

Research to Inform the Prevention of Asthma in Health Care

ICR SUPPORTING STATEMENT – PART B Collections of Information Employing Statistical Methods

**DIVISION OF RESPIRATORY DISEASE STUDIES
FIELD STUDIES BRANCH
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH**

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Principal Investigators:

Paul K. Henneberger
Co-Project Officer/Epidemiologist
Phone: 304-285-6161
Fax: 304-285-5820
Email: pkh@cdc.gov

M. Abbas Virji
Co-Project Officer/Industrial Hygienist
Phone: 304-285-5797
Fax: 304-285-5820
Email: fnb8@cdc.gov

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1. Respondent Universe and Sampling Methods

The respondent universe comprises all members of the 1199SEIU (Service Employees International Union) United Healthcare Workers East in New York City, who can be categorized into one of the following job categories:

- Certified Nursing Assistant
- Licensed Practical Nurse
- Registered Nurse
- Central Supply Worker
- Environmental Service Worker
- Lab Technician
- Operating Room Technician
- Respiratory Therapist
- Dental Assistant

Based on current information from 1199SEIU, there are approximately 15,000 union members who would be eligible to participate in this survey. Union member from all job categories will be recruited for participation. A previous survey of asthma among healthcare workers achieved a response rate of 66% (Delclos 2007). Because we will be recruiting among healthcare workers who are 1199SEIU members and all contact will be through official union channels, we expect to achieve a substantially better response rate (>80%) to our recruitment effort. Based on the response rate of the previously mentioned survey, a sample of 6,250 union members will be recruited, with a goal of surveying 5,000 healthcare workers.

2. Procedures for the Collection of Information

Methods for Completing Survey

Participation in this survey consists of completion of the Asthma-in-Health-Care survey. Once a participant has been recruited they will be provided with two methods for completing the survey.

The first method available to participants is to complete the online version hosted on the CDC website. Participants will be able to access the website hosting the survey using a unique identifier provided by 1199SEIU that accompanied the recruitment letter and informed consent information. It is anticipated the online survey will take approximately 30 minutes to complete. However, participants will have the option to complete the survey in sections by logging onto the CDC website hosting the survey using the login information provided in their recruitment letter. Participants will not have the option to return to previously answered questions if they return to complete the survey at a later date. When the survey is complete, the data will be stored initially at the CDC Mid-Tier Data Center and then sent to the CDC/NIOSH research team.

The second method available to participants for completing the survey is by Computer Assisted Telephone Interview (CATI). NIOSH has contracted with Research Triangle Institute (RTI) International to provide epidemiology support and conduct the telephone interviews. RTI has subcontracted with the SEIU Communications Center (CC) (a subsidiary of 1199SEIU) to place the telephone calls and interview participants. Included in the recruitment letter will be a phone number that participants can use to call into the SEIU CC and complete the survey by interview with a SEIU CC staff member. Prior to completion of the survey, the SEIU CC staff

member will ask if the participant has read the informed consent information. If they have not, the interviewer will read the consent information to the participant. After the participant has been given the informed consent information they will give verbal consent to the interviewer and then complete the survey. It is anticipated that the phone interview will take approximately 30 minutes to complete. Data from completed surveys will be copied onto CDs and sent by express mail service (e.g., FedEx or UPS) to the CDC/NIOSH research team.

Participants will have two weeks from receipt of the recruitment letter to complete the survey (either online or by phone). After this two week period, reminder postcards will be mailed to any non-responding potential participants. At the same time, the SEIU CC will also begin making phone calls to non-responders asking them to participate in the study and complete the survey by phone using the same interview procedure already described. The SEIU CC will attempt seven contacts with each potential participant before they will be labeled as a non-responder. If a union member agrees to participate and completes the online version of the survey in the timeframe when the SEIU CC is attempting phone calls they will be removed from the list of non-responders.

Power Analysis

Sample size calculations were conducted to estimate the number of participants from 1199SEIU that will be needed to address exposures and outcomes of interest. The findings reported by Delclos and colleagues provide clues about the frequency with which exposures occur in a cohort of healthcare workers (Delclos 2007). Four exposures were selected from their publication to cover a range of frequencies: 6% spills at work, 21% contact with adhesives/solvents/gases on surfaces, 46% instrument cleaning, and 71% use of cleaning agents to clean surfaces (Delclos 2007). A hypothetical exposure was also considered that occurred for 12% of participants. We used a standard formula to compute sample sizes that was developed for logistic regression with one bivariate exposure variable and one bivariate confounder (Demidenko 2007). For the calculations, the confounder was based on female gender, which we estimated at 68% of the participants using findings from the prior NIOSH-VA study (Zeiss 2003). We consistently used a power of 0.80, a significance level (alpha) of 0.05, and an odds ratio (OR) of 2.0. Three outcomes were considered: the prevalence of asthma-like symptoms and the 10-year incidence of asthma among all participants, and the 1-year incidence of exacerbation among those with asthma. The findings are presented in Table 1. For prevalence of asthma-like symptoms and the 10-year asthma incidence, a sample size of 4400 would be sufficient for all exposure-outcome pairs considered. For 1-year exacerbation of asthma, a sample size of 5,000 would suffice for the three higher-prevalence exposures, but not for the two exposures considered with prevalence less than 21%. The sample sizes required for the lower-frequency exposures for this outcome are so much larger than 5,000 (i.e., 7,750 and 14,417) that they cannot be justified.

Table1: Sample size calculations for logistic regression, binary exposure and a binary confounder*

<u>Exposures</u>		<u>Sample sizes with different outcomes*</u>		
Type of exposure	Exposure Prevalence**	Prev. asthma-like symptoms, 0.1[§]	10-year asthma incidence, 0.02[†]	1-year exacerbation of asthma, 0.24 in asthmatics[‡]
Spill at work	0.06	1431	4376	14417
Hypothetical	0.12	791	2488	7750
Adhesives/solvents/gases used on surfaces	0.21	529	1729	4988
Instrument cleaning	0.46	403	1433	3429
Cleaning surfaces	0.71	548	2081	4262

* For these calculations, power=0.80 and statistical significance=0.05 to detect an odds ratio (OR) of 2.0 for the exposure. For the confounder, we assumed: a prevalence of 68%, based on the prevalence of female gender as observed in VA-NIOSH study (Zeiss 2003); OR=2.3, as based on the association of female gender with the prevalence of asthma from the study by Delclos and colleagues (Delclos 2007); and OR=2.0 for the relationship between gender and the exposure. The estimated frequency of the different outcomes assumes there is no exposure and the confounder=0

** Exposure prevalence based on findings from study by Delclos (Delclos 2007), except for hypothetical 0.12

† The 10-year incidence of asthma for adults is approximately 0.04 based on data from the National Health Interview Survey, 1980-1996 (Rudd 2007). We assumed incidence=0.02 if no exposure and confounder=0.

‡ From the NIOSH Workplace Exacerbation of Asthma study, 0.43 of adults with asthma reported an exacerbation event (i.e., unplanned care for asthma) in the past 12 months (Henneberger 2008). We assumed 1-year cumulative incidence=0.24 in those unexposed asthmatics with confounder=0. To derive the total number of participants needed, we first calculated the number of asthma cases needed, then derived the total number of participants by assuming current asthma prevalence=8.4% (CDC 2007).

§ Based on unpublished data from a NIOSH-VA study of healthcare workers in 3 VA medical centers, in which 19% of participants reported an asthma-like symptom (Zeiss 2003). We assumed prevalence= 0.10 if no exposure and confounder=0. ____

3. Methods to Maximize the Response Rates to Deal with Nonresponse

In order to maximize the response rates, a standard recruitment process will be implemented. All communication with potential participants will be done through 1199SEIU or the SEIU CC. At no time will direct contact between NIOSH and the union members take place.

An initial recruitment letter, briefly introducing the study will be sent to a sample of 6,250 1199SEIU members. At the same time, a short description of the study and its purpose will be posted in the 1199SEIU newsletter. One week after the introductory recruitment letter, a second mailing will be initiated by 1199SEIU. The second mailing will include a letter requesting participation, instructions how to complete the Asthma-in-Health-Care survey, and the informed consent information.

Two weeks after the second mailing, potential participants who have not completed the survey online or by phone will be sent a reminder post card instructing union members interested in participating to complete the survey online. At this time, phone calls will also be initiated by

the SEIU CC contacting union members who have not completed the online survey or dialed in to complete the survey by phone. During this phone call SEIU CC staff will ask if the union member is interested in participating. If they would like to participate the SEIU CC staff will complete the consent procedure and conduct the survey at that time. Copies of correspondence material (i.e., initial contact letter, recruitment letter and informed consent information, newsletter language, reminder postcard, interview scripts, survey instructions, survey, Spanish language survey, electronic survey, and results letter) with potential participants and participants can be found in appendix E through N. The five contacts with potential participants is similar to the approach used by Delclos (2007) in their survey of healthcare workers and is based on standard approach for internet surveys, which should allow us to achieve the highest response rate possible (Dillman 2000).

4. Tests of Procedures or Methods to be Undertaken

The survey for this study will be administered either online or by telephone. Telephone interviews will be conducted by personnel at the SEIU CC, trained by and under the management of RTI.

The development and modification of the survey was started in 2009 and has been conducted with advice from collaborators with experience studying asthma among health care workers. The survey includes sections on respiratory symptoms, asthma, medical history, home, accidental spills, employment history, and demographics. The questions on respiratory symptoms and asthma were adopted from a questionnaire developed at the University of Texas and from the 2nd European Community Respiratory Health Survey (ECRHSII) (<http://www.ecrhs.org/>) (Delclos 2006). The survey will be used to gather the variables necessary to examine the associations between asthma outcomes and workplace exposures in healthcare. In general, these variables include information on demographics, work history, selected occupational exposures, respiratory health outcomes, and potential confounders (e.g., cigarette smoking, allergy status). The parts of the survey that were developed by NIOSH personnel and not modified from previous questionnaires (i.e., medical history, home, accidental spills, employment history, and demographics) have gone through cognitive review by staff at the National Center for Health Statistics (NCHS). The survey has been modified based on the results of that cognitive review.

Outcome variables of interest include incidence of asthma among those without asthma during the 10 years before the survey; incidence of asthma exacerbation among those with current asthma during the past year; and prevalence of asthma-related symptoms during the past year. A range of qualitative or semi-quantitative exposure metrics collected by means of survey questionnaire and quantitative exposure metrics developed through the JEM along with confounders will be calculated for all study participants, and used in the epidemiologic exposure-response analyses. From the questionnaire, the qualitative exposure metrics include the performance of tasks or products (chemicals) used recorded as yes/no, while the semi-quantitative exposure metrics include frequency (day per week) and duration (hours per day) of tasks performed or products used. The quantitative exposure metrics from the JEM include average exposures to 14 specific VOCs and TVOC. The survey focuses on current employment (i.e., the last 12 months) and employment 5 years earlier. The past 10 years was chosen as the

time frame for onset of asthma, and the job held five years before interview will be used to characterize occupational exposures during those 10 years (exclusive of the past 12 months).

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals will be involved in the design, collection and analysis of the data obtained in this study:

Paul Henneberger – Co-Project Officer, CDC NIOSH DRDS, 304-285-6161, pkh0@cdc.gov

M. Abbas Virji - Co-Project Officer, CDC NIOSH DRDS, 304-285-5797, fnb8@cdc.gov

Michael Humann – Project Fellow, CDC NIOSH DRDS, 304-285-6193, uzo1@cdc.gov

Jean Cox-Ganser, CDC NIOSH DRDS, 304-285-5818, jjc8@cdc.gov

Ju-Hyeong Park, CDC NIOSH DRDS, 304-285-5967, gzp8@cdc.gov

Aleksandr Stefaniak, CDC NIOSH DRDS, 304-285-6302, boq9@cdc.gov

Eileen Storey, CDC NIOSH DRDS, 304-285-6382, eps4@cdc.gov

Brian Tift, CDC NIOSH DRDS, 304-285-6315, dlf0@cdc.gov

Xiaoming Liang, CDC NIOSH DRDS, 304-285-6217, cro9@cdc.gov

George Delclos, University of Texas, 713-550-9459. George.delclos@uth.tmc.edu

Gerald Hobbs, West Virginia University, 304-293-3607, ghobbs@stat.wvu.edu

Maria Mirabelli, Wake Forest University, 336-716-2011, mmirabel@wakeheatlh.edu

Jan Paul Zock, Center for Research in Environmental Epidemiology, 34 93 214 73 00
jpzock@creal.cat

Bill Borwegen, Service Employees International Union, 202-730-7385, bill.borwegen@seiu.org

Mark Catlin, Service Employees International Union, 202-730-7290, mark.catlin@seiu.org

Steve Schrag, Service Employees International Union, 203-574-7966,
steven.schrag@sbcglobal.net

Bobby Hocson, Service Employees International Union Local 1199, 212-408-8418,
bobbyh@1199.org

Brendan Shaw, Service Employees International Union Communications Center, 212-603-3783,
brendans@seiucc.org

Michael Witt, Research Triangle Institute International, 919-990-8346, witt@rti.org

Dan Liao, Research Triangle Institute International, 301-816-4605, dliao@rti.org

Kristina Peterson, Research Triangle Institute International, 919-485-7722, kpeterson@rti.org

Matthew Strobl, Research Triangle Institute International, 919-541-7395, mstrobl@rti.org

Kathy Mason, Research Triangle Institute International, 919-541-7010, mason@rti.org

Ariana Napier, Research Triangle Institute International, 919-316-3499, anapier@rti.org

References

CDC. Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007

Delclos GL, Arif AA, Aday L, et al. Validation of an asthma questionnaire for use in healthcare workers. *Occup Environ Med* 2006; 63:173-179

Delclos GL, Gimeno D, Arif AA, et al. Occupational risk factors and asthma among health care professionals. *Am J Respir Crit Care Med* 2007; 175:667-675

Demidenko E. Sample size determination for logistic regression revisited. *Stat Med* 2007; 26:3385-3397

Dillman D. Mail and internet surveys: the tailored design method. New York: John Wiley & Sons; 2000.

Henneberger P LX, Preusse PA, Sama SR, Milton DK. . Occupations associated with exacerbation of asthma. *Proc Am Thoracic Soc* 2008; 4:A525

Rudd RA, Moorman JE. Asthma incidence: data from the National Health Interview Survey, 1980-1996. *J Asthma* 2007; 44:65-70

Zeiss CR, Goma A, Murphy FM, et al. Latex hypersensitivity in Department of Veterans Affairs health care workers: glove use, symptoms, and sensitization. *Ann Allergy Asthma Immunol* 2003; 91:539-545