Lifecycle of molecular microbiology diagnostic technology: Cost versus clinical benefit before becoming obsolete.

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4i Centre for Interventions in Infection Inflammation & Immunity

Hosted by Paul Webber
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Objectives

- Understand that all technology undergoes cycles of innovation

- Describe evolution of testing from early conventional microbiology tests, through to emergence of high throughput molecular arrays that can target multiple microbial pathogens in single runs

- Discuss:

  how novel promising tests can become routinely and widely used, before being superseded by faster or more precise assays;

  how turnaround time is of critical importance;

  how choice of test platform now can dictate investment flexibility in the future;

  and how costs can be deceptive

Introductions

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Foundation Chair and Director of Research

School of Medicine
University of Limerick

Limerick Ireland

Me:

Microbiologist.

Email: colum.dunne@ul.ie

Colleagues:

Clinical and Medical Microbiologists and Biochemists.

UHLG and international.

Anatomy, engineering, gastroenterology, hospital management, immunology, infection prevention and control, nursing, paediatrics, physiology, respiratory medicine, surgery, surveillance, technology transfer.

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Challenges

Journal of Hospital Infection xxx (2016) 1–7

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

An Irish outbreak of New Delhi metallo-β-lactamase (NDM)-1 carbapenemase-producing Enterobacteriaceae: increasing but unrecognized prevalence

C. O'Connor [a,b], M. Cormican [c,d], T.W. Boo [c], E. McGrath [c,e], B. Slevin [d], A. O'Gorman [d,e], M. Commane [e], S. Mahony [b], E. O'Donovan [e], J. Powell [a], R. Monahan [a], C. Finnegan [a], M.G. Kiernan [b], J.C. Coffey [b], L. Power [a], N.H. O'Connell [a,b], C.P. Dunne [b,*]

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K. pneumoniae Carbapenemase

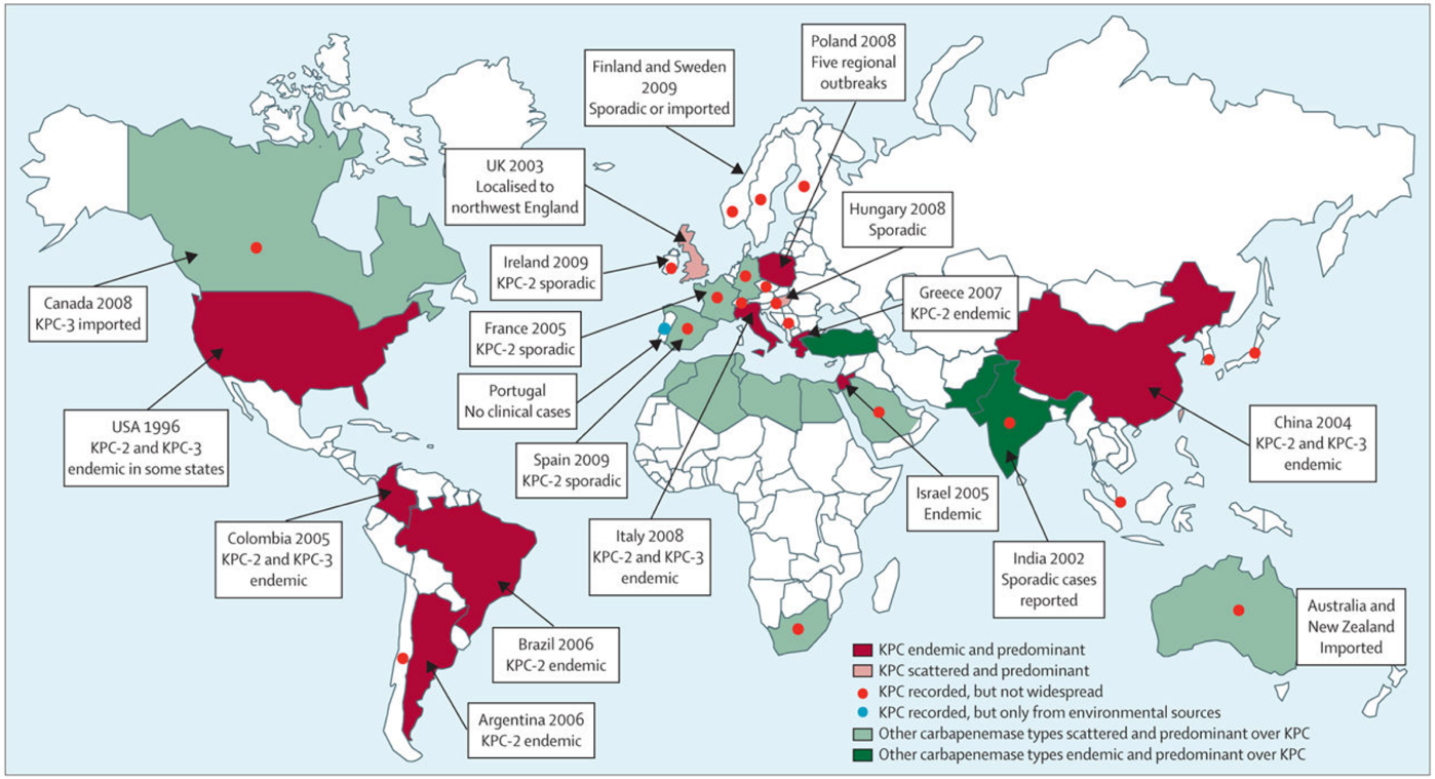
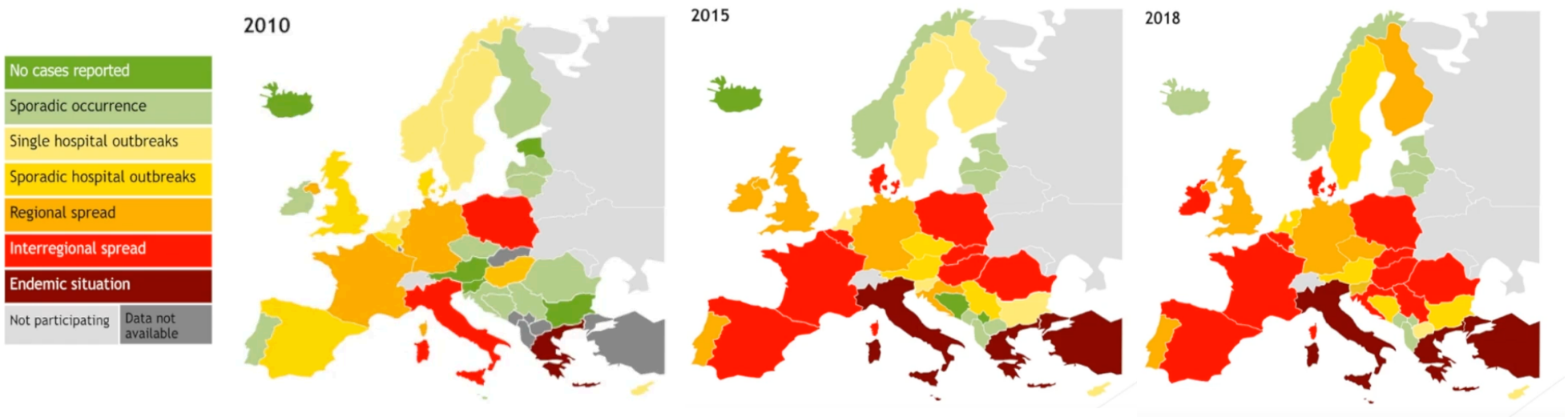


Figure. Epidemiological features of producers of *Klebsiella pneumoniae* carbapenemases by country of origin
Other carbapenemase types include VIM, OXA-48, or NDM. KPC=*Klebsiella pneumoniae* carbapenemase.

Munoz-Price LS, Poirel L, Bonomo RA, et al. Clinical epidemiology of the global expansion of Klebsiella pneumoniae carbapenemases. *Lancet Infect Dis*. 2013;13(9):785-796.

Progression of Outbreaks 2010 - 2018



ECDC. https://www.ecdc.europa.eu/en/antimicrobial-resistance/threats-and-outbreaks

Irish (Limerick) incidence

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Letter to the Editor

Limerick: forever associated with five lines of rhyme or infamous for irrepressible carbapenemase-producing Enterobacteriaceae for all time?

Our current analysis has identified two fatal KPC bacteraemias, three intra-abdominal theatre-derived samples positive for CPE, with *K. pneumoniae* ($N = 80$), *Klebsiella oxytoca* ($N = 30$), and *Citrobacter freundii* ($N = 17$) dominant. Indeed, our 2011 outbreak documented transmission of these strains between Irish hospitals.[6] Subsequent to this outbreak, CPE screening has been performed, in accordance with national guidelines, via rectal swab or stool specimen, for all patients

Journal of Hospital Infection xxx (2014) 1

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journal homepage: www.elsevierhealth.com/journals/jhin

Letter to the Editor

Against the onslaught of endemic carbapenemase-producing *Klebsiella pneumoniae*, the war is being lost on the Irish Front

Madam,

In the context of the excellent report of successful control screening policy whereby all HDU and ICU transfers are isolated until determined to be negative for KPC carriage.

Despite these measures, control has been ineffective and we have experienced simultaneous incidences of seven cases in June 2012, five cases in January 2014, and four cases in April 2014, with significant morbidity and mortality. In light of our inability prevent KPCs, we are debating the value of completing a study of local community carriage and revision of empirical first-line treatments, or even prophylaxis.

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Incidence, management and outcomes of the first *cfr*-mediated linezolid-resistant *Staphylococcus epidermidis* outbreak in a tertiary referral centre in the Republic of Ireland

C. O'Connor[a,b,c], J. Powell[a], C. Finnegan[a], A. O'Gorman[b], S. Barrett[d], K.L. Hopkins[e], B. Pichon[e], R. Hill[e], L. Power[a,b], N. Woodford[e], J.C. Coffey[c], A. Kearns[e], N.H. O'Connell[a,b,c], C.P. Dunne[c,*]

JMM Case Reports (2014) DOI 10.1099/jmmcr.0.000075

Case Report

Clustered multidrug-resistant *Bordetella petrii* in adult cystic fibrosis patients in Ireland: case report and review of antimicrobial therapies

Aislie Carleton,[1] Brian Casserly,[1,2] Lorraine Power,[2] Barry Linnane,[1,2] Grainne O'Flaherty,[2] James Powell,[2] Peig Hartnett,[2] Jonathan Collins,[3] Philip Murphy,[4] Dervla Kenna,[5] Nuala H. O'Connell[1,2] and Colum Dunne[1]

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JMM Case Reports (2015) DOI 10.1099/jmmcr.0.000089

A case of fatal daptomycin-resistant, vancomycin-resistant enterococcal infective endocarditis in end-stage kidney disease

Ciara O'Connor,[1,2] Liam F. Casserly,[3] Junaid Qazi,[3] Lorraine Power,[1] Cathriona Finnegan,[1] Nuala H. O'Connell[1,2] and Colum P. Dunne[2]

Infection Inflammation & Immunity

Patients, Carers, Families

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Letter to the Editor

Becoming patient-centred: sobering insight into CPE-positive patients' experiences of clinical care

by communication to them of their CPE and the explanatory leaflets provided. Further, they used emotive terms such as 'leper', 'pariah' and 'plague' to describe their treatment by staff, clearly demonstrating the need for consistent, effective education of healthcare professionals regarding multi-drug-resistant organisms and holistic needs of affected patients.

As healthcare professionals, we often do not look beyond specimens and infection control aspects of managing patients with CPE. However, the impact of a CPE diagnosis on patients

Journal of Hospital Infection
Volume 101, Issue 2, February 2019, Pages 194-195

Letter to the Editor

Opportunities lost may be the greatest cost of CPE outbreaks

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Received 11 October 2018, Accepted 15 October 2018, Available online 22 October 2018.

Journal of Hospital Infection 92 (2016) 309–320

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Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Review

Hand hygiene-related clinical trials reported since 2010: a systematic review

L. Kingston [a,*], N.H. O'Connell [b,c], C.P. Dunne [c]

Journal of Hospital Infection 111 (2021) 6–26

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Review

Hand-hygiene-related clinical trials reported between 2014 and 2020: a comprehensive systematic review

C. Clancy [a], T. Delungahawatta [a], C.P. Dunne [a,b,*]

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Journal of Hospital Infection 105 (2020) 116–118

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Commentary

Antimicrobial coating innovations to prevent infectious disease: a consensus view from the AMiCI COST Action

C.P. Dunne [a,*], P.D. Askew [b], T. Papadopoulos [c], I.C. Gouveia [d], M. Ahonen [e], M. Modic [f], N.F. Azevedo [g], S. Schulte [h], P. Cosemans [j], A. Kahru [k], K. Murzyn [m], C.W. Keevil [n], M. Riool [o,p], M.M. Keinänen-Toivola [e], on behalf on the AMiCI Consortium

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Clinical Biochemistry 52 (2018) 26–32

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/clinbiochem

Clustered interventions to reduce inappropriate duplicate laboratory tests in an Irish tertiary hospital

Hugh Brady[a], Laura Piggott[b], Suzanne S. Dunne[b], Nuala H. O'Connell[b,c], Colum P. Dunne[b,*]

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[b] Centre for Interventions in Infection, Inflammation & Immunity (4i) and Graduate-Entry Medical School, University of Limerick, Limerick, Ireland
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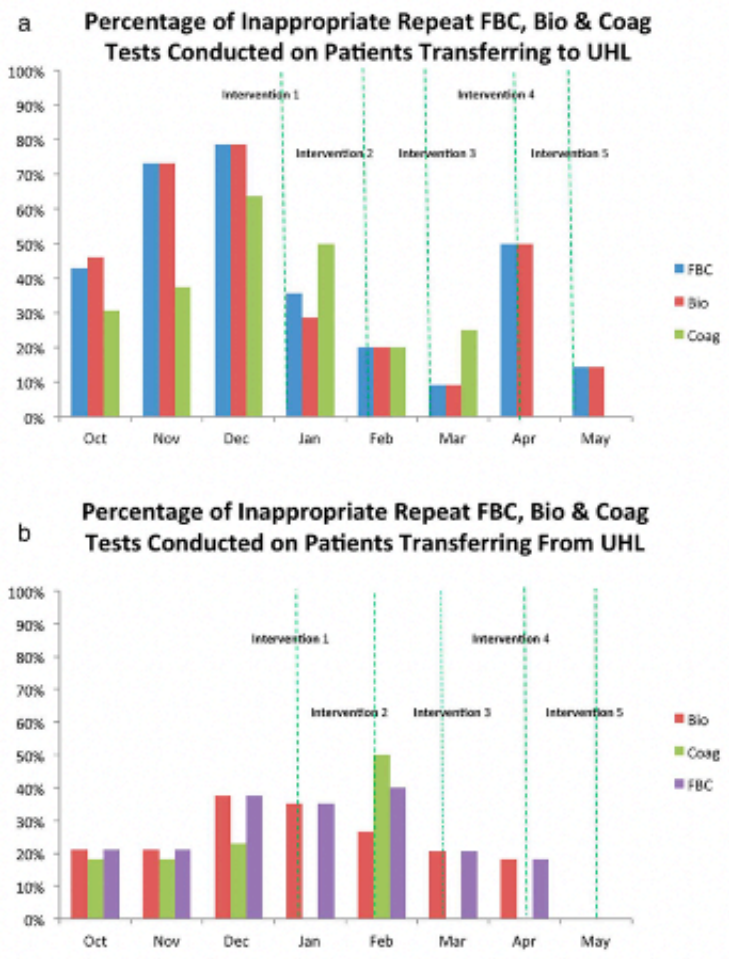

Fig. 2. a. Inappropriate testing of patients transferred to University Hospital Limerick (UHL) from other group hospitals (JHNS).
b. Inappropriate testing of patients transferred to other group hospitals (JHNS) from University Hospital Limerick (UHL).

Brady H, Piggott L, Dunne SS, O'Connell NH, Dunne CP. Clustered interventions to reduce inappropriate duplicate laboratory tests in an Irish tertiary hospital. Clin Biochem. 2018 Feb;52:26-32.

Testing

Bioengineered 5:3, 155–160; May/June 2014; © 2014 Landes Bioscience

A commentary on the role of molecular technology and automation in clinical diagnostics

Ciara O'Connor[1,2], Marie Fitzgibbon[1], James Powell[1], Denis Barron[1], Jim O'Mahony[3], Lorraine Power[1], Nuala H O'Connell[1,2], and Colum Dunne[2,*]

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Keywords: clinical microbiology, MALDI, PCR, patient care, impact

Table 1. Turnaround time (TAT)* for microbial identification**

	MALDI-TOF		Conventional microbiology		Reduction of mean TAT
	Mean	Min- Max	Mean	Min- Max	
Gram-positive and Gram-negative	11.12***	2.0–27	28.62	18.0–60.0	17.5
Gram-positive only	13.41	2.0–27.0	27.88	20.0–55.0	14.47
Gram-negative only	5.36	2.0–20.0	28.55	18.0–60.0	23.19

*TAT = turnaround time. **Over a 6 wk period, 150 blood samples at University Hospital Limerick, Ireland. *** All values are in hours

O'Connor C, Fitzgibbon M, Powell J, Barron D, O'Mahony J, Power L, O'Connell NH, Dunne C. A commentary on the role of molecular technology and automation in clinical diagnostics. Bioengineered. 2014 May-Jun;5(3):155-60.

PLOS ONE

RESEARCH ARTICLE

A retrospective observational study of the impact of 16s and 18s ribosomal RNA PCR on antimicrobial treatment over seven years: A tertiary hospital experience

TeeKeat Teoh[1,2], Rachel McNamara[3], James Powell[1], Nuala H. O'Connell[1,2], Colum P. Dunne[2]*

1 Department of Clinical Microbiology, University Limerick Hospital Group, Limerick, Ireland, **2** Centre for Interventions in Infection, Inflammation & Immunity (4i) and School of Medicine, University of Limerick, Limerick, Ireland, **3** Department of Medicine and Infectious Diseases, University Hospital Limerick, Limerick, Ireland

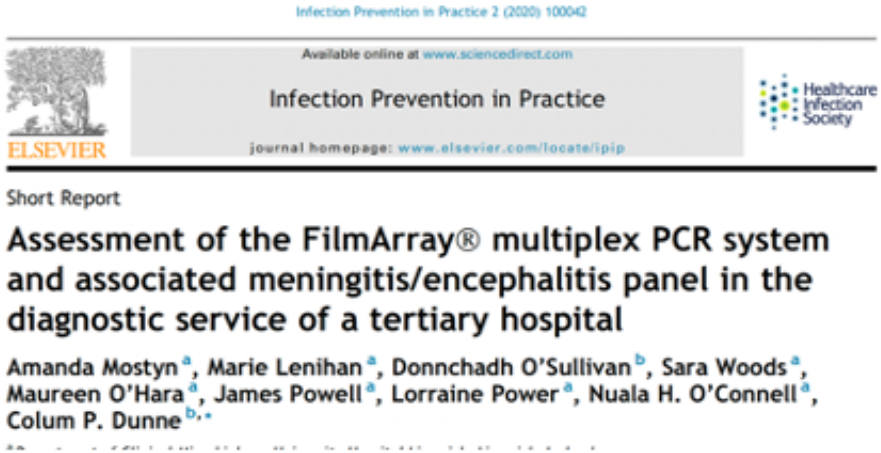
Conclusion

There was limited impact of 16s PCR results on antimicrobial treatments. Relevance to practice was affected by relatively long turn-around-time for results. Utility may be increased in specialised surgical centres, or by reducing turn-around-time. Enrichment culture should be considered on samples where 16s PCR is requested. There remains limited evidence for use of 18s PCR in clinical management, and further studies in this area are likely warranted.

Teoh T, McNamara R, Powell J, O'Connell NH, Dunne CP. A retrospective observational study of the impact of 16s and 18s ribosomal RNA PCR on antimicrobial treatment over seven years: A tertiary hospital experience. PLoS One. 2021 Oct 12;16(10):e0258552.

- Meningitis / Encephalitis Test Panel
  - Impact of faster lab-based multiplex test results on outcomes comparing aseptic meningitis (93) to viral (54) and bacterial (21) meningitis.
  - Evaluation
    - Accuracy / Correlation to predicate
    - CCU admissions
    - 90-day readmissions
    - Avg length of stay
    - 30- and 90-day mortality

    - Satisfied performance requirements
    - Provided faster results
    - Eliminated gram stains



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journal homepage: www.elsevier.com/locate/ipip

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Healthcare Infection Society

Short Report

Assessment of the FilmArray® multiplex PCR system and associated meningitis/encephalitis panel in the diagnostic service of a tertiary hospital

Amanda Mostyn [a], Marie Lenihan [a], Donnchadh O'Sullivan [b], Sara Woods [a], Maureen O'Hara [a], James Powell [a], Lorraine Power [a], Nuala H. O'Connell [a], Colum P. Dunne [b,*]

Mostyn A, Lenihan M, O'Sullivan D; Woods Sara, O'Hara M, Powell J, Power L, O'Connell NH, Dunne CP. Assessment of the FilmArray® multiplex PCR system and associated meningitis/encephalitis panel in the diagnostic service of a tertiary hospital. Infection Prevention in Practice, Vol 2, Issue 2, June 2020, 100042.

PLOS ONE

RESEARCH ARTICLE

Outcomes of implementation of the FilmArray meningoencephalitis panel in a tertiary hospital between 2017 and 2020

TeeKeat Teoh[1,2,3], James Powell[1], Jillian O'Keeffe[1], Eoghan Donlon[4], Lisa Dillon[1], Marie Lenihan[1], Amanda Mostyn[1], Lorraine Power[1], Peter Boers[4], Patrick J. Stapleton[1,3], Nuala H. O'Connell[1,2,3], Colum P. Dunne[2,3]*

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* colum.dunne@ul.ie

Centre for Interventions in Infection Inflammation & Immunity

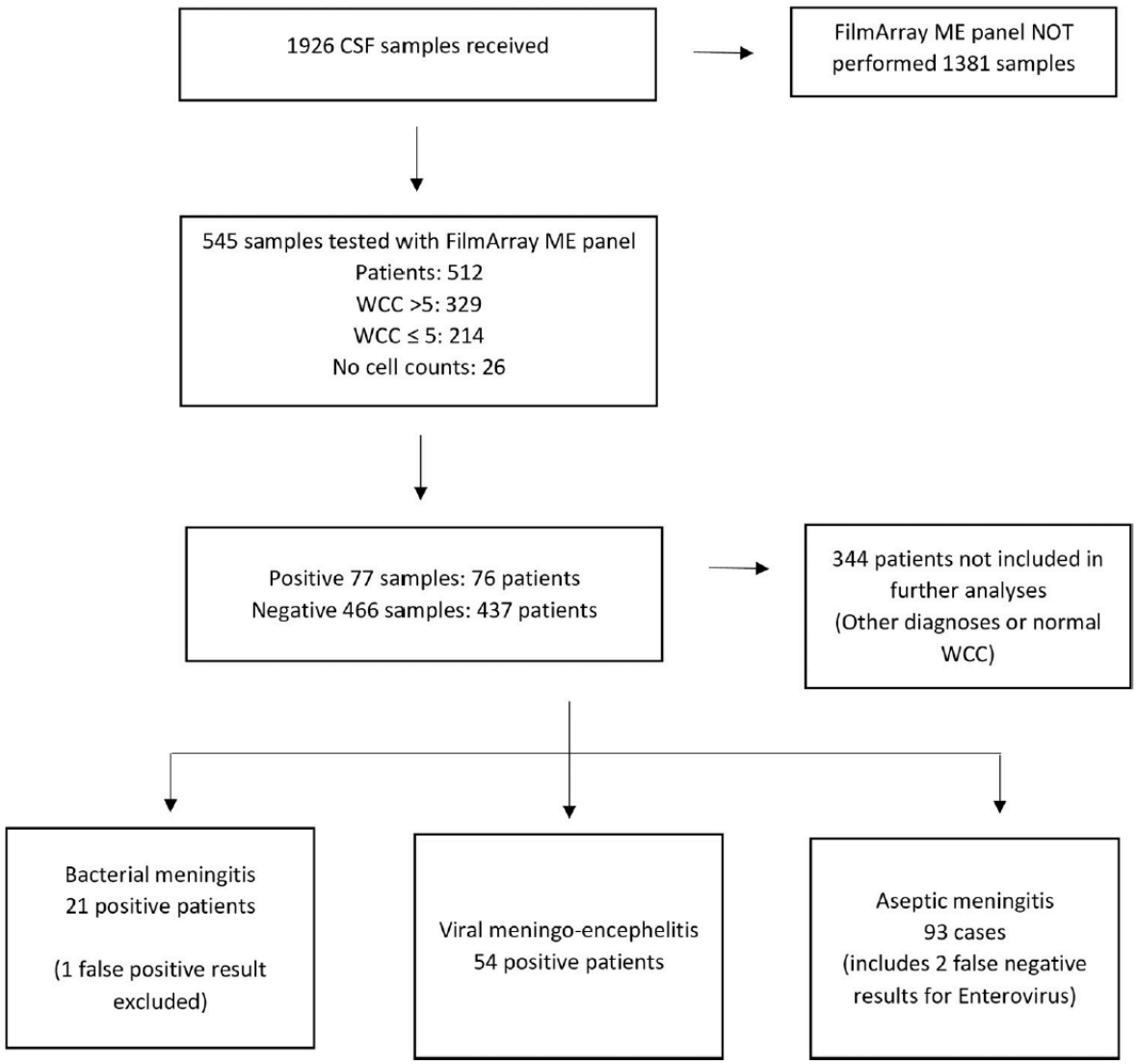

Fig 1. CSF samples and patients during study period.

https://doi.org/10.1371/journal.pone.0265187.g001

Table 1. Positive results for FilmArray ME panel in study.

Target	FA Positive	Culture Positive	Samples referred to the NVRL	PCR Confirmed NVRL	Discordant FA positive, NVRL neg	Discordant FA negative, NVRL positive	Concordant positive FA/ NVRL	Concordant negative FA/ NVRL
Streptococcus pneumoniae	10	3	N/A	N/A	N/A	N/A	N/A	N/A
Neisseria meningitidis	4	0	N/A	N/A	N/A	N/A	N/A	N/A
Listeria monocytogenes	2	0	N/A	N/A	N/A	N/A	N/A	N/A
Group B beta-haemolytic streptococci	4	2	N/A	N/A	N/A	N/A	N/A	N/A
Haemophilus influenzae	1	0	N/A	N/A	N/A	N/A	N/A	N/A
Escherichia coli	0	1	N/A	N/A	N/A	N/A	N/A	N/A
Enterovirus [a]	22	N/A	103	2	0	2	0	99
Varicella-zoster virus [a]	16	N/A	103	1	0	0	1	102
Human herpes virus 6[a,c]	10	N/A	19	2	0	0	2	17
Herpes simplex virus (HSV) 1[a]	1	N/A	103	2	1	2	0	100
Herpes simplex virus (HSV) 2 [a]	3	N/A	103	0	0	0	0	103
Human parechovirus[a,c]	2	N/A	19	2	0	0	2	17
Enterovirus & human herpesvirus 6[b]	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Cytomegalovirus [ac]	0	N/A	6	2	0	2	0	4

FA, FilmArray ME panel; NVRL, National Virus Reference Laboratory

[a] Only a limited number of samples were sent for corroboratory testing in the NVRL based on clinical need as determined by the Medical Microbiologist.

[b] Two samples tested with 2 positive targets on the FimArray ME panel. Both samples were not referred for any corroboratory testing.

[c] Enterovirus, HSV-1, HSV-2 and VZV is routinely performed for samples referred to the NVRL. Human parechovirus and HHV-6 is only tested in samples for patients under the age of 1 or upon special request. CMV is only available upon special request.

https://doi.org/10.1371/journal.pone.0265187.t001

Table 3. Specimens that underwent duplicate testing for viral targets.

		Reference Lab		
		Detected	Not Detected	
FilmArray ME panel	Detected	7	1	8
	Not Detected	6	89	95
		13	90	103

https://doi.org/10.1371/journal.pone.0265187.t003

Conclusion

In our hands, implementation of the FilmArray ME panel was relatively straightforward. We experienced a transition in our workflow processes that enabled streamlining of CSF diagnostics and the safe removal of Gram staining in those samples being tested by this molecular assay. Coupled to this improvement, there was a positive clinical impact on patient care due to rapid turnaround time to results.

Journal of Hospital Infection 110 (2021) 45–51

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

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

T.K. Teoh [a,b,d], J. Powell [a], J. Kelly [c], C. McDonnell [b], R. Whelan [c], N.H. O'Connell [a,b,d], C.P. Dunne [d,*]

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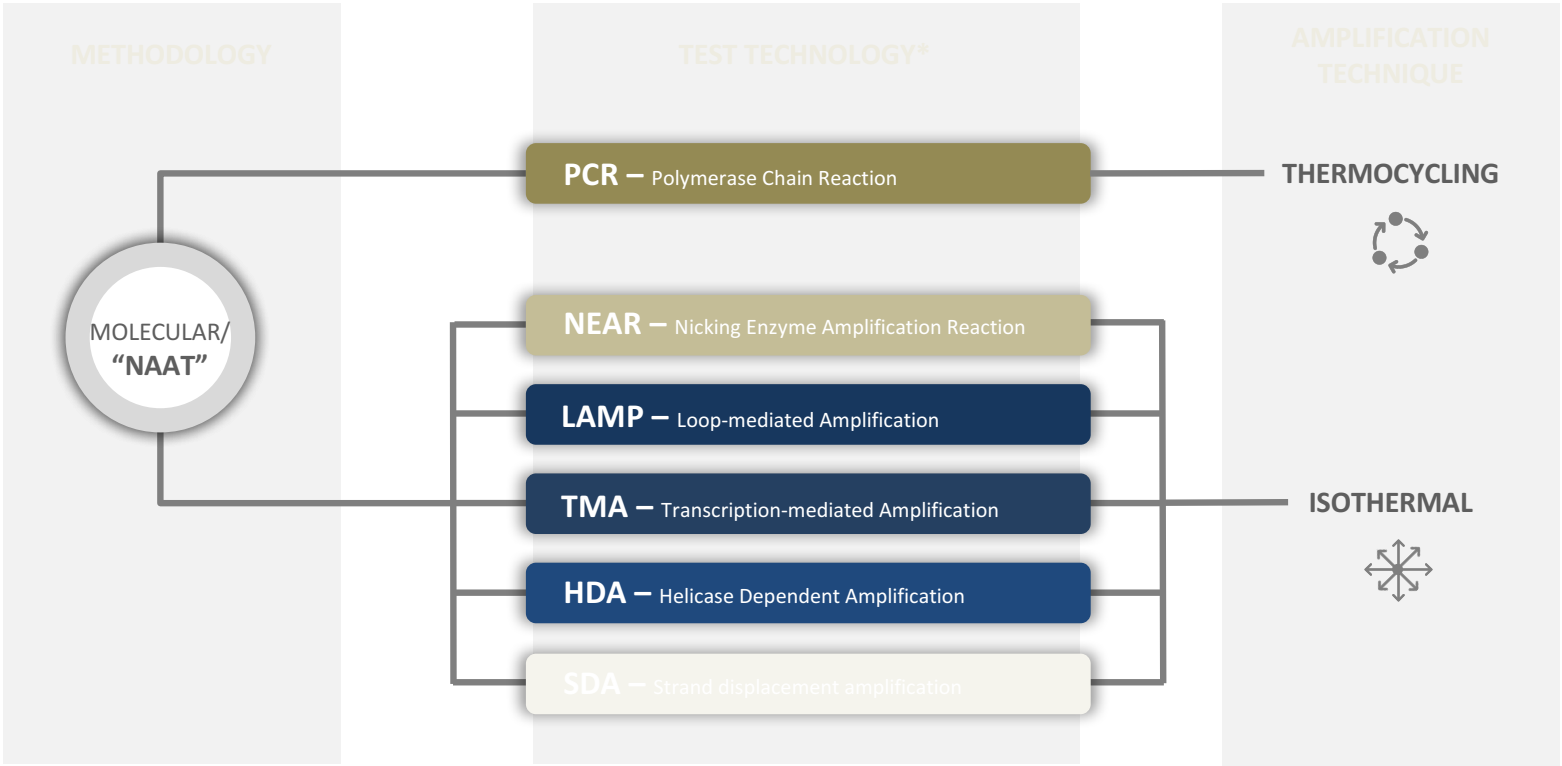
Study Objectives

- Understand the influence of POCT in the ED on patient flow, isolation facilities, admission, and treatment during peak influenza seasons
- Assess the impact of POCT on incidence of “ED-acquired” influenza
- Determine performance characteristics of rapid molecular influenza test system compared to the laboratory

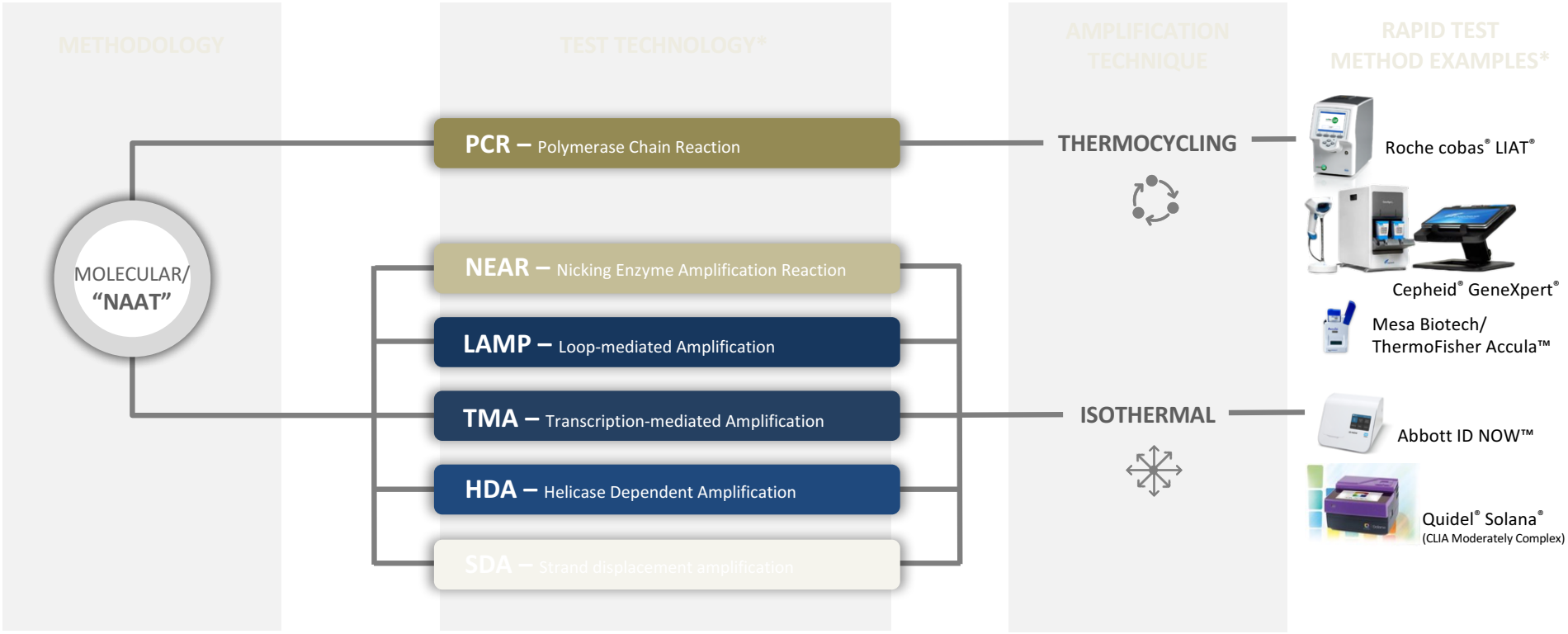
Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

Molecular (NAAT) Test Technologies



NAAT, Nucleic Acid Amplification Test
*CDC, Nucleic Acid Amplification Tests (NAATs), updated June 16, 2021. Includes those with amplification, accessed Oct 27, 2021.

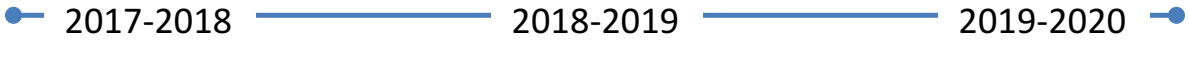
Molecular (NAAT) Test Technologies



NAAT, Nucleic Acid Amplification Test
*CDC, Nucleic Acid Amplification Tests (NAATs), updated June 16, 2021. Includes those with amplification, accessed Oct 27, 2021.

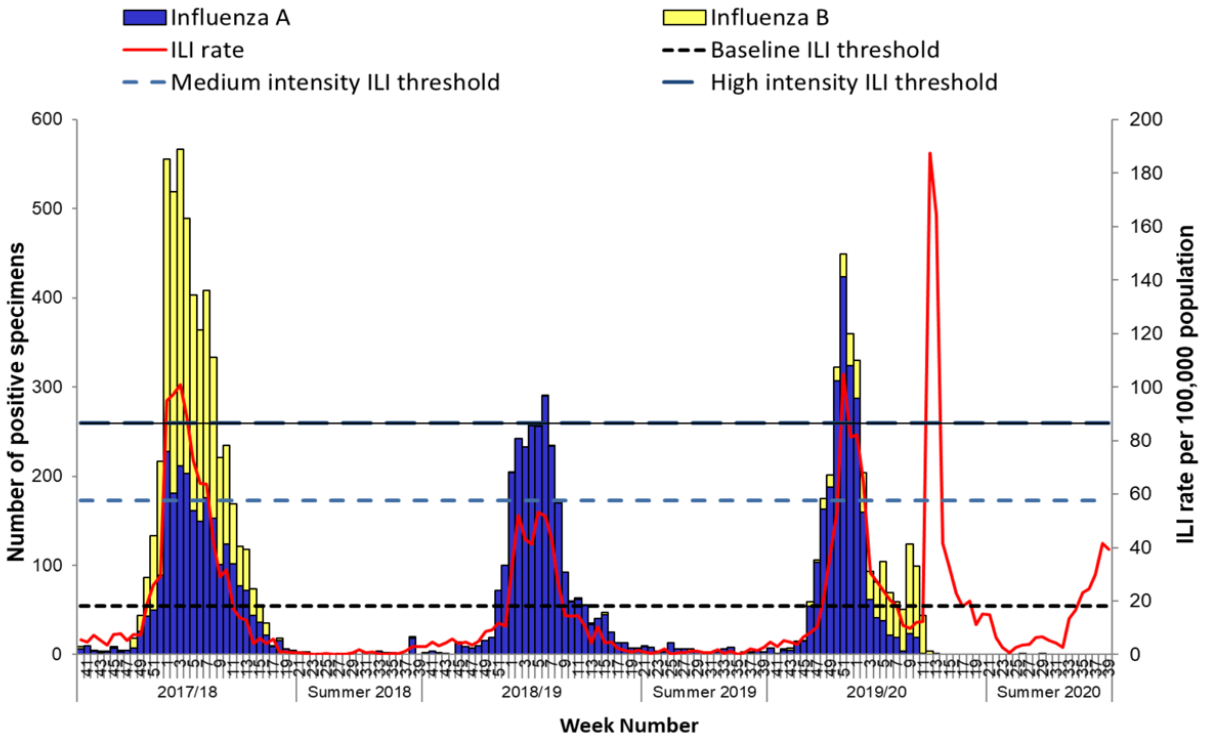
Evaluation of Rapid POCT of Influenza in the ED

STUDY PERIOD: INFLUENZA SEASONS



Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

Positive Influenza A and B Specimens Tested by the National Virus Reference Laboratory Across 3 Flu Seasons[1]



Influenza Season Duration During Study Period: 14 weeks 9 weeks 12 weeks

1. Health Protection Surveillance Centre (HPSC). Influenza Surveillance in Ireland – Weekly Report. Influenza Surveillance Report week 39 2020.

Evaluation of Rapid POCT of Influenza in the ED

STUDY PERIOD: INFLUENZA SEASONS

2017-2018 — 2018-2019 — 2019-2020

PRE-POCT:

RAPID TESTING IN THE LABORATORY

Rapid Molecular

Available: 0800-2000, or next day.

POCT IMPLEMENTATION:

RAPID TESTING IN THE ED

Rapid Molecular

Available: 24/7

Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

Evaluation of Rapid POCT of Influenza in the ED

STUDY PERIOD: INFLUENZA SEASONS

2017-2018 — 2018-2019 — 2019-2020

PRE-POCT:

RAPID TESTING IN THE LABORATORY

Rapid Molecular

Available: 0800-2000, or next day.

POCT IMPLEMENTATION:

RAPID TESTING IN THE ED

Rapid Molecular

Available: 24/7

OUTCOMES EVALUATED:

- Absolute number of confirmed healthcare-associated influenza cases (>48 hrs of admit)
- 30-day intensive care unit admissions
- 30-day all cause mortality
- Average ED admissions
- Average ED wait time while waiting for ward bed

Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

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.

Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

Total Lab Tests	2409	2311	2430

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

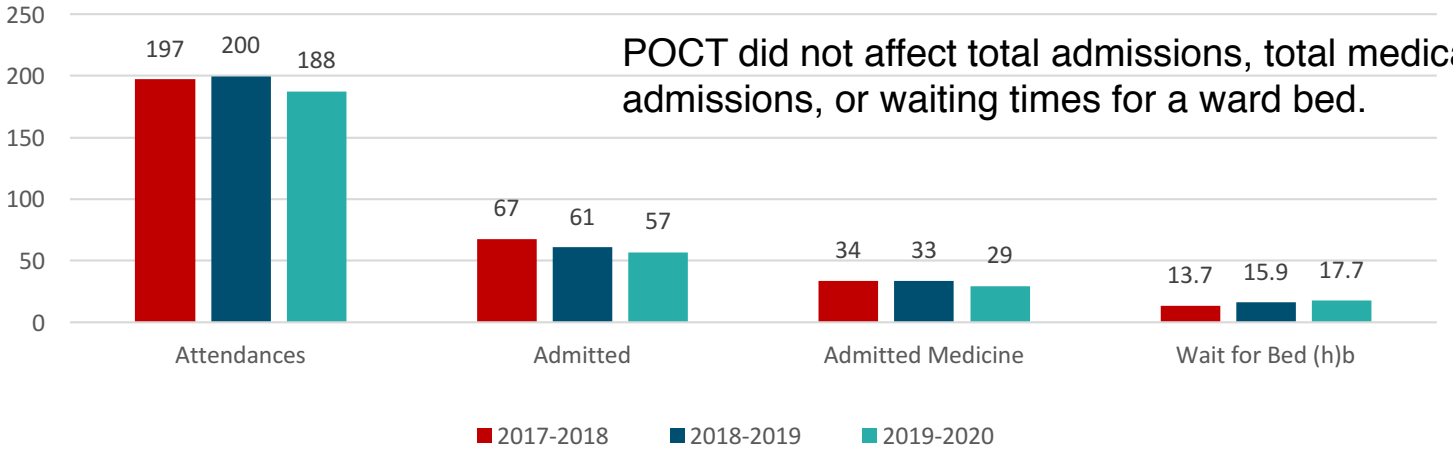
Variable	2017–2018	2018–2019	2019–2020
Total POCT		504	685
Age, median (IQR)	Not applicable	59 (40–74)	68 (49–79)
Sex			
Male		238 (47.3%)	334 (48.7%)
Female		266 (52.7%)	351 (51.3%)
All influenza positive cases			
Total positive influenza cases diagnosed by:	402	313	335
POCT result		120	136
Age, median (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.

No significant difference in 30-day all-cause mortality rate or intensive care unit admission rate for influenza-positive patients.

Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

Average ED Attendances, Admissions, and Bed Wait Times Across Three Influenza Seasons



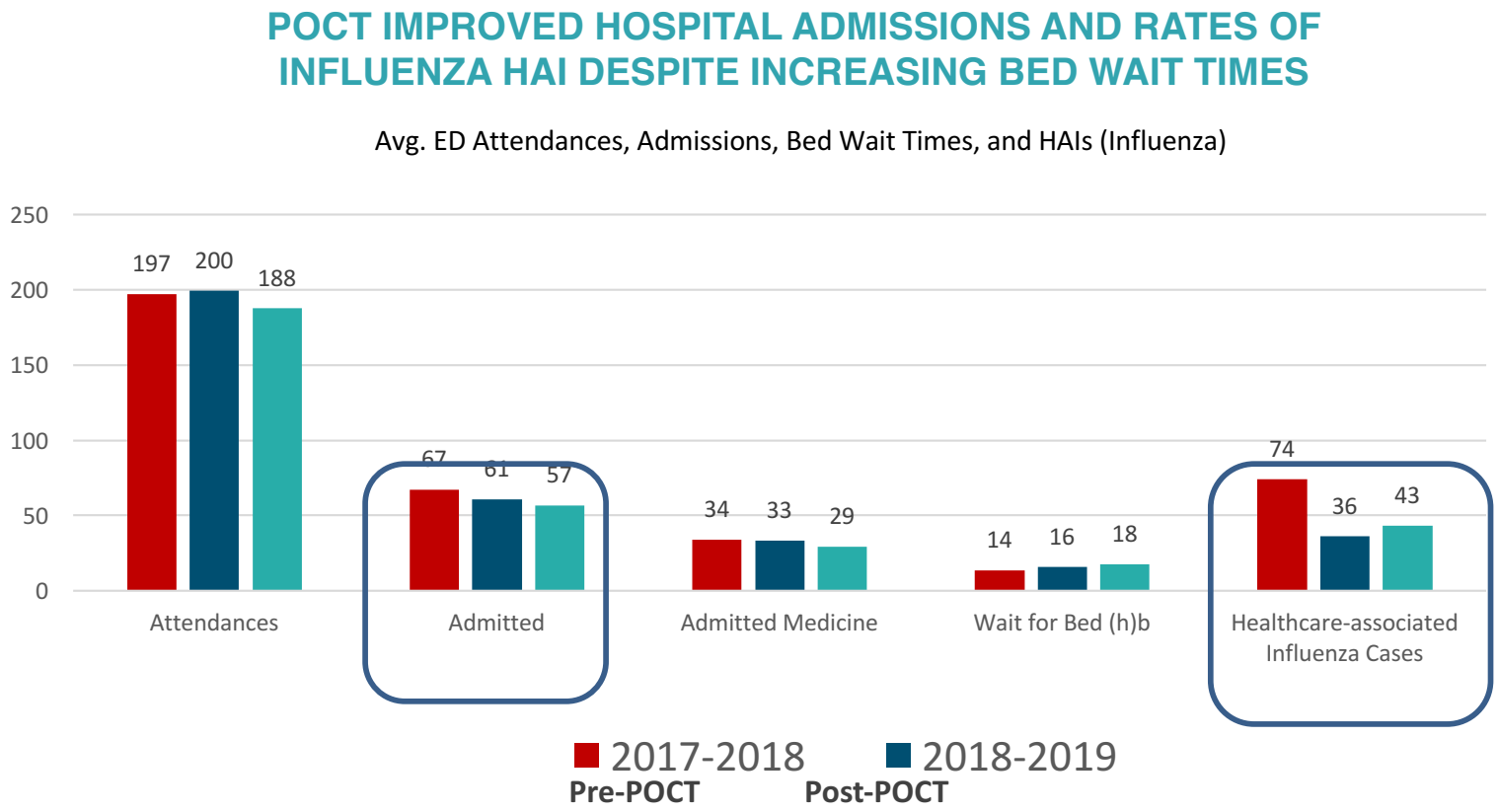
POCT did not affect total admissions, total medical admissions, or waiting times for a ward bed.

	2017-2018	2018-2019	2019-2020
Attendances	**197.0** (196) [57.24]	**199.5** (198) [59.45]	**187.5** (188) [54.42]
Admitted	**67.3** (66) [23.69]	**60.7** (60.5) [20.50]	**56.8** (56.5) [18.26]
Admitted Medicine	**33.8** (33) [13.07]	**33.4** (33) [14.07]	**29.4** (30) [11.36]
Wait for Bed (h)[b]	**13.7** (13.5) [16.97]	**15.9** (14.7) [17.48]	**17.7** (14.7) [19.56]

[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.

Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

Metrics Across 3 Influenza Seasons Pre-/Post-POCT Implementation



Teoh TK, Powell J, Kelly J, McDonnell C, Whelan R, O'Connell NH, Dunne CP. Outcomes of point-of-care testing for influenza in the emergency department of a tertiary referral hospital in Ireland. J Hosp Infect. 2021 Apr;110:45-51.

POCT Performance

- Reliable performance characteristics

Pathogen	Sensitivity	Specificity	PPV	NPV
Influenza[1]	90.6%	99.2%	97.8%	96.3%
Influenza B[1] (note: only 11 cases in 2 seasons)	100%	93.6%	50%	100%

  - Consistent with Kanwar et al., prospective study of influenza diagnosis in children[2]
- Studies have varied in performance[3,4]
  - Sponsored clinical study reported 95% sensitivity and 97.9% specificity ≤ 7 days of symptom onset[4]
  - Evaluations should include those in the intended patient population
- Consideration: Sensitivity and specificity alone should not dictate test adoption[5]
  - Balance sensitivity and rapidity of results on positive clinical impact
- Co-infection rates increase need for combination testing protocols for SARS-CoV-2 and influenza

1. Teoh TK, et al. J Hosp Infect. 2021 Apr;110:45-51.
2. Kanwar N, Michael J, Doran K, et al. Comparison of the ID Now Influenza A & B 2, Cobas Influenza A/B, and Xpert Xpress Flu point-of-care nucleic acid amplification tests for influenza A/B virus detection in children. J Clin Microbiol 2020;58:e01611e9.
3. Mitchell SL, George KS. Evaluation of the COVID19 ID NOW EUA assay. J Clin Virol 2020;128:104429.
4. Abbott. [press release, October 7th, 2020]. https://www.prnewswire.com/newsreleases/abbott-releases-id-now-covid-19-interim-clinical-studyresults-from-1-003-people-to-provide-the-facts-on-clinical-performance-and-to-support-public-health-301147308.html
5. Mina MJ, Parker R, Larremore DB. Rethinking Covid-19 test sensitivity e a strategy for containment. N Engl J Med 2020;383:e120.

Conclusions

- Adoption of ED POCT for influenza was a success in diagnostic utility and infection control
  - Reduction in HAI influenza
  - Positively impact on operational management; patient flow, isolation, cohorting in a crowded ED
- Confidence in Findings
  - No significant variation in ED presentations across the three influenza seasons
  - Many cohort into small bedded areas as part of routine infection prevention and control practice, however, a cohort ward dedicated to influenza was not available in any season.
    - Concluded the observed reduction of healthcare-associated influenza was due to a reduction of transmission within the ED enabled by readily available POCT results
  - Favorable impact despite elongated 2017-2018 influenza season and vaccine mismatch (poor coverage for circulating influenza B/Yamagata lineage), and partially explains the relatively high influenza B activity during that influenza season.
- 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.

Rapid Molecular COVID-19 Testing in the ED (Jan 2022)

TEST RESULT	# SPECIMENS
SARS CoV-2 DETECTED **(POSITIVE)**	141
SARS CoV-2 Not detected **(NEGATIVE)**	688
GRAND TOTAL	**829**

17% COVID-19 POSITIVITY RATE

Testing data through January 12, 2022.

Summary

- Important to consider range of potential improved outcomes with implementation of POCT.
- Clinically focus initiative to reduce cross-transmission and hospital-acquired influenza in the ED (and onward throughout hospital).
- The adoption of POCT for influenza virus in the ED was a success in its diagnostic utility and infection control / isolation purpose.
- Need user-friendly, easily operable POCT device with rapid results available directly to clinical staff.
- The COVID-19 pandemic has ignited interest in timely diagnostics .
- Important to understand co-infection rates and have rapid differential diagnosis of viral respiratory infections with similar clinical presentations.

Future Potential / Opportunities

- Infection prevention and control
  - Not aware of published studies providing quantitative data regarding POCT use in prevention of hospital acquired Influenza and / or COVID.
  - There is an opportunity to determine efficacy in facilities that have managed viral illness and transmission before, and then following, adoption of POCT.
- Screening of admitted patients / Cohorting of admissions (inpatients)
  - There is likely potential for expanded use of POCT in management of HAI risk. Based on accuracy > lateral flow testing.
  - Specifically, routine / regular inpatient (and staff) testing to avoid occult colonization or infection and onward transmission.

Messages to take home:

- Technologies come and go
- Choice of one has implications regarding scope and scale of tests…critical path!
- Some platforms expand while others contract
- Platforms may succeed based on rapid TAT rather than cost
- Arrays that test for multiple targets are developing quickly and may reduce need for referral labs
- POC molecular testing has considerable specificity and sensitivity…
- …and may allow effective patient management

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April 28, 2022	*(FREE Teleclass)* **HOW DO WE IMAGINE OUR FUTURE? THE INFECTION PREVENTION "CRYSTAL BALL INITIATIVE"** Speaker: **Dr. Hugo Sax**, HumanLabZ, Switzerland
May 5, 2022	*(FREE Teleclass)* **SPECIAL LECTURE FOR WHO CLEAN HANDS DAY** Speaker: **Prof. Didier Pittet**, University of Geneva Hospitals, Switzerland
May 12, 2022	**PREVENTION AND MANAGEMENT OF POST-OPERATIVE SEPSIS** Speaker: **Dr. Cindy Hou**, Jefferson Health, New Jersey
May 19, 2022	***C. DIFFICILE* ASYMPTOMATIC CARRIERS: SHOULD WE WORRY ABOUT THEM?** Speaker: **Prof. Yves Longtin**, McGill University, Montreal
May 25, 2022	*(South Pacific Teleclass)* **PATIENT-FOCUSED ANTIMICROBIAL RESISTANCE SURVEILLANCE: DATA FROM THE GROUND UP** Speaker: **Dr. Paul Turner**, Cambodia Oxford Medical Research Unit, Angkor Hospital for Children, Cambodia
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