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Pertussis and the Minnesota State Fair: Demonstrating a Novel Setting for Efficiently Conducting Seroepidemiologic Studies

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Abstract

Seroepidemiologic studies, which measure serum antibody levels produced in response to infection and/or vaccination, can be valuable tools for gaining insight into population level dynamics of infectious diseases. However, because seroepidemiologic studies are expensive and logistically challenging, they are not routinely conducted for surveillance purposes. We have identified a novel venue, state fairgrounds, in which annual sera samples from a population may be rapidly collected with minimal recruitment expenses. We conducted a pilot pertussis seroepidemiologic study over the course of 3 days at the 2016 Minnesota State Fair to determine if this setting, which hosts nearly 2 million visitors over 12 days each year, is viable for facilitating larger seroepidemiologic studies. A total of 104 adults and children were enrolled to provide a finger stick blood sample for serologic testing and to take a written survey regarding recent cough illness and pertussis vaccination. The survey was used to distinguish between antibodies induced by vaccination and pertussis infection. Elevated antibodies suggestive of recent infection were found among two adults. The prevalence of undetectable antibodies, suggestive of susceptibility, was 72.3% (95% CI 59.6, 85.1%) among 7–17 year olds, 53.8% (95% CI 26.7, 80.9%) among 1–6 year olds, and 23.3% (95% CI 8.2, 38.5%) among adults. Our ability to rapidly enroll participants and collect satisfactory specimens suggests that seroepidemiologic studies with 1000–2000 participants could efficiently be completed over the 12-day course of the Minnesota State Fair. This setting raises the possibility of efficiently conducting annual population-based seroepidemiologic studies to supplement traditional public health surveillance in estimating disease prevalence, monitoring vaccine impact, and identifying at-risk groups.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Research Involving Human Participants All procedures performed in this study involving human participants were in accordance with the ethical standards of the University of Minnesota and the Minnesota Department of Health Institutional Review Boards and with the 1964 Helsinki declaration.

Informed Consent Written informed consent was obtained from study participants aged 18 years or older and from guardians of participants under the age of 18 years. Written informed assent was obtained from participants aged 7–17 years.

Keywords

Serology; Infectious diseases; Vaccination; Pertussis

Introduction

Seroepidemiologic studies, which measure sera antibody levels produced in response to infection and/or vaccination, can be valuable tools for gaining insight on population level dynamics of infectious diseases [1]. The use of seroepidemiologic studies in pertussis research illustrates their contribution to estimating population susceptibility and infection prevalence. Pertussis (whooping cough) is a bacterial respiratory infection with illness characterized by paroxysmal coughing that may be followed by vomiting and a whooping noise upon inhalation. Compared to unvaccinated children, adults and previously vaccinated children may experience less severe illness [2, 3]. Surveillance in the United States, which consists of case reports from health care providers and laboratories, underestimates true pertussis incidence by primarily capturing clinically apparent disease. Infections that remain undetected have contributed both to the persistence of cyclic pertussis outbreaks every 2–5 years and to the resurgence of pertussis following near elimination in the 1970s [4, 5]. In various populations, seroepidemiologic studies have been conducted to identify adults as a common source of unrecognized transmission [6–8]. Additionally, seroepidemiologic studies have been used to identify age groups with low pertussis antibody levels suggestive of susceptibility due to waning of vaccine-acquired immunity [9]. Because vaccination records cannot capture the unobserved effects of vaccine failure, waning immunity, and natural boosting (boosting of immunity in partially immune individuals exposed to infection), serologic data can complement vaccination records and provide a more accurate measure of population immunity [10, 11].

Pertussis seroepidemiologic studies have previously been conducted to identify potential areas for public health intervention and to assess vaccine impact on population immunity; however, seroepidemiologic studies are commonly restricted to one time point, limiting their ability to elucidate temporal trends [8, 9, 12]. Campbell et al. conducted serologic testing at three time points (1997, 2002, and 2007) that coincided with different phases of the epidemic cycle of pertussis [13]. They found that an increased prevalence of undetectable antibody levels among children preceded a record pertussis outbreak in Australia. Though Campbell et al. measured population antibody levels at three time points that coincided with different points of the pertussis epidemic cycle, the surveys were conducted in non-consecutive years and spanned 10 years, during which time changes were made to both the pertussis vaccine composition and schedule. To build upon previous seroepidemiologic research, one would ideally conduct a study that sampled a single population annually in consecutive years over the full epidemic cycle of pertussis, which typically lasts 2–5 years years. Understanding demographic-specific temporal trends in susceptibility and undetected infections as they relate to the recurrence of outbreaks would highlight opportunities for targeted interventions to disrupt sustained transmission. However, seroepidemiologic studies can be expensive and logistically difficult to conduct. Consequently, seroepidemiologic

studies are not routinely used to assess population-based temporal trends of infectious diseases [14].

The main challenge presented by prospective seroepidemiologic studies that aim to monitor changes in population-level immunity over time is collecting sera samples from a wide range of age groups drawn from the same population. Specimen collection for serologic testing is generally expensive, time consuming, and labor-intensive. Alternatively, relying on stored sera limits our ability to track immunity prospectively while monitoring changes in the epidemiology of a given disease in a given time and place. Previous pertussis seroepidemiologic studies that utilized population sampling to recruit several 100 participants to study centers have reported enrollment periods approaching 1 year, a rate that would be taxing for studies seeking to obtain annual samples [8, 12]. In a study that measured immunity among school-aged children, Kelly et al. reported that the cost per specimen from a population-based random sample was 11 times greater than the cost per specimen obtained from residual sera [15]. Though immediately available, samples obtained from residual sera from diagnostic laboratories are subject to selection bias and may not be generalizable to a population of interest [16]. A trade-off therefore exists between expenditure of time and money and enrollment of a tailored study sample that can provide a complete picture of population level dynamics over time.

Notably, the National Health and Nutrition Examination Survey (NHANES) has been collecting sera specimen annually in the United States since the 1980s. However, the manner in which the specimens are collected is intended to provide a sample that is representative of the nation as a whole. As such, the sample cannot be assumed to be representative of individual states [17]. This limits the usefulness of these data for understanding state-level trends in vaccine-preventable diseases. Importantly, Rohani et al. examined state-specific pertussis incidence rates over time and found that trends varied by spatial location [18]. States may experience varied trends in vaccine-preventable diseases due to demographics, state laws, and surveillance practices [19]. Consequently, nationwide samples may be inadequate for certain research questions. The need exists for state-specific venues that can provide an opportunity to collect sera specimens on an ongoing basis.

We hypothesize that state fairgrounds may provide a novel venue for conducting seroepidemiologic studies by enabling recruitment of a large number of individuals in a short period of time at a relatively low cost. The Minnesota State Fair attracts between one and two million visitors over a 12 day period each year, with visitors encompassing a large age range and representing diverse backgrounds [20, 21]. We hypothesize that this venue will allow us to efficiently conduct a pilot pertussis seroepidemiologic study on a sample of Minnesota residents consisting of both adults and children. If this setting is deemed feasible following our pilot study, we foresee it facilitating larger seroepidemiologic studies for both pertussis and other infectious diseases, with an emphasis on studies dedicated to assessing temporal serologic trends in a specific population.

Methods

Study Population

Study participation was open to individuals aged 1 year and older with primary residence in Minnesota. Individuals under the age of 18 years required permission from a legal guardian to participate. We used an age-stratified sampling mechanism with an enrollment goal of 90 total participants drawn equally from the following age groups: 1–6, 7–17, and ≥ 18 years. The bounds of these age groups were based in part on the recommended pertussis vaccination schedule, which calls for five doses of pertussis-containing vaccine by the age of 6 years [22]. As waning of vaccine-acquired immunity has been observed following completion of the pertussis vaccination series, we anticipated these age groups to differ with respect to estimates of susceptibility and undetected infections [11, 23, 24]. Although heterogeneity in exposure to vaccination recommendations and infection exists in these age groups, particularly among adults, the sample size of this pilot study restricted further stratification.

Participant Recruitment

Participant recruitment and enrollment occurred over a 3-day period (August 29, August 31, and September 1) at the 2016 Minnesota State Fair. The University of Minnesota (UMN) has an existing research facility on the fairgrounds, the Driven to Discover (D2D) building. In 2016, 12,476 fairgoers participated in 26 UMN research projects on the fairgrounds. Two methods were used to recruit participants: (1) a UMN D2D mobile application detailing the nature of the study and outlining study eligibility; (2) active recruitment using study staff stationed outside of the D2D building.

Sample Collection and Serologic Testing

Serologic testing was conducted on participant blood samples to quantify pertussis antibody levels. A minimum of 50 μL of blood was collected by finger stick and allowed to clot for 30 min at room temperature. Specimens were centrifuged on site in Serum Separator Tubes (SST) for 90 s at 6000–15,000×*g* to isolate serum from blood cells. Centrifuged samples were immediately refrigerated. Specimens were transported on ice to the Minnesota Department of Health Public Health Laboratory (MDH–PHL) for testing at the end of each day. Antibody levels were quantified using an IgG anti-PT ELISA assay that was developed by the Centers for Disease Control and Prevention and validated at MDH–PHL for use with acute or convalescent serum specimens [25]. The assay measures antibody levels against pertussis toxin, a pertussis-specific antigen that is produced by the bacterium *Bordetella pertussis* and is a component of pertussis vaccines. We categorized antibody levels according to commonly used cut-off values, with a concentration above 62.5 IU/mL indicating infection or vaccination within the past year (Table 1) [26]. An undetected infection was defined as a participant who met all of the following criteria: (1) had antibody levels > 62.5 IU/mL; (2) reported no pertussis vaccination within the past year; (3) reported no diagnosis of pertussis by a healthcare provider within the past year. Participants with undetectable antibody levels (< 5 IU/mL) were considered susceptible [26].

Survey

Study participants completed a brief, paper-based survey. To distinguish between recent vaccination and recent infection in individuals with elevated antibody levels, participants were asked to self-report whether they had received a pertussis-containing vaccine (DTaP, DTP, or Tdap) within the past year. Additionally, participants were asked if they had been diagnosed with pertussis or experienced a cough illness lasting at least 2 weeks during the past year. Individuals reporting a cough illness were asked if the coughing occurred in spasms (paroxysmal coughing), if the coughing was followed by vomiting (post-tussive vomiting), and if the coughing was followed by a high-pitched “whoop” noise (whooping). The presence of one of these symptoms in addition to a 2 week cough meets the clinical case definition for pertussis and was used to determine if an infection was clinically apparent [27]. Basic demographic information (age, gender, race, ethnicity, education, and home zip code) was also collected from participants during the survey.

Ethical Considerations

This study was reviewed and approved by the UMN and MDH Institutional Review Boards. Written informed consent was obtained from study participants aged 18 years or older and from guardians of participants under the age of 18 years. Written informed assent was obtained from participants aged 7–17 years.

Results

The primary aim of this study was to determine the feasibility of conducting a rapid seroepidemiologic study in the unique setting of a fairground. We were able to reach our total enrollment goal and obtain specimens that were satisfactory for testing (i.e., sufficient volume, integrity uncom-promised). We conservatively anticipated processing five participants per hour during each of our three allotted study shifts on the fairgrounds. Each shift lasted 6 h, totaling an expectation of 30 participants per day. We easily exceeded our projected rate of enrollment on the first day of the study with over 50 study participants enrolled. During the remaining 2 days of the study, we intentionally slowed recruitment efforts, as our study budget restricted testing to 90 specimens. Based on recruitment numbers from this pilot study, projected enrollment for a future seroepidemiologic study is shown in Table 2. Note that the projected numbers are based on conducting a study during one of the two available 6 h shifts on the fairgrounds each day. Enrollment numbers would double if both shifts were used.

We enrolled 104 participants to ensure that we would have 90 testable specimens in the event that specimens were of insufficient volume, haemolysis occurred during collection, or specimens were processed incorrectly. Children aged 1–6 years were difficult to enroll without active recruitment by study staff, which resulted in the decision to allow a larger percentage of participants in the older age groups. The demographics of study participants are shown in Table 3. We compared the demographics of study participants to Minnesota demographics from the 2016 American Community Survey (ACS) to assess if our sample was representative of the state population. Study participants were primarily white and not Hispanic or Latino, similar to the state’s racial and ethnic profile. Compared to the

Minnesota population, study participants were more likely to be female and to reside within the seven county metro area.

The distribution of serologic results is shown in Fig. 1. The prevalence of undetectable antibody levels was 53.8% (95% CI 26.7, 80.9%) in the 1–6 year age group, 72.3% (95% CI 59.6, 85.1%) in the 7–17 year age group, and 23.3% (95% CI 8.2, 38.5%) in the ≥ 18 year age group. Self-report of pertussis vaccination in the past year among individuals with undetectable antibody levels was 42.9% (95% CI 6.2, 79.6%), 14.7% (95% CI 2.8, 26.6%), and 14.3% (95% CI 0.0, 40.2%) in the 1–6, 7–17, and ≥ 18 year age groups, respectively. Of note, elevated antibodies suggestive of recent infection were found among two adults, neither of whom reported vaccination, pertussis diagnosis, or pertussis-specific symptoms in the past year.

Discussion

The results of this pilot study demonstrate that a fairground setting is a viable option for efficiently conducting seroepidemiologic studies within the scope of a state population. Our ability to enroll participants and collect satisfactory specimens suggests that larger seroepidemiologic studies with 1000–2000 participants could feasibly be completed over the course of 12 days. Specifically, a fairground setting could facilitate annual population sampling to monitor serologic trends in a single population over time. Contrary to relying on residual sera or NHANES samples, our specimen collection allowed for sampling of tailored subgroups and collection of disease-specific variables (i.e., self-report of symptoms, vaccination history, and clinical diagnosis) via participant surveys.

The limited sample size of our pilot study prohibits statistical inference; however, our data suggest that children may have a higher prevalence of undetectable pertussis antibody levels than do adults. Heightened susceptibility among children as compared to adults has been observed in seroepidemiologic surveys in other countries [13, 28]. Specifically, Campbell et al. observed an increased prevalence of undetectable antibody levels among children preceding a record outbreak in Australia [13]. Observing temporal variation in the prevalence of undetectable antibody levels among children despite consistent vaccination coverage may be suggestive of a change in the circulation of *B. pertussis* within a population. Our pilot study demonstrates that we could feasibly use the Minnesota State Fair to obtain annual sera samples over the course of a full epidemic cycle to find a reliable surveillance measure that is indicative of an impending outbreak year. Additionally, demographic-specific trends interpreted in combination with routine surveillance data may highlight a subgroup in which targeted intervention could disrupt sustained transmission between outbreak years. Although cut-off values for serologic pertussis testing are not definitive, focusing on relative changes over time in a single population will produce directly comparable results that should be subject to less uncertainty as we use seroepidemiologic studies to better understand local dynamics of the epidemic cycle of pertussis [26].

In addition to providing estimates of population susceptibility and infection prevalence for infectious diseases, large seroepidemiologic studies conducted on fairgrounds could be used to efficiently monitor vaccine impact [28]. Serologic data can inform public health policy by

identifying susceptible subgroups that may benefit from an adjustment to vaccine recommendations. Importantly, the fixed timing of the state fair each year would control for seasonal effects [29]. Although our study focused on pertussis, this unique opportunity for serologic surveillance could be extended to other infectious diseases, including influenza. Miller et al. used sera samples collected in two consecutive years to establish an immunity profile in an English population before and after a wave of influenza infection [30]. The authors concluded that continued serologic studies would be beneficial to understanding the epidemiology of specific subtypes and providing data to inform parameters for prediction models. State fairgrounds present a logistically simple solution for such sustained research.

We acknowledge that our study sample may not be representative of the state of Minnesota. Metropolitan residents were overrepresented, which is not unexpected given that the fairgrounds are located in a metropolitan county. Future studies could stratify enrollment based on county of residence or adjust the target population to the seven county metro, which contains over half of the state's population. Additionally, selection bias in our study is possible if health status or vaccination status impacted participation. Under this assumption, we would expect participants to be less likely to have pertussis and more likely to be vaccinated as compared to non-participants. However, since we were assessing pertussis illness over the past year with serologic results, we would still expect to capture a high percentage of previously infected individuals. Of note, we did not meet our enrollment goal for children under the age of 6 years. Enrolling young children required active recruitment by study staff stationed outside of the research building, and this age group was not preferentially targeted for enrollment until the last day of the study. Studies seeking to enroll participants in this age group, or from any specific subgroup, would benefit from targeted recruitment for the duration of the study. Additionally, our study's self report of vaccination within the past year would benefit from verification with vaccine records.

We recognize that at this time, Minnesota may be uniquely positioned to leverage such an opportunity due to the existence of UMN's D2D building dedicated to staging research projects on the state fairgrounds. Additionally, Minnesota had the second highest total attendance among state fairs in 2016 [31]. To our knowledge, no other state is utilizing a fairground setting to access a sample of residents for research purposes, specifically serological surveillance. Minnesota can serve as a model for implementing this novel sampling mechanism that bypasses many of the logistical challenges of seroepidemiologic studies.

In conclusion, the results of this pilot study demonstrate that state fairgrounds can be utilized to recruit participants for seroepidemiologic studies with minimal expenditure of time or money. Our results raise the possibility of conducting routine population-based seroepidemiologic studies to supplement traditional public health surveillance in estimating disease prevalence, monitoring vaccine impact, and identifying at-risk groups.

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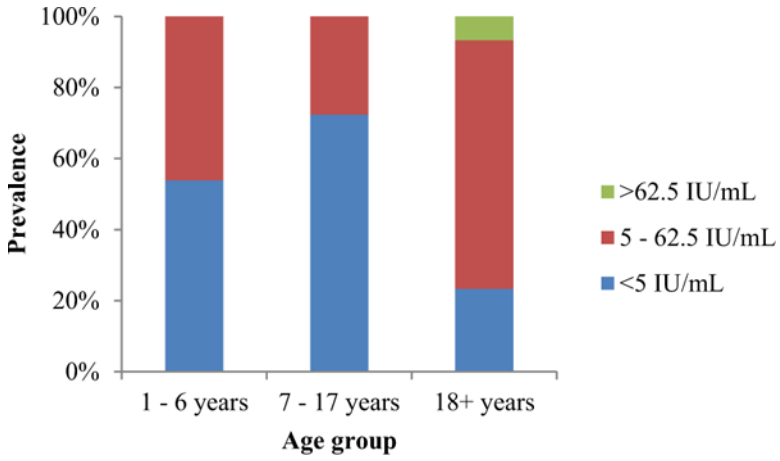

Fig. 1.
IgG anti-PT antibody levels (IU/mL) in 2016 sample of Minnesota residents

Table 1

Interpretation of IgG anti-PT ELISA results

IgG ELISA result	Interpretation
< 5 IU/mL	Susceptible
5–62.5 IU/mL	Non-recent vaccination or infection with pertussis
> 62.5 IU/mL	Recent[a] vaccination or recent infection with pertussis

[a]Recent refers to past 12 months

Table 2

Enrollment numbers for pilot study and projection to future studies

	Pilot study	Future study
Total participants	104	1200
Study duration (days)[a]	3	12
Recruitment rate (participants/h)	5.8	16.7

[a]One study shift per day consisting of 6 h

Table 3

Participant demographics compared to 2016 population of Minnesota

Variable	Study N (%)	Minnesota 2016 ACS (%)
Age group		
1–6 years	18 (17.3%)	N/A[a]
7–17 years	53 (51.0%)	N/A[a]
≥ 18 years	33 (31.7%)	N/A[a]
Race		
American Indian or Alaskan Native	0 (0.0%)	1.1%
Asian	2 (1.9%)	4.7%
Black or African American	4 (3.9%)	6.0%
Hawaiian or other Pacific Islander	0 (0.0%)	0.0%
White	88 (84.6%)	83.3%
Multiracial	6 (5.8%)	2.8%
Other	3 (2.9%)	2.0%
Unknown	1 (1.0%)	0.0%
Ethnicity		
Hispanic or Latino	7 (6.7%)	5.2%
Not Hispanic or Latino	95 (91.3%)	94.8%
Unknown	2 (1.9%)	0.0%
Highest level of education completed		
≤ High school diploma or GED	69 (66.3%)	N/A[a]
High school diploma or GED	14 (13.5%)	N/A[a]
Associate's or bachelor's degree	13 (12.5%)	N/A[a]
Graduate or professional degree	5 (4.8%)	N/A[a]
Unknown	3 (2.9)	N/A[a]
Metropolitan resident		
Yes	68 (65.4%)	55.0%
No	33 (31.7%)	45.0%
Unknown	3 (2.9%)	0.0%
Gender		
Female	60 (57.7%)	50.2%
Male	44 (42.3%)	49.8%

[a]Study data not compared to Minnesota population due to age-stratified sampling