Augmentation of influenza surveillance with rapid antigen detection at the point-of-care: results of a pilot study in Tasmania, 2004

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Abstract

Tasmania contributes very few laboratory confirmed cases to Australia's national influenza surveillance statistics. In 2004, a study was conducted to pilot test sentinel syndromic surveillance for influenza-like illness supplemented by point-of-care testing using the Binax Now Flu A Test Kit and by viral culture, to assess the feasibility and acceptability of this method of surveillance. Overall, the goal of such a system would be to increase laboratory surveillance activity within Tasmania and increase the number of specimens sent for viral culture. Five sites participated in the study, including three public hospital emergency departments and two general practices. Despite being conducted during a period of low influenza activity, the pilot study demonstrated that augmentation of syndromic surveillance with point-of-care testing is both feasible and acceptable but is best conducted in the general practice setting. *Commun Dis Intell* 2006;30:201–204.

Keywords: influenza; laboratory diagnosis

Introduction

Influenza is a highly contagious, febrile, acute respiratory disease in humans. The incidence of influenza is estimated at 500 million cases annually, or one in every three of the world's population per year.[1] A definitive diagnosis of influenza requires laboratory confirmation, since clinical diagnosis on the basis of clinical symptoms is not sensitive and the predictive value of clinical diagnosis of influenza in the absence of an epidemic is only 30–40 per cent.[2]

Diagnostic tests for influenza fall into four categories: virus isolation; detection of viral nucleic acid; detection of viral proteins; and serological diagnosis. Viral isolation i.e. culture, is the current gold standard for laboratory diagnosis. Detection of viral nucleic acid is widely used for typing and subtyping influenza viruses. The advantage of nucleic acid amplification tests (NAAT) is their high sensitivity and specificity, more rapid turn-around time, an expanded range of specimen types suitable for testing, and the ability to detect viruses that are difficult to grow in cell culture.[3,4] However, NAAT is not universally available and significant time delays in centres with poor access to influenza NAAT-capable laboratories preclude its clinical usefulness, reducing the number of tests clinicians order.

Tests that detect viral proteins at the point-of-care are becoming more common. They are easy to perform and results are available in less than an hour. However, they are considerably less sensitive than culture or NAAT.[5] A positive test is useful, for both directing initiation of therapy in the clinician's office and making a positive diagnosis of influenza in patients with influenza-like clinical syndromes.[6] As the technology is continuing to advance, the test sensitivity is likely to improve.

In Tasmania, laboratories have very limited diagnostic capability for influenza. Specimens for culture, serology and NAAT are all sent interstate for processing. This creates substantial time delays before results become available. As a consequence, testing rates by Tasmanian clinicians for influenza are very low and Tasmania contributes very few laboratory confirmed cases to Australia's national influenza surveillance statistics.

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Public health surveillance for influenza is necessary to determine the distribution of illness, detect outbreaks, monitor changes in disease agents and facilitate planning.[7] Increasingly, non-traditional methods of surveillance are being utilised. Point-of-care testing trials for influenza have been conducted in Hawaii and Germany. These trials have demonstrated that integrating influenza rapid antigen testing into public health surveillance, by coupling rapid tests with cultures, improves testing rates by clinicians (as an immediate result is provided by the point-of-care test) and enhances influenza surveillance (as the culture specimen allows the reference centres to characterise circulating viral strains and to detect fully new variants).[8,2]

The aims of this study were to pilot test sentinel syndromic surveillance for influenza-like illness (ILI) in Tasmania, supplemented by point-of-care testing using the Binax Now Flu A Test Kit and by viral culture, to assess the feasibility and acceptability of this method of surveillance.

Methods

Surveillance was conducted between May and October 2004. The case definition adopted for ILI was: presentation with cough, fever (greater than or equal to 37.5 degrees Celsius) and fatigue.[9]

Five sites were recruited to the project. These were the Departments of Emergency Medicine (DEM) of the Royal Hobart Hospital, Launceston General Hospital and North West Regional Hospital, East Devonport Medical Centre and the After Hours Doctors Service at Derwent Park. The sites were selected to represent the geographical transport entry points into Tasmania. The Royal Hobart Hospital and After Hours Doctors Service are both in Hobart, in southern Tasmania. Domestic flights enter Hobart from Sydney, Brisbane and Melbourne. Cruise ships dock in Hobart, arriving from multiple international destinations. The Launceston General Hospital is in Launceston in northern Tasmania. Domestic flights from Sydney and Melbourne enter Launceston. The North West Regional Hospital is in Burnie in north-west Tasmania. The City Medical Practice is in Devonport, also in north-west Tasmania. East Devonport is the main entry point for domestic passenger ships arriving by sea into Tasmania.

A site co-ordinator was nominated for each sentinel site. Staff from the Tasmanian Department of Health and Human Services Communicable Diseases Prevention Unit (DHHS-CDPU) briefed the coordinator on the project and requirements for reporting. Medical staff at each site were trained in the use of the Binax Now Flu A Test Kit. They were briefed on the case definition for influenza and the reporting requirements for each patient in the study. The information collected included: the surveillance period dates, the number of patients in each reporting period meeting the case definition for ILI, the sex and age of each case, and whether or not the case had been vaccinated against influenza in 2004.

Data were entered into an Excel spreadsheet and descriptive statistical analysis undertaken using Excel 2000. At the conclusion of the project DHHS-CDPU staff administered purpose-designed surveys to each of the site coordinators, seeking information regarding the feasibility and acceptability of the surveillance system, and the clinical utility and ease of use of the point-of-care test.

Results

Influenza-like illness (ILI)

During the surveillance period, reports were received from all sites as per the reporting requirements of the study.

From all sites there was a total of 53 patients satisfying the study criteria for the clinical diagnosis of ILI, as defined by the case definition above. Of these, 40 (76%) were tested with the Binax Now Flu A Test Kit. No positive results for influenza were obtained using the Binax Now Flu A Test Kit and no clinical specimens were sent for culture.

Influenza vaccination status was recorded for 30 of the 53 cases of ILI (56%). Of these, 7 (23%) were recorded as having received influenza vaccine in 2004.

Survey results

Survey results were received from 3 of the 5 participating sites (response rate = 60%).

Procedural aspects of the surveillance method

The written information supplied to each site was considered adequate for the purposes of the project and available public health support was sufficient. Respondents indicated that the case definition of ILI was simple and easy to apply for the purposes of surveillance and to indicate which patients should receive a point-of-care test. The availability of a rapid test for influenza was regarded as an incentive to test patients. However, respondents did indicate that incentives for their involvement in surveillance activities would improve their participation and that without incentives it was unlikely they would continue to act as sentinels.

Feasibility and acceptability of the point-of-care test

The majority of respondents considered the Binax Now Flu A Test Kit easy to use. However, the time taken before results could be read (15 minutes) was an inconvenience in both DEM and general practice settings. Within the DEM it was not feasible to ensure that the quality of nasal specimens collected by different staff members remained of a consistently high quality. This was not identified as an issue in the general practice setting.

Discussion

Influenza activity in Australia during 2004 was low. A total of 2,116 cases of laboratory-confirmed influenza were reported via the National Influenza Surveillance Scheme, which was 41 per cent lower than the number of reported cases in 2003.[10] In Tasmania, there were two notified cases of laboratory-confirmed influenza A and one case of laboratory-confirmed influenza B during 2004. However, because ILI was present, pilot testing of sentinel surveillance could still be undertaken. In general, participants viewed the surveillance system favourably as an appropriate method of influenza surveillance in Tasmania.

There were multiple barriers to conducting surveillance for influenza in the DEM setting. It was not possible to ensure that all staff-members were identifying and recording patients who met the case definition of ILI or that testing for influenza A of all patients who met the case definition was occurring. Additionally, it was not possible to identify whether the staff-members using the Binax Now Flu A Test Kit were using the test or taking nasopharyngeal samples appropriately. It was felt that staff did not have the time to undertake sufficient education or training to ensure that the testing protocol was reliable between users. After the sample was acquired, it took 15 minutes before the result could be read. In a busy emergency department, this was seen as a barrier to the test's use. Staff did identify that lack of remuneration was a barrier for undertaking surveillance activities.

Surveillance in general practice was more acceptable and feasible. Staff could be appropriately trained and educated on the use of the test in this setting. The time taken before the result could be read was seen as only a small additional time burden. Case ascertainment was more complete and the protocols for the study were more rigorously applied. However, general practitioners also identified that the lack of remuneration for their participation was a barrier – particularly as the presence or absence of influenza did not necessarily alter their patient management.

Workforce capacity within the DHHS-CDPU was also an issue identified in this study. Frequent and regular communication with sentinel sites was necessary to ensure compliance with data reporting requirements. Data collection and analysis were also labour intensive. The workforce requirements within the DHHS-CDPU were significantly underestimated and future surveillance using this method will need to address this.

There are significant limitations with the point-of-care test itself. The sensitivity of the point-of-care test is only 65–77 per cent compared with culture or NAAT testing for known circulating influenza strains and is probably much lower for pandemic strains (point-of-care tests are unlikely to detect pandemic strains of influenza). However, in spite of this, clinical trials have demonstrated that a positive test is clinically useful and by coupling the point-of-care test with viral culture, a sufficiently sensitive test is utilised that is capable of detecting pandemic strains.[6] Many viruses cause ILI in patients and are not generally distinguishable from influenza on clinical grounds alone. These include respiratory syncytial virus, rhinovirus, human corona viruses, human metapneumovirus, adenovirus, picornavirus and parainfluenza virus.[3] Antigen detection is not useful for differentiating between these viruses.

The pilot study demonstrated that augmentation of syndromic surveillance with point-of-care testing is both feasible and acceptable. However, the setting in which this form of surveillance is best conducted is general practice. The procedural barriers within the DEM setting were far greater and the model can be more efficiently applied within the general practice setting, without sacrificing breadth of surveillance.

To adopt this form of surveillance within Tasmania, selected general practitioners could be targeted. Financial remuneration for service providers would almost certainly be necessary. Teams at each participating general practice (including practice nurses, practice managers and general practitioners) could be formed to conduct sentinel surveillance. This would ensure that continuity of surveillance is maintained and would improve data collection, timely reporting and minimise the time burden on the general practitioner by efficiently utilising practice support staff.

It is also foreseeable that this method of surveillance could be conducted by health personnel via Community Assessment and Information Centres that would become operational in the Tasmanian response to a pandemic influenza threat.

Overall, the goal of such a system would be to increase laboratory surveillance activity within Tasmania and increase the number of specimens sent for viral cul-

ture. This would establish an improved and enhanced method of influenza surveillance in Tasmania, which is an important inter-pandemic priority.

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