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Novel Inhaler use among children attending school southern Manhattan in September of 2001: An Observational, Controlled Trial

A. Study Purpose and Rationale:

The terrorist attacks in September of 2001 resulted in tremendous loss of life and inflicted an incalculable toll on those in Manhattan and in Washington D.C. at the time, as well as on the families of passengers on the three commercial airline jets used in the attacks. The extent of the damage inflicted on Manhattan specifically has yet to be fully seen; it is feared that those with direct exposure to the pollutants that resulted from the collapse of the Twin Towers and the subsequent recovery and clean up efforts will continue to suffer health consequences many years into the future.

It has been shown that residents of the affected area had increased incidence of respiratory illness and serious psychological distress in the aftermath of this disaster. With respect to respiratory symptoms, those in the affected area reported higher rates of new onset upper respiratory symptoms after 9/11. Previously healthy residents of the area also had more respiratory-related unplanned medical visits and more new medication use after 9/11 (Lin et al).

Those with direct exposure to high levels of pollutants, including rescue workers people who were south of Canal Street on September 11^{th,} have been and are continuing to be studied to determine both the short and long term health consequences of this disaster. However, the effects of chronic lower level exposure to the dust and fumes that lingered in southern Manhattan for many months after this event are not as well examined. The effects of these exposures on developing lungs are also less clear. There is evidence that children with an established diagnosis of asthma prior to September of 2001 did experience worsening of their symptoms (Szema AM et al). The purpose of this study is to establish whether there was an increase in the actual incidence of asthma as well. This study will look specifically at children who were in the 1st-3rd grades in schools south of Canal Street in September of 2001 to determine if their incidence of asthma has increased compared to a control population elsewhere in New York City.

B. Study Design and Statistical Analysis

This will be an observational, cohort study looking at children who are now in 6th-8th grades. These middle-school aged children will receive a questionnaire asking several simple questions: Were you in the same school system in September of 2001? Did you use an albuterol inhaler for asthma? Do you use an albuterol inhaler now? Does anyone at home smoke? In this study, inhaler use will serve as a proxy for respiratory disease rather than subjective questions in order to minimize potential recall bias. However, it is still possible that those families living and working in close proximity to the WTC site were more concerned about respiratory symptoms, and were therefore more likely to seek medical attention than people without direct exposure.

The study will consist of two arms: the exposed group of children and a similar cohort of 6^{th}-8^{th} graders elsewhere in NYC. In order to minimize confounding variables, an attempt will be made to choose a school system for the control group with similar ethnic and socio-economic characteristics as the school system chosen in the exposure group. The Chi-square test was used to estimate the number of subjects needed to effectively power this study. The average incidence of asthma in NYC was estimated to be 5%, and the effect was expected to be 10%. Using this calculation, both arms of the trial are estimated to need 500 subjects. The chi-squared test will then be used to determine if there is a statistically significant difference in the proportion of children with novel use of an albuterol inhaler after September 11, 2001. Logistical regression analysis will be used to control for environmental exposure to tobacco smoke at home. Other risk factors such as pollution and allergen exposure are expected to be similar in the exposure and control groups. A subgroup analysis will also be done to look at boys and girls separately.

C. Study Procedure
Each subject in this study will be asked to fill out just one simple questionnaire.

D. Study Drugs/Medical Devices
Not applicable

E. Study Questionnaires
As stated above, the questionnaire will have the following questions:
1. Were you in the same school system in September of 2001?
2. If yes, have you remained in that school system until now?
3. Did you use an albuterol inhaler before September of 2001?
4. Do you now use an albuterol inhaler?
5. Does anyone at home smoke?

F. Study Subjects/Recruitment of Subjects:
This study will include both boys and girls in the 6^{th}-8^{th} grades. As stated above, an attempt will be made to find a school system for the control population with similar ethnic and socioeconomic characteristics as the exposure group, although there will not be an attempt made to find individual children with these backgrounds. Inclusion criteria will be boys and girls in the 6^{th}-8^{th} grades in the chosen school systems. Exclusion criteria will be having a serious pre-existing respiratory disease, such as cystic fibrosis.

Because the study subjects will be minors, the children's parents or legal guardians will have to give informed consent. It is planned that each child will be given both the informed consent and the questionnaire to bring home and return to school if the parents wish to participate in the study. There will be an incentive to the child to actually bring these forms home and then bring them back to school, such as a movie pass.

G. Confidentiality of Study Data:

The only identifying information on the questionnaire will be is the subject a boy or a girl, and what is his/her age. The informed consent will necessarily include identifying information.

H. Potential Risks:
The only identifiable risk to the subjects in the study and their families is possible psychological distress at memories of this time period.

I. Potential Benefits:
There is no direct benefit to the study subjects. However, the hope is that this information will be valuable for assessing the impact of low level toxic exposure on developing lungs.

J. Compensation to subjects:
As stated above, there will be a small incentive for participation such as a movie ticket.