Opportunities for point of care testing
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The NHS response to the Covid-19 pandemic has highlighted the potential of new models of healthcare delivery including point of care (POC) diagnostics. These can help to optimise processes, improve efficiency and promote patient safety outside hospital.

This publication showcases examples of successful NHS-industry partnerships facilitated by the Oxford AHSN which have led to fewer hospital admissions and better pre-hospital diagnosis.

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Reducing unnecessary admissions

Ready and easy to use CRP reagent
- All in one: three reagents in same cartridge
- Two cartridges per box
- Each cartridge offers 50 tests
- No need to take the cartridge out after use

Ideal for small samples
- Capillary and venous blood
- No sample pre-treatment
- Full Blood Count (FBC) mode on whole blood
- Full Blood Count + C-Reactive Protein (CRP) mode on whole blood

Whole blood sampling
- Open tube
- Tube adapters for standard and micro tubes
- Holder for secure sampling
- Easy handling

Improving pre-hospital diagnosis

New opportunities
Reducing unnecessary admissions

Unique CRP analyser reduces unnecessary admissions

In paediatric emergency medicine blood tests are performed in those children in whom a diagnosis is unclear and often helps with decision-making about the necessity for admission in these children. A C-Reactive Protein (CRP) assay is a commonly used blood test to assist with clinical decision making, particularly as a potential proxy indicator for presence or absence of bacterial infection. It is generally used in conjunction with the results of a full blood count (FBC). The test is normally performed in the hospital laboratory and, once received in the lab, results take on up to 60-90 minutes. The time from needle to result can be considerably longer.

As well as measuring the accuracy of the point of care (POC) instrumentation against lab values at the John Radcliffe (JRH), Stoke Mandeville (SMH) and Wexham Park (WPH) hospitals, we also conducted a service evaluation by investigating whether the introduction of POC testing for CRP and FBC at SMH and WPH could provide more rapid decision-making in a range of common paediatric conditions.

From the horizon-scanning exercise we selected the Microsemi CRP/FBC from Horiba as the POC device for evaluation. This is a unique automated haematology analyser that can simultaneously measure FBC (19 parameters) including three-part white blood cell differential (3-Diff) and CRP using whole blood treated with EDTA-2K anticoagulant. This bench top POC testing machine allows micro sampling from whole blood (FBC: 10μL / FBC+CRP: 18μL). Results are available in four minutes for FBC+CRP (15 tests/hour) and one minute for FBC (55 tests/hour).

Laboratory staff validated and set up the Horiba Microsemi devices comparing POC results against results from the standard laboratory analyser. A paper audit form was used to collect data on the time of availability of blood results and decision-making by the treating clinician. Laboratory held data was used to determine the agreement of results in the clinical setting with standard laboratory assays. Initial evaluations from the laboratories JRH, SMH, WPH concluded that the POC device was sufficiently accurate to continue with the evaluation in a clinical setting.

The most common presentations at SMH were abdominal pain (particularly in those children aged over five and fever without apparent source (FWAS). Other diagnoses were lymphadenitis, tonsillitis, gastroenteritis, deliberate overdose and haematemesis. The majority of children at WPH had an initial diagnosis of either fever or sepsis. Patients presented at the JRH with limpness, rash and fever. The differences in conditions seen likely reflect the differences in the departments.

The mean delay between the result from the POC test being available and the result from the laboratory being available was 3 hours and 5 minutes. Overall the POC test was useful in decision-making for children with abdominal pain, FWAS, limp and petechial rash and could have resulted in earlier decision-making approximately 75% of the time. The use of the POC machine could have shortened the time to decision-making about antibiotic use. In one particular case the high CRP result on the POC machine prompted urgent registrar review and initiation of IV antibiotics. The patient had pyelonephritis and use of the POC machine shortened time of decision-making by 50 minutes.

By the end of the evaluation period, the team was more familiar with the machine and the logistical issues encountered were ironed out. They were not felt to represent a significant barrier to the ongoing use of the machine but consideration needs to be given to this when setting up the machine and standard operating procedures. York Health Economics Consortium (YHEC) carried out an economic analysis across the three hospitals. The results indicate that the use of the Horiba POC device would result in a modest net annual saving for each of the hospitals. The savings are the result of reduced nursing and consultant or registrar time. There are also potential savings from quicker treatment decisions when a delay could have adverse effects on the patient’s condition. Other important benefits include the reduced waiting time for patients and their family and carers. The reduction in time waiting for test results can result in improved patient flow, particularly important at peak times, which might also create the opportunity to redesign process and generate further benefits.

Microsemi CRP/FBC from Horiba
Summary findings for combined CRP and whole blood point of care test in various settings

1. Hospital settings:
   - Using POC as a replacement for lab test could have resulted in more rapid decision-making in 63% of cases at Stoke Mandeville Hospital (SMH), 82% of cases at Wexham Park Hospital (WPH) and 53% of cases at John Radcliffe Hospital (JRH).
   - For children admitted from Paediatric Decision Unit (SMH), an earlier decision could have been made in 35% of cases, saving an average of 173 minutes.
   - For children discharged from PDU (SMH), an earlier decision could have been made in 87% of cases, saving an average of 109 minutes per case.
   - For children referred to a specialty from A&E at SMH, an earlier decision regarding referral could have been made in 63% of cases, saving an average of 106 minutes per case.
   - The POC result could have been used for more rapid decision-making regarding the use of antibiotics in approximately 52% of cases (SMH) and 65% (JRH).
   - Annual savings approximately £60,000 per year across the three hospitals.

2. Primary care settings:
   - Reduction of (unnecessary) admissions to secondary care
   - Management of patients with greater clinical certainty (49% of cases)
   - Receiving a different intervention than had the POC tests not been available (40% of cases)
   - Quicker decision-making (including being able to secure admission for several patients to secondary care and ensuring they received the most appropriate care, that may not have otherwise been admitted).
   - Providing reassurance for staff and, in particular, patients that an accurate diagnosis was being made early in the treatment pathway.
   - The budget impact analysis performed using the economic model suggests that using the POC test in a primary care setting could be cost-saving over five years.

The Horiba Microsemi was accurate in both the WCC and CRP readings, when compared with the lab values.

- There was good correlation between the lab and POC machine.
- The maximum difference was 12.89 (POC White Cell Count (WCC) 20.3, LAB WCC 33.19).
- The differences in the two sets of WCC results would not have affected clinical decision-making.
- The WCC as measured by the POC machine was sufficiently accurate to base clinical decision-making on.
- At WPH (see Figures 1a and 1b), the CRP POC result was compared to a Roche analyser in the laboratory. Sysmex was also used for the comparison of WCC.
- At the JRH, comparison of the analyser was against the Abbott Architect c16000 for CRP and the Sysmex XN series Full Blood Count currently operational in Oxford University Hospitals NHS Foundation Trust laboratories including the John Radcliffe.
Deployment of the Microsemi CRP analyser can streamline existing diagnostic pathways and improve patient flow through busy acute hospital departments by giving a rapid determination (within four minutes) of a patient’s combined FBC and CRP result from a whole blood EDTA sample, without having to wait on the availability of lab results.

Horiba also supplies the five-part diff FBC analyser suitable for rapid near-patient testing (Yumizen H500). This easy-to-use, intuitive instrument gives an FBC result complete with a five-part differential in just over one minute. It only uses three routine reagents, minimising storage space requirements. The H500 has proved popular since its 2017 launch across a variety of different applications, including in chemo clinics (to minimise the exposure time of susceptible patients whilst on site), Emergency Departments and Denzapine (Clozapine) testing.
Improving pre-hospital diagnosis

The i-STAT Alinity is an easy-to-use, portable blood analyser that delivers real-time, lab-quality diagnostic test results at the point of care. Built on the proven technology of the i-STAT 1 System, the i-STAT Alinity’s award-winning design features a more intuitive interface that simplifies the testing process even further, allowing for minimal operator training.

Working with Abbott Point of Care, laboratory professionals led by Point of Care Manager, Ian Smith, have built a POC testing service across Oxford University Hospitals and Oxford Health NHS Foundation Trusts. Using Abbott POC i-STAT and i-STAT Alinity Systems has enabled clinicians to perform diagnostic blood testing at the patient’s bedside in multiple departments at the John Radcliffe Hospital. Integrating POC testing directly into the patient care pathway has driven multiple, system-wide efficiencies.

Early Pregnancy Assessment Clinic

Building on the success of community care linked to the central lab, the Early Pregnancy Assessment Clinic (EPAC) within Oxford University Hospitals is moving to the community. With up to 6,000 appointments a year, this specialist unit provides care for women with problems in early pregnancy, such as a miscarriage or ectopic pregnancy. OUH sought a diagnostic solution that would allow the clinic to move to the community. The primary test needed for this clinical situation is the β-hCG test, which the i-STAT System offers. With IT connectivity already in place with the central lab at the OUH, the clinic move can be easily initiated.

Out-of-Hours GP Service

Older people with frailty are frequently seen in their own homes by out-of-hours (OOH) clinicians as they cannot easily get to an urgent care centre. These patients are at higher risk of having serious illnesses which require hospital treatment, but these are hard to detect without blood tests. This project conducted with the National Institute for Health Research Community Healthcare MedTech and In Vitro Diagnostics Co-operative aimed to improve the diagnosis of serious illness by introducing POC blood tests during OOH visits. The blood tests could detect or rule out serious illness, allowing clinicians to make better decisions and avoid unnecessary hospital admissions. This was the first time POC blood tests had been included in an OOH primary care service. The impact on patients and outcomes will be disseminated in a peer-reviewed journal. This was a project led by University of Oxford Department of Primary Care Health Sciences in partnership with Oxford Health, funded by the Health Foundation and supported by the Oxford AHSN. Patients appreciated the convenience of having the tests at home, and being able to receive rapid results, which then provided reassurance or helped inform subsequent care decisions. Clinicians who used the tests were positive about the benefits. They said the POC test results helped them make diagnoses and complete their clinical assessments. The added value of the Oxford AHSN in this project was firstly the support in purchasing the technology, which is often an element of projects which is not funded by funding agencies, and secondly in facilitating a data sharing agreement in order to explore the impact of this intervention across the healthcare landscape.
Using POC testing in community hospitals

For most of the community hospitals in Berkshire Healthcare NHS Foundation Trust, blood samples are sent to the pathology department. This can often be a lengthy process (with average turnaround time being 24 hours) and can lead to a delay in diagnosis and first-line treatment. As part of their Better Care Fund initiative, Wokingham Community Hospital introduced the use of two POC diagnostic tests. The blood samples taken from patients were immediately tested using the POC devices on the ward. The immediate availability of the results supports clinical judgement and helps with a timely diagnosis and appropriate treatment.

Wokingham Community Hospital purchased two different POC diagnostic test devices for their elderly inpatient unit and wanted to evaluate the impact of attaining results more quickly and understand how it could help the nurses make effective decisions regarding treatment. The Oxford AHSN assisted by reporting the economic cost–consequence analysis of the two tests, determining what the cost benefit would be and extrapolating the potential benefits for other community hospitals.

The results from this quality improvement project showed a self-reported improved confidence in clinician decision-making and patient disposition. This confidence was validated by improved discharge on scene and re-contact rates. An unintended outcome of the project was the accumulation of practical knowledge on the use of POC in the pre-hospital arena.

A budget impact model was produced for the use of the i-ST A T blood test analyser in ambulance service settings to measure the impact of using POC testing to reduce pressure on ambulance service resources.

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POC blood tests inform decision-making for patients with acute frailty syndromes

Findings from use of i-STAT Alinity

- **Inclusion:** Patients aged over 65 with acute frailty syndromes and unclear care pathway needs presenting to the ambulance service.
- **Timeframe:** Six months led by Advanced Clinical Practitioner Dolly (Melinda) McPherson.
- **Staff:** Four Specialist Paramedics and four Frailty Paramedics, South Central Ambulance Service NHS Foundation Trust (SCAS), Reading, Berkshire, UK.
- **Methods:** During the service evaluation, patients in whom the best destination was unclear after history taking and physical examination, received POC blood testing (CG4+ and CHEM8+) to aid decision-making. A budget impact model was constructed to estimate the financial consequences of adopting the new intervention in addition to existing standard of care.

The service evaluation showed that use of POC blood testing has a positive impact on all stated aims. The project results, whilst taken from a small sample size, show utility for POC blood testing in both the pre-hospital environment and in the field of frailty.

Discharge on scene increased from 49.7% to 82.1% and recontact within seven days was reduced from 14.7% to 11.5%. Testing had most utility in the assessment of patients with cognitive impairment, ‘long lie’ patients and patients with ongoing chest infections, less in patients with sepsis.

**Case 1**
82 year old female with learning difficulties presenting with a fall. Blood testing identified new hyponatremia with acidosis. The patient was diagnosed with pneumonia in hospital.

**Case 2**
86 year old female recently discharged on furosemide presenting with immobility. Furosemide induced hypokalaemic metabolic acidosis discovered requiring admission.

**Case 3**
94 year old female with prolonged time on floor post fall, POC blood test for creatinine used with RIFLE criteria to exclude acute kidney injury so patient referred to GP for follow-up bloods.

**Case 4**
92 year old female with recurrent falls. POC blood test identified anaemia as possible cause and patient was referred to GP for primary care management.

The potential savings for SCAS were estimated to be £9.8 million in Year 1, £10 million in Year 2 and in Year 3 which gives a combined total of £29.8 million. (see Figures 3a and 3b)

For the SCAS region, according to the National Audit Office, the ambulance population (3,123,473) was split by age with 21.9% of patients over the age of 65 (876,527)

All patients in the model received CHEM8+ blood test and 30% received CG4+ test based on the service evaluation data.

With 51% of patients conveyed by ambulance and 52% of admissions from ED attendance, use of blood testing gives total cost savings from short and long stay of £6.75 million

Total ED attendance costs saved was £1.9 million with total savings from patient handover of £356,000

Cost of cartridges versus ambulance savings was £158,000 and total costs of revisits was £96,000

Extrapolated to the population of the NHS in England, cost savings would be in the region of £138 million per annum.
Point of care influenza testing

Influenza virus testing is not required to make a clinical diagnosis of influenza in patients with suspected influenza, particularly during increased influenza activity when seasonal influenza A and B viruses are circulating in the local community. However, influenza virus testing can inform clinical management when the results may influence clinical decisions such as whether to initiate antiviral treatment, perform other diagnostic testing or to implement infection prevention and control measures for influenza.

Rapid molecular assays are a kind of molecular influenza diagnostic test to detect influenza virus nucleic acids in upper respiratory tract specimens with high sensitivity (90-95%) and specificity. Rapid molecular assays are available that produce results in approximately 15–30 minutes. Rapid influenza diagnostic tests are antigen detection assays that can detect influenza viral antigens in 10–15 minutes with moderate sensitivity and high specificity.
Influenza infections can pose a significant healthcare burden during winter months. UK guidance (PHE version 7.0 Oct 2016) advises that patients with suspected influenza are isolated to reduce transmission, and, where indicated antiviral treatment should be started within 48 hours of presentation. Empiric isolation can be challenging where isolation capacity is limited and patients may not present with a classic influenza-like illness.

Almost all influenza cases seen in the hospital (Data from Royal Berkshire Hospital, 2016 Flu Season) begin in the community. If we can diagnose promptly and treat effectively in the community, these patients will not come to hospital (admission avoidance) plus it will significantly reduce the flu-associated morbidity and mortality from secondary bacterial infections. Often only secondary infection is treated and an influenza test is not carried out. Rapid POC testing for influenza virus could also reduce unnecessary antibiotic prescribing for viral respiratory infections.

During the 2015/16 flu season the Public Health England Laboratory in the North East placed a molecular POC device in the emergency department (ED) assessment suite. Parallel testing of a proportion of samples throughout the season showed good concordance with the laboratory assay. Influenza was detected in respiratory samples from 158 patients (97% POC tested) in comparison to 88 detected by laboratory testing in 2014/15.

- Results were available a median of 1 day and 9 hours earlier by POC
- Antivirals were prescribed a median of 1 day and 4 hours earlier
- Patients were isolated a median of 12 hours earlier

POC testing resulted in a reduction in median time to diagnosis, isolation, antiviral prescription and discharge. The greatest reduction was seen in time to result and time to antiviral prescription. While guidance recommends empirical antiviral prescribing and isolation without delay, in practice clinicians often wait for laboratory confirmation of infection, possibly due to a lack of isolation capacity locally or atypical presentation of influenza. With the time to result reducing from a median of 1 day and 15 hours to 5 hours (including assessment time) it is more likely antiviral prescriptions will be received within the 48-hour window. POC testing for influenza was found to be beneficial in the management of influenza infections and improved the isolation of patients during the 2015/16 period in the North East.

Improved pathway for Royal Berkshire Hospital (RBH): Patients who meet criteria will have flu test (Roche cobas Liat) at point of care and will receive a result in up to 20 minutes. If the patient tests positive and is otherwise well, they will be treated with Tamiflu (Oseltamivir) and will be sent home from where they presented (either ED or community unit), or if seen by an out-of-hours GP, the patient will remain at home. If the patient tests positive and warrants admission, they will be isolated, and treatment started immediately, as well as treatment for any secondary conditions.

The first part of the evaluation started in mid-December 2017 in the ED at RBH. Due to the pressures experienced by ED during this period with a rising number of flu cases, the department consumed more than the 20 tests per day anticipated. What they did not expect was the overwhelming enthusiasm from the ED department who have commented on the positive impact of the test.

“Despite the current bed-crisis and the increasing numbers of flu patients - I want to encourage you all to keep testing for flu (and treating it!). A positive flu test can be annoying as it creates bed management problems - but actually our early testing is leading to decreased length of stay, decreased secondary infections and decreased mortality (aka We’re saving lives!) Importantly - we are also exposing less in patients to flu causing less cross infection and we’ve not had to close wards because of flu. The trial is being extended and we have more tests to use. We are being encouraged to think ‘flu’ in those elderly less specific presentations (often afebrile). The POC machine only has a capacity of 3/hr - but within that - we should be testing a lot of the medically admitted patients. This is a brilliant piece of kit and should make caring for our flu patients much better!”

David Clarke – ED Consultant Lead

**Benefits:**

- Less bed time – Less hospital time by testing in community – Fewer admissions
- Appropriate and early use of Tamiflu – Lower use of prophylaxis
- Reduction in secondary cases – Treated for both flu AND secondary infection

The POC test costs £15 more than the lab test, however savings within the cohort, median length of stay saving three bed days per patient at £400 per night. For 192 positive results from 563 tests undertaken in ED, this equates to around £222,000 saving.

- Length of stay (p<0.001). Days from admission to antivirals (p<0.001)
- Standard care: 6 days. Standard: 2 days (range 0-17), 98% received
- Point of care test: 3 days. Point of care test: 0 days (range 0-3), 96% received
Point of care influenza testing in acute medical unit

A new POC test to detect flu was used in the Acute Medical Unit (AMU) at Stoke Mandeville Hospital (SMH) by Buckinghamshire Healthcare. The test developed by Fujifilm Medical Systems is based on silver-amplified lateral flow technology in a simple cartridge with an automated reader. The test requires minimal hands-on time and sample preparation making it ideal for use in a busy department.

The Oxford AHSN assisted in the setting up of the real-world evaluation, pulling the key clinical stakeholders together for initial meetings, drafting the protocols and data collection procedures alongside the trust’s lead microbiologist and the AMU staff who would be using the test, organising training and logistics and helping with day-to-day queries.

The test enabled clinicians to quickly and easily diagnose and treat patients with flu, often resulting in a shorter stay in hospital, and saving around £200 per patient tested. The test was only run in a small unit in the emergency medicine department, but once commissioned use will be extended to the emergency department for use at the ‘front door’ of the hospital.

All nurses using the test agreed that it helped a lot with management of infectious patients and reduced the impact of flu that is usually seen on the unit, as well as reducing pressures on other departments if patients were transferred. Other similar studies have shown cost savings in the region of £200 per patient tested, as well as showing that POC flu testing can reduce length of stay by half.

Buckinghamshire Healthcare is now in the process of commissioning the test for the AMU and emergency departments at SMH. This was the first adoption site in the UK for the Fujifilm IMMUNO AG.
Rapidly identify viral cases requiring immediate isolation and confirmatory molecular testing

Two studies prospectively evaluated the utility of FebriDx to rapidly identify viral cases requiring immediate isolation and confirmatory molecular testing from non-infectious patients or bacterial infections requiring antibiotics. The studies are summarised below.

Utility of FebriDx in early identification of possible Covid-19 infection

FebriDx was shown to be 100% sensitive for Covid-19 infections compared to 82.9% for RT-PCR (initial test). The specificity of both FebriDx and RT-PCR was 100%. FebriDx also correctly identified 8/8 bacterial infections (100% sensitive and 92.5% specificity). Single biomarker CRP was unable to differentiate viral from bacterial infections due to the considerable overlap in values. This was also the case for procalcitonin and leukocyte counts. The use of FebriDx would have prevented seven Covid-19 negative patients being exposed to Covid-19 positive patients caused by the delay in RT-PCR test results. FebriDx can be successfully deployed as a reliable triage test among hospital or ED patients suspected to have Covid-19.

Real-world diagnostic accuracy of a host response POC test in hospitalised patients with suspected Covid-19

The study prospectively evaluated the real-world diagnostic accuracy of the FebriDx test for the confirmation of viral infection in adults hospitalised with Covid-19. FebriDx was shown to be 93% (110/118) sensitive and 86% (112/130) specific for identifying viral infections in Covid-19 patients compared to PCR. Several patients with FebriDx viral positive results (negative by PCR) had classical radiological features of Covid-19 and were likely to be true positives despite negative PCR results. Due to the very high Negative Predictive Value (NPV), FebriDx viral negative patients can be rapidly cohorted in non-Covid-19 areas allowing FebriDx viral positive patients to be immediately isolated while awaiting confirmatory PCR testing. FebriDx was shown to be highly accurate to rapidly detect Covid-19 infections and could be rapidly deployed as a front door triage tool in hospitals and urgent care centres to overcome current issues of delayed diagnosis from PCR testing.
Opportunities for point of care testing

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