Final project report preparation and format

This final project report has been prepared by Human Capital Alliance (International) Pty Ltd for the Quality Use of Pathology Program, Department of Health, Australia.

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Paper-based publications

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Recommended citation


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Acknowledgements

We acknowledge this country as belonging to the Aboriginal and Torres Strait Islander peoples of Australia. Australia is the only place in the world where Aboriginal and Torres Strait Islander Australians belong. There is no place in Australia where this is not true.

In addition, Human Capital Alliance (International) Pty Ltd wish to acknowledge and thank Departmental staff who commented on several drafts of this project report. A number of industry stakeholders also contributed through participating in the employer interviews, stakeholder workshops, providing documentation and sound knowledge and advice through personal communications. The Consumer Health Forum also assisted with arranging and providing access to consumers through workshops.

Human Capital Alliance

Human Capital Alliance (International) Pty Ltd is a management and research consultancy firm specialising in helping clients align their resources to their organisational goals. HCA is a Sydney based organisation with associates in all of the States and Territories.

Since its establishment in 1989, HCA has successfully worked with the public, non government and private sectors, completing assignments spanning a diversity of content and contexts, including workforce analysis, program and organisational review, social research, human resource planning, strategic planning, training and education and evaluation. HCA has an excellent understanding of most health areas especially from the public health, workforce and service delivery structures perspective. HCA has a strong reputation for listening to and collaborating with clients in order to find innovative solutions that work.

Comprising a small core staff group of consultants, project management experts and experienced social researchers, HCA boasts of an extensive network of professional associates and alliances across Australia and overseas who are thought leaders in their respective fields of expertise. This enables HCA to take on a strategic, multi-disciplinary but practical, no nonsense approach to its consultancies. HCA’s work over the years has entailed the successful completion of over 200 small, medium and large research consultancy projects for the public and private sectors which have demanded a wide range of expertise and methodological approaches across a variety of industries.

For further information about HCA go to the Human Capital Alliance website.
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<td>ABS</td>
<td>Australian Bureau of Statistics</td>
</tr>
<tr>
<td>ACT</td>
<td>Australian Capital Territory</td>
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<tr>
<td>ANZSCO</td>
<td>Australian and New Zealand Standard Classification of Occupations</td>
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<td>CAJA</td>
<td>Competency Assessment and Job Assessment</td>
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<td>CHF</td>
<td>Consumers Health Forum</td>
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<td>CLSI</td>
<td>Clinical Laboratory Standards Institute</td>
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<td>CSHISC</td>
<td>Community Services and Health Industry Skills Council</td>
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<tr>
<td>DoH</td>
<td>Department of Health</td>
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<tr>
<td>ED</td>
<td>Emergency Department</td>
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<tr>
<td>FAD</td>
<td>Field Assessment Document</td>
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<tr>
<td>GP</td>
<td>General practitioner</td>
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<td>HCA</td>
<td>Human Capital Alliance</td>
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<td>KIMMS</td>
<td>Key Incident Monitoring &amp; Management Systems</td>
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<tr>
<td>NAACLS</td>
<td>National Accrediting Agency for Clinical Laboratory Science</td>
</tr>
<tr>
<td>NATA</td>
<td>National Association of Testing Authorities</td>
</tr>
<tr>
<td>NCVER</td>
<td>National Centre for Vocational Education Research</td>
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<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
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<tr>
<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<tr>
<td>PoCT</td>
<td>Point of care testing</td>
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<tr>
<td>QAP</td>
<td>Quality Assurance Program</td>
</tr>
<tr>
<td>QASEC</td>
<td>Quality Assurance Scientific and Education Committee</td>
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<td>QUPP</td>
<td>Quality Use of Pathology Program</td>
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<tr>
<td>RCPA</td>
<td>Royal College of Pathologists of Australasia</td>
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<tr>
<td>RTO</td>
<td>Registered training organisation</td>
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<tr>
<td>SMEG</td>
<td>Subject Matter Expert Group</td>
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<td>SNP</td>
<td>Sullivan Nicolaides Pathology</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
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<td>SRA</td>
<td>Specimen reception area</td>
</tr>
<tr>
<td>TAFE</td>
<td>Technical and further education</td>
</tr>
<tr>
<td>VET</td>
<td>Vocational education and training</td>
</tr>
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<td>WA</td>
<td>Western Australia</td>
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<td>WHS</td>
<td>Work, health and safety</td>
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Executive summary

Background

The Quality Use of Pathology Program (QUPP) within the Department of Health (DoH) commissioned Human Capital Alliance (HCA) to investigate best practice in pathology collection practices for Australia. The objectives of the Best Practice Pathology Collection project were to research, investigate, analyse and provide insight into:

1. The current national and international best practice in pathology specimen collection (with a particular focus on phlebotomy);
2. The quality and safety issues associated with effective and consumer-focused collection services;
3. The identification of a core set of minimum competencies and possible performance measures that would be appropriate in the Australian health care setting to ensure that the relevant safety risks and consumer satisfaction issues are adequately addressed; and
4. The identification of training and ongoing proficiency maintenance strategies that are currently in place in Australia.

Pathology tests are an essential part of the healthcare system, used to aid medical practitioners in the diagnosis of disease, assist in preventive health, acute care, management of chronic conditions and more recently genetic research Plebani (2006). In the financial year 2011/2012 (up until June 30) there were over 114 million pathology occasions of service (or tests) in Australia initiating a Medicare benefit. Additionally, significant pathology testing is undertaken in hospitals in the public health sector—it is estimated that up to 40% of all pathology testing in Australia is conducted in this sector.

These figures place into perspective the enormous importance of pathology testing to the health system as a whole and to the health outcomes of individuals using the health system in particular.

Collection of pathology samples

The pathology test process has three stages. The process from a medical practitioner’s referral for a pathology test (in a hospital or community setting), through to the collection and transporting process until it is registered at the laboratory is called the pre-analytical phase. In the analytical phase the sample is analysed and quality control and assurance processes are conducted to ensure the accuracy of the result. The final stage is called the post-analytical stage and involves the referring medical practitioner interpreting the test results and communicating a treatment decision to the patient.

This project is concerned with the processes of collecting pathology samples for analysis — essentially the pre-analytical stage of the pathology process. The need for appropriate and documented collection processes and the possession of minimum competencies for sample collection and handling, and the maintenance of those competencies to ensure ongoing quality of service, has been identified by the National Pathology Accreditation Advisory Council (NPAAC), the Royal College of Pathologists of Australasia (RCPA) and the Consumers Health Forum of Australia (CHF) as a high priority issue and an area where greater attention to promoting best practice could lead to better patient outcomes.

There is a large amount of evidence from the literature that identifies the pre-analytical stage as the area in which the majority of errors occur within pathology testing, thus supporting the focus of this study. Plebani (2006) for instance states:

“Most errors are due to pre-analytical factors (46–68.2% of total errors); while a high error rate (18.5–47% of total errors) has also been found in the post-analytical phase.”
He notes that this is in direct contrast to pathology systems within the laboratory where sustained effort has resulted in significant reduction of errors. Similarly, Bonini, et.al. (2002) in a mini review of the literature on errors in laboratory medicine and found:

“... all available studies demonstrated that a large percentage of laboratory errors occur in the pre- and post-analytical phases, with fewer mistakes occurring during the analytical step”.

This investigation aimed to better understand what best practice in pathology collection looks like, what are the key obstacles to obtaining best practice in Australia, and how it is created and sustained primarily through compliance to appropriate processes, within quality assurance systems, by relevantly competent pathology collectors.

Industry and consumer perspectives on collection quality and safety

A distinction is made in this report between an industry perspective (that is from pathology laboratories themselves and associated industry bodies and professional associations) and a consumer perspective (patients who are having samples collected for testing) of pathology testing services. Two fundamental differences between the industry and consumer perspectives can be demonstrated in regard to (1) how the perspectives are formed and, (2) the primary focus of the quality and safety concerns.

In regard to how perspectives are formed, industry relies almost completely on quantitative data gathered through quality assurance processes and specifically constructed research projects. Consumer perspectives though, are most often formed through qualitative data, based on personal experience or knowledge of the collective experience of others.

In terms of the focus of quality and safety concerns, industry’s perspective is primarily (though not exclusively) on the quality of the pathology specimen to be tested. Problems occurring during pathology collection processes are identified in a number of ways. The most common way is when a specimen is rejected at the laboratory’s specimen reception as it has been incorrectly labelled, contaminated, collected into an inappropriate anti-coagulant, or the sample quality is compromised, for example, haemolysed or clotted samples.

In terms of the focus of consumers on the other hand, the primarily interest is on the safety and comfort of the patient, although clearly they also have an interest in the quality of the sample. This tends to translate into an emphasis on the quality and safety of the pathology collector. While both industry and consumers consider the process, for consumers this is more about the degree of confidence and safety in the way the collector relates to the patient than the quality of the sample obtained.

While collection processes contribute disproportionately to pathology errors, it is worth placing the total number of errors into perspective. The Key Incident Monitoring & Management Systems (KIMMS) data collection project within the RCPA Quality Assurance Program (QAP) has found that pathology errors identified each quarter in Australian pathology laboratories ranged from only 1.38% to 1.56% of all pathology service episodes.

Best practice pathology collection

‘Best practice’ pathology collection is a set of agreed techniques and procedures that represent the best way in which health workers can collect a quality pathology sample whilst maintaining the safety of their patients and themselves. To establish best practice pathology collection both the service (a consumer focus) and technical (a laboratory focus) processes need to be considered. The study found best practice can be approached by addressing the following three components:

1. Building a consensus on the technical aspects or procedure that is undertaken by pathology collectors when collecting blood. This component is described well in the international
literature on best practice blood collection, also described as phlebotomy or venepuncture. The procedure needs also to consider consumer expectations.

2. Maintaining structured quality assurance systems linked to accredited management standards such ISO 15189, in conjunction with laboratory systems to detect errors in samples and collection procedures; and

3. Assessing and maintaining competence of pathology collectors (including customer service competencies) through training programs that develop the correct skills, attitudes and techniques required and can provide a structure from which to assess individual competence and benchmark practice.

The study has revealed that Australian pathology collection is close to world best practice standards certainly in terms of outcomes of sample collections, but nevertheless falls short of what could be achieved in terms of best practice for the entire consumer experience.

Australian practice is strongest in regard to compliance to quality assurance systems and continuous improvement maintained through existing regulatory systems which include NPAAC Guidelines; National Association of Testing Authorities (NATA)/RCPA accreditation assessment arrangements; pathology organisation internal quality assurance and continuous improvement systems; and KIMMS data collection within the RCPA QAP. However, in one sense this strength is also a weakness because it focuses almost exclusively on the quality outcome of pathology specimens.

Parts of the Australian pathology collection workforce can also be considered highly competent by world standards. The preferred qualification of industry, the Certificate III in Pathology, maps well to best practice although it can be improved further. The concerns though are that a significant proportion of the workforce (estimated to be almost half) remains unqualified. Of even potentially greater concern is that a significant proportion of collections are undertaken by non-specialist pathology collection people – general practitioners, practice nurses, medical scientists, interns and nurses in specific hospital wards and emergency departments. KIMMS data indicates this part of the collection workforce contributes disproportionately to total pathology collection errors.

**Bridging gaps in best practice pathology collection**

It is the conclusion of this study that the most effective pathway to best practice pathology collection requires:

- Adoption of well defined competencies for the technical aspects of collection which reduce infection risks to patient and collector;
- Recognition of the patient as a customer and inclusion of customer service competencies in the core training and ongoing assessment of collectors;
- Strong policies and procedures that define how pathology samples are to be collected, stored and transported; and
- A pathology collection workforce that is competent and presents to consumers with a credible qualification and in a professional manner.

The first two of these requirements are best met through appropriate training arrangements. Many of the employers interviewed in the course of this project also concluded that increasingly improved training was the key to progressing towards best practice pathology collection. They advocated adoption of the Certificate III in Pathology as the minimum level of training that is required as preparation for safe pathology collection practice. A majority of pathology laboratories, both public
and private, were attempting to set this benchmark as the minimum for recruitment in their own organisations, although there remain many unqualified pathology collectors in pathology services.

In moving towards a compulsory requirement for pathology collectors to be appropriately qualified (at the Certificate III level), two impediments need to be negotiated:

1. The Certificate III qualification, as it is currently constructed, is deficient in at least two aspects. The first relates to knowledge that would underpin a greater understanding of the policies and procedures applied in practice (and thus enhance the application of skills). The second relates to competence in ensuring consumer experiences in pathology collection add to, rather than detract from their satisfaction in the total health journey and hopefully improve health outcomes. Resolving these deficiencies would involve changing the structure of the current Certificate III and some initial thoughts that may assist future work in this area are provided in this study (see Appendix F) and have been developed with the Community Services and Health Industry Skills Council (CSHISC); and,

2. The current implementation of the Certificate III course varies considerably in quality between training providers, a fact that undermines the credibility of the qualification and confuses employers in their own training and recruitment activities. The preference of employers for training to be either completely or mostly on the job in nature is endorsed by this study. Ideally, pathology collectors should be trained through a traineeship or apprentice type approach, employed and trained largely on the job with their practical learning supplemented and supported by appropriately timed and delivered conceptual learning that provides the theoretical underpinning for practice.

In addition to the training of (specialist) pathology collectors, other individuals who collect pathology specimens (nurses, GPs (general practitioner), Aboriginal Health Workers, etc.) in lieu of pathology collectors, need to have received minimum levels of training. The employer interviews and subsequent workshops run in conjunction with the CSHISC identified competence in a single unit of the Certificate III in Pathology qualification as appropriate — ‘HLTPAT306C Perform blood collection’. There would be no compelling reason why training for this unit needed to be anything other than an on the job, in-house training process.

In regard to the second two of the best practice requirements developed above, it would seem appropriate to strengthen the current regulatory processes to better guarantee workforce competence standards. In addition to the training arrangements discussed above (compulsory Certificate III as minimum competency standard by agreed date, demonstrated competence of non-specialist collectors to perform blood collection, relevant training programs in place), this could be achieved by:

- Pathology laboratories providing effective procedure manuals to all potential collectors that document and prescribe routine pathology collection performance and work processes (including ensuring consumer satisfaction) as part of a quality assurance system; and,

- Providing evidence of ongoing and accessible courses, the quality of which can be supported by regularly auditing as a requirement of continued registration as a registered training organisation (RTO) with appropriate education authorities.

In regard to the first dot point above, current procedures undertaken by the pathology collection workforce are biased to the technical aspects of blood collection and have little to no focus on consumer experiences. This will need to be rectified since it represents an important area of concern that weakens the perception of an area of health service that otherwise is making significant efforts to provide best practice services.
Chapter 1 - Background to the project

A broad perspective on pathology testing in Australia

Pathology tests are an essential part of the healthcare system, used to aid medical practitioners in the diagnosis of disease, assist in preventive health, acute care, management of chronic conditions and more recently genetic research. Plebani (2006) states that:

“Laboratory services have a great influence on clinical decision-making: 60–70% of the most important decisions on admission, discharge, and medication are based on laboratory test results.”

In the financial year 2011/2012 (up until June 30) there were over 114 million pathology occasions of service (or tests) in Australia initiating a Medicare benefit. The distribution of these services across the broad pathology service types is shown in Table 1. This number of tests represents a minimum, since not all testing in the private pathology sector is captured through Medicare benefit claims. Additionally, significant pathology testing is undertaken in hospitals in the public health sector — it is estimated that up to 40% of all pathology testing is conducted in this sector.

Table 1: Summary of pathology tests receiving a Medicare benefit (2011/2012)

<table>
<thead>
<tr>
<th>MBS Pathology Service groups</th>
<th>Total services</th>
</tr>
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<tbody>
<tr>
<td>P1 Haematology</td>
<td>16,306,681</td>
</tr>
<tr>
<td>P2 Chemical</td>
<td>41,219,183</td>
</tr>
<tr>
<td>P3 Microbiology</td>
<td>12,153,893</td>
</tr>
<tr>
<td>P4 Immunology</td>
<td>3,179,089</td>
</tr>
<tr>
<td>P5 Tissue Pathology</td>
<td>2,799,768</td>
</tr>
<tr>
<td>P6 Cytopathology</td>
<td>2,001,144</td>
</tr>
<tr>
<td>P7 Cytogenetics</td>
<td>184,036</td>
</tr>
<tr>
<td>P9 Simple Basic Tests</td>
<td>577,458</td>
</tr>
<tr>
<td>P10 Patient Episode Initiation</td>
<td>35,181,860</td>
</tr>
<tr>
<td>P11 Specimen Referred</td>
<td>491,540</td>
</tr>
<tr>
<td>Total</td>
<td>114,094,652</td>
</tr>
</tbody>
</table>

Over the seven year period from 2005/06 to 20011/12 services claimed under Medicare grew by 37%, approximately 31 million pathology occasions (from 82.889 million to 114.094 million billable item numbers). In the consultations undertaken by HCA in their study of the pathology scientists labour market (HCA, 2011), trend figures of a compound growth rate of close to 5% per annum were thought to be reasonable and were largely accepted although overall growth figures were understood to disguise quite different growth rates between pathology service groups.

The place of pathology collection

The pathology test process has three stages. The process from a medical practitioner’s referral for a test (in a hospital or community setting), through to the collection and transporting process until it is
registered at the laboratory is called the **pre-analytical** phase. In the **analytical phase** the sample is analysed and quality control and assurance processes are conducted to ensure the accuracy of the result. The final stage is called the **post-analytical** stage and involves the referring medical practitioner interpreting the test results and communicating a treatment decision to the patient.

As these three phases indicate, for all of these tests to be performed a specimen needs to be collected. Pathologists and medical scientists in pathology laboratories conduct tests on samples of blood, tissue or body fluid taken from patients. Traditionally, these samples were mostly collected by nurses, but today are collected by specially trained pathology collectors as well as doctors, nurses, pathologists and in some cases medical scientists. They are collected in public and private hospitals, medical clinics, community collection centres, from patients in their homes and in GPs rooms.

Historically, pathology collection work was primarily (and still largely is) associated with drawing blood samples, and this is referred to in many places as phlebotomy ("to cut a vein" in Greek) \(^1\). The World Health Organisation (WHO) (2010) notes collecting blood samples:

> *“... has been practised for centuries and is still one of the most common invasive procedures in health care. Each step in the process of phlebotomy affects the quality of the specimen and is thus important for preventing laboratory error, patient injury and even death.”*  

There is no direct relationship between the number of tests performed and collection activities since a single sample can support multiple tests, however the information in Table 1 can be regarded as an indication of the significant volume of collections required each year. Data collected, through the KIMMS project within the RCPA QAP, from 72 pathology laboratories identifies 28.208 million samples having been collected in the calendar year 2011.

### Why are we investigating pathology collection?

This project is concerned with the processes of collecting pathology samples for analysis — essentially the pre-analytical stage of the pathology process.

All pathology collection processes in Australia are subject to the NPAAC Guidelines. The NPAAC standards and guidelines detail requirements for collection centre premises, staffing, equipment, documentation/instruction, collection procedures, safety and transport and storage of specimens. The relevant standards are assessed under the NATA/RCPA accreditation assessment arrangements and must be met in order to ensure eligibility for Medicare funding.

Despite adherence to these standards and guidelines there is human effort involved in the collection process and errors occur. KIMMS project data from the RCPA QAP identifies between 1.3% and 1.5% of all tests are associated with pre-analytical (collection) ‘incidents’. Statistically, at least from a pathology laboratory’s technical perspective, the error rate associated with pathology collection is low but still able to be decreased. The level of ‘incidents’ occurring from a consumer perspective is largely unknown with the number of formally lodged customer complaints likely to be a misleading indicator.

Poor specimen collection techniques are associated with a significant risk to patients and to the collector. The need for appropriate and documented collection processes and the possession of minimum competencies for specimen collection and handling, and the maintenance of those competencies to ensure ongoing quality of service has been identified by NPAAC, the RCPA and the CHF as a high priority issue and an area where greater attention to promoting best practice could...
lead to better patient outcomes. The Workforce Advisory Committee (WAC) (a subcommittee of the Pathology Agreement Advisory Committee\(^2\)) has identified potential increased risk of competence deficiencies associated with low volume pathology collection centres, where competence may be problematic due to low patient numbers. Low volume pathology collection centres tend to occur in rural and remote areas but equally applies in situations where collection occurs in the absence of pathology collectors, for example in emergency departments, general practice surgeries, etc.

This investigation aims to understand better pathology collection quality and safety issues, what best practice looks like, and how it is created and sustained primarily through compliance to appropriate processes, within quality assurance systems, by relevantly competent pathology collectors.

\(^2\) A five-year Pathology Funding Agreement between the Government and the pathology sector came into effect from 1 July 2011. While the Agreement is primarily a mechanism to manage pathology outlays, it also provides for the development of many other initiatives including “… ensuring a sustainable, workforce for pathology”
Chapter 2 - Project objectives and methodology

Project objectives

The QUPP within the DoH commissioned HCA to investigate best practice in pathology collection practices for Australia. The specific objectives of the Best Practice Pathology Collection project were to research, investigate, analyse and provide insight into:

1. The current national and international best practice in pathology specimen collection (with a particular focus on phlebotomy);
2. The quality and safety issues associated with effective and consumer-focused collection services;
3. The identification of a core set of minimum competencies and possible performance measures that would be appropriate in the Australian health care setting to ensure that the relevant safety risks and consumer satisfaction issues are adequately addressed; and
4. The identification of training and ongoing proficiency maintenance strategies that are currently in place in Australia.

The methodology applied to this project, in terms of the activities undertaken in order to achieve the above objectives, are overviewed in Figure 1.

Specific component activities of the investigation are described more fully in the following text sections.

Literature review (Box A)

The project commenced with a review of national and international literature to identify:

- Current national and international best practice in pathology collection practices, with a focus on phlebotomy; and
- National and international phlebotomy and pathology collection training and ongoing proficiency maintenance strategies.

The search process included attempting to source known literature from the HCA team members, stakeholders and Departmental representatives as well as using key words associated with the area of ‘pathology work’, with ‘processes’ and with ‘competence’ to search relevant abstract databases and search engines. The relevant search engines included:

- Cochrane;
- Medline;
- Australian Medical Index and PubMed electronic databases; and,
- Internet search engines (Google Scholar, Scirus, Dogpile, UK Health Centre).

As well, specific internet sites of State and Federal health authorities in Australia and overseas as well as relevant websites of professional associations were explored.

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3 For example ‘pre-analysis’, ‘collection’, ‘specimen’, ‘phlebotomy’, etc.
4 For example ‘systems’, ‘procedures’, ‘manuals’, etc.
5 For example ‘behaviours’, ‘knowledge’, ‘capability’, etc.
The ‘search’ processes uncovered relevant ‘grey’ or unpublished literature from national and international sources as well as the more traditional published literature in technical journals. This included analysed but unpublished data, for instance the KIMMS project data from the RCPA QAP. In addition grey literature on outcomes from the CHF, Consumer Consultation ‘Quality Use of Pathology Consumer Consultation Project’ in 2010 was also able to be accessed.

The results of the literature search identified that:

- There is sufficient literature available to describe the technical component of best practice blood collection processes but there was limited available literature on the customer services aspects of the process;
- There is literature available to describe best practice quality assurance systems that pathology organisations require to enable them to deliver best practice pathology services;
Limited literature was identified to describe best practice in ongoing training and professional management systems; and

There was abundant literature on quality and safety issues for effective and consumer focused blood collection practices.

The literature has been used throughout the project to add value and insight to other project components and is referenced throughout this report.

Consultations with employers and stakeholder organisations (Box B)

A total of 22 consultations with pathology collector employers were undertaken across public, not for profit and private pathology organisations, within hospitals and community based services, and across urban and rural locations. Only one small (private) pathology organisation was able to be interviewed (a number of small private providers were approached but declined to participate in the process). A list of employers interviewed is provided in Appendix A. The employer interviews followed an approved interview schedule available at Appendix B.

Employer interviews were undertaken with senior managers (or other relevant designated officers i.e. ‘Pathology Collections Manager’ or ‘Training Managers’, etc). The interviews were structured to discuss what work collectors/phlebotomists are undertaking within their organisations and to collect the following documentation for further analysis:

- Position descriptions were requested from each employer to analyse descriptions of the roles, and required skills, attributes of employed collectors/phlebotomists;
- Procedural documentation including Standard Operating Procedures. These were analysed to gain an understanding of current operating procedures and quality control processes; and
- Training manuals, training matrixes and induction procedures. Examination of these documents provided an understanding of in-house training programs and ongoing assessment of competency and continuing professional development practices within the sampled employers.

At all employer organisations, the interviewers were shown procedural documentation and training manuals, however in the majority of circumstances, these documents were not to be removed from the premises for further analysis as they were considered the intellectual property of the employer organisations. Employers interviewed however were, on the whole, prepared to provide sample job descriptions and their forms used for ongoing competency maintenance assessments. All documentation collected was analysed; the results of which are provided within this report.

Consultations with consumers (Box C)

Eight focus groups with pathology collection services consumers — organised in conjunction with the CHF, the Health Care Consumers Association (ACT), Health Consumers (NSW), Health Issues Centre (VIC), Health Consumers (QLD) and National Aboriginal Community Controlled Health Organisation (NACCHO) — were conducted in December 2012 in four different cities. The number of participants that attended the focus group discussions in each location is detailed in Table 2. Due to the time of year (the Christmas and holiday season in December), participant numbers were lower than desired however a large amount of data was collected from the committed individuals who did attend.

The aim of the focus groups was to collect details on the experiences and expectations of consumers of pathology collection services in order to identify the required competencies of collectors/phlebotomists from the consumer perspective. A copy of the guide regarding the conduct of the focus group consultations is provided in Appendix C.
Table 2: Consumer focus groups

<table>
<thead>
<tr>
<th>Location</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sydney</td>
<td>2</td>
</tr>
<tr>
<td>Melbourne</td>
<td>6</td>
</tr>
<tr>
<td>Canberra</td>
<td>13</td>
</tr>
<tr>
<td>Brisbane</td>
<td>12</td>
</tr>
<tr>
<td>NACCHO (held in Canberra offices)</td>
<td>3</td>
</tr>
</tbody>
</table>

**Competency workshop with key stakeholders (Box D)**

Simultaneously to this ‘Best Practice in Pathology Collection’ project the CSHISC was undertaking a review of the National Health Training Package including the pathology related qualifications (Certificates III and IV in Pathology). A pathology Subject Matter Expert Group (SMEG) had been formed for the purpose of helping CSHISC review the pathology qualifications in the Training Package.

HCA approached the CSHISC to work collaboratively instead of independently with the potential to duplicate effort or develop conflicting outcomes. Accordingly HCA and the CSHISC collaboratively conducted two workshops (one in Sydney and one in Brisbane). These workshops gathered operational/supervisory individuals identified through the employer consultations with other individuals that were already part of the CSHISC review processes (members of their pathology SMEG).

These workshops replaced the originally proposed Competency Assessment and Job Assessment (CAJA) type group sessions outlined in the Project Plan, although a modified form of CAJA was still included in the workshop process. The change in process was primarily because the required competencies were by this stage well understood as informed by the other completed project activities — hence the more exploratory CAJA approach became less relevant. Instead, the applied approach sought to validate the proposed pathway and thus added significantly more value. The workshops canvassed:

- The comprehensiveness of the current Certificate III and IV and the vocational outcomes realistically associated with each;
- Ideas around qualification issues, including the relationship to the Laboratory Operations qualifications;
- Additional competencies for inclusion in each of the Certificates, especially customer service competencies; and
- Methods and processes for identifying and defining any further gaps.

Existing competency standards (in the Health Training Package) and those identified through the literature review and employer interviews served as a starting point for the workshop discussions with the participants.

The workshop process, and a list of attendees, is provided at Appendixes D and E respectively.

**Examination of current training efforts (Box E)**

The project team examined data from the National Centre for Vocational Education Research (NCVER) on enrolments and completions of participants in the national Certificate III and IV in Pathology. This data provided an understanding of the numbers of students completing the current
national training program. A desk analysis of the Certificate III and IV was undertaken to understand how it could satisfy (or not) competency demands of best practice pathology collection.

Similarly, training documentation gathered through the employer interviews (see Box B in Figure 1) were examined and audited for its capacity to deliver in entirety (or part) the necessary competencies of the pathology collection workforce.

The report structure

The findings from the five (5) stages of investigative project methodology activities are described in the following chapters. As noted above in relation to the literature review, the findings are not reported generally in neat method activity components but rather in relation to specific content areas as follows:

- Australian and International pathology collection practice;
- Pathology collection quality and safety perspectives;
- Best practice pathology collection;
- The pathology collection workforce; and,
- Minimum core competencies for pathology collection.

Similarly, the report does not neatly respond to each of the project objectives. Discussion on each of the project objectives appear within the chapters of this report as identified in Table 3 below.

<table>
<thead>
<tr>
<th>Project Objective</th>
<th>Chapter 3</th>
<th>Chapter 4</th>
<th>Chapter 5</th>
<th>Chapter 6</th>
<th>Chapter 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>The current national and international best practice in pathology specimen collection (with a particular focus on phlebotomy)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>The quality and safety issues associated with effective and consumer-focused collection services</td>
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<tr>
<td>The identification of a core set of minimum competencies and possible performance measures that would be appropriate in the Australian health care setting to ensure that the relevant safety risks and consumer satisfaction issues are adequately addressed</td>
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<tr>
<td>The identification of training and ongoing proficiency maintenance strategies that are currently in place in Australia</td>
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</tbody>
</table>

Chapter 8 provides a discussion of the main issues related to achieving best practice pathology collection and offers a summary of findings.
Chapter 3 - Australian and International pathology collection practice

Practice in Australia

Pathology collection is undertaken in a range of health service settings across Australia including public and private hospitals, community based collection rooms, aged care facilities, through home visits and within GPs rooms. The two largest providers of publicly funded pathology testing are public hospitals and large private laboratories, but there is also collection and testing of pathology specimens by a smaller number of not for profit hospitals and a number of small (often specialised) private pathology laboratories.

Pathology collection practice in public hospitals

There is variation between pathology collection processes within public hospitals based on historical ways of organising work and service delivery approaches. However, within the majority of public hospitals that were interviewed for this project, the pathology department employs and directs ‘specialist’ pathology collection staff who visit most, if not all hospital inpatient wards each morning to collect samples for pathology tests ordered by medical practitioners within the hospital. The typical ‘morning’ session is from 8 am to 2 pm, but in some cases may be until 4pm. If a pathology sample is required to be collected outside the hours of availability of collection staff, a doctor, or more often a nurse, may collect a sample for testing. However, in most wards this did not account for a significant proportion of total tests performed. Interestingly, all pathology collector employers interviewed identified, based on KIMMS data, that there were a higher proportion of errors in samples collected by nurses and doctors than by specialised pathology collectors. This was attributed to the strict collection protocols and procedures that collectors adhered to and the lack of defined practice of non-specialised staff. This is discussed in greater detail in Chapters 4 and 7.

In most public hospitals there are a number of service areas where pathology specimens are not routinely collected. As a general rule, pathology collectors do not collect within public hospital emergency departments. This was mainly attributed to the 24 hour nature of emergency departments and the continuous call on test results. Many employers interviewed for this project identified that their laboratories reported a higher incidence of pre-analytical errors in samples collected from emergency departments, samples collected by clinical staff (doctors, nurses) or medical scientists. In some public hospitals certain other specialised service delivery areas did not utilise pathology collection staff including neonatal intensive care, maternal, oncology and intensive care services.

Most outpatient clinics within public hospitals also had dedicated pathology collection staff who worked within the normal operating hours of the outpatient clinics. Some of these outpatient clinics also provide visits to patient homes for collections when patients were not able to attend the hospital. In some cases, pathology collection staff undertook collection ‘rounds’ in facilities linked to the acute care hospital, for instance, in associated aged care facilities or inpatient mental health services.

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6 In one hospital the pathology collection staff were employed and managed from the division of nursing and directed by the Director of Nursing, despite being paid for out of the pathology department budget.
Private hospital practice

Larger private hospitals and not for profit hospitals operate similarly to public hospitals with the exception that they were more likely to also operate collection centres in the community. The reasons for this were twofold — on the one hand, to generate income that might develop a level of self-sufficiency in funding, and on the other, to construct and retain relationships with GPs and doctors referring to the hospital. Other private hospitals interviewed for this project were serviced by private pathology laboratories. Unlike the public hospitals where collections tend to be organised around ‘morning’ ward rounds, in a large proportion of private hospitals consulted for this project, private pathology services offer private hospitals a 24 hour service.

Community based pathology collection practice

Currently within Australia there are three major private pathology organisations, Sonic Healthcare, Healthscope and Primary Healthcare. These three organisations operate the majority of Australia’s private, community based pathology collection services due to widespread amalgamations in a highly competitive pathology market. Private pathology organisations create relationships with individual doctors, medical centres and other health services within their geographic areas to be able to provide accessible, quality pathology services with the fastest turn-around-time to their patients.

The private pathology organisations that were interviewed for this project tend to be organised around a central urban based laboratory with numerous collection rooms located in suburbs around the laboratory and extending into regional areas. These collection centres can be staffed by one or more collectors and have been located to allow easy access for patients. These community collection centres have varying operating hours that are determined by the pathology service. Private laboratories have also established collection services within many GPs clinics to provide easy access for patients. Whilst there are cost implications, private pathology organisations do offer some home visit services to patients (often with two collectors to perform the collection due to safety reasons) in urban areas that are not able to attend collection services.

Whilst the majority of private pathology organisations are held under the umbrella of the three large private organisations mentioned above, there still remains a number of small, privately owned pathology laboratories in WA, SA and NSW that were identified for this project. They have established their services around a similar model to their competitors, but attempt to develop strong relationships with their specific medical practitioner ‘clientele’. They are able to make independent decisions about their staffing and operational procedures which will be discussed in Chapter 6 of this report.

Types of pathology specimen collections

The types of pathology specimen collections that are undertaken through collection processes are potentially many, and vary between pathology services. A list of the most likely types of pathology specimen collection is provided in Table 4 together with an indication of the types of tests undertaken commonly within hospitals or within community collection services. Note that in community collection centres some non-pathology testing is performed for cardiology purposes (e.g. electrocardiogram readings) but in the more specialist segmented environment of a hospital this not the practice.
### Table 4: Types of pathology tests according to where they are collected

<table>
<thead>
<tr>
<th>Types of pathology specimens collected</th>
<th>Within hospitals / public and private</th>
<th>Outside hospitals / community collection centres/outpatient clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood including evacuated or non-evacuated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autologous blood collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial blood collection (blood gases)</td>
<td></td>
<td>Rarely undertaken</td>
</tr>
<tr>
<td>Skin or capillary blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine or faeces collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swab collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin scrapings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naso pharyngeal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antenatal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNA parentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point of care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol and other drug testing services for employers etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea breath tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mantoux testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cannulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG (electrocardiogram)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holter monitor and blood pressure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pathology collection is denoted by the blue shading. The white on the Table indicates that the specimen type is not collected.

**International practice**

The process of collecting a blood sample from a vein, capillary or artery is fairly standard across the developed world. All samples would be collected into an evacuated tube collection system and there are only a small number of suppliers of these systems. Some samples would be collected using a syringe and needle although this is not a recommended procedure because of the greater risk of needle stick injury and haemolysis. Syringe collects are often used by staff who have not been trained in the use of the evacuated tube collection system - usually medical or nursing staff.
The organisation of collection centres does differ in different countries in terms of access and ownership. In the UK, the majority of pathology testing and hence, phlebotomy, takes place in the public National Health Service (NHS) system. Patients attend their local GP who will take the sample or they will attend a hospital outpatient collection area.

In the US, Canada, Germany and New Zealand there is a mixed system of public and private pathology providers and hence, different types of collection services available. GPs and hospitals provide the same service as they do in the UK, but in these other countries, as in Australia, there is a much greater level of pathology testing undertaken by private providers. The approximate percentage of testing undertaken by private pathology providers in selected countries is similar to Australian estimates of 60% viz.:

- Germany (60%);
- USA (46%); and,
- Canada (50%).

In those countries where there are private providers it is likely that the patient will present to a collection centre (or station) which may be stand-alone or be situated in a building with other medical services, most often a GP or group of GPs. Collection centres may be placed in suburbs based on the presence of GP or specialist providers, on major roads or near transport links to enable ease of access (recalling that many tests are fasting), near other healthcare providers (eg. X-ray) or in developing areas with high densities of potential patients (either young or old). Collection centres can range from a single person operation, often with limited opening hours, to large specialised collection centres which operate extended hours and provide a broader range of specialised testing such as drug screening, challenge tests, holter monitor and breath tests.

The placement of collection centres is a major focus of the marketing strategy of private laboratories aimed at increasing visibility to drop in patients or proximity to key referrers. Private collection centres are seen by pathology organisations to be the customer face of pathology and the location, appearance, comfort, ease of accessibility, operating hours and efficiency are critical in ensuring customer, both patient and referrer, satisfaction.

The problem confronted by Australian hospitals noted earlier in this Chapter of a significant proportion of pathology collection errors being attributed to non-specialist pathology collectors, has also been described in other countries. The UK Association of Clinical Biochemistry (2011) has published results from two studies undertaken of pathology collection in emergency departments, one in the UK that found more than 50% of the clinical laboratory samples collected by non-specialist collection staff used the wrong equipment, such as using syringes, instead of vacuum tubes with special needles. Researchers also found that about half of the samples were mishandled for laboratory testing, raising the risk of contamination. The same article identifies similar research in the USA which showed a haemolysis rate for emergency department specimens of 22.4%, compared to 3.9% among inpatient units (where specialist collectors are deployed). The study also pointed out that, because patients’ haemolysed specimens often had to be recollected and retested, wait time for results increased to an average of 56 minutes. Non-specialist collection staff are often not familiar with and therefore tended not to use the evacuated collection tube system for samples. This is discussed in greater detail in Chapter 4.

In the developing world the emphasis is on safety to the patient and collector and this is the thrust of the World Health Organisation (WHO) (2010) guidelines. In developed countries the emphasis is on improved collector efficiency and customer service. Perhaps the most developed and accessible quality improvement data comes from the UK NHS (2010) quality improvement program eQUIPP.
(Quality, Innovation, Productivity and Prevention). eQUIPP represents a whole of NHS program to improve all aspects of health care provision by the use of lean and quality improvement tools. The scope of the program can be seen in Figure 2 below:

**Figure 2: Overview of eQUIPP program in the UK**

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7 QIPP website - for quality improvement in National Health Services.
Chapter 4 - Quality and safety issues

Overview

In Chapter 1 the need for this study was raised and briefly canvassed. The motivation for the study is predicated on the existence of some quality and safety problems, and that current practice could be sub-optimal or at least amenable to improvement.

In this Chapter, the extent of pathology collection quality and safety problems is explored in more detail. A distinction is made in this examination between an industry perspective (that is from pathology laboratories themselves and associated industry bodies and professional associations) and a perspective from consumers of pathology testing services.

This distinction is important to understand as it raises the need for improvements in pathology collection and in the development of policy options. This is discussed further in later chapters. In the following sections two fundamental differences between the industry and consumer perspective will be demonstrated in regard to (1) how the perspectives are formed and, (2) the primary focus of the quality and safety perspectives.

In regard to how perspectives are formed, industry relies almost completely on quantitative data gathered through quality assurance processes and specifically constructed research projects. Consumer perspectives though, are most often formed through qualitative data, based on personal experience or knowledge of the collective experience of others.

In terms of the focus of quality and safety, industry’s perspective is primarily (though not exclusively) on the quality of the pathology specimen to be tested. Consumers on the other hand, primarily focus on the safety of the patient, although clearly they also have an interest in the quality of the sample.

Industry perspectives on quality and safety

Problem identification

Problems occurring during pathology collection processes are identified in a number of ways. The most common is when a specimen is rejected at the laboratory’s specimen reception as it has been incorrectly labelled, contaminated, collected into an inappropriate anti-coagulant, or the sample quality is compromised, for example, haemolysed or clotted samples. On receipt of results, referring doctors may realise that the test referral has been incorrectly interpreted, the patient incorrectly identified, incorrect or insufficient tests were undertaken or the results trigger an unexpected result for the patient.

A systematic way of identifying problems within pathology collection comes from the collection and analysis of sample data that forms part of the laboratory quality system. This data has been used in a number of attempts to identify causes of error and recommendations for system improvements. Within Australia, pathology organisations collect data throughout the pathology testing process to identify errors and make quality improvements through the KIMMS project. The KIMMS project was initiated by the Quality Assurance Scientific and Education Committee (QASEC) of the RCPA. KIMMS project data from 2011 strongly suggests that most problems in Australia are identified through laboratory quality control/improvements systems (see Table 5).
Table 5: Proportion of problems detected by means of detection in selected Australian pathology services in 2011 (based on KIMMS data)

<table>
<thead>
<tr>
<th>Means of incident detection</th>
<th>Quarterly data collection, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jan-Mar</td>
</tr>
<tr>
<td>Complaint (problem detected from outside the service)</td>
<td>4.5</td>
</tr>
<tr>
<td>Quality system (problem detected by internal processes)</td>
<td>95.5</td>
</tr>
</tbody>
</table>

The contribution of collection processes to pathology problems

As noted in Chapter 1, the focus of this study is on the pre-analytical processes. There is a large amount of evidence from the literature that identifies the pre-analytical stage as the area in which the majority of errors occur within pathology testing, thus supporting this focus. Plebani (2006) for instance states:

“Most errors are due to pre-analytical factors (46–68.2% of total errors), while a high error rate (18.5–47% of total errors) has also been found in the post-analytical phase.”

He notes that this is in direct contrast to pathology systems within the laboratory where sustained effort has resulted in significant reduction of errors. Lippi, Guidi, Mattiuzzi, and Plebani, (2006) also note that a:

“... lack of standardised procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process.”

Similarly, Bonini, Plebani, Ceriotti, and Rubboli (2002) in a mini review of the literature on errors in laboratory medicine and found that:

“... even when different study designs, patient numbers, and discovery techniques were used, the distribution of errors across the different phases of the entire testing process was very similar. This comes through despite the large differences in actual error frequencies. In particular, all available studies demonstrated that a large percentage of laboratory errors occur in the pre- and post-analytical phases, with fewer mistakes occurring during the analytical step.”

While collection processes contribute disproportionately to pathology errors, it is worth placing the total number of errors into perspective. Dale and Novis (2002) conducted research with pathology organisations in the US, Canada, Australia and South Korea to determine the success rate of blood collection on the initial encounter. They found that of 833,289 encounters of pathology testing considered, 829,723 (99.57%) were successful. Similarly KIMMS data from 2011 identified total pathology errors identified each quarter ranged from 1.38% to 1.56% of all pathology service episodes.

What errors are being made?

Khoury, Burnett and Mackay (1996) identified in an Australian survey on transcription and analytical errors that the transcription error rate was up to 39% (most frequent errors associated with misidentification of the requested tests, the requesting doctor and/or the patient). The laboratory with the worst performance had errors in 46% of requests and the three best performing laboratories achieved an error-free reporting of only 85%, with only one achieving 95%. They
identified a further critical pre-analytical factor affecting test results was the evaluation of specimen adequacy. The WHO (2010) also identifies clerical errors in completing forms and identifying patients as common.

Dale and Novis (2002) identified the most common types of errors as follows:

“Phlebotomies were unsuccessful because patients were not fasting as directed (32.2%), phlebotomy orders were missing information (22.5%), patients specimens were difficult to draw (13.0%), patients left the collection area before specimens were collected (11.8%), patients were improperly prepared for reasons other than fasting (6.3%), patients presented at the wrong time (3.1%), or for other reasons (11.8%). Only 2153 specimens (0.3%) were unsuitable; these samples were haemolysed (18.1%), of insufficient quantity (16.0%), clotted (13.4%), lost or not received in the laboratory (11.5%), inadequately labelled (5.8%), at variance with previous or expected results(4.8%), or unacceptable for other reasons (31.1%).”

Plebani (2006) in an investigation of pathology collection errors in different settings found overall that ...

“..., inappropriate quantity and quality of specimens account for over 60% of pre-analytical errors, while additional causes, such as incorrect identification of the specimen, lack of due signature, empty tube, lack or wrong compilation of the accompanying form, sample not in ice, tube broken in the centrifuge, urine not acidified or without volume indication present, show a lower prevalence.”

The KIMMS data categorises the two main types of pre-analytical errors as:

- Identification problems; and
- Sample problems.

The five main identification problems have been encountered by the KIMMS data include:

- Unlabelled sample;
- Mislabelled sample – any mismatch or discrepancy of identification;
- Insufficiently labelled sample – less than two identifiers;
- Transfusion labelling requirements – no collector signature, no time and date of collection; and
- Sample suspected to be from wrong patient – wrong blood in tube.

Bayley (2011) identifies that at the time of collection there is a three-way patient and sample identification process that includes identification of the patient face-to-face, pathology request documentation and sample label. When the sample reaches the laboratory for testing, there is only a two-way identification process: sample label and pathology request documentation. Up to this point errors are made due to human errors and processing a sample with an identification problem leads to misallocation of a test result to the wrong patient, resulting in negative health outcomes for the patient. Identification errors can only be recognised by chance once they reach the laboratory. To ensure these samples are not tested and results incorrectly reported they must be rejected for analysis.

At the time of sample collection, errors are made prohibiting a sample from being processed within the laboratory. The most common errors identified by Bayley’s interpretation of the KIMMS data include:

- Sample not collected;
- Incorrect sample type;
- Haemolysed sample;
• Clotted sample;
• Incorrect fill level of sample – e.g. coagulation tests;
• Insufficient sample;
• Contaminated sample – e.g. sample taken from drip arm; and/or
• Incorrect sample storage or transport.

Bayley (2011) attributes the majority of these errors to problems with the collector’s skill and adherence to procedures (although sometimes the condition of the patient can cause sample problems). She suggests samples received at the laboratory that are not suitable to be analysed must be rejected and a request made for the sample to be collected again. Obviously in some cases a sample cannot be recollected and these must be processed with comments about the circumstances of sample conditions. In cases where a sample can be recollected, there are issues of patient safety and distress as well as increased cost and time implications for all involved.

The WHO (2010) discusses problems that arise in relation to maintaining sample quality through transportation to the laboratory:

“Jostling and jarring of test tubes in transit can lyse or break open red blood cells, causing false laboratory results.”

There are also effects due to temperature variations on samples as they are transported. Interviews with employers and other stakeholders in this study suggested transport issues were only ever a problem in remote areas, particularly when transporting samples from remote Aboriginal primary health care services. However, this only makes up a very small fraction of total tests in Australia.

Who makes the errors?

Dale and Novis (2002) in a study of practices in several countries, including Australia, found facilities staffed by laboratory-administered phlebotomists reported lower rates of error than facilities staffed by non-laboratory-administered phlebotomists. Interestingly, their data accorded with comments provided by pathology laboratories gathered through the employer interviews, that pathology collection staff had higher success rates than other nursing and medical staff performing blood collection. This was especially noticeable in public hospitals where, as noted in Chapter 2, the performance of pathology collection work was often starkly divided between specialist pathology collectors and clinical staff in different departments and wards. Thus, those service departments with 24 hour or significant after hour service delivery requirements (e.g. emergency departments, obstetrics departments) or departments where the routine collection approach of laboratory controlled collectors was not appropriate (e.g. cancer clinics) tended to have higher error rates.

A similar observation was offered by private community based employers, who noted that pathology specimens collected through general practices accounted for a disproportionate share of the total pre-analytical errors. This broad belief about collection problems mostly being associated with non ‘specialist’ pathology collection workforce is generally supported by KIMMS data as detailed in Table 6 below.

8 And therefore after hours pathology request patterns.
Table 6: Proportion of total pathology problems detected by source of incident in selected Australian pathology services in 2011 (based on KIMMS data)

<table>
<thead>
<tr>
<th>Root source of incident</th>
<th>Proportion (%) of total errors in each quarter</th>
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<tbody>
<tr>
<td></td>
<td>Jan-Mar</td>
</tr>
<tr>
<td>Source of incident outside laboratory control</td>
<td>60.2</td>
</tr>
<tr>
<td>Source of incident within control of laboratory</td>
<td>31.4</td>
</tr>
<tr>
<td>Source of incident mixed</td>
<td>8.3</td>
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</tbody>
</table>

Plebani (2006) in an investigation of the difference in errors between inpatient and outpatient pathology collections, found a significant difference regarding the frequency of errors between outpatients and inpatients (more errors in inpatient services). Plebani reasoned that at least some of this difference could be related to competence:

“... This difference should be related, in part, to the higher complexity of examinations performed and multiple blood drawings for inpatients, but also to the more accurate control assured by laboratory personnel who perform sample drawings for outpatients. On the other hand, the blood drawing performed by ward personnel, with a higher turnover and less specific skills, may lead to an increase in the number of mistakes.”

Lippi, Guidi, Mattiuzzi, and Plebani, (2006) also identified a considerable difference between the error rates for pathology collections for in- and outpatients (0.60% vs. 0.039% respectively). They concluded that patient care involving non-laboratory personnel seems to account for the majority of errors, representing 95.2%.

Consumer perspectives on quality and safety issues

As noted at the start of this Chapter, consumer perspectives on pathology collection services focus more on the patient than on the pathology sample or specimen. This tends to translate into an emphasis on the quality and safety of the pathology collector. While both industry and consumers consider the process, for consumers this is more about the degree of safety in the way the collector relates to the patient than the quality of the sample obtained (although this is accepted as a predetermined outcome).

Issues of quality and safety identified by consumers

The CHF undertook an investigation of consumer issues in relation to pathology services within Australia in 2010. A range of issues spanning the pathology sectors across Australia were discussed, amongst these were some elements of pathology collection. The CHF draft summary document (Jan 2010) identified:

- Communication was a major concern for consumers, particularly on instructions to prepare for tests, the ‘out of pocket’ costs and when results would be available;

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Note that this is the reverse of the Australian public hospitals, but in this case the laboratory controlled collection workforce is associated with collection in the outpatient setting.
Access (and equity of access) was a major concern for all consumers, especially those in rural, remote or regional areas, with disabilities, cultural and linguistically diverse consumers, aged and from low socioeconomic backgrounds. Equity of access related to ‘out of pocket’ costs, access to a range of tests, choice of laboratories and physical access to tests and laboratories;

- Availability of services and staff, especially quality practitioners and laboratories;
- Desire to increase access to point of care testing;
- Safety and quality of pathology testing – lack of consumer confidence (possibly due to lack of information) in accreditation processes and the existing standards; and
- Perceived inconsistencies between States and Territories – consumers wanted laboratories across the country to be standardised to ensure the same quality of service.

Specifically for pathology collection processes the CHF summary of consultations (June 2010) identified that consumers recognise:

“...the importance of ensuring positive identification of both the patient and the pathology sample. It is essential that the person administering the test or taking the sample ensures correct identification of the patient at the time the sample is taken and then correct labelling of the sample before analysis. Ramifications of an incorrectly identified sample could be catastrophic for the consumer. Unfortunately, there were many examples provided by consumers of samples being attributed to the wrong consumer.”

Consumers also noted that the pathology accreditation process is limited only to what happens in pathology laboratories. While acknowledging pathology services had “put their own house in order”, they argued that problems still existed at the interface between the doctor, the pathologist and the consumer which fall outside accreditation. Problems were reported, for example, in the ordering of tests, the collection of samples at collection centres and the communication of results.

In the USA, Dale and Howanitz (1995) conducted a large survey to measure patient satisfaction at 540 pathology collection organisations. They identified a similar set of factors that impacted on patient satisfaction to those more recently identified by CHF. They summarised these factors into three main areas of quality and safety concern as follows:

- Characteristics of the organisation offering the service, such as the facilities, ease of access, technology in use, flexibility and scope of services available;
- Individual characteristics of the employees providing the service, such as their attitude, skill, responsiveness, and ability to make decisions; and
- Unique characteristics of each patient, such as their previous experiences or expectations, personality traits and level of health.

The first two of these dot points were also raised frequently during consultations with consumers. Their thoughts on these issues are discussed below.

**Access to pathology services**

Access to pathology services was a major issue for consumers who lived in urban, rural and remote areas of Australia and each of these locations posed different challenges as consumers wanted access to services located near to where they live. Access to pathology services is also a concern for mobility challenged consumers i.e. the elderly, non-drivers or financially disadvantaged consumers who can only use public transport and need to access pathology collection services on the bus routes or train lines. Consumers viewed that the best solution to improve access to pathology services was
to co-locate with GP services. For a number of elderly and disabled mobility challenged consumers, their preference was for pathology collection services to come to their homes.

In urban areas access issues were around the ability of consumers to locate the collection services, excessive waiting times (and lack of ability to book appointments), and the varying and often restrictive hours of operation. In rural and remote areas, consumers have to travel distances to access pathology collection centres. The sample is then sent to city laboratories to be processed, which creates delays in access to the results and resultant diagnostic and treatment delays which impact on the health of the consumer.

In all locations, the structure and amenities of the pathology collection service were of interest to consumers. Consumers reported that the pathology collection centres required a room to provide privacy for the consumers when handing in samples for testing or discussing the tests that were undertaken. Standard requirements considered essential for customers in pathology collection centres include a water fountain, comfortable chairs, bathroom and the provision of advice on waiting times for collections.

Within the ACT consumer consultations, an issue around the interchange between public and private pathology services and how it affects consumers’ access to services was identified. During the recent whooping cough outbreak in the ACT access to pathology services was a significant concern to many consumers. It was reported by interviewees that they believed that all mouth swabs collected were sent to QLD for testing as public providers were unable to send samples to private labs for processing. This created major delays in obtaining results and meant quarantining practices were compromised. Consumers therefore identified a need for streamlining processes especially between public and private pathology systems. Significant ‘systems’ issues were identified by consumers during this period as follows:

- timeliness of results;
- closing the loop of referral and receipt of pathology results;
- the nexus between private and public is seen as a barrier; and
- sick leave for infected workers or school absences were not confirmed for some time due to the lag time in waiting for receipt of results, resulting in the disease being further contracted by other students and work colleagues.

**Technical competence of individual pathology collectors**

Regular consumers of pathology collection (especially blood collection) services reported a perception that some collectors possess better skills than others. This perception was based on their experiences of previous blood collections. Essentially, consumers identified that their technical concerns were centred on the ability of pathology collectors to find and access a vein within three attempts and that consumers were not bruised as a consequence of the procedure. Consumers suggested that if a collector had made three unsuccessful attempts to draw blood that they would prefer it if another more experienced collector was sought to complete the blood collection.

It was acknowledged however, that some medical conditions can make accessing a vein difficult for collectors and only collectors with sufficient experience (regardless of their qualification) should be undertaking these types of collections. Similarly, experiences from consumers regarding collections from infants and children identified the need for experienced and competent collectors in order to reduce the trauma of the experience and therefore reduce the chances of the consumer developing...

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10 A number of consumers suggested that a pathology collector should not be taking blood samples unsupervised unless they had at least six months experience.
phobias. A number of consumers also commented that GPs were on the whole ‘not great’ at blood collection and that they preferred pathology collection staff to take blood.

A further technical competency identified by consumers was the ability to identify and be able to respond when something ‘out of the ordinary’ occurred. This meant a greater understanding of medical complications from procedures than a general ‘first aid’ course\(^\text{11}\). This included the ability to respond appropriately to an adverse situation, identify when it was appropriate to refer to another more experienced or appropriately skilled collector, when to isolate issues and how to take the action required.

Infection control was identified as a technical concern for a number of consumers. They discussed a need for pathology collectors conducting invasive procedures with infection control risks to undergo some form of nationally uniform competency based assessment which includes quality and monitoring components in line with credentialing requirements of the wider health workforce. Consumers were not concerned at what level this should be (Cert III/IV, etc.,) but were adamant that this credential should be from an “external body”, not by the employer.

The CHF in their report on the 2010 consultations advocated the introduction of credentialing of the people who collect samples at collections centres. They further argued for the creation of stronger links between assessment of pathology collection processes and collectors and other accreditation processes that currently focus mostly on laboratories.

**Issues of customer service — pathology collection process from a consumer perspective**

Consumers discussed a range of expectations of pathology collection services, especially around ‘customer service’ competencies of the individual collectors. Regularly, consumers reported that they attended pathology collection services with limited communication with the pathology collector about what was occurring and this was a major concern as they were ‘customers’ of the collection service who wanted to be treated with respect and be fully informed of the procedures they were receiving. One consumer summarised this well:

> “Most consumers want to be walked through a process, even when they are likely to know what it is all about. I went three times in one week to have blood drawn and was only ever asked my name and date of birth. I was not given any information about what was happening to me. Consumers feel collection staff should treat them each time as if it is their first visit and explain the procedures. Too often no explanation is provided and questions are never invited.”

Consumers reported that pathology collectors who would engage them in conversation and were prepared to discuss the medical requirements and needs of the consumer and would take advice about from which arm to attempt to collect blood. Other collectors who would not engage the consumer in conversation or would disregard consumer advice and attempt to draw blood from the ‘wrong’ arm, caused unnecessary distress and bruising to the consumer. In order to improve the accuracy of the sample collected and improve the experience for consumers, it was suggested that pathology collection staff should be required to...

> “...explain every detail of the process to consumers as if it was their first time as part of the process required”.

Consumers advised that in any other medical procedure the health care worker explained the procedure in detail and that an invasive procedure such as blood collection should be no different. In addition, consumers often required information about how the results would be processed and communicated back to them and felt that this should form part of the explanation of process.

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\(^\text{11}\) Interestingly, industry sources have argued (see Chapter 7) that not all collectors require first aid competence, but that such competence needs to be available in every collection situation.
The importance of ‘customer satisfaction’ as an indicator of the quality of pathology collection services is emphasised through data from the USA. The Q-Probes (95-04) quality data collected by the College of American Pathologists has found that high quality phlebotomy services require that phlebotomy staff possess both technical expertise and strong interpersonal skills. In the Q-Probes customer service issues (discourteous, wait times, poor service) represented 60% of complaints about the pathology collection process, with discomfort (28%) and bruising representing the remainder.

In order to provide consumers with a satisfactory pathology collection experience, the consumer discussions identified the following ‘customer service’ attributes and competencies required for pathology collectors:

- Empathy;
- Use electronic health records;
- Ability to work with very ill consumers;
- Ability to work within an ethical code of conduct;
- Respect a consumer’s privacy;
- Ability to communicate openly;
- Ability to manage ‘out of the ordinary’ responses within a collection process;
- Cultural awareness and sensitivity; and
- Ability to deal with clients who have mental health issues or impairments as a result of physical or mental disabilities.

Consumers noted in the consultations that patients may lodge a complaint with a collection service if they are dissatisfied with the way in which they have been treated by a collector or because of poor procedure, for example excessive bruising or nerve damage from a blood collection procedure. However, they thought generally that the processes for lodging complaints were onerous, and therefore likely to minimise actual complaints lodged, a thought reflected by Dale and Howanitz (1995). The CHF in its report on the 2010 consultations noted specifically the need to implement transparent complaints processes to encourage and review consumer complaints in relation to pathology testing.

Specific consumer services issues

In order to address communication challenges for pathology collection services with non-English speaking background consumers, a number of consumers suggested that a mandatory brochure (to be given to consumers from the requesting doctor) and signs displayed in waiting rooms that explain the pathology collection process in various languages should be developed. This information should include, a description of the process of request/test/report pathology cycle, billing advice, what to expect from the pathology collection service, what will happen during different collection types, what will happen to the sample, how the results will get communicated to consumers, how long each process take and complaints processes.

In Aboriginal primary health care services, particularly those located in remote areas, the level of training pathology collectors have received is largely unknown which can lead to a great variation in competence. A unique problem is experienced in these communities during the identification and labelling of samples as Aboriginal consumers may have identical names, shifting names and often their date of birth is unknown.

Furthermore, specimen transport from remote clinics or storage problems can increase the potential for samples to be haemolysed and provide false high potassium readings. These services rely on the
private laboratories in the major cities to process the test results again creating delays in receipt of results.
Chapter 5: Defining best practice pathology collection

‘Best practice’ is a set of agreed techniques and procedures that represent the best way in which health workers can collect a quality pathology sample whilst maintaining the safety of their patients and themselves. WHO (2010) identifies the safety issues for patients can include bruising at the site of puncture, fainting, nerve damage and haematomas. Contaminated samples can result in incorrect results from testing which can lead to misdiagnosis and wrong or unnecessary treatments and recalling patients to redo the test:

“... the touch of a finger to verify the location of a vein before insertion of the needle increases the chance that a specimen will be contaminated. This can cause false blood culture results, prolong hospitalization, delay diagnosis and cause unnecessary use of antibiotics.”

WHO (2010) identifies risks to health workers must be considered in light of the fact that needles used to collect blood samples carry a large volume of blood that, in the event of an accidental puncture, may transmit disease. Risks can be increased when phlebotomists:

- recap used needles using two hands (the use of one hand ensures that at no time there is contact with the needle point);
- recap and disassemble vacuum-containing tubes and holders;
- reuse tourniquets and vacuum-tube holders that may be contaminated with bacteria and/or blood; or
- work along with confused or disoriented patients who may move unexpectedly contributing to needle stick injuries.

Quality and safety issues underpin the need to establish best practice in pathology collection services. As mentioned in Chapter 4, the pathology industry relies on the collection and auditing of quantitative data collected within laboratory systems to identify problems with samples or collection processes, the emphasis is therefore on the sample not the patient. Consumers rely on qualitative data collected that details issues that have occurred during conduct of the pathology collection service and are focused on the patient rather than the sample. To establish best practice pathology collection both the service (customer focus) and technical (laboratory focus) processes are considered and is established by three components:

1. A consensus on the technical aspects or procedure that is undertaken by pathology collectors when collecting blood from a vein. This component is described well in the international literature on best practice blood collection, also described as phlebotomy or venepuncture. The procedure needs also to consider consumer expectations.

2. Structured quality assurance systems linked to accredited management standards such ISO 15189, in conjunction with laboratory systems to detect errors in samples; and

3. Assessing and maintaining competence of pathology collectors (including customer service competencies) through training programs that develop the correct skills and techniques required and can provide a structure from which to assess individual competence and benchmark practice.
Technical aspects / procedures in blood collection

Whilst there is not a lot of literature available that defines the entire best practice pathology collection process, there are examples that relate to the technical components of collecting blood from a vein (venepuncture or phlebotomy). The WHO (2010) conducted a systematic literature review and examined evidence of best practice phlebotomy in developed nations to develop a set of guidelines to “improve the quality of blood specimens and the safety of phlebotomy for health workers and patients, by promoting best practices in phlebotomy”. The guidelines are intended to be adopted and adapted to suit pathology collection practices internationally and will be reviewed again in 2014. To ensure patient safety, WHO (2010) identified that the following is required for best practice phlebotomy:

- Health workers must be trained to conduct the specific types of collections they will be undertaking;
- Health worker training must include techniques to ensure that the specimen collected is adequate and teach practices to reduce the risk of contamination, clerical error, infection and injury;
- Special training and practice is required for health workers collecting blood samples from children and infants;
- Health workers must practice appropriate hand hygiene before and after dealing with each patient and wearing well fitting non-sterile gloves;
- Blood should be taken in a dedicated location that ensures patient comfort and privacy;
- All work surfaces including work counters and chair arms should be cleaned with disinfectant at the start of each shift and when visibly dirty;
- Health workers should follow the guidelines on patient identification, hand hygiene, use of gloves, skin disinfection, use of appropriate blood-sampling devices and safe transportation of laboratory samples; and
- Respect patients’ rights by including patient consent and cooperation in collection practices. This can be helped by providing simple written information on the procedure.

Clinical Laboratory Standards Institute (CLSI) is an international organisation that develops standards and guidelines to promote the development and use of voluntary consensus standards for the health care community. Maxwell (2010) from the American Society of Phlebotomy Technicians describes CLSI’s updated phlebotomy practices in relation to guidelines (and technical requirements) for the steps in conducting a venepuncture. The CLSI guidelines were endorsed by Riedell and Carroll (2010) in a review of optimal blood culture practices which included an examination of blood collection practices in efforts to assist in the reduction of bloodstream infections.

In the UK, Lavery and Ingram (2005) provide guidance on the theory and practice of venepuncture (collecting blood from a vein) in an attempt to describe best practice for this process. They believe that the practice of venepuncture should be universal and not dependent on what type of health worker is conducting it, namely: phlebotomists, clinical support workers, registered nurses, midwives and medical staff and all should be training to best practice standards. Lavery and Ingram also specifically provide direction for ‘good practice’ when utilising a vacuum system, a butterfly device and generally for blood cultures.

Specifically in relation to emergency departments in the UK, Lowe, Stike, Pollack, Bosley, O’Brien, Hake, Landis, Billings, Gordon, Manzella, and Stover (2008) identified that experienced nurses can reduce the number of haemolysed specimens by collecting blood through venepuncture instead of through intravenous catheters. This practice created a best practice standard of care for emergency
department settings which can also be applied to all hospital settings. Within the research method the processes of conducting a venepuncture were identified and can be used to help build an understanding of best practice blood collection.

Within Australia, no published literature was identified that discussed best practice processes for pathology collection. However, throughout the employer interviews procedures manuals were viewed that largely covered the best practice processes outlined in the international literature above, especially the WHO (2010) processes.

A comparison of each of the procedures provided from the above literature was undertaken to develop a consensus of the literature on best practice steps in a blood collection procedure. The results of this comparison are shown in Table 7 below. The shaded boxes represent a procedural step included in each literature sources’ description of best practice.

**Table 7: Comparison of international literature on best practice blood collection technique**

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<tr>
<td>Assemble equipment</td>
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<tr>
<td>Identify and prepare the patient</td>
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<tr>
<td>Verify fasting or dietary states</td>
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<td></td>
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<tr>
<td>Checking for latex sensitivity or other allergies</td>
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<tr>
<td>Check pathology request form</td>
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<td></td>
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<tr>
<td>Position the patient</td>
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<tr>
<td>Select the site</td>
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<tr>
<td>Perform hand hygiene and put on gloves</td>
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<td></td>
<td></td>
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<tr>
<td>Apply tourniquet</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disinfect the entry site</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Take blood</td>
<td></td>
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<tr>
<td>Fill the laboratory sample tubes</td>
<td></td>
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<tr>
<td>Draw samples in the correct order</td>
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<tr>
<td>Invert (rotate) tubes immediately</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Check patient and venepuncture site (apply pressure)</td>
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<tr>
<td>Label the tubes correctly whilst patient is present</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Clean contaminated surfaces and complete patient procedure</td>
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<td></td>
<td></td>
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<tr>
<td>Prepare samples for transportation</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Clean up spills of blood or body fluids</td>
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Structured quality assurance systems and prevailing regulatory processes to ensure best practice pathology collection services

As introduced in Chapter 1, every Australian medical (pathology) laboratory seeking rebates from the federal government must be accredited by NATA and RCPA. The NATA/RCPA accreditation process is informed by NPAAC which produces standards and guidelines defining minimal requirements for best practice laboratories. NPAAC use ISO 15189 as the basic standard and develops other more specific standards where ISO 15189 is perceived to be deficient or where there is a particular public risk from a procedure. In terms of pathology collection processes and procedures then the overarching standard used to develop and accredit minimal standards is the ISO 15189 standard together with the NATA Field Assessment Document (FAD) which elaborates on and clarifies particular clauses of ISO 15189, and the particular NPAAC Guidelines for Collection Rooms.

ISO 15189 is written in the form of a Quality Systems Standard based on the generic ISO 9000 but specialised to pathology laboratories. The processes of sample error detection and system improvement are based on the concept of non-conformance, audit and management review. Laboratories are geared to collecting non-conformances and dealing in a systematic way with these to identify the underlying problem and change the process so that the error is eliminated where possible. Auditing involves reviewing current operating procedures against documented procedures to see if there is consistency. Audits should also lead to changes to these procedures where improvements can be made. Management review is a formalised process where all the non-conformances, audits, customer complaints and feedback are reviewed to ensure they have been effectively acted upon and that there is a plan to audit the entire system.

Pathology collection services are managed under this framework to ensure best practice is observed. Errors detected by the laboratory or customer complaints will be formally analysed and reviewed via the quality systems process. It should be recognised that laboratory non-conformances tend to be specimen based rather than patient based as the laboratory receives specimens and does not usually deal directly with the patient. Non-conformances about specimen quality and quantity are readily detected and feedback would be given to the relevant collector. Problems with patient interactions or bruising consequent to drawing blood would only become apparent to the collection centre if the patient complained.

When a pathology laboratory is assessed by NATA/RCPA, its quality system would be reviewed and any collection errors raised would be reviewed to ensure an appropriate process was followed. Standard operating procedures are based on meeting the ISO 15189 standard plus the NPAAC guideline. These guidelines assess the pathology laboratory however the collection centres are commonly located remote to the pathology laboratory. Whilst the NATA/RCPA accreditation process of assessment against NPAAC standards and guidelines based on ISO 15189 to define minimal standards is considered generally to be acceptable for good laboratory practice, these guidelines are insufficient to identify competence in individual pathology collectors. The guidelines do not stipulate any performance or competence requirements for pathology collection staff such as a designated qualification.

Competence

To ensure best practice in pathology collection services, pathology collection staff should be assessed as competent against best practice guidelines or qualifications that cover not only the technical component of the role (described above) but also the customer service component. Lavery and Ingram (2005) believe that maintaining competence is essential to ensure best practice venepuncture and that it requires knowledge, skill and application using clinical judgement as well as the need to maintain competence through regular practice, supervision and assessment.
The range of individuals within health service structures that perform pathology collection each bring different competencies to the process of collecting a pathology sample. The consumer and employer consultations identified medical staff, including doctors and nurses, brought customer service competencies to the task but lacked competence in the technical and procedural (e.g., patient identification and labelling tubes) components of the blood collection process. Conversely, specialist pathology collectors often appeared to lack customer services competencies but were competent in the technical and procedural components of a blood collection.

An essential area of the pathology collection process is the way the service is delivered to customers including reception, administration of the request documentation, patient identification, informing the patient of the process and identifying any previous problems or risks and interpreting the needs of individual patients. As mentioned above, the best practice processes described cover the technical processes of collecting blood but not the way the service is delivered. The exceptions to this are identified by Lavery and Ingram (2005) as follows:

- “Determine the patient’s preferred site for the procedure based on his or her previous experience”.
- “Allow the patient time to ask questions and express concerns about the procedure.”

Both of these items arose in the consumer consultations as requiring improvement in the way that collection staff provided their service.

Whilst the current motivation of the pathology industry is to monitor best practice through the quality assurance systems that focus on samples rather than patients, there is no strong articulation of best practice in the service delivery component of pathology collection processes. This highlights the need to look for broader practice in customer service as the current procedures are deficient.

An investigation of existing competencies required for pathology collectors in Chapter 7 of this report identified the US National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) as the closest to best practice. However, the NAACLS competencies still do not sufficiently cover the customer services competencies required for the role. Within Australia, the current relevant qualification (Cert III in Pathology) compares reasonably well with the NAACLS competencies and is seen as credible by employers, however it also lacks sufficient customer service content.

**Performance measures**

In order to assess the performance of an individual or organisation against best practice in pathology collection a range of measures can be employed that include:

- Ensuring organisational standard operating procedures are developed in line with best practice pathology collection;
- Observing pathology collection staff are following standard operating procedures;
- Observing pathology collection staff performing the pathology collection process. In the case of blood collection count how many attempts before a successful attempt resulted in a quality sample;
- Monitoring and acting on customer complaints;
- Laboratory quality assurance systems identifying samples are labelled correctly;
- Laboratory quality assurance systems assessing the quality of the sample to be analysed;
- Assessing competency of all staff conducting pathology collection services against best practice qualifications or processes.
Chapter 6 - The pathology collection workforce

Current pathology collection workforce characteristics

The pathology collection workforce includes individuals employed by pathology service delivery organisations across public, not for profit and private hospitals and private community based laboratories to collect samples for analysis from patients across a range of services discussed earlier in this document (Chapter 3). The employer interviews found the terminology used by phlebotomist and pathology collectors were similar (but not by the same employer), however, terminology often varied between states and territories, and even within jurisdiction between service settings. The terminology employed by pathology collectors appeared to be the most commonly utilised within the pathology sector, especially in the private sector laboratories.

Within the Australian and New Zealand Standard Classification of Occupations (ANZSCO) there is no specific classification for pathology collectors, instead they are included in the broader occupational classification of Medical Laboratory Technician (Code 311213). The definition for this occupation is as follows:

Persons who perform routine medical laboratory tests and operate diagnostic laboratory equipment under the supervision of medical laboratory scientists and pathologists. Their primary tasks are taking, collecting and labelling blood, urine and other samples from patients, preparing and staining slides and tissue sections for blood and histological examination, performing diagnostic tests on tissues and body fluids and analysing the chemical constituents of blood, urine, faeces and tissues, and testing for diseases by looking for the presence of antibodies and the products of immune response in samples.

Because there is no separate classification for pathology collectors in the ANZSCO classification structure, it is impossible to obtain reasonable estimates of the workforce size. The Australian Bureau of Statistics (ABS) 2006 Population Census however, estimates the medical technician workforce to be 11,676, of which a significant proportion would be collectors, though this proportion will vary between pathology service settings. In hospitals, especially public hospitals, the pathology collection workforce is a comparatively small proportion of total service staffing. In the community based private pathology laboratories though, the number of pathology collectors is much larger, the result of much more complex and geographically distributed collection structures. Michael Legg and Associates (2010) calculated that pathology collectors in the private laboratory sector account for one third of total staff numbers as shown in Table 8 below.

Table 8: Distribution of staff to major workforce categories in private pathology laboratories

<table>
<thead>
<tr>
<th>Broad workforce category</th>
<th>% of total staffing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathologists</td>
<td>3%</td>
</tr>
<tr>
<td>Medical Scientists</td>
<td>21%</td>
</tr>
<tr>
<td>Medical Technicians</td>
<td>4%</td>
</tr>
<tr>
<td>Laboratory Assistants</td>
<td>12%</td>
</tr>
<tr>
<td>Pathology Collectors</td>
<td>33%</td>
</tr>
<tr>
<td>Couriers</td>
<td>7%</td>
</tr>
<tr>
<td>Clerical</td>
<td>17%</td>
</tr>
<tr>
<td>Support</td>
<td>3%</td>
</tr>
</tbody>
</table>
In 2010, the Australian Government deregulated the number of collection rooms that pathology organisations could operate opening up the way for numerous new collection centres to be established. The Financial Review noted:

“Primary, the nation’s largest private medical centre operator and one of the biggest pathology providers, opened the most collection centres after deregulation, adding 560 sites as at June 30. Rival Sonic Healthcare has added 364 centres, while private-equity-owned Healthscope added 322. The remaining industry players added 218 centres.”

It is estimated that this growth added approximately 35% to the number of collection centres in Australia, imposing a significant growth in demand for pathology collection staff even if a majority of these new collection centres were quite small.

Responding to these workforce demands in such a short time frame could obviously challenge employers to maintain the uniform standard of collection centres with appropriately competent pathology collection staff, although none of the employers that were interviewed identified this as an immediate problem. Some of the demand was no doubt ameliorated by private pathology organisations creating more relationships with individual doctors, medical centres and other health services within their geographic areas. While this approach would reduce the demand for pathology collectors, it could increase the pathology collection error rate. As has been identified earlier, the competence of non ‘specialist’ persons (more occasionally) collecting pathology specimens tends to be lower than for laboratory controlled (and trained) specialist pathology collection staff.

This sudden growth in demand for pathology collection labour has probably hastened a longer term trend in the decline of the use of nurses in pathology collection work. The longer term trend has been underpinned by the relative imbalance in the cost of employing nurses over pathology collectors and the inability for nurses to maintain their registration status if only undertaking collection tasks. Apart from some complex pathology collection procedures employment of nurses in pathology collection now seems to be constrained to a few public hospitals only where traditional ways of organising the work (for instance having pathology collection work administered from a Department of Nursing rather than pathology) or specialised collection processes (for instance specialist hospitals where the patient population routinely present sample collection challenges) prevail. Only two of the hospitals interviewed for this project reported that they had continued their historical practice of employing registered nurses rather than pathology collectors, arguing this was justified on the basis of the type of patients they were servicing. These organisations focused on very ill pre-surgery and cancer patients where collections were considered more difficult and it was believed patient needs were best serviced by a level of professionalism and empathy in the collector that was best provided by registered nurses. An example of both work organisation and the composition of the patient population affecting the collector workforce is the Peter MacCallum Cancer Institute where pathology collection staff report to the Director of Nursing and are all nurses, and patients are required to frequently give blood from difficult to locate veins.

Pathology collector entry level qualifications

There is no mandatory requirement for pathology collectors to have a particular qualification however the laboratories that employ them are subject to strict guidelines for accreditation by NPAAC. This places an imperative on laboratories to demonstrate minimum competence of pathology collectors to perform the work adequately. Additionally, consumers are increasingly demanding demonstrated minimum competence levels of workers who are undertaking reasonably frequent invasive procedures. The CHF consultation processes (June 2010) identified that consumers...
were concerned that credentialing of pathology collectors is not mandatory. They noted more generally that it was important to ensure:

“... there is increased transparency and accountability about the collection practices. Development of mechanisms to ensure adherence to proper procedures at collection centres, established with the involvement of consumers so that their experiences of the pathology process can be taken into account, would also play an important role in the credentialing process.”

The most obvious way of demonstrating competence is to point to a qualification — in this context the suitable qualification being the Certificate III in Pathology (course code HLT32612). All employers interviewed understood this and accordingly had been for some years attempting to gradually replace any unqualified collection staff with those holding the Certificate III qualification. Nevertheless, most employers still had a significant proportion of their staff who did not hold a Certificate III.

Figure 3 below, based on 2006 ABS Population Census data, indicates that just over one third of laboratory technicians (ANZSCO code 311213) at the time were unqualified. While not an entirely accurate measure for the pathology collection workforce (because code 311213 also includes laboratory assistant and technician workforce), it could reflect the data collected from interviewed employers on their pathology collection staff composition.

**Figure 3: Distribution of the Medical Laboratory Technicians (ANZCO 311213) workforce category by highest qualification attained**

![Bar chart showing distribution of qualification levels](image)

**Key to levels of qualification attained**

A = Bachelor Degree and above  
B = Advanced Diploma and Diploma Level  
C = Certificate IV  
D = Certificate I to III  
E = Year 12 or below/ No educational attainment/ Inadequately described  
F = Not stated

**Source:** ABS Population Census, 2006
While one third of unqualified staff represents a high proportion of the pathology collection workforce, many employers would contend that this portion of the workforce tends to be composed of older and more experienced workers who they would claim had learnt their skills on the job over many years and were therefore potentially more ‘qualified’.

The Certificate III in Pathology is in the National Health Training Package and like other equivalent qualifications is competency based, and therefore has no expected timeframe for completion. There are six core units of competency for the Certificate III as shown in Table 9 below.

**Table 9: Comparison of units of competency for Certificates III and IV in Pathology**

<table>
<thead>
<tr>
<th>Units required</th>
<th>Certificate III</th>
<th>Certificate IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core units</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSFLM303C</td>
<td>Contribute to effective workplace relationships</td>
<td>BSFLM303C Contribute to effective workplace relationships</td>
</tr>
<tr>
<td>BSBMED301B</td>
<td>Interpret and apply medical terminology appropriately</td>
<td>BSBMED301B Interpret and apply medical terminology appropriately</td>
</tr>
<tr>
<td>HLTFA311A</td>
<td>Apply first aid</td>
<td>HLTFA311A Apply first aid</td>
</tr>
<tr>
<td>HLTIR301C</td>
<td>Communicate and work effectively in health</td>
<td>HLTIR301C Communicate and work effectively in health</td>
</tr>
<tr>
<td>HLTIN301C</td>
<td>Comply with infection control policies and procedures</td>
<td>HLTIN301C Comply with infection control policies and procedures</td>
</tr>
<tr>
<td>HLTWHS300A</td>
<td>Contribute to WHS processes</td>
<td>HLTWHS300A Contribute to WHS processes</td>
</tr>
<tr>
<td>HLTHIR402D</td>
<td>Contribute to organisational effectiveness in the health industry</td>
<td>HLTHIR402D Contribute to organisational effectiveness in the health industry</td>
</tr>
<tr>
<td>HLTHIR405B</td>
<td>Show leadership in health technical work</td>
<td>HLTHIR405B Show leadership in health technical work</td>
</tr>
<tr>
<td>HLTHIR506C</td>
<td>Implement and monitor compliance with legal and ethical requirements</td>
<td>HLTHIR506C Implement and monitor compliance with legal and ethical requirements</td>
</tr>
<tr>
<td><strong>Elective group A – work in pathology collection</strong></td>
<td>HLTPAT305D Operate efficiently within a pathology and specimen collection environment</td>
<td>HLTPAT305D Operate efficiently within a pathology and specimen collection environment</td>
</tr>
<tr>
<td>HLTPAT306D</td>
<td>Perform blood collection</td>
<td>HLTPAT306D Perform blood collection</td>
</tr>
<tr>
<td>HLTPAT308D</td>
<td>Identify and respond to clinical risks associated with <strong>pathology specimen collection</strong></td>
<td>HLTPAT304D Collect specimens other than blood</td>
</tr>
<tr>
<td>HLTPAT410D</td>
<td>Collect pathology specimens other than blood for specialised testing (Note pre-requisite of HLTPAT304D)</td>
<td>HLTPAT410D Collect pathology specimens other than blood for specialised testing (Note pre-requisite of HLTPAT306D)</td>
</tr>
<tr>
<td>HLTPAT411D</td>
<td>Perform blood collection for specialised testing (Note pre-requisite of HLTPAT306D)</td>
<td></td>
</tr>
</tbody>
</table>

Another eight elective units must be selected, which is guided by the desired pathway of study for individuals wanting to work as a pathology collector or as a pathology assistant (in the laboratory). For the purposes of this study, the pathology assistant pathway is not relevant and therefore not discussed. For the pathology collection pathway, three of the eight elective units must be those...
identified as ‘Group A electives’ (see Table 9 above). The other five can be selected from a pool of relevant electives — the most likely choices for an individual pursuing a vocation in pathology collection work are shown in Table 10.

Table 10: Elective choices for Certificates III and IV in Pathology most relevant to pathology collection

<table>
<thead>
<tr>
<th>Pathology Certificate III</th>
<th>Pathology Certificate IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>AURS241608A Carry out cash and/or credit/funds transfer transactions</td>
<td>HLTAP301B Recognise healthy body systems in a health care context</td>
</tr>
<tr>
<td>BSBCMM201A Communicate in the workplace</td>
<td>HLTCA402D Perform holter monitoring (Note pre-requisite of HLTCA401D)</td>
</tr>
<tr>
<td>BSBCUS201B Deliver a service to customers</td>
<td>HLTPAT407D Perform electrocardiography (ECG)</td>
</tr>
<tr>
<td>BSBCUS301B Deliver and monitor a service to customers</td>
<td>HLTPAT409D Perform intravenous cannulation for sample collection</td>
</tr>
<tr>
<td>HLTPAT301D Receive and prepare pathology specimens</td>
<td>HLTPAT412D Collect arterial blood samples</td>
</tr>
<tr>
<td>HLTPAT303D Transport specimens and blood products</td>
<td>HLTPAT414D Measure spirometry / flow volume loop</td>
</tr>
<tr>
<td>HLTPAT304D Collect pathology specimens other than blood</td>
<td>HLTPAT420B Perform specialist and technically difficult collections (Note pre-requisite: HLTPAT411D)</td>
</tr>
<tr>
<td>HLTPAT315C Provide donor care</td>
<td>HLTTRAH302C Undertake home visits</td>
</tr>
<tr>
<td>HLTPAT316C Pack and consign blood products</td>
<td>HLMAMP402C Assist with clinical procedures in a medical practice (Note pre-requisite of HLFTA311A Apply first aid)</td>
</tr>
<tr>
<td>HLTRAH302C Undertake home visits</td>
<td></td>
</tr>
</tbody>
</table>

In Victoria, the entry level qualification appears to be the Certificate IV in Pathology (qualification code HLT41812). The Certificate IV contains a number of the Certificate III qualification conditions (at least the core units) within its own requirements, either as core units or pre-requisite obligations, the latter of which effectively make those units ‘core’. The Certificate IV also requires completion of seven elective units, many of which are determined by the chosen pathway of pathology collection which identifies effectively five mandatory units for completion (see Table 9) and another two from a bank of relevant units of competency (see Table 10).

All employers interviewed for this project outside Victoria confirmed that the Certificate III qualification provided a sound theoretical base to the work of pathology collectors for their organisations, but they noted that extensive practical experience and training for collectors in addition to the theory was required before they were work ready.

To demonstrate how employers choose (‘package’ in the terminology of vocation education and training) units of competency from Table 10 to suit the purposes of their particular work

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13 Note that at the Certificate IV level alternative ‘specialisation’ streams may be chosen which includes ‘Team leadership and supervision’ and ‘Workplace training and assessment’.

14 The qualifications were clearly not designed in this way, although employers can of course choose to set the hurdle for entry to an occupation higher than that envisaged in the Health Training Package. In Victoria it seems, based on the data from employer interviews, the choice of Certificate IV as the entry level qualification was influenced more by Victorian Government funding policy (training and education sector) than any expressed need articulated by the health sector.
environments, two of the interviewed employers’ ‘packaging’ approaches to the Certificate III qualification are detailed in Table 11 below. Employer A is a public hospital, and employer B a private community based laboratory. Of the 14 required units of competency to obtain the qualification, both have chosen the mandatory six ‘core’ units (not included in Table 10) and the three Group A electives putting the trainees onto a pathology collection pathway. Employer B though, has also included a unit from the Group B electives, allowing trained employees to potentially ‘cross-over’ from collection into specimen reception at the front end of laboratory procedures. Employer A has attempted to increase the trainee’s collection capacity in the form of more advanced blood collection and other pathology specimen collection and to enhance customer service competence. Employer B has also attempted to increase the collection skills range of the trainee by including advanced specimen collection competencies, including some cardiology testing procedures (almost never performed by pathology collectors in the public sector). Note that the additional ‘technical’ collection competencies sought by employer B for their trainee are at the expense of customer service type competencies.

Table 11: Comparison of the Certificate III qualification packaging approach of two interviewed employers

<table>
<thead>
<tr>
<th>Unit code</th>
<th>Elective units of competency</th>
<th>Employer</th>
<th>Unit level</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLTPAT306D</td>
<td>Perform blood collection</td>
<td>✓</td>
<td>3A</td>
</tr>
<tr>
<td>HLTPAT308D</td>
<td>Identify and respond to clinical risks associated with pathology specimen collection</td>
<td>✓</td>
<td>3A</td>
</tr>
<tr>
<td>HLTPAT305D</td>
<td>Operate efficiently within a pathology and specimen collection environment</td>
<td>✓</td>
<td>3A</td>
</tr>
<tr>
<td>HLTPAT317C</td>
<td>Operate effectively within a pathology testing environment</td>
<td>✓</td>
<td>3B</td>
</tr>
<tr>
<td>BSBCUS301B</td>
<td>Deliver and monitor a service to customers</td>
<td>✓</td>
<td>3</td>
</tr>
<tr>
<td>HLTPAT304D</td>
<td>Collect pathology specimens other than blood</td>
<td>✓</td>
<td>3</td>
</tr>
<tr>
<td>HLTPAT301D</td>
<td>Prepare &amp; receive pathology specimens</td>
<td>✓</td>
<td>3</td>
</tr>
<tr>
<td>HLTPAT411D</td>
<td>Perform blood collection for specialised testing</td>
<td>✓</td>
<td>4</td>
</tr>
<tr>
<td>HLTHIR403C</td>
<td>Work effectively with culturally diverse clients and co-workers</td>
<td>✓</td>
<td>4</td>
</tr>
<tr>
<td>HLTC402D</td>
<td>Perform Holter Monitoring</td>
<td>✓</td>
<td>4</td>
</tr>
<tr>
<td>HLTC401D</td>
<td>Perform Electrocardiography</td>
<td>✓</td>
<td>4</td>
</tr>
</tbody>
</table>

There was extensive discussion with employers about the perceived benefit or value that the Certificate IV offered to their organisations over the Certificate III. The Certificate IV elective units are structured to offer three particular areas of skill or interest for pathology collectors namely, specialist collection, team leadership and supervision and workplace training and assessment. Most employers struggled to justify the Certificate IV as a means to develop ‘specialist’ pathology collection competence, arguing that the Certificate III provided the requisite skills and knowledge to perform the vast bulk of pathology collection work. Skills for difficult or specialist type pathology collections for example, neo-natal collections, collections from extremely ill patients with difficult to locate veins or cancer patients were able to be trained within the workplace, essentially as an ‘add
on’ to the Certificate III\(^{15}\), so hence there was no need for a ‘specialist’ collection qualification. These collections were discussed as ‘advanced’ competencies within specifically trained experienced staff. In the workshops (discussed in greater detail below), these advanced skills were considered insufficient to warrant a further Certificate IV qualification but could be developed into a ‘skills cluster\(^{16}\)’ appropriate to the needs of the employer organisation.

Within the employment or industrial structures of pathology collection services interviewed as part of this project, the need for ‘supervisor’ or ‘team leader’ collectors was limited. There are very few (most commonly reported 2-3) levels of pathology collection staff, therefore a very limited career progression structure. This situation was similar for trainers of pathology collectors within the employer organisations interviewed. Nevertheless, some employers did accept that development for a team leadership/supervision or trainer role could be appropriate, but acknowledged that the number of workers that might need such training was very small. In order to develop these competencies in an individual, rather than pursuing a Certificate IV in Pathology, attendees at the workshops advocated completion of either the Certificate IV Training and Assessment or Certificate IV in Frontline Management.

**Training for pathology collection qualifications**

There were four reasonably distinct approaches to training pathology collectors identified through the employer interviews and consultations with other stakeholders. These approaches can be described as follows:

**A. Completely ‘in-house’** — A pathology laboratory/service employer has become a RTO and is delivering the Certificate III\(^{17}\) entirely in-house with self-employed trainers through classroom based instruction and structured on the job experiences. The duration of training in this category varied but normally required about 6 months to achieve the desired vocational outcome (less if the trainee entered the course with some relevant competencies).

**B. Mostly ‘in-house’** — Similar to above, the pathology service employer has taken control of most of the parameters of training but not attempted to become a RTO and hence needs to ‘partner’ with an appropriate RTO to have trainees assessed and conferred their recognised (national) qualification. The auspicing RTO could be public or private sector, but seemed mostly to be a private sector RTO. A specific variation on this approach is in WA through Pathwest, where the training is all provided in-house, but not auspiced by a RTO. The course is provided by Royal Perth Hospital, which has been conducting a pathology collection course for over 20 years. The course is run four times a year and is structured over a six week period. It is open to the public and any fee paying student. The program is run in conjunction with the hospital and its success (attributed to by employers interviewed) is due to the way in which it rotates students within the wards to ensure that on completion they have experienced approximately 200 blood

\(^{15}\) This is demonstrated in Table 11 where both Employer A and B have included the Certificate IV unit HLTPAT411D in the Certificate III qualification.

\(^{16}\) A skills cluster is a set of relevant industry competencies gained to meet the needs of performing a job function. A skills cluster is a group of competencies that are less than those required to complete a full qualification.

\(^{17}\) No examples of in-house training for the Certificate IV were identified, although, so long as the RTO has relevant ‘scope’ (accredited to deliver the qualification) there is no real impediment to delivering a Certificate IV outcome. Indeed, given the smaller number of enrolments in the Certificate IV (see Table 12) in States and Territories other than Victoria, in-house training for the Certificate IV is arguably the most viable approach.
collections. A ‘qualification’ is provided by the Royal Perth Hospital to graduates of the training program but not one that can be nationally recognised.\(^\text{18}\)

**C. External training + on-the-job** — In this arrangement the bulk of the training occurs in classroom or simulated workplace settings within the education provider’s (RTO) facilities, and this is followed by a period of structured on the job experience clinical practice placing the ‘theory’ into practical context. The amount of time spent in clinical practice varies but most commonly was four weeks (approximately 140 hours). Investigation of international training systems for pathology collectors identifies specific requirements in the amount of hours that students receive practical or clinical experience. The US NAACLS Standards of Approved Educational Programs for the Phlebotomist identify a requirement of 100 hours practical/clinical experience plus didactic or theoretical teaching. The American Medical Technologists organisation provides standard qualifications for phlebotomists that require 120 hours clinical experience for registration.

**D. External only** — All of the training is completed off-the-job in the education institute’s training facilities, through a combination of classroom based theory and simulated practical experience. This type of approach was seemingly limited exclusively to a small number of private RTOs with accreditation to deliver the Certificate III. There was some suggestion by employers that this type of training delivered qualifications in as little as two weeks but this was not able to be verified.

Employers generally seemed to be most enamoured by type A and B approaches above.\(^\text{19}\) The majority of employers identified that the skill of pathology collectors was mainly developed through their experience in the role. Obviously, the more practical experience obtained, generally the higher level of skill achieved. In most organisations interviewed, employers explained that their organisational induction processes added value to the competency of pathology collectors (within their organisation environment) around procedures relevant to their organisation and especially around expectations of the customer service aspects of their roles. This added to the value of an ‘in-house’ training approach. Employers reported difficulties though, in employing individuals who had undertaken the Certificate III through type D approaches as the course was delivered over too brief a time period and with little to no practical experience. Some employers felt for the ‘graduates’ of such programs, since they would be unlikely to obtain a pathology collector job and were often no better off in obtaining entry to a type A or B training initiative than someone with no previous pathology collection learning experience.

Whatever the training approach adopted, as indicated earlier, obtaining a recognised qualification (with the current exception of WA\(^\text{20}\)) is increasingly becoming the aim of employers. This is reflected in trends in enrolment and completions statistics of the Certificate III and IV Pathology courses obtained from NCVER. Over the last 5 years (2012 data is not yet available) there has been a steady increase nationally in total enrolments in both the Certificate III and IV courses, with the more specular growth being in the Certificate IV. The growth in Certificate III enrolments over the five year period has been approximately 6% per annum, while growth in the Certificate IV enrolments has been almost 34% per annum.

\(^{18}\) Of course this does not prohibit other employers effectively ‘recognising’ this qualification by recruiting graduates from the Pathwest course. The administrators of the Royal Perth course are current mapping its content to the Certificate III and IV in Pathology in an attempt to establish its similarities to the national qualifications.

\(^{19}\) The consultant team itself was particularly impressed with the apparent quality of some of the type A and B training programs, with these efforts being outstanding examples of VET system endeavour.

\(^{20}\) Although even they are currently mapping the Royal Perth Hospital course to the Certificate III to potentially be able to award the qualification in the future.
Table 12: Enrolments in relevant national pathology courses, 2007 to 2011

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Year of enrolment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2007</td>
</tr>
<tr>
<td>HLT3010221 – Certificate III in Pathology Specimen Collection</td>
<td>486</td>
</tr>
<tr>
<td>HLT32607 – Certificate III in Pathology</td>
<td>13</td>
</tr>
<tr>
<td>TOTAL Certificate III</td>
<td>499</td>
</tr>
<tr>
<td>HLT41802 – Certificate IV in Pathology Specimen Collection</td>
<td>162</td>
</tr>
<tr>
<td>HLT41807 – Certificate IV in Pathology</td>
<td>18</td>
</tr>
<tr>
<td>Total Certificate IV</td>
<td>180</td>
</tr>
<tr>
<td>TOTAL Certificate III &amp; IV</td>
<td>679</td>
</tr>
</tbody>
</table>

Source: NCVER, 2012

Not all enrolments make it through the course. Actual completions are shown in Table 13. Somewhere between 40 and 50% of enrolments complete the course, which is still high by vocational education and training (VET) standards.

Table 13: Course completions in relevant national pathology courses, 2007 to 2011

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Year of enrolment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2007</td>
</tr>
<tr>
<td>HLT30102 – Certificate III in Pathology Specimen Collection</td>
<td>190</td>
</tr>
<tr>
<td>HLT32607 – Certificate III in Pathology</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL Certificate III</td>
<td>190</td>
</tr>
<tr>
<td>HLT41802 – Certificate IV in Pathology Specimen Collection</td>
<td>112</td>
</tr>
<tr>
<td>HLT41807 – Certificate IV in Pathology</td>
<td>0</td>
</tr>
<tr>
<td>Total Certificate IV</td>
<td>112</td>
</tr>
<tr>
<td>TOTAL Certificate III &amp; IV</td>
<td>302</td>
</tr>
</tbody>
</table>

Most enrolments traditionally have been in Victorian courses adopting a type C approach. In Victoria, this is facilitated by apparently strong relationships between many of the larger hospital pathology service providers and a selected number of well established and respected technical and further education (TAFE) educational institutes. The typical enrolment distribution pattern is well illustrated in the 2011 enrolment data (Figure 4). This pattern holds true for both the Certificate III and IV.

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21 Note that HLT30102 was modified in 2007 and subsequently replaced by HLT32607, but the qualifications are ostensibly equivalent. Similarly, HTL41802 was replaced in 2008 by HLT41807.

22 Note that some graduations from certain courses take some years to complete.
Figure 4: Enrolments in Pathology Certificates III & IV in 2011 by State and Territory

Figure 4 again highlights the strength of Certificate IV training in Victoria *viz. a viz.* most other states and territories with the exception of South Australia. WA pathology employers, as noted previously, were very keen to employ graduates from the Royal Perth Hospital program; and therefore across the state there currently is little reliance on the Certificate III or Certificate IV. However, as the Royal Perth Hospital program is currently being mapped to the Certificate III it is intended to change this in the future. In the Northern Territory, training of small numbers of workers was essentially type B in nature but the link to an external RTO has been tenuous from year to year, thus explaining the apparent zero enrolments. In Tasmania, numbers of enrolments are declining with 22 in 2012 and 9 in 2013.
Chapter 7 - Best practice pathology collection competencies

Industry expectations of competence

Competence requirements of pathology collectors are determined by the work they perform. Employers that were interviewed described the key tasks that were undertaken by pathology collectors as part of their job performance included:

- Meeting and greeting patients on arrival at a collection room;
- Customer service;
- Patient identification;
- Performing the specimen collection;
- Data entry/IT skills;
- Follow-ups with patients;
- Reporting to doctors;
- Sending out results electronically or more occasionally by fax, phone or delivery; and
- Troubleshooting or managing recollections when required.

Customer satisfaction was a commonly reported goal in the employer interviews. However, customer service skills – especially empathy for very ill patients, dealing with difficult patients, patients from varied cultural backgrounds and identifying patients correctly were described as the major problems identified by employers with the collection staff. In addition, describing billing processes and payment requirements was part of the customer service competencies that could be better supported.

Many of the employers interviewed possess a set of de facto competency standards developed internally to guide training efforts, and to underpin initial and ongoing competency assessment. These standards are embedded in training guidelines, standard operating procedures, procedures manuals, competency checklists etc. An analysis of competency related documentation gathered from employers23 during interviews was conducted, which is reported below in the section on ‘Perspectives on competence from the literature’. It is worth mentioning here that customer service is not apparent in the employer competency checklists that were scrutinised (certainly not reflective of the professed importance of this area of competence able to be gleaned from the interviews) — rather, the technical competencies required to ensure a correct specimen collection are emphasised.

More broadly, industry through the Workforce Steering Subcommittee of the Pathology Associations Council (PAC) (2009), has developed competency based standards for medical scientists which also covers the work of technicians and assistants (pathology collectors). While the majority of the standards cover laboratory work, a significant part of the first unit of these competency standards detail elements and performance criteria for the collection of pathology samples (relevant components are reproduced in Table 14 below). These elements and performance criteria provide a useful overview of the work and procedures that pathology collectors perform.


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23 In the main employers were willing to provide documents on competency requirements but less so to make available training materials and procedure manuals which they believed more fundamental to their competitive advantage.
Table 14: PAC (2009) competency standards for medical pathology laboratory science

<table>
<thead>
<tr>
<th>Element</th>
<th>Criteria for assessment and performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Ensure the appropriateness of sample collection procedures</td>
<td></td>
</tr>
<tr>
<td>1.1.1 Correct request form is received as set out in established protocol.</td>
<td></td>
</tr>
<tr>
<td>1.1.2 Identification of patient and demographic information is established.</td>
<td>Request form is checked for patient name, date of birth, gender, unit record number, ward, location, photographic identification, third part identification (e.g. relation, nurse etc.).</td>
</tr>
<tr>
<td>1.1.3 Appropriate action is taken when request appears inconsistent with patient information data.</td>
<td>The requestor is contacted to clarify apparent inconsistency and senior staff consulted as required. Incidents are documented.</td>
</tr>
<tr>
<td>1.1.4 Patient preparation and specimen collection is consistent with test(s) requested.</td>
<td></td>
</tr>
<tr>
<td>1.1.5 Patient is informed of procedure, advised of possible associated risks, and agreement to proceed is obtained.</td>
<td>If patient refuses to have sample collected, refer to requestor, refer to senior laboratory staff. Patient anxieties are considered, discussed and referred to senior staff.</td>
</tr>
<tr>
<td>1.1.6 Collection is performed, consistent with established protocols and safe working practices.</td>
<td>Patient’s condition is monitored before, during and following specimen collection and action taken consistent with the observations.</td>
</tr>
<tr>
<td>1.1.7 Specimen is collected into an appropriate container, then immediately and correctly labelled according to established protocols and regulations including minimum labelling requirements.</td>
<td>Labelling could include nature of specimen (e.g. urine, CSF), name, date of birth, ward, unit record numbers, date/time, collector identified on specimen and request form.</td>
</tr>
<tr>
<td>1.1.8 Specimen is transported in a safe and timely manner under appropriate conditions according to established protocols and regulations.</td>
<td>Ensure use of biosafety bag, appropriate packaging and conditions for transport (temperature, lid secured).</td>
</tr>
</tbody>
</table>

Examination of pathology collection competency ‘standards’

A search of relevant websites and appropriate abstracts identified a small number of national and international efforts that focused on describing the skill and knowledge requirements of competent pathology collectors (or phlebotomists generally in the USA). The most useful sources of insight to competency requirements identified were from the:

- NAACLS, a USA based organisation;
- New Zealand Institute of Medical Laboratory Science (NZ IMLS);
- International Phlebotomy, USA; and
- PAC Competency Standards for Medical Laboratory Work.
The most complete of these statements of competence for pathology collection has been provided by the NAACLS — it forms a benchmark for other standards against which they can be compared for completeness. A comparison was undertaken against the NAACLS competencies with the abovementioned standards as well as the Australian Certificate III in Pathology and a small sample of Australian pathology laboratories using what documentation was available from these sources. The Certificate III rather than the Certificate IV in Pathology was used for this comparison as this was the qualification most widely accepted by employers interviewed for this project as the industry standard. Main points that can be elicited from the comparison include:

- The Certificate III in Pathology is most similar to the NAACLS set of competencies than any other set of competency standards, covering nearly all the main areas of competence in the NAACLS standards at least to some degree;
- The areas of competence which are identified as required for pathology collection work by most competency standards are primarily areas of practice such as workplace and safety and infection control, ensuring patient safety, following standard procedures to collect specimens and understanding of requisitioning, specimen transport and specimen processing;
- The areas of NAACLS competence least cited by other competency standards are the theory elements, relating to the anatomy and physiology of body systems and pathologic conditions associated with the body systems, knowledge of collection equipment, various types of additives used and special precautions necessary and substances that can interfere in clinical analysis of blood constituents; and
- Some of the non-technical areas of competence identified in the benchmark NAACLS standards, such as communication skills, confidentiality, professional behaviour and customer service skills generally, are afforded scant attention by many of the other competency standards.

Most of the employers interviewed used competency checklists to measure fitness or readiness to work unsupervised, as well as performing an ongoing assessment of competence. Nearly all employers had also developed systems that identified errors in samples unsuitable for analysis and that required recollection. Identification of these samples was then attributable to the individual collector who would then receive specific training to rectify their processes to avoid further errors.

Pathology collection competencies identified by workshop participants

Two workshops were held in February 2013 with senior pathology collectors and managers of pathology collection operations, conducted by HCA in conjunction with the CSHISC. The process adopted for these workshops is outlined in Chapter 2 and detailed more in Appendix D.

The starting point for the discussions was to identify the different roles within pathology collection or allied work. The Brisbane workshop identified three (partly overlapping) pathology collection roles and an allied, pathology assistant role\textsuperscript{24}. The three of most interest were:

- Job 1: Pathology Collector (entry level collector who can do most roles independently);
- Job 2: Advanced Pathology Collector (more experienced and having gathered additional ‘specialist’ competencies); and,

\textsuperscript{24} This fourth role, which is considered important by only a small number of employers, is not discussed further in this report since it is outside the project scope. It is likely however to continue to influence the CSHISC to retain the ‘collector’ and ‘assistant’ pathways in the Certificate III and IV in Pathology.
- Job 3: Collector, Specimen Reception Area (SRA) assistant, Laboratory assistant (multi-skilled role, possibly only relevant in some public sector laboratories or small, remotely located laboratories).

In essence, this list of roles allows for only a two level ‘career’, since jobs one and three are effectively at the same level of skill (although job three has a greater breadth of skill requirement). In the Sydney workshop, a single role only of pathology collector was identified, although something of a distinction between basic and advanced skills was acknowledged.

Both workshops demonstrated remarkable uniformity in identifying the competencies required of entry level or basic pathology collectors. This included all of the following (note most of these are in the Certificate III in Pathology):

- Understand\textsuperscript{25} role of pathology collectors within the healthcare system;
- Identify and comply with policies and procedures to maintain work health and safety (WHS) processes and safety for patients including children;
- Comply with policies and procedures for infection control, isolation techniques, aseptic techniques and methods for disease prevention;
- Demonstrate knowledge of anatomy of blood collection sites suitable for safe collection;
- Understand and ensure the appropriateness of sample collection procedures;
- Identify the various types of additives used in blood collection, and explain the reasons for their use;
- Identify the evacuated tube colour codes associated with the additives;
- Describe substances that can interfere in clinical analysis of blood constituents and ways in which the pathology collector can help to avoid these occurrences;
- List and select the types of equipment needed to collect blood by venepuncture;
- Identify special precautions necessary during blood collections by venepuncture;
- Describe and demonstrate the steps in the preparation of a puncture site when performing blood collections;
- List the effect of tourniquet, hand squeezing and heating pads on capillary puncture and venepuncture;
- Recognise proper needle insertion and withdrawal techniques including direction, angle, depth and aspiration, for venepuncture;
- Describe and perform correct procedure for capillary collection methods on infants and adults;
- Identify alternate collection sites for venepuncture and describe the limitations and precautions of each alternate site;
- Name and explain frequent causes of blood collection complications. Describe signs and symptoms of physical problems that may occur during blood collection;

\textsuperscript{25} The competency lists provided to workshop participants consisted of competencies written behaviourally (that is beginning with a verb identifying an observable behaviour such as ‘comply’ or ‘recognise’) and cognitively (that is beginning with a verb denoting knowledge such as ‘understand’ or ‘list’).
• List the steps necessary to perform a venepuncture and/or capillary puncture in chronological order;
• Ensure appropriateness of sample preparation and packing for transport;
• Comply with a professional code of ethics (the Australian Pre-analytical Network, incorporating the Australian Phlebotomy Association, has been developing a professional code of ethics);
• Communicate (verbally and nonverbally) effectively and appropriately with culturally diverse clients and co-workers within the workplace;
• Maintain confidentiality of privileged information on individuals;
• Model professional appearance and appropriate behaviour;
• Work effectively with Aboriginal and/or Torres Strait Islander people;
• Interpret and apply medical terminology appropriately (including pathology terminology);
• Provide reception services for a pathology collection practice;
• Respond effectively to client behaviours of concern;
• Follow procedures for receiving and processing client feedback and complaints;
• Determine needs of client population and meet client needs and expectations;
• Receive and prepare samples for testing;
• Use laboratory application software;
• Perform pathology tests; and
• Undertake home visits.

Somewhat controversially, the competence “Apply first aid limited to fainting and bleeding” was deemed not to be mandatory (or ‘core’ in the terminology of the Training Package) since some employers (for instance acute care hospitals) are likely to actively discourage pathology collectors to administer first aid26.

Both workshops confirmed earlier formed opinion, based especially on the interviews with employers, that the current Certificate III in Pathology is the appropriate and sufficient qualification for the great proportion of pathology collection work. With this qualification as preparation for work, a pathology collector should be able to perform the following procedures independently, to acceptable levels of quality27 and within reasonable time limits:

• Coagulation;
• Urea breath tests;

26 There is a seeming inconsistency in this finding when compared with earlier discussions in Chapter 4 about the desire of consumers for pathology collectors to have greater first aid competence. This can be resolved if the consumer expectations are considered to be more for community practice than in hospitals, where the need for first aid skills will clearly be less pressing.

27 There was some debate in the workshops about the number of times a collector would need to demonstrate competence in a procedure and to what level of accuracy, however the relevant revised units of competency in the Health Training Package will be prescriptive on this issue and provide for increased standards to be satisfied before competence is recognised.
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- Blood cultures;
- Dexamethasone;
- NPA (QML);
- Obese Patients;
- Oncology patients;
- Disabled patients;
- Paediatrics 5-18 years old; and
- Point of care testing.

A more experienced or ‘advanced’ pathology collector would need more training and as a consequence would be able to do some or all of the following more complex procedures:

- All arterial blood;
- Arterial blood gases;
- Sweat tests;
- Mantoux testing;
- NPA (SNP);
- Venesections;
- Synacten;
- Adrenal vein;
- Cannulation;
- Technically difficult patients (including older, sick, obese, neonates, drug addicts, Paediatrics 0-5 years old); and
- Pap smears.

In addition, more advanced pathology collectors might be expected to understand cross contamination and to monitor compliance of other staff with relevant policies and procedures.

Despite the formidable look of this second list of ‘advanced’ procedures, participants at the workshops claimed this did not require additional training to the level of another qualification (for instance a Certificate IV). Rather they believed it amounted to just a few additional units of competency (indeed possibly just one … “Perform specialist and technically difficult collections”) that could be recognised through a ‘Statement of Attainment’ or as a ‘skills cluster’.

Similarly, an experienced pathology collector working in an environment where extra precautions were required in regard to handling of collected specimens (for instance, testing for inappropriate substance use in a work setting such as a mine, testing for illicit drug use in a sports testing regime, or testing for drugs of abuse in a methadone or residential rehabilitation program) might be required to complete a ‘skills cluster’ consisting of:

- Understand drugs of abuse;

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28 Although pap smears are rarely done by collectors and are more likely to be done by general practitioners or pathologists.
Conduct clinical trails; and,
Administer a chain of custody.

The main justification for a Certificate IV qualification offered by employers in the interviews was indeed, not to develop advanced pathology collectors but rather to turn experienced collectors into trainers or supervisors. The Sydney workshop identified that individuals that advance from pathology collector to management or training roles need to maintain an understanding of all of the above relevant competencies but would benefit more from a Certificate IV in Frontline Management or Training and Assessment (respectively) for supervision or training roles. Trainers who were assessing pathology collectors would obviously need to maintain ([pathology collection) competence themselves.

In reviewing the competencies workshop, participants identified as essential, to perform pathology collection work well (best practice). Furthermore, participants felt the following areas were not covered (or covered adequately) through the current Certificate III course:

- Basic computer skills/use of office equipment;
- Transportation of blood specimens;
- Understanding and communicating to consumers legal requirements of request and consent forms (and gathering patient history in relation to organisational policy to support this);
- Customer service – explaining procedure and identifying special needs of patient, especially language and literacy needs, i.e. finding best way of communicating with patient;
- Teamwork/working with others within a professional health care team;
- Troubleshooting; and,
- Ability to evaluate own scope of practice (limitations of own skills) and act within that scope.

To achieve best practice levels of competence for pathology collection, the current Certificate III qualification needs to be enhanced by including these areas of competence.
Chapter 8 - Towards best practice pathology collection

Best practice components

This study has attempted to demonstrate that best practice in pathology has three major components:

- Competent pathology collectors who have been ‘accredited’ as possessing a complete set of skills and knowledge to perform all of their work requirements;
- Supported by well documented procedures for relating with consumers and collecting pathology specimens to specific standards; and
- Operating within a quality system environment.

Many Australian pathology services can boast to be near world best practice in some of these components, but generally not all three. Despite the tangible proximity to achieving best practice in some or several of the components, there is still a perception that services are more distant from achieving best practice.

This could be a result of what this investigation has revealed — two ways of conceiving best practice in pathology collection. There is the technical best practice perspective exemplified by the WHO (2010) guidelines on drawing blood and the other customer focused concept of best practice in a pathology collection setting. The former deals with infection and trauma risk minimisation to the patient, the collector and other people who may come into contact with the discarded collection apparatus. The later encompasses customer satisfaction in dealing with a very accessible and frequently used component of the health care system.

Laboratories, despite rhetoric in regard to customer service, are sample focused, promoting a more technical approach. This is understandable, as an appropriately collected and preserved sample is essential to produce a meaningful result. In most laboratories, all of the performance indicators identify technically related quality outcomes. Laboratories, and the training they provide, therefore concentrate on samples and safety. The greatest concerns of laboratories tend to relate to samples not collected by laboratory staff. It could be argued that doctors and nurses who collect samples would be more focused on the patient rather than the sample and perhaps this is the fundamental basis of the problem, a different focus.

Conversely, the training for the Certificate III is focused on the sample rather than the patient. The systems that laboratories use to report errors such as the KIMMS system are again sample focused, partly because of the difficulty in capturing minor bruising and customer feedback, but partly because for the laboratory the sample represents the faceless patient. The competencies that are evaluated at training and for ongoing assessment are technical competencies not customer service issues unless these are reported.

In contradistinction, the feedback from patients deals with customer service issues and generally not technical issues. Patients see the collection centre as an outreach of the health care system where they expect to be given advice about the process and the result and to be dealt with efficiently and with courtesy as in a pharmacy. Customers do not expect long delays or having difficulty accessing a collection room during ‘normal’ business hours. They expect the collector to be professional, empathetic, aware of diversity, and a source of advice on the testing. It is assumed that the collector is well trained in the technical aspects of the role.
Gaps in best practice

A comprehensive evaluation of the Australian and overseas literature has identified best practice to consist of:

- Adoption of well defined competencies for the technical aspects of collection which reduce infection risks to patient and collector;
- Recognition of the patient as a customer and inclusion of customer service competencies in the core training and ongoing assessment of collectors;
- Strong policies and procedures that define how pathology samples are to be collected, stored and transported; and
- A pathology collection workforce that is competent and presents to consumers with a credible qualification and in a professional manner.

Available statistics on the quantity and nature of errors associated with collection of pathology specimens suggests that Australian processes and outcomes are technically comparable with world practice, with similar error rates, similar types of error, and similar sources of error (see Chapter 4). Many Australian practices (in a significant number of pathology laboratories), include quality control systems, policy and procedure documentation, and preparation and training of pathology collectors, could be justifiably offered as examples of best practice. The mismatch between customer and provider perceptions of ‘quality’ relate to a specimen versus patient focus as mentioned earlier.

Notwithstanding the undoubted high standards many organisations are striving to attain and in part achieving, there is great variability in both pathology collection practice and outcomes across the Australian pathology industry. The main gaps in best practice pathology collection that have been identified in this study, common to most Australian pathology laboratories and present often even for the best institutions, are as follows:

- A significant proportion of the pathology collection workforce is formally unqualified or insufficiently trained. This problem is historic in so far as formal, structured training in the form of the Certificate III in Pathology is a comparatively new phenomenon and there are many collectors in the workforce who predate significant acceptance of the Certificate III. The problem is also current as there remains variation in the quality of Certificate III courses between states and territories and even within jurisdictions between courses. Moreover, turnover in the pathology collection workforce is high, promoting a high replacement demand for pathology which the current training supply struggles to satisfy;
- The majority of identified technical errors in pathology collection are able to be attributed to, ironically, highly qualified health workers but whose competence in collecting samples with evacuated tube systems is undermined by insufficient regularity of practice (particularly drawing blood) and sometimes a disregard for detailed protocols. For instance, nurses in emergency departments and other hospital contexts where pathology collectors are not

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29 Variations exist due to the delivery of the course by different types of RTOs (private courses, industry providers) and in the availability of training opportunities to practice blood collection techniques on real people (on the job).
Best practice pathology collection, November, 2013

routinely engaged, medical practitioners and nurses in general practice settings are called upon to collect specimens irregularly; and,

- Even in the case of (technically) well trained and competent pathology collection personnel, sometimes consumer confidence and satisfaction is still diminished by the lack of a credible qualification and/or poor customer service skills. The latter is most manifest in an inability (or unwillingness) to communicate with consumers about the processes they are undergoing or will undergo and the reasons and purposes of the pathology collection. Confidence can be further undermined in the case of poor skills (repeated failed attempts to find an appropriate vein for instance) especially when these promote adverse outcomes (e.g. bruising).

In the next few sections of this Chapter these problem areas that constrain pathology laboratories from progressing towards best practice and possible solutions will be discussed.

Training solutions

Many of the employers interviewed in the course of this project offered a view that increasingly improved training was the key to progressing towards best practice pathology collection. They advocated adoption of the Certificate III in Pathology as the minimum level of training that is required as preparation for independent pathology collection practice. A majority of pathology laboratories, both public and private, were attempting to set this benchmark as the minimum for recruitment in their own organisations.

While this approach is laudable, there remain two impediments to it delivering the desired outcomes:

1. The Certificate III qualification, as it is currently constructed, is comprehensive and covers much of the knowledge and skill required for best practice pathology collection work, but is deficient in at least two aspects. The first relates to knowledge that would underpin a greater understanding of the policies and procedures applied in practice (and thus enhance the application of skills). The second relates to competence in ensuring consumer experiences in pathology collection add to, rather than detract from their satisfaction in the total health journey and hopefully improve health outcomes (including the accuracy and acceptance of pathology results). In the previous Chapter, a number of specific gaps in the design of the Certificate III qualification were identified. Specifically, this would involve changing the structure of the current Certificate III and some initial thoughts that may assist future work in this area are provided in Appendix F.

2. The implementation of the Certificate III course varies considerably in quality between training providers. In Chapter 6, different modes of delivery of the course were detailed, and the preference of employers for training to be either completely or mostly on the job in nature was identified. This would seem to be the most sensible approach, given that a Certificate III is meant to be a practical preparation for work. The Australian Qualifications Framework for instance describes a ‘graduate’ of a Certificate III course (any course at that level) as having …

- Cognitive, technical and communication skills to interpret and act on available information.
• Cognitive and communication skills to apply and communicate known solutions to a variety of predictable problems and to deal with unforeseen contingencies using known solutions.

• Technical and communication skills to provide technical information to a variety of specialist and non-specialist audiences.

• Technical skills to undertake routine and some non-routine tasks in a range of skilled operations.

It is this latter problem that could prove the more intractable in terms of providing the highest quality of training and education for pathology collectors in Australia. Ideally, pathology collectors should be trained through a traineeship or apprentice type approach, employed and trained largely on the job with that practical learning supplemented and supported by appropriately timed and delivered conceptual learning that provides the theoretical underpinning for practice.[30] This ideal training and education scenario requires a strong and effective partnership between the workplace (pathology laboratory) and training provider (normally a TAFE but could also be a private training provider organisation)[31]. Some of the best examples of training of pathology collectors in Australia (indeed some of the best examples of any vocational training and education) highlight where the ‘partnership’ has been subsumed within the one organisation, that is, the pathology laboratory has become a RTO and can therefore manage all of the training and confer qualifications.

Making a Certificate III in Pathology a minimum requirement to perform pathology collection work is thus a necessary means of improving workforce competence but will require changes to the way training is implemented, as well as potentially impacting on costs for pathology organisations. The way training courses are implemented will need to be influenced in order to ensure consistent and uniform standards of worker competence are achieved. This can partly be done by changing the way key units of competency in the Certificate III qualification are written such that training delivery and assessment of competence must be completed in the workplace. In addition, pathology laboratories need to be educated as to how they can make their current (often not inconsiderable) investment in training pathology collectors more effective through fashioning an appropriate relationship with an education partner (RTO), demanding the right product, and holding the partner to account for outcomes.

In addition to the training of (specialist) pathology collectors, other individuals who collect pathology specimens (nurses, GPs, Aboriginal Health Workers, etc.) in lieu of pathology collectors, need to have received minimum levels of training. The employer interviews and subsequent workshops run in conjunction with the CSHISC identified competence in a single unit of the Certificate III in Pathology qualification as appropriate:

• HLTPAT306C Perform blood collection

There would be no compelling reason why training for this unit needed to be anything other than on the job, in-house training processes. Pathology laboratories could regularly offer a short course based on the unit of competency to individuals identified though quality control systems as

[30] This would have to be considered in relation to possible impacts on organisational pay rates for pathology collectors.

[31] Private registered training organisations (RTO) have garnered a poor reputation in the pathology setting. There is no inherent reason though why private RTOs should deliver poorer outcomes, especially if quality collaboration with a workplace can be established.
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consistently creating collection errors. Ongoing competency could be assessed by associated laboratory staff.

**Regulatory solutions**

In an Chapters 4 and 5 it was noted that a pathology collection centre’s processes and procedures are assessed against ISO 15189 standards together with the NATA FAD which elaborates on and clarifies particular clauses of ISO 15189, and the particular NPAAC Guidelines for Collection Rooms. Irrespective of the veracity of this approach, it was further noted that collection centres are commonly located remote to the pathology laboratory, yet it is generally only in the vicinity of the laboratory from which a ‘sample’ of centres for assessment are chosen. Moreover, the NPAAC Guidelines are broad and are essentially insufficient to identify and assess competence in individual pathology collectors. The guidelines do not stipulate any performance or competence requirements for pathology collection staff such as a designated qualification.

It would seem inappropriate to seek to change the current regulatory approach to pathology services in Australia, certainly by adding another or separate layer of regulation for the pathology collection workforce. Rather, the current regulatory processes could be strengthened to better guarantee workforce competence standards. This could be achieved by:

- First the simplest way of measuring standards of competence is the Certificate III in Pathology (after modification). All pathology collectors entering the workforce after a certain date (eg. January 1, 2014) would be required to have at least the Certificate III qualification.

- Second, all other (laboratory controlled) pathology collectors (such as GPs, nurses) must be able to demonstrate formal achievement (in the form of a recognised Statement of Attainment) of competence in ‘HLTPAT306C Perform blood collection’ within a certain period of auditing (eg. 12 months). More broadly, evidence of routine assessment of pathology collectors (annually) against a competency checklist that mimics at least the Certificate III (and probably allows for idiosyncratic needs of each pathology laboratory) would be essential.

- Third, all collection centres would need to be able to demonstrate a minimum proportion of appropriately qualified staff (eg. at least half) by a set date (eg. January 1 2015). In single person collection centres this will imply the collector has a Certificate III or better qualification. As each year passes, given comparatively high workforce turnover, the proportion with a qualification should increase.

- Fourth, for pathology laboratories above a certain size, they must be able to demonstrate sufficient people are being trained in the Certificate III, in a genuine partnership with a RTO, to satisfy at least replacement workforce demand generated by staff turnover. Appropriate trainer/learner documentation (competency lists, trainer guides, assessment tools, etc.) must be made available to demonstrate the quality and comprehensiveness of training processes.

- Fifth, laboratories need to provide effective procedure manuals to all potential collectors that document and prescribe routine pathology collection performance and work processes as part of a quality control system.

- Sixth, evidence must be provided of ongoing courses made accessible to persons not in the control of the pathology laboratory collecting blood and other pathology specimens as a part of their job. Given the emphasis on competency development, some focus on regulation of education and training effort would seem appropriate. The quality of training processes adopted by RTOs is regularly audited as a requirement of continued registration. In theory,
this should inspire confidence in the outcomes of training conducted by RTOs, in practice, the auditing ensures adequate systems are in place but has limited capacity to directly assess the outcomes of training and competency assessment. In the short to medium term a focus on pathology regulatory systems (over which there is more potential influence) seems the wisest course of action, with efforts to drive training standards through greater willingness by pathology laboratories to place demand for Certificate III qualified staff.
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## Appendix A - Details of consultations with employers and stakeholder organisations

<table>
<thead>
<tr>
<th>State</th>
<th>Organisation &amp; service type</th>
<th>Contact person interviewed</th>
<th>Date of interview &amp; team member who conducted interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>QLD</td>
<td>Sullivan Nicolaides Pathology (SNP) (Large Private provider )</td>
<td>Michael Harrison</td>
<td>Interview conducted 13th of September by Tony Badrick</td>
</tr>
<tr>
<td>QLD</td>
<td>Pathology Qld (Public provider)</td>
<td>Lois Higginson</td>
<td>Interviewed conducted 17th of September by Tony Badrick</td>
</tr>
<tr>
<td>QLD</td>
<td>Mater (Not For Profit provider)</td>
<td>Mark Maguire</td>
<td>Interviewed conducted 28th of August by Tony Badrick</td>
</tr>
<tr>
<td>QLD</td>
<td>QML pathology (Large Private provider)</td>
<td>Tracey McDonald</td>
<td>Interviewed conducted 4the of September by Tony Badrick</td>
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<td>NT</td>
<td>Northern Territory Government Pathology Service, Royal Darwin Hospital (Public provider)</td>
<td>Michael Lynch</td>
<td>Interviewed conducted 20th of September by Lee Ridoutt</td>
</tr>
<tr>
<td>WA</td>
<td>PathWest QE2 (Public provider)</td>
<td>Leesa Ivey</td>
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<td>Interview conducted 5th of September by Victoria Pilbeam and Joanne Bagnulo</td>
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<td>ACT</td>
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<td>Gus Koerbin/Charmaine Grey</td>
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<td>ACT</td>
<td>Capital Lab (Large Private provider)</td>
<td>Ian Clarke/Steve Peak</td>
<td>Interview conducted September 6th by Lee Ridoutt</td>
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<tr>
<td>TAS</td>
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<td>Laurie Bott/Richard Hanlon</td>
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<td>Centre path Royal Hobart Hospital Pathology Services (Public Provider)</td>
<td>Dr Peter VerVaart</td>
<td>Interview conducted September 14th by Lee Ridoutt</td>
</tr>
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<td>State</td>
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<td>Contact person interviewed</td>
<td>Date of interview &amp; team member who conducted interview</td>
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<td>Interview conducted 29th of August by Joanne Bagnulo</td>
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<td>SA</td>
<td>Gribbles Pathology</td>
<td>Fiona Leverington</td>
<td>Interview conducted 29th of August by Joanne Bagnulo</td>
</tr>
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<td>Royal Melbourne Public Pathology (Public Provider)</td>
<td>Cynthia Lewis</td>
<td>Interview conducted October 11th by Lee Ridoutt</td>
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<td>Interview conducted 10th of October by Victoria Pilbeam</td>
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<td>Nuala Hannify</td>
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Appendix B – Employer/stakeholder interview schedule

<table>
<thead>
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<th></th>
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<td>Position Role:</td>
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Question 1. Can you describe the nature and extent of pathology collection centres in your organisation?

Interviewer probe (collect data wherever possible):

- Collection points ... how many of what type (e.g. hospital, community, home, GP surgery, etc.)?
- Staffing ... How many? What type (different job titles)? What is the background of staff (qualifications)? Is there a staff description?
- What types of specimen collection are performed? Roughly what is the proportional frequency of collection? E.g.:
  - blood including evacuated or non-evacuated
  - autologous blood collection
  - arterial blood collection (blood gases)
  - skin or capillary blood
  - urine or faeces collection
  - swab collection
  - ECG
  - holter monitor & blood pressure
  - monitor collection
  - urea breath tests
  - Mantoux testing
  - other routine pathology specimen collections?

- Is there a difference between collection points in size? Workload? Staffing numbers or skill levels?
Question 2. What are the key tasks or ‘work’ in your opinion which collectors / phlebotomists are undertaking as part of their job performance?

Interviewer probe:
- Look for divisions of labour or differentiation between job titles in terms of the work performed

Question 3. Are the roles (WORK) and required skills and attributes of collectors / phlebotomists reflected in your procedural documentation — for instance the ‘Collections Instruction Manual’, Standard Operating Procedures (SOP), job descriptions, customer service policies, etc.?

Interviewer probe (seek documentation wherever possible):
- Need to seek documents consistent with NPAAC ‘Guidelines for Approved Pathology Collection Centres’
- Look for documentation with regard to technical aspects, customer service, emergency procedures, OHS ....
Question 4. What are the ‘skills’ and ‘attributes’ that are required of employed specimen collectors / phlebotomists within your organisation?

Interviewer probe:

- Might need to look at ‘generic’ (required by all staff) and ‘specific’ (to designated job titles or roles / functions) skills.
- Explore different types of skills ... technical, customer service, first aid, OH&S, clerical / administration.
- Interesting to understand how skill requirements conceived. Approach to conceptualisation?
- Are these unique to the organisation or pretty representative of what is required of most collectors/phlebotomists regardless of employer?

Question 5. How do you ensure that the competencies (skills, knowledge, attitudes) staff requires to perform specimen collection well are possessed and maintained?

Interviewer probe (collect documentation wherever possible):

- What are the initial selection requirements? Qualifications? Skills assessment?
- Is there an induction training?
- Are there any ongoing in house training programs? External courses that staff are obliged to attend?
• Is there an ongoing assessment of competency or continuing professional development practices? Against what competencies is the assessment undertaken?

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**Question 6.** In carrying out your operations does your organisation utilise any other pathology collection services i.e. nurses, doctors, medical scientists or other trained pathology staff?

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**Question 7.** What are your key quality and safety concerns in regard to pathology collection in your organisation?

Interviewer probe (subjects may not want to answer this question):

• Do they think that competence is indeed a factor? A major factor?
• If there are other aspects of quality and safety they think apply, what are they? How do they sit relative to competence?
• Is there variation across the organisation? Are there some types of collection centres they consider higher risk?
Appendix C — Consumer discussion group schedule

1. Does anyone want to describe a specific experience (either positive or negative) with pathology collection services?

   Probe questions:
   - What were the contributing factors to the experience?
   - How did you assess the performance of actual collection workers? What were the things you considered when assessing whether they were competent or not?


2. What are your expectations of pathology collection services?

   Probe questions:
   - What are the things you look for in a pathology collection service?
   - What skills, knowledge, attributes, etc. do you expect the staff to have?
   - What in terms of services do you expect from pathology collection providers?
3. Are there any specific quality and safety issues associated with effective and consumer focused pathology collection services you wish to identify?

4. Any others to add?

THANK YOU FOR YOUR TIME
### Appendix D — Industry workshop outline on Pathology collection Qualifications

**Workshop outline**

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<thead>
<tr>
<th>TIME</th>
<th>PROCESS</th>
<th>RESOURCES</th>
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<tr>
<td>9.30-9.45 am</td>
<td>Introduction and brief outline of the genesis and purpose of the Workshop and anticipated outcomes.</td>
<td>CSHISC PowerPoint presentation</td>
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<tr>
<td>9.45-11 am</td>
<td>White board exercise - job roles (at different levels of expertise) of pathology collectors and assistants are detailed. Particular effort devoted to exploring relationship to existing or possibly proposed qualifications. Broad competence requirements of each job identified. This work will build on initial discussions within CSHISC Pathology SMEG.</td>
<td>HCA &amp; CSHISC White Board</td>
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<tr>
<td>11-11.30 am</td>
<td>Modified CAJA - One or more groups of participants provided a list of competencies (in the form of cards) and asked to allocate competencies to identified jobs / proposed qualifications. Finalised lists to be examined for any possible missing competencies.</td>
<td>HCA List of competencies (or set of cards)</td>
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<tr>
<td>11.30-12.15 pm</td>
<td>Provide outline of current assessment requirements in Health Training Package. Facilitate broad group discussion on industry requirements prior to unsupervised practice. Seek agreement on feasible assessment requirements in terms of workplace and ‘live’ practice assessment.</td>
<td>CSHISC PowerPoint presentation</td>
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<tr>
<td>12.15 to 12.30 pm</td>
<td>Summarise outcomes from the day referring back to Workshop objectives and seek ‘sign-off’ from the group on agreed positions.</td>
<td>CSHISC / HCA</td>
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32 The competencies were constructed primarily from the competencies available for ‘packaging’ in the Certificate III in Pathology but supplemented by NAACLS competencies and customer service competencies (Australian National Training Authority, 2001) where apparent gaps in the Certificate III available competencies were apparent.
Appendix E – Industry workshop attendees

Brisbane

- Kathy Jays - San (Not For Profit provider) - Sydney Adventist Hospital
- Kayleen Bertram - SNP
- Leanne Taylor - SNP
- Lois Higginson - Pathology QLD Health Services Support Agency, QLD Health
- Mark Maguire - Mater Health
- Rosemary Cooper
- Tony Badrick - Australian Association of Pathology Practices
- Tracy Macdonald - QML Pathology
- Lee Ridoutt & Victoria Pilbeam from HCA
- CSHISC-Dorothy Rao & Nicola Burridge

Sydney

- Dianne Drinkwater - St John of God (Not For Profit)
- Heather Rainbird - Royal Hobart Hospital
- Jane O’Keefe - Douglass Hanly Moir (Large Private provider)
- Kathy Jays - San (Not For Profit provider) - Sydney Adventist Hospital
- Kristy De-George - Austin Pathology (Public Provider)
- Leesa Ivey - PathWest QE2 (Public provider)
- Madelyn Duckmanton - IMVS Pathology/SA Path (Public Provider)
- Victoria Pilbeam from HCA
- CSHISC-Dorothy Rao & Nicola Burridge
Appendix F - Initial thoughts on possible enhancements to the existing Certificate III in Pathology

The Sydney and Brisbane workshop processes identified a number of areas within the Certificate III where future adjustments may be considered to enhance the skills and competency of pathology collectors. These areas were also identified as those that were less visible in the comparison to best practice pathology collection and initial thoughts on possible enhancements to particular units within the qualification, and assessment requirements are set out below. Please note these are initial suggestions and reflected stakeholder input during the research process.

BSB MED301B – Medical terminology. This unit is obviously not specific to pathology and therefore the range statement only includes general medical terminology. It would be recommended that the unit be revised to include relevant pathology terminology.

HLTHIR301C – Communicate and work effectively in health. This unit includes the confidentiality issues that consumers consulted for this project identified. It therefore should remain a core unit.

BSBFLM303C – Contribute to effective workplace relationships. This unit may be reviewed for relevance and possibly replaced with BSBCUS301B.

HLTPAT305D – Operate efficiently in a pathology and specimen collection service. This is a very short unit that only has two elements. It may be useful to consider enhancing it by suggesting to add the missing customer service competencies around identifying and meeting the language/disability/cultural needs of patient, billing information, modelling professional appearance and appropriate behaviour and following professional code of ethics (or in the lack of those at the moment organisational code of ethics). Once these changes have been made it could be a core unit.

BSBCUS301B – Deliver and monitor a service to customers. This unit is borrowed from the Business Services Training Package and is not a health specific unit of competency. If we agreed to enhance HLTPAT305D as suggested above this could stay as is as deals with identifying customer needs (including communication, organisational requirements) delivering a service to customers and monitoring and reporting on service delivery.

HLTPAT306D – Perform blood collection. This unit is close to international best practice and could be used to assess competence in other medical staff eg doctors and nurses who collect blood. Assessment requirements of this unit could be strengthened to ensure assessment must take place in the workplace with real patients, using the following equipment — evacuated tube system, vacutainer, winged, or needle and syringe — and in a first attempt conduct 25 successful collections from a range of patients to include different ages and gender but excluding paediatrics. This unit should remain a core unit.

HLTPAT308D – Identify and respond to clinical risks associated with pathology specimen reception. This unit seems to cover how to collect appropriate information from the patient, identify whether this collect is within your scope of practice and refer if required. Once reviewed, it should be a core unit.
Suggested core units for pathology collector:

- HLTHIR301C – Communicate and work effectively in health
- BSBMED301B – Medical terminology (or new specific path unit)
- HLTIN301C – Comply with infection control policies and procedures
- HLTWHS300A – Contribute to WHS processes
- HLTPAT305D – Operate efficiently in a pathology and specimen collection service
- BSBCUS301B – Deliver and monitor a service to customers
- HLTPAT306D – Perform blood collection
- HLTPAT308D – Identify and respond to clinical risks associated with pathology specimen reception

Next order of priority units would be (electives to make sure are kept):

- HLTHIR403C Work effectively with culturally diverse clients and co-workers
- HLTHIR404D Work effectively with Aboriginal and/or Torres Strait Islander people
- HLTPAT303D Collect pathology specimens other than blood
- HLTPAT316C Pack and consign blood products

The remaining units for example Undertake home visits, ECG, Holter monitor etc would remain and be utilised by organisations to meet their specific needs.