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Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland

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SUMMARY

Background: Seasonal influenza causes significant morbidity and mortality, and represents a recurring financial burden for community- and hospital-based treatment. Nosocomial outbreaks exacerbate the impact of influenza. Rapid diagnosis of influenza has been shown to reduce transmission. However, point-of-care testing (POCT) in emergency departments and prudent direction of patients with the virus to reduce hospital-acquired infection (HAI) have not been evaluated widely.

Aim: To assess performance characteristics of the Abbott ID NOW™ Influenza A & B 2 system, impact on incidence of hospital-acquired influenza, and admission rate ratio for patients who have POCT compared with laboratory testing. POCT was introduced in the 2018–2019 influenza season. Data from then were compared with preceding and subsequent seasons.

Methods: Records of POCT and laboratory testing for the 2017–2018, 2018–2019, and 2019–2020 influenza seasons were analysed. Sensitivity and specificity of POCT were compared pairwise with Xpert Flu A/B/RSV. Patient admission rates and time of waiting for admission were compared.

Findings: Compared to laboratory assay, POCT demonstrated sensitivity of 90.6% (95% confidence interval (CI): 78.6–96.5) and specificity of 99.2% (95.2–100) for influenza A, with 51.4% and 41.9% reductions in numbers of HAIs observed in the two seasons when POCT was available, respectively. The admission rate ratio for influenza cases diagnosed by POCT compared with laboratory diagnosis was 0.72 (95% CI: 0.53–0.97; $P = 0.031$).

Conclusion: POCT for influenza appears a feasible strategy for testing of patients during peak influenza virus season, with potential to reduce HAI. The relatively rapid turnaround time may also benefit clinical management of patients presenting at emergency departments with suspected influenza.

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Introduction

Seasonal influenza causes significant morbidity and mortality yearly. Its burden with respect to healthcare costs is significant. In the EU, it is estimated that the economic impact of seasonal influenza ranges between €6 billion and €14 billion annually [1]. Yan *et al*. estimated that, in the USA, yearly seasonal influenza costs between US$2 and 5.8 billion in healthcare costs alone [2]. Notably, costs are elevated when cases involve children, and when influenza B is prevalent [2,3]. Associated care represents a considerable recurring financial burden with respect to both community- and hospital-based healthcare. However, in the latter case, nosocomial outbreaks exacerbate the impact of influenza on hospital management and clinical care. For example, Sendi *et al*. reported a small outbreak involving 18 patients in a rehabilitation unit costing $112,131 in direct and indirect expenses, including staff illness [4]. Similarly, Marbus *et al*. estimated the cost of hospitalization in the Netherlands for each adult influenza patient to be between €4,934 and €10,665 [5].

Prior to advent of rapid influenza diagnostic testing (RIDT), turnaround time for influenza testing could be as long as days due to referring for centralized laboratories where local testing is unavailable. In that context, Alveraz-Lerma *et al*. reported increasing mortality and poorer outcomes for critically ill patients associated directly with delayed influenza A (H1N1) diagnosis [6]. It is, therefore, reasonable to state that as RIDT is now available commercially and relatively inexpensively, rapid diagnostic testing for influenza has potential to support appropriate bed management of patients, both in isolation and cohort areas, and to enable optimized patient care.

There are several commercial assays available for point-of-care testing (POCT) that allow rapid turnaround of results. The Abbott ID NOW™ Influenza A & B 2 (previously Alere i Influenza A+B) is an isothermic multiplex polymerase chain reaction (PCR) device that detects influenza A and B. Although the sensitivity and specificity are slightly lower than other real-time PCR assays, ease of use makes it an ideal POCT or near-patient care device with results available in ≤20 min [7,8]. Unfortunately, despite perceived benefits of POCT for influenza, many studies report conflicting results regarding impact on clinical care. A meta-analysis of the clinical utility of POCT for influenza in the ambulatory setting showed no effect on admissions or antibiotic prescribing, but demonstrated a reduction in other investigations ordered and increased antiviral prescribing [9]. Conversely, another systematic review on the impact of POCT for patients with acute respiratory tract infection reported reduced antibiotic prescribing in influenza-positive patients [10].

Few studies focus on the use of POCT for adult patients in the emergency department (ED) setting. However, both Trabbitoni *et al*. and Lankelma *et al*. reported reduction in admissions of patients tested with point-of-care technology for influenza [11,12]. The former also reported a reduction in time spent in the ED. To our knowledge no study has looked at the impact of ED POCT in reducing healthcare-associated influenza cases specifically. Therefore, in this study, our objective was to understand the influence of introducing POCT on ED use of isolation facilities within the department during peak influenza seasons. Particular emphasis was placed on potential reduction in acquisition of influenza in the ED and assistance with patient flow or treatment. Molecular technologies are also becoming increasingly pivotal in addressing diagnostic conundrums in infectious diseases and actionable case management [13,14]. We have previously described the role of timely diagnosis of infectious pathogens, in conjunction with appropriate infection control measures, in reducing transmission of microorganisms and curtailing of potential outbreaks [15,16]. Therefore, in this study, we continued this focus in attempting to determine performance characteristics of POCT in comparison with our laboratory facilities.

Methods

Setting

The University Limerick Hospital Group (ULHG) comprises six acute hospitals including one tertiary referral hospital, three level-two hospitals with acute medical assessment units, one maternity hospital, and one orthopaedic hospital.

The ED in University Hospital Limerick (UHL) serves a population total of ∼473,000. The UHL ED is the only one within the hospital group and is the referral point for the region. In 2019, the ED attendances were 71,315 with an average of 195 presentations per day [17]. The ED has 24 single-room isolation facilities and six single resuscitation bays. Despite being below the national benchmark for the average length of stay in medical inpatients (5.3 vs 6.3 days), due to bed capacity issues it is subject to prolonged delays in transferring patients to ward beds [18]. Importantly, and relevant to this study, influenza vaccine uptake for UHL's healthcare staff was 41.5%, 41.0%, and 40.1% for the 2017—2018, 2018—2019, and 2019—2020 influenza seasons, respectively [19—21]. From January 2018, a POCT assay using the Alere i Influenza A+B (renamed Abbott ID NOW™ Influenza A & B 2 for the 2019—2020 influenza season) was placed into the emergency department of UHL.

Ethical approval

This study was approved by the Research Ethics Committee of University Limerick Hospital Group, Limerick, Ireland.

Patient data

Data for all three influenza seasons were collected retrospectively from multiple sources; however, all patient data were anonymized in compliance with the General Data Protection Regulation. Results of POCT influenza investigations were collated from stored paper records for 2018—2019 and 2019—2020. Paper records were used during

these two influenza seasons due to lack of appropriate software to interface the POCT device directly with the laboratory information management system (DXC/iLAB). Paper records were used for both recording and notification purposes to the Irish Department of Public Health, and hospital infection prevention and control teams. Where available, comparative results and laboratory-derived results were collated using the LIM system (DXC/iLAB). Data specific to patient episodes and admissions were identified and retrieved using the hospital's electronic Inpatient Manager System (iPMS) as were ED data pertaining to initial patient presentation, admission, and bed waiting times. Durations of peak influenza seasons were determined using Irish national surveillance data.

Adult patients (defined as aged $\geq$16 years) who had undertaken a POCT for influenza, or who tested positive for influenza using laboratory assays, during the three influenza seasons were included in the analyses. The criteria for POCT in the ED are described in Box 1. A key outcome was the number of confirmed healthcare-associated influenza cases that occurred during the peak of each influenza season. All patients with a laboratory-confirmed influenza result on a nasopharyngeal swab collected after 48 h of admission were defined as healthcare-associated influenza cases. This definition is in accordance with the European Centre for Disease Prevention and Control (ECDC) definition for healthcare-associated infections [22].

A further outcome was the admission rate ratio for patients who received a POCT influenza result versus a laboratory-based result. To determine this, admission numbers for all positive influenza cases with a POCT result were compared with the admission numbers for all positive influenza cases determined using a laboratory-based assay. The impact of POCT for influenza on average admissions via the ED, and average time spent in the ED for those admitted patients while awaiting a ward bed, were analysed for each of the three influenza seasons.

Test performance characteristics

Performance characteristics of the Abbott ID NOW™ Influenza A & B 2 were explored. The sensitivity, specificity, positive predictive value and negative predictive value were calculated for all POCT results sent for duplicate testing using a laboratory-based assay. For clarity, training was provided by the manufacturer to all ED clinicians and nurses for 6 weeks prior to the installation of the POCT device at the beginning of each influenza season. The POCT device was available for routine clinical use from January 15th, 2019 to May 9th, 2019 and November 28th, 2019 to February 28th, 2020. The device was removed at the end of the influenza season. Notably, the decision to remove the POCT equipment in February 2020 was due to the evolving nature of the SARS-CoV-2 situation in Europe and the perceived limited utility of an influenza-only assay.

Performance of the POCT, for all three seasons, involved a single nasopharyngeal swab in UTM®: Viral Transport Medium (Copan Diagnostics, Brescia, Italy) for patients fulfilling case criteria for influenza. Validation was performed concurrently by comparison of POCT results with those of the Xpert Flu A/B/RSV (Cepheid, Sunnydale, CA, USA).

During the pre-POCT influenza season of 2017—2018, the standard of care test was the Xpert Flu A/B/RSV located in UHL's laboratory. However, after-hours routine testing was not available prior to implementation of POCT due to staffing constraints. Upon adoption of POCT, the testing process involved collection of a nasopharyngeal swab that could be performed by trained ED physicians or nurses, and was available 24 h, 7 days a week. During the validation period (and afterwards if samples provided invalid or suspect results), the same swab with the viral transport media was sent to the laboratory for confirmatory diagnostic analysis using the Xpert Flu A/B/RSV system. ED samples referred for in-house testing were stored at room temperature in the laboratory and tested upon arrival if between 08:00 and 20:00, or during the next business day if received after 20:00. During the validation period for the 2018—2019 season, a performance issue was noted whereby influenza A and B were reported together, or influenza B reported alone (as national surveillance data showed very minimal influenza B circulating). All swabs with such POCT results were referred for confirmatory testing. In addition, five samples were referred for testing using the Luminex NxTAG Respiratory Pathogen Panel (bioMérieux, Marcy l'Etoile, France) at the Irish National Virus Reference Laboratory (NVRL, Dublin) due to request for respiratory syndromic testing in addition to influenza testing.

Box 1
Patient testing criteria for use of emergency department point-of-care testing (POCT) for influenza

Patient who may have an influenza-like illness with:
Typical symptoms
- Fever
- Cough
- Sore throat

May also cause
- Shortness of breath
- Headache
- Myalgia

POCT for influenza to be considered in patients with influenza like-illness. Those patients should be isolated and/or asked to wear a mask pending clinical decision or test result.

POCT for influenza is not recommended for patients who do not have influenza-like illness.

Statistics

Analyses were performed using Microsoft Excel 2016 (V16.0); $P \leq 0.05$ was considered statistically significant.

Results

In Ireland, the reported peak influenza season lasted 14, 9, and 12 weeks for the 2017—2018, 2018—2019, and 2019—2020 seasons, respectively. In the 2017—2018 season, influenza B/Yamagata lineage and influenza A (H3N2) were the dominant circulating strains, with lower but still significant levels of influenza A(H1N1)pdm09 [23]. In the 2018/2019 season, there was co-circulation of influenza A(H1N1)pdm09 and influenza A(H3N2) with little influenza B activity (0.03% of all samples sent to the national virus reference laboratory) [24]. At the

time of writing, the season summary for the 2019–2020 season was still awaited, but it was known that the season was dominated by influenza A, with low levels of circulating influenza B [25]. Influenza incidences during the 2017–2018 and 2019–2020 seasons crossed the threshold for medium intensity prevalence levels during their peaks, but the 2018–2019 season was defined as low intensity (according to the Irish Health Protection Surveillance Centre) [23–25]. Our POCT and laboratory results for influenza reflected the national data.

There was no significant variance in laboratory tests requested across the three influenza seasons with 2409, 2311, and 2430 tests requested at UHL between October and May for 2017–2018, 2018–2019, and 2019–2020, respectively. In all, 518 and 709 POCTs were performed for the 2018–2019 and 2019–2020 seasons, respectively. Table I shows data on daily presentations, admissions, and bed waiting times for the ED for all three influenza seasons. The 2018–2019 influenza season had the highest daily attendance across the three influenza seasons (mean: 199.7 per day), although admission rates were lower than the previous season (reduction of 9.8%). Increasing wait times (mean: 13.7, 15.93, and 17.93 h for 2017–2018, 2018–2019, 2019–2020, respectively) for a bed across the three seasons reflects ongoing bed capacity issues in Ireland generally and specifically the mid-West region where this study focused.

Performance characteristics

During the early phase of POCT assay implementation in the 2018/2019 influenza season there was a global performance issue with the assay, leading to false-positive results. Prompt recognition of this issue led to corrective actions requiring duplicate parallel laboratory testing. Duplicate laboratory testing was required on 25.3% (131/518) and 10.8% (77/709) of samples in the 2018–2019 and 2019–2020 influenza seasons, respectively. All of these tests, except for five, were performed using Xpert Flu A/B/RSV. Those five samples were sent for syndromic respiratory panel testing and were referred to the national viral reference laboratory. The issue was resolved by the manufacturer for the 2019–2020 season.

Overall, having corrected for all results reporting positive for influenza A and B concurrently ($N = 15$), the calculated sensitivity for influenza A was 90.6% (95% confidence interval (CI): 78.6–96.5), specificity was 99.2% (95.2–100), positive predictive value was 97.8% (87.8–99.9), and negative predictive value was 96.3% (91.1–96.6). Performance characteristics for influenza B were as follows: sensitivity 100% (67.9–100), specificity 93.6% (88.6–96.6), positive predictive value 50% (28.8–71.2), and negative predictive value of 100% (97.1–100). However, only 11 confirmed influenza B cases with pairwise testing were diagnosed using POCT across the two influenza seasons.

Healthcare-associated influenza outcomes

Upon implementation of POCT, there was a marked reduction in the number of observed healthcare-associated influenza cases. Seventy-four cases of healthcare-associated influenza cases were detected in 2017–2018 prior to implementation of POCT. By contrast, there were 36 healthcare-associated influenza cases during the 2018–2019 influenza season (five cases before and 31 after POCT had been implemented), and 43 cases for the entire 2019–2020 influenza season. This reflects a reduction of 51.4% and 41.9% for the 2018–2019 and 2019–2020 seasons, respectively.

The ward admission rate ratio from the ED was further determined for patients who had a confirmed influenza diagnosis using either POCT or routine laboratory diagnostics. The ratio associated with POCT vs a laboratory-based result (obviously with longer turnaround time) was 0.72 (95% CI: 0.53–0.97; $P = 0.031$). Availability of POCT did not affect total admissions, total medical admissions, or waiting times for a ward bed (Table I). There was no significant difference in 30-day all-cause mortality rate or intensive care unit admission rate for influenza-positive patients across all three influenza seasons (Table II).

Discussion

POCT for influenza had an overall positive impact on hospital operational management. The Abbott ID NOW™ assay demonstrated satisfactory performance characteristics in relation to practical implementation across two influenza seasons. However, in the 2018–2019 influenza season (then referring to the Alere i Influenza A+B test) there was a significant issue with respect to false-positive results associated with concurrent influenza A and B reporting. Chapin *et al.* reported similar poor specificity for influenza A and B in their study [9]. By the 2019–2020 season, the manufacturer had been acquired and the new multinational company owner resolved the poor performance characteristics of the assay. Clearly, this issue highlights the requirement for awareness of the limitations of individual assays, alongside vigilance regarding aberrant results contradicting, or at odds with, expected results. Indeed, adoption of new diagnostic technology should be complemented by quality assurance programmes that ensure appropriate standards of commissioning and validation. In our hands, following resolution of this specific problem, the Abbott ID NOW™ Influenza A & B 2 demonstrated acceptable sensitivity and specificity. Our observations mirror those of Kanwar *et al.*, who also reported reliable

Table I
Average emergency department attendances, admissions, and average wait for a bed across the peak of three influenza seasons[a]

Date period	Attendances	Admitted	Admitted medicine	Wait for bed (h)
Dec 11th, 2017–Mar 18th, 2018	197 (196) [57.24]	67.3 (66) [23.69]	33.77 (33) [13.07]	13.7 (13.5) [16.97][b]
Dec 31st, 2018–Mar 3rd, 2019	199.52 (198) [59.45]	60.68 (60.5) [20.50]	33.44 (33) [14.07]	15.93 (14.7) [17.48][b]
Dec 2nd, 2019–Feb 23rd, 2020	187.5 (188) [54.42]	56.80 (56.5) [18.26]	29.44 (30) [11.36]	17.7 (14.7) [19.56][b]

[a] Mean (median) [2 standard deviations].
[b] Further advanced statistical analysis of curve not performed but it is expected that data would reflect a positively skewed distribution.

Table II
Comparison of patients who had a point-of-care test (POCT) or had influenza across the three influenza seasons

Variable	2017–2018	2018–2019	2019–2020
Total POCT		504	685
Age, median (IQR)	Not applicable	59 (40–74)	68 (49–79)
Sex			
Male		238 (47.3%)	334 (48.7%)
Female		266 (52.7%)	351 (51.3%)
All influenza positive cases			
Total positive influenza cases diagnosed by:	402	313	335
POCT result		120	136
Age, median (IQR)		49 (37–67)	64 (31–78)
Male	Not applicable	60 (50%)	64 (47.1%)
Female		60 (50%)	72 (52.9%)
Laboratory result	402	193	199
Age, median (IQR)	68 (49–78)	59 (41–76)	66 (39–78)
Male	187 (46.5%)	89 (46.1%)	81 (40.7%)
Female	215 (53.5%)	104 (53.9%)	119 (59.3%)
Influenza A (total)	149	313	290
Age, median (IQR)	64 (44–76)	54 (39–72)	67 (42–79)
Male	72 (48.3%)	149 (47.6%)	123 (42.4%)
Female	77 (51.7%)	164 (52.4%)	167 (57.6%)
Influenza B (total)	253	0	45
Age, median (IQR)	70 (53–80)	Not applicable	34 (27–62)
Male	115 (45.5%)	Not applicable	22 (48.9%)
Female	138 (54.5%)	Not applicable	23 (51.1%)
30-day all-cause mortality	11 (2.7%)	13 (4.2%)	14 (4.2%)
30-day ICU admission	7 (1.7%)	7 (2.2%)	7 (2.1%)

IQR, interquartile range; ICU, intensive care unit.

performance characteristics in their prospective study of influenza diagnosis in children [7].

By contrast with Kanwar *et al.*, our focus was on assessment of POCT to detect influenza when presenting at the ED and, specifically, the impact of POCT on patient flow in a crowded ED. An absolute reduction in numbers of healthcare-associated influenza between the pre- and post-implementation periods was observed. The ability to expedite allocation of confirmed influenza cases into isolation rooms within the ED while awaiting an isolation or cohort bed on the ward was the clinical focus for implementation of POCT; the objective was reduced cross-transmission within the department. In short, our findings suggest that early availability of influenza results can reduce healthcare-associated infections across the hospital. Similar reduction in cases of influenza diagnosed after 72 h of admission was observed by Garvey *et al.* when POCT was adopted in an acute medical assessment unit in a large teaching hospital [26]. In general, influenza-positive patients are cohorted into small bedded areas as part of routine infection prevention and control practice but, in our situation, a cohort ward dedicated to influenza was not available in any season. Therefore, it is reasonable to conclude that the observed reduction of healthcare-associated influenza was due to a reduction of transmission within the ED that was enabled by readily available POCT results, informing appropriate bed placement. We are confident in this observation as we did not see a significant variation in ED presentations across the three relevant influenza seasons and, in fact, although waiting times for an inpatient bed for 2018–2019 and 2019–2020 would most likely have increased the risk of healthcare-associated infections, we noted decreased incidences. This was itself interesting despite the elongated influenza season peak in 2017–2018 and the 2017–2018 vaccine mismatch, with poor coverage for the influenza B/Yamagata lineage circulating, which at least partially explains the relatively high influenza B activity during that influenza season [23].

In our setting, once POCT had been established, a lower admission rate was observed for patients presenting to hospital with suspected influenza. This is consistent with other studies suggesting that timely POCT results — even with sensitivities inferior to laboratory testing — can assist with clinical decision-making, albeit not necessarily in the ED [13,27,28]. The SARS-CoV-2 (COVID-19) pandemic has kindled interest in timely diagnostics to differentiate viral respiratory infections with similar clinical presentations. Whereas sensitivity of >90% for influenza appears sufficient for reduction of healthcare-associated influenza outbreaks in our study, it may be insufficient for COVID-19. An Abbott ID NOW™ COVID-19 test is now available as a POCT for COVID-19. An initial study reported poor sensitivity, although a sponsored clinical study described 95% sensitivity and 97.9% specificity within seven days of symptom onset [29,30]. Mina *et al.*, however, argued that consideration of the sensitivity and specificity alone should not dictate the adoption of a PCR assay [31]. In that context, our observations suggest that balance between sensitivity and the rapidity of results may result in positive clinical impact. It is likely, however, that the COVID-19 pandemic has reduced utility of influenza-only POCT and that emphasis would more valuably be

placed on a combined assay for detection and differentiation of SARS-CoV-2 and influenza A or B.

The limitations of our study relate to its retrospective design, and therefore that a causal relationship could not be confirmed between implementation of POCT and admission rate ratio or reduction in healthcare-associated influenza cases. Only 18 influenza B cases were detected using POCT, correlating with patterns observed in national data. Thus, the sensitivity and positive predictive value for influenza B cannot be defined, and may not be reliable in seasons when influenza B may be dominant. Further, due to the lack of electronic patient or prescribing records, the impact of POCT on antimicrobial prescribing for patients with confirmed influenza was not possible. Notably, prescriptions of oseltamivir were not studied. Finally, cost-analysis of the benefits of POCT was not performed as bed capacity during influenza season operates beyond 100% in our hospital group, and impact of reduction in admissions due to influenza cases cannot be determined specifically. However, indirect savings due to reduction in healthcare-associated influenza cases or outbreaks were likely achieved.

In conclusion, the adoption of POCT for influenza virus in the ED was a success in its diagnostic utility and infection control purpose. A user-friendly, easily operable POCT device, with rapid results for virus infection available directly to clinical staff, assisted in clinical decision-making and allowed appropriate isolation of patients with influenza. This resulted directly in associated reduction in hospital-acquired influenza infection.

Conflict of interest statement
None declared.

Funding sources
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