

# **Information Collection on Cause-Specific Absenteeism in Schools and Evaluation of Influenza Transmission within Student Households**

**Request for OMB Approval of a Revision to a Currently Approved Information Collection**

**0920-1039**

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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 revision to a currently approved information collection on Cause-Specific Absenteeism in Schools. This revised information collection will focus on evaluating the role of influenza-like illness (ILI)-specific absenteeism in schools in predicting community-wide influenza transmission and detecting within-household transmission of influenza in households from which a student has been absent from school due to an ILI. 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. Information on cause-specific absenteeism and within-household transmission 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 pre-kindergarten to 12th grade (4K-12) schools and their household members (Attachment C1 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)

	P K	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	27 8							575
Oregon Middle									26 2	28 6					548
Oregon High											25 3	28 6	25 1	30 4	1094
<b>Total Oregon School District</b>	<b>13</b>	<b>255</b>	<b>243</b>	<b>268</b>	<b>254</b>	<b>249</b>	<b>297</b>	<b>278</b>	<b>262</b>	<b>286</b>	<b>253</b>	<b>286</b>	<b>251</b>	<b>304</b>	<b>3499</b>

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 300 subjects.

Based on the proposed sample size of 300 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%.

The proposed revision adds a third component to the study, involving the detection of within-household transmission, that will include both survey and biospecimen collection from the household members of eligible students absent due to ILI. A participation rate of 80% from student households is expected, yielding 240 participating families from 300 enrolled students. We estimate that the average household has 4 members including the participant. Accordingly, we would estimate 720 participating household members. We estimate that it will take less than 5 minutes for household members to complete the in-person survey on Day 0 and Day 7 (Household Study Form). Biospecimen collection will likewise take less than 5 minutes per day for household members to complete on both Day 0 and Day 7.

## **2. Procedures for the Collection of Information**

In addition to the original aim of this approved information collection to assess the role of ILI-specific absentee monitoring systems to predict community-wide influenza transmission, this revision adds an aim of also evaluating within-household transmission of influenza in households where a student was absent from school with ILI. This information collection will be conducted for a period of four years in 4K-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. Biospecimen will also be obtained by surveillance assistant during the household visit via nasopharyngeal or oropharyngeal swab. A foam nasal swab will be used in the nostril with the most discharge to collect material for Rapid Influenza Detection Testing (RIDT)

In this revision, household members will also be asked to participate in the revised information collection, whereby informed consent and assent for the household members will be obtained by the study team (Attachment C3a – Household Member Consent/Assent Forms). The surveillance assistant will collect and record data on consenting household members using the Household Study Form (Attachment C4a- Household Study Form). Household members, not present at the time of the household visit, will have the option to complete the study form once they return home and consent/assent to participation, if it is within 24hrs of the initial visit. A designated adult will assist in completion of the form for participating children. Additionally, during the home visit, the research team will obtain nasopharyngeal or oropharyngeal swabs for RT-PCR from consenting household members present at the time of household visit. Participating household members not present at the time of the home visit will provide a nasal swab specimen within 24 hours of the home visit to be stored in the refrigerator until it can be collected by the study team. Seven days following the home visit, all household participants and the designated adult for participating children, excluding the student participant, will complete the "Follow-up" portion of the form (Attachment C4a- Household Study Form) and the designated adult will obtain nasal swab specimens from all household members except for the student participant, to be stored in the refrigerator until specimen pick-up by the research team.

The information collection tools have been submitted as part of this information collection in the statement provided to OMB. 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 (attachments C5 and C6).

Student information collection tools will record symptoms associated with ILI-related absence, travel information (related to influenza exposure), influenza vaccination history, and any antiviral treatment received during this episode of ILI. Household member information collection tool will record household composition, influenza vaccine status, symptoms and severity of illness, related healthcare visits, diagnosis, and treatment, and on (missed) work or school.

#### 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. Additionally, within-household transmission will be assessed and quantified. 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 Community Mitigation Guidelines. 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 7 days. We estimate four absences per student per year in our burden estimates. The estimated burden time for each response is 25 minutes for (absent) students and 20 minutes for household members.

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

During the initial three years of the study, response rate was progressively increasing when information about the study was reaching to a wider community in this school district. Family Educational Rights and Privacy Act (FERPA) that protects the privacy of student education records, precludes the study team from contacting student families directly. Therefore, various methods for encouraging students and their parents to contact the study team were developed:

- The existing message in the absentee call-in line that Oregon school district has been using routinely for the past several years, was modified to include an invitation to participate in the study: *“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”*
- Close collaboration with school and school district administrators allows to promote the study during school events, via electronic letters to parents and on school websites.
- Currently, a token of appreciation for a respondent’s time and interest is provided to each student participant. In the newly added household component, a \$30 gift card will be provided to each participating family as an incentive for completion of the household study. Informal polling of families was conducted by the study team that indicated that this would be an appropriate amount. The card would be provided at the time of specimen pick-up.
- The study team provides results of rapid influenza testing to parents within one day of the household visit and biospecimen collection. This was demonstrated to serve as an incentive for student families to participate in the study and increased participation.
- The study is promoted in the community with 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.

- Study team conducts home visits instead of inviting participants to come to the office
- Study team attempts to re-contact participants up to a maximum of three times (by phone, text, or email) before the person is considered a non-respondent.

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 used in the previous three years of the study and was previously deployed 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

#### **References**

- 1) Kara EO, Elliot AJ, Bagnall H, Foord DG, Pnaiser R, Osman H, Smith GE, Olowokure B. Absenteeism in schools during the 2009 influenza A(H1N1) pandemic: a useful tool for early

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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.