

Information Collection on Cause-Specific Absenteeism in Schools
Request for OMB Approval of a New Information Collection

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Statement B

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PART B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ) proposes a new information collection on Cause-Specific Absenteeism in Schools. This information collection will focus on evaluating the role of influenza-like illness (ILI)-specific absenteeism in schools in predicting community-wide influenza transmission. Influenza transmission among school-aged children and young adults is frequently predictive of subsequent community transmission. Therefore, early recognition of school-based transmission of influenza could contribute to the timely implementation of mitigation efforts to reduce morbidity and mortality in the wider community (1-2).

The project will be implemented in one school district in Madison, Wisconsin. There are six k-12 grade schools in the participating district in Madison. Information on cause-specific absenteeism will be obtained through telephone contact and in-person interviews.

This information collection will be implemented in Oregon School District, Wisconsin and will target students attending kindergarten to 12th grade (K-12) schools (Attachment C1 Protocol, Attachment C2 School District Approval Letter). The district enrolls about 3,500 students in the following six schools: Oregon High School, Oregon Middle School, Rome Corners Intermediate, Netherwood Knoll Elementary, Prairie View Elementary, and Brooklyn Elementary.

Table 1. Number of students by grade in Oregon School District, Wisconsin (National Center for Education Statistics data, 2012-2013)

	PK	KG	1	2	3	4	5	6	7	8	9	10	11	12	Total per school
Netherwood Knoll Elementary	8	86	90	89	88	83									444
Prairie View Elementary	2	85	71	90	90	79									417
Brooklyn Elementary	3	84	82	89	76	87									421
Rome Corners Intermediate							29 7	278							575
Oregon Middle									262	286					548
Oregon High											253	286	25 1	304	1094

One of the primary goals of the study is to assess the comparability between surveillance based on multiple layers of complimentary influenza surveillance centered on this school district. The principal goal is to establish the comparability of the various data streams, e.g. all-cause absenteeism, illness-associated absenteeism, ILI-associated absenteeism and community-based ILI prevalence. For planning purposes, a correlation of 0.8 was defined between daily or weekly (depending on the temporal resolution of the data stream) variance-stabilized (square-root transformed) counts as an indication of good agreement between the data streams. For weekly counts, the available 111 weeks (37 weeks/year times 3 years) of data will provide 97% assurance that the lower limit of the 95% confidence interval for the correlation coefficient will be no less than 0.8 when the true correlation is at least 0.9. For daily counts, the available 528 days (176 days/year times 3 years) of data will provide 95% assurance that the

lower limit of the 95% confidence interval for the correlation coefficient will be no less than 0.8 when the true correlation is at least 0.85. Thus, the proposed study will be able to identify data streams that are strongly concordant.

A second component of the study involves specimen collection in children with ILI-associated illnesses. The principal goal is to estimate the positive predictive value of ILI-associated illness as a marker of influenza-related illness during each school year/influenza season. The average number of illness-related absences in the Oregon school district is 60-90 per day based on the historical data collected by student absentee monitoring system in Oregon school district, 5-10 of them are ILI related. For the 37 week long school year the number of ILI-related absences is 925-1850. Assuming 30% response rate, an average annual sample size is 500 subjects.

Based on the proposed sample size of 500 specimens per year, the margin of error (half-width of the 95% confidence interval) for the estimated positive predictive value will be at most 4.5%. If the true PPV is 21.4% (based on preliminary data from the Influenza Incidence Surveillance Project), with 90% assurance, the margin of error will be at most 3.8%.

2. Procedures for the Collection of Information

This information collection aims to assess the role of ILI-specific absentee monitoring systems to predict community-wide influenza transmission and will be conducted for a period of three years in kindergarten to 12th grade (K-12) schools of Oregon school district, Wisconsin.

Students and parents/guardians in the school district will be informed about the opportunity to participate in the study at school events, through promotion of information about the study in the community through flyers, posters, post-cards etc. and also using an existing call-in absentee messaging system. In this absentee phone line (the existing message will be modified to include an invitation to participate in the study).

When a student is absent from school and has symptoms such as a sore throat, fever, or other respiratory symptoms, his/her parent or guardian, or an adult student (age 18 or older), can call the study telephone number directly to learn more about participation in this study. The phone will connect to an enrolling surveillance assistant. The surveillance assistant will describe the program and will screen for inclusion and exclusion criteria using the Screening Form. If the student meets eligibility criteria and is willing to proceed, arrangements will be made for a face-to-face household visit for obtaining informed consent and assent, data and specimen collection. During the household visit, trained surveillance assistant will use the Acute Respiratory Infection and Influenza Surveillance Form to collect information about student's illness.

The information collection tools have been submitted as part of this information collection in the statement provided to OMB (see attachments to Statement A). Information collection tools have been reviewed and approved by the IRB at the University of Wisconsin with CDC review and deferral to that IRB. Renewal of IRB approval will be done annually for the duration of the study. An approval letter from the University of Wisconsin and CDC's deferral approval are included with this new information collection request (see attachments to Statement A).

Information collection tools will record symptoms associated with ILI-related absence, travel information (related to influenza exposure), influenza vaccination history, any antiviral treatment received during this episode of ILI.

During the home visit a nasopharygeal or a high oropharyngeal specimen for multiplex PCR testing will be obtained. A foam nasal swab will be used in the nostril with the most discharge to collect material for Rapid Influenza Detection Testing (RIDT).

Estimation procedures

Outcomes will include descriptions of ILI-specific absenteeism over time and the statistical association (including a lag period) between absentee data and influenza surveillance data. Corrections will be made for over/under sampling, non-response, non-standard distributions, covariates, and other unanticipated phenomenon that may skew or bias the information collection and analyses.

Degree of accuracy needed for the purpose described in the justification

DGMQ collects information in order to plan and implement health programs and activities relevant to its public health mission, primarily related to updating CDC's Pre-pandemic Guidance (as described in statement A). The use of simple but scientifically sound recruitment strategies will ensure that DGMQ and partners will collect quality data to inform the potential utility and limitations of cause-specific school absenteeism on community-wide influenza transmission.

Unusual problems requiring specialized sampling procedures

Unusual problems requiring specialized sampling are not expected with this new information collection. If situations occur during the course of the project implementation, requests for changes in the proposed methodologies will be provided to OMB.

Any use of periodic (less frequent than annual) data collection cycles to reduce burden

This information collection will minimize the requests from project participants to the extent possible. Requesting information on multiple episodes of absences from one student may be possible over the course of a project if the period between episodes is at least 30 days. We estimate four absences per student per year in our burden estimates. The estimated burden time for each response is 35 minutes.

3. Methods to Maximize Response Rates and Deal with Non-response

The following procedures that have proven effective in previous studies, will be used to obtain at least an 80% response rate:

- Collaboration with school administrators to promote study in each participating school routinely (flyers and posters) and during school events
- Promotion of the study in the community including posting flyers, sending postcards home with sick students from school, district wide email reminders, district wide postcards sent to students, booklets with information about the study included in the student registration folders before the beginning of each school year.
- The existing message in the absentee call-in line that Oregon school district has been using routinely for the past several years, will be modified to include an invitation to participate in the study. This message would be based on informal feedback from parents within the district: "If your child is sick with a cold or the flu he or she may be eligible to

participate in a public health study looking at the causes of school absences in the Oregon School District. If your family decides to participate, a trained research associate will come to your home at your convenience to ask some brief questions regarding your child's illness and obtain samples from your child using a swab. For participating, your child will receive a Barnes and Noble, iTunes or Firefly Coffeehouse gift card in the amount of \$20. For more information about the study, please call (608) 265-3164"

- Informing respondents of what the project is asking, why it is being asked, who will see the results, and how the results will be used, as well as discussing how respondents will benefit from the results and how the findings will be put into action.
- Only 2.2% of students in the district are with Limited English Proficiency. Due to the small proportion, bilingual forms will not be developed.
- A token of appreciation for a respondent's time and interest will be given to research participants.
- Addressing data security and anonymity with parents/guardians and students over 18 years of age.
- Conducting home visits instead of inviting participants to come to the office
- Informing respondents how much time the project will take so that they know what to expect.
- Attempting to re-contact participants up to a maximum of three times (by phone, text, or email) before the person is considered a non-respondent.
- Obtaining support for information collections from trusted community, education, health and business leaders from the targeted school population.

Possibilities of non-response will pertain to situations when the parent of absent student does not contact researchers to learn about the participation in the study, when parents refuse to provide consent, or when potential candidates are not available for home visit. Widely promoting information about the study in schools and the community, establishing good working relationships with school administrations to promote the study and receive information about absence students on a daily basis, availability of the incentives (including reporting RT-PCR results to participants) for participation in the study are expected to be helpful in maximizing response rate.

4. Test of Procedures or Methods to be Undertaken

The information collection tools that will be used in this project are statistically valid as well as linguistically and culturally appropriate for the targeted populations. The importance of utilizing culturally and linguistically appropriate instruments and procedures is well-documented in the literature and is an important aspect of designing and implementing DGMQ's activities and programs.

The targeted populations in Madison, Wisconsin have participated in previous state-based influenza related research and several of the information collection tools were developed and used in these public health projects. For example, the acute respiratory infection and influenza surveillance form used in Madison has been deployed for the past four years as part of the Wisconsin component of the Influenza Incidence Surveillance Project and was based on a long-standing form used more than 30 years for respiratory virus surveillance by the Wisconsin State Laboratory of Hygiene.

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

The following individuals were consulted to provide advice about the design of statistical and sampling procedures that will be undertaken as part of these data collection activities:

- Clive Brown, MBBS, Associate Director for Science, Division of Global Migration and Quarantine
- Christine Prue, PhD, Health Communication Specialist, Office of the Director, National Center for Emerging and Zoonotic Infectious Diseases
- Hongjiang Gao, PhD, Statistician, Office of the Director, Division of Global Migration and Quarantine
- Jianrong Shi, Statistician, Office of the Director, Division of Global Migration and Quarantine
- Laura Kann, PhD, Program Director, Division of Adolescent and School Health

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- 2) Sasaki A, Hoen AG, Ozonoff A, Suzuki H, Tanabe N, Seki N, Saito R, Brownstein JS. Evidence-based tool for triggering school closures during influenza outbreaks, Japan. *Emerg Infect Dis* 2009;15:1841-3.