Rapid on-site molecular Point of Care Testing during influenza outbreaks in aged care facilities improves antiviral use and reduces hospitalisation

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Abstract

Objective: Western Sydney Local Health District (WSLHD) measured the utility and validity of rapid molecular point-of-care testing (POCT) in aged care facilities (ACFs) experiencing influenza-like illness (ILI) outbreaks against routine laboratory testing.

Methods: A descriptive epidemiological study into 82 respiratory outbreaks reported across 63 ACFs within WSLHD supporting approximately 6,500 residents aged ≥65 years and staffed by ~6,500 employees, from 1 August 2018 to 31 December 2019.

Results: WSLHD Public Health Unit performed on-site testing at 27 ACF outbreaks (34%), while 53(66%) ACFs conducted only routine laboratory testing. The Xpert®Xpress Flu/RSV molecular PCR provided a sensitivity and specificity of 100%. Those with on-site testing, antiviral prophylaxis was prescribed at 75% of facilities within 24 hours of testing, as opposed to 32% of those using laboratory testing ($p<0.01$). There were 24 of 181 ACF residents hospitalised in the POCT group compared to 76 of 357 in the laboratory-only group (OR=0.57; $p=0.02$).

Conclusions: On-site ACF testing is reliable and practical for early identification of influenza, enabling timely use of antiviral treatment and prophylaxis, and was associated with decreased hospitalisation.

Public health implications: Enhanced respiratory surveillance and on-site testing should be strongly considered as part of routine management of respiratory outbreaks in ACFs and may reduce outbreak severity.

Key words: aged care, respiratory viruses, public health, influenza, point of care testing

Respiratory viruses are highly infectious agents that adversely affect the health of adults aged ≥65 years.[1] In closed population settings such as aged care facilities (ACFs) in particular, respiratory viruses are highly transmissible amongst older residents and staff.[2]

Widespread immunisation for both influenza and coronavirus disease-19 (COVID-19) of ACF residents and staff before the beginning of each winter is supported by public health authorities and has received Australian Government Department of Health (DoH) funding through the National Immunisation Program since 1999 and 2021 respectively.[3] However, sometimes the influenza vaccine being used has the potential for virus strain mismatch and lower effectiveness, as happened in 2017 in NSW. Immunosenescence in the elderly also leads to lower effectiveness, especially against influenza A/H3N2.[2] SARS-CoV-2 is also a major threat in ACFs, but is preventable.[4] Rhinovirus, respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) infections are not yet vaccine-preventable, emphasising the need for good infection control during influenza-like illness (ILI) outbreaks.[5]

In New South Wales (NSW), Australia, all laboratory-confirmed cases of influenza and now COVID-19, are required to be notified to public health authorities within 72 hours of a positive result, as mandated by the NSW Public Health Act 2010.[6] However, while not mandatory, the reporting of respiratory outbreaks by institutions, including ACFs, is strongly recommended by the DoH and the Communicable Diseases Network Australia (CDNA).[7] Public health units can assist in providing timely recommendations to ACFs for outbreak identification and management to encourage best practice in accordance with the *Guidelines for the Prevention, Control and Public Health Management of Influenza Outbreaks in Residential Care Facilities in Australia*.[8]

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A key recommendation of the outbreak guidelines is the initiation of antiviral therapy (such as oseltamivir) within 72 hours from the onset of influenza-like illness (ILI) symptoms as therapy to the affected residents (cases) and as chemoprophylaxis to unaffected residents and staff (or close contacts); this reduces viral shedding and minimises transmission.[8] Oseltamivir has been shown to reduce the severity of influenza but there are gaps in the literature evaluating the effectiveness of oseltamivir prophylaxis in preventing the transmission of influenza in ACFs.[9] A major hurdle to instituting oseltamivir quickly is the timely identification of influenza.[2] Early notification and timely institution of infection prevention control measures can be critical in reducing hospitalisation and outbreak severity.[3]

Reverse transcriptase-polymerase chain reaction (RT-PCR) is the gold-standard in laboratory confirmation of viral pathogens.[9] Clinically, a laboratory confirmation of influenza (A/B) is required for an accurate diagnoses.[2] In order to initiate early antiviral therapy and avoid unnecessary antibiotic use, rapid influenza diagnostic tests (RIDTs) - immunoassays that detect viral antigens - became the main point of care test in aged care facilities due to the rapid turnaround time. However, RIDTs lack sensitivity (ranging from 50-70%).[10] Although current RT-PCR used in the laboratory can produce a result within hours, the overall process from specimen collection to transport, laboratory testing itself, and providing the result to an ACF often leads to a delayed diagnosis of between 24–72 hrs.[1]

More recently, molecular point of care testing (POCT) assays with high analytical sensitivity and specificity have become available, with rapid turnaround times of between 15–30 minutes, providing an accurate diagnosis in over 95% of patients.[11] A study into the use of rapid RT-PCR technology has demonstrated that this may increase appropriate antimicrobial use, may reduce use of hospital resources, and decrease the cost of patient management.[12]

The study was designed to test the effectiveness of the Xpert® Xpress Flu/RSV (Cepheid Inc, Sunnyvale, CA, USA) molecular assay used by the Flu team and measure the impact it had on ILI outbreaks against the gold standard laboratory-based multiplex PCR that was used routinely.

Methods

Western Sydney Local Health District (WSLHD) located in metropolitan Sydney in NSW, has approximately 6,500 residents aged ≥65 years who reside in 63 ACFs. Between 1 August 1 2018 and 31 December 2019, the Western Sydney Public Health Unit (WSPHU) 'Flu team' carried out comprehensive public health education and surveillance for ILI outbreaks in WSLHD ACFs including forming a mobile unit to undertake POCT in ACFs.

A descriptive epidemiological study into 82 respiratory clusters that were reported across 63 ACFs within WSLHD was conducted on the use of on-site molecular PCR POCT by the PHU as an early intervention. The study was approved by WSLHD Human Research Ethics Committee (ETH00822). Trying to address our practical guideline-driven questions through an RCT would not have been feasible, partly because getting informed consent would have reduced timeliness and representativeness (through lowered recruitment).

Study population

All residents and staff in WSLHD ACFs where a cluster of ILI was notified to the WSPHU between 1 August 2018 and 31 December 2019. An outbreak was a cluster of ILI that met the case definition in accordance with the CDNA Guidelines,[8] defined as three or more epidemiologically-linked cases in residents or staff within three days (Figure 1).

The intervention

The WSPHU assembled a novel 'Flu team' that focused on improving respiratory outbreak management, including on-site POCTs in ACFs. Key activities included pre-winter preparedness education via annual face-to-face workshops about ILI management (2018/9). Individual visits to 56 of 63 ACFs were conducted to foster better relationships and encourage notification to the PHU of a suspected ILI outbreak. At the time of outbreak notification, the Flu team provided support with an initial visit, where possible, and then during the outbreak they monitored progress and provided infection prevention and control (IPAC) advice and education.

During the on-site visit, all residents with an ILI had a respiratory sample collected (nasopharyngeal swab or combined nose and throat swab) by a Flu team nurse or ACF health care worker. Swabs were placed into 3mL of universal transport media (Copan Diagnostics Inc., Murrieta, CA, USA). An aliquot of the fluid was used for testing for influenza A and B viruses and RSV on-site by the Flu team using the Xpert® Xpress Flu/RSV according to manufacturer's instructions. The turnaround time for these tests is between 15 to 30 minutes. The ACF was then immediately informed of the on-site test results. If influenza A, B, or RSV were detected in ≥2 swabs tested, an outbreak was declared.[8] As well as infection control measures, the PHU routinely recommended antiviral treatment (and prophylaxis for contacts) for all residents with ILI where an influenza outbreak was declared and it was administered within the recommended 72 hours window. All samples collected on-site were also transported to the World Health Organization, National Influenza Centre reference laboratory (Centre for Infectious Diseases and Microbiology Laboratory Services [CIDMLS], NSW Health Pathology-Institute of Clinical Pathology and Medical Research) for routine testing for influenza and other respiratory viruses (including influenza A/B, RSV, rhinoviruses, enteroviruses, parainfluenza viruses, human metapneumovirus, adenoviruses, and coronaviruses) using the remaining fluid in the universal transport media.

Data collection and analysis

An illness register and influenza outbreak report form was developed using Microsoft Office Suite 2013 (Microsoft Corporation, Redmond, Washington, USA) by the WSPHU in collaboration with National Centre for Immunisation & Research Surveillance (NCIRS). The illness register is completed daily by ACFs and sent to the PHU, with missing data points collected prospectively during the study period to ensure completeness. An outbreak report form was completed by the WSPHU at the closure of an outbreak, including facility information, case, hospitalisation, and death summaries for an outbreak. Collection of these data points as well as laboratory data, facilitated analysis of the three outcomes of the study: sensitivity and specificity of molecular PCR POC testing, antiviral usage and ACF outbreak characteristics. Positive and negative POCT results were compared with results of the gold standard laboratory PCR test with sensitivity and specificity of the POCT determined on this basis. Descriptive analyses of the outbreak were undertaken on de-identified data from the illness register and

outbreak report form and was categorised into two groups based on whether the ACF received on-site POCT by the WSPHU or not. Microsoft Excel (version 16.49) was used for processing of raw data. Univariate analysis, odds ratios (OR), significance tests (Kruskal-Wallis H test) were completed using R studio (version 1.3.1056). *p*-values <0.05 were considered statistically significant.

Results

A total of 82 clusters of respiratory illness were reported to the WSPHU. Two ACFs utilised another POCT diagnostic platform and were excluded. Of the remaining 80 clusters notified to the PHU, there were 73 confirmed viral outbreaks across 43 ACFs (20 ACFs had multiple outbreaks) comprising of 1,084 ILI cases (861 residents and 223 staff). There were 43 influenza outbreaks – 38 with influenza A as the primary pathogen (including 256 residents and 51 staff). The subtypes of 22 outbreaks were identified, with A/H3N2 in 16 outbreaks (including at least three A/Switzerland/8060/2017-like, the A/H3N2 component in the 2019 influenza trivalent vaccine) and the remainder were due to A/H1N1. Both H1N1 and H3N2 influenza A subtypes were identified simultaneously during two outbreaks.

Outcome one: Sensitivity & specificity of molecular PCR POC testing

POCT was performed in 27 clusters of ILI (34%) while 53 clusters (66%) were tested using routine laboratory-based PCR laboratory only (non-POCT); 12 influenza and one RSV outbreaks were confirmed by POCT. A total of 98 samples from symptomatic residents and staff were collected and tested on-site, of which influenza A, influenza B and RSV were detected in 28, one and one respectively (Table 1).

All but four samples were confirmed by multiplex RT-PCR at CIDMLS within 24 hours of specimen collection – four samples returned a low positive result (Ct values >30) during on-site POC testing, with a negative result reported by the laboratory. An investigation was undertaken into the four discordant results. The four cases were symptomatic and three had direct epidemiological links to an influenza outbreak; laboratory specialists ([personnel]) determined that the routine dilution practices likely resulted in the false negative results and their discordant findings were deemed false negatives. Therefore, the Xpert® Xpress Flu/RSV had a sensitivity and specificity for influenza A of 100%, assuming that the laboratory-based PCR results were incorrect.

Outcome two: Antiviral prophylaxis and treatment uptake

Antivirals as both treatment and prophylaxis were prescribed at 9 (75%) of 12 POC-tested influenza outbreaks within 24 hours of notification to WSPHU. One additional facility, using POC testing, also used antivirals within 72 hours, yielding an overall (treatment and prophylaxis) prescription rate of 83%. In contrast, only 48% of non-POC-tested influenza outbreaks were prescribed antivirals within 72 hours (Table 2) (p=0.04). In 10 of the 12 POCT outbreaks, antiviral treatment (83%) was prescribed to all symptomatic residents, with one facility opting out of its use as prophylaxis, within 24 hours, as opposed to 18 of 31 (58%) in the laboratory-based PCR testing group.

There was no statistical difference between groups in relation to treatment between the POC and laboratory-based tested groups within 72 hours (92% vs 77%) (Table 2).

Outcome three: ACF outbreak characteristics

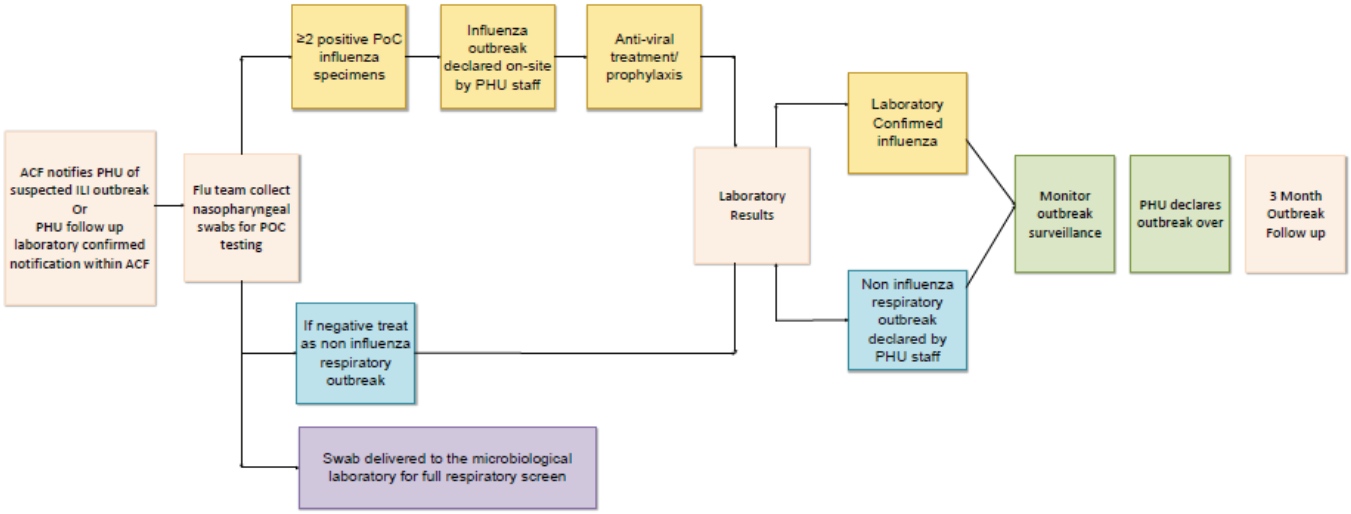
The median time for an ACF to notify the WSPHU of an influenza outbreak was two days in the POCT group and five days (3–8 days) in the non-POCT group (p<0.001). The hospitalisation rate was lower in the POCT group during influenza outbreaks: 13.3% in comparison to the non-POCT group of 21.3% (OR 0.57 [CI] 0.34–0.93; p=0.02). The mortality rate during influenza outbreaks occurring in ACFs utilising POCT appeared lower at 3.9%, compared to ACFs that did not utilise POCT which was 7.3% (Table 3) – (p=0.12).

Other causative pathogens that were identified by routine surveillance included hMPV (n=6), parainfluenza types 1 & 3 (n=5),

Table 1: Summary of molecular point-of-care tests that detected respiratory viruses compared to laboratory-based PCR testing.

Result for ACF Residents tested	POCT (n=98)	CIDMLS (n=98)
Influenza A	28	25
Influenza B	1	1
RSV	1	0
Negative	68	68

Figure 1: The enhanced Public Health Surveillance Model.



rhinovirus (*n*=18), RSV (*n*=4), with multiple pathogens being identified at seven clusters as well as five outbreaks where a viral pathogen was not identified. Interestingly, POCT tested, non-influenza outbreaks were also found to notify the PHU earlier (Table 3b) – *p*=0.0438.

Discussion

ILI outbreaks in ACFs due to influenza, COVID-19, or other viruses, are of major concern, due to hospitalisations and deaths. For the study period, POCT was found to be practical and reliable in identifying outbreaks earlier and enabling timely use of influenza antivirals. Our results support previous evidence that diagnostic POC RT-PCR is valid and can be as reliable as the gold-standard laboratory-based RT-PCR (>95%) for influenza, and should be considered for other highly transmissible viruses, such as COVID-19.[12] PCR is more sensitive compared to commercially available RIDTs.[10] Furthermore, the Xpert® Xpress platform has been described as the 'best studied' molecular point-of-care system.[13] With a turnaround time of less than two hours, the results can impact patient care.[11] This is relevant also to COVID-19 outbreaks that continue to emerge and are highly transmissible, and therefore more rapid results may help prevent the spread.

Residents of ACFs often have close living quarters and may share their care staff, both within and across facilities, so that staff are more likely to be vectors of transmission than relatives who usually visit/interact less often.[14] Therefore, the consideration of testing staff on-site may be a timely intervention to reduce both the introduction and transmission of respiratory viruses.

NSW Health recommend antiviral treatment and prophylaxis (oseltamivir) as per the Commonwealth CDNA Guidelines. Although there are multiple recognised protocols across ACFs, all suggest the implementation of antivirals within 72 hours.[15] Despite some conflicting evidence on the effectiveness of antivirals use in ACFs, more data are emerging.[14]

Meshreky *et al.* previously reported that the median time for ACFs in NSW for antivirals to be initiated for influenza virus infection was 8.5 days after symptom onset.[16] Often, the delay in diagnosing influenza can result in lesser and later use of oseltamivir and higher rates of antibiotic use.[17]

Our findings suggest that facilities where real-time POCT was conducted had higher rates of timely oseltamivir treatment and prophylaxis, with 83% of ACFs instituting this within the CDNA recommended timeframe; expedited by the availability of timely testing results and early public health support.

Public health nurses and doctors routinely uses antiviral treatment for laboratory confirmed influenza, which may explain why we found no statistical difference in the proportion of residents given antiviral treatment among those using POCT or laboratory testing. However, our study suggests an effective and early strategy for the timely institution of antiviral prophylaxis within ACFs.

Importantly, hospitalisations due to influenza outbreaks were significantly lower when ACFs used POCT, reducing the possibility by 43%. Although our study is small and observational, it is supported by a recent study that found antiviral prophylaxis prevented a high percentage of influenza cases during outbreaks, particularly in ACFs with high-level care and dementia units.[15] This may be relevant to ACFs struggling to manage the threat of COVID-19. It can be noted that ACF residents are generally frail with numerous comorbidities and live in similar conditions across facilities. This was demonstrated in data collected via the PHU's illness register (including a clinical frailty scale, comorbidities and recent medical history), which was why these have not been reported on by this paper.

Additionally, the study found that ACFs conducting POCT notified the PHU within a median of two days from the first onset of symptoms, in comparison to the ACFs that conducted only routine laboratory testing (median four days). This is better than another recent study in NSW where the median time ranged from 5.4 to seven days.[3] Earlier public health support, can ensure the timely intervention of effective infection prevention control measures that include antiviral therapies, and adequate personal protective equipment

Table 2: Comparison of antiviral treatment and prophylaxis prescriptions based on point of care and laboratory-based PCR testing in influenza outbreaks.

Antiviral prescription during outbreak	POCT (n=12)		Non-POCT (n=31)	
	Within 24hrs	Within 72hrs	Within 24 hrs laboratory confirmation	Within 72 hrs laboratory confirmation
As prophylaxis	9 (75%)	10 (83%)	10 (32%)	15 (48%)
As treatment	10 (83%)	11 (92%)	18 (58%)	24 (77%)

Table 3a: Comparison of ACF Influenza outbreaks by POC and laboratory PCR testing.

	POCT (n=12)	Non-POCT (n=31)	*p*-value
Median Length of Outbreak (days)	18.5 (IQR 14.0 – 24.3)	15.0 (12.5– 20.0)	0.2685
Median days until PHU notification	2.0 (IQR 1.0 – 4.0)	5.0 (3.0-8.0)	0.0038*
Median resident clinical attack rate (%)	12.0% (IQR 9.0% – 19.0%)	11.0% (4.0%-19.0%)	0.3712
Median staff clinical attack rate (%)	4.0% (1.0% – 8.0%)	2.0% (1.0%-4.0%)	0.6679
Number of ACFs administering prophylaxis – during outbreak	11.0 (92.0%)	22.0 (71.0%)	0.15
Number of ACFs administering treatment – during outbreak	11.0 (92.0%)	29.0 (94%)	0.83
Number of ILI hospitalisations	24 (n=181) (13.3%)	76(n=357) (21.3%)	0.02*
Number of Influenza-related deaths	7(n=181) (3.9%)	26(n=357) (7.3%)	0.12

Note:
**indicates statistical significance (p<0.05).*

Table 3b: Comparison of ACF Non-influenza outbreaks by POC and laboratory PCR testing.

	POCT (n=12)	Non - POCT (n=18)	*p*-value
Median Length of Outbreak (days)	11.0 (9.0 – 18.0)	12.0 (11.0 – 21.0)	0.2868
Days until PHU notification	2.0 (1.0 – 2.3)	4.0 (2.3 – 5.0)	0.0438*
Resident clinical attack rate (%)	12.0% (8.0%– 21.0%)	9.0% (7.0%-16.0%)	0.3627
Staff clinical attack rate (%)	2.0% (1.0% – 4.0%)	1% (0.0% -1.0%)	0.0796
ILI hospitalisations	11(n=143) (7.6%)	18 (n=180) (10%)	0.47
Influenza-related deaths	3 (n=143) (2.1%)	3 (n=180) (1.7%)	0.78

Note:
**indicates statistical significance (p<0.05)*

Many factors influence the notification of ILI outbreaks, in ACFs to PHU, such as delays in outbreak recognition, non-typical ILI symptoms and the gap between education and clinical practice.[3] Our findings highlight the timely use of POCT as an additional measure in ACFs that enables timely prescription of antivirals, which in turn may prevent hospitalisation. Recent findings reported that for each day an ACF delayed reporting an influenza outbreak, there was a 6% increase in hospitalisations and the duration of the outbreak was prolonged by 0.42 days each delayed day.[15]

We did not find any significant difference in the median length of the outbreaks or attack rates in residents or staff. This may be due to our small sample size, or the comparable level of trained ACF staff available to implement correct Infection Prevention and Control procedures.[14]

Our study has several limitations. POCT was offered by the PHU as an option to ACFs to enhance the early detection of influenza A, B and RSV; reporting of ILI was not enforced, and ACFs with better surveillance or staffing levels may be better represented in the POCT group (27 of 80 ACF outbreaks). As POCT was only available during business hours, ACFs would collect samples for routine laboratory testing after-hours. POC testing was only conducted in 27 ILI outbreaks, partly because there was no mandate for ACFs to report respiratory outbreaks to the PHU during 2018/9. Delays by ACFs in recognising an outbreak do occur but may be reduced if the PHU is notified when even a single laboratory-confirmed influenza case arises. Our practical translational findings need verification in another setting using a similar model of engagement and partnership between PHUs, diagnostic laboratories, general practitioners and ACFs. The work was conducted according to standard procedures and had ethics approval for a low and negligible risk study. A randomised controlled trial might produce more compelling results but is impractical as consent requirement would reduce participation and antiviral therapy is already routinely recommended in influenza outbreaks.

We continue to conduct surveillance for respiratory viruses in Western Sydney ACFs; individual cases and outbreaks are found rapidly by enhanced surveillance so that infection control is instituted quickly. With the emergence of COVID-19, more interventions and strategies need to be considered in order to strengthen ACF and PHU reporting processes to ensure early public health support.

More research would be beneficial in confirming the role of timely POCT for reducing outbreak size and severity in ACF settings.[12]

Conclusion

The results of this study showed that POCT is reliable and practical for the early identification of influenza in ACFs. Frequent movement of the Xpert® Xpress to perform on-site POCT did not reduce its performance in the field. The timely identification of influenza outbreaks prompts earlier intervention with antiviral treatment and prophylaxis, which may reduce hospitalisation and death. Improving outbreak management is critical in reducing respiratory disease in elderly people living in assisted living institutions.

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