

Point of care standards – moving from Wet Prep to Coaguchek

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Blackpool Anticoagulation Dosing Advisory Service (ADAS) provides point of care testing (POCT) and computer assisted dosing to 7,000 registered patients on oral anticoagulation therapy in the Blackpool and Fylde area.

The service recently went through an intensive process of changing their POCT from Wet Prep to Coaguchek across the entire service, with a 9 month timescale from project initiation to Coaguchek go live.

This change in POCT was driven by a number of factors:

- The current liquid Thromboplast reagent was due to be discontinued by the supplier in April 2015 and the service had enough stock up until mid-June, which dictated that the change in POCT had to be completed by mid-June at the very latest.
- A desire to improve the quality and reproducibility of INR results by reducing the complexity of the process and thereby the potential for error.
- The mandatory introduction of ISO 15189:2012 Medical Laboratory Standards and ISO 22870:2006 POCT standards saw the laboratory due for inspection in September 2015 and the POCT due at some point over the next 12-18 months. Achieving accreditation will reduce the risks associated with POCT and allow recognition of the department's competence with the standards set.
- Standardisation of methodology across the Trust including Cardiology who use Coaguchek.
- Immediate result availability for domiciliary visits.
- Reduce operator error and large numbers of repeat INR tests which caused delays and uncertainty to patients.

A risk assessment of the entire clinic process was undertaken as part of the initial stage of the project and a number of potential risks were highlighted. Firstly, there are no unique patient identifiers linked directly to the result. Secondly, sampling error risks included air bubbles in the sample; insufficient volume of the sample; and squeezing of the patients finger to obtain the sample, all of which could lead to an erroneous result. Risks were also identified in reagent preparation and stability. Furthermore, risks involving the POCT devices included no user login, therefore no audit trail; no quality control lockout function or fail safe; and limited linearity of the KC4 coagulometers resulting in repeat INR tests for any results that fell below 1.5 or above 4. Finally, the failure of printers used in the wet prep service provision often led to staff manually writing INR results onto each visit report form, posing transcription error and incorrect dosing risks.

Trialling the Coaguchek against the KC4 and the laboratory TOP analyser (ACL TOP) highlighted a closer correlation between the Coaguchek and the ACL TOP than the KC4. In addition, there was a 90% reduction in repeat INRs in clinic when using the Coaguchek. This further supported the move to the Coaguchek devices.

With 120,000 tests per year, 18 clinic sessions (90-150 patients per session) and 120 domiciliary visits per day, costs were determined for the introduction of Coaguchek POCT devices, printers and the COBAS IT 1000 software and the ADAS team presented to the commissioners, separately detailing the service specification/requirements and the recommended change in provision.

The Coaguchek devices, printers and COBAS software were procured via NHS Supply Chain (SC) and clinical justification for procuring these was presented as no other coagulation analysers on the framework complied with the specifications that had been submitted by ADAS. This enabled ADAS to procure the devices quickly in order to meet the tight timescales and ensure continuation of service.

ISO Standards

ISO standards cover every aspect of the patient, test and result pathway and the following are a selection of the more analytical and technical standards that the new POCT devices enable the ADAS service to meet:

- Patient unique identifier linked directly to the results – all patient books have an NHS barcode and this is scanned into the Coaguchek prior to performing a test.
- A full audit trail of users, tests and quality control actions performed on the devices.
- Regular quality control checks are carried out and the devices have a lockout facility.
- Results are validated by an appropriate individual.
- Pre-acceptance of reagent to check integrity following transportation process and storage facilities are fully validated through daily monitoring and recording of temperatures.
- Staff training and competency monitored.
- Full validation of new systems documented including the evaluation of systems; change controls; validation protocols; plan; and risk assessment.

The ADAS service now currently operates with 2 medical laboratory assistants (MLAs) at most clinics with 3 Coaguchek devices per MLA. Clinics see between 90 to 150 patients attending in each morning and afternoon session.

The service is also moving towards full compliance with ISO standards; real time transmission of results from the Coaguchek devices into DAWN directly from the community setting and real time dosing on domiciliary visits.