**Quantifying the Effectiveness of NYC Policy Initiatives on Chronic Disease Prevention**

The overall aims of this proposal are to systematically detail the timing and substance of health-relevant New York City (NYC) policies and initiatives from 2002-2013 and to evaluate the effectiveness of these efforts in reducing chronic disease morbidity and mortality rates. The deleterious influences of tobacco smoke, obesity, low dietary quality, and air pollution on chronic disease development have been well established and in response, select local governments around the country have taken policy action to mitigate the adverse effects of these exposures. NYC has been at the vanguard of policy efforts to decrease the population burden of chronic disease using a multi-sectoral approach. For example, NYC policies implemented since 2002 have used a combination of taxation, regulation, marketing, and infrastructure investment to make healthy choices more attractive and available.[1](#_ENREF_1) Preliminary evidence suggests that specific policies have influenced risk factor prevalence[2-4](#_ENREF_2) and even clinical disease event rates[5](#_ENREF_5) and life expectancy.[6](#_ENREF_6) Yet health interventions supported by strong observational evidence often fail to demonstrate effectiveness when implemented in real-world settings. Prominent recent examples include the hypotheses that hormone replacement therapy and a low-fat diet would prevent cardiovascular disease (CVD); hypotheses that were ultimately not supported in the large and carefully conducted Women’s Health Initiative randomized trials.[7-10](#_ENREF_7) Therefore, despite preliminary evidence suggesting that NYC public health initiatives during the past decade may have resulted in a reduction in select chronic disease event rates (acute myocardial infarction hospitalization, for example), it is important to rigorously test and demonstrate that chronic disease morbidity and mortality, broadly defined, are on the decline. Importantly, there is currently no comprehensive catalog of NYC policy interventions relevant to health occurring since 2002. Therefore, some key questions are: 1) what specific policies have been implemented, by which government agencies and partner organizations, and what was the temporal and spatial pattern of dissemination and implementation; 2) to what extent can reported declines in chronic disease event rates be attributed to recent NYC policies and initiatives (as opposed to medical advances or expanded health care access); 3) to what extent can the effects associated with specific policies be separately estimated. Therefore, we propose the following aims:

1. To systematically catalog the nature and deployment of policies and initiatives relevant to public health, and the evidence-base available to inform our understanding of the likely health impact. We will specifically focus on policies and programs enacted from 2002-2013 in NYC related to the following four chronic disease risk factors: i) tobacco, ii) obesity, iii) diet quality, and iv) air quality.
2. To model cause-specific time trends for chronic disease hospitalization and mortality rates in NYC and NY State using data from 1990-2013. We will focus the chronic diseases that are among the leading causes of mortality: CVD, cancer and chronic obstructive pulmonary disease (COPD).
3. To conduct causally informative observational analyses such as a natural experimental[11](#_ENREF_11) and interrupted time series designs[12](#_ENREF_12) for evaluating the linkage of NYC policy interventions (aim 1) with respect to modeled temporal trends in chronic disease outcomes (aim 2). Accordingly, we hypothesize the following, after standardizing for age, gender and race/ethnicity:
   1. Observed chronic disease hospitalization and mortality rate reductions for 2002-2013 will be greater than the expected rates based on historical 1990-2001 NYC trends.
   2. Chronic disease hospitalization and mortality rate reductions will be greater in NYC (due to more comprehensive and aggressive policy approaches) versus the remainder of NY State.
   3. Different policy initiatives will have distinguishable effects on chronic disease burden by using known differential latency periods and magnitude across specific chronic disease outcomes.

To address these aims, we propose to systematically and comprehensively describe of the policy environment relevant to chronic disease prevention in NYC during the past decade and to concurrently assemble secondary data sources to assess the magnitude of effect on chronic disease outcomes that can be attributed to these policies. We will review and build on the solid foundation of scientific evidence that has been used to both justify and maintain successful polices, and harness the recent changes and ongoing surveillance to inform the future of a multi-sectoral approach to health promotion in NYC and other urban centers.

**SIGNIFICANCE**

The burden of chronic diseases is substantial both globally and in the United States as they consistently represent the leading causes of death and disability among developing and developed nations.[13](#_ENREF_13) [14](#_ENREF_14) Among the most deadly chronic diseases, are atherosclerotic cardiovascular disease (CVD) and cancer which accounted for >65% of global mortality in 2002. This is projected to remain quite stable through the year 2020 at which point CVD and cancer together will account for nearly 40 million global deaths – nearly twice the number of deaths projected for 2020 due to injuries and infectious disease combined.[13](#_ENREF_13) In addition, respiratory diseases including emphysema and chronic obstructive pulmonary disease (COPD) are projected to become the third most common cause of death by 2020, accounting for another 10% of global mortality. The increasing concentration of populations into urban centers, while previously discussed as potentially contributing to risk[15](#_ENREF_15), also represents an opportunity to enhance the public’s health through the enactment of local health promotion efforts in densely populated cities such as New York City (NYC).

It is well established that leading modifiable risk factors for chronic disease development include tobacco use, excess adiposity, low dietary quality, and exposure to particulate air pollution. In the case of tobacco, despite incredible advances in our understanding of tobacco’s role in chronic disease development over the last 50 years, it remains the single leading cause of premature death in the United States.[16](#_ENREF_16) The 2004 Surgeon General’s report found convincing evidence for a direct causal relationship between tobacco use and at least twelve different forms of cancer [17](#_ENREF_17)and the role of tobacco smoke in CVD morbidity and mortality is equally compelling.[18](#_ENREF_18), [19](#_ENREF_19) Estimates for the year 2000 suggest that tobacco accounted for 435,000 annual deaths in the US. Likewise, excess adiposity and associated behavioral patterns (excess calorie intake, insufficient physical activity, inadequate sleep)[20](#_ENREF_20) in combination with inadequate nutrition and harmful dietary exposures (e.g., to trans fats, sodium, sugar) are the underlying cause of an estimated 400,000 annual deaths despite existing public health guidelines.[21](#_ENREF_21) The number of deaths attributed to particulate air pollution, while decreasing,[22](#_ENREF_22) is estimated at 24,000 annually.[16](#_ENREF_16)

While several of these risk factors are situated in daily lifestyle practices, it can be argued that the structural environment that creates easy access to tobacco and poor food choices, barriers to accessible and affordable healthy food options, and neighborhood barriers to increase and maintain physical activity, individual’s agency or choice, is, in fact, limited.[23](#_ENREF_23) Consequently, there is great promise for continuing decreases in select chronic disease morbidity and mortality, in part, through population-based approaches to risk factor control.[24](#_ENREF_24) Indeed, there are notable examples stemming from both population-based interventions and natural experiments of how broad, population-based interventions can modify population risk factor profiles and reduce chronic disease rates. For example, in the cardiovascular disease literature the North Karelia Project (NKP) in Finland is a compelling example of how macro-level forces rooted in policy and risk factor denormalization were successfully deployed in lowering coronary heart disease rates. The NKP targeted smoking, total cholesterol and blood pressure[25](#_ENREF_25) and resulted in a decrease in CHD mortality by 2.9% per year that was sustained for a decade.[24](#_ENREF_24) Other evidence for the role of macro-level forces have come from natural experiments spawned from economic hardship in Cuba and Europe,[26](#_ENREF_26), [27](#_ENREF_27) as well as policy initiatives in the US.[28](#_ENREF_28), [29](#_ENREF_29)

Despite great potential for broad population-based interventions, including public health policy, in reducing disease burden, there are few examples of such programs in the United States. Responding in part to this dearth of community-based health promotion success stories, the Institute of Medicine stated that the “United States’ public health system is in shambles.”[30](#_ENREF_30) For example, despite focused public health interventions across the US[5](#_ENREF_5), [29](#_ENREF_29) there is no clear model for what an effective and efficient public health system looks like vis-à-vis chronic disease prevention since the traditional focus has been on hygiene and infectious disease prevention.[31](#_ENREF_31) Nor have there been models that explicitly consider public health priorities to be fundamentally engrained in all aspects of government (e.g., transportation, environment, crime, education, urban planning and the economy are all contributors to the public’s health).

During the last decade, in New York City, the Bloomberg administration has laid a foundation for a comprehensive, multi-sectoral approach to primary prevention of chronic disease at a city-wide scale. The administration has aggressively pursued public health policy via both traditional and novel means (see appendix table). For example, some novel approaches include smoking restrictions in public spaces including parks and beaches, calorie labeling requirements, a ban on trans fats, and a commitment to planting 1,000,000 trees.

However, there are only a limited number of studies that have evaluated the effectiveness of these policy interventions, and all of them have focused on a specific intervention or subset of interventions without considering the fact that multiple other interventions were occurring simultaneously. Therefore currently available evidence provides only limited support for causal inference regarding specific interventions. Moreover, there are currently no published data on cause-specific chronic disease secular trends to answer the big question: Are New Yorkers less likely to die or be hospitalized for CVD, cancers, and COPD as the result of this comprehensive multi-sectoral approach to health promotion?

Therefore, the current proposal aims to be the first comprehensive evaluation of the multi-sectoral public health policy approach targeting chronic disease reduction in NYC during the last decade.

**INNOVATION**

This proposal is innovative in its combination of the following three factors: i) timing of implementation (coinciding with the conclusion of the Bloomberg administration); ii) proximity to key players and data sources (investigators are located at Columbia University in the City of New York and have active support from the NYC department of health and mental hygiene); and iii) the proposed analytical approach which will use advanced methods for causal inference in observation data.

We believe this is a historic moment for public health policy. It is difficult to think of any other time or place in which such a broad multi-sectoral approach to public health policy has been implemented in a well-defined U.S. population with a long-standing, high quality health-outcomes data collection infrastructure in place. To date there are few evaluations of Bloomberg-era policy and none that have comprehensively considered the influence of all policies collectively. Therefore, we have a unique opportunity in NYC to systematically evaluate the degree to which broad-based policy initiatives can meaningfully influence the public’s health by looking at big-picture hospitalization and mortality trends as well as nuanced questions regarding the lag period for health policies to affect population-level metrics (i.e., age-adjusted hospitalization and mortality rates).

We believe our plan to use interrupted-time series analysis in the context of Bloomberg era policy (or what is in fact a very unique natural experimental design) is also an important innovation. The natural experimental design developed in Aims 2-3 relies on assumptions quite distinct from those of most observational studies on personal risk factors and CVD.[6](#_ENREF_6) Confounding and reverse causation at the individual level represent major threats to the validity of observational analyses of smoking or diet as determinants of CVD risk. Yet policy changes implemented at a municipal scale are, for the most part, outside of the control of individual residents, thus representing an exogenous source of variation. Instead, the natural experiment analysis relies on consistency of outcome measurement quality over time, and the ability to quantify and account for secular and spatial patterns that correlate with policy deployment. Thus, our efforts to address Aim 1 (cataloging the timing and content of major NYC public health policies beginning in 2002) will support the temporal detail needed to support valid interpretation of population health trends observed in Aims 2-3. Further, we will advance a comprehensive understanding of multi-sectoral policy effectiveness by assessing the most common underlying preventable causes of death[16](#_ENREF_16) and chronic diseases which are major contributors to total mortality.

The cost effectiveness of the proposed approach should not be overlooked. Specifically, by utilizing SPARCS hospitalization data as well as mortality data collected by NYC and NY state we will have the advantages of high-quality, standardized hospitalization and mortality data, allowing for unprecedented levels of generalizability to New York residents without the extreme time and financial burdens of building a large scale longitudinal data collection infrastructure.

Based on the work in aims 1 – 3, we also will be poised to develop an infrastructure enabling the future estimation of national chronic disease mortality trends (using death certificates available via CDC) as well as chronic disease related health care utilization and costs (using Medicaid and Medicare data). This in turn would enable a comparison of secular trends in NYC against other comparable cities and regions that have not implemented similar policies or those municipalities that have taken a different approach to deploying chronic disease prevention policies. Finally, this project will set the stage for scientifically rigorous evaluations of specific multi-sectoral health policies (e.g., trans fat bans, clean buses, greenway infrastructure) with relevance to major chronic diseases (CVD, cancer, and COPD) using a natural experimental design.

**APPROACH**

We propose to systematically catalog and describe the public health policies and initiatives enacted in NYC from 2002 through 2013, and to concurrently quantify the magnitude of effect on chronic disease outcomes that can be attributed to this set of interventions.

*Cataloging the public health policies and initiatives*

Preliminary efforts have been initiated to catalog the policies and initiatives enacted in NYC over the past decade (Appendix Table 1). However, a systematic assessment is needed to fill in gaps and add specificity. To do so, we plan to review the scientific literature, online government reports and websites, and articles from local news outlets. Review by the NYC Department of Health and Mental Hygiene and consultation as needed with other city agencies is planned to ensure accurate representation of the nature and timing of each policy and the organizations involved. To this end, we have a letter of support from Commissioner Farley demonstrating strong support and need for this proposal and a willingness to mobilize resources as necessary.

Literature review

For each of our four focal areas--(i) tobacco, ii) obesity, iii) dietary quality, and iv) air quality--we will conduct a literature review. This research synthesis project will include published literature from peer-reviewed journals 1960 through 2013. When available, we will use previous reviews or meta-analyses, and review only the more recent literature for which synthesis is not available. One goal in reviewing the literature will be to assemble available information on the strength of evidence and latency period for linking each risk factor with chronic disease hospitalizations and mortality, including any differences in the known associations across chronic diseases that may assist us in disentangling the effectiveness of concurrent interventions. For example, previous literature on tobacco control measures suggests a more rapid effect on cardiac outcomes such as myocardial infarction compared with pulmonary outcomes such as emphysema or lung cancer. Based on this information, our analytical models would be set up to properly account for any expected lag effects. A second goal is to evaluate the evidence base for policy approaches to reduce the risk factor in the population, drawing on previously assembled evidence (e.g., Community Prevention Guide, [www.thecommunityguide.org](http://www.thecommunityguide.org)). Third, we will use citation networks to assess the timing of scientific consensus on the link between each of these risk factors and specific chronic disease outcomes, building on the work of Drs. Uri Shwed and Peter Bearman[32](#_ENREF_32). The proposed approach to consensus assessment leverages the observation that most citations in the peer-reviewed scientific literature are supportive, indicating agreement. Contentious topics are thus characterized by separate polarized clusters within the citation network, whereas these clusters tend to coalesce as consensus is formed.

We will identify studies from the published research literature utilizing mainly the Web of Science, PubMed, and the archived records of collaborators. PubMed search terms will be developed and tested building on experience from previous systematic literature reviews[33](#_ENREF_33). We will include studies published in peer-reviewed journals that include at least 100 individuals with measures of the risk factor and report either on (1) associations of the risk factor with chronic disease outcomes or (2) associations of a population-level intervention with the risk factor. Each reference will be screened, and structured abstraction forms will be used to summarize and organize the key methods and findings of each study. Sample abstracted data will be discussed with the entire study team to ensure that there are opportunities for feedback and modification during the data abstraction process.

Ongoing investigations (Drs. Kim Isett and Miriam Laugesen, personal communication) within New York City have suggested that the current administration has been cognizant of the scientific evidence base to support their policies. We propose to further probe this observation in order to understand when policy interventions have fallen with respect to the development from exploratory and divergent investigations toward consensus.

Online sources

The online search for information on the policies and initiatives enacted from 2002 through 2013 will be conducted through locally-based governmental and news websites (e.g., PlaNYC2030, NY Times). In addition, topical databases (e.g., www.no-smoke.org, www.yaleruddcenter.org/legislation) and Lexix Nexis (http://www.columbia.edu/cu/lweb/eresources/databases/2100385.html) will be used to search for records that include terms related to each of the focal risk factors and NYC (including any NYC boroughs). Although our focus is on the changes that potentially affected the health of NYC residents, we will also briefly record information on the timing and nature of any similar changes affecting NY state or other urban centers that are noted in these resources.

Key outputs of our review of online sources will include a detailed database, a schematic timeline, and a social network display of the organizations involved in implementation. The database will include an entry for each policy or initiative describing the nature of the proposed change, exact date or estimated month and year of enactment, the date or range of dates for full implementation, any notes on focal location or spatial prioritization for early implementation (e.g., Trees for Public Health neighborhoods identified for early tree planting as part of the MillionTreesNYC initiative), and the organizations involved in implementation. The appendix table provides a foundation for this effort and will be checked and expanded during the study period. A second database with only location, nature of the policy, and implementation date or period will be used to record available information for policy efforts outside of NYC. Using information from the NYC health-relevant policy database that we will compile, a schematic timeline will be developed showing moments or periods of policy enactment, color-coded to correspond with our 4 focal risk factors. This timeline can then be used to both construct and communicate information on the number of policies enacted relevant to different risk factors throughout the period from 2002-2013. Finally, the database information on organizations involved in implementation will be used to construct a two-mode social network. Two-mode social networks can be used to show how actors are linked to each other through shared participation in an activity or event.[34](#_ENREF_34), [35](#_ENREF_35) To do so, we will review our database to identify and code all unique city agencies and community organizations, and generate a matrix showing the involvement of each unique organization across all policies in the database. The goal will be to create an intuitive display showing the multi-sectoral collaborations among agencies and organizations to enact the diverse set of interventions.

Review and consultation with local experts

The credibility and completeness of our policy documentation will be crucial, and we plan to seek input from local experts beginning in October 2013. Distribution and review of draft materials, personal interviews, and group meetings will be conducted to allow for any omissions or errors to be brought to light. Although the project will provide opportunities for feedback and strive to ensure accuracy, the independence of the project funding and investigators from the city agencies involved in policy deployment is also crucial, and publication will not be contingent on the favorability of study results.

The approximate timeline for cataloging policies and initiative is as follows:

June 2013-July 2013 Conduct preliminary literature reviews, working with Biostatistics Enrichment Summer Training (BEST) scholars (summer undergraduate interns pursuing future graduate study in Public Health)

Sept 2013-Nov 2013 Update and organize table of policies and initiatives, expanding entries to a database format and create draft schematic timeline

Nov 2013-Jan 2014 Iterative process of consultation, review, and feedback to complete database and timeline

Feb 2014-Aug 2014 Generation of bi-modal social network display and a manuscript documenting the multi-sectoral approach to public health promotion

*Linking policies and initiatives to chronic disease hospitalizations and mortality*

Hospitalization data:

Hospitalization data will be obtained via the publicly available data provided by The New York Statewide Planning and Research Cooperative System (SPARCS): http://www.health.ny.gov/statistics/sparcs/operations/overview.htm

As described on their website, SPARCS is a comprehensive data reporting system resulting from cooperation between the health care industry and government. SPARCS collects patient level detail on patient characteristics, diagnoses and treatments, services, and charges for every hospital discharge, ambulatory surgery patient, and emergency department admission in New York State. The enabling legislation and regulations for SPARCS are located under Section 28.16 of the Public Health Law (PHL), [Section 400.18](http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525652c00634a29?OpenDocument) of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York (NYCRR). Data standardization is ensured by the Universal Data Set (UDS) Specification, which includes reporting codes for use with the UB-92 paper form and an electronic format. The resulting system streamlines multiple data submission formats into a single format, removing redundant reporting requirements for hospitals and other health care facilities. The current SPARCS format, which represents a subset of the fields within the complete UDS specification, has been required for submitting records to SPARCS since 1994 discharges and therefore the majority of dates under study in this proposal (1990-2013) are covered by this reporting requirement.

Mortality data:

Mortality data will be obtained from the New York State Department of Health and the New York City Department of Health & Mental Hygiene (NYCDOHMH) and we have a letter of support from Commissioner Farley to assist in acquiring these data. Specifically, data requests will be submitted to both the New York State Department of Health and NYCDOHMH requesting cause specific mortality data for the outcomes specific to this proposal (see below). We will request that the mortality data include age, gender, county of residence and month of death to ensure that our data structure is compatible with our planned analyses described below in the statistical analysis section. All analyses will be based on individual level death and hospitalization data coupled with population census information (at the county level) to generate rates.

Definition of cause-specific outcomes (hospitalization and mortality)

We will comprehensively consider cardiovascular disease (including coronary heart disease and cerebrovascular disease), cancer outcomes, and COPD (the top leading causes of death in the United States) in this proposal. We will also consider more focused subsets of these outcomes based on the subsets that are expected to be most strongly influenced by NYC policy initiatives (e.g., atherosclerotic CVD, tobacco-related cancers, emphysema). Definitions will use both ICD-9 (below) and ICD-10 codes.

Any CVD:

Coronary disease: coronary disease will be defined by the following ICD-9 codes: 401-405, 410-417, 420-429, 440-448, 451-459.

Cerebrovascular disease: ICD-9 codes 430-438

Atherosclerotic CVD:

Acute Myocardial Infarction: International Classification of Diseases, 9th revision, codes 410

Cerebral vascular disease: ICD-9 codes 430 through 438 will be used for total CVA. ICD-9 433, 434, & 436-438 will be used to specify nonhemorrhagic stroke while ICD-9 codes 430-432 will identify hemorrhagic stroke. CVA outcomes will exclude hemorrhagic stroke as these events are often of nonatherosclerotic origin.

Any Cancer:

Cancer (neoplasms) will be defined by the following ICD-9 codes: 140-239.

Tobacco-related cancers:

In this proposal we will define tobacco-related cancers based on the 2004 report of the Surgeon General on The Health Consequences of Smoking[17](#_ENREF_17) which determined there to be sufficient evidence on which to conclude a causal relationship between tobacco use and the following cancers (site and morphology codes referenced parenthetically based on the ICD for Oncology, third edition [ICD-O-3]): lung and bronchus (C34), larynx (C32), oral cavity & pharynx (C0-14), esophagus (C15), stomach (C16), pancreas (C25), kidney and renal pelvis (C64--65), urinary bladder (C67), cervix (C53), and acute myeloid leukemia (M9840, 9861, 9866, 9867, 9871--9874, 9891, 9895--9897, 9910, 9920).[36](#_ENREF_36), [37](#_ENREF_37)

For data abstraction, these ICD-O-3 cancer outcomes will be converted to ICD-9 codes derived from published conversion algorithms allowing for ICD-O code conversion to ICD-9: <http://seer.cancer.gov/tools/conversion/>

Respiratory Diseases:

Chronic obstructive pulmonary disease will be defined by the following ICD-9 codes: 490–496

Emphysema will be defined by the following ICD-9 code: 492

**Statistical Analysis**

Global outcome definitions: This proposal will focus on chronic disease mortality and hospitalization rates occurring from the years 1990 – 2012. We will start in the year 1990 because it will allow for the generation of robust secular time trends beginning over a decade before Bloomberg took office and initiated many of the multi-sectoral policies of interest. The analytical approach described below will be applied generally to all outcomes whether events of interest are deaths or hospitalizations. For simplicity, in our description of the analytical approach we will refer to our general dependent variable as the “outcome”. Secular trends for the following seven outcomes will be developed based on the aforementioned data sources and outcome definitions: 1. all CVD, 2. atherosclerotic CVD (combined fatal AMI and nonhemorrhagic stroke), 3. all cancer, 4. tobacco-related cancers, 5. all COPD, 6. emphysema, and 7. total chronic disease outcomes (CVD, cancer, or COPD). All rates will be annualized and directly age standardized to the age distribution of NY state[5](#_ENREF_5) using publically available United States Census data: http://www.census.gov/popest/data/counties/asrh/2011/index.html

“Intervention” definition: Our primary analyses will define “intervention” using a global approach that simply considers January 1st, 2002 as the demarcation between pre- and post-intervention time points. We will also consider how our results are impacted by instead using January 1st, 2004 as the cut point because it occurs 2 years after Bloomberg was inaugurated and ~6 months following the implementation of the first quantifiable, large-scale public health intervention by the Bloomberg administration (smoke-free workplace and smoke free restaurant policies).[5](#_ENREF_5) We acknowledge there are limitations to using either global definition (if the date is too early or too late there will be model misspecifications due to either limited time for the intervention to have an impact on event rates or potential contamination of intervention effects in the “pre-intervention” period, respectively. However, we wish to specify an a priori model that will be amenable to easy interpretation for the general public while still based on sound scientific expectations. In addition, we will construct a time-varying count of policies relevant to each of our four focal risk factors (e.g., count of enacted tobacco policies) to allow for dose-response evaluation.

For analyses focused on specific policy initiatives, we will use implementation date to define pre- vs. post-intervention based on our findings from the comprehensive literature review. Therefore, intervention dates will vary across models used to test different interventions (eg., tobacco bans or trans fat bans). To account for lag periods, the actual date of intervention will be defined as the date of actual implementation + expected lag time based on prior literature. For example, if a comprehensive smoking ban took effect in July 1st, 2002 and we expect a 3 month latency period before any population level influence on our outcomes might be expected, the intervention date would be defined as October 1st, 2002.

We will use two different general approaches to testing our hypotheses regarding the influence of NYC public health policy on CVD and cancer outcomes. First, is interrupted time-series analysis, which allows for the testing of causal hypotheses that outcome rates will follow a different trajectory before vs. after a clearly defined intervention (or interruption). Interrupted time-series analysis is regarded as a strong quasi-experimental design alternative for hypothesis testing when randomized designs are not feasible[12](#_ENREF_12). Second, we will use Poisson regression models to test whether or not the time trend in outcome rates differ between those observed in NY state (excluding NYC) vs. NYC as has been done for similar causal analysis of policy effectiveness[29](#_ENREF_29). A more detailed description of these models is provided below.

Interrupted-time series analysis will be used to determine if secular trends in the aforementioned outcomes diverge from expected trends based on the observed time-series leading up to any given policy intervention date according to the method described by Wagner and colleagues.[12](#_ENREF_12) A segmented linear regression model will be applied to monthly age-adjusted outcome rates (hospitalizations or deaths/10,000 people). Our statistical model is formalized below and includes the following: Ŷ (monthly age-adjusted outcome rate), β0 (baseline outcome rate), β1 (coefficient for the secular time-trend in outcomes rates during the pre-intervention period), β2 (coefficient representing the change in level of outcome rate during the post-intervention period) and β3 (an interaction term corresponding to the change in secular trends after vs. before the intervention period. A statistically significant β3 coefficient will be interpreted as evidence that of change in secular outcome trends due to the intervention. A residual error ε will be assumed to have a normal distribution, and robust standard errors will be used if this assumption appears to have been violated. The variables in our model will be operationalized as follows:

time=continuous linear variable corresponding to month and year of event

intervention=dichotomous variable corresponding to whether month of event occurred pre vs post intervention

The model is formalized as follows:

Ŷ = β0 + β1\*time + β2\*intervention + β3\*time\*intervention + ε

|  |
| --- |
|  |
| **Figure 1: Observed number of hospital admissions for acute myocardial infarction and predicted number of hospital admissions in the absence of a comprehensive smoking ban, by month: New York State, 2002–2004 (Juster et al. AJPH, 2007)** |

Figure 1 provides a visual representation of data which can be analyzed using this approach. This figure is based on a time-series analysis specifically focused on one aspect of NYC public health policy (a comprehensive smoking ban) and its influence on hospital admissions for myocardial infarction. This specific example demonstrated that observed AMI hospitalization rates were lower than expected hospitalization rates in the years following a smoking ban introduction, yet may not have fully accounted for the other concurrent policies. The figure demonstrates a growing difference between expected and observed rates following the ban lending support for the notion that a comprehensive smoking ban led to declines in AMI hospitalization. As such, this provides a useful example of how our planned interrupted time-series analytical approach can quantitatively evaluate the effectiveness of both specific and broad public health policy interventions on a variety of chronic disease outcomes – both fatal and nonfatal.

Poisson regression

Poisson regression models (see below for model) will be used to regress outcome rates on residence (living in NYC or NY State excluding NYC), intervention (modeled as a binary variable corresponding to pre- vs. post-intervention calendar time) and a residence\*intervention interaction term (to assess if any differences in outcome rates between the pre and post-intervention time periods differ by residence). The regression model will also include an offset variable corresponding to total population estimates for NYC and NY State based on publicly available census data: <http://www.census.gov/popest/data/counties/asrh/2011/index.html>

A residual error ε will be assumed to have a Poisson distribution, and a correction for over-dispersion or robust standard errors will be used if this assumption appears to have been violated.

The formal models is here:

LOG(λ) = β0+β1\*intervention+β2\*residence+β3\*intervention\*residence+LOG(population total)+ε

Power

There is a robust literature on the analysis of public health policy effectiveness geared towards chronic disease outcomes.[5](#_ENREF_5), [12](#_ENREF_12), [29](#_ENREF_29) Relative to that literature, our current proposal will have event numbers much larger (due to the inclusion of multiple disease endpoints, a larger time period, and larger source population] than previous studies which have had sufficient power to demonstrate modest intervention effects. Therefore we are confident that power will be sufficient in our proposed study, which does not rely on a statistical sample but instead uses all observed outcome events. For example, for Poisson regression to have 90% power to detect an incident rate ratio of 0.90 (a 10% reduction in outcome rate in NYC vs. NY State) would only require 4500 outcomes to detect a difference. Based on only one year of data (2011) from New York State (http://hcupnet.ahrq.gov) the number of AMI events alone exceeds 30,000. Therefore, we will have a number of outcomes that far exceeds sample size requirements. Nevertheless, as this project relies on an analysis of all actual deaths and hospitalizations in NY state, there is no better alternative to the current proposal from the standpoint of power – i.e., we cannot propose larger sample size and still maintain the same level of internal validity.

**Limitations and Strengths**

This proposal has a number of limitations that should be recognized at the outset of this project. First, our focus will be on linking policies to relatively distal consequences in the form of clinical disease and subsequent mortality, and we will not have data available on all of the behavioral and biological pathways that may mediate such associations or be more sensitive to the policy effects. Second, this study rests on the deployment of interventions that were not randomized, overlapped in timing of initiation and target health conditions, and were in some cases broadly defined or multi-pronged. Third, the focal risk factors do not have a one-to-one or deterministic relationship with the selected specific chronic disease outcomes. Concurrent policy changes, economic shifts, scientific discoveries or natural disasters may complicate our ability to identify the consequences of a particular policy. The health outcomes identified in this proposal may in some cases be misclassified and may also omit less common diseases shaped by policies and subsequent risk factor reduction; such non-differential misclassification or omission could lead to an underestimation of policy effectiveness for preventing the total population-level disease burden.

Despite these limitations, the proposed project has several notable strengths. It takes advantage of an unprecedented opportunity to investigate the multi-sectoral approach to promoting urban health undertaken in New York City. The inventory of policies and the investigation of their effectiveness in preventing disease and mortality will be intertwined and informed by consultation with local agencies including the NYC Department of Health and Mental Hygiene. Yet the independence of this project from the agencies enacting policy change adds credibility to any favorable outcomes, and will allow for greater openness to investigating unintentional negative consequences of health-relevant policies. Multiple strategies will be deployed to disentangle the effects of policies on specific health outcomes, using time-series, comparison locations, and evidence-based assumptions. Although the timeline for accomplishing the proposed work will be a challenge, the planned research strategy leverages previous investments in health surveillance. Moreover, the timelines of this research will potentially inform future administrations and establish an infrastructure for future investigations.

**CONCLUSION**

The evaluation of health-relevant policies, even those founded on strong observational evidence, is crucial. Such evaluations offer an opportunity to move from tightly controlled efficacy studies to investigations of effectiveness under realistic circumstances. Moreover, agreement within the scientific community may be overturned by new evidence, particularly if that new evidence does not rely on the standard assumptions of observational analyses. The proposed project will add to the current understanding of what has been done to prevent chronic disease at the population level within New York City under the recent administration, and to the growing body of evidence available to inform health promotion policies in an era of limited resources.

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