

HISTOPATHOLOGY IN NEW SOUTH WALES

A Business Improvement Strategy

May 2011



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Executive Summary

Histopathology services play a vital part in cancer diagnosis for the majority of tumour streams. Fast, accurate histopathology is crucial in finding cancer early, diagnosing it correctly, and choosing and monitoring the best treatment for each patient.

In New South Wales (NSW) and across Australia, there is a growing shortage of tissue pathologists. This shortage is placing histopathology departments under pressure.

In response to concern from the *Royal College of Pathologists of Australasia (RCPA)* about the shortage of tissue pathologists, the Cancer Institute NSW investigated whether process improvements could be made in order to relieve pressure on histopathology services.

The first step in this project was to engage an external consultant, *Amica Consulting Pty Ltd*, to conduct a pilot project at a public metropolitan histopathology department.

This pilot project identified opportunities to reduce turnaround times – the time taken between the collection of a specimen and reporting of results - even though core processes were consistent with best practice.

Building on the outcomes of the pilot, the consultants were then engaged to undertake a validation project, with three components:

- **Diagnostic analysis:** repeating the pilot at a regional public histopathology laboratory and to develop processes and methods applicable to all laboratories;
- **Process improvement:** implementing the program of improvements at the public metropolitan histopathology laboratory that had been identified during the pilot; and
- **Management operating system:** developing a management operating system for potential deployment to other laboratories across NSW.

During the project, quantitative data was collected and analysed to establish a baseline performance from both sites. Staff members at each facility were also actively involved in mapping laboratory processes and identifying opportunities for improvement.

In the validation phase, suggested solutions were tested and the management operating system was implemented and changes in performance were monitored.

Key Findings

The key findings of the pilot project were:

- **A strong case for change:** Even though core processes were consistent with best practice and turnaround times matched those of similar Australian public laboratories, there are still opportunities to reduce turnaround times;

The key improvement opportunities were:

- **Reducing the proportion of cases missing cut-off times for the next process step**
- **Accelerating the progress of medium-sized samples**

There were few mechanisms to actively manage turnaround, meaning that the scope to manage the progress of a case through the laboratory was limited.

The key findings and outcomes of the validation project were:

- **Similar opportunities identified:** The diagnostic analysis at the regional public laboratory (where core processes were again consistent with best practice) identified similar opportunities to the metropolitan facility to reduce turnaround times by streamlining process steps for cases.
- **Streamlining workflow:** The process improvement program at the public metropolitan laboratory streamlined workflow by minimising interruptions, improving use of space, rationalising code structure and reducing opportunities for error.
- **New guidelines trialed:** The process improvement program established agreed turnaround time guidelines for all categories of histopathology samples and implemented a number of changes that will enable immediate gains to be made.
- **Better systems management:** The development of a management operating system enabled the flow of cases through the laboratory to be better monitored and provided generic formats for the use of KPIs.

Applicability of findings to other pathology services

Pathology services in Australia are provided by both the public and private sectors. Public laboratories are based in public hospitals. Private laboratories are predominantly community based, carrying out tests at the request of GPs, private hospitals, contracted arrangements with some public hospitals and community-based specialists.

Whether privately or publicly owned, most histopathology services are located in large centralised laboratories in capital cities. These laboratories are commonly associated with a network of smaller regional laboratories, often located within hospitals (public and private) or satellite laboratories.

The project methodology and generic solutions developed during this project are likely to be applicable in similar public laboratories statewide.

However, the following challenges will influence future rollout initiatives beyond the project sites:

- **Centralised reporting:** The network structure of pathology services in NSW limits the scope for centralised reporting. Each pathology service tends to use methods that best suit them locally.
- **Consistent information:** Partial privatisation of pathology services in NSW has resulted in the lack of uniformity of information systems.
- **Consistent data:** The lack of common procurement systems makes it difficult to standardise data, information and operating systems.
- **Customer requirements:** Pathology services are also driven by customer requirements, resulting in a diverse reporting environment.

This report describes the findings and outcomes of the pilot and validation projects.

Introduction and Background

Histopathology services provide a vital part of cancer diagnosis for the majority of tumour streams. Fast, accurate histopathology is crucial in finding cancer early, diagnosing it correctly, and choosing and monitoring the best treatment for each patient.

Histopathology is the microscopic examination of tissue to make a specific diagnosis of disease or monitor therapeutic progress. The process involves many steps and requires close attention to scientific, technical and administrative detail. It is a critical part of the cancer patient's journey; each specimen belongs to a person waiting for cancer diagnosis or staging. Therefore both speed and accuracy are critical.

Histopathology laboratories are under growing pressure due to a shortage of tissue pathologists in NSW and across Australia. The resulting pressure on workload is likely to become more pronounced as cancer incidence rises and changing technology and more complex diagnostic pathways lead to increased reviews. This will make it increasingly difficult to provide efficient services on a finite budget, especially in rural areas.

The factors driving the increasing demand for pathology services include:¹

- Greater cancer prevalence with increased longevity,
- Higher emphasis on evidence-based medicine that depends on pathology for decision making,
- Increased use of pathology testing for eligibility for subsidised drug therapy and monitoring,
- Increased consumer expectation that testing is part of diagnosis and treatment.

The RCPA has raised concerns about the shortage of tissue pathologists through various government channels, including the Cancer Institute NSW Pathology New South Wales Oncology Group (NSWOG). While the remit of the Cancer Institute NSW does not include the determination of pathology training positions in NSW, initiatives focusing on process improvement and redesign in pathology services are possible. As a result, the Cancer Institute NSW has explored opportunities for process improvement that might relieve pressure on histopathology services.

Pathology services are generally familiar with the culture and methodology of process redesign as competitive pressure over the past 10 years has encouraged many laboratories to explore and implement business improvement strategies.

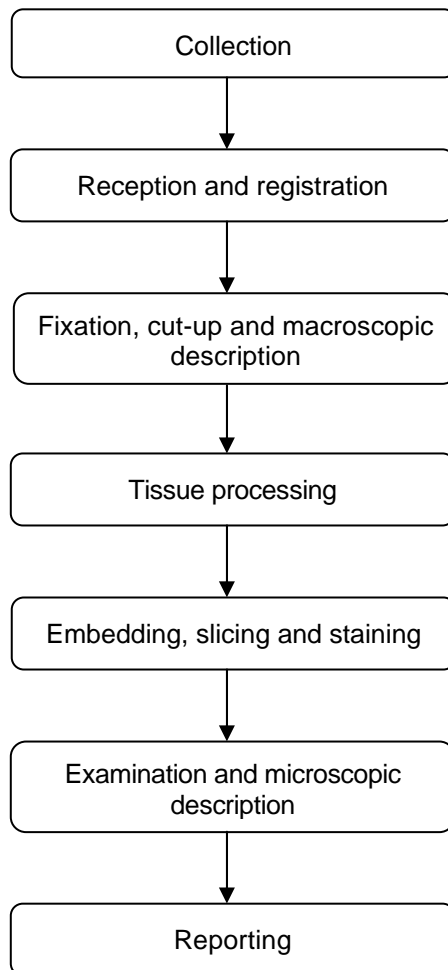
The Histopathology Process

The main steps of the histopathology process are as follows (see also Figure 1):

- **Collection:** the specimen (a piece of tissue, such as a biopsy) is collected from the patient, placed in a container and sent to the laboratory (or picked up by laboratory staff) with a request form.
- **Reception and registration:** the specimen is received in the laboratory and registered in the laboratory's information system, along with an identification number and clinical details.
- **Fixation, cut-up and macroscopic description:** The specimen is fixed in a chemical such as formalin to prevent degradation, and cut into samples for processing. A description of the macroscopic appearance is dictated. Samples are put into cassettes bearing the case identification number. (A 'case' consists of all samples from the same patient.)
- **Tissue processing:** The cassettes are put into a machine that treats the tissue to gradually remove the water and replace it with paraffin. Processing may be done overnight.

- **Embedding, slicing and staining:** The tissue sample is taken from the cassette and embedded into extra paraffin to create a 'block'. It is cut into very thin slices then placed on glass slides. Staining makes cell structures visible under the microscope.
- **Examination and microscopic description:** A pathologist looks at the slides under a microscope and may request additional slides or tests. The microscopic description is dictated.
- **Reporting:** The pathologist's report presents the histological findings and diagnosis. The pathologist dictates the report, a laboratory assistant transcribes it, the pathologist reviews and signs off, and the report is sent to the requester by email, fax or post.

Figure 1: The Histopathology Process



Histopathology departments in NSW do not use a single information system. The most commonly used systems are *Auslab* and *PathNet*. *Auslab* is used in the two laboratories which participated in this project.

The Project Approach (Methodology)

The *Smarter Models of Care Program* under the NSW Cancer Plan 2007–2010 aimed to examine and redesign key models of clinical service provision in cancer care. A major element of this program was the Business Improvement Strategy (BIS), which worked with cancer service staff at all levels to analyse operational processes and then embed and sustain improvement.

A business improvement strategy in healthcare looks at the processes that underpin the delivery of clinical care, rather than clinical practice itself.² Many processes in healthcare have developed organically. Staff and managers are not generally able to devote time, attention or money to thinking about the way things are organised, meaning that even in well-performing facilities there may be opportunities for improvement. The BIS approach aims to identify and minimise delays, unnecessary steps and potential for error.³

The Radiotherapy Business Improvement Strategy (RTBIS), (2006-2009), was the first project in the BIS stream. It achieved measurable improvements in waiting times and treatment capacity across NSW. By the end of the project, all participating centres demonstrated a measurable and theoretically sustainable increase in capacity of 16 per cent across all units. Where they existed, waiting lists were reduced in most centres. A set of packaged electronic business tools was also developed as a result of this project to assist units to address real time mandatory reporting, management of key performance indicators, treatment capacity and rostering.⁴

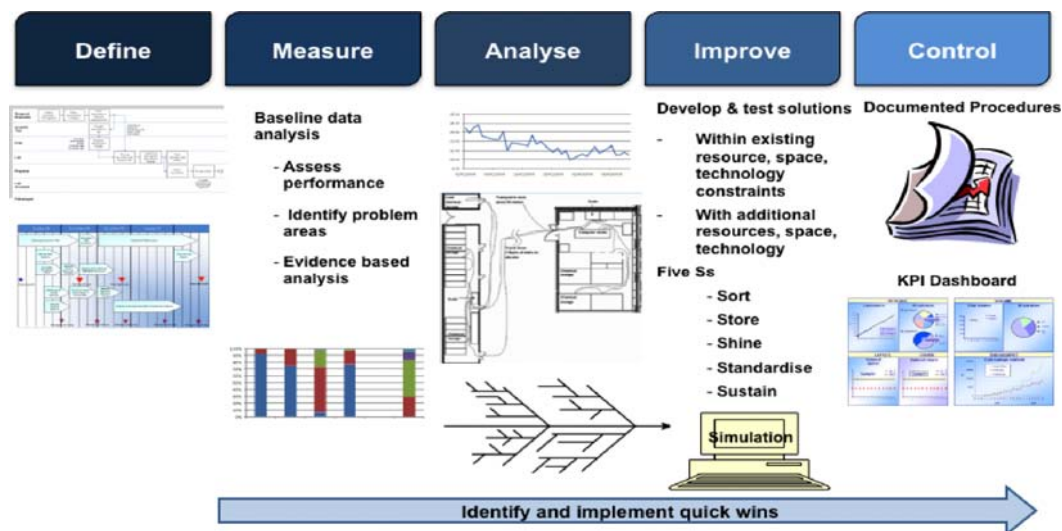
The Histopathology Business Improvement Strategy (HPBIS) represents the next stage in the Cancer Institute BIS program, employing a similar methodology to the RTBIS.

The project investigated whether business processes in histopathology departments can be fine-tuned to enable more efficient and effective passage of specimens.

The Cancer Institute NSW BIS generic approach involves five stages, as shown in Figure 2:⁴

- **Define:** Agree on opportunities to be addressed.
- **Measure:** Set improvement targets. What data are available today? What additional data are needed?
- **Analyse:** Analyse and evaluate the data. Decide improvement requirements.
- **Improve:** Prioritise improvement opportunities. Generate action plans for most improvement opportunities.
- **Control:** Implement improvement plans. Monitor to ensure benefits are locked in.

Figure 2: The five stages of the BIS approach



To begin the project, a pilot project was carried out at a single metropolitan public histopathology laboratory⁵ within a pathology network in NSW.

Based on the outcomes of the pilot project, an external consultant, *Amica Consulting Pty Ltd* was then engaged to undertake a validation project at the same site and at a histopathology laboratory of a similar size in a regional setting within the same pathology network.⁶

A steering group was established with representatives from Cancer Institute NSW, the pathology network and *Amica* to complete this validation project.

The outcomes from each project component are as follows:

- Establishment of a broad baseline position,
- Mapping of the current processes and workflows using process mapping,
- Engagement of unit staff in critiquing the current processes,
- Identification of key issues to solve,
- Validation of solutions,
- Development of a Management Operating System to assist in operational performance management.

Results and Discussion

The pilot and validation projects of the HPBIS included several project components (see Figure 3) with associated objectives. This section reports on the results from each component.

Figure 3: HPBIS-Pilot and Validation project components

HPBIS Project Components		Objectives
Pilot Project		To identify and quantify the scope for improvement; quantify the benefits that could be expected; describe the high-level changes required in processes, workflow and systems; consider the impact of potential newer technologies; secure the agreement of participants to the changes required and prepare a high-level business case for implementation.
Validation Project	Diagnostic analysis	To repeat the pilot process at a public regional histopathology department of similar size to that of the metropolitan site to develop further processes and methods potentially applicable to other NSW laboratories.
	Process improvement	To implement the program of improvements identified in the pilot project at the public metropolitan histopathology laboratory.
	Management operating system	To develop and test a potentially transferable management operating system for wider deployment across NSW, including a common set of key performance indicators (KPIs).

Pilot Project

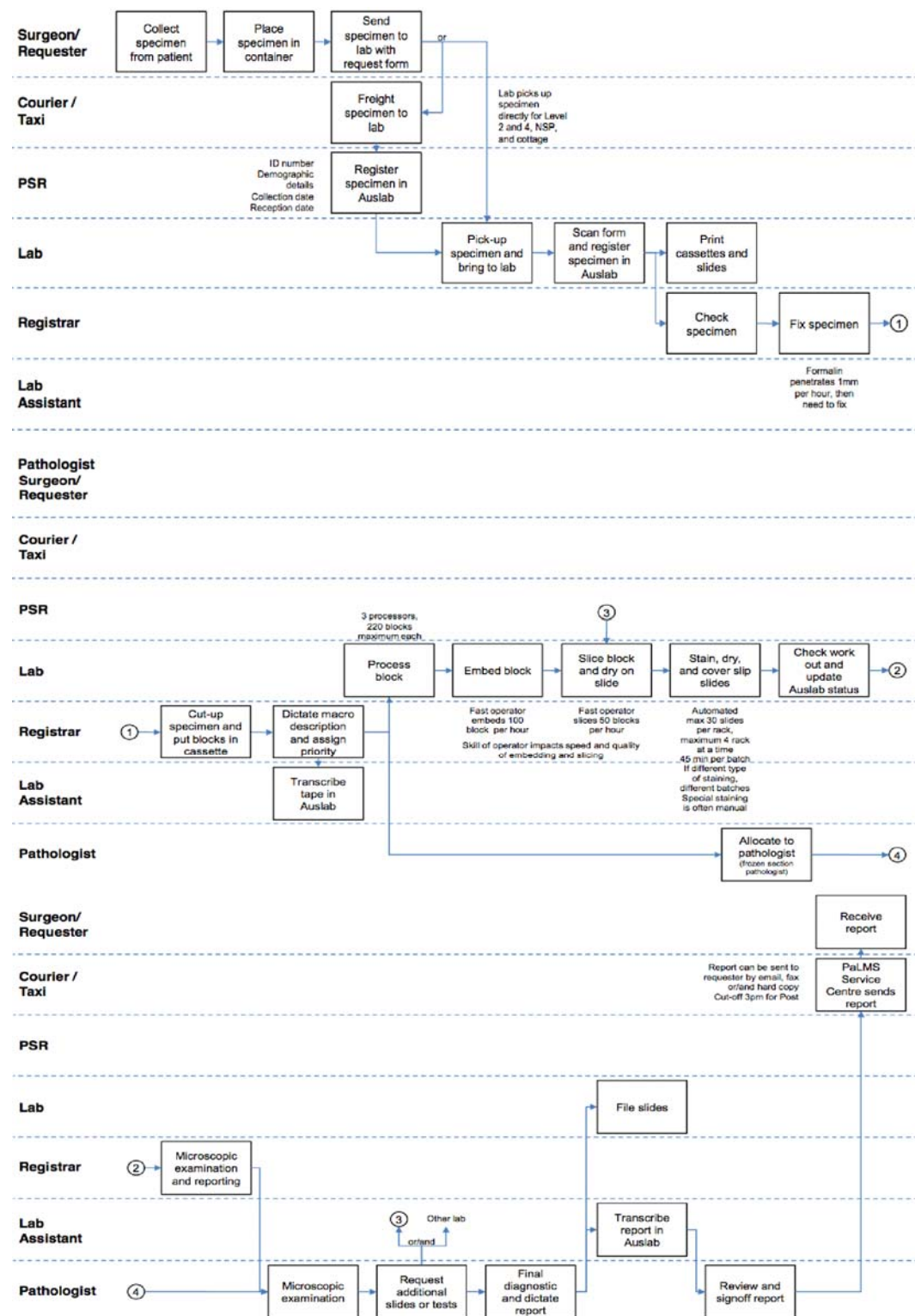
The pilot project was carried out at a single public metropolitan histopathology laboratory, between March and May 2009.

Initially, a broad baseline position was reached by briefing and consulting all staff that would be involved, key stakeholders and department heads. Following this consultation, the project team worked with the staff to map current processes and workflows.

Process mapping is a visual tool for understanding workflows end-to-end. A 'swim-lane' style of process map was used, with individual roles listed down the left hand side of the map in 'lanes' stretching horizontally across the map (see Figure 4).

The resulting process maps recorded process steps from the time a specimen is collected until the result is reported.

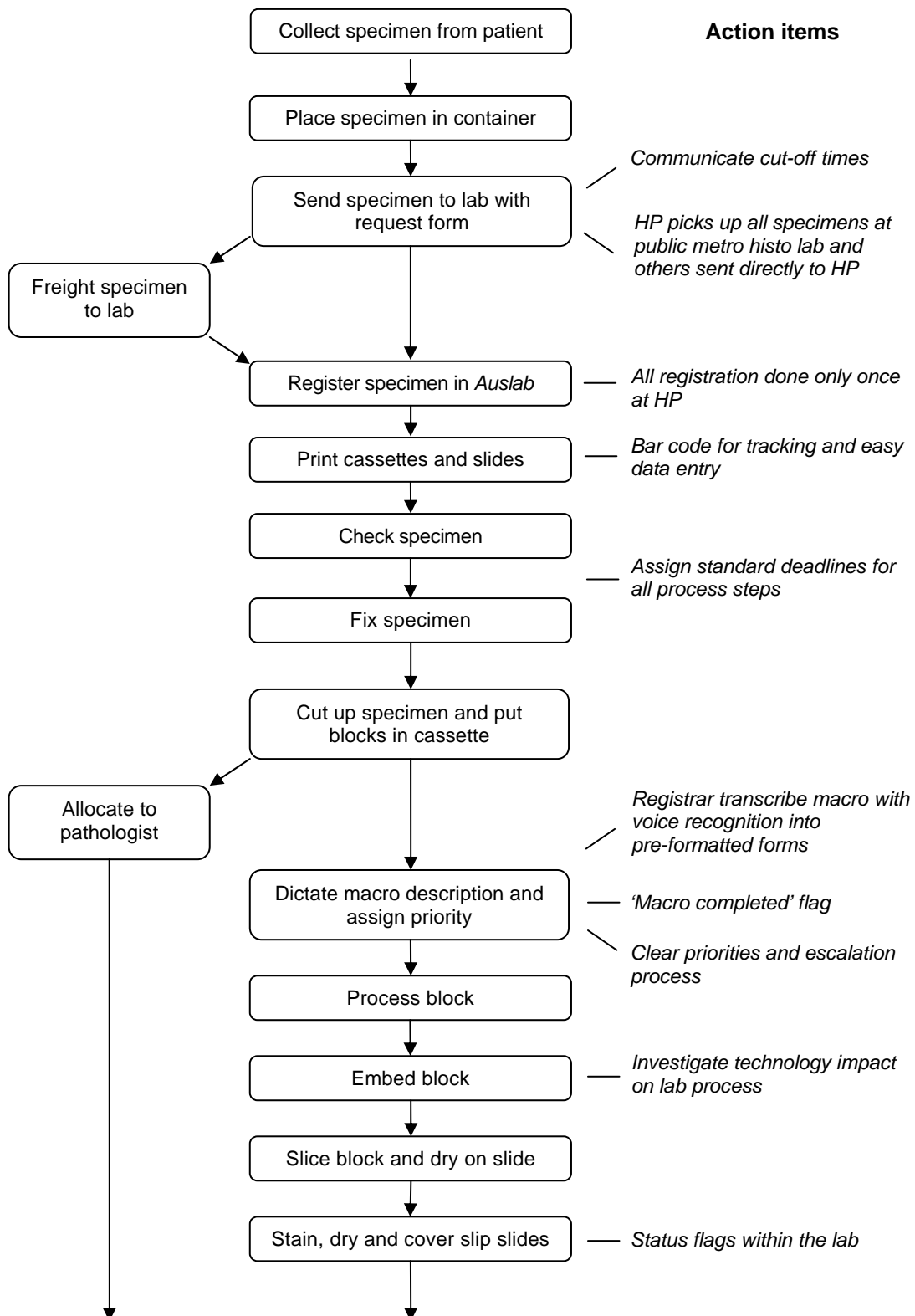
Figure 4: Swim-lane process map

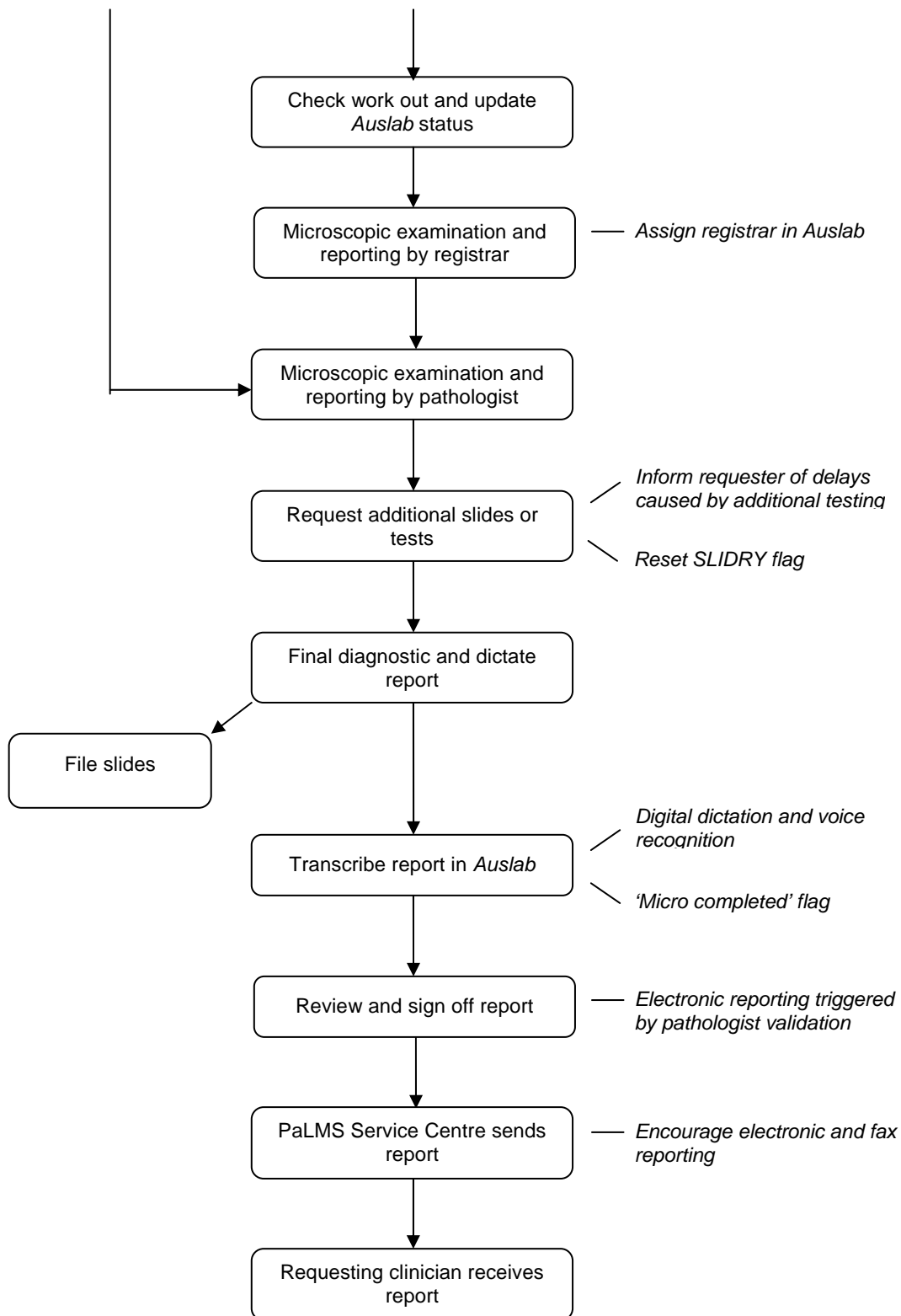


These process and workflow maps were then critiqued by staff who identified bottlenecks at key points in the process (numbered in Figure 4). Particular emphasis was placed on resources and equipment with high or low utilisation.

A workshop was then carried out to identify the action items for each step at the pilot site and possible solutions (Figure 5). For a full listing of issues identified and solutions suggested, see Appendix 1.

Figure 5: Action items identified by process step: pilot project





The main sources of quantitative data were derived from an analysis of all histopathology cases recorded in *Auslab* from January to March 2009, and a detailed review of random cases in the laboratory on one single day.

The final stage of the pilot project involved communicating the findings and conclusions to stakeholder groups. This was done through one-on-one meetings with key stakeholders and a final presentation to the project steering group.

The results from the pilot project included:

- Identification of opportunities to reduce turnaround times. The potential solutions were tested during the subsequent validation project.
- Establishing a strong case for change across the histopathology process. Core processes in place at the public metropolitan histopathology laboratory were consistent with best practice, with throughput and turn around times matching those of comparable laboratory settings.
- Streamlining end-to-end workflow to remove inefficiencies and reduce exceptions.
- Identification of opportunities to implement new technologies to speed up the process (e.g. voice recognition capability for registrars to transcribe macroscopic descriptions directly into pre-formatted forms).

Validation Project

The validation project had three components including:

- **Diagnostic analysis;**
- **Process improvement and**
- **Management operating system**

Diagnostic Analysis:

The first component of the validation project at the public regional histopathology laboratory repeated the pilot process conducted at the metropolitan histopathology laboratory. A similar methodology was used and conducted between November 2009 and June 2010.

Core processes were found to be consistent with best practice, as they were at the public metropolitan histopathology laboratory. A full list of opportunity areas identified for each process step at the public regional histopathology laboratory has been completed (see Appendix 2).

The main result from this component of the validation project was a reduction in the proportion of cases missing cut-off times for the next step in the process. This was identified as a key opportunity to reduce turnaround times.

Process Improvement:

The second component of the validation project was to implement a process improvement program at the public metropolitan histopathology department. It was designed to:

- Validate the outcomes of the pilot project.
- Continue to improve workflow in the laboratory, from the time the specimen was received and registered through to macroscopic description.
- Continue to accelerate end-to-end turnaround times.

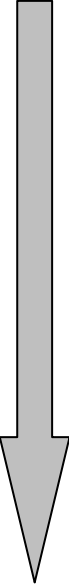
The objective of this part of the process improvement program was to set and meet turnaround time targets for all categories of histopathology. The project did not set out to reduce end-to-end turnaround times *per se* due to concern that this might bring pressure to compromise on reporting standards.

This part of the project delivered new guidelines for turnaround time, structured by specimen type. Each guideline set a due date for validation, stated in terms of a number of days after receipt in histopathology.

The guidelines were developed by the pathologists, and determined by clinical need, patient requirement and physical constraints.

Agreement to the guidelines was a significant achievement from a process improvement perspective. Figure 6 shows the extent of process changes enabled by the establishment of turnaround guidelines.

Figure 6: Process changes enabled by introduction of turnaround guidelines



Process step	Process changes
Receipt and registration	Consolidated set of codes Quarantined registration Technician assistant accountability for accuracy Additional QA
Cut-up, macro description	Cassettes colour-coded by due date
Tissue processing	Rapid run eliminated Day run eliminated
Embedding, slicing, staining	
Micro description	Allocation rules formalised and automated
Reporting	Target largest requesting clinicians by volume for email/fax delivery Lobby for later print/post deadlines Unbilled report introduced

The results from this component of validation project included:

- The development of a set of turnaround guidelines, with targets for different types of sample.
- Implementation of minor changes at the public metropolitan histopathology laboratory, including:
 - Collection of samples from various locations at the metropolitan histopathology laboratory
 - Delivering couriers directly to histopathology laboratory
 - Implementation of digital dictation for macro and micro reporting.
 - Extension of report printing deadlines for the final run.
 - Streamlining the workflow by minimising interruptions, making better use of space, rationalising *Auslab* codes and reducing the potential for errors.

For a complete list of activities, see Table1.

Table 1: Activities carried out to improve workflow during the process improvement program

<p>Equipment</p> <ul style="list-style-type: none">• provided a hard drive for the PC in the cut-up room• installed PC dictation software• progressed procurement of P-label machines and scanners• drafted a business case for slide writers <p>Shelving</p> <ul style="list-style-type: none">• costed materials required• built new shelving <p>Error recording and quality</p> <ul style="list-style-type: none">• implemented a new error recording sheet and quality check <p>Registration and quality</p> <ul style="list-style-type: none">• reviewed process maps and developed improvements• finalised new procedures <p>Pilot of new process</p> <ul style="list-style-type: none">• reviewed Auslab codes• rationalised code structure from >600 to 160• provided laminated code list for registration staff• set up the work area for debuging, registration and printing• established a staff roster for each activity• agreed a process for recording specimens collected from PSR• developed a set of simple instructions for staff• briefed staff in the new process• developed new case prioritisation (colour coding) process.
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Management Operating System

The third component of the validation project was to build a management operating system for histopathology, including a common set of key performance indicators (KPIs).

A management operating system is a framework for regularly collecting and reporting on a small standard set of key performance indicators.

The purpose of building a histopathology management operation system was to assist managers to understand day-to-day laboratory operations and provide information to improve performance.

During the pilot project, the project team developed a series of scripts for extracting data from the histopathology table and from the audit trail in *Auslab* to potentially populate the management operating system (Table 2).

Table 2: Data extracted from Auslab into an Excel spreadsheet for each case

<p>Basic case data, such as:</p> <ul style="list-style-type: none">• lab number• case number• billing type• patient MRN• specimen type• urgency• complexity• pathologist assigned <p>Requesting clinician data, such as:</p> <ul style="list-style-type: none">• requesting doctor• facility and ward <p>Volumetric data, such as:</p> <ul style="list-style-type: none">• number of specimens• number of jars• number of blocks• number of slides• number of slides recut <p>Special case identifiers, such as:</p> <ul style="list-style-type: none">• immuno-histochemistry• frozen section• bone marrow trephine• electron microscopy• review case <p>Case progress timestamps, such as:</p> <ul style="list-style-type: none">• date and time specimen collected• date and time case created• date and time received in first lab• date and time received in anatomical pathology• date and time slides ready for the pathologist• date and time case validated by pathologist• date and time case reported.
--

The validation project built on this work by developing a set of common KPIs and generic report formats that could be used to set targets, and to evaluate whether interventions achieved their goals. The study found managers at the public metropolitan histopathology laboratory were able to extract information from *Auslab* daily and used it for operational performance management.

The results from this component of the validation project included:

- Confirmation that data similar to that extracted during the pilot phase could be extracted from other *Auslab* sites.

- Confirmation that additional timestamps can be added to *Auslab* without recourse to the system vendor.
- Generic report formats developed for the following KPIs as shown in Figure 7:

Figure 7: Management operating system report formats

1.1 Volume of cases by priority

Cases Received	All Cases	AP Cases	Urgent Cases	Priority 1	Priority 2	Priority 3	Priority 4	Cases > 12 Slides
Yesterday								
This Week								
This Month								
This Year to date								
Last Year to date								

1.2 Volume of slides by priority

Slides Received	All Slides	AP Slides	Urgent Slides	Priority 1	Priority 2	Priority 3	Priority 4	Review Cases
Yesterday								
This Week								
This Month								
This Year to date								
Last Year to date								

1.3 Pathologist reporting capacity, by case due date

Pathologist	Hrs Available/ Capacity per hour	Due Today Cases/Slides	Due Tomorrow Cases/Slides	Due Day 3 Cases/Slides	Due Day 4 Cases/Slides	Due Day 5 or later Cases/Slides
Yesterday						
This Week						
This Month						
This Year to date						
Last Year to date						

1.4 End-to-end turnaround by step, in working days

Cases Reported	Collection to Reception	Reception to Lab	Lab to Macro	Macro to Assigned / Ready	Assigned / Ready to Validated	Validated to Reported	End to End TaT
Yesterday							
This Week							
This Month							
This Year to date							
Last Year to date							

1.5 Percentage of cases missing cut-offs

Cases Reported	Collection to Reception	Reception to Lab	Lab to Macro	Macro to Assigned / Ready	Assigned / Ready to Validated	Validated to Reported
Yesterday						
This Week						
This Month						
This Year to date						
Last Year to date						

1.6 Percentage of cases ready by 11am, by number of slides per case

Cases Ready	Cases with 1 or 2 Slides	Cases with 3 or 4 Slides	Cases with 5 or 6 Slides	Cases with 7 or 8 Slides	Cases with 9 or 10 Slides	Cases with 11 or 12 Slides	Cases with more than 12 Slides	All Cases
Yesterday								
This Week								
This Month								
This Year to date								
Last Year to date								

1.7 Clinical variability

Pathologist	Cases	Slides	Slides per Case	% HISL 6 & 7	% Cases with Recuts	% Slides Recut	% Cases Validated on Day Ready	% Cases Ready by 11am
Dr A								
Dr B								
Dr C								
Dr D								
Total Department								

Summary of report findings

Most cancer patients will never set foot in a histopathology department. Yet rapid, accurate reporting of these results is an essential part of the patient journey, both for diagnosis and therapeutic monitoring.

The Histopathology Business Improvement Strategy looked for opportunities to increase throughput and turnaround times in histopathology.

The need to be more efficient is driven by external factors such as a shortage of tissue pathologists, rising cancer incidence, budget constraints and increasing moves toward evidence based medicine, requiring more support from pathology services that will all place greater pressure on the ability of laboratories to operate effectively in years to come.

The project found it is possible to become more efficient, even in well-run laboratories. The key to improving end-to-end turnaround times is to increase the proportion of cases achieving cut-off times between the steps of the process.

With input from histopathology staff and managers, the business improvement strategy analysed the factors contributing to delays throughout the process and found that histopathology teams do not always have the tools to actively manage turnaround times.

In response, a management operating system was built, in this case using data extracted from *Auslab* to enable monitoring of key performance indicators and rational utilisation of pathologist capacity. This system provides a generic reporting framework that can also be used by laboratories using other information systems.

Following the identification of factors contributing to delays, a process improvement program was implemented streamlining workflow and helping cases to move more efficiently through the laboratory.

It is pleasing to note that the project methodology and generic process improvement solutions developed during this project have the potential to be applied in similar public laboratories statewide.

However, the following challenges will influence future rollout initiatives beyond the project sites:

- The networked structure of pathology services in NSW limits the scope for centralised reporting. Each pathology service tends to use methods that best suit them locally.
- Partial privatisation of pathology services in NSW has resulted in lack of uniformity of information systems.
- Lack of common procurement systems makes it difficult to standardise data, information and operating systems.
- Pathology services are also driven by customer requirements, resulting in a diverse reporting environment.

If these challenges can be addressed in reforming pathology services in NSW under the National Health Reforms, the process improvement methodology and generic management operating system generated through this project could potentially be deployed at other laboratories to best utilise scarce histopathology resources, in particular histopathologists.

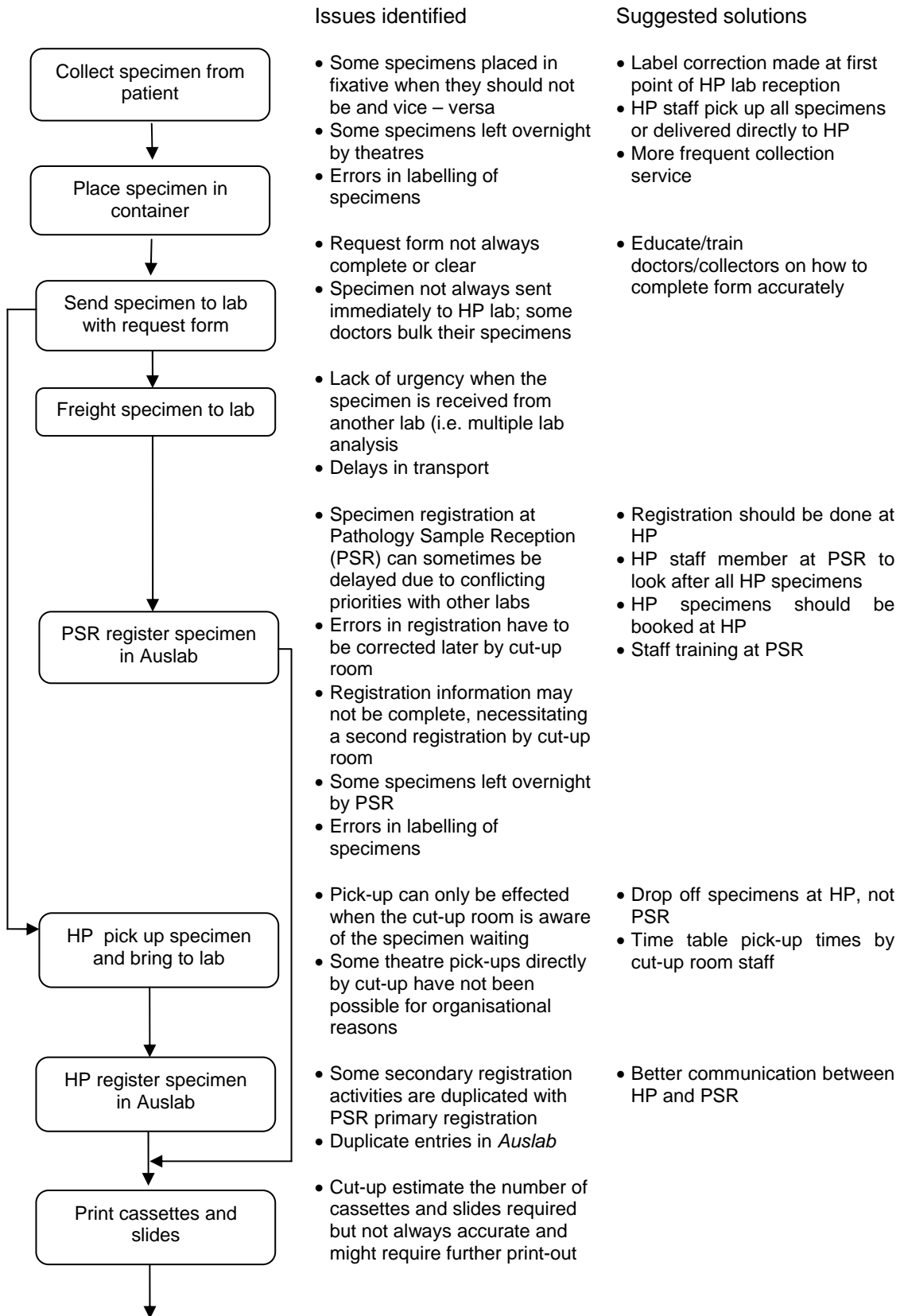
Abbreviations and Acronyms

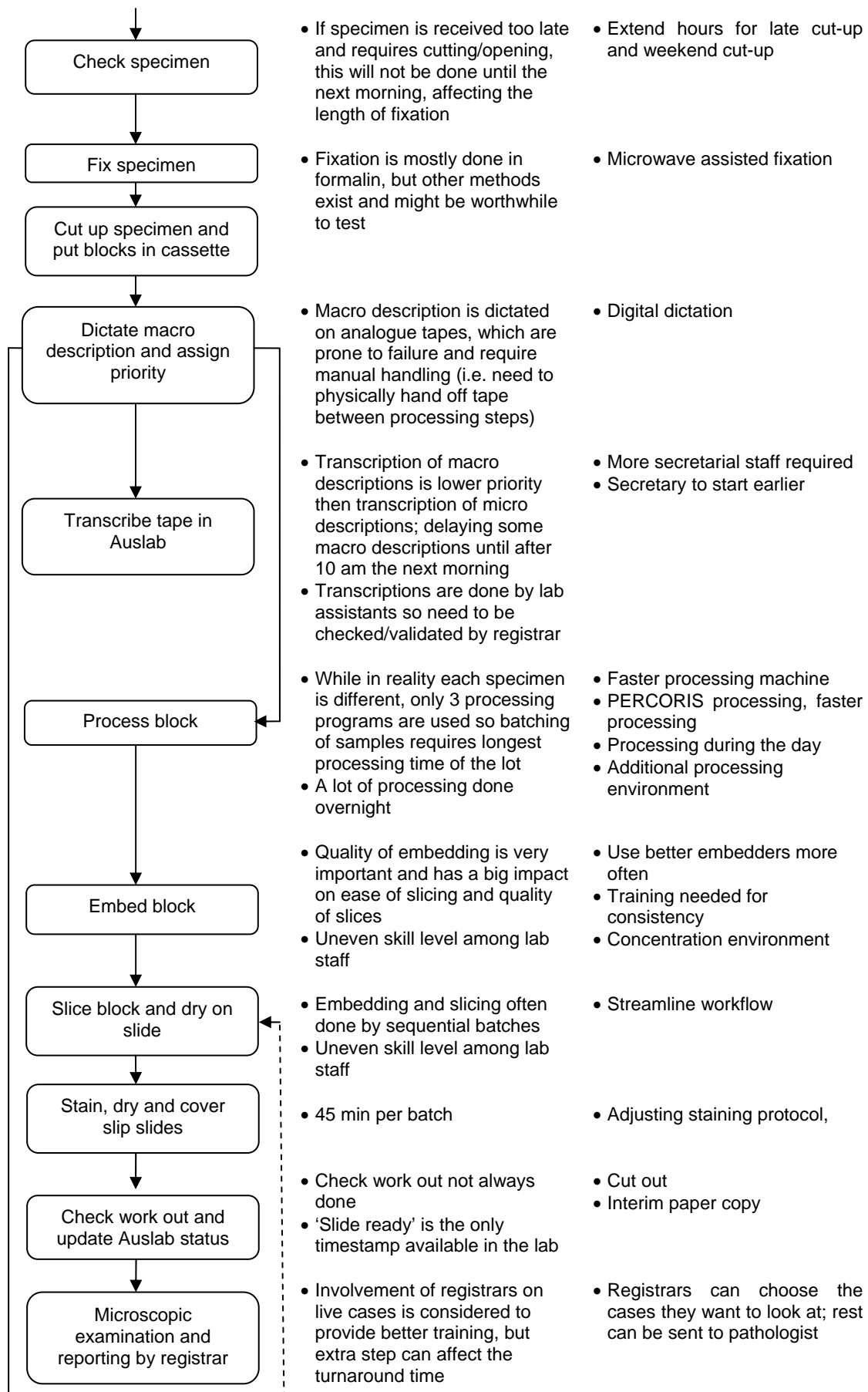
BIS	Business improvement strategy
HP	Histopathology
KPIs	Key performance indicators
MRN	Medical record number
NSW	New South Wales
NSWOG	New South Wales Oncology Group
PSR	Pathology sample reception
QA	Quality assurance
RTBIS	Radiotherapy Business Improvement Strategy
RCPA	Royal College of Pathologists of Australasia

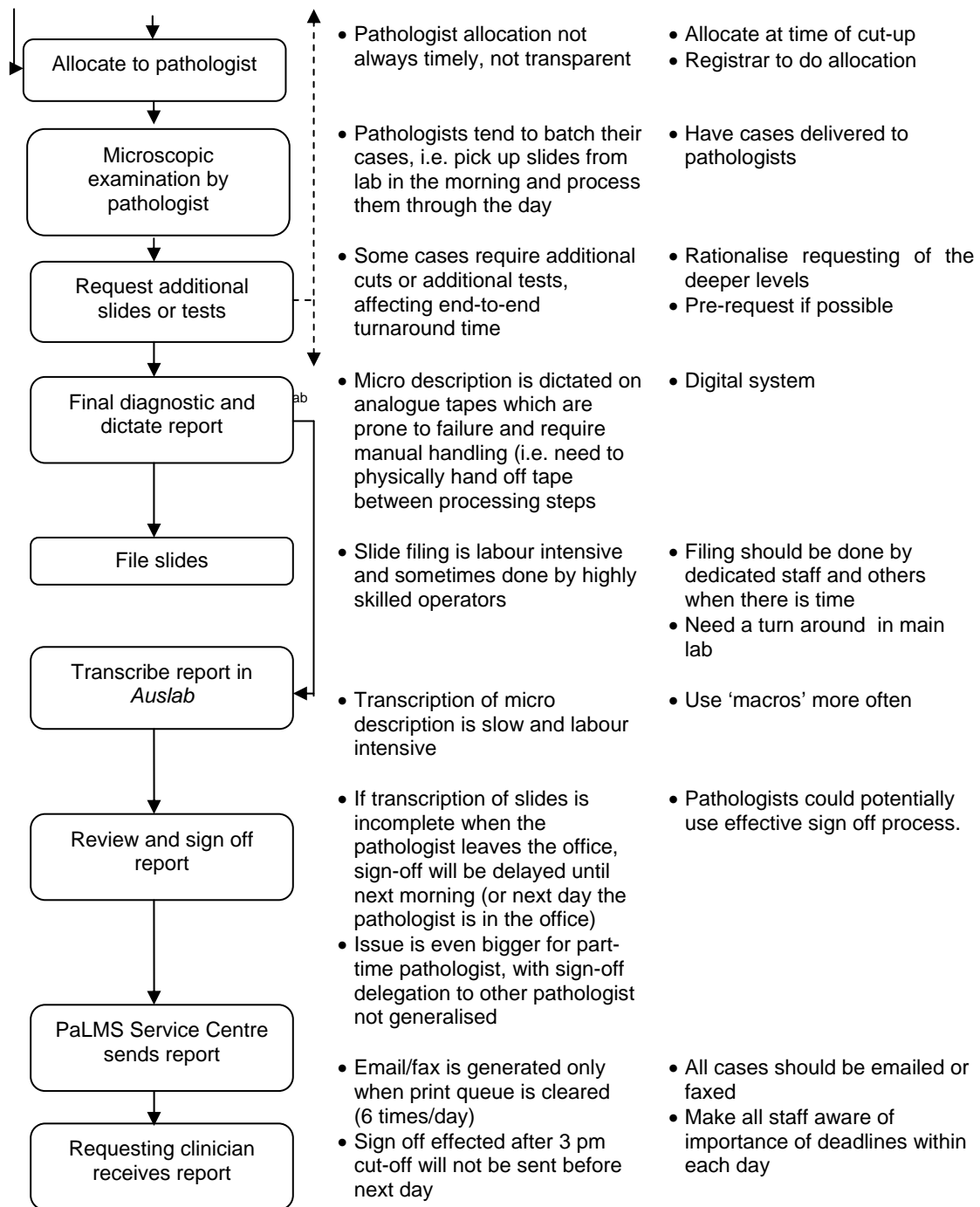
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Appendix 1: Issues and solutions identified at a public metropolitan histopathology laboratory







Appendix 2: Issues and solutions identified at a public regional histopathology laboratory

