

Automation of urinalysis at the Point of Care across Imperial College Healthcare NHS Trust – a pilot project

Project lead and author: Olubunmi Martindale-Sheldon

Co-investigators: Gareth John, Kate Agunabor, Wilbert Gwangwadza and Edwin Turner

Senior responsible officer and report approver: Prof Tricia Tan

1. Introduction

POCT urinalysis involves carrying out urine chemistry tests at the Point of care, nearer to the patients. The POCT urinalysis reagent strips allow for the measurements of the following in urine: Bilirubin, Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity and Urobilinogen (depending on the strip type). These measurements are used to assist diagnosis in the following areas: kidney function, urinary tract infections, metabolic disorders (such as diabetes mellitus) and liver function. The urinalysis strips also measure physical characteristics including acid-base balance and urine concentration.

POCT urinalysis is in use across all Divisions in over 150 clinical areas within Imperial Healthcare NHS Trust, with an annual usage figure of >300,000 test strips (based on 2013/2014 figures received from Pharmacy).

POCT urinalysis is generally used in the Trust to screen patients so that only positive samples are sent to the Lab for confirmation or further analysis. It is generally recommended that the original sample be sent to the laboratory if any of the following analytes are positive: Blood, Protein, Nitrite or Leukocyte.

1.1 Background

POCT urine chemistry analysis is currently being done manually (dipstick method) across the majority of clinical areas requiring this service at Imperial College Healthcare NHS Trust.

The dipstick method is based on colour development and it relies on the ability of the user to accurately interpret the colour type and intensity. This method is subjective and open to interpretational error. Test results are transcribed into patient notes with potential for transcription error. No quality assurance procedures such as Internal Quality Control or External Quality Assurance (IQC or EQA) are in place and it is difficult to prevent use by untrained staff. There is significant potential for erroneous results and inappropriate/delayed patient management (e.g. missed cases of urinary tract infection [UTI]).

It is anticipated that automating the processes from testing through to reporting will significantly minimise the risks to patient safety whilst safeguarding staff and the Trust (in cases of litigation or patient queries). The automated readers have a QC and operator lock-out facility ensuring only trained staff can use the device and appropriate QC checks are carried out prior to patient test. Test results will automatically transmit to electronic patient records – saving staff's time and eliminating possible transcription errors. Results will be readily accessible and traceable with a full audit trail.

The safety and governance measures associated with the fully automated systems will enable the Trust to demonstrate compliance with relevant quality standards such as MHRA/UKAS and achieve accreditation for the service.

This project involves piloting automated readers and assessing the benefits over the manual dipstick method, with the hope of rolling urinalysis automation to the rest of the Trust.

1.2 Aim

- The aim of the project is to pilot use of fully networked automated readers and assess the benefits of this method over the manual dipstick method and semi-automated method (automation without IT connectivity to electronic patient records). Benefits measured will include data quality, governance, cost and any efficiency or time savings that may result.
- At the end of the study, a report will be submitted to the sponsor of this project – Patient Safety Translational Research Centre (PTRSC), Imperial College London.
- If the pilot demonstrates significant benefits to both patients and the Trust, the study report will be taken forward to the Trust management with recommendations to consider funding and rolling out fully networked systems to all areas carrying out urinalysis.

2. Materials & Methods

The project was implemented in two stages:

Stage 1 – IT/Connectivity

This stage involved installing the fully automated readers in relevant clinical areas and connecting these analysers to the Laboratory information system (Sunquest) and Hospital information system (Cerner) so as to allow automatic data transfer from the analysers via Sunquest to Cerner.

The process includes:

- Virtual server build
- Loading the analyser data management system software (RAPIDComm V5.0) on to the server
- Installing network Points in clinical areas and installing the analysers
- Implementing ADT feed in to RAPIDComm
- Testing results sent to RAPIDComm
- Cerner urinalysis tests build
- Interfacing RAPIDComm in to Cerner
- Carrying out end to end acceptability testing

Results and associated data must be able to transfer successfully from the analysers via Sunquest to Cerner for this stage of the project to be successful.

It is worth mentioning that this aspect of the project had to be completed before any significant progress could be made with the project.

Stage 2 – actual testing/piloting

This stage involved piloting the automated readers and comparing this method of testing to the manual method.

2.1 Automated reader used in the Study

Name of analyser	Siemens Clinitek Status+ urine chemistry analyser The analyser can be used as a stand-alone device or can be connected to Laboratory/Hospital information systems
Intended use	The analyser is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, Urobilinogen, and Human Chorionic Gonadotropin (hCG), depending on the reagent in use on the device. The analyser can be used for Urinalysis testing and can also be used for urine hCG (pregnancy) testing . This study however focuses on the urinalysis aspect which uses the Multistix urinalysis reagent (detailed below)
Assay methodology	The analyser uses the principle of reflectance photometry to read and evaluate the Multistix urinalysis test strips. Light from light emitting diodes (LEDs) inside the instrument illuminates a fixed “read area” on the reagent strip. Light reflected off the test strip pads is subsequently detected by the instrument’s detector. The amount of light reflected at specific wavelengths from the test strip pads depends on the degree of colour change in the pads and is directly related to the concentrations of the measured analytes in the urine sample. The reflected light is then converted by the instrument’s microprocessor and software into clinically meaningful results shown on the display screen or printed by the integrated printer.
Total assay time	< 2 minutes
Sample type	Fresh urine sample (no preservatives) <ul style="list-style-type: none"> Sample mixed before testing and tested within two hours after voiding. If unable to test within the recommended time, specimens can be refrigerated, and returned to room temperature before testing. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein test results. Work areas and specimen containers should always be free of detergents and other contaminating substances.
Temperature range of assay	The optimum operating range of the analyser is 22-26°C; at temperatures below 22°C, urobilinogen and leukocyte results may be erroneously low and at temperatures above 26°C, high. This is because strip reactivity increases with temperature.
Reagents storage and stability	Siemens Multistix urinalysis test strips are firm plastic strips immobilised with separate reagent areas (test pads). At Imperial NHS, the Multistix 8SG reagent strips are in use which measures: Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein and Specific Gravity. The test strips are stable at 15–30°C until the manufacturer’s expiry date. They must be kept away from direct sunlight, moisture and heat to avoid altering reagent reactivity. Desiccant must be retained in the reagent container with the lid tightly replaced at all times.
QC materials & stability	Siemens IQC Chek-Stix Combo (2 levels – positive and negative controls). These are stable at 15–30°C until the manufacturer’s expiry date Prepared control solutions are stable for 3hrs after preparation at temperatures below 30°C.
Method of calibration	The analyser is self-calibrating. The analyser automatically performs a system check (“self-test”) each time it is turned on and each time a test is run using the white calibration bar on the test strip table. DO NOT move or bump the test table while the instrument is calibrating.

Onboard analyser storage	The analyser memory can store up to 950 patient test results, and 200 authorized operators at any one time. This information is stored in the memory whether the analyser is powered on or off For stand-alone systems, once test results reaches 950, the first one is overwritten and so on.
---------------------------------	---

2.2 Participating Clinical areas

Nine clinical areas of medium to high urinalysis strip usage were chosen at random. These areas were grouped into three and each group represents a method type. This is to enable a direct comparison of the three methods under study (i.e. manual, semi-automated and fully automated methods).

Group 1: Manual dipstick method

- A&E, St. Mary's Hospital
- Gynae OPD, Hammersmith Hospital
- Main OPD, Charing Cross Hospital

These areas carried out the urine tests manually.

Group 2: Semi-automated method

- Renal OPD, St. Mary's Hospital
- Renal OPD, Hammersmith Hospital
- 7 North, Charing Cross Hospital

These areas carried out urinalysis with the aid of an automated reader. However, the readers are not connected to the laboratory information system (Sunquest) or hospital information system (Cerner), resulting in the need for the test results to be manually transcribed from the analyser print-outs to the electronic patient record (Cerner).

Group 3: Fully automated method

- Planned Investigative Unit (PIU), St. Mary's Hospital
- Lewis Suite, Hammersmith Hospital
- Clinical Decision unit, Charing Cross Hospital

These areas carried out urinalysis using automated readers which have been connected to both Sunquest and Cerner.

2.3 Samples used

For this study, the following samples were used:

- Internal quality control (IQC) reference materials provided by the device manufacturer
- External quality assurance (EQA) reference materials provided by an independent EQA scheme provider (WEQAS)
- Fresh patient urine samples

The same sets of samples were processed using all three methods and resulting data & processes compared. The methods will be evaluated for data quality, governance or lack of this, cost and time/efficiency savings.

Reference standards for comparison purposes:

- For IQC, references will be made to the supplied manufacturer's reference ranges
- For EQA, reference will be to the consensus values provided by the EQA scheme organiser
- For patient samples, a competent POCT staff will first process the samples (using an automated reader) before handing the samples over to clinical staff to process on all three methods.
- Samples chosen at random (10 samples) will be sent to the Microbiology Lab and results compared against those obtained by the competent POCT staff to ensure reference results are in good agreement with the Lab method results.

2.4 Measurements

2.4.1 Data Quality

The same sets of samples were processed using all three methods and the resulting data & processes compared.

- IQC sample – same sets of IQC material (negative & positive levels) reconstituted by POCT staff were given to clinical staff to analyse for all three methods. This was done over several days to allow for different members of staff to process these thereby reflecting the normal practice.
- EQA sample – six different distributions of EQA (a total of 18 samples) were analysed by clinical staff using all three methods.
- Patient sample – >90 urine samples were analysed using all three methods.

We will assess:

- *Results accuracy* – how each method compares to the reference values for all the sample types (i.e. patient, EQA and IQC samples). Scoring is based on the total number of correctly resulted analytes (when compared with the reference values) expressed as a percentage of the total number of analytes tested (see Appendix 1 – data quality spreadsheet).
- *Transcription error rate* – percentage of incompletely or incorrectly recorded results

2.4.2 Governance

For this aspect of the study, audits were carried out assessing data over a 3-month period for all three methods, specifically looking at training, quality assurance (IQC & EQA), result recording, reagents traceability as well as the ability to accurately trace operators of POCT kits and patients tested using the kits based on the records kept. Results were audited against UKAS requirements.

The audit was carried out with the aid of questionnaires used to collate responses to the quality questions below:

- Are operators trained & certified? Is there evidence of this?
- Have appropriate IQC been done? Is there evidence of this?
- Does the clinical area participate in an appropriate EQA scheme?
- Are the reagents used for testing traceable (e.g. in case of recall)?
- Are operator and patients identifiable along with test results?
- Does the test result reporting/format meet the minimum criteria required by UKAS ISO 15189/22870 standards?

2.4.3 Cost and efficiency savings

This aspect of the study assesses the time used by staff to carry out urinalysis (from testing through to reporting), identify wastage (if any) due to unnecessary duplicate testing, and whether any condition may have been missed.

- *Staff time* – to assess this, we will calculate the average time taken for each method and estimate the cost of this in staff time
- *False Positives* – results for 99 patient samples processed by all three methods were compared to the reference values and any false positives identified per sample. This is based on the assumption that if any of the following analytes (Blood, protein, nitrite or leukocyte) is positive at the Point of Care, the original sample will be sent to the Lab for re-testing/confirmation. A false positive result would mean sending more samples to the Lab than necessary thereby wasting the Trust's resources and patient's time.
- *False Negatives* – results for 99 patient samples processed by all three methods were compared to the reference values and any false negatives identified per sample. This is based on the assumption that if all the following analytes (Blood, protein, nitrite or leukocyte) is negative at the Point of Care, the original sample will not be sent to the Lab resulting in possible misdiagnosis/inappropriate care for patients.

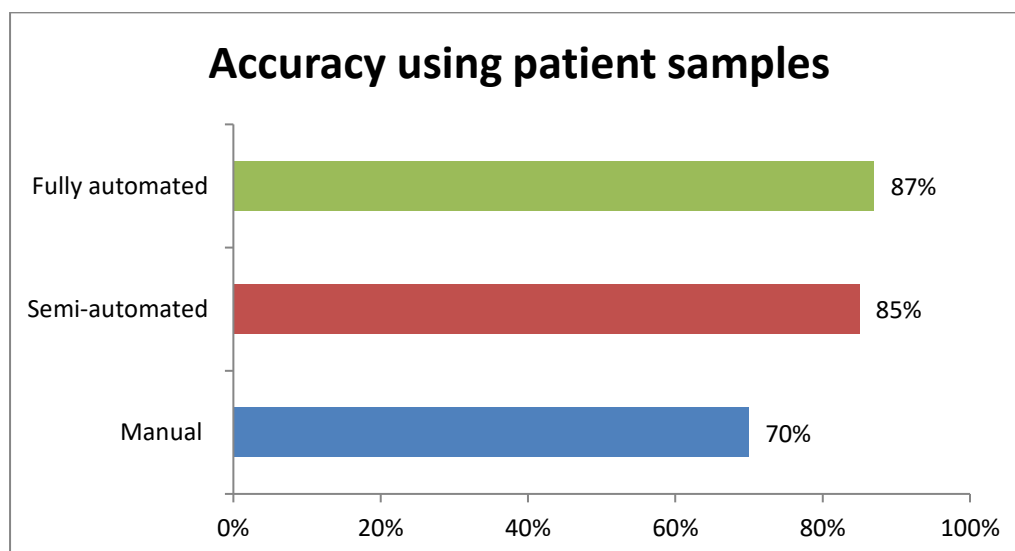
3 Results

3.1 Data Quality

3.1.1 Results accuracy

Patient samples

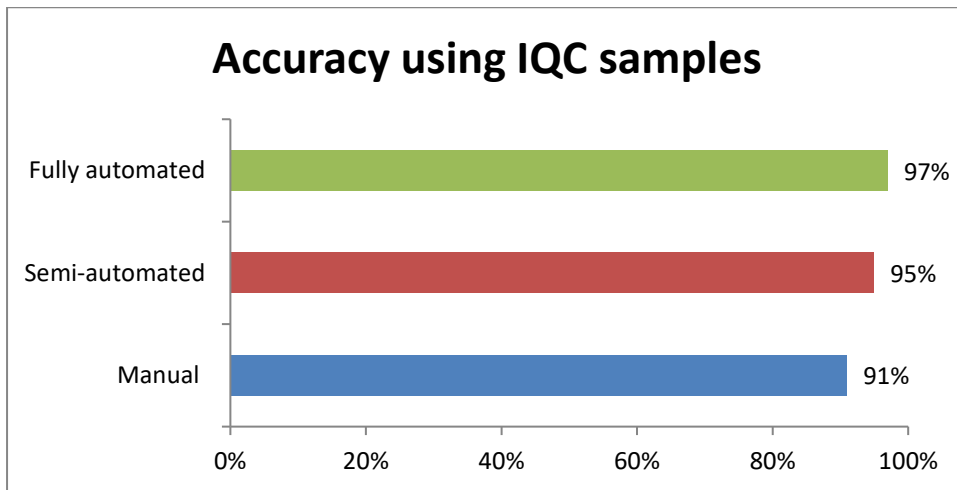
A total of 99 patient samples were processed using all three methods and the results compared against the reference values generated by competent POCT staff.



Comments: The automated methods performed at least 15% better than the manual method. However, the findings indicated that a 13-15% error rate still occurs in general for POCT urinalysis regardless of the method used.

IQC samples

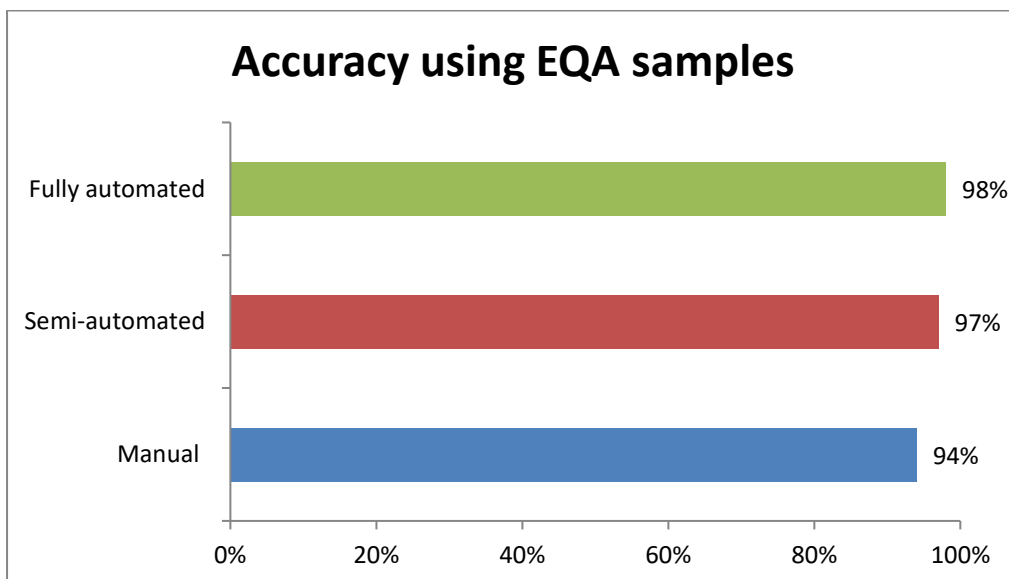
A total of 90 IQC samples were processed using all three methods and the results were compared to the manufacturer reference values.



Comments: All methods achieved high scores however, the automated methods performed better in terms of closeness of results to the reference values, with at least 4% better accuracy.

EQA samples

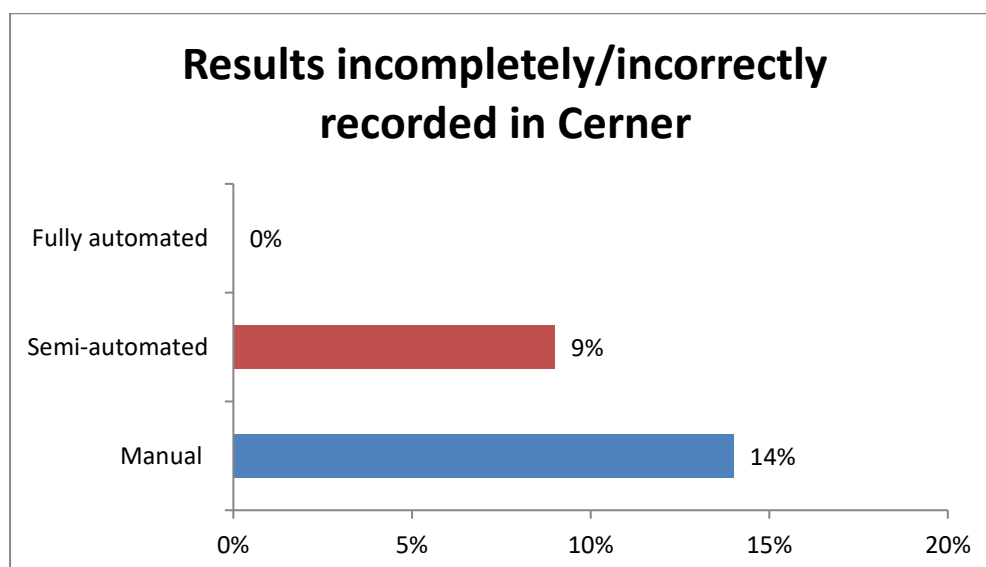
A total of 18 EQA samples (from six different distributions) were processed using all three methods and generated data were compared to the WEQAS (EQA scheme organizer) reference values.



Comments: All methods achieved high scores however, the automated methods still performed better in terms of closeness of results to the reference values, with at least 3% better accuracy.

3.1.2 Transcription error rate

A total of 99 patient samples were processed using all three methods and records were checked for any transcription error.



Comments:

- No transcription errors were observed for the fully automated method. Although the analyser prints out the results, the users did not have to manually enter the results on Cerner as the results are automatically transmitted to the electronic patient records.
- For the Semi-automated method, the analysers are not linked to the electronic patient records so results are printed out from the analyser and manually transcribed into the patient's record. The transcription error rate for this method was 9% of the total results.

Note: the results print out on a thermal paper which fades overtime hence the need to manually transcribe the results for a more permanent record.

- For the manual method, most clinical staff tend to write results on a paper and then manually transcribe into Cerner. The transcription error rate for the manual system was 14%, which is the highest error rate observed (compared to the other methods).

3.1.3 Microbiology method versus POCT reference method (patient samples only)

Due to the unavailability of a corresponding Lab method for all the analytes on the urinalysis test strip, trained POCT staff provided the reference values for patient samples by first processing the samples (using an automated reader) before handing them over to clinical staff to process. This part of the study is an additional measure to validate the POCT reference method and ensure the results compare well with the Lab method.

10 patient samples selected at random were sent to the microbiology Lab for MC&S and the results compared to those obtained by competent POCT staff (using the automated reader). There are only two tests on the strips with corresponding Lab method (Blood and leukocytes) so only these two were considered in the scoring. Scoring is based on the total number of correctly resulted analytes (when compared with the reference values) expressed as a percentage of the total number of analytes under consideration.

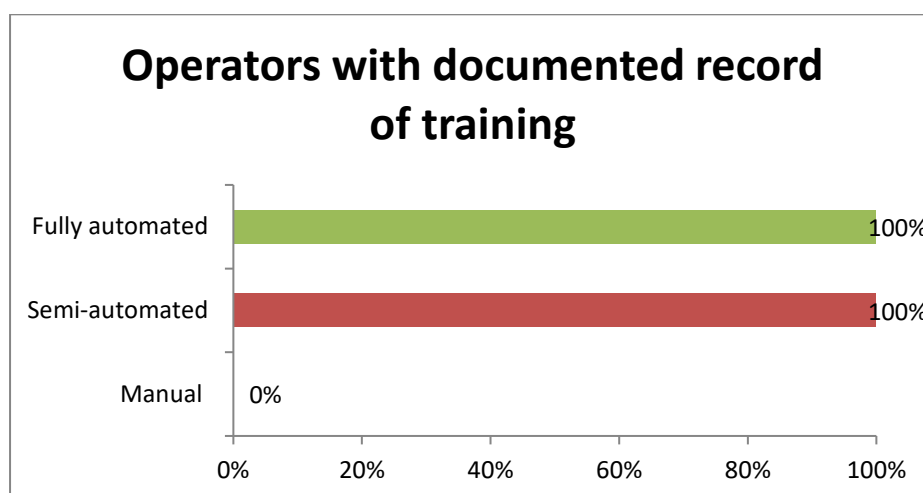
90% of the POCT reference results were in agreement with the Microbiology lab results (please see Appendix 1 for data).

3.2 Governance

3.2.1 Training audit

UKAS accreditation requirement for training: “Only personnel who have completed the training and demonstrated competence shall carry out POCT. Records of training/attestation (or certification) and of retraining and re-attestation (or recertification) shall be retained.” (ISO 22870; 5.1.4b)

Training records for clinical staff processing samples in each of the method group were checked. The figure below demonstrates the observed findings:



Comments: There was no evidence to demonstrate the training and competency of staff carrying out urinalysis in the manual areas. However, all staff using the automated systems have documented evidence of training and competency.

3.2.2 IQC audit

UKAS requirement for IQC:

“The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.” (ISO 15189; 5.6.2.1) “The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.” (ISO 15189; 5.6.2.3) “Frequency of internal QC should be specified for each device.” (ISO 22870; 5.6.6c)

All participating clinical areas were audited over a 3-month period to check compliance with IQC procedures for all three methods. These findings are presented in the table and the figure below:

IQC (audit over 3 months)			
Questions	Manual	Semi-automated	Fully automated
Does the area carry out IQC testing?	No	Yes	Yes
Is the frequency of IQC testing in line with the Standard operating procedures (SOP)	No SOP in place	Yes in 67% of the areas	Yes
Method of recording IQC data?	Not done or recorded	POCT record book	Electronic
Are staff able to use device if IQC fails?	Yes	Yes in 67% of areas	No

Comments:

- The manual areas are not carrying out IQC checks and also do not have a standard operating procedures (SOP) which is an essential ISO requirement for safe use of POCT. SOP is in place for the two automated methods (semi and fully automated).
- The semi-automated method areas carry out IQC checks but not at the recommended frequency. Also, staff are able to use the device without carrying out IQC checks or if IQC fails.
- The fully automated system areas carry out IQC checks in line with recommended frequencies. The system makes it impossible for staff to use the device without carrying out appropriate IQC checks. Also, the device will only permit use if the IQC checks have been passed.

3.2.3 EQA audit

UKAS requirement for EQA: "Where available, participation in an external quality assessment (EQA) shall be required (see ISO/IEC 17043). In the absence of an EQA scheme, the laboratory director, or designated person, should establish an internal quality assessment scheme involving the circulation of samples or replication of the test within the laboratory." (ISO 22870; 5.1.4b)

EQA (audit over 3 months)			
Questions	Manual	Semi-automated	Fully automated
Does the area participate in EQA testing?	No	Yes	Yes in 67% of the areas
Is the frequency of EQA testing in line with the SOP?	No SOP in place	Yes	Yes for areas participating in EQA
Method of recording EQA data?	Not done or recorded	POCT record book/analyser print-outs/EQA request form	Electronic

Comments:

- None of the manual areas are participating in an EQA scheme.
- All of the semi-automated method areas participate in an EQA scheme and at the required frequency.
- For the fully automated method, most of the areas participate in EQA scheme, the remaining area are yet to be registered on an EQA scheme as the analyser is not routinely used. However, for all registered areas, EQA testing was being done at the required frequency.

Note: Standalone POCT e.g. manual areas can participate in EQA as long as the clinical area registers with an ISO approved EQA scheme and takes responsibility for EQA sample analysis and reporting. Currently none of the manual areas across Imperial NHS are registered on an EQA scheme.

3.2.4 Reagent audit

UKAS requirement for reagent records: "A record shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed." (ISO 22870; 5.3.2e)

Reagents (audit over 3 months)			
Questions	Manual	Semi-automated	Fully automated
Of FIVE randomly reviewed time points (five different days), number of times the Lot Number of the reagent was recorded (%)	0%	87%	100%
Method of recording reagent information?	Not recorded	POCT record book/Electronic	Electronic
Are staff able to use device expired reagents using this method	Yes	Yes in 67% of the areas	No

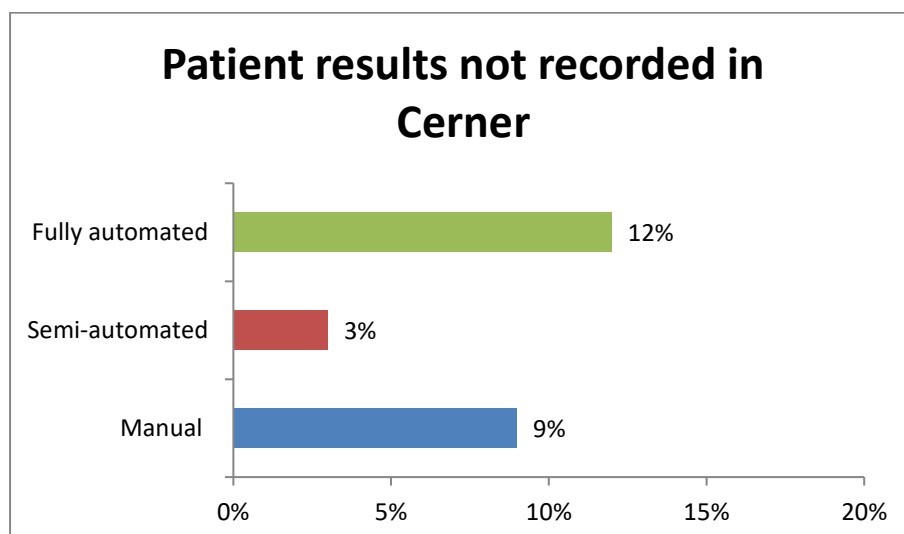
Comments:

- For the manual areas, there is no evidence that reagents lot numbers were being recorded. This makes it difficult to ascertain which reagent is used for any particular test e.g. in case of clinical incidents, product recalls, etc. Also, staff are able to use expired reagents with this method which is against manufacturer's recommendation and may invalidate patient results.
- For the semi-automated areas, staff were recording reagent information but not all of the time. Also, staff are able to use expired reagents with this method in some of the clinical areas.
- For the fully automated areas, reagent information (lot number, expiry date etc) are automatically logged onto the system and the device will not allow staff to use expired reagent.

3.2.5 Result recording

UKAS requirement for Reporting of results: "POCT results shall be permanently recorded in the patient's medical record. The identity of the person performing the test should be recorded." (ISO 22870; 5.8.3)

99 patient samples were given to clinical staff to process for all 3 methods. Records were subsequently checked to ensure all results have been entered on to Cerner (patient permanent record system).

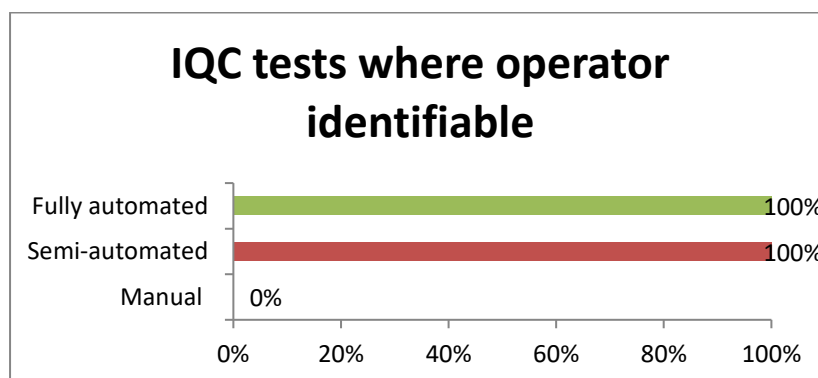


Comments:

- For the manual system, 9% of patient results were not recorded in the patient permanent record (Cerner).
- For the semi-automated system, 3% were not recorded on Cerner. However, these results are held on the analysers until they are deleted off the system (the analyser can only hold up to 950 patient results at any one time) so it is still possible to lose results if not manually transcribed onto Cerner.
- For the fully automated system, 12% of the patient results were not available on Cerner at the time of the audit due to IT connection issues. However results are stored on the instrument data manager (RapidComm) so results are never lost. Also, based on the information provided by the device manufacturer, these results should automatically transmit to the patient records on Cerner once IT link is restored. Further audit will need to be carried out to verify this assumption.

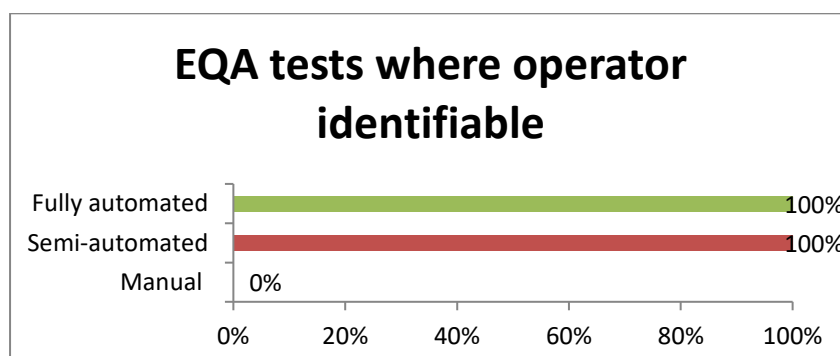
Operator Identification (traceability) UKAS requirement: "POCT results shall be reported with necessary details.... The identity of the person performing the test should be recorded." (ISO 22870; 5.8.2 & 5.8.3)

An audit over a 3-month period was carried out to check if IQC tests could be traced back to the operators, please see findings in the figure below:



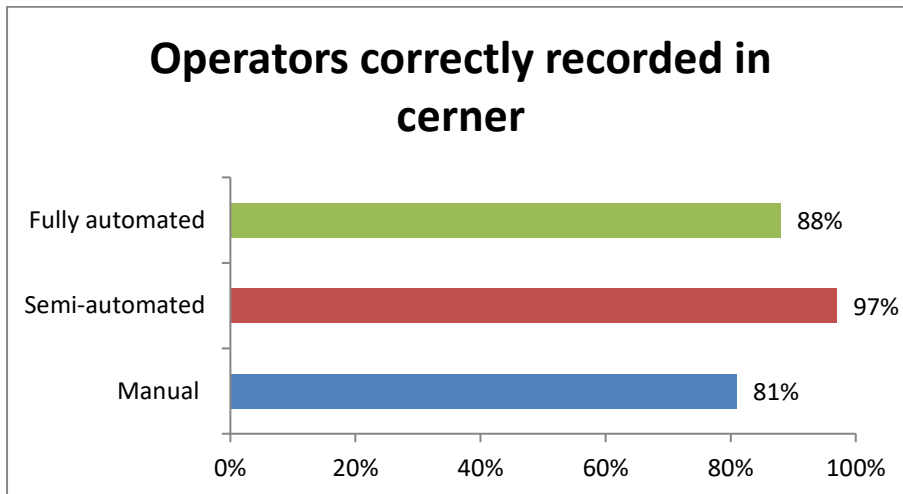
Comments: For the manual method, no IQC was done or recorded but for the automated systems (semi and fully automated), all staff involved in the IQC testing were identifiable.

An audit over a 3-month period was carried out to check if EQA tests carried out could be traced back to the operators, please see findings in the figure below:



Comments: For the manual method, no EQA was done or recorded but for the automated systems (semi and fully automated), all staff involved in the EQA testing were identifiable.

99 patient samples were processed using all three methods. Patient records (on Cerner) were subsequently checked to see if patient results could be traced back to the personnel that carried out the urine tests. Please see the figure below for findings:

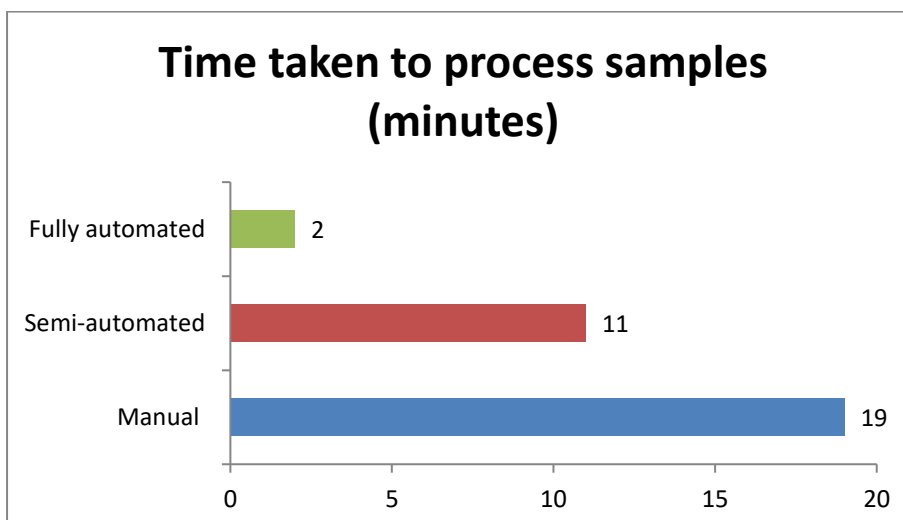


Comments:

- For the manual method, 19% of the operators were not correctly recorded.
- For the semi-automated method, 3% of the operators were not recorded. A review of the data showed that this 3% non-compliance was due to not recording the patient results at all on Cerner. As such, for all results entered onto Cerner, the operators were correctly recorded.
- For the fully automated system, 12% of the operators were not on Cerner. Also, review of the data indicated that this 12% non-compliance was due to results yet to transmit on to Cerner at the time of the audit. As such, for all results recorded onto Cerner for this method, the operators were correctly recorded.

3.3 Cost and efficiency savings

3.3.1 Time taken by clinical staff per method (from testing through to reporting)



Comments: The figure above indicates that using a fully automated system will save 17 minutes per test on average. As we process about 300,000 samples per annum, this equates to an estimated cost saving of about £1,066,750 in staff time (see table below for details):

nurse band 5 salary mid-point	£24,547
nurse mid-point hourly cost	£12.55

Salary data Source <https://www.rcn.org.uk/employment-and-pay/nhs-pay-scales-2017-18>

Note: Different grades of staff carry out urinalysis in the Trust including healthcare assistants, nurses and doctors. For the purpose of this cost estimate, a band 5 nurse was considered appropriate.

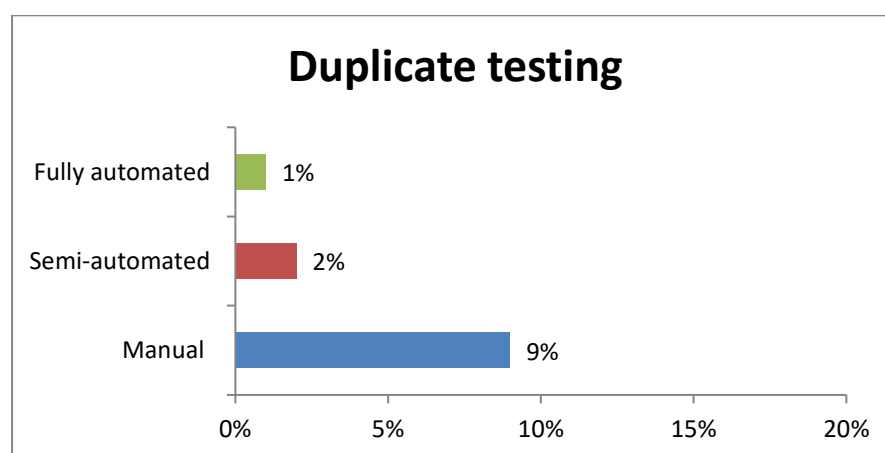
Time saving per test (minutes)	17
number of tests per year	300000
total time saving (minutes)	5100000
total time saving (hours)	85000
total cost saving per year in staff time	£1,066,750

Staff time saving may not always result in an overall financial savings however it may well result in time better spent in other areas of care.

3.3.2 False Positives

POCT should screen out negatives so only true positives are sent to the Microbiology Lab for Microscopy, culture and sensitivity tests (MC&S).

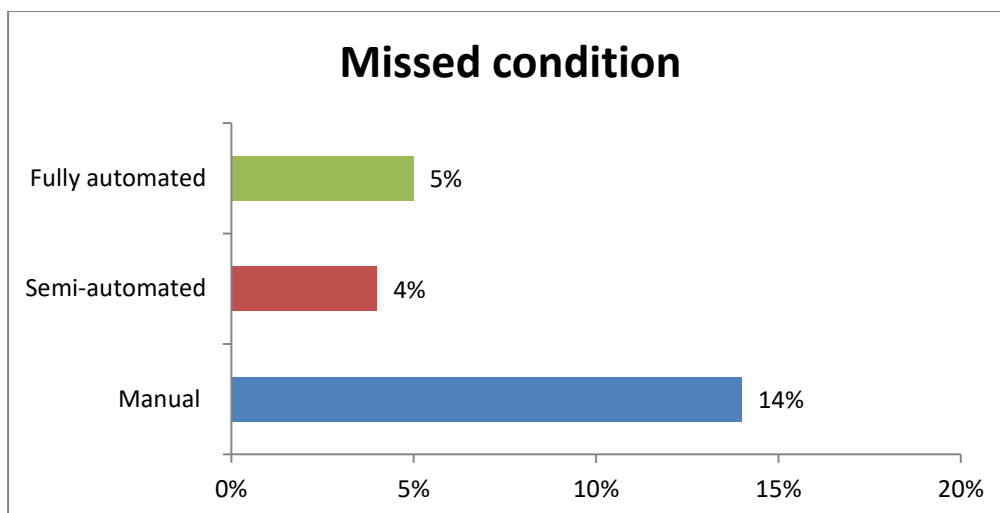
For this part of the study, 99 patient samples processed using all three methods were compared to the reference values and any false positives identified per sample. A false positive result would mean sending the samples to the Lab for re-testing resulting in delay for patients waiting on test results as well as waste of Trust's resources both at the Point of Care and in the Lab.



Comments: With the manual method, at least 7% more samples will have to be sent to the Lab for retesting compared to the automated methods.

3.3.3 False Negatives

For this part of the study, 99 patient samples processed using all three methods were compared to the reference values and any false negatives identified per sample. False negatives can result in misdiagnosis/inappropriate care for patients, as samples are generally not analysed any further if they test negative.



Comments: The manual method has more potential to miss conditions such as UTI when compared with the automated methods (14% for manual versus $\leq 5\%$ for automated systems). When a patient's condition is missed, they may be sent home and may get better, or come back into the hospital which means tests will have to be repeated, or they may get worse quite quickly after the initial wrong diagnosis, with potential for litigation.

4 Summary of Findings

4.1 Data quality

Result accuracy – Results obtained for patient, IQC and EQA samples indicated that the automated method performed significantly better than the manual method ($\geq 15\%$ better performance with patient samples, $\geq 4\%$ better performance with IQC samples and $\geq 3\%$ better performance with EQA samples when compared with the manual method).

Transcription error rate – No transcription error was observed for the fully automated system however transcription errors were observed for both the semi-automated method (at 9%) and manual method (at 14%).

POCT reference method test – In the absence of a true gold standard for the patient samples, trained POCT staff provided reference values by testing the samples first (using an automated reader) before handing them over to clinical staff to process. It was therefore essential as part of this study to ensure results obtained by the POCT staff is accurate and compares well with the Lab method. Findings indicated acceptable performance for the POCT reference method (at 90%) when compared with the Lab method.

The findings may also indicate that the automated reader in use in the Trust is only able to provide up to 90% level of accuracy when compared with the Lab method. However the sample size was quite small (10 samples) so difficult to conclude on this and further work (method verification work) may be required to establish this.

4.2 Governance

Using UKAS requirements for POCT accreditation as standards, retrospective audits were carried out to check if training, IQC, EQA, reagent and result recording for all three methods meet the minimum quality requirements.

Training – only the two automated methods had evidence of staff training, no training or competency record are available for the manual method.

IQC checks – only the two automated methods had evidence of IQC checks, no IQC checks are carried out for the manual method. The IQC checks for the semi-automated method were however not conducted at the required frequency; the method could also be used if IQC fails. For the fully automated method, the system will not allow use if IQC fails or if not done at the required frequency. Also, IQC are manually recorded in log books for the semi-automated method but are kept electronically for the fully automated system without any need for transcription.

EQA scheme participation – Staff in the manual areas do not participate in external quality assessment scheme, only those using the automated methods do.

Standard operating procedure (SOP) – No SOP in place for the manual method, only the automated methods have SOPs.

Reagent audit – No evidence to show that reagent information (e.g. lot numbers) were being recorded for the manual method, these are however being recorded for the automated methods. For the semi-automated method however, this was not being recorded at all times. Also, for both manual and semi-automated methods, staff were able to use expired reagents however this is not possible with the fully automated systems as the system will reject any expired reagents.

Result recording – There is potential for patient test results not to be recorded for the manual and semi-automated method, but the fully automated system mitigates this. The study findings indicated that 9% of patient results were not recorded for the manual method. This reduced to 3% for the semi-automated method. However for the fully automated method, 12% were not recorded at the time of the audit due to IT connection issues although the assumption is that these results will automatically transmit once IT links are restored. Results are however permanently stored on the instrument data manager. Further work should be carried out to verify that interface issue does not lead to loss of data and that results will indeed automatically transmit to Cerner once IT links are restored. It is worth mentioning that users always get a print-out of test results for immediate patient care pending data transfer to Cerner thus incurring no delay in patient management.

Operator identification – All staff involved in IQC and EQA sample processing were identifiable for the two automated methods, the manual methods are not participating in EQA or IQC checks. For patient samples, 19% of users were not recorded for the manual method. This reduced to 3% for the semi-automated method. For the fully automated system, 12% of the results were still waiting to be transmitted due to IT connection issues however, for all patient results recorded onto Cerner for this method, the operators were correctly recorded.

4.3 Cost and efficiency savings

Time taken by staff to process sample (from testing through to reporting) – The manual method takes about 19 minutes to complete, this is reduced to 11 minutes for the semi-automated method whilst the fully automated method takes 2 minutes. Using a fully automated method will therefore save 17 minutes per test on average. The Trust processes about 300,000 samples per annum so this equates to an estimated cost saving of about £1,066,750 in staff time.

Duplicate testing – With the manual method, at least 7% more samples will have to be sent to the Lab for retesting when compared to the automated methods.

Missed conditions – The manual method has more potential to miss conditions such as UTI when compared with the automated methods (14% for manual versus ≤5% for automated systems).

5 Conclusions

The two automated methods performed significantly better than the manual method in all areas assessed (data quality, governance, cost and efficiency). However the fully automated system demonstrated more benefits over the semi-automated method (stand-alone analyser) specifically by:

- eliminating transcription error
- ensuring appropriate quality control checks are carried out and passed, prior to device use
- allowing for automatic logging and storage of reagent information whilst also ensuring the integrity of reagents used (i.e. ensuring only in-date reagents can be used on the device)
- ensuring all results (patients, IQC, EQA) are appropriately recorded with no loss of data
- ensuring operators are correctly recorded with the required level of detail to allow for traceability
- significantly reducing the amount of time spent per sample with potential cost savings

It is worth mentioning though that the fully automated system relies on active IT links and there were times during the course of this pilot project that results were not transmitting across to the patient electronic records due to IT connection issues. However, the data remained on the analyser and were also permanently stored on the instrument data manager. In addition, the analysers provided result print-outs for immediate patient care therefore no negative impact on patients.

6 Recommendations

Use of the fully automated system will enable the Trust to provide a safer and more efficient POCT urinalysis service than currently, as well as meet relevant accreditation standards. The fully automated method has QC and operator lock-out facilities which can be centrally and remotely managed by the Pathology POCT team to ensure analysers can only be used by competent staff and only when appropriate QC checks have been done. A fully automated system will ensure consistency, standardisation (e.g. of units) and improved level of accuracy (than currently) whilst significantly saving on staff time.

Based on the findings from this study, we would recommend the use of fully automated system over the manual or semi-automated methods. The required IT links for the analysers have been put in place as a result of this pilot project so any new analyser can easily be connected to the hospital information system. There is however a need to test the capability of the established IT links in handling a larger roll-out especially as we have previously identified some issues with data transmission to Cerner.

The implementation of fully automated testing will have capital and ongoing cost implications and this should be considered prior to implementation.

Appendix 1 – Study data (raw data)

Data quality spreadsheet



Data quality ALL.xlsx

Microbiology vs POCT reference results



Micro vs POCT
reference results.xlsx

IQC/EQA/Reagent Audit data



Audit data ALL.xlsx

Cost and efficiency data



Cost & Efficiency
data ALL.xlsx

Appendix 2 – Data Summary



Data summary table
ALL.xlsx

Acknowledgements

- Project sponsor – Patient Safety Translational Research Centre (PSTRC) Imperial College London (part of the National Institute for Health Research [NIHR])
- Patient Safety Challenge Dragon's Den panel of judges – Prof. the Lord Ara Darzi, Yasmin Alibhai-Brown, Martin Bromiley and Shona Maxwell
- Participating clinical areas – staff and responsible managers
- Microbiology Laboratory – staff and responsible managers
- Darragh Murphy – Pharmacy department
- Stephen Snewin – Pathology
- Phil Brown – Pathology
- Charlotte Mustoe – Pathology
- Yehani Wedatilake – Pathology
- Manfred Almeida – Pathology
- Oluwaseun Wete – Pathology
- Ozlem Yasar – Pathology
- Liakim Ladipo – Pathology IT
- Dr Paul Holloway
- Trust Cerner team
- Siemens
- Wales External Quality Assessment Scheme (WEQAS) – EQA provider