Evaluating the impact of ISO 15189 on an Irish histopathology laboratory

Laboratory accreditation is a valuable asset that delivers real results. Here, Linda O'Connor, Alison Malkin and Breffnie Carroll explore the steps one histopathology laboratory in Drogheda took to realise the benefits.

Accreditation is the acknowledgement that the laboratory has reached and maintains a certain standard of quality. Pre-accreditation, quality standards in hospital laboratories were perceived to exist but were undocumented. The difference post-accreditation is having to prove that this standard of quality actually exists and is maintained.

An Irish hospital laboratory is recognised as accredited when an accreditation body such as the Irish National Accreditation Body (INAB) inspects or audits the hospital laboratory and grants it accreditation status. Accreditation status gives the laboratory formal recognition that it is competent to carry out specific tasks. The INAB uses the internationally recognised standard ISO 15189 (Medical Laboratories – Requirements for Quality and Competence) to assess the hospital laboratory.

It is mandatory for blood banks in Ireland to be accredited, because of the requirements of the EU Directive 2002/98/EC, which sets standards of quality and safety for the collection, testing, processing, storage and distribution of blood and blood components.[1] For all other departments in the hospital laboratory, accreditation is voluntary.

ISO 15189 is an international standard that specifies requirements for quality and competence for medical laboratories. ISO 15189 is part of the ISO 9000 group of standards that addresses quality management. According to the International Organization for Standardization,[2] "A standard provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose".

The ISO 15189 Standard provides a framework for the design and improvement of a process-based quality management system (QMS) for hospital laboratories. In order to achieve accreditation status, hospital laboratories were required to modify their system of work and design a QMS to ensure compliance with the ISO 15189 standards. The subsequent modifications to work processes had a significant impact on the hospital laboratories.

In the case of economic businesses, the impact of accreditation would be measurable based on economic value and profit. In the case of public hospital laboratories, the impact of accreditation

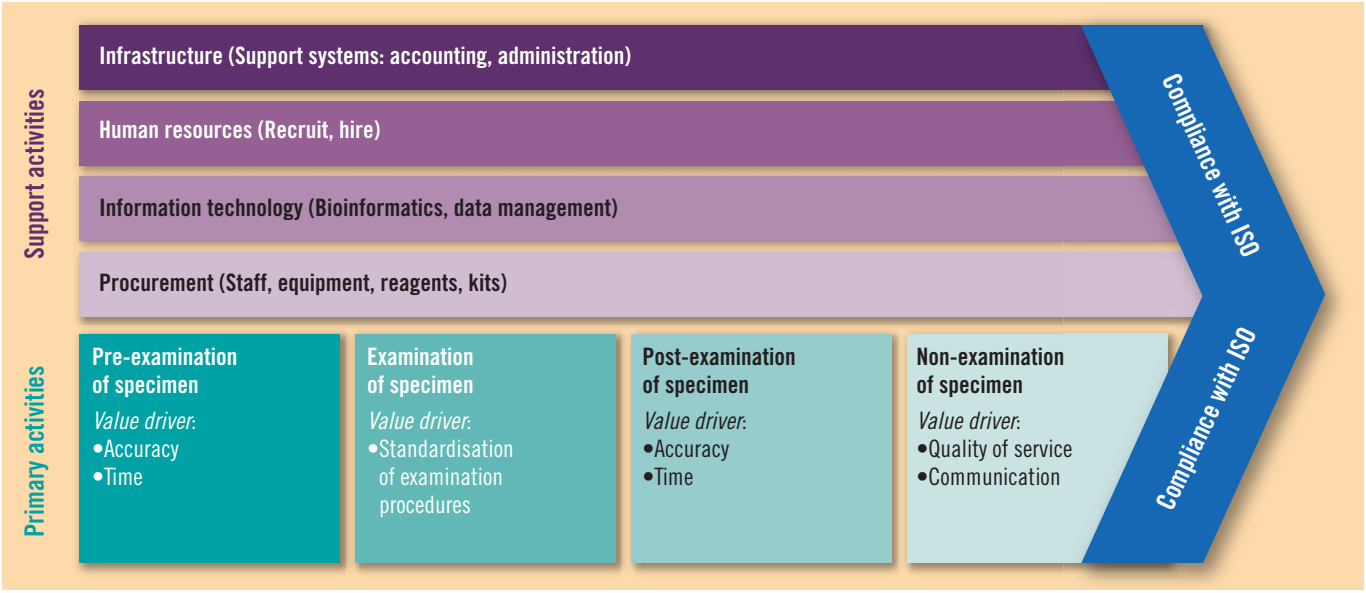

Fig 1. Value chain for the laboratory.

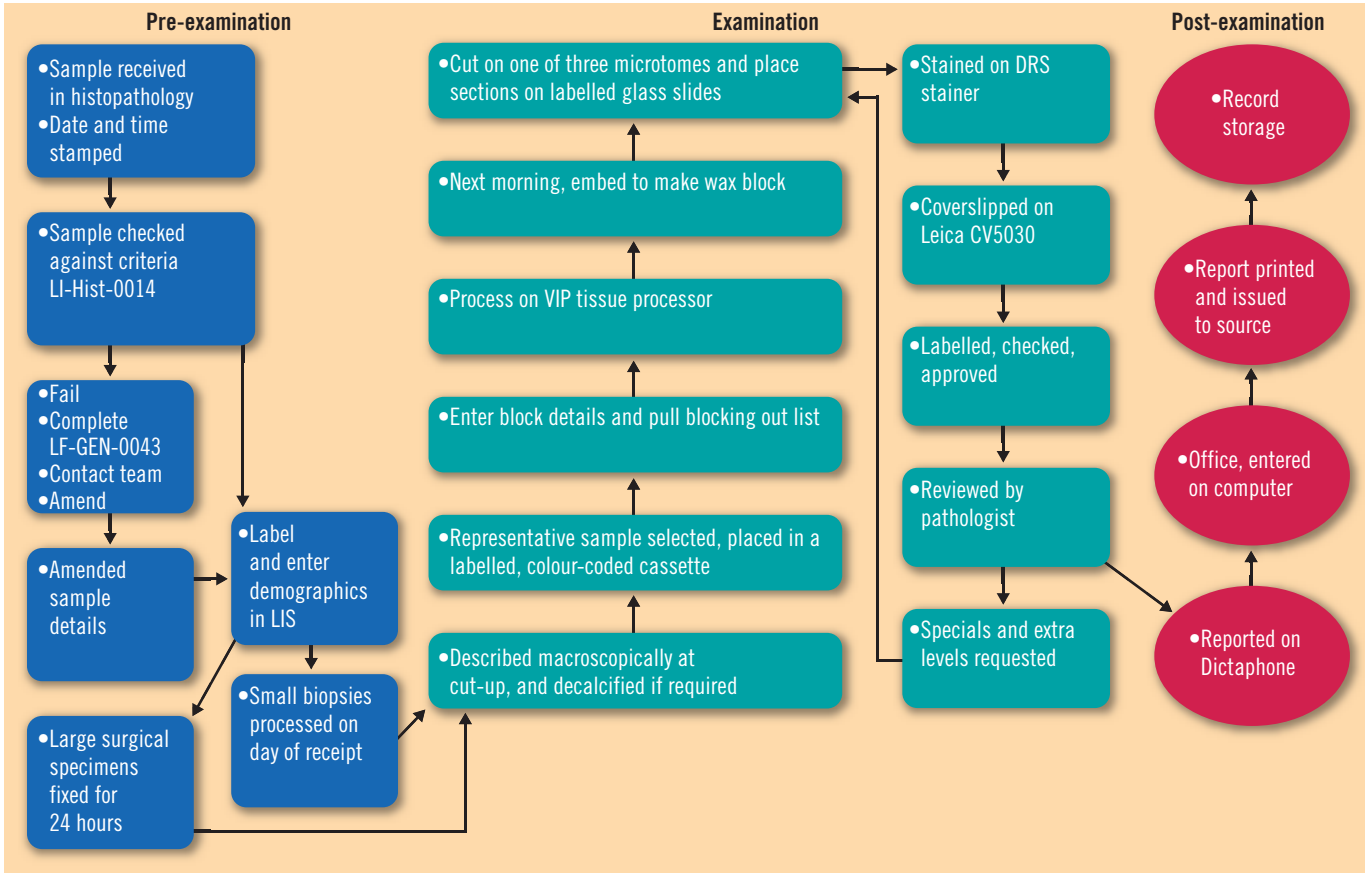

Fig 2. Process flow chart for a formalin-fixed specimen.

cannot be measured on these factors, as the laboratory and the hospital are not-for-profit. To date, there are limited published data on the impact of ISO 15189 on hospital laboratories. Even the ISO Methodology 2013 states that "The preliminary analysis dedicated to hospitals did not allow to complete the assessment and to quantify the benefits of standards for one or more institute".

This study proposes a new model/method applicable to a hospital laboratory setting to assess the impact of ISO 15189 on hospital laboratories using non-economic markers.[2]

Methodology

According to the ISO Methodology[3] there is a four-step approach which can be used to assess the impact of any standard. The four steps are:

- Understand the value chain.
- Identify the impact of the standards.
- Analyse the value drivers and determine operational indicators.
- Assess the impacts and calculate the results.

For the purpose of this study, a modification of this method will be used instead. The amended method is more suited to a hospital laboratory:

- Analyse the value chain.
- Determine the value drivers.
- Define the key performance indicators.
- Collect information and measure the impact.

Analyse the value chain

A value chain is a sequence of activities that is required to generate a product. It works by breaking down the system of work into strategically relevant pieces, so that value drivers and performance indicators can be visualised.[4] In laboratory terms, a value chain is the sequence of activities required to obtain a result for any specimen. It can be divided into primary activities and support activities.

Primary activities make up the process flow. They are the steps that bring the process from input to output. For the laboratory, primary activities can be broken down into pre-examination, examination, post-examination and non-examination stages. Secondary activities are those that support the primary function and include human resources, administration, and information technology (Fig 1).

Using the four primary activities in the value chain, a detailed process flow chart was compiled for the throughput of a specimen through the laboratory (Fig 2) This was used to examine each of the primary activities in detail in order to select the value drivers.

Determine the value drivers

Once the process flow for the laboratory had been defined, the value drivers could be determined. Value drivers are variables that create value. For economic businesses, value drivers are aspects of the company that increase the value of the product and give the company a competitive advantage.[5] For the laboratory, the value drivers are non-economic and more difficult to define. They can be defined as aspects of the laboratory that increase the value of the service.

The value drivers were chosen by performing a risk assessment for each stage of the process flow and determining what aspects of the process increased the value of the laboratory. The overall value driver is compliance with ISO 15189, as this is the all-embracing value driver that increases the value of the service and assures the clinicians that the laboratory provides a high quality of service.

Value drivers for the pre-examination process

For the pre-examination process, the factors that would cause the process to fail and were most relevant to the value of the laboratory were:

Instructions for the transport of the specimen to the laboratory. From the risk assessment of the pre-examination process for histopathology specimens, if specimens were damaged or lost on the way to the laboratory they could not be replaced. For fresh samples, if there was a delay the sample would deteriorate and would not be suitable for analysis. For these reasons accuracy in transport details and timeliness of delivery were the value drivers selected for this stage of the process.

The laboratory criteria for specimen acceptance. Looking at the risk assessment, if the laboratory accepted a specimen that was labelled incorrectly or had insufficient details to confirm the identity of the patient, and resulted in a patient getting the wrong

result, the process would fail. For this reason, accuracy was the most relevant value driver.

Instructions for pre-examination storage. From the risk assessment, if the specimen was stored incorrectly or was stored as a fresh specimen for a long period of time, it would be rendered unsuitable for processing and the process would fail. Accuracy in defining the storage conditions and the timeliness of storage were the relevant value drivers.

For the pre-examination process, accuracy and time efficacy were the value drivers that were selected.

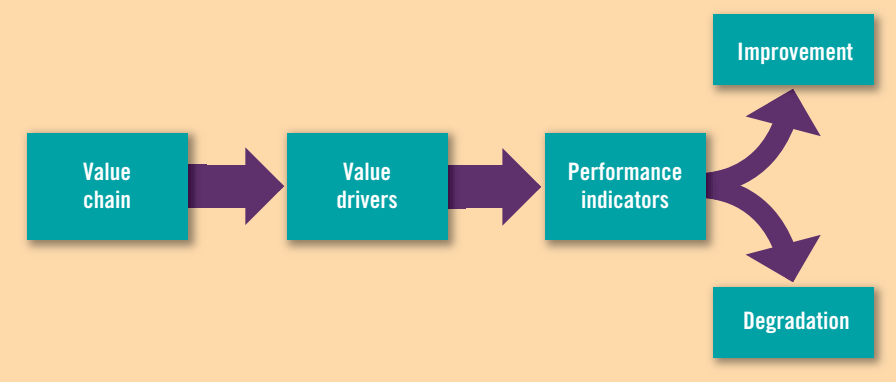

Fig 3. Assessing the impact.

Value drivers for the examination process

From a risk assessment of the examination process, the factors that would cause the process to fail and were most relevant to the value of the laboratory were:

Verification of examination procedures. This is the assurance that all test procedures are implemented correctly and produce accurate, reproducible results. It is the assurance to clinicians that the methods used to obtain the results are precise and accurate. From the risk assessment undertaken in the laboratory, if the verification of a procedure in the examination process failed, the results would be incorrect.

An example is Highman's Congo Red procedure for staining amyloid in formalin-fixed tissue.6 If the procedure was incorrect the amyloid would not stain or would stain with variable intensity. If there was no standardised procedure defined for this stain in the laboratory, the result would be variable staining intensity for amyloid.

The QMS ensures that each method has a defined, documented, standardised procedure that produces accurate results. In the case of the amyloid staining, having a standardised procedure ensures that no matter who performs the stain, the results are always the same. For this reason, the standardisation of examination procedure was selected as a value driver.

Validation of examination procedures. This is the assurance that the correct procedures are available to obtain the results for the diagnosis. Validation of test procedures ensures that the clinicians' needs are met. An example of this is the availability of antibodies for immunocytochemistry (ICC). If the clinician is investigating a lymphoma, the relevant antibodies must be available for ICC analysis in the laboratory to confirm the diagnosis. If these antibodies were not available, the diagnosis would not be possible. The clinicians must be assured that a standardised process flow is in place for the diagnosis of each disease process. Based on validation and verification, and their importance in the examination process, the value driver selected for this examination process was standardisation.

Value drivers for the post-examination process

Looking at a risk assessment for the post-examination process, all of the risks involved accuracy and timing. The factors that would cause the process to fail and were most relevant to the value of the laboratory were:

The procedure for the reporting of results. This stage of the process involves the medical secretaries transferring the report from the Dictaphone to the computer, and the pathologist reviewing the report and authorising it. The report must then reach the correct destination. Accuracy is imperative at this stage as an error could result in misdiagnosis. The report could also be sent to the wrong clinician. Timeliness is also relevant as the amount of time that the result awaits transcription and authorisation will ultimately affect turnaround time. The value drivers selected for this process were accuracy and time efficacy.

The details for the storage, retention and disposal of specimens. This stage of the process is just as important as the other stages as the specimen must be traceable at all times. This would be extremely relevant if the pathologist needed to re-look at the specimen. There is a procedure in place to ensure that all specimens are retained for a minimum of four weeks or until the final report is issued. The location description must be precise and accurate to prevent the untimely disposal of the specimen. The specimen must also be disposed of appropriately. The QMS ensures that disposal procedures are defined. For these reasons, the value drivers for this stage are accuracy and time efficacy.

Value drivers for the non-examination process

The non-examination process involves a review of the quality of the service. This process strives to ensure that the laboratory meets the clinicians' needs and maintains a high standard of quality. This is achieved in a number of ways.

The first method used to assess the quality of service is the review of internal quality control (IQC) and external quality assessment (EQA) results and the communication of these results to all relevant members of staff. This is most relevant in the case of a fail for either of these results. A procedure should be in place to decide on a corrective and a preventative action to prevent any further failures.

The second method used to assess the quality of service is auditing. A schedule of audits is drawn up annually to ensure that the laboratory maintains compliance with the requirements of ISO 15189. Throughout the year staff undertake the audits and meet on a regular basis to discuss the results and continually improve all processes.

The third method used to assess the quality of the service is the use of user satisfaction surveys to ensure that the laboratory meets the clinicians' needs.

Based on these factors, the value drivers that were selected to represent the non-examination process were quality of service and communication.

Define the key performance indicators

Performance indicators are measureable variables that demonstrate either an improvement or a deterioration in the performance of the laboratory. They are based on the value drivers described above. Performance indicators are the means by which the impact of a standard can be determined (Fig 3).

For the histopathology laboratory, there were two aspects of performance to consider. The first was patient services. Had the implementation of ISO 15189 had any impact on the patient services? The second was the laboratory itself. Had the implementation of ISO 15189 had any impact on the running of the laboratory?

Performance indicators needed to be selected to answer both of these questions. The value drivers were divided into two sections; those that could be used to assess the impact on patient services and those value drivers that could be used to assess laboratory procedures.

Looking back at the selection of the value drivers, those that related to patient services were time efficacy, accuracy and quality of service. The value drivers that related to the laboratory procedures were standardisation, communication and the ISO 15189 standard itself. Performance indicators now had to be selected from the value drivers.

Time efficacy

A performance indicator had to be selected that would enable time efficacy to be reviewed as a value driver. It was decided to use turnaround time (TAT) as the performance indicator. By comparing

Table 1. Performance indicators and their measurement method.

Value driver	Area of impact	Performance indicator	Measurement method	Result type
Time	Patient services	Turnaround time	Pre-accreditation vs. post-accreditation	Quantitative
Accuracy	Patient services	External quality assessment	Pre-accreditation vs. post-accreditation	Quantitative
Quality of service	Patient services	Clinician user satisfaction survey	Survey results, pre-accreditation vs. post-accreditation	Mixed method
Standardisation	Histopathology laboratory	Quality management system	Ethnography	Qualitative
Communication	Histopathology laboratory	Staff survey	Survey results	Mixed method
ISO 15189 standard	Patient services and histopathology laboratory	ISO 15189 implementation	Focus interview	Qualitative

TATs before and after the implementation of ISO 15189, it was possible to evaluate whether ISO 15189 had a positive or a negative effect on the timeliness of reporting and ultimately on patient services. This comparison would involve quantitative analysis.

Accuracy

The performance indicator selected to enable accuracy to be reviewed as a value driver was EQA results. By comparing these results pre- and post-accreditation, it was possible to evaluate the impact of ISO 15189 on the accuracy of the results and therefore on patient services. This comparison would involve quantitative analysis.

Quality of service

A performance indicator had to be selected to enable a review of the quality of the service. The best way to review this was to ask the service users if they were satisfied with the service they received from the laboratory. A user satisfaction survey was used for this purpose to assess the clinician satisfaction.

A clinician survey had been undertaken pre-accreditation and the same survey was distributed post-accreditation. A comparison between the two sets of results could be undertaken. The survey allowed the clinicians to submit comments also and these could also be reviewed. Using the survey as a performance indicator allowed a quantitative comparison of the results pre- and post-accreditation but also a qualitative comparison of the comments. This method of research was therefore regarded as mixed method.

Standardisation

The performance indicator selected to review standardisation as a value driver was the QMS because it could demonstrate the effectiveness of the standardisation of procedures on the laboratory. A pre- and post-accreditation comparison was not possible for this performance indicator because the QMS was created as a result of accreditation. In this case the research method of choice was ethnography. The researcher was the quality coordinator in the histopathology department and was involved in the compilation of the QMS and was therefore in a position to assess the efficacy of the QMS as a performance indicator.

Communication

A performance indicator had to be selected to assess communication as a value driver. The area of impact of this value driver was the laboratory. A staff survey was used as the performance indicator to assess staff opinion on the impact of ISO 15189 on the laboratory with regard to communication. The survey questions were carefully selected to obtain staff opinions on the impact of ISO 15189 on the laboratory and the way in which the standard had affected their work. The method of research employed was mixed method as the survey allowed staff to submit comments as well as yes/no answers.

ISO 15189 standard

Using ISO 15189 as a value driver meant that the best performance indicator that could be used to assess the impact of the standard on the laboratory was the actual implementation of the standard. A method had to be defined that would assess the impact of the implementation of the standard on the laboratory. A pre- and post-accreditation comparison was not suitable and the survey had already been used for the assessment of communication as a value driver.

What would really be relevant to assess the performance indicator was staff opinion on the implementation, but not as a survey because this would be too limiting. It was decided to use a focus group interview as the method of measurement as this would allow staff to articulate freely about the impact of the implementation of ISO 15189 on the department.

The impact of implementing the standard could then be evaluated by studying the selected performance indicators. Table 1 illustrates the performance indicators and their measurement method.

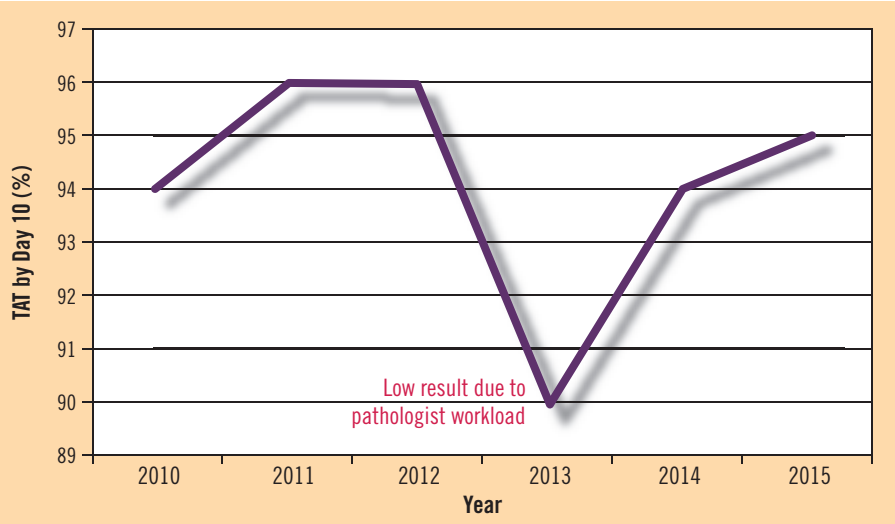

Fig 4. Turnaround time pre- to post-accreditation.

Results

Using the various research methods above, each performance indicator was assessed to evaluate their impact of the implementation of ISO 15189 on the histopathology laboratory.

Turnaround time

The TATs were reviewed from 2010 to 2015 (one-year pre-accreditation and four years' post-accreditation) to see if there had been an improvement since the implementation of ISO 15189. Figure 4 shows that the implementation of ISO 15189 had no obvious impact on TATs.

Pre-accreditation, a monthly TAT report was generated. A copy was given to each pathologist but there was no plan or record of actions taken for long TATs.

Post-accreditation, a review of TATs is performed every month and is included in the quality meetings to ensure that there is an attempt to keep 100% of the TATs below 10 days. In the case where a TAT exceeds 10 days a non-conformance is opened and the corrective action, root cause analysis and preventive action are discussed.

Accreditation has therefore changed the way the histopathology laboratory reviews and acts on extended TATs.

External quality assessment results

All UK NEQAS EQA results were reviewed for the years 2011–2015 to see if there was an improvement in the scores as a result of the implementation of ISO 15189. The purpose of this was to compare the results pre- and post-accreditation. The outcome was that the high standard of staining had not changed as a result of the implementation of ISO 15189.

Pre-accreditation, if one of the slides scored low (≤5/10 or ≤10/20), the slides would be reviewed, the comments would be discussed informally and the in-house controls would be monitored to ensure they were satisfactory. There was no formal procedure for the investigation of a low score, and borderline scores of 5/10 or 10/20 were not investigated.

Post-accreditation, there is a formal, standardised procedure for recording EQA results. This report is brought to the monthly quality meetings. The results are discussed and the review form is completed. This ensures that any issues that have arisen are inclusive, transparent and are discussed as a team to find a solution.

In the histopathology department, the implementation of ISO 15189 had a significant impact on the way EQA is handled.

Clinician user satisfaction survey

The clinician user satisfaction survey was a useful and informative performance indicator. The comparison between the pre- and post-accreditation surveys showed that clinicians saw the implementation of ISO 15189 as a positive move. The survey gave the clinicians the opportunity to voice their suggestions for improvements to the quality of service.

Quality management system

Pre-accreditation there was no formal QMS. For this reason, a pre- and post-accreditation comparison was not possible for this performance indicator because the department has gone from having no documented QMS to a well-defined one. Pre-accreditation, all tasks were carried out by the staff under the supervision of the chief medical scientist. Post-accreditation, a QMS was designed to ensure standardisation of all procedures and ensure traceability and transparency for all procedures. It is the comparison of the standardisation pre- and post-accreditation that makes the QMS a relevant performance indicator.

Taking an ethnographic view of the QMS, there are five main benefits:

Organisational effectiveness: The laboratory now has an improved organisational effectiveness. There are established objectives. The laboratory communicates the objectives and performance relative to these objectives (as well as action plans to close gaps) and the result is that the laboratory becomes more effective. This effectiveness is now measureable using audits and feedback.

User satisfaction: Having a defined QMS assures service users that high standards are maintained. These users are encouraged to feed back into the system using the many open lines of communication such as surveys and meetings.

Compliance with ISO 15189 is improved: The QMS is based on the ISO 9000 Standard and compliance with ISO 15189 is integrated into the QMS. This facilitates the fulfilment of the requirements of the standard and makes inspection less challenging.

Improvement of laboratory culture: The standardisation of system processes gives employees confidence in their work. They know that they are working with procedures that will be the same today,

tomorrow, next week and next month. This promotes a positive work atmosphere.

Improved documentation: The QMS ensures that documentation is standardised, audited and reviewed.

There are four main disadvantages to the introduction of a QMS:

Cost: The detailed breakdown of the cost involved in the introduction of the QMS and the implementation of ISO 15189 is beyond the scope of this paper but there are two types of cost to consider: i) initial set-up cost – for the histopathology department, implementation of ISO 15189 resulted in a complete renovation of the laboratory because the environment was deemed unsuitable by INAB; and ii) ongoing cost – in order to maintain the QMS and comply with ISO 15189, there are many ongoing annual costs such as regular servicing of equipment, replacement of faulty equipment, temperature mapping of equipment, calibration of pipettes, replacement of expired reagents, stains and antibodies, registration fees for the EQA schemes, and INAB inspection fees.

Extensive training: At the outset of accreditation, there was extensive training required for all staff involved in the QMS. This included training on the QMS, the use of Q-Pulse, auditing and risk assessments. This resulted in pressure on staff to maintain TATs while learning about the new system of work.

Employee resistance: The introduction of the QMS required all staff to have a change in attitude to the method of the system of work. Some staff members were fearful of the changes and constant communication was necessary to maintain a positive work ethos.

Disruption of work processes: It was noted that there was a disruption in work processes while ISO 15189 was being implemented. This disruption is also noticeable in the weeks surrounding an INAB inspection every year.

Review of the QMS as a performance indicator

Looking at the QMS as a performance indicator, it has had an overall positive impact on the histopathology laboratory because it has resulted in a standardisation of procedures which is one of the value drivers for the department.

Staff survey

In January 2016, a user feedback survey was compiled and distributed to all histopathology staff. This was conducted to obtain feedback from staff on their views on the implementation of ISO 15189. The survey was distributed to the nine histopathology staff members and the closing date was one week from distribution. The survey gave an insight into staff views on the impact of the implementation of ISO 15189 (Fig 5). The survey showed that 100% of the staff saw the implementation of ISO 15189 as a positive step. It also indicated that 40% of staff members felt that they needed more training in some aspects of the QMS and accreditation. This was to be expected as the department has only been accredited for four full years. As a result of this survey, extra training has been added to the continual improvement schedule for staff.

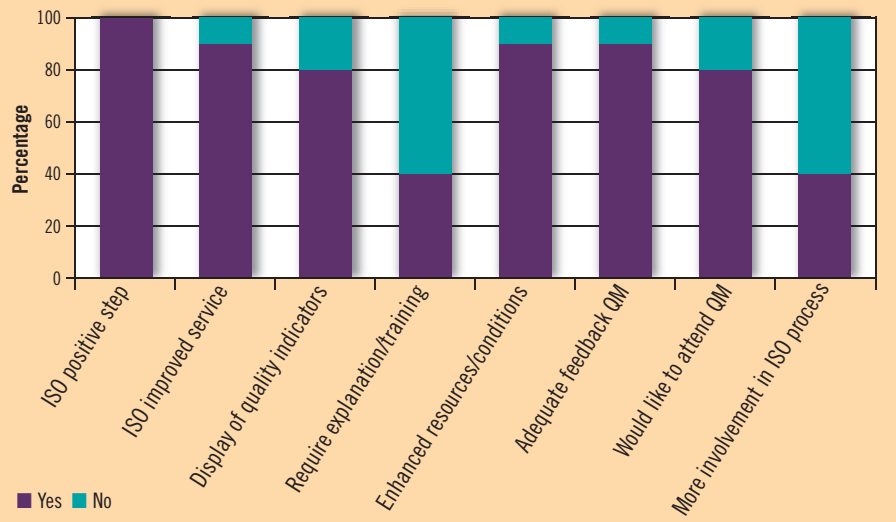

Fig 5. Histopathology staff survey results.

ISO 15189 implementation

Initially, the choice of the ISO 15189 implementation as a performance indicator seemed questionable because it was difficult to define a measurement method. When it was decided to use the focus group interview as the choice of method, it became apparent that it was the ideal method because it voiced the opinions of the staff undertaking the implementation of the standard. From the focus group interview it was obvious that staff saw the implementation of the standard as a positive step. The negative issues that arose could easily be addressed over the next few years and mainly involve converting from paper records to electronic ones. This would eliminate the 'double-jobbing' that staff described. The choice of internal audits should also be reviewed on a regular basis to ensure that they are informative, relative and contribute to the continual improvement of the QMS. Results from the focus group interview indicated that the overall impact of the implementation of ISO 15189 was a positive one.

Discussion and conclusions

The aim of this study was to develop a method to evaluate the impact of the ISO 15189 standard on an Irish public hospital histopathology laboratory. Using a modification of the ISO Methodology method,[3] a laboratory value chain was defined, a process flow was created and, from this, value drivers were determined. Based on the value drivers, a set of six performance indicators were selected. Using these performance indicators, various research methods could be employed to evaluate the impact of the implementation of the standards on any public hospital laboratory.

The six performance indicators showed that ISO 15189 had, overall, a positive impact on the laboratory. Staff were impressed with the standardisation of methods, the traceability of work and the transparency of non-conformances. The most interesting observations from this project were that there were no improvements in either TAT or EQA as a result of the implementation of ISO 15189. From the focus group review and the ethnographic analysis, the negative impacts were the paper trails and the inspections. These negatives should be used as constructive ways to move forward.

Compliance with ISO 15189 is an ongoing necessary expense but should be regarded as a valuable asset that delivers real results. To go back to a time pre-accreditation where there was no process standardisation would be unthinkable.

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