Incidence, Latency, and Survival of Cancer Following World Trade Center Exposure

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List of Abbreviations

BRANY	Biomedical Research Alliance of New York
DOHMH	New York City department of Health and Mental Hygiene
DUA	Data Use Agreement
EMS	Emergency Medical Services
FDNY	Fire Department of the City of New York
GRC	General Responder Cohort
HR	Hazard Ratio
IRB	Institutional Review Board
ISMMS	Icahn School of Medicine at Mount Sinai
MMTP	Medical Monitoring and Treatment Program
MOU	Memorandum of Agreement
NDI	National Death Index
NIOSH	National Institute for Occupational Safety and Health
NYC	New York City
NYS	New York State
NYSCR	New York State Cancer Registry
PAH	Polycyclic aromatic hydrocarbons
PCB	Polychlorinated biphenyls
PCDD	Polychlorinated dibenzo-p-dioxins
PCDF	Dibenzofurans
RRW	Rescue Recovery Worker
SEER	Surveillance, Epidemiology, and End Results Program
WTC	World Trade Center
WTCHR	World Trade Center Health Registry

Abstract

The terrorist attacks on the World Trade Center (WTC) on 9/11/2001 (9/11) involved collision of two aircraft into the buildings and the combustion of many thousands of pounds of jet fuel. The subsequent collapse on the towers, and the rescue/recovery effort that followed, led to large numbers of responders being exposed to a wide variety of hazardous material including cement dust, glass, asbestos, lead, polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs), organochlorine pesticides, and polychlorinated furans and dioxins. We wished to examine cancer incidence, latency, and survival in WTC rescue/recovery workers exposed to these known and potential carcinogens. Three cohorts of rescue and recovery workers have been established since the WTC disaster, the Fire Department of the City of New York (FDNY) Cohort; the General Responder Cohort, maintained by Icahn School of Medicine at Mount Sinai (ISMMS); and the World Trade Center Health Registry (WTCHR), maintained by New York City Department of Health and Mental Hygiene (DOHMH). Each of the three cohorts had reported modest and mostly non-statistically significantly elevated cancer rates post-exposure to the WTC-site have been reported despite limited follow-up time 9/11/2001. We combined the three cohorts to account for individuals who are in more than one cohort, to increase the sample size, and to make the results more generalizable. We examined incidence, latency, and survival controlling for age, sex, race, and calendar time since exposure.

Our findings confirmed prior studies in individual cohorts for elevated incidence of thyroid cancer (all 3), skin melanoma (2 of 3), prostate cancer (2 of 3), and confirmed prior studies in individual cohorts showing reduced incidence of lung cancer, and found modestly elevated incidence of tonsil cancer, previously not reported. Some gastrointestinal cancers, female breast cancer, and uterine cancer were found to have lower than expected incidence, findings worthy of further investigation. We did not confirm prior findings in the individual cohorts of elevated rates of hematologic cancers. Rescue/recovery workers experiencing higher intensity exposures had higher rates of prostate and thyroid cancer and of all cancers combined compared to responders with lower exposure. We found an unexpectedly short induction/latency period between exposure and incidence for prostate cancer and skin melanoma, part of which might have been from increased medical surveillance or screening. An important finding was a strong survival benefit for rescue/recovery workers who enrolled in a World Trade Center Medical Monitoring and Treatment Program (WTC MMTP) sponsored by the National Institute for Occupational Safety and Health (NIOSH). This benefit was observed for most cancers, both cancers with elevated incidence and cancers with reduced incidence.

This work has added to the understanding of long-term consequences of WTC-exposure and should encourage prompt surveillance efforts after future environmental disasters. The nature of the strong survival benefit is particularly worthy of further study; if programs such as the WTC MMTP could be generalized beyond the WTC cohorts there could be tremendous benefits for workers who develop cancer after exposure to carcinogens.

Section 1

Significant or Key Findings

Findings are presented separately for each Specific Aim

Specific Aim 1: To create a cohort of all rescue/recovery workers from all three WTC-responder cohorts, using the common exposure definitions previously developed (8) and combining data to include unique individuals, without double counting those who are being followed by multiple cohorts; and then to use this combined WTC cohort to estimate all-cancer incidence and incidence of specific cancer subtypes and to compare to local, state, and national reference populations.

We successfully combined and deduplicated the three cohorts into a single large analytic cohort of WTC rescue/recovery workers, and linked the Combined Cohort to data from 13 state cancer registries, National Death Index, and New York State and New York City Vital Records. We further harmonized exposure information. This shows that it is possible to combine occupational cohorts, even those not initially established with the intent of future harmonization or combination.

Our findings confirmed prior studies in individual cohorts for elevated incidence of thyroid cancer (all 3), skin melanoma (2 of 3), prostate cancer (2 of 3), confirmed prior studies in individual cohorts showing reduced incidence of lung cancer, and found modestly elevated incidence of tonsil cancer, previously not reported. Some gastrointestinal cancers, female breast cancer, and uterine cancer were found to have lower than expected incidence, findings worthy of further investigation. We did not confirm prior findings in the individual cohorts of elevated rates of hematologic cancers. Most of the cancers found to have lower incidence are believed to have long induction/latency periods. Rescue/recovery workers experiencing higher intensity exposures had higher rates of prostate and thyroid cancer and of all cancers combined compared to responders with lower exposure.

Further follow up of the Combined Cohort will help to estimate the long-term impact of WTC exposure on incidence of these cancers.

Specific Aim 2: To estimate the time at which the relative risk for specific cancer subtypes significantly increases among the highest exposed in this combined WTC cohort using change point models.

We detected significant change points for two cancer sites, skin melanoma and prostate cancer. For both, the timing of the change points implied a shorter than expected induction/latency period. We did not detect significant change points for any other cancer subtypes. Disasters such as the WTC building collapse provide unique opportunities to assess the impact of a short-term environmental exposure on incidence of cancer and other diseases. Further follow up of the Combined Cohort could provide some of the best evidence possible regarding the induction/latency period for additional cancer sites, and could quantify the degree to which increased medical surveillance and/or screening might have contributed to the shorter induction/latency periods.

Specific Aim 3. To calculate observed and relative survival at 1, 3 and 5 years of cancer patients in the combined WTC cohort for the most common cancers in the WTC population.

We found a strong survival benefit to those in the Combined Cohort who were enrolled in a World Trade Center Medical Monitoring and Treatment Program (WTC MMTP) sponsored by the National Institute for Occupational Safety and Health. The benefit was observed for most, but not all, cancer sites, and it was strong both for cancers with lower-than-expected incidence and for cancers with higher-than-expected incidence. The magnitude of the survival benefit was greater than the benefit from screening

observed in randomized studies. Combined Cohort members not in a WTC MMTP did not experience this benefit. Further research can help to assess the causes of this benefit and can assist in translating this benefit to other occupational cohorts.

Translation of Findings

These findings support the hypothesis that no-cost care and social support provided by WTC-medical monitoring and treatment programs is associated with improved survival of WTC rescue/recovery workers with cancer. As the survival benefit was observed both for cancers with lower-than-expected incidence and for cancers with higher-than-expected incidence, it supports the decision to provide coverage for a wide variety of cancer sites. In the future these benefits might be translatable to other occupational cohorts.

Research Outcomes/Impact

The findings from this study can guide the WTC Health Program approach to managing and treating a variety of cancers. It can also help to provide guidance on medical monitoring and treatment in other occupational cohorts and for those exposed to other environmental disasters.

Section 2

Scientific Report

Background

The terrorist attack and building collapse of the World Trade Center that took place on September 11, 2001 exposed tens of thousands of rescue/recovery workers along with hundreds of thousands of residents and other workers to the dust and smoke containing numerous irritants, toxins, and carcinogens. Fires continued at the site into December and recovery work continued for almost a year. Little effective protective equipment was available at the beginning of the rescue/recovery effort. This work took place at the site itself, near the site as damaged infrastructure needed to be rebuilt often in the presence of such dust, at New York City Medical Examiner facilities, and in transportation via truck and barge to the Fresh Kills Landfill in Staten Island.

Extensive analyses of the components of the dust were performed shortly after the disaster.[1] Among the known, potential, or possible carcinogens that were discovered in the dust were combustion by-products including polycyclic aromatic hydrocarbons (PAHs); consumer product chemicals including flame retardants such as polybrominated biphenyls; asbestos; industrial chemicals including benzene, polychlorinated biphenyls (PCBs), and dioxins [Polychlorinated dibenzo-p-dioxins (PCDDs), Dibenzofurans (PCDFs)]; arsenic and inorganic arsenic compounds; metals and metal compounds of cadmium, chromium, and lead; pesticides including hexachlorobenzene, heptachlor, 4,4 DDE; 2,4 & 4,4 DDT, mirex, and chlordanes; silicates; and solvents including chlorides and trichloroethylene. Notably, radiation levels were not found to be above background levels.

Our review of the evidence, supported by a NIOSH-convened expert panel in 2009, was that there was strong evidence for the association of one or more exposures with leukemia/lymphoma, lung cancer (including mesothelioma), and cancer of the larynx, ovary, skin, bladder, and kidney; some evidence for association(s) with cancers of the pharynx, stomach, colon and rectum, pancreas, esophagus, prostate, breast, brain/central nervous system, liver, thyroid, stomach, pancreas, uterus, and cervix; and evidence from animal studies for association(s) with soft tissue sarcomas, cancer of the adrenal glands, and sinonasal neoplasms. The biological plausibility informed attempts to investigate associations between World Trade Center exposure and a broad spectrum of cancer sites. Unfortunately we do not have information regarding specific components of the gases present on the first day of the exposure; and exposure information is non-specific regarding these components.

In addition to the ethical imperative to support responders to a national disaster, there were important scientific questions that can be answered through the study of the incidence, latency, and survival of cancer after World Trade Center exposure. This is a rare example of a relatively short-term exposure followed by long term follow-up, and can thus inform regarding the induction/latency period about which for most cancers there is little evidence from human epidemiologic studies. This is also a potential opportunity to study the impact of screening programs, of medical monitoring, and of treatment and support in a well characterized cohort. There is also the potential for learning new insights regarding cancer biology, an opportunity beyond the scope of this project but hopefully one which will be fulfilled in the future.

Specific Aims

The Specific Aims and Hypotheses of the study were as follows:

Specific Aim 1: To create a cohort of all rescue/recovery workers from all three WTC-responder cohorts, using the common exposure definitions previously developed and combining data to include unique individuals, without double counting those who are being followed by multiple cohorts; and then to use this combined WTC cohort to estimate all-cancer incidence and incidence of specific cancer subtypes and to compare to local, state, and national reference populations.
Hypothesis 1: With more time elapsed since 9/11 and a larger sample size, we have a better opportunity to identify an increased incidence of longer latency cancers associated with environmental exposures, such as bladder cancer, non-Hodgkin lymphoma, and skin melanoma.

Specific Aim 2: To estimate the time at which the relative risk for specific cancer subtypes significantly increases among the highest exposed in this combined WTC cohort using change point models.
Hypothesis 2a: Thyroid cancer incidence will begin to be elevated shortly after WTC exposure.
Hypothesis 2b: Incidence of hematologic cancers and skin melanoma will be elevated starting five years after WTC exposure.
Hypothesis 2c: No change point will be observed for solid tumors other than for thyroid cancer, and in particular colorectal, breast, prostate or lung cancer, suggesting that the average latency period between exposure and incidence may be longer than our 15-year follow-up period or that the WTC exposure is not a risk factor for these cancers.

Specific Aim 3. To calculate observed and relative survival at 1, 3 and 5 years of cancer patients in the combined WTC cohort for the most common cancers in the WTC population.
Hypothesis 3: Compared with cancer patients in New York State as a whole, WTC-exposed cancer patients will have longer survival after accounting for demographic factors and temporal trends.

Methodology

Three cohorts of rescue/recovery workers were established shortly after the WTC disaster. The first is the Fire Department of the City of New York (FDNY) cohort, with 5 physical health clinics and a data coordinating center near FDNY headquarters. The FDNY cohort includes firefighters, emergency medical services (EMS) workers, and a small number of non-uniformed personnel employed on or before 9/11/2001. In theory this is an open cohort but almost all persons potentially eligible have been enrolled. Those on active duty as of that date have been followed from that date; retiree volunteers were added later. The second is the General Responder Cohort, with five 5 Clinical Centers of Excellence managing a total of eight clinics, includes police officers, construction workers, communications workers, medical examiner office, cleanup workers, non-FDNY EMS workers, firefighters from fire departments other than FDNY, community volunteers, and others. This is an open cohort, as it is still possible to enroll. The third cohort is the World Trade Center Health Registry, which includes all kinds of rescue/recovery workers, and unlike the other two is not a medical monitoring and treatment program (MMTP). This is a closed cohort as all enrollment was complete by the end of 2005. The World Trade Center Health Registry also includes a large cohort of community residents and workers not engaged in the rescue/recovery effort; they are not part of this study; but a similar future study focusing on survival should target that population, including the WTCHR members and also those survivors who are part of a separate WTC MMTP. Also not included in this study are persons in the national monitoring program for WTC rescue/recovery workers not living in or near the New York metropolitan area, nor those in a program for Pentagon or Shanksville survivors.

Each of the three cohorts had previously reported incidence of cancer by site in their rescue/recovery worker population compared to general population.[2 3 4 5] Thyroid cancer was found to be elevated in all three cohorts, skin melanoma, and prostate cancer were elevated in two of the three, non-Hodgkins lymphoma and multiple myeloma in one of the three. Reduced incidence of lung cancer was observed in two of the three cohorts. There were numerous non-significant increases in incidence, some of which may be due to short follow-up and/or long induction/latency periods. Thyroid cancer incidence for FDNY firefighters was also elevated compared to incidence in the prexisting NIOSH firefighter cohort.[6]

We sought to pool the cohorts to achieve greater statistical power and to obtain more robust and reproducible results. We now present, for each Specific Aim, the Methods specific to that Aim, Results, and brief Conclusions.

Specific Aim 1.

To create a cohort of all rescue/recovery workers from all three WTC-responder cohorts, using harmonized exposure definitions previously developed and combining data to include unique individuals, without double counting those who are being followed by multiple cohorts; and then to use this combined WTC cohort to estimate all-cancer incidence and incidence of specific cancer subtypes and to compare to local, state, and national reference populations.
Hypothesis 1: With more time elapsed since 9/11 and a larger sample size, we have a better opportunity to identify an increased incidence of longer latency cancers associated with environmental exposures, such as bladder cancer, non-Hodgkin lymphoma, and skin melanoma.

Methods and findings from the first part of this Aim have been published.[7 8] The creation of the cohort required a massive administrative and data management task, involving two World Trade Center Data Centers, the World Trade Center Health Registry, thirteen state cancer registries, National Death Index, New York City and New York State Vital Records, and two data analysis teams. The administrative and linkage efforts took just over three years out of the original four-year grant award to obtain the data. Figure 1 shows the complexity of the administrative flows: subsequent discoveries during data analyses would reduce the total number in the Combined Cohort to 69,100.

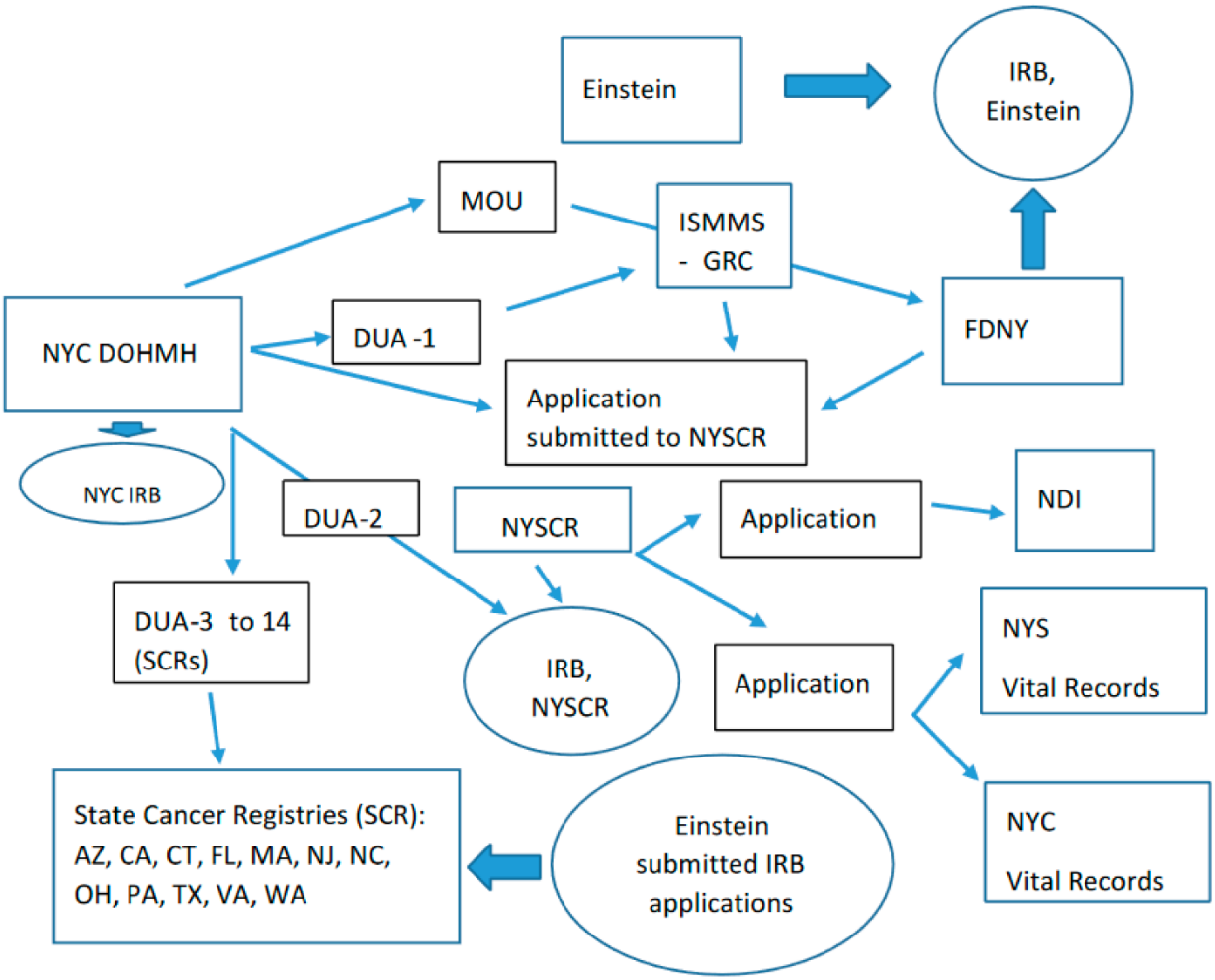

Figure 1. Administrative agreements across study entities. Abbreviations: IRB, Institutional Review Board; MOU, Memorandum of Agreement; ISMMS, Icahn School of Medicine at Mt Sinai; GRC, General Responder Cohort; FDNY, Fire Department of New York; NYC DOHMH, New York City Department of Health and Mental Hygiene; Einstein, Albert Einstein College of Medicine; DUA, Data Use Agreement; NYSCR, New York State Cancer Registry; NDI, National Death Index; NYS, New York State; NYC, New York City; SCR, State Cancer Registry; AZ, Arizona; CA, California; CT, Connecticut; FL, Florida; MA, Massachusetts; NJ, New Jersey; NC, North Carolina; OH, Ohio; PA, Pennsylvania; TX, Texas; VA, Virginia; WA, Washington.

The New York State Cancer Registry acted as "honest broker" to deduplicate the cohort to take into account the fact that there are members enrolled in more than one of the three source cohorts, and that incident cancers can appear in more than one state cancer registry. Figure 2 shows the results after the deduplication.

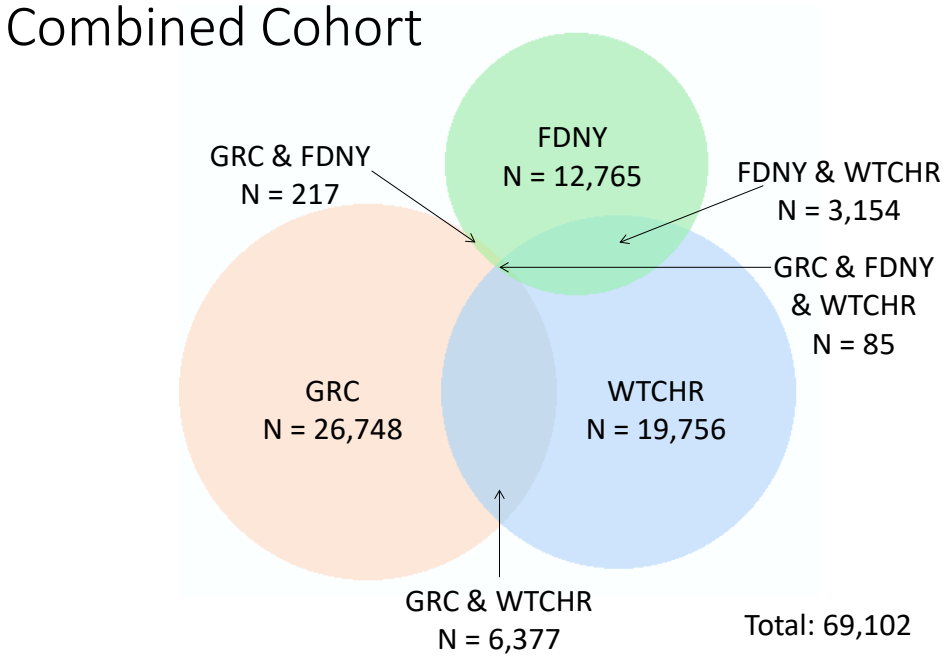

Figure 2. Results of deduplication of the Combined Cohort performed by the New York State Cancer Registry.

In the cohort, 69% were age 30-49 as of 9/11/2001; 16% identified as Hispanic, and 9% as Black; 85% were Male, 59% were never-smokers, 71% had enrolled in at least one of the cohorts by the end of 2004. 36% first arrival at site on 9/11/2001, 18% on 9/12/2001, 19% 9/13-17/2001, and 18% later. 7% were never at the World Trade Center site but elsewhere, such as the Fresh Kills Landfill or the Office of Chief Medical Examiner of the City of New York. A harmonized exposure measure was developed, with 19%, 18%, 7%, 49% for A, B, C, D dust exposure (A is highest) respectively. 37% directly worked on the "pile" of debris at the site.

Findings from the second part of Aim 1 have been published.[9] Standardized Incidence Ratios (SIRs) were used to compare the observed incidence of cancer in the Combined Cohort to the New York State population. SIRs are robust to small strata sizes and are similar to a relative risk model that includes all interactions for all stratification variables. Stratification variables are required to be categorical. A limitation of SIRs is that it is not possible to compare two SIRs with each other to get relative risk except under strong assumptions of homogeneity across strata. We compared both First Primary Cancers, and All Primary Cancers, to the New York State reference population. Table 1 shows SIRs for some cancers of incidence.

Cancer site (SEER recode)	All primary cancer		First primary cancer	
Comparison to NYS General Population	Obs.	SIR (95% CI)	Obs.	SIR (95% CI)
All sites	3611	0.95 (0.92 to 0.98)	3236	0.96 (0.93 to 0.99)
Oral cavity and pharynx (20010-20100)	121	0.91 (0.76 to 1.09)	109	0.96 (0.79 to 1.16)
Tonsil (20070)	43	1.37 (0.99 to 1.84)	40	1.40 (1.00 to 1.91)
Tongue (20020)	43	1.02 (0.74 to 1.38)	38	1.06 (0.75 to 1.46)
Larynx (22020)	34	0.74 (0.52 to 1.04)	30	0.74 (0.50 to 1.05)
Lung and bronchus (22030)	249	0.61 (0.53 to 0.69)	200	0.59 (0.51 to 0.67)
Mesothelioma (36010)	9	1.38 (0.63 to 2.62)	8	1.51 (0.65 to 2.98)
Melanoma of the skin (25010)	236	1.42 (1.24 to 1.61)	204	1.43 (1.24 to 1.64)
Prostate (28010)	1061	1.18 (1.11 to 1.25)	1001	1.19 (1.11 to 1.26)
Thyroid (32010)	208	1.78 (1.54 to 2.03)	189	1.81 (1.57 to 2.09)

Table 1. Standardized Incidence Ratios for selected cancers of interest, for All Primary Cancers, and First Primary Cancers. Green indicates lower incidence in the WTC Combined Cohort than in the New York State comparison population; Red indicates higher incidence.

The statistics reflect cases through the end of 2015. 649,724 and 624,620 person-years of follow-up were observed for All Primary Cancers, and First Primary Cancers, respectively.
The elevated incidence in tonsil cancer had not been previously reported in any WTC cohort. Our findings confirmed prior studies in individual cohorts for elevated incidence of Thyroid cancer (all 3), Skin melanoma (2 of 3), Prostate cancer (2 of 3), and confirmed prior studies in individual cohorts showing reduced incidence of Lung Cancer.

Table 2 shows that a number of gastrointestinal cancers were found to have lower than expected incidence, a finding worthy of further investigation:

Cancer site (SEER recode)	All primary cancer		First primary cancer	
Comparison to NYS General Population	Obs.	SIR (95% CI)	Obs.	SIR (95% CI)
Esophagus (21010)	44	0.85 (0.62 to 1.15)	43	0.96 (0.69 to 1.29)
Stomach (21020)	56	0.84 (0.64 to 1.09)	52	0.89 (0.66 to 1.16)
Colon and rectum (21041-21052)	233	0.74 (0.64 to 0.84)	212	0.76 (0.66 to 0.87)
Colon excluding rectum (21041-21049)	143	0.71 (0.60 to 0.84)	133	0.76 (0.64 to 0.90)
Rectum and rectosigmoid (21051-21052)	90	0.78 (0.62 to 0.95)	79	0.76 (0.60 to 0.95)
Liver and intrahepatic bile duct (21071-21072)	61	0.66 (0.50 to 0.84)	54	0.64 (0.48 to 0.83)
Pancreas (21100)	67	0.71 (0.55 to 0.91)	56	0.68 (0.51 to 0.88)
Urinary bladder (including in situ) (29010)	149	0.78 (0.66 to 0.92)	130	0.81 (0.67 to 0.96)
Kidney and renal pelvis (29020)	158	0.89 (0.76 to 1.04)	137	0.92 (0.77 to 1.09)

Table 2. Standardized Incidence Ratios for gastrointestinal and related cancer sites for the WTC Combined Cohort compared to the NYS reference population.

We did not confirm prior findings in the individual cohorts of elevated rates of hematologic cancers, as shown in Table 3.

Cancer site (SEER recode)	All primary cancer		First primary cancer	
Comparison to NYS General Population	Obs.	SIR (95% CI)	Obs.	SIR (95% CI)
Non-Hodgkin lymphoma (33041-33042)	189	1.04 (0.90 to 1.20)	162	1.01 (0.86 to 1.18)
Multiple myeloma (34000)	62	1.07 (0.82 to 1.37)	56	1.09 (0.82 to 1.42)
Leukemia (35011-35043)	118	1.04 (0.86 to 1.24)	102	1.04 (0.85 to 1.26)
Hodgkin lymphoma (33011-33012)	22	0.81 (0.51 to 1.23)	20	0.80 (0.49 to 1.23)

Table 3. Standardized Incidence Ratios for hematologic cancers in the WTC Combined Cohort compared to the NYS reference population.

We also observed reduced incidence of some gynecological cancers, previously not reported, as shown in Table 4.

Cancer site (SEER recode)	All primary cancer		First primary cancer	
Comparison to NYS General Population	Obs.	SIR (95% CI)	Obs.	SIR (95% CI)
Female breast (26000)	**162**	**0.82 (0.70 to 0.96)**	**140**	**0.82 (0.69 to 0.96)**
Corpus uterus and NOS (27020, 27030)	**31**	**0.66 (0.45 to 0.94)**	**29**	**0.67 (0.45 to 0.96)**
Ovary (27040)	15	0.84 (0.47 to 1.38)	15	0.94 (0.53 to 1.55)
Testis (28020)	37	0.81 (0.57 to 1.12)	35	0.82 (0.57 to 1.13)
Brain and other nervous system (31010, 31040)	50	0.89 (0.66 to 1.17)	45	0.87 (0.63 to 1.16)

Table 4. Standardized Incidence Ratios for additional cancer sites in the WTC Combined Cohort compared to the NYS reference population.

We also performed internal analyses within the cohort using Cox regression models adjusted for age as of 9/11/2001, sex, race and ethnicity, smoking status, and year of enrollment. Results are shown in Table 5.

WTC exposures	All sites		Tonsil		Melanoma-skin		Prostate		Thyroid	
Date of arrival at WTC site	No.	aHR (95% CI)	No.	aHR (95% CI)	No.	aHR (95% CI)	No.	aHR (95% CI)	No.	aHR (95% CI)
9/11/2001	1223	**1.47 (1.32-1.64)**	20	2.07 (0.87-4.92)	83	1.39 (0.89-2.16)	405	**1.61 (1.33-1.95)**	82	**1.77 (1.11-2.81)**
9/12/2001	589	**1.34 (1.19-1.51)**	9	2.10 (0.80-5.50)	40	1.47 (0.91-2.38)	189	**1.35 (1.09-1.68)**	30	1.39 (0.81-2.37)
9/13-17/2001	643	**1.32 (1.17-1.48)**	8	Referent	32	1.14 (0.70-1.88)	190	**1.25 (1.01-1.54)**	34	1.49 (0.89-2.49)
≥ 9/18/2001	572	Referent			34	Referent	155	Referent	28	Referent
Trend		**1.12 (1.08-1.15)**		1.23 (0.89-1.71)		1.11 (0.97-1.28)		**1.16 (1.09-1.23)**		**1.17 (1.02-1.35)**
Worked on pile	1279	1.03 (0.95-1.11)	23	1.24 (0.59-2.60)	107	1.37 (0.99-1.91)	415	1.09 (0.95-1.25)	72	0.74 (0.52-1.06)
Direct 9/11 dust exposure	1242	**1.21 (1.12-1.31)**	19	1.31 (0.66-2.59)	84	1.17 (0.86-1.59)	404	**1.30 (1.14-1.49)**	77	1.19 (0.87-1.63)

Table 5. adjusted Hazard Ratios (aHR) for arrival time at the WTC site, whether the study participant worked on the debris pile, or was directly exposed to dust at the WTC site on 9/11/2001, for All Cancer Sites and for four selected cancer sites. Red indicates elevated hazard for that exposure/site.

Earlier arrival at the site is a measure of higher exposure intensity. There were dose-response trends for All Cancer Sites, Prostate Cancer, and Thyroid Cancer. Direct exposure to dust on 9/11/2001 was associated with higher incidence of All Cancers and Prostate Cancer. No association was found between having worked on the debris pile and cancer incidence.

We also evaluated racial-ethnic differences in cancer incidence in the Combined Cohort.[10] Figure 3 shows preliminary findings. In these preliminary internal analyses using parametric piecewise exponential survival models, Blacks had a significantly higher prostate cancer rate and reduced thyroid and colorectal cancer rates when compared to White participants. Hispanics had lower rates for five cancer sites analyzed.

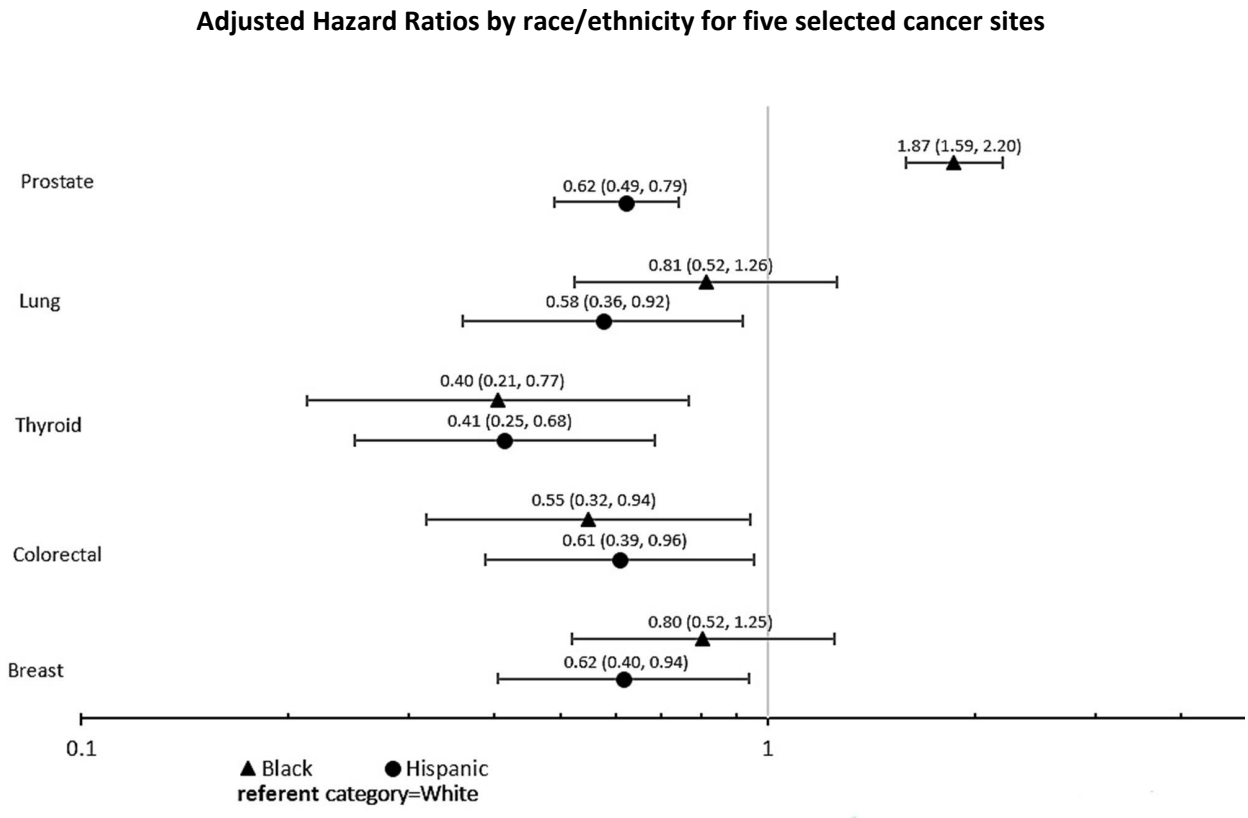

Figure 3. Internal analysis evaluating ethno-racial subgroups within the WTC Combined Cohort using parametric piecewise exponential survival models. All models controlled for age, calendar year, and sex (as appropriate). Lung cancer models also controlled for cigarette smoking (ever vs. never). Breast cancer was restricted to female participants.

In a secondary external analysis, rates in the Combined Cohort were compared to rates in the general population of New York State (NYS). We found that non-Hispanic Black participants had a significantly elevated rate of prostate cancer (HR=1.22; 95% CI=1.05-1.40), and lower rates for lung cancer (HR=0.47; 95% CI=0.31-0.71) and colorectal cancer (HR=0.37; 95% CI=0.22-0.62) compared to the NYS rates. Hispanic participants had lower rates for lung cancer (HR=0.59; 95% CI=0.37-0.92) and colorectal cancer (HR=0.53; 95% CI=0.34-0.81). Non-Hispanic Whites had a lower hazard for lung cancer (HR=0.63; 95% CI=0.56-0.72). A manuscript including these and other related findings has been drafted and is under review as of the date of this report.

Specific Aim 2: To estimate the time at which the relative risk for specific cancer subtypes significantly increases among the highest exposed in this combined WTC cohort using change point models.

Hypothesis 2a: Thyroid cancer incidence will begin to be elevated shortly after WTC exposure.

As part of an ancillary CDC/NIOSH study ("Detection and Incidence of Thyroid Cancer among Three Cohorts of WTC-Exposed Rescue and Recovery Workers", U01 OH011681 and U01 OH011931, PI: Rachel Zeig-Owens), we examined the temporal pattern of thyroid cancer incidence rates over a 14 year follow-up period. We estimated incidence using parametric piecewise exponential survival models. These models have advantages over Cox regression models in that hazard ratios also have relative rate interpretation, baseline hazards provide actual estimates of baseline incidence rates, and change points can be estimated from the data. We stratified the analyses by whether in individual was enrolled in a World Trade Center Medical Monitoring and Treatment Program (WTC-MMTP and WTC-non-MMTP) and compared incidence to those in a New York State reference population.

Figure 4 shows that incidence was elevated among those in a WTC-MMTP, but not in those in the WTC-non-MMTP group, compared to the reference population and that while there was a trend towards increasing incidence over time, there was no specific change point detected at which time the increase accelerated. These are consistent with a hypothesis that incidental detection contributes to higher observed incidence of thyroid cancer in WTC rescue/recovery workers.[11]

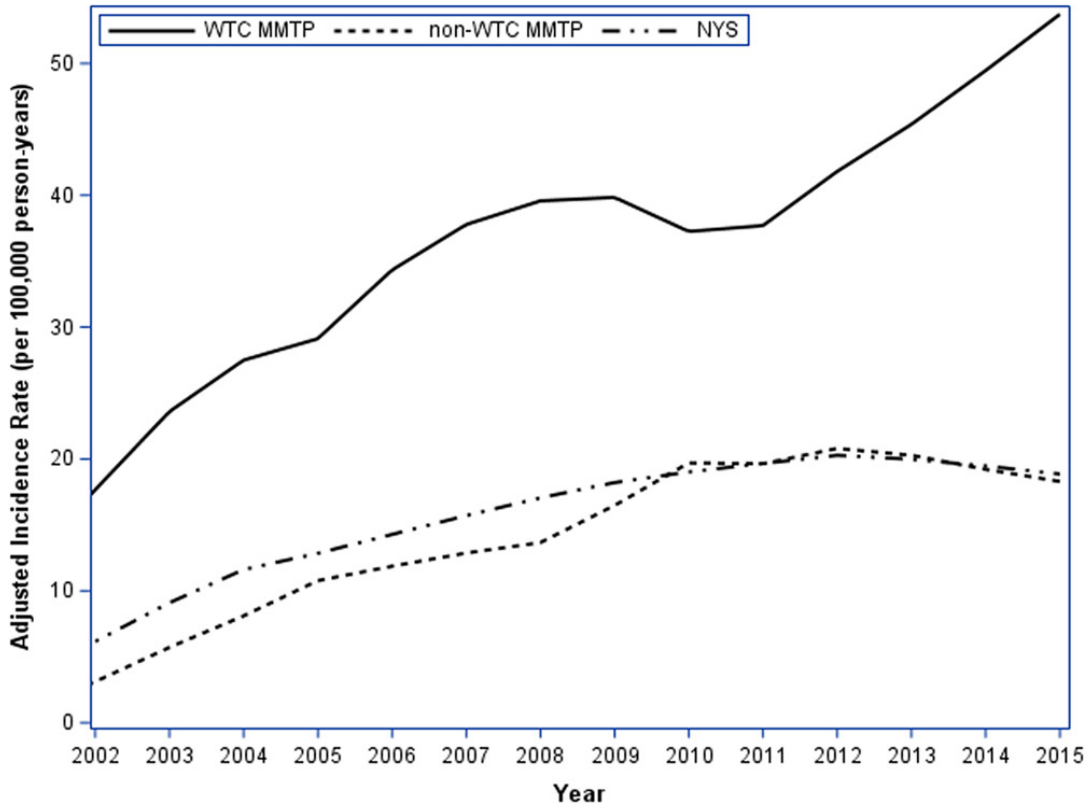

Figure 4. Adjusted Thyroid Incidence Graph. Models are controlled for race/ethnicity, sex and age throughout follow-up; rates are centered at non-Hispanic white race/ethnicity and ages 50–54; rates are displayed per 100,000 person-years. Solid line: smoothed adjusted incidence curve for point estimates of each year of a WTC Combined Rescue/Recovery Cohort member who was enrolled in a Medical Monitoring and Treatment Program (MMTP); dashed line: smoothed adjusted incidence curve for point estimates for each year of a WTC Combined Rescue/Recovery Cohort member who was not enrolled in a Medical Monitoring and Treatment Program (non-MMTP); mixed dashed and dotted lines: smoothed adjusted incidence curve for point estimates of each year using New York State population rates.

Hypothesis 2b: Incidence of hematologic cancers and skin melanoma will be elevated starting five years after WTC exposure.

We found that incidence of cutaneous melanoma was elevated beginning in 2005, earlier than expected. There was very low incidence in the first three years after exposure.[12]

Period of Follow-Up	N Cases	Person-Years	HR	95% CI
2002–2004	6	44,731	0.65	0.30–1.49
2005–2015	241	446,761	1.34	1.18–1.52

Table 6. Hazard Ratio of Cutaneous Melanoma by WTC Responder Status. Results of Comparison with NYS Rates. The model estimates the hazard in two distinct intervals, from 2002 to 2004 and from 2005 to 2015, and estimates the change point from the data. The model are adjusted for age, sex, and calendar year. Abbreviations: CI, confidence interval; HR, hazard ratio; NYS, New York State; WTC, World Trade Center.

Evidence that the elevated incidence is more likely due to WTC dust exposure rather than sun exposure comes from an examination of the locations of the melanoma tumors, as shown in Table 7.

Description	WTC N (row %)	WTC Rate	NYS N (row %)	NYS Rate
Skin of trunk	112 (45.3)	19	15,990 (33.8)	11.2
Skin of upper limb and shoulder	45 (18.2)	11.4	11,844 (24.1)	8.2
Skin of lower limb and hip	32 (13.0)	7.6	9,089 (19.3)	6.5
Skin of scalp and neck	22 (8.9)	5.3	3,194 (6.6)	2.2
Skin of other and unspecified parts of face	18 (7.3)	3.8	4,626 (9.0)	3.1
Skin, NOS	11 (4.5)	1.2	2,104 (4.1)	1.4
External ear	≤5 (1.6)	1	1,336 (2.8)	0.9
Overlapping lesion of the skin	≤5 (0.8)	0.4	62 (0.0)	0
Skin of eyelid	≤5 (0.4)	0.1	186 (0.3)	0.1
Localized	187 (75.7)	39.6	34,657 (71.4)	24.2
Regional	14 (5.7)	3.3	4,490 (9.3)	3.1
Distant	11 (4.5)	1.4	2,021 (4.2)	1.4
Unknown	35 (14.2)	5.5	7,346 (15.1)	5.1

Table 7. Selected Clinical Characteristics of Cutaneous Melanoma Cases Abbreviations: NOS, not otherwise specified; NYS, New York State; WTC-RR, WTC Combined Rescue/Recovery Cohort; US, United States. Rates are presented per 100,000 and are age and sex standardized to the US 2000 non-Hispanic White population.

A larger fraction of tumors were located on the trunk, which would have not been directly exposed to sunlight, in the WTC cohort than in the NYS reference population. The good news for patients is that most of the increased incidence is from localized tumors, which have a more favorable prognosis.

Hypothesis 2c: No change point will be observed for solid tumors other than for thyroid cancer, and in particular colorectal, breast, prostate or lung cancer, suggesting that the average latency period between exposure and incidence may be longer than our 15-year follow-up period or that the WTC exposure is not a risk factor for these cancers.

We found a shorter-than-expected induction/latency period for prostate cancer in our cohort.[13] Incidence was significantly elevated beginning in 2007 compared to the New York State reference cohort. Internal analyses examining the effects of arrival time showed similar findings. Figures 5 and 6 show the findings.

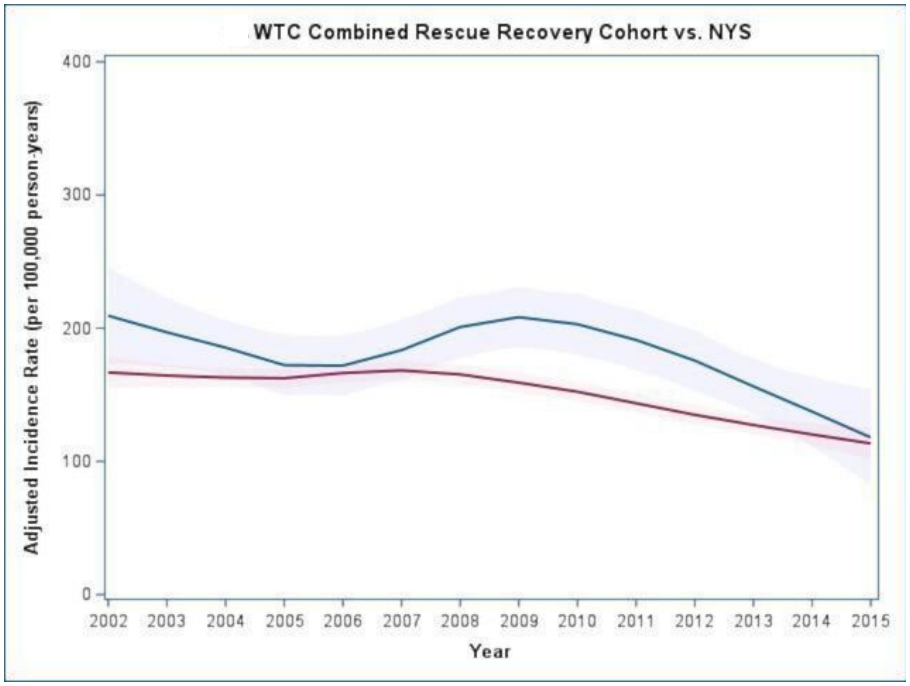

Figure 5. Adjusted prostate cancer incidence rates in WTC Combined Cohort versus NYS. WTC, NYS, comparison population; models are controlled for race/ethnicity and age; rates are centered at non-Hispanic white race/ethnicity and ages 50–54; rates are displayed per 100 000 person-years. Blue lines: smoothed adjusting incidence curves for WTC combined rescue/recovery cohort; red lines: smoothed adjusting incidence curves for NYS comparison population. Line shadows represent 95% CI.

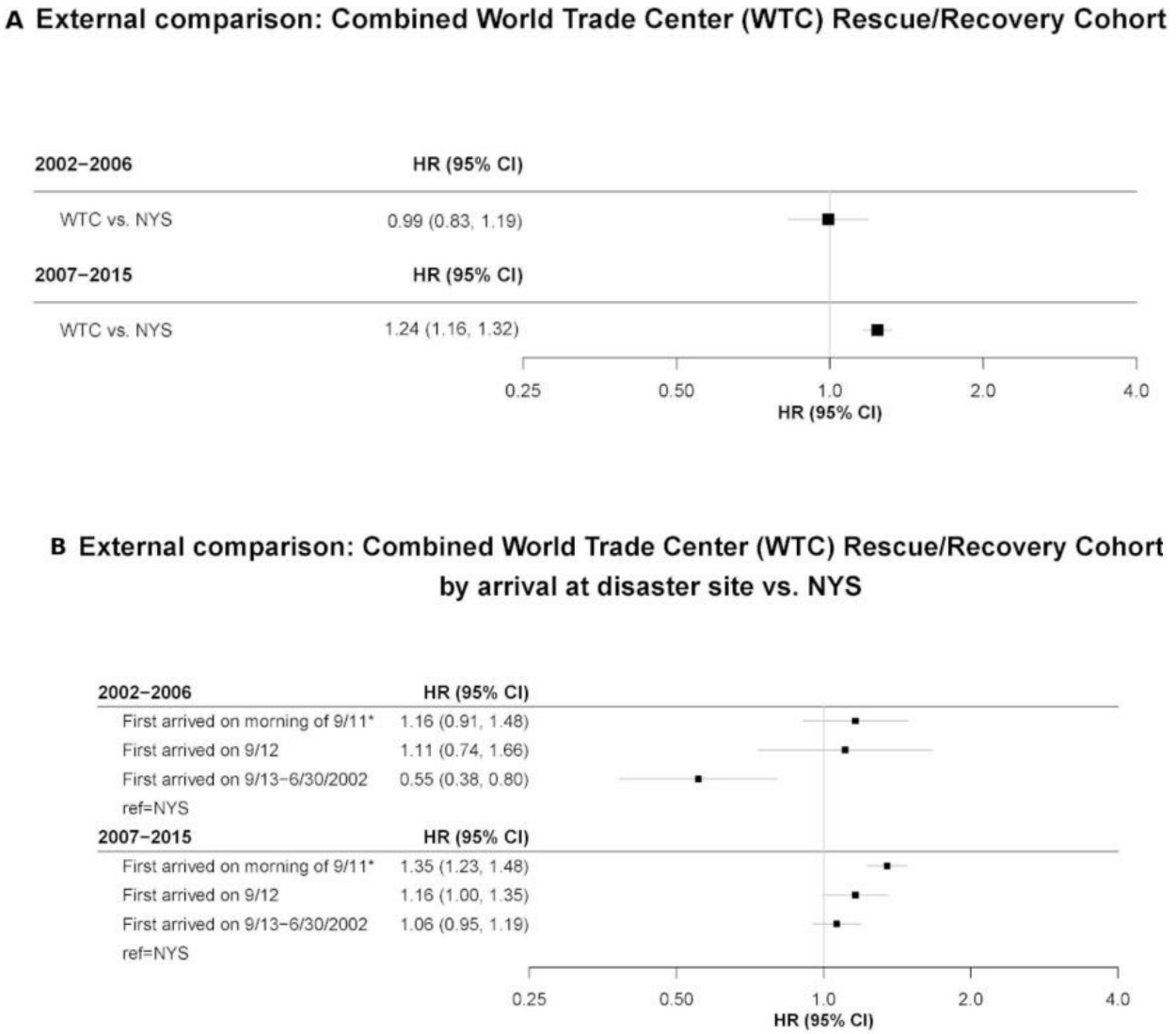

Figure 6. Change Point Models for Incident Prostate Cancer among WTC rescue/recovery workers: 3/12/2002-12/31/2005. "9/11" = 9/11/2001. Best-fitting models all had one change point in 2006. All analyses control for age and race/ethnicity. (A) includes the entire Combined WTC rescue/recovery cohort (n=54 394). (B) is restricted to those who self-reported an arrival time or dust-cloud exposure at the WTC sites, age 30+ at diagnosis and not non-Hispanic American Indian race/ethnicity (n=50 961). *Arrived on morning of 11 September or self-reported dust cloud exposure. NYS, New York State.

We cannot at this time rule out increased surveillance playing a role in the shorter than expected induction/latency period. Future research should investigate screening patterns, and whether the relative incidence returns to one with sufficient follow-up.

Additionally, we have been assessing the potential impact of choice of comparison cohort on estimates of relative incidence, and the temporal trends in incidence. We compared change points and incidence rate ratios observed with three different comparison populations, New York City, New York State, and SEER21. Piecewise exponential survival models adjusting for age, race/ethnicity, and calendar year were fit. We found minor differences in the conclusions depending on the comparison population. With NYC as the comparison population, there was evidence for a change point that would mean an increase in incidence in the WTC-exposed population beginning in 2007, however, the increased incidence ratio in

the later period was not statistically significant, unlike our findings comparing the WTC-exposed population to the NYS population. Comparing the WTC-exposed population to SEER21, the incidence rate ratio increased after 2008 rather than 2007.[14] Figure 7 shows the incidence rate ratios for each of the model comparisons.

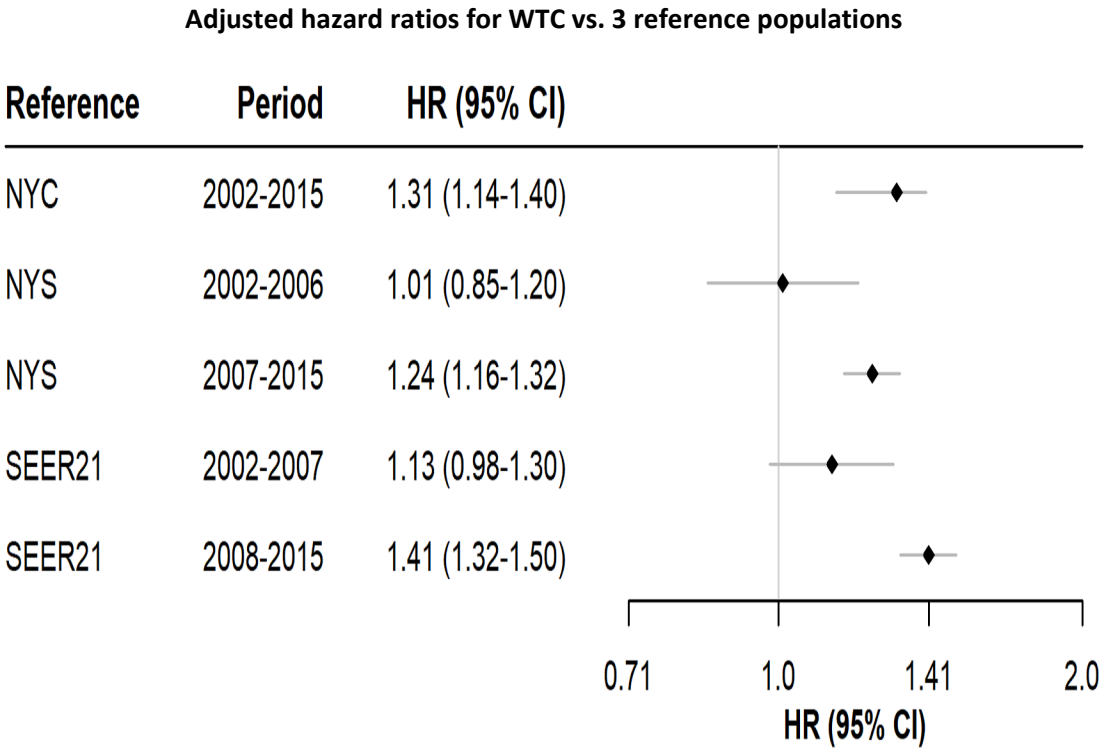

Figure 7. Hazard ratios (incidence rate ratios) for prostate cancer incidence in the WTC Combined Cohort vs. New York City (NYC), New York State (NYS), and SEER21 populations, with 95 percent confidence intervals.

Additional analyses have been completed and a manuscript is being written. Choice of a correct comparison population is an important issue in evaluating cancer risk in a population and a separate study with an occupationally similar comparison cohort is being conducted by our team.

Specific Aim 3. To calculate observed and relative survival at 1, 3 and 5 years of cancer patients in the combined WTC cohort for the most common cancers in the WTC population.
Hypothesis 3: Compared with cancer patients in New York State as a whole, WTC-exposed cancer patients will have longer survival after accounting for demographic factors and temporal trends.

We analyzed rescue/recovery workers who are in a WTC Medical Monitoring and Treatment Program (WTC MMTP) separately from rescue/recovery workers who were not. The plots are of Kaplan-Meier estimates of survival curves; lower values on the y scale correspond to higher mortality. Figure 8 shows mortality for the first twelve years of follow-up. Those persons with cancer who are in a WTC MMTP have much lower mortality (longer survival) than the general population and those not in a WTC MMTP have mortality rates that are more similar to the general population. [15]

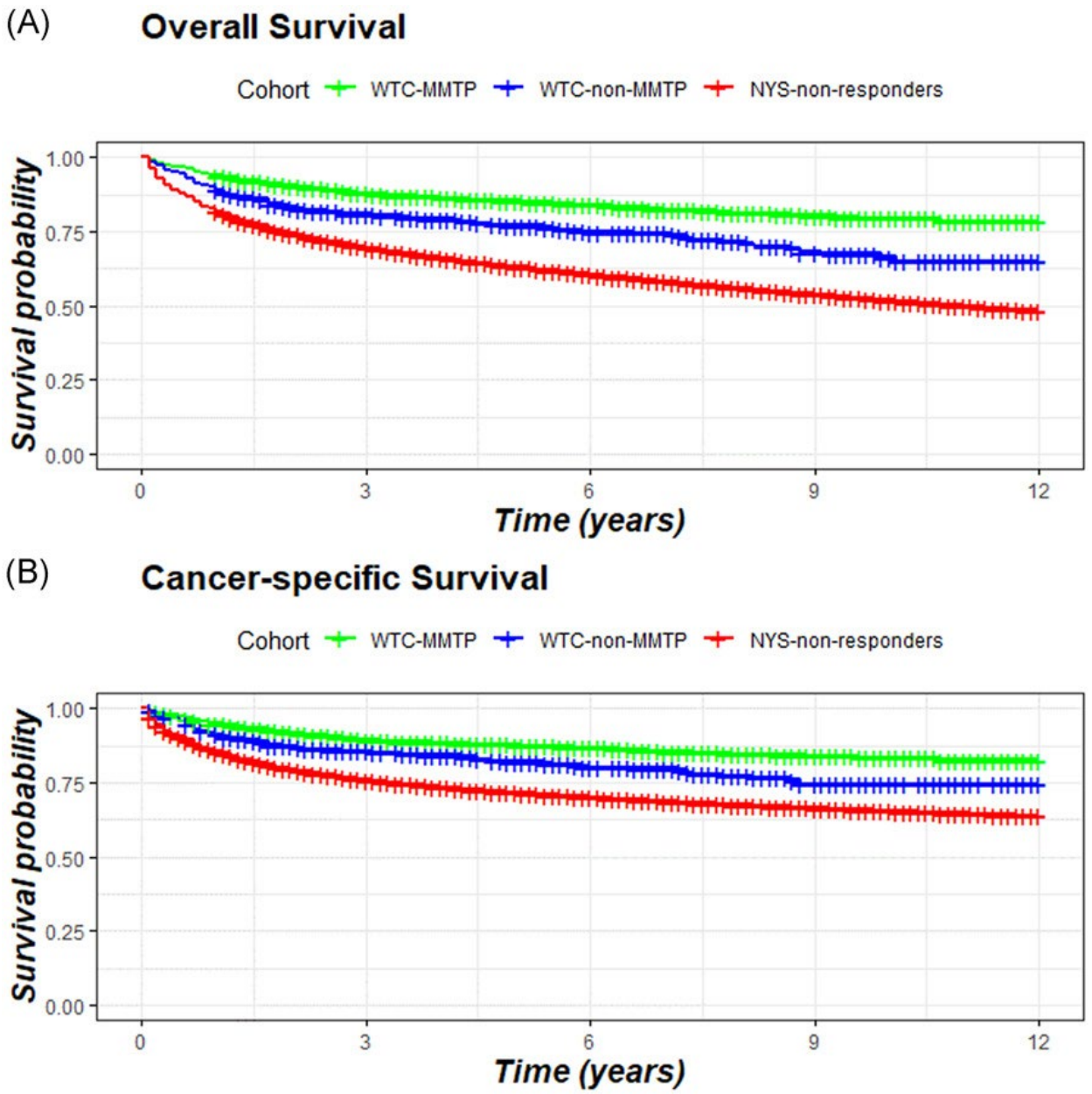

Figure 8. Kaplan–Meier plots: (A) All-cause and (B) cancer-specific survival. Follow-up starts at the time of diagnosis log-rank $p < .001$. NYS-non-responders, all other cancer patients who were residents of the 11-southernmost counties of New York State and were not included in one of the WTC-responder cohorts; WTC-MMTP, cancer patients enrolled in the World Trade Center Medical Monitoring and Treatment Program; WTC-non-MMTP, WTC-exposed cancer patients who were NOT enrolled in the WTC-MMTP.

The magnitude of the survival benefits were estimated using parametric piecewise exponential survival models, similar to those used in Aim 2. All models controlled for age at diagnosis (in 5-year groupings), race/ethnicity (Hispanic, non-Hispanic White, non-Hispanic Black, non-Hispanic Asian/Pacific Islander, non-Hispanic other), sex, year of diagnosis, and cancer site. Cancer incidence data were ascertained through the end of 2015 and mortality data through the end of 2016. We conducted two primary analyses. In one, follow-up started on the date of diagnosis and ended at death or December 31, 2016, whichever occurred first. In a second analysis, we started follow-up on January 1, 2005, to account for potential

lead-time bias. Figure 9 shows the results for all-cause and cancer-specific mortality. We included cancer stage in the models in order to address possible length bias, and used both a fixed time and the date of cancer diagnosis as time zero in the models in order to address potential lead time bias. cancer diagnosis as time zero in the models in order to address potential lead time bias.

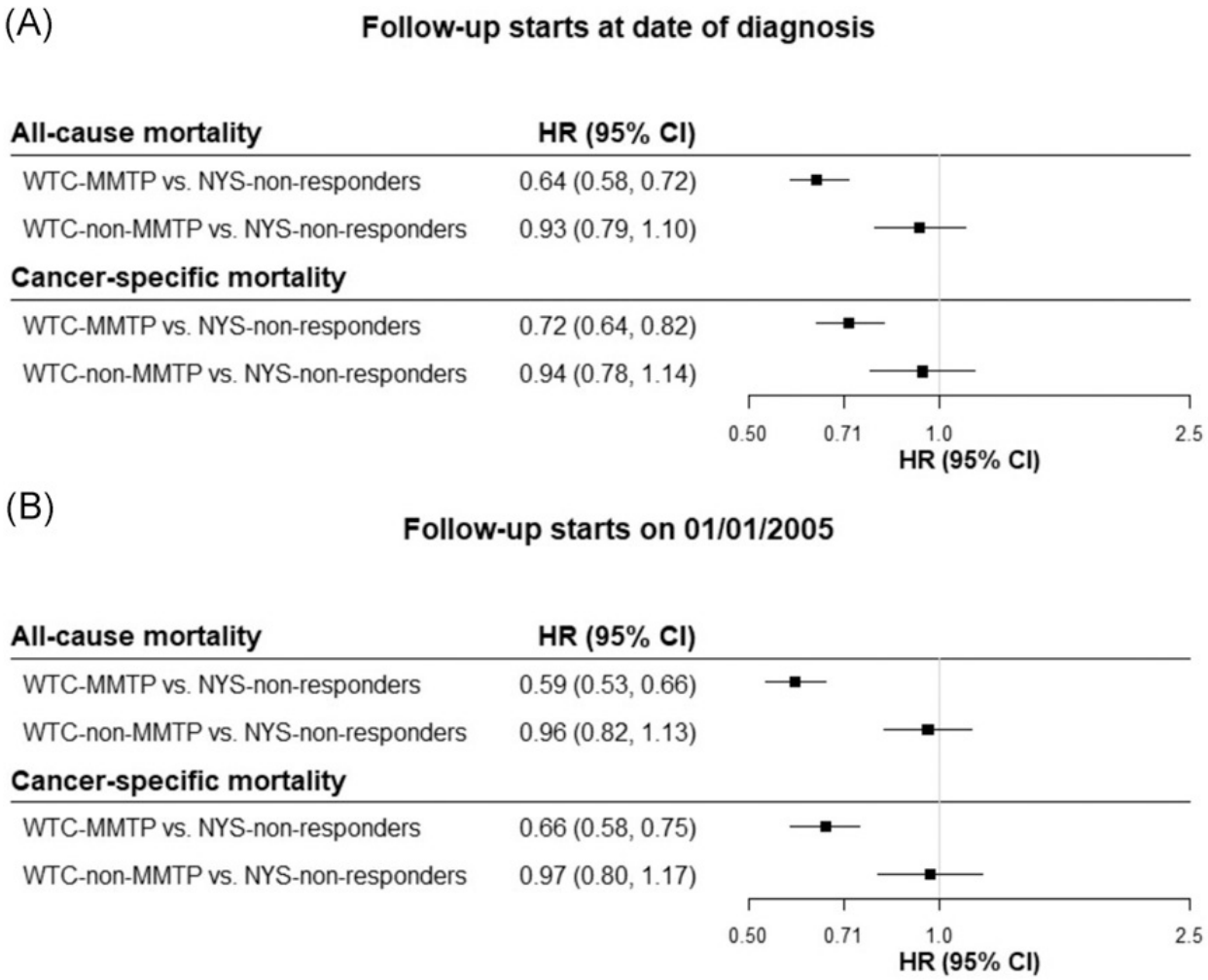

Figure 9. All-cause and cancer-specific mortality risk. Models controlled for calendar year, age, race/ethnicity, sex, cancer stage and site. 95% CI, 95% confidence interval; HR, hazard ratio; NYS-non-responders, all other cancer patients who were residents of the 11 southernmost counties of New York State and were not included in one of the WTC-responder cohorts.
WTC-MMTP, cancer patients enrolled in the World Trade Center Medical Monitoring and Treatment Program; WTC-non-MMTP, WTC-exposed cancer patients who were NOT enrolled in the WTC-MMTP.

There was a surprisingly large statistically significant survival benefit to being in an NIOSH-funded WTC MMTP. RRWs not in a WTC-MMTP had modest and non-significant survival advantages over the general population. Table 8 shows benefits by cancer site for all-cause mortality.

Primary cancer diagnoses				SIRs for all-cause mortality vs. NYS general population (95% CI)			
	N (%)			Follow up begins at diagnosis date		Follow up begins 1/1/2005	
Site	MMTP	non-MMTP	NYS	MMTP	non-MMTP	MMTP	non-MMTP
Prostate	659 (32.4)	162 (28.7)	93,135 (16.2)	**0.62 (0.44, 0.88)**	0.92 (0.54, 1.55)	**0.59 (0.42, 0.84)**	0.88 (0.52, 1.49)
Melanoma of the skin	138 (6.8)	20 (3.5)	17,436 (3.0)	0.54 (0.27, 1.08)	0.82 (0.20, 3.27)	0.52 (0.26, 1.05)	0.90 (0.22, 3.60)
Colon and rectum	136 (6.7)	32 (5.7)	53,767 (9.4)	**0.48 (0.31, 0.74)**	1.11 (0.60, 2.06)	**0.50 (0.32, 0.76)**	1.10 (0.59, 2.05)
Lung and bronchus	110 (5.4)	42 (7.4)	58,386 (10.2)	**0.74 (0.56, 0.97)**	0.88 (0.60, 1.28)	**0.59 (0.44, 0.78)**	0.76 (0.52, 1.10)
Kidney and renal pelvis	95 (4.7)	27 (4.8)	17,756 (3.1)	**0.36 (0.16, 0.79)**	1.23 (0.51, 2.96)	**0.37 (0.17, 0.82)**	1.40 (0.58, 3.38)
Myeloma	35 (1.7)	15 (2.7)	10,183 (1.8)	0.49 (0.22, 1.10)	0.50 (0.16, 1.54)	0.49 (0.22, 1.10)	0.48 (0.15, 1.48)
Pancreas	35 (1.7)	9 (1.6)	15,256 (2.7)	**1.66 (1.15, 2.39)**	1.18 (0.61, 2.27)	1.10 (0.76, 1.58)	**2.31 (1.20, 4.44)**
Brain/other nervous system	28 (1.4)	10 (1.8)	6,327 (1.1)	1.11 (0.70, 1.76)	0.87 (0.42, 1.83)	1.07 (0.67, 1.71)	0.97 (0.46, 2.04)
Esophagus	26 (1.3)	9 (1.6)	4,852 (0.9)	0.65 (0.36, 1.18)	1.15 (0.55, 2.43)	0.60 (0.33, 1.09)	1.81 (0.86, 3.80)
Liver	26 (1.3)	8 (1.4)	10,588 (1.8)	0.74 (0.44, 1.22)	1.00 (0.50, 2.01)	0.73 (0.44, 1.21)	**2.25 (1.12, 4.50)**

Table 8. Standardized Incidence Ratios for all-cause mortality for different cancer cites stratified by membership in WTC-MMTP. All models controlled for calendar year, age, race/ethnicity, sex (except prostate), and stage; models are restricted to participants aged 40 and older. Bold indicates $p < 0.05$. Abbreviations: HR, hazard ratio; NYS-non-responders, all other cancer patients who were residents of the 11-southernmost counties of New York State and were not included in one of the WTC-responder cohorts; WTC-MMTP, cancer patients enrolled in the World Trade Center Medical Monitoring and Treatment Program; WTC-non-MMTP, WTC-exposed cancer patients who were NOT enrolled in the WTC-MMTP.

Significant survival benefits to RRWs in a WTC-MMTP were observed for prostate cancer, for which incidence was elevated in RRWs,[9] and in colon/rectum and lung/bronchus, for which incidence was lower than the general population. Non-significantly increased survival was also seen for skin melanoma, for which we observed increased incidence; myeloma, for which incidence was similar to the comparison general population; and for esophageal cancer and liver cancer, where incidence was lower than in the general population. These findings argue against the survival benefit being the result of lead time bias caused by early detection. In addition, the benefits are larger than what has been observed in controlled trials of cancer screening. No survival benefit was observed for pancreatic cancer, or cancer of the brain/central nervous system. It should be a high research priority to confirm these findings with comparisons to comparable occupational cohorts, and if confirmed, to investigate how these benefits may

be made available to other communities beyond the WTC-exposed community. We believe that this is the most important finding in the study as it demonstrates the benefits that the World Trade Center Health Program provides to members of the program.

Conclusion.

"Incidence, Latency, and Survival of Cancer Following World Trade Center Exposure" has succeeded in all its aims, in the process overcoming numerous administrative challenges. We have identified cancer sites with increased incidence in the WTC-Exposed population, and cancer sites with lower incidence than in the general population. We identified two cancer sites with shorter induction/latency periods than expected. We identified a strong survival benefit for persons with cancer who are in a NIOSH WTC Medical Monitoring and Treatment Program. Further research should include additional follow-up to determine whether the patterns of incidence relative to comparison populations change over time, particularly in cancers believe to have long induction/latency periods. Further research should also compare WTC-Exposed rescue/recovery workers to additional comparison cohorts, especially cohorts consisting of individuals in similar occupations. Most importantly, future research should examine the survival benefit we have observed to see whether it continues with longer follow-up, and to identify aspects of the program that can be generalized to other cohorts. We have arranged for continued maintenance of the cohort through NIOSH contract with FDNY, and have transferred the IRB monitoring responsibilities from Albert Einstein College of Medicine to Biomedical Research Alliance of New York (BRANY) as a single IRB. These organizational changes will facilitate research from the current team and from new collaborators in the future.

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Cumulative Inclusion/Enrollment Table

View Burden Statement

PHS Inclusion Enrollment Report

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

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title (must be unique):** Incidence, Latency, and Survival of Cancer Following World Trade Center Exposure

* Delayed Onset Study? ☐ Yes ☒ No

If study is not delayed onset, the following selections are required:

Enrollment Type	☐ Planned	☒ Cumulative (Actual)
Using an Existing Dataset or Resource	☒ Yes	☐ No
Enrollment Location	☒ Domestic	☐ Foreign
Clinical Trial	☐ Yes	☒ No

NIH-Defined Phase III Clinical Trial ☐ Yes ☒ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	25	163	0	1	10	0	0	0	0	199
Asian	254	873	0	2	11	0	0	0	0	1,140
Native Hawaiian or Other Pacific Islander	36	93	0	1	4	0	0	0	0	134
Black or African American	1,627	4,777	0	28	73	0	0	0	0	6,505
White	5,714	40,839	0	118	494	0	0	0	0	47,165
More than One Race	108	314	0	571	2,412	0	0	0	0	3,405
Unknown or Not Reported	445	2,760	0	1,801	5,546	0	0	0	2	10,554
Total	8,209	49,819	0	2,522	8,550	0	0	0	2	69,102

Report 1 of 1

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To ensure proper performance, please save frequently.

Inclusion of Gender and Minority Study Subjects

See Inclusion Enrollment Table. The study population included 10,731 women, and 22,549 participants who were not non-Hispanic White.

Inclusion of Children

All persons in the study needed to be 18 as of September 11, 2001, and therefore are all over 21 today.

Materials Available for Other Investigators

Materials are available to other investigators in accordance with the Data Sharing Plan, attached as a separate document.