DOI:10.1111/j.1750-2659.2011.00306.x
www.influenzajournal.com

Original Article

Emerging point of care tests for influenza: innovation or status quo

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Accepted 10 October 2011. Published Online 22 November 2011.

Background Point of care tests (POCTs) for influenza potentially offer earlier diagnosis, enabling specific treatment, infection control measures and greater patient convenience and satisfaction. Current POCTs have limited sensitivity, some cannot distinguish influenza types, none differentiate subtypes and are relatively expensive.

Aims To identify and characterise influenza POCTs expected to be available for clinical use in the UK by mid-2013, highlighting those with potential benefits over existing tests.

Methods Potential developers of influenza POCTs were identified through known manufacturers' websites, Medical Technology trade associations, the EuroScan International Network, an expert advisory group and by searching relevant online sources. Identified companies were asked to provide standard information on relevant technologies.

Results Fifty-six companies were identified, and 29 (52%) responded, identifying 57 potentially relevant technologies. Of these, 40 (70%) were already available or had undetermined status and 5 (9%) were excluded as time to results took over 60 minutes. Of the remaining 12 emerging POCTs, 10 (83%) reportedly enabled differentiation of influenza types and eight differentiation of A subtypes. Nasopharyngeal swabs were the most commonly acceptable sample type; the sample volume ranging from 80 μl to 1·4 ml.

Discussion Most identified emerging influenza POCTs offered differentiation of influenza type and subtype. Tests claiming this capability include several incorporating reverse transcription polymerase chain reaction assays; though, these also had the longest time to result. However, whilst some identified POCTs exhibit high sensitivity and specificity, most lack published clinical data for assessment, and the overall costs of these technologies remains largely unknown.

Keywords Diagnosis, emerging health technology, influenza, innovation, point of care testing.

Please cite this paper as: Tayo A *et al.* (2012) Emerging point of care tests for influenza: innovation or status quo. Influenza and Other Respiratory Viruses 6(4), 291–298.

Background

In the United Kingdom, the majority of patients suffering from influenza, who seek medical assistance, present in primary care.[1] Diagnosis is routinely made on the basis of a typical clinical syndrome (influenza like illness), which in periods of high community influenza activity is considered sufficiently reliable to guide the use of specific antiviral medications; determine prognosis and the likelihood of serious complications; and offer advice on infection control measures.[2] At other times, and in cases where rapid action may be necessary (e.g. to confirm an outbreak) or the presentation is atypical, diagnostic testing may be necessary. Current practice requires that a suitable sample is transported in a timely manner and an appropriate transport medium to a laboratory for processing, testing and subsequent reporting.[3,4] Depending on the setting, this may be logistically difficult and introduces delays in clinical decision making. Laboratory tests routinely employed for detection of influenza viruses include virus culture, immunofluorescence (IF) and reverse transcription polymerase chain reaction (RT-PCR) assays.[3,5] These have the capability to identify and distinguish different influenza types and subtypes and can be used with a wide range of acceptable specimen types. Virus culture and RT-PCR assays are the gold standard for influenza detection, demonstrating both sensitivity and specificity. However, RT-PCR may take 4–6 hours to perform and virus culture may take up to 7 days for a result. Diagnosis using IF can be achieved in 1–4 hours, but sensitivity and specificity of detection by IF may be low.

In contrast, point of care tests (POCTs) allow both sampling and analysis to take place in the same setting, and the result is available without reference to a standard laboratory.[6,7] This encompasses tests requiring varying degrees

of manual versus automated processing that can be categorised as non-instrumental disposable systems, single or multireagent test strips, small hand-held analysers and larger desktop analysers for use in clinics.[8] The World Health Organisation (WHO) suggest an ideal POCT should be affordable, sensitive, specific, rapid, robust, equipment-free and delivered to those who need it.[9] POCTs have the potential to allow earlier diagnosis leading to earlier introduction of specific treatment, establishment of effective infection control measures and greater patient convenience, involvement and satisfaction.[10–12]

In response to the perceived need for more rapid results at the point of care to aid decision making, manufacturers have marketed a number of POCTs for influenza viruses, based on immunochromatographic assays, enzyme immunoassay or lateral flow assay to identify the influenza virus antigen.[13–15] However, laboratory confirmation of the result is typically required. Current commercially available tests, whilst showing specificity in the range 85–100%, have been criticised for limited or variable sensitivity (between 10% and 80% when compared to laboratory-performed RT-PCR or viral culture for influenza),[15–17] leading to false-negative results, most notably when influenza activity is high in the community. False-positive results may also be obtained, particularly when the prevalence of influenza in the community is low. Existing POCTs may not distinguish between influenza types and do not differentiate influenza subtypes,[18] which could aid the management of outbreaks, direct antiviral treatment (where circulating subtypes have different antiviral susceptibilities), allow identification of human infection with avian influenza (in settings where this may be suspected) and provide a useful surveillance tool. In addition, these tests may be relatively expensive to perform per test and have a limited shelf-life (1–2 years).[19] There is therefore a need for a validated, sensitive and rapid POCT for influenza that also has the capability to both reliably distinguish influenza A and B, and influenza A subtypes. This need has been recognised with the European Union (EU) Seventh Framework Programme currently financing initiatives to develop improved POCTs for influenza,[20,21] and the development of simple diagnostic tests is a research priority for the WHO.[22] We sought to identify and characterise emerging POCTs for influenza that were expected to be available and marketed for clinical use in the UK within the subsequent 3 years (by July 2013 at the latest) and to highlight those with the potential to offer additional benefit over currently available tests.

Methods

The review was carried out during May and June 2010. Potential developers active in the field of point of care testing for influenza were identified through interrogating websites of known manufacturers of POCTs, through an expert advisory group, through direct communications with Medical Technology trade associations in the UK, Europe and America and through members of the EuroScan International network[1] (Figure 1). In addition, a search of online sources (see Box 1) was carried out using pre-determined search terms.

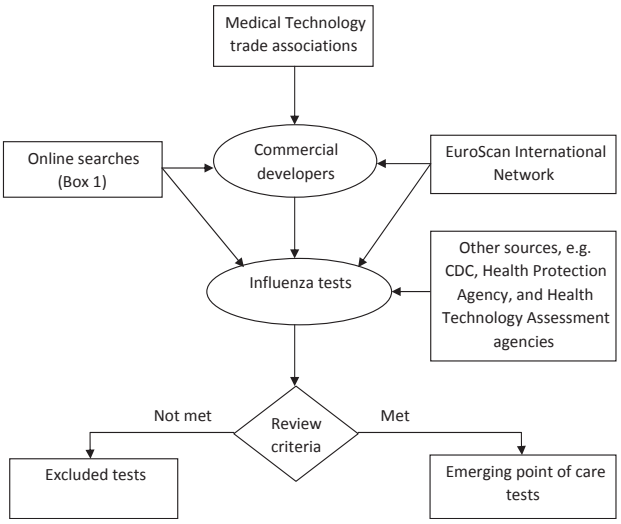

Figure 1. Flowchart illustrating process of identifying point of care tests for influenza currently in development and selecting those for inclusion in the review.

Diagnostic tests for influenza were included if they were:

1. New or emerging, that is either CE marked/FDA approved or expected to be so within 2 years and/or for which marketing in the UK was planned to start within 3 years.
2. They had a point of care application, that is were being developed to be used in settings such as GP surgeries, hospital wards, health units, pharmacies and polyclinics.
3. And they had potential or claimed to add benefit compared with existing technologies, for example, improved accuracy, ability to identify subtypes, rapid time to result and increased portability.

The main exclusion criterion was turnaround time to results, with tests having turnaround times of more than 1 hour excluded.

Companies identified through the search that appeared to have relevant products and/or active development pipe-

[1]EuroScan is the international information network on new and emerging health technologies (http://euroscan.org.uk). It has 20 members who are situated in Europe, Scandinavia, Israel, Australia and Canada.

Box 1. Online sources searched to identify point of care tests for influenza currently in development

Diagnostic product listings (medical diagnostic websites)
Technology databases of horizon scanning and health technology assessment organisations.
Public Health Government Agencies: Health Protection Agency (HPA) and the Centers for Disease Control and Prevention (CDC).
Licensing organisations within and outside the European Union: list of products approved by the European Medicines Agency (EMA) and the United States (US) Food and Drugs Administration (FDA).
Clinical trial databases of ongoing research of investigational products and technology transfer arms e.g. Medical Research Council (MRC) Technology.
Bibliographic databases: Medline, Embase and the Cochrane library.
Internet search engine: Google.

lines were contacted directly and asked to complete a pro forma requesting information on relevant technologies such as indication, intended place of use, size, sensitivity and specificity. The review criteria were then applied to the tests identified to develop a table of relevant tests. Advice from an advisory group of experts was sought on clinical relevance and/or potential benefits.

Results

Fifty-six companies who were potentially developing point of care diagnostic tests for influenza were initially identified and contacted for further information. Twenty nine (52%) of these companies responded, and from the information provided, 57 technologies were identified as being potentially relevant. Of these, 40 (70%) were either already available, newly launched (i.e. in the early stages of adoption) or the status was undetermined. Five technologies (9%) took over 60 minutes to produce a result, so were deemed not to meet the review criteria. The remaining 12 (21%) were classified as emerging, that is had not yet been adopted by the health system and appeared to meet the review criteria (Table 1). Two of the tests came under the umbrella of the research projects being financed by the EU Seventh Framework to develop improved rapid POCTs for influenza.

Of the 12 tests that met the criteria, 10 (83%) were reported to enable differentiation of influenza types A and B, 8 (67%) were reported to enable differentiation of selected influenza A subtypes [including H1N1(2009) in seven cases and H3 in six cases], and one test was reportedly specific for detection of human influenza A subtypes (without differentiation) only. In addition, two tests also enabled differentiation of H5 subtype viruses. Four tests were reported to allow simultaneous running of more than one sample at a time; nasopharyngeal swabs were the most commonly acceptable sample type, with 50% of the emerging POCTs reporting use with this specimen type. Throat swabs, nasal washes, aspirates and nasal swabs were also acceptable for some POCTs. No information on acceptable sample type was provided for three of the 12 emerging POCTs. The volume of clinical sample required for testing varied, ranging from 80 μl to 1·4 ml where this information was provided. Where time to result with the emerging POCTs was given, the most rapid turnaround time for any of the POCTs was within 15 minutes and ranged up to 1 hour.

Discussion

We identified 12 emerging POCTs for influenza; one (3M Rapid Detection Flu test) has since been discontinued. Eleven were reported to provide type and/or subtype differentiation, including identification of H1N1(2009) and H3 in most cases. Tests claiming to offer this capability included several which incorporate RT-PCR, in addition to those which enhance currently available assays. Many of these tests are also expected to be fully automated and in some cases use closed systems (e.g. Liat influenza A/2009 H1N1 assay and XPERT Flu A&B panel), which can reduce the potential for human error and contamination, and those using an RT-PCR methodology are reported to take from 45 minutes to 1 hour to produce a result. In a busy clinic, this may itself represent a barrier to 'point of care' use, requiring a patient to remain isolated in the clinic, whilst results are awaited. In addition, whilst some of the identified emerging POCTs appear to have comparable sensitivity and specificity for influenza with the 'gold standard' RT-PCR methodology,[24,25] most currently lack published clinical data on which to base an assessment. Improvement in the negative predictive value and also the positive predictive value of emerging POCTs compared with currently available POCTs is critical to their usefulness; though, it is likely that laboratory confirmation will still be required at times of low influenza activity (to reduce false-positive results) and to confirm negative results. In addition, the performance of individual tests and their effective use are likely to depend on training and familiarity, use of suitable sample type and appropriate quality assurance processes.[26] The likely future cost of these tests once launched (including the replacement costs and shelf-life of the consumable components) is also unknown at present.

Table 1. Emerging technologies that met the review criteria

Technology name	Developer	Influenza type/subtype	Technology description	Sample type	Sample volume	Time to result	Development stage	Developer-reported benefits
3M™ Rapid Detection Flu A+B	3M	Differentiates A and B	Qualitative immunochromatographic lateral flow assay. Benchtop. Weight: 2·5–5·5 kg. Maximum of six tests can be run simultaneously	Nasal wash/aspirate; NP swab/aspirate	150 μl	15–20 minutes	Discontinued as review undertaken	Lateral flow cartridge inserted into reader. Eliminates user subjectivity in interpreting results. Three hundered results can be stored on system
DPP Multiplex Influenza Test	Chembio	Differentiates A and B, and selected A subtypes including H1N1(2009) and H3	Antigen detection using Dual Path Platform (DPP) technology. DPP is a chromatographic immunoassay; up to five tests can be included in each cassette	Not reported	Not reported	Not reported	Developer reports that prototype development has been completed. Clinical trials expected	Developer reports that DPP technology has significant advantages over lateral flow such as ability to accommodate multiple sample types, faster results, improved sensitivity/specificity and elimination of lateral flow aggregation issues
Enigma ML	Enigma	Differentiates A and B, and selected A subtypes	RT-PCR. Benchtop (30 cm × 35 cm). Approx. eight tests can be run in random access fashion	NP swab or throat swab	n.a.	45 minutes	In development at the time of this review. Clinical trials expected.	Fully automated real-time PCR device with high-level multiplexing. No manipulation of the swab prior to inserting into the instrument. Suggested to have diagnostic performance equivalent to central laboratory systems.
FilmArray Respiratory Panel	Idaho technology	Differentiates A and B, and A subtypes H1, H1(2009) and H3	Multiplexed RT-PCR. Benchtop 25·4 cm × 39·3 cm × 16·5 cm. Weight: 9 kg (20 lb.). System can run more than 100 tests simultaneously	NP swabs and aspirates	250 μl	≤1 hour	FDA approved	Integrates sample preparation, amplification, detection and analysis in one easy-to-use system capable of analysing up to 120 tests per sample in ≤1 hour
Flu A+B-Neo (ImmunoAce)	TAUNS	Differentiates A and B	Immunochromatographic assay Hand-held (8 cm × 2 cm × 0·5 mm). Weight: 5 g.	Pharyngeal swab, nasal wash and aspirate	80–120 μl	Within 15–30 minutes	Not available in Europe. No EU partner identified at the time of this review	Highly sensitive immunochromatographic detection kit. Rapid test time (usually 3–8 minutes)

Table 1. (Continued)

Technology name	Developer	Influenza type/subtype	Technology description	Sample type	Sample volume	Time to result	Development stage	Developer-reported benefits
Flu A-Neo	TAUNS	Detects but does not differentiate influenza A human subtypes only (H1, H2 and H3)	Immunochromatographic assay. Hand-held (8 cm × 2 cm × 0·5 cm). Weight: 5 g.	Specimen type for human cases undecided	80–120 μl	Within 15–30 minutes	In development at the time of this review. Clinical trials expected.	Highly specific for human influenza A (H1, H2 and H3) and detects nucleoproteins. Allows rapid differentiation between human and avian origins for influenza A
FluArray	Collaborative (EU Seventh Framework)	Expected to differentiate A and B, and selected A subtypes, including H1N1(2009) and H3	Automated portable microarray immunoassay	Not known	Not known	Expected <30 minutes	In development at the time of this review. Clinical trials expected	Automated. Differentiation of influenza subtypes at POC
Liat™ Influenza A/2009 H1N1 Assay	IQUUM Inc.	Detects influenza A and differentiates selected A subtypes, including H1N1(2009) and H3	RT-PCR assay. Benchtop (20 cm × 20 cm × 10 cm). Weight: approx. 3000 g. Runs one test at a time; single analyser can run up to 16 samples per shift. Anticipated cost of test and analyser reported as commercially confidential	NP swab	n.a.	26 minutes–1 hour	FDA Emergency Use Authorisation (EUA)	Rapid time when compared with other similar assays such as nucleic acid test. Combines the gold standard with rapidity in results and does not require specialised personnel. Also removes possibility of cross-contamination because of its closed system
MSD Influenza Tests	Meso Scale Diagnostics	Differentiates A and B, and A subtypes: H1N1 [seasonal, not H1N1(2009)], H3N2 and H5N1	*In vitro* multiplexed immunoassay using monoclonal antibodies, ruthenimum-derivative labels and a solid-phase carbon surface for qualitative detection and discrimination of the nucleoproteins	Nasal swab	n.a.	15 minutes	Currently in clinical trials.[23] Granted investigational device exemption (IDE) by FDA	Company report test has ability to detect novel strains of influenza A as these will not be subtyped by this test
PortfastFlu	Collaborative (EU Seventh Framework)	Expected to differentiate A and B, and selected A subtypes, including H1N1(2009) and H3	Sample preparation, nucleic acid amplification, microarray hybridisation and fluorescent readout expected to be integrated into one single portable system using technologies such as microfluidics and on-chip sample preparation	Not known	Not known	Expected between 30 minutes and 1 hour	In development at the time of this review. Clinical trials expected	On-site detection of influenza virus in clinical or veterinary samples, including avian and current porcine flu, as well as H and N subtyping of other various known influenza A viruses

Table 1. (Continued)

Technology name	Developer	Influenza type/subtype	Technology description	Sample type	Sample volume	Time to result	Development stage	Developer-reported benefits
Ultra Influenza A&B	Genzyme	Differentiates A and B	Hand-held	NP, nasal, and throat swabs/aspirates	Not known	<20 minutes	Expected launch in 2012	A novel technology that could provide an assay sensitive enough to provide a very high negative predictive value. This would prevent unnecessary overuse of antiviral treatments and potentially reduce the likelihood of antiviral resistance
XPERT® Flu A&B Panel	Cepheid	Differentiates A and B, and A subtype H1N1 (2009)	RT-PCR. Requires a computer or laptop; models weight 8–57 kg, allowing variable numbers of tests to be run simultaneously. Sensitivity reported as 92% [H1N1(2009)] and 88·9% (influenza A), and specificity reported as 100%	NP swab; nasal aspirate/wash	1·4 ml of nasal aspirate/wash	Around 50 minutes	CE marked	Because of the ease of use and minimal hands on time, every individual test can be performed immediately, combining PCR accuracy with the rapidity of rapid tests. This is an incremental change on a recently introduced test

EU, European Union; FDA, Food and Drugs Administration; NP, nasopharyngeal; RT-PCR, reverse transcription polymerase chain reaction.

The methods used in this study rely on obtaining information on technologies from developers.[27] Good existing relationships between the National Horizon Scanning Centre and the *in vitro* diagnostic industry, the comprehensive search strategy and involvement of commercial trade associations meant that we were able to produce a complete list of likely large and medium sized commercial developers. However, such developers may be unwilling or unable to provide useful intelligence at an early stage of development and may regard information as commercially confidential, particularly on the performance of the test and marketing plans. The majority of the tests identified were either being developed by, or with the support of, a major *in vitro* diagnostic manufacturer. Tests may initially be developed by individuals, academic institutions or small start-up companies, and those likely to be commercially successful are frequently acquired by larger companies prior to market; as such, it may be difficult to determine whether a company or product development is still active, which may account for the limited response to our information requests.

The adoption of POCTs for influenza into routine UK clinical practice is currently limited by the poor performance and high relative costs of currently available tests, as well as the inability to distinguish influenza types and subtype; a truly innovative POCT would need to be rapid, able to distinguish influenza A and B, differentiate key influenza A subtypes and have a sensitivity equivalent to that of the gold standard. We have identified a number of tests in a late stage of development that have the potential to offer benefits over the currently available options. In particular, POCTs employing RT-PCR methodology may be available and marketed over the next 1–2 years, and these have the potential to overcome many of these barriers to more widespread acceptance; though, their cost (as yet unknown) and the time taken to produce a result may still limit their diffusion into routine practice. The outcome of studies on the clinical application and usefulness of these POCTs once available will be of much interest.

Conflict of interest

It is the policy of the Health Protection Agency (HPA) to work in co-operation with the pharmaceutical, biotechnology, vaccine, diagnostic and other healthcare-related industries to facilitate the development of products and technologies beneficial to health. These relationships are managed on an arms-length, contractual and commercial basis, including the charging of fees under standard terms and conditions. In this context, HPA maintains active relationships with a broad range of companies in the UK and internationally.

Two of the projects to develop new point of care tests for influenza identified in the submitted manuscript are EU Framework Phase 7-funded projects, with HPA a collaborator in both; JE has been directly involved in research in only one of these projects ('Flurray'), with HPA receiving funding for staff and conducting the research for relevant parts of the project as a collaborator in the consortium awarded the funding. The involvement of HPA in the Flurray project ended in December 2010.

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