respiratory illnesses, gastroesophageal reflux, and mental health problems including PTSD, depression, and anxiety.

The WTC EHC expanded its ability to provide medical and mental health treatment through recruitment of personnel and development of training for both medical and mental health WTC-focused treatment.

The WTC EHC enhanced the infrastructure to allow data management and analysis to address utilization and financial reporting requirements, and to enable evaluation of adverse health effects and long-term treatment outcomes and needs.

In addition to collaborating with community groups, the WTC EHC worked with the NYC Department of Health and Mental Hygiene (DOHMH) World Trade Center Health Registry (WTCHR) through its Treatment Referral Program (TRP) to contact WTCHR members who reported symptoms and offer them the opportunity to be screened for unmet health needs and to enroll in care.

HHC conducted outreach initiatives through public information campaigns, including subway advertising, television and radio spots, and multi-language ads in targeted neighborhood ethnic newspapers to reach potential patients from the Chinese, Hispanic, Polish, and other linguistic minorities.

Other accomplishments include assessing data about WTC EHC patients related to clinical understanding of lung function, longitudinal analysis of lung function, inflammatory biomarkers associated with WTC pulmonary symptoms and lung function, association of persistent mental health symptoms and physical symptoms, identification and confirmation of cancer cases, and prevalence of other symptoms such as headaches. This resulted in publications documenting the presence of upper and lower respiratory symptoms in the WTC EHC population, pathologic findings, co-existence of medical and mental health illness in the community population, adverse health effects in children, and longitudinal improvement in lung function in WTC EHC participants.

Section 1

Significant (Key) Findings

The program reinforced the need to provide screening, medical, and mental health care to community populations affected by environmental disasters. Using the WTC disaster, we demonstrated that interdisciplinary treatment programs could be implemented to provide medical and mental health care for community populations that lack the organized infrastructure of labor unions or other formal programs. Moreover, we demonstrated the need for targeted outreach for difficult to reach populations, including those with unmet health needs. We demonstrated the chronic presence of upper and lower respiratory symptoms in this population and described novel non-invasive methods to evaluate these symptoms using impulse oscillometry in addition to standard screening spirometry. These studies suggest that additional, perhaps more sensitive measures of lung function can be used when assessing exposed population. Finally, we documented adverse health outcomes from WTC exposures, but improvement in health outcomes over the study period.

Translation of Findings

The results of our program suggest that early screening and treatment interventions should be implemented for community populations affected by environmental disasters. Moreover, we suggest that standard as well as potentially more sensitive pulmonary function screening studies should be

implemented when a respiratory exposure is suspected in community as well as other populations to help understand respiratory symptoms. Finally, we demonstrated improvement in lung function, reinforcing the need for treatment programs for community populations affected by environmental disasters.

Outcomes/Impact

This project lead to improvements in health in the population as documented by the recruitment of populations with unmet health needs, the detection of symptoms, the documentation of objective lung function abnormalities including in those with normal standard screening spirometry, and the detection of co-existent mental and medical symptoms. Moreover, the program documented the need and impact of focused outreach for patients with unmet health needs, including those with mental health symptoms. Efficacy of the program was demonstrated by the recruitment of patients, and the documentation of improved lung function over time. The program has important implications for future disasters including the demonstration that community outreach is important and that screening for subtle lung function abnormalities as well as mental health symptoms should be implemented after an environmental disaster. Outcomes should be explained and classified in one of the ways noted below.

The program has important implications for improving practice. The findings from this program:

- Reinforce the need to include local community members in health screening and treatment after environmental disasters;
- Reinforce the need for targeted outreach for difficult to recruit patients with unmet health needs;
- Reinforce the use of sensitive techniques to monitor lung function after an environmental disaster; and
- Reinforce the need for inter-disciplinary programs to provide care for community populations.

Intermediate outcomes from this program can be demonstrated by at least three measures:

- The use of outreach measures by the NYC Department of health to reach populations;
- The incorporation of sensitive lung function measurements in screening programs by the NYC Department of Health; and
- The subsequent legislation of these activities in the implementation of the James Zadroga 9/11 Health and Compensation Act, which included community members.

End outcomes can be demonstrated by:

- Documentation of improved lung function in patients enrolled in the WTC EHC.

Section 2

Scientific Report

Specific Aim 1 – Enhance the screening of individuals with unmet World Trade Center-related health needs by collaborating with the New York City Department of Health and Mental Hygiene (DOHMH) World Trade Center Health Registry (WTCHR) to identify those in the targeted population with unmet needs who are tracking in the Registry.

We negotiated a subcontract with a Memorandum of Understanding between the NYC Health and Hospitals Corporation (HHC) and the NYC Department of Health and Mental Hygiene World Trade Center Health Registry (NYC DOHMH), which was signed on 1/5/2009. This subcontract allowed us to screen registry members for those with unmet health needs and self-reported physical health symptoms and/or probable PTSD. Screening was performed for registrants who participated in the 2006 – 2007 follow-up survey, as well as for those that did not participate in the follow-up survey (non-registrants identified from the 2003 – 4 survey). This screening resulted in the launching of the 9/11 Treatment Referral Program (TRP). Participants were initially identified with unmet medical needs, and subsequently with unmet mental health needs as well as medical needs.

In addition, as part of this collaboration, we

- Identified and recruited key staff for the project;
- Developed protocols for outreach;
- Worked with the Division of Mental Hygiene and other mental health providers to identify outreach strategies for "hard to reach" enrollees with severe posttraumatic stress disorder; and Developed outreach materials, including an individualized letter, a 9/11 Treatment Referral Program (TRP) brochure and reply card (English, Spanish and Chinese). The Registry finalized a phone script and intake tool.
- Training of outreach staff in the following areas:
    - Services available at the WTC EHC, including a walkthrough of a typical appointment and introductions to key EHC staff;
    - Registry's call script and protocol; and
    - Motivational Interviewing (MI).

Over 7,000 individuals were identified who fit criteria. Outreach to these individuals was performed in several ways:

- The WTCHR sent a "pilot" mailing to 250 members of the first target group (mailing sent 11/25/09). The mailing included a personalized letter and a TRP brochure. The contact rate (inbound calls to the TRP) for this mailing was 8.4% (21/250).
- The WTCHR included the 9/11 TRP brochure in the August 2009 Annual mailing. This brochure was sent to ALL enrollees residing in the NYC metropolitan area. The contact rate (inbound calls to the TRP) for the mass mailing was 0.09% (43/45,429).

- Registry staff attended several local Community Board Meetings to discuss the WTCHR treatment referral program.
- Information about the Treatment Referral Program and the WTC EHC (including program materials) was featured on the DOHMH 9/11 health website.
- WTC EHC, the WTC Health Coordinator's Office, and the Registry are collaborating on pediatric outreach (including a letter to parents of children in area schools on 9/11 and a letter to NYC pediatricians). These letters were mailed during the last week of February 2010.
- The Treatment Referral Program was presented to the Registry's Community Advisory Board and to the CAC for feedback.

Of the 7,518 enrollees targeted, 16.4% were TRP participants. Almost one-third (32.4%) of participants scheduled a first-time appointment at the WTC EHC. Preliminary unpublished findings indicate that scheduling an appointment was significantly associated with self-reported unmet health care need, post-traumatic stress disorder (PTSD) and poor daily functioning (14 or more days of poor physical or mental health per month) (p-values <0.05) and was not associated with gender, race/ethnicity, income or education. The Registry is preparing to submit a manuscript based on their evaluation of the TRP.

Specific Aim 2 – Enhance current World Trade Center Environmental Health Center program by:

2. a. Expanding medical and mental health treatment services to a larger population.

By the end of the grant period (9/29/2008 through 9/28/2011), we evaluated 5,820 unique individuals from September 2005 through September 28, 2011 – only 180 patients or a 3% reduction of our original estimate of 6,000. This includes 89 pediatric patients 18 years or less. Of these patients, at the time of the end of the granting period, we had been notified of 10 deaths. Some patients have been transferred out of our program or to other WTC programs as appropriate. After review of our patient list, we identified 5,669 unique patients who we submitted as "grandfathered" patients under the "Clinical Centers of Excellence for Survivors Living in the New York City Area Program," as funded by the James Zadroga Health and Compensation Act of 2010. We estimate that 27% reported upper respiratory symptoms at time of evaluation; 74% reported lower respiratory symptoms; and 54% scored positive for a mental health symptom of PTSD, anxiety, or depression. Over time, we saw a shift in the exposure categories of our patients and by the last quarter, new enrollees included 25% local residents; 56% local workers; 17% local worker and resident; and 5% students.

2.a.1 Staff recruitment and credentialing

Throughout the duration of the project, we have recruited and trained medical and mental health physicians and psychologists for treatment of WTC-related illnesses. We have recruited support staff, including nurses, social workers, patient care associates, and clerical staff and trained them in the specific needs of the program. We have recruited and trained administrative staff. Throughout the program, we have had continued staff attrition and replacement, but maintained staffing of clinical staff.

2.a.2. Providing routine monitoring for the recruited population.

The WTC EHC has been developed to include an Initial Visit, including a medical and mental health evaluation as well as laboratory testing, CXR, and pulmonary function testing. We have put in place procedures to optimize that all patients undergo this initial evaluation. In addition, we began recalling patients for routine monitoring after the Initial Visit. We recruited staff to focus on monitoring and put in place procedures, questionnaires, and protocols to accomplish these goals. Letters were sent to our patients on a rolling basis, based on the first date of their Initial Visit. We sent letters to all participants from years 2005 – 2009 and many from 2010. We recorded reasons for non-response to monitoring invitation (deceased, change of address and patient not reached, change of telephone, not interested). We worked with our Community Advisory Committee and local community presentations to reinforce the need for patients to return for their Monitoring Visits.

2.a.3. Staff Training

Training for internists, pulmonary doctors and other specialists as well as ancillary staff was implemented and maintained throughout the duration of this grant. All personnel received training in Good Clinical Practice. All personnel completed the CITI tutorial and were trained in HIPAA rules and regulations. New personnel are also trained in CITI tutorial, HIPAA rules and regulations. All staff updates training as required by the institution. Mental health staff continue to undergone additional training in HIPAA and approach to outside referrals as well in order to maintain confidentiality and avoid issues of conflict of interest.

Weekly clinical medical sessions were held for review of patient care and development of treatment programs. These sessions were approved for CME credits. The weekly medical session was attended by physicians from Bellevue and Gouverneur, with telephone access for Elmhurst. These meetings included reviews of WTC EHC procedures as well as cases from differing sites with a focus on cases from new physicians as well as those that were difficult to manage or had diagnostic dilemmas. Sessions were attended by the pulmonary physiologists, the cardiologist and have included presentations by specialists. Each case was reviewed for the approach to medical diagnosis, treatment, and WTC relatedness.

We instituted a monthly joint medical and mental health clinical conference to discuss cases with complex interdisciplinary issues. This conference was attended by medical and mental health staff.

Weekly mental health sessions were maintained to review patients who had positive scores on their mental health screening. These patients were assessed for further in-depth evaluation or referral on a case-by-case basis. Patients who needed more emergent psychiatric care were also reviewed.

Pertinent articles for medical and mental health issues, as well as those directly pertaining to WTC health issues were emailed to all clinical personnel as appropriate. Clinical personnel attended pertinent educational programs to enhance appropriate clinical skills, including attendance at the WTC Scientific meeting.

2.b. Providing greater in-depth evaluation.

We treated enrolled patients to provide specialty cardiac, gastrointestinal and ENT services. Because of the frequent complaint of headache and paresthesias, we included neurologic services to help evaluate these complaints. These were services that were include in our original application, were the medical evaluation was reviewed by a specialist in headaches (reported previously), and a specialist in peripheral neuropathy. Characterization of the headaches and paresthesias reported by many in our program remains ongoing.

We described patients with lower respiratory symptoms and consider them to have a spectrum of etiologies for these symptoms, which we now classify as irritant-induced asthma, low vital capacity with probable air-trapping, interstitial lung disease, as well as sarcoidosis.

2. c. Providing enhanced long-term treatment

We have treated patients with upper and lower respiratory symptoms that have remained persistent and chronic. We have transitioned many of our patients to the status of chronic disease patients with appropriate long-term goals of disease control rather than cure with attempts to improve quality of life, including occupational goals. We identified additional complaints of intermittent rashes and paresthesias as well as atypical chest pain and continue to evaluate these ongoing complaints. We reviewed our current treatment algorithms in an ongoing process. We revised our approach to WTC attribution to new terminology from the WTC program, and reviewed the revised recommendations of attribution as substantially likely (> 50%) to have contributed to, caused, or aggravated a condition. We identified the need to educate patients repeatedly about chronic illness as opposed to cure. We continue to train our social work program to identify ways to enhance the return of individuals to a functional life.

Specific Aim 3: Expand and develop the systems of infrastructure necessary to allow data management and analysis to meet any utilization and financial reporting requirements, and to enable evaluation of adverse health effects and long-term treatment outcomes and needs by:

3.a. Developing a data mart to integrate clinical, demographic, and financial data.

We worked closely with the HHC Clinical Information Systems with repeated meetings to develop a data mart. We hired personnel, determined the scope of the project, reviewed all current data sources including telephone logs, Visit 1 Medical and Mental Health Questionnaires, Monitoring Medical and Mental Health Questionnaires, laboratory data and Ancillary services and visit logs, and finance claims data. We developed a system to allow rapid download of our lung function studies with quality assurance checks.

3.b. Expanding the data analysis team to enhance data evaluation and improve resource usage.

We worked closely with our analytic group, which includes biostatisticians for data analysis. These staff helped with analytic projects which included, but was not limited to:

- Understanding clinical analysis of lung function;
- Longitudinal analysis of lung function;
- Inflammatory biomarkers in association with WTC pulmonary symptoms and lung function;
- Association of persistent mental health symptoms and physical symptoms;
- Prevalence of additional symptoms including headache;
- Identification and confirmation of cancer cases; and
- Longitudinal symptoms.

Inclusion Enrollment Table

Program Director/Principal Investigator (Last, First, Reibman, Joan MD

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

Study Title: World Trade Center Non-Responder Program

Total Enrollment: 4858 Protocol Number:

Grant Number: 5E110H009630

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**	
Hispanic or Latino	853	841	0	1694	**
Not Hispanic or Latino	1486	1598	0	3084	
Unknown (individuals not reporting ethnicity)	42	38	0	80	
Ethnic Category: Total of All Subjects*	2381	2477	0	4858	*
Racial Categories					
American Indian/Alaska Native	22	26	0	48	
Asian	413	573	0	986	
Native Hawaiian or Other Pacific Islander	10	10	0	20	
Black or African American	460	254	0	714	
White	806	1002	0	1808	
More Than One Race	54	39	0	93	
Unknown or Not Reported	590	599	**0**	1189	
Racial Categories: Total of All Subjects*	2355	2503	0	4858	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)					
Racial Categories	**Females**	**Males**	**Sex/Gender**	Total	
American Indian or Alaska Native	16	22	0	38	
Asian	**2**	2	0	4	
Native Hawaiian or Other Pacific Islander	6	8	0	**14**	
Black or African American	31	23	0	54	
White	226	256	0	482	
More Than One Race	16	14	0	30	
Unknown or Not Reported	556	516	0	1074	
Racial Categories: Total of Hispanics or Latinos**	853	841	0	1694	**

*These totals must agree.

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Publications

Peer Reviewed Articles

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4. Friedman SM, Maslow CB, Reibman J, Pillai PS, Goldring RM, Farfel MR, et al. Case-Control Study of Lung Function in World Trade Center Health Registry Area Residents and Workers. Am J Respir Crit Care Med 2011.

5. Kazeros A, Maa MT, Patrawalla P, Liu M, Shao Y, Qian M, et al. Elevated Peripheral Eosinophils Are Associated with New-Onset and Persistent Wheeze and Airflow Obstruction in World Trade Center-Exposed Individuals. J Asthma 2012.

6. Maslow CB, Friedman SM, Pillai PS, Reibman J, Berger KI, Goldring R, et al. Chronic and acute exposures to the world trade center disaster and lower respiratory symptoms: area residents and workers. Am J Public Health 2012; 102:1186-94.

7. Liu M, Qian M, Cheng Q, Berger KI, Shao Y, Turetz M, et al. Longitudinal spirometry among patients in a treatment program for community members with world trade center-related illness. J Occup Environ Med 2012; 54:1208-13.

8. Trasande L, Fiorino EK, Attina T, Berger K, Goldring R, Chemtob C, et al. Associations of World Trade Center exposures with pulmonary and cardiometabolic outcomes among children seeking care for health concerns. Sci Total Environ 2013; 444:320-6.

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2. Parsia S YH, Young S, Turetz ML, Marmor M, Wilkenfeld M, Kazeros A, Caplan-Shaw CE, Reibman J. . Characteristics of Sarcoidosis in Residents and Workers Exposed to World Trade Center (WTC) Dust, Gas, and Fumes Presenting for Medical Care. American Journal of Respiratory and Care Medicine 2010; 181:A1740.

3. Turetz M BK, Goldring RM, Caplan-Shaw CE, Kazeros A, Parsia S, Liu M, Cheng Q, Reibman, J. Symptoms and lung function including impulse oscillometry in a diverse population with World Trade Center dust exposure. American Journal of Respiratory and Critical Care Medicine 2010; 181:A3797.

4. Qian M CQ, Liu M, Shao Y, Berger KI, Parsia S, Turetz M, Kazeros A, Goldring RM, Reibman J. Longitudinal analysis of lung function in diverse populations with World Trade Center dust/fume exposure after 9/11. American Journal of Respiratory and Critical Care Medicine 2011; 183:A4790.

5. Cheng X, Shao, Y., Reibman, J., Qian M., Liu, M., Kazeros, A., Parsia, S., Marmor, M., Caplan-Shaw, C., Goldring, R.M., Berger, K.I. . Distal Lung Function Predicts Improvement in Spirometry in Community Members Enrolled in a WTC Treatment Program 2012.

6. Zhang E SY, Qian M, Berger K, Kazeros A, Parsia S, Ghumman M, Chokshi N, Caplan-Shaw C, Liu M, Cheng X, Marmor M, Goldring R, Reibman J. Systemic Inflammation is Associated with Lung Function Abnormalities Following WTC Dust Exposure in Community Members. American Thoracic Society Abstract 2013

Chapters

1. Hughes C, Flynn K, Hall C, Reibman, J. The Role of Community Advocacy Groups in Environmental Protection: Example of 9/11. Environmental Policy and Public Health: Air Pollution, Global Climate Change, and Wilderness, Rom W. Ed. Jossey-Bass, John Wiley and sons, publisher. 2011.

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