



## Major Article

## Take-home kits to detect respiratory viruses among healthcare personnel: Lessons learned from a cluster randomized clinical trial



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## A B S T R A C T

**Background:** Health care personnel (HCP) working in outpatient settings routinely interact with patients with acute respiratory illnesses. Absenteeism following symptom development and lack of staff trained to obtain samples limit efforts to identify pathogens among infected HCP.

**Methods:** The Respiratory Protection Effectiveness Clinical Trial assessed respiratory infection incidence among HCP between 2011 and 2015. Research assistants obtained anterior nasal and oropharyngeal swabs from HCP in the workplace following development of respiratory illness symptoms and randomly while asymptomatic. Participants received take-home kits to self-collect swabs when absent from work. Samples mailed to a central laboratory were tested for respiratory viruses by reverse transcription polymerase chain reaction.

**Results:** Among 2,862 participants, 3,467 swabs were obtained from symptomatic participants. Among symptomatic HCP, respiratory virus was detected in 904 of 3,467 (26.1%) samples. Self-collected samples by symptomatic HCP at home had higher rates of viral detection (40.3%) compared to 24% obtained by trained research assistants in the workplace ( $P < .001$ ).

**Conclusions:** In this randomized clinical trial, take-home kits were an easily implemented, effective method to self-collect samples by HCP. Other studies have previously shown relative equivalence of self-collected samples to those obtained by trained healthcare workers. Take-home kit self-collection could diminish workforce exposures and decrease the demand for personnel protective equipment worn to protect workers who collect respiratory samples.

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## BACKGROUND

In the workplace, health care personnel (HCP) are routinely exposed to viruses that cause acute respiratory illnesses (ARI,<sup>1,2</sup>). Transmission of infections among and between HCP, patients and co-workers, and workplace absenteeism pose major productivity and economic challenges.<sup>2–4</sup> During large, infectious disease outbreaks, such as the current Coronavirus Disease 2019 (COVID-19) pandemic, timely and wide availability of diagnostic assays facilitate surveillance and improve understanding about community disease burden. Unfortunately, already strained clinical care facilities can become increasingly stressed during a pandemic, resulting in shortages of personal protective equipment (PPE) and staff.<sup>5</sup> In attempts to mitigate this burden, alternative testing methods have been employed including walk-through and drive-through remote testing sites.<sup>6–9</sup> Drive-through testing in particular has been successful at greatly reducing the use of gowns and masks,<sup>6</sup> maintaining social distancing outdoors, and offering a convenient method for most families and healthcare workers.<sup>7–9</sup> However, there are still some limitations to using drive-through or walk-through remote sites for testing. Since testing is still performed by HCP, the burden on staff is not mitigated and sometimes increased due to the need for additional nonclinical staff to coordinate the remote testing site's activities.<sup>9</sup> Although PPE use is decreased, staff must at least change gloves between each patient so there is only a small reduction in demand on gloves.<sup>6</sup> Site-specific challenges could include patients not following pre-screening or specified line procedures,<sup>9</sup> and “hot zones” for uncooperative children to be tested outside a car, requiring more PPE turnover and increasing potential exposures.<sup>8</sup> As additional testing is sought, universal issues are longer lines of cars, delays in obtaining and communicating results, and extended working hours.<sup>7,9</sup> Home collection of samples could further reduce PPE use, staff burden, and potential exposures, while potentially increasing patient satisfaction by avoiding long lines and occurring in the convenience of one's own home. For HCPs, in home collection of respiratory samples to identify viral respiratory pathogens may decrease workplace exposures and decrease ‘presenteeism’ since knowledge of a viral infection should encourage HCPs to quarantine at home until the infectious period has passed.

The Respiratory Protection Effectiveness Clinical Trial (ResPECT,<sup>10,11</sup>) was conducted at seven geographically distributed U. S. health systems between 2011 and 2015 and compared several types of respiratory protection in preventing viral respiratory infections among HCP. In order to compare rates of respiratory illness and infection stratified by intervention type for this parent study, research assistants (RAs) obtained nasal and oropharyngeal (N/OP) swabs from symptomatic, as previously described,<sup>10,11</sup> and asymptomatic HCP who reported to work. In addition, each HCP was provided take-home kits (THKs) to self-collect respiratory samples in their home to avoid the problem of presenteeism.<sup>12–14</sup> The rates of detection of respiratory viral pathogens isolated from these two sampling methods were compared in this secondary analysis. To determine the feasibility and utility of this approach, we compared the number and rate of respiratory pathogens detected in samples obtained by RAs from only the symptomatic participants to those symptomatic HCPs self-collected at home using THKs.

## METHODS

### Setting and participants

ResPECT<sup>10,11</sup> was a cluster randomized clinical trial conducted over four 12-week influenza/respiratory virus seasons between 2011 and 2015 among HCP working in 137 outpatient settings at seven medical centers from across the United States. The research protocol

was registered at clinicaltrials.gov (NCT01249625) and approved by the Institutional Review Boards at the National Institute for Occupational Safety and Health (protocol #10-NPPTL-O5XP) at the Centers for Disease Control and Prevention, the seven clinical study sites, and the affiliate sites where data and samples were stored. Study subjects signed written informed consent.

All participating HCP were surveyed daily for signs and symptoms consistent with respiratory infections: fever, tachypnea, coryza, lymphadenopathy, vomiting/nausea, diarrhea, cough, sputum production, fatigue, malaise, headache, sore throat, dyspnea, chills, sweats, arthralgias/myalgias/body aches, and/or other gastrointestinal symptoms.<sup>10,11</sup> Swabs were collected prospectively by RAs whenever a HCP reported symptoms in their workplaces or by self-collection at home using a THK, except when symptoms occurred within seven days from a previous sample collection. Additionally, RA-obtained samples were collected twice for each participant during each 12-week influenza/respiratory virus season: once during a randomly assigned week at each study site within the first 6 weeks and again during the last six weeks. When the randomly timed swabs were obtained, participants were asked if they were experiencing symptoms of respiratory illness. Participants with study-defined respiratory symptoms<sup>10,11</sup> when randomly scheduled for an asymptomatic swab were labeled “symptomatic.” Only samples from symptomatic participants were compared in this analysis.

### Data collection

An Internet-based survey tool, Research Electronic Data Capture (REDCap; Vanderbilt, Nashville, TN<sup>15</sup>), was used to monitor participant signs and symptoms to ensure timely information collection and assure collection of symptomatic samples within the period of viral shedding.<sup>16</sup>

### Swab collection and testing

Trained RAs collected N/OP flocked swabs (FLOQSwabs in Universal Transport Medium (99-08024), Diagnostic Hybrids; Athens, OH) from HCP with symptoms of ARIs. Before the start of each respiratory virus season, THKs containing these swabs were provided to each study participant to self-collect their own swabs at home, if and when they developed ARI symptoms while absent from work. If participants reported to work with symptoms, RAs obtained the samples. Once a THK was used, a new one was provided to the participant for future self-collection, if needed.

In addition to flocked swabs, THKs contained RA contact information, instructions and pictograms for obtaining N/OP swabs (Appendix A), instructions for safely and properly returning the specimens (Appendix B), and directions for shipping (Appendix C) under Category B (UN3373) dangerous goods and hazardous materials.<sup>17</sup> Participants placed the swabs in one 3 mL specimen tube containing universal transport medium for returning by courier to microbiology laboratory at each study site.

All respiratory samples were aliquoted into 500  $\mu$ L volumes, frozen at  $-80^{\circ}\text{C}$ , and tested for 17 viruses (Appendix D) by RT-PCR and electrospray ionization mass spectrometry (RT-PCR/ESI-MS).<sup>18,19</sup> Nucleic acid was extracted from each aliquot with the Arrow Viral NA kit (DiaSorin, Stillwater, MN), and each extract was amplified and analyzed with the respiratory virus surveillance 2.5 kit via the PLEX-ID platform (Abbott Molecular, Des Plaines, IL). Positive control reactions from the NATtrol Respiratory Validation Panel 3 (Zeptomatrix Corporation, Buffalo, NY) were included in each extraction and amplification run. Positive reactions were defined as those with a Q score  $\geq 0.9$ , where the Q score is a measure of the confidence of an identified positive. The respiratory virus surveillance kit identified influenza A and B, adenoviruses, four endemic coronaviruses, rhino/

**Table 1**

Total count, ratio, and viral capture effectiveness (VCE) for all collected samples, positive samples, and pathogens identified across all influenza/respiratory virus seasons. Samples are evaluated by research assistant-obtained swabs (RA) and those self-collected (take-home kits, THK)

Type	Total count			% of Total pathogens identified				Viral capture effectiveness (VCE)			
	THK	RA	Total	THK	RA	Total	<i>P-value*</i>	THK	RA	Total	<i>P-value*</i>
Total symptomatic samples collected <sup>†</sup>	439	3028	3467								
	12.7%	87.3%									
Total symptomatic samples positive for acute respiratory illnesses (ARIs) <sup>‡</sup>	177	727	904					40.3%	24.0%	26.1%	<.001
	19.6%	80.4%									
Total pathogens identified <sup>§</sup>	181	746	927					41.2%	24.6%	26.7%	<0.001
	19.5%	80.5%									
Adenovirus	2	7	9	1.1%	0.9%	1.0%		0.5%	0.2%	0.3%	
Coronavirus (HKU1, NL63, OC43, 229E)	54	274	328	29.8%	36.7%	35.4%		12.3%	9.0%	9.5%	<.05
Influenza A & B	54	106	160	29.8%	14.2%	17.3%	<0.001	12.3%	3.5%	4.6%	<.001, <sup>  </sup>
Metapneumovirus	3	38	41	1.7%	5.1%	4.4%		0.7%	1.3%	1.2%	
Parainfluenza Viruses (PIV) 1–4	4	6	10	2.2%	0.8%	1.1%		0.9%	0.2%	0.3%	<.05
Rhino/Enteroviruses	45	233	278	24.9%	31.2%	30.0%		10.3%	7.7%	8.0%	
Respiratory Syncytial Virus (RSV)	19	82	101	10.5%	11.0%	10.9%		4.3%	2.7%	2.9%	

\**P*-value refers to take-home kit (THK) vs research assistant-obtained (RA) samples.

<sup>†</sup> Total and percent symptomatic samples from all swabs collected.

<sup>‡</sup> Total and percent lab-confirmed positive samples from all symptomatic swabs collected.

<sup>§</sup> Total and percent pathogens identified from all symptomatic samples collected. Each sample and unique pathogen identified from a single sample count individually in the table (i.e. some samples diagnosed with >1 pathogen).

<sup>||</sup> *P* < .05, RA-obtained vs. Total samples.

enteroviruses, human metapneumovirus, respiratory syncytial virus (RSV), and parainfluenza viruses (PIV) 1–4.

### Data analysis

Based on RT-PCR/ESI-MS results, the number and percentage of total pathogens by each collection method were compared in this post-hoc subanalysis. We defined effectiveness for each specimen procurement method as the viral capture effectiveness (VCE), expressed as the ratio of positive samples over total samples (Table 1 and Fig 1). A two-sided, two-sample *z*-test was used to determine the significance of differences between sample proportions, with a *P* < .05 considered significant. All analyses were done using R version 3.6.1 statistical software (R Foundation for Statistical Computing, Vienna, Austria).

## RESULTS

### Enrollment and swab collection

There were 1,602 unique participants that provided a symptomatic swab from 2011 to 2015 (2,292 person-seasons). Of the person-seasons with a symptomatic swab, 1,891 provided only an RA-obtained sample and never used a THK while 401 provided at least one THK sample (Table 2). Most participants were female, Caucasian, influenza-vaccinated 30–59 year olds working in adult patient-care facilities. Clinicians (nurses and physicians) make up a higher proportion for THK usage than for RA-only samples, while the proportion of clinical support and administrative staff providing at least one THK is smaller than those that only provided RA-obtained samples.

Among 2,862 unique participants from 2011 to 2015, 3,467 swabs were obtained from symptomatic participants (Table 1). Of those, 3,028 (87.3%) were procured by RAs while 439 (12.7%) were self-collected (Fig 1A). Respiratory viruses were identified in 904 (26.1%) of all 3,467 samples tested, including asymptomatic and symptomatic HCW: 177 (19.6%) were self-collected and 727 (80.4%) were RA-obtained.

The VCE for home self-collected swabs was 40.3% compared to 24.0% for those obtained from symptomatic HCW in the workplace by RAs across all years (*P* < .001, Fig 1B, Table 1). The increased rate of isolation of viral pathogens from self-collected swabs was

observed for all respiratory virus seasons, and reached significance for seasons 1, 2, and 4 (Table 1).

### Virus prevalence

The proportion of each pathogen among all identified pathogens overall years of the study varied significantly by collection method. Influenza A and B (29.8% vs 14.2%, *P* < .001) constituted a greater proportion of the positive self-collected swabs compared to RA-obtained swabs (Table 1). Adenovirus, coronaviruses, rhino/enteroviruses, metapneumovirus, PIV 1–4, and RSV each made up comparable proportions of total pathogens identified by either collection method.

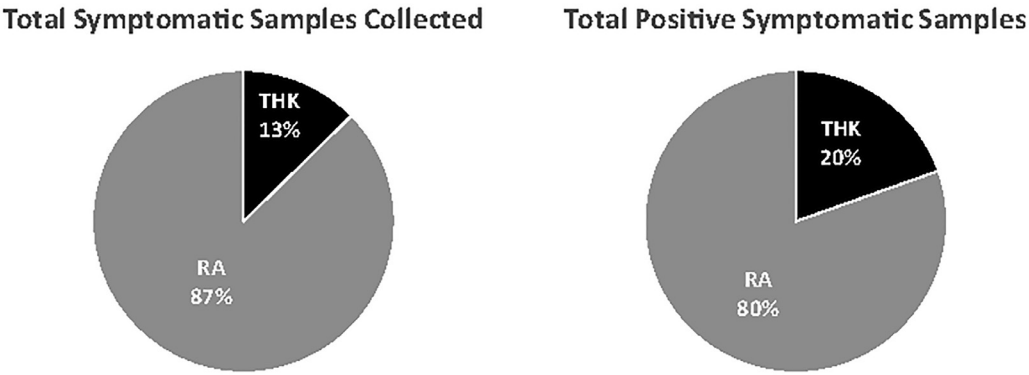
### VCE

To account for the disparate rates between collection methods for both ARIs as well as specific viral pathogens, the VCE was calculated for each pathogen count relative to all samples tested. Self-collected swab VCEs were greater than those from RA-obtained swabs for coronaviruses (12.3% vs 9.0%, *P* < .05), influenza A and B (12.3% vs 3.5%, *P* < .001), and PIV 1–4 (0.9% vs 0.2%, *P* < .05, Table 1). The addition of self-collected samples at home led to a significant recovery of detected influenza A and B viruses versus using RA-obtained swabs alone (4.6% vs 3.5%, *P* < .05). The VCE for adenovirus, rhino/enteroviruses, metapneumovirus, and RSV was similar between collection techniques.

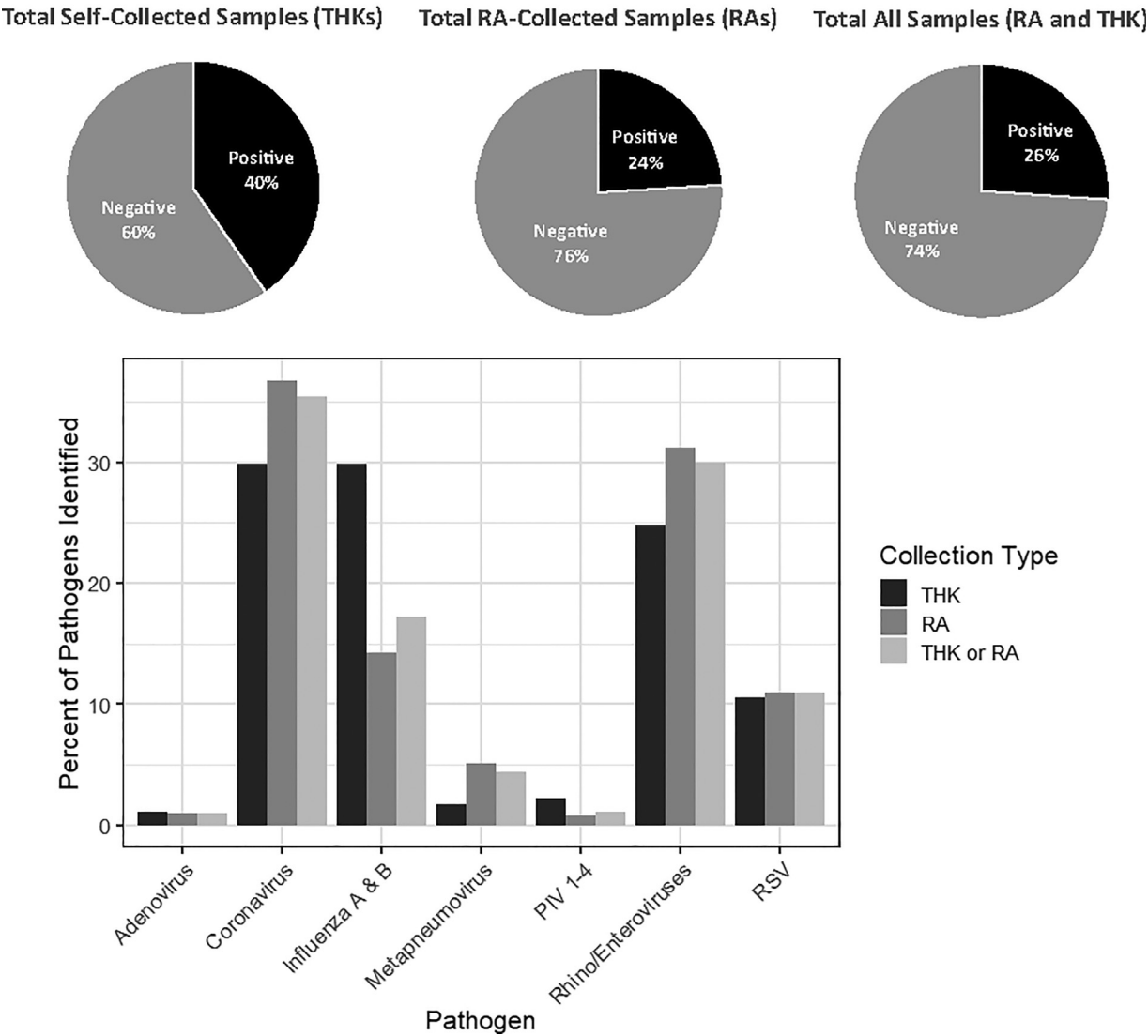
## DISCUSSION

We found that home collection methods to diagnose viral respiratory infections were feasible and acceptable. Self-collection at home is an attractive option for obtaining samples and it may reduce costs and time to diagnosis, aid in treatment and foster improved infection prevention practices because of potentially earlier identification. Furthermore, it can enhance public health surveillance by more easily reaching those not accessing medical care.<sup>20–24</sup> There is a strong preference to collect specimens at home over coming to a medical facility or even a drive-through setting.<sup>25</sup> When testing for SARS-CoV-2, the virus that causes COVID-19, regardless of the type of specimen, a recent survey shows that most participants (>84%) found the process acceptable and 87% were confident in their ability to successfully

A.



B.



Pathogen	THK (%)	RA (%)	THK or RA (%)
Adenovirus	1	1	1
Coronavirus	30	35	34
Influenza A & B	30	14	17
Metapneumovirus	2	5	4
PIV 1-4	2	1	1
Rhino/Enteroviruses	25	31	30
RSV	11	11	11

**Fig 1.** Ratio of pathogens by collection method. (A) Relative proportion of research assistant-obtained (RA) and self-collected (take-home kits, THK) total symptomatic samples collected (left panel) and total positive symptomatic samples (right panel). (B) Relative proportion of positive and negative samples from swabs collected (top panels) and distribution of identified pathogens from positive samples (bottom panels) for all self-collected (THK) swabs (black), RA-obtained swabs (dark grey), and all swabs collected (light grey).

**Table 2**

Demographics of person-seasons with a symptomatic swab, evaluated for each person-season by those receiving only research assistant-obtained swabs (RA) versus those ever using self-collection (take-home kits, THK)

	RA only*	THK ever*
Total	1891	401
Sex		
Male	257 (13.6)	54 (13.5)
Female	1634 (86.4)	347 (86.5)
Race/Ethnicity		
Asian	150 (7.9)	28 (7.0)
Black	516 (27.3)	49 (12.2)
Caucasian	988 (52.2)	284 (70.8)
Native Hawaiian/Pacific Islander	4 (0.2)	2 (0.5)
Native Person	14 (0.7)	4 (1.0)
No Race Reported	52 (2.7)	4 (1.0)
Other	167 (8.8)	30 (7.5)
Hispanic or Latino	341 (18.0)	39 (9.7)
Age (in y)		
18–29	304 (16.1)	53 (13.2)
30–39	581 (30.7)	142 (35.4)
40–49	454 (24.0)	98 (24.4)
50–59	427 (22.6)	66 (16.5)
60–69	122 (6.5)	42 (10.5)
70+	3 (0.2)	0 (0)
Influenza vaccination status <sup>†</sup>		
Vaccinated	1549 (81.9)	366 (91.3)
Not vaccinated	330 (17.5)	34 (8.5)
Job category		
Administrative	198 (10.5)	29 (7.2)
Clinical support	308 (16.3)	41 (10.2)
Environmental/housekeeping/ support associate	23 (1.2)	4 (1.0)
Nurse	782 (41.4)	198 (49.4)
Other	214 (11.3)	38 (9.5)
Physician	235 (12.4)	63 (15.7)
Registration/reception	90 (4.8)	21 (5.2)
Social worker/pastoral care	41 (2.2)	7 (1.7)
Site		
Children's Colorado	105 (5.6)	64 (16.0)
DC VA	156 (8.2)	19 (4.7)
Denver Hospital	411 (21.7)	84 (20.9)
Denver VA	137 (7.2)	58 (14.5)
Houston VA	193 (10.2)	46 (11.5)
Johns Hopkins	569 (30.1)	116 (28.9)
NY VA	320 (16.9)	14 (3.5)
Patient population		
Adults	1098 (58.1)	184 (45.9)
Pediatrics	389 (20.6)	116 (28.9)
Both	404 (21.4)	101 (25.2)

\*The same participant could appear in both categories and multiple times in the RA category due to the nature of the study.

<sup>†</sup>13 participant-seasons did not report influenza vaccination status.

perform the sampling.<sup>26</sup> Some self-collected specimens, outside this study, would have been collected in a health care environment, potentially increasing risk of exposures and utilization of PPE. Without the inclusion of the self-collected specimens, other important viral infections would have been missed or under-reported. Self-collected swabs obtained by HCPs with ARI when provided with swabs and procedure training were a viable tool to obtain surveillance information. This strategy provided consistent results that were reproducible over several years in the multiple settings participating in a large clinical trial. These findings are similar to those from other studies that highlighted self-collection as a potential diagnostic method that could be adopted in healthcare settings and for public health surveillance of acute respiratory infections, including pandemics such as the recent COVID-19 pandemic.<sup>16,20–24,27–30</sup>

Others have used self-collection successfully. Several investigators used telephone “hotlines” as a surveillance tool for circulating viruses and provided self-collection kits to callers who reported cold or flu-like symptoms.<sup>20,22,24</sup> Most of those respondents did not report problems with the self-collection method, supporting its feasibility. One

of those studies<sup>22</sup> showed an increased lag time of up to 6.1 days between symptom onset and testing due to the double-mailing method, (1) from study staff to participants and (2) returning samples to the study laboratory. Self-collection captured the influenza/respiratory virus season in the community within one week of detection through other surveillance systems; decreasing the lag time of double-mailing could improve the efficiency of home self-collection surveillance.<sup>22</sup> The Seattle Flu Study, initially used to identify influenza, pivoted to diagnosis of COVID-19 and used courier services to send swabs to participants and return them to the laboratory.<sup>31</sup> Those authors reported a two day turn-around in an urban setting. Both this latter study and our study suggest this strategy can be used for widespread testing of populations with or at risk for developing respiratory viral infections. Future studies and clinical practices using designated sites for pick-up of kits and drop-off sites for self-collected swabs could decrease the delay in obtaining results associated with mailing and packaging.

Comparing self-collection to swabs obtained by trained personnel, Larios et al.<sup>28</sup> had subjects self-collect a flocked mid-turbinate (MT) swab in one nostril, and then had a study-trained nurse obtain a flocked nasopharyngeal swab from the other nostril as soon as possible after the MT swab, most within 24–48 hours. The combined sensitivity for five respiratory viruses was 90% and supported the use of self-collected MT swabs, similar to those used in the current study. The peak viral shedding was within the first or second day of acute illness, substantiating the need for prompt testing. Other studies support these findings and found that self-collection was not only an equivalent method to trained HCP swabbing (combined 100% sensitivity and 98% specificity for 15 respiratory pathogens), but was preferable.<sup>16,21,27</sup> Following the emergence of the COVID-19 pandemic, additional studies emerged comparing self-collection to HCP obtained swabs.<sup>29,30</sup> In the Denmark study, researchers found 84.2% diagnostic sensitivity for self-collected oropharyngeal and nasal swabs compared to 89.5% for HCP oropharyngeal swabs.<sup>30</sup> The Australian study with more than twice the sample size found better sensitivity with a self-collected nasal and throat combined swab (100% for COVID-19; 94% other respiratory viruses) compared to either throat and nasal swabs or throat and nasopharyngeal swabs performed by HCPs (96% COVID-19; 91% other respiratory viruses).<sup>29</sup> In each of those studies, there were slight variations in the methods utilized compared to those in the current study. Studies differed on the number of nostrils swabbed by each method, but generally sampled only one naris, whereas our sampling combined a double-nostril and oropharyngeal swab. Only one of these prior studies included throat swabs,<sup>29</sup> but most did use a similar flocked nasal swab; 2 studies<sup>27,29</sup> used a foam-tipped swab. In all cases, and despite different methodologies, participants generally found the self-collection method easy to follow and often more acceptable than having to report to a healthcare facility for testing.

Our data (Table 2) broadly suggests that clinicians are more likely to self-administer THKs than supporting staff, with nurses and physicians making up a greater proportion of participant-seasons with at least one THK in comparison to administrative and clinical support staff. The proportions for both nurses and physicians increased for THK usage compared to RA-only samples (8% increase for nurses and 3.3% for physicians). Conversely, the proportions for clinical support and administrative staff decreased for THK usage compared to RA-only samples (6.1% decrease for clinical support and 3.3% drop for administration). Similarly, nearly 10% more clinicians used at least one THK compared to nonclinical staff. It is conceivable that the more clinical-based personnel would feel more confident self-swabbing. Due to the cluster randomization and matching done to balance site-level rather than participant-level characteristics, we do not have enough information to draw definitive conclusions or make a statement as to the significance of these differences.



While our study demonstrates take-home kit feasibility across multiple sites, it has a few important limitations. First, a direct comparison between the 2 sampling methods was not done. It would have been informative to compare results from both a self-collected and an RA-obtained sample for the same symptomatic event, but this was not feasible based on the study design. Although there were differences in the time to laboratory delivery of samples (mailed THKs vs. hand-delivered by RAs), we attempted to minimize other types of variation by using the same flocked swabs and similar storage techniques in both methods. All samples were analyzed in a single, central laboratory using the same technology. Second, only participants reporting certain symptoms were included in this analysis. This may have resulted in missing participants who were infected but asymptomatic; however, these differences would likely have affected participants equally. Third, symptoms were self-reported and may have underestimated illness among HCP who often work while ill.<sup>12</sup> Importantly, despite this culture of “presenteeism” in health care settings,<sup>13,14</sup> in the present study, many HCP adhered to their health-care facility’s policy to stay home when symptomatic with respiratory illnesses as evidenced by the number of THKs utilized. This finding may explain why the VCE was higher for THK as the participants were sicker and shedding more viruses when the sample was obtained. This may also have led to identification of pathogens that cause more severe symptoms, fever, and absenteeism, namely influenza A and B, and possibly coronaviruses, was identified more often from self-collected swabs done at home.

Garber and Phelps<sup>32</sup> claimed that a new approach to a clinical intervention is justifiable as long as it is as cost-effective as or more so than the current method. Although the standard recommendation for sick HCP is to stay home until symptoms subside, negating the ability to track the epidemiology of circulating respiratory viruses, the ResPECT Study<sup>10</sup> suggests that THKs may be a very low cost way to accomplish this while adhering to quarantine recommendations. While no formal cost analysis was done, costs associated with a self-collected N/OP swab (including swab sets, specimen bags, printed instructions, and average shipping fee) was approximately \$9.40 per sample. There would be a minimal additional cost for training the participant to self-swab. Charges for a healthcare provider or RA salary to obtain a swab vary by location but are generally significantly higher. Based on our rough estimates, self-collection is a relatively low-cost method when compared to the time required to obtain a swab within a medical facility and it avoids potentially infectious exposures. In addition to clinical applications, a low-cost self-collected specimen method at home could enhance the scope of research projects by diverting funds spent on staffing to those for testing.

Prior to employing these methods in future studies or for clinical purposes, additional factors should be considered. First, the ability of participants to obtain their own samples correctly is critical. In the present study, participants were trained HCP familiar with the swab techniques, and written and visual instructions were provided (Appendices A–B). There were nevertheless a few instances in which a participant did not completely follow these instructions. For example, a few samples were returned with mold growing in the tube, indicating an environmental contamination.<sup>33,34</sup> Another participant returned an empty tube without the required swab. While perfect participant adherence is difficult to ensure in any research study, the few participants that sent an unusable sample were successfully retrained on appropriate sample collection methods without future incident. Prior studies suggest that even most non-healthcare workers are able to obtain and ship self-collected samples without errors.<sup>35</sup> However, it is conceivable that a subset of patients, such as those with severe arthritis, may be unable to self-swab. Second, self-collected swabs should be sent to the designated laboratory in a relatively timely manner to avoid potential environmental

contaminants.<sup>33,34</sup> Pre-filled labels were used in the present study to ship Priority Overnight. THKs for self-collected swabs (research or clinical) should include similar prefilled shipping materials or an option for a minimal contact drop-off location. Third, we did not examine the impact of varying “shelf” lives of the kits in varying environmental conditions (eg, in participants’ lockers, vehicles, or homes). New kits were distributed at the beginning of each season and after each use. Still further study would need to be undertaken to determine the viability of these kits under nonideal situations, which may differ from the labeled expiration dates on the swab collection kits.

Until technology is inexpensive and practical enough to remotely test samples in the field or at home, researchers and clinicians will remain dependent on laboratories to process and analyze samples. This means that it will continue to be crucial to obtain adequate samples and return them to a laboratory. Although sample collection by a trained provider or investigator has been the gold standard, there is a growing body of data supporting self-collection of samples for other infectious diseases, (eg, gonorrhea, chlamydia, human papilloma virus<sup>36–41</sup>). THKs could be a cost-efficient method to obtain samples without sacrificing quality for investigative studies with a large number of participants, some residing at a far distance from the study site, and limited resources or study staff. Clinically, there is value in use of THKs for HCP, as HCP can self-collect as soon as symptoms develop, supporting the decision to stay home unless testing reveals they can safely return to work, especially as more point-of-care rapid tests are developed. There are areas for further investigation, including the use of these strategies for emerging respiratory infections, such as COVID-19 or avian influenza, where the goal is to rapidly limit exposure and reduce PPE usage by those obtaining the samples.

In conclusion, this study demonstrated the feasibility of N/OP self-collection by trained HCPs using THKs across multiple respiratory virus seasons and a variety of locations. THKs were a low-cost and well-tolerated method of obtaining swabs. They may reduce potentially infectious exposures and PPE usage for testing within medical facilities, easing some of their burden. Take-home kits could prove especially useful in areas affected by COVID-19 or large infectious disease outbreaks, and HCP could be trained in advance to obtain specimens at home. While challenges would remain, such as education and training, take-home kits could improve and facilitate research for public health and infection prevention investigations, and over time could potentially become a widely accepted diagnostic and surveillance method.

## DISCLAIMER

The findings and conclusions in this manuscript are the authors’ own and do not necessarily represent the views of the Centers for Disease Control and Prevention, the National Institute for Occupational Safety and Health, the Department of Veterans Affairs, or other affiliates. Mention of product names does not imply endorsement.

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## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.ajic.2021.02.001>.

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