Validation of a brand new point of care device and its impact on service

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Leeds Anticoagulant Service has over 10,000 patients and covers most of the Leeds area. Traditionally a laboratory-based service, point of care testing (POCT) was initiated in out-patient clinics in 2012 to improve turnaround time, which could reach 1½ hours. The current service is primarily 'Dose and Post' with patients attending clinics in the morning, samples sent to the labs in the afternoon, results sent from the labs into DAWN AC and a letter sent to the patient with results also going to the GP.

Whilst the service is efficient, it isn't particularly patient friendly or clinically responsive and these issues alone are driving the change to POCT, enabling the patient to be tested, obtain their INR and dose and to receive treatment, if necessary, at the point of contact within clinic.

Transformation funding was secured by the anticoagulant service and subsequently, Roche Coaguchek machines were procured for use within the OP clinics which vastly improved patient turnaround time.

Recently however, a Pathology Managed Service Contract has been signed with Siemens who are currently developing a hand-held POCT device (Siemens Xprecia Stride) and consequently asked Leeds to evaluate the devices within their clinics.

Leeds agreed to evaluate the Stride as Siemens were their managed service provider, but also because initial appraisal found that the machines were easy to use and in terms of cost, are very competitive.

The purpose and scope of the evaluation exercise was to compare the results of the Xprecia Stride against both ACL TOP and Roche Coaguchek XS Pro. If suitable, the machines would be used in out-patient and community clinics to provide INR results. The devices would also be used by the phlebotomy team for home visits so that any out of range results could be dealt with immediately rather than the samples sent to the GP and a wait of up to 24hrs before they were returned to the AC service, as was previously the case with the venous blood samples.

Patients from across both hospital and community sites were selected according to eligibility criteria which determined three separate population groups for the evaluation:

- **Population 1:** Subjects stable on warfarin and having received treatment for more than 3 months
- **Population 2:** Subjects not receiving any anticoagulation therapy and not known to have a coagulation disorder
- **Population 3:** Subjects being initiated on warfarin and on treatment for less than 3 months

Within each clinic, two capillary finger-prick samples were to be taken with one tested on the Stride and one on the Coaguchek. In addition, venous samples were taken to be tested on the laboratory equipment so that all 3 sets of results could be used for comparison.

Statistical Analysis

Linear regression and visual data were used to review the linearity and comparability of the Siemens Stride against the current lab technology - ACL TOP - and Roche Coaguchek.

An overall negative bias was found with the Siemens machines running on average 0.2 INR units lower than the ACL TOP in the normal to therapeutic range, and around 0.46 INR units lower than the Roche Coaguchek devices.

The following table contains a summary of the positives and negatives of the Xprecia Stride device:

Positive	**Negative**
• Easy to use, very intuitive • Barcode reader enables all reagent strips to be scanned • USB port for easy data export of patient results and daily quality controls • Software included that facilitates staff identification • Sensitive touch screen • On board tutorials that cover a range of topics including the controls on the device and how to carry out the patient testing • Low blood volume: 6uL compared to 8uL required by the Coaguchek • On-board storage for up to 640 patient INRs • Test strip ejection button prevents the need to touch the strips	• Currently no EQA scheme due to the newness of the device, however a pilot scheme is due to be setup • The test strips for the Stride are slightly smaller than the Coaguchek so a little more 'fiddly' • Potentially would like more memory • Software not fully networkable yet so sits on a standalone PC/laptop. Would like a data link into DAWN AC for results • Runs on AA batteries – not practical with high numbers of patients. Have asked Siemens if they can produce a rechargeable unit

The team at Leeds Anticoagulation Service would like to extend the validation and further explore the bias shown in the results to determine what, if any, clinical impact it would have. If the extended validation proves successful, then Leeds will look at implementing the Xprecia Stride POCT device across the entire anticoagulation service.