NSW GOVERNMENT Health Pathology

Clinical Services Plan 2019 - 2025

Version 2: 2021

Acknowledgement of Country

NSW Health Pathology acknowledges the traditional custodians of the lands on which we work and pay our respects to ancestors and Elders, past, present and emerging.

We are committed to honouring Australian Aboriginal and Torres Strait Islander peoples' unique cultural and spiritual relationships to the land, waters and seas and their rich contribution to society.

Version 2: 2021

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1. Executive Summary

This is NSW Health Pathology's inaugural Clinical Services Plan. This is our blueprint for how we will develop clinical and scientific services towards 2025 and beyond. It asks questions about what pathology services will be needed into the future and how they should be delivered.

1.1. Why have a Clinical Services Plan?

NSW Health Pathology (NSWHP) provides essential services in a dynamic and competitive environment. Scientific and technological advancements will continue to drive change in pathology services but at a faster rate than ever before. This will inevitably affect the way NSWHP structures and delivers its services.

NSWHP needs and will continue to adapt and transform to ensure the community has a reliable, sustainable public pathology and forensic service fit for the future needs of the people of NSW.

1.2. What we do

Pathology investigations are an integral part of clinical decision-making and pathologists are an essential part of the patient's clinical team.

We support high quality patient care by providing information and expert medical opinion for accurate and timely diagnosis and clinical decision-making. Pathologists also contribute to clinical research and teaching in both undergraduate and postgraduate settings. Teams of specialised scientific and technical staff are vital to the delivery of our expert pathology services across the State.

NSWHP's Forensic & Analytical Science Service (FASS) plays a major role in helping NSW create better health and justice systems. It provides a range of expert scientific and pathology services to NSW Health, the criminal and coronial justice system, NSW Roads and Maritime Services, Corrective Services NSW, Community Corrections and other partner organisations.

NSWHP provides:

- pathology and diagnostic medicine services in more than 60 laboratories
- phlebotomy services supporting inpatients in public, private and aged care facilities, as well as outpatient clinics and 100 collection services in local hospitals and 48 community collection centres.
- statewide services in genomics, point of care testing, public health pathology, biobanking, perinatal post-mortem
- forensic medicine, criminalistics and forensic & environmental science services
- courier services and
- client/customer and patient/community advocacy.

NSWHP's specialised pathology services are comprised of eight clinical streams, including:

- Pre and post analytical
- Transfusion
- Chemical pathology
- Haematology
- Microbiology
- Immunology
- Anatomical pathology
- Forensic Pathology

1.3. What the future looks like for NSWHP

NSWHP will become a more integrated statewide service that enables expertise and diagnostic care to be enhanced and equitably accessed across the state. This will be achieved connecting and leveraging the capacity and capabilities of all laboratories and ensuring we can respond to critical events or emergencies through our business continuity plans.

Pathologists, scientists and technicians will maximise their role as customer advocates and will increase direct clinical engagement and support to our clinical colleagues.

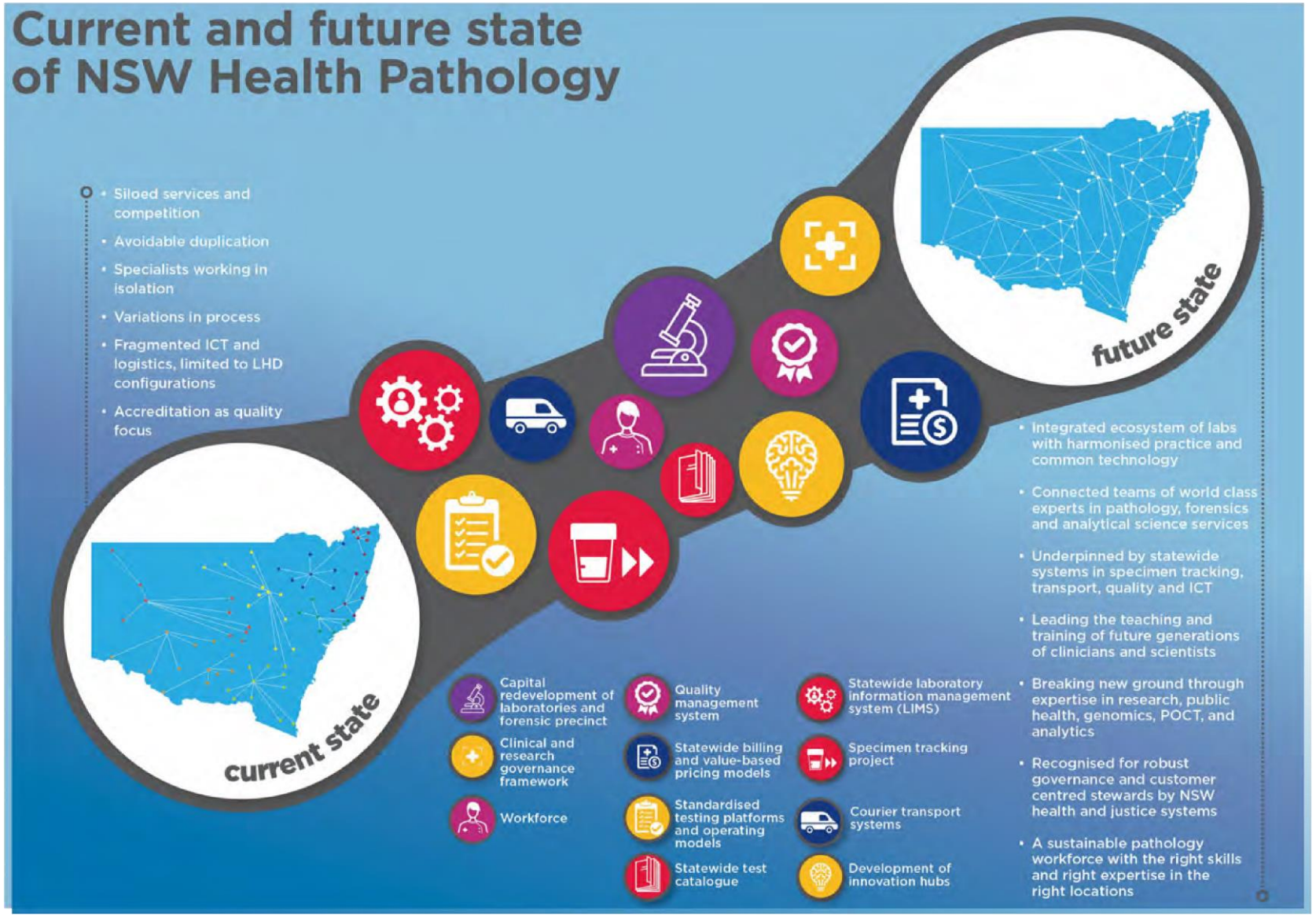
We will enhance clinical use and interpretation of pathology diagnostic results and data. Access to vital forensic medicine and science services will be enhanced by redesigning and modernising laboratory services models across NSW.

We will lead the way in teaching, training and research in diagnostic and forensic pathology to deliver better outcomes and experiences for the community.

NSWHP is committed to creating an integrated statewide service model, which will:

- connect and leverage NSWHP's capacity and capabilities
- enhance services and expertise
- provide equitable access to services
- maximise the role of pathologists and scientists as customer and patient advocates
- increase direct clinical engagement
- enhance clinical interpretation of diagnostic results and data and
- refine and advance capability to reduce error in patient care

Current and future state of NSW Health Pathology



1.4. What our customers want and need

NSWHP will enable a single, connected and integrated pathology service delivering high quality innovative **services**.

These services will support clinical decision making and provides advice for patients, no matter where they present in the system.

Our services will be supported by business continuity plans that ensure we continue to deliver the best service and respond effectively to emergencies or critical events.

We will harness new technology and science to reimagine laboratories, what they can provide and how they operate. Service models will be updated to embrace new technology and ways of working to better meet customer needs.

Collection services within hospital facilities will be developed to provide greater flexibility for patients in location, scheduling and comfort.

Community-based collection locations will be enhanced to reduce attendance at hospital campuses. Home-based collection services will also be considered to support patients being treated in the community.

We will enhance customer engagement technology that allows more 'direct to consumer' services and access to their personal health information. Our collection staff will be better able to support patients up to and during collection visits and empower them with accurate and timely information on their tests to inform their discussion of results with their treating clinicians.

NSW Families will benefit from a timely forensic medicine service with agency partners of criminalistics, forensic and environmental science service having access an integrated array of services and data.

NSWHP envisages an enhanced role in screening and monitoring of general health conditions and chronic diseases, enabling integration of primary and secondary care for these patients, and greater presence in the community.

1.5. Projecting future service demand

In 2017/18 NSWHP received almost 9.5 million pathology requests (resulting in higher numbers of tests), **3.8%** higher than 2016/17.

The majority (94%) of requests came from patients attending public hospitals and collection centres.

The remaining requests (6%) were from private hospitals and other agencies. These do not include Point of Care Testing (PoCT) conducted outside NSWHP laboratories.

Hospital activity is projected to increase between 1.9 to 2.1% per year between 2016/17 to 2025/26. This will be driven by:

- population numbers
- population ageing (particularly the number of residents over 65 years); and
- changes in disease patterns and treatment models.

Pathology requests are increasing at a higher rate than this.

To project NSWHP activity system-wide, this Clinical Services Plan is based on an interim estimate rate of 3 to 4% per year of average growth in pathology services to 2025/26 across NSW.

Due to significant regional variations in projected growth rates across NSW, activity projections for specific hospital laboratory redevelopments

should be linked to projected growth in acute hospital activity for that hospital or local health district.

Further technological advances (such as growth in tests arising when precision medicine research is translated into clinical practice) will also drive the potential for significantly higher rates of growth in pathology services.

In the longer term, NSWHP will work towards developing a more sophisticated methodology to project patient related demand that links NSWHP requests with hospital activity at the level of primary diagnosis.

NSWHP will then model projected pathology demand using NSW Government population projections and NSW Ministry of Health projected increases in emergency department attendances and acute hospital separations for NSW hospitals.

Demand for FASS services are significantly different to clinical pathology services. This demand is expected to grow in line with demand from customers such as the NSW Justice system, and changes in government policy such as drug testing and requires an alternative projection methodology.

1.6. How will the future change what we offer?

Science

Advances in science, medicine and technology are driving rapid change that will transform the way diagnostic services are structured and delivered. NSWHP must make the most of these innovations to match evolving patient and community needs. Status quo is not an option.

For NSWHP, transformational change is already occurring with developments in miniaturisation, near patient testing, automation, digitisation, molecular pathology, genomics, enhanced connectivity, Internet of Things (IoT), bioinformatics, biobanking and more.

Bioinformatics is the pathway to precision medicine. Developments in information technology and biotechnology will expand the volume and value of data. NSWHP is the custodian of a wealth of individual patient and system-wide health data, which will become a rich and important resource to plan better outcomes and experiences for clinicians and patients.

People at the centre

Patients, communities and clinicians now have greater expectations for a direct relationship with health service providers and more direct access to, and individual ownership of, health data.

NSWHP is committed to putting people at the centre of all it does, striving for equal access to its life-changing and life-saving clinical and scientific services irrespective of culture, age, background or location.

1.7. What will be our future model of service?

The focus is services not tests

The focus of a single, connected and integrated NSWHP will be delivery of high quality innovative **services** that enable better models of care, provides reliable test results to support clinical decision making and collaborates with clinicians to treat patients, no matter where they present in the system.

This will entail a change from a model focusing on collection of specimens and provision of **testing geographically tied to the site** at which patients may present. This focus will mean considering where services should be provided rather than a sole emphasis upon where the test is run.

We will respond to the increasing expectations of health consumers, patients and communities for more direct access and ownership of individual results and health data.

Our business continuity planning will be foundational to ensuring our ability to deliver our services when and where they are needed.

Integration is the key

NSWHP was established on a business case and premised on the belief that the future of pathology does not lie in replicating the private pathology model of service or retaining the status quo in the public pathology model. A new model is required that balances broad-scale need for equity of access, the growing need for local clinical engagement, and use of scale (capacity and capability) to create efficiencies in delivery of services.

Ongoing clinical service planning will further develop pathology service models to embrace new technology and ways of working to better meet evolving customer and patient needs. Staff will be supported, equipped and developed to provide these new service models.

Large hubs will provide specialised pathology services for smaller laboratories that do not have sufficient patient or clinician numbers to support safe, efficient and effective service provision. Strengthening the connections between NSWHP's clinical and scientific experts will help ensure all patients receive the same high standard of diagnostic care whenever and wherever they come in contact with a NSWHP service.

This integrated model will be supported by an agile, efficient and modern logistics, and courier system. This will help ensure the safety and integrity of each sample being transported and help patients receive the answers they need when they need them. In concert with this a perpetual inventory management system integrated with vendors and our LIMS will ensure continuity of laboratory supplies to deliver our services.

1.8. How we achieve this

NSWHP has developed a baseline conceptual framework for laboratory service models as a foundation for clinical services planning in pathology.

The Framework considered essential pathology tests needed onsite because they are required within four hours or less by clinicians; as well as access to more specialised levels of hospital and health services requiring expertise, equipment, supervision and/or interpretation.

The Framework presents a baseline expectation of what tests should be provided as a minimum at each tier of the hospital system and is interdependent on successful implementation of the key enabling architecture (single Laboratory Information Management System, test catalogue, logistics, etc). It is a dynamic model that will be updated regularly to respond to ongoing service redesign projects which will influence architecture for key services (e.g. microbiology, digital morphology, flow cytometry).

The Framework's rationale is based on the following key criteria:

- urgency/critical turnaround times to support clinical services provided by hospital clinicians
- ability to transport samples and the impact of digital technology to assist this process
- minimum test volumes and total cost/test onsite versus total cost/test referred. This also considers risks and costs of additional handling, packing, transport, etc
- workforce requirements, including core competencies and supervision
- technology required to deliver the tests and support the service
- teaching and training requirements.

The Framework will enable clearer and more explicit input by NSWHP into hospital Clinical Services Plans and align the crucial role pathology plays in future integrated care models across the state. It will also provide guidance for laboratory redevelopment plans, equipment procurement, workforce planning, IT and logistics planning, as well as engagement with Local Health Districts and specialty networks, Health Infrastructure and NSW Ministry of Health.

To support the delivery of an integrated model of service over the next six years, NSWHP will:

- invest in new technology and science to transform pathology and forensic services
- bring together disparate information systems, test directories and information technology platforms to standardise testing systems and statewide processes and procedures
- streamline service models and enhance local engagement with local health districts and specialist networks to enable better value diagnostic pathology
- expand access to specialty pathology services to improve patient outcomes and experiences
- align infrastructure, equipment and workforce
- develop robust business continuity plans for our whole service, and
- continue to develop a more robust clinical governance structure and standardised quality system.

1.9. Recommendations

All recommendations made by this Clinical Services Plan (CSP) are aligned to the *NSWHP Strategic Plan – Towards 2025* and will form the foundation of service design discussions with customers, stakeholders and staff.

NSWHP will review and prioritise this CSP's recommendations into our annual operations plan to ensure implementation over five years. NSWHP develops an operational plan annually, which is cascaded down into each Executive Director's operational plan.

This guides the work plans for teams and details who is responsible for what and in what timeframe. This also enables planning for budgets or program management.

Each NSWHP staff member's personal development plan is also aligned to the strategic and operational strategies.

All NSWHP business cases, briefs, operational plans and work plans will reference the relevant Strategic Plan, Towards 2025, lead strategies and/or Clinical Services Plan recommendations.

This CSP's recommendations are outlined in the following pages.

1. Keep people healthy and safe

Our goals:

- Deliver services that contribute to better health and safety
- Extend our quality services to our communities with the greatest need
- Lead expert diagnostic support to predict and prevent ill health

Our lead strategies	CSP recommendations	How we will achieve these recommendations
1.1 Partners in safer, healthier communities	1.1.1 Maintain public health capacity	a. we will maintain direct linkages with NSW Health Protection and other NSW Health agencies to ensure coordinated approaches to public health issues b. NSWHP's Laboratory Information Systems (LIMS) will continue electronic notifications of relevant public health laboratory results to NSW Health c. we will establish a Public Health Pathology Advisory Committee to guide our public health activities d. we will identify emerging trends in pathology that support public health initiatives e.g.: metagenomics, antimicrobial resistance testing etc.
1.2 Broader access to diagnostic and forensic services	1.2.1 Increase access to services closer to home and in the community	a. we will resource pilot initiatives that provide community value or improved quality/reliability of Point of Care Testing (PoCT) b. we will align public health laboratory work across our laboratories. This includes human testing in NSWHP hospital laboratories, and environmental testing in our Forensic & Analytical Science Service (FASS). c. our Perinatal Post-Mortem Service will improve access to perinatal post-mortem examinations in regional and rural settings.
1.3 Innovative people-centred care	1.3.1 Pilot innovative care models	a. we will explore options for regional mobile clinic collection and pathology services to reach vulnerable communities.

2. Deliver world-class services where safety is first

Our goals:

- We are passionate in our pursuit and commitment to excellence in quality, safety and innovation

Our lead strategies	CSP recommendations	How we will achieve these recommendations
2.1 Quality and excellence driven culture	2.1.1 Improve patient and customer experiences	a. we will develop the customer service capability of our staff. b. our Pre and Post Analytical Stream will develop a new, modern collection model. We'll start by developing specifications for community collection centre kiosks and trialling new patient booking systems.
	2.1.2 Provide community value and quality in PoCT	a. we will undertake pilot initiatives to improve quality and reliability of PoCT.
2.2 Set the standards	2.2.1 Improve quality management and manage risks from specimen transport	a. we'll develop a single Statewide Quality Management System (QMS). b. our Pre and Post Analytical Clinical Stream will establish an integrated electronic tracking system to track specimens from collection to archiving. c. our Transfusion Clinical Stream will: – improve blood transport and ensure minimal wastage of blood products. – implement new laboratory technology to harmonise and improve testing services across NSW. – engage with local health districts to ensure safe and effective use of blood.
	2.2.2 Set the standards in PoCT	a. we will participate in state, national and international PoCT service initiatives to strengthen NSW public pathology's position.
2.3 Statewide network with strong local connections	2.3.1 Standardise service delivery across NSW	a. our clinical streams will develop standardised operating procedures to optimise laboratory services across the state. b. we will embed standardised Point of Care Testing (PoCT) service delivery into the core function of all our laboratories.

3. Integrate systems to deliver truly connected care

Our goals:

- We are trusted leaders in connecting our partners and communities to better care and outcomes

Our lead strategies	CSP recommendations	How we will achieve these recommendations
3.1 Shaping innovative services	3.1.1 Pursue innovative strategies	a. our Public Health service will work with our clinical streams, particularly the Microbiology Clinical Stream, to ensure appropriate, timely and cost-effective laboratory services relevant to public health.
3.2 Systems integration	3.2.1 Develop and implement comprehensive laboratory service models	a. for each tier of the system in the Laboratory Service Models Framework, a pathology service model would describe: – minimum test profiles provided onsite – how offsite send-aways are managed – how the core laboratory component functions – describes how central specimen reception functions – the role of PoCT and how it links with laboratory services – the breadth of the role of pathologists (beyond the laboratory into clinical care) – a baseline workforce profile and how supervision is provided – how the laboratory is managed – how services are provided to other networked laboratories b. in the next six to 12 months, we will: – review each laboratory against the baseline laboratory service models to discover local variation and visualise the differences and similarities. – undertake system-wide co-design with clinicians to refine laboratory service models. – further consult with operations directors and local pathology directors to refine the proposed Laboratory Service Models Framework – achieve consensus and implement laboratory service models across current services. this will ensure future services are developed in line with the Laboratory Service Model Framework. c. further refine the baseline laboratory service models following completion of key clinical redesign projects in flow cytometry, digital morphology and deliberations of key microbiology working groups.

3. Integrate systems to deliver truly connected care

	3.2.2 Improve service delivery through clinical stream key priorities	a. our Pre and Post Analytical Stream will trial an e-ordering system for hospital outpatients and investigate options for a statewide e-orders system for inpatients and community patients. b. our Transfusion Clinical Stream will implement new blood management and blood transfusion services technology, including smart blood fridges and systems for remote release of blood products. c. our Haematology Clinical Stream will integrate Point of Care Testing (PoCT) and laboratory-based testing across the state. d. our Chemical Pathology Stream will: – create statewide standards for testing platforms, reference intervals, operating procedures and high-risk result alert thresholds – develop new service delivery models across multiple customer settings to improve customer experiences. e. our Microbiology Clinical Stream will develop a technology-enabled service model that will deliver comprehensive and responsive services to both metropolitan and regional patients. These emerging technologies will include rapid nucleic acid testing and PoCT. f. our Anatomical Pathology Clinical Stream will: – develop electronic transfer of results to clinician's preferred device in their preferred format. – develop uniform reporting of cancer cases consistent with RCPA protocols for structured reporting of cancer. – ensure timely access for patients to genomic tests in cancer. – develop and identify specific subspecialty expertise among our pathologists to improve access to expert primary diagnosis or second opinion consultation in our anatomical pathology departments. g. our Immunology Clinical Stream will integrate PoCT and laboratory-based testing across the state. h. our Public Health service will consolidate complex and specialised public health testing.

3. Integrate systems to deliver truly connected care

3.2 Systems integration	3.2.3 Improve statewide service delivery	a. we will consolidate complex genomic testing at a small number of our sites and provide centralised data from a cloud-based service to leverage economies of scale.
	3.2.4 Develop statewide systems	a. we will continue to develop statewide systems to integrate services, including: – statewide Laboratory Information Management System (underway) – statewide test catalogue (underway) – standardised testing platforms (underway) – standardised Point of Care Testing (PoCT) service delivery in all laboratories (underway) – statewide integrate inventory management system with LIMS and vendor capacity aligned to our activity demands
	3.2.5 Improve system integration through clinical stream initiatives	a. our Pre and Post Analytical Clinical Stream will work collaboratively with other clinical streams to develop a service model that integrates a pre-analytical specimen processing and transport system. b. our Chemical Pathology Clinical Stream will streamline workflows to increase operating efficiencies, particularly by integrating core testing for all disciplines within the core laboratory setting. c. our Microbiology Clinical Steam will: – use near-patient-testing platforms and automation of culture-based testing to re-configure laboratory services. – enhance integration of host genetics with microbe-diagnostics (whole genome, microbiome).
	3.2.6 Integrate forensic and analytical science disciplines and laboratories to improve information to stakeholders	a. FASS will develop an enhanced service delivery model to better connect forensic and analytical science services and leverage off specialist capabilities. b. FASS will also map our current forensic & analytical science capabilities and develop a strategic roadmap to enable an enterprising workforce to deliver integrated services.

3.3 Connected communities of care	3.3.1 Collaborate and engage with local health districts, clinical practitioners and patients to develop customer-focused services that meet the expected clinical demand	a. our Pre and Post Analytical Clinical Stream and Immunology Clinical Stream will engage with local health districts, clinical practitioners and patients to improve clinical collaboration. b. we will formalise our collaboration with The Children's Hospital, Westmead Genomics within our genomics service and potentially NSW Newborn Screening. c. we will improve integration of our Perinatal Post-Mortem Service with referring services and maternal foetal medicine units. d. we will improve engagement with local health districts and specialised health networks to ensure clearer systems for collaborative planning, as well as the role of local teams in this process. e. we will ensure business continuity plans are in place and integrated with local health districts and specialised health networks to provide assurance of our ability to maintain services and meet clinical demand.

4. Develop and support people and culture

Our goals:

- We are a great place to work where our staff are consistently supported to learn and excel
- Our performance is built on trust, leadership and teamwork

Our lead strategies	CSP recommendations	How we will achieve these recommendations
4.1 Foster diversity, inclusivity and creativity	4.1.1 Move toward diversification and extension of skills	a. we will continue to shift towards core laboratory configuration. b. we will increase our investment in clinical scientists with increased scopes of practice. c. we will increase the available 'cut-up' technical skills in our scientific staff. d. we will continue cross discipline education and training of technical and scientific staff across haematology, chemical pathology and transfusion. e. we will invest in microbial genomic training for scientists and pathologists.
4.2 Nurture collaboration	4.2.1 Nurture collaboration with our staff and partners	a. we will educate and train local health district staff and clinicians in the use of Point of Care Testing (PoCT). b. we will develop agreed definitions of pathology-related terms to be used across our organisation.
4.3 Safe, supportive workplaces	4.3.1 Understand the workforce implications of CSP strategies	a. will we review the potential impact of this CSP's strategies on workforce configuration within our laboratories
	4.3.2 Review the education and training needs of our workforce	a. we will develop our training program to respond to and reflect changes in modern technologies, service configurations and clinical service innovations. This will ensure our pathology workforce has the necessary skills and knowledge to adapt to a changing professional landscape. b. we will liaise with universities and medical schools to include pathology as a fundamental component of their course work and curriculums. c. we will invest in a flexible statewide training program, including developing clinical leadership capability. d. we will increase intern and junior medical officer rotations in pathology.
4.4 Dare to experiment	4.4.1 Review career structures and pathways	a. we will establish a career pathway for scientists which explicitly includes quality, research and teaching roles. b. we will increase patient education in personalised PoCT, health literacy and use of genomics information.

5. Support and harness research and innovation

Our goals:

- We are partners in translational research where discoveries move rapidly from the lab to the community
- We uncover answers that matter by pursuing innovation possibilities in all we do

Our lead strategies	CSP recommendations	How we will achieve these strategies
5.1 Grow research opportunities	5.1.1 Develop research opportunities for statewide services	a. we will leverage research funding through the NSW Ministry of Health's Office of Health and Medical Research, the National Health and Medical Research Council (NHMRC) and other funding agencies (e.g.: the Australian Government's Medical Research Future Fund) to enhance our role in public health. b. we will further align our genomics initiatives with the NSW Health Genomics Strategy, including research and translation medicine. c. NSWHP will continue to pursue opportunities in biobanking and collaboration in research to improve the way disease is detected, diagnosed and treated.
5.2 Bring new ideas to life	5.2.1 Implement clinical stream key priorities	a. our clinical streams will establish a collaborative research framework between chemical pathology and other clinical and laboratory specialties, including development of increased research capability within the Forensic & Analytical Science Service (FASS), universities and other research institutes. b. our clinical streams will engage with local health districts, universities and/or medical research institutes to collaborate on research projects. c. our Immunology Clinical Stream will: – seek opportunities in assessment of new technologies and small contracted research work. – maximise our position as the scientific body with the largest number of Australian immune disorder patient samples to boost research opportunities.
5.3 Space to innovate	5.3.1 Develop spaces to innovate	a. we will work with partners and stakeholders to build innovative partnerships (that may include advanced simulation, innovation laboratory and genomics sequencing laboratory and participate within innovation precincts)
5.4 Celebrate our expertise	5.4.1 Recognise clinical research	a. we will document research projects, evaluate results and celebrate our expertise. b. we will raise awareness of published research and promote evidence-based best practice across our organisation.

6. Enable advances in technology, data and analytics

Our goals:

- We are pioneers of emerging technologies, tools and data analytics

Our lead strategies	CSP recommendations	How this will be achieved
6.1 Agility in technology adoption	6.1.1 Implement clinical steam key priorities	a. our Haematology Clinical Steam will: – Develop a new model of service that uses new technology to improve service configuration. – Implement a digital morphology system and roll-out new haematology, coagulation and flow cytometry analysers across the state to standardise testing. b. Our Chemical Pathology Clinical Stream will embrace new technologies, such as mass spectrometry, proteomics, genomics and metabolomics to ensure we remain leaders in the discipline. c. Our Microbiology Clinical Stream will: – Develop a framework for implementing high-volume automated culture testing systems at selected laboratories. – Consider applying artificial intelligence to laboratory workflows and testing. d. our Anatomical Pathology Clinical Stream will: – Introduce new enabling technologies, such as whole slide imaging and use of a digital microscope rather than the current optical microscope for most routine reporting. – Re-evaluate how we can best provide technical laboratory processes such as tissue processing and slide production, immunohistochemistry and in-situ hybridisation. e. Our Immunology Clinical Stream will adopt new technologies across the state to improve service delivery. f. We will establish an electronic tracking system, integrated with the single LIMS, to track specimen movement from collection to archiving. g. Adopt modern integration methodologies that are compliant with our Service Oriented Architecture, thus reducing the reliance on legacy point to point integrations. h) Drive the use of Fast Healthcare Interoperability Resources (FHIR) standards for communications via mandatory selection criteria on new products

6.2 Grow digital capability	6.2.1 Ensure statewide services are enhanced by digital capacity	a. We will resource ICT middleware to enable prompt implementation of new Point of Care Testing (PoCT) technology across the state. b. We will ensure the NSW Genomics information technology strategy ('cloud' storage, analytics etc) supports public health pathogen genomics development. c. Digitally transform processes that are manual and/ or geographically bound. d. Align to the NSW Premier's 'Tell Us Once' Priority (by 2023) by designing the patient's NSWHP digital encounter in the context of their entire digital experience.
6.3 Leverage our data and expertise	6.3.1 Develop future projection methodologies that underpin clinical service and infrastructure planning	a) We will develop benchmarks and planning guidelines for pathology services. b) We will develop projection methodologies for NSWHP demand. c) Develop clinical analytics and visualisations which combine different elements of patient information with Pathology results to deliver more powerful and valuable insights for clinicians, patients and Service/business planning.
6.4	6.4.1 Deliver increased patient/consumer control and access to their personal health information	a) Information Services will adapt to provide increased consumer control and access to their personal health information. This can include: – capacity for patient self-registration. – direct to patient/consumer messaging system (e.g. SMS) – timely access to urgent public health information – integrated services with Service NSW Call Centre – NSWHP Call Centre capacity – AI enabled services that amalgamate diagnostic, vital signs and clinical information

7. Deliver future-focused infrastructure and strategic commissioning

Our goals:

- We invest in infrastructure designed and curated to be fit-for-purpose and the future
- We are leaders of strategic provisioning and commissioning of services that our customers and communities value

Our lead strategies	CSP recommendations	How we will achieve these recommendations
7.1 Create labs of the future	7.1.1 Improve laboratory design	a. We will develop laboratory design guidelines. b. We will work with Health Infrastructure (HI) to develop new health facility guidelines. c. We will complete a white paper to define the core laboratory.
	7.1.2 Develop NSWHP infrastructure to support future services.	a. We will improve access to the NSW Capital Works program for redevelopment of pathology laboratories by: - consulting with local health district service planners and other key stakeholders, including local pathology directors, to ensure pathology is included in early development of clinical service plans and proposed hospital redevelopments. - consulting with the NSW Ministry of Health and HI to improve infrastructure processes. - Increasing collaboration with The Children's Hospital, Westmead across a range of pathology-related opportunities. - continuing to develop the Forensic Precinct in western Sydney. b. We will continue to plan and implement major laboratory redevelopments across NSW. c. We will redesign each focus area of the Forensic & Analytical Science Service (FASS) laboratory to eliminate unnecessary handling, remove duplication of processes and streamline workflows. Capital investment recommendations from this redesign will include a drive towards greater automation and equipment to eliminate and control risks (health and quality). For other assets, FASS will address capital costs by utilising funding from other sources, including a recurrent capital subsidy from the NSW Ministry of Health. d. We will develop a governance, monitoring and endorsement structure for laboratory design. e. We will develop additional guidelines (eg: decanting hints) and design notes. f. We will undertake a condition of laboratories audit to inform future infrastructure decisions.

7. Deliver future-focused infrastructure and strategic commissioning

7.2 Smarter, sustainable services	7.2.1 Improve logistics and courier systems to support clinical services	a. We will design and implement a statewide specimen tracking system. b. We will configure the specimen transport network in an agile and efficient way.
	7.2.2 Develop a framework for training the next generation of laboratory staff and sustaining the workforce	a. We will actively pursue options to increase the available supply of qualified and skilled staff. b. We will improve and better target our recruitment strategies and practices. c. We will increase our focus on developing our staff at all levels and provide greater opportunities for staff to access and participate in training and development programs. d. We will support our ageing workforce by introducing greater flexibility in work arrangements (where appropriate) and transition to retirement programs. e. We will review and project staffing needs and gaps to address potential workforce shortages and ensure succession planning fills identified gaps. f. We will increase our efforts to build partnerships and collaborative efforts with educational institutions. g. We will ensure clinical service and workforce planning are highly integrated to enable us to identify and respond to our future service and workforce needs. h. Our clinical streams will collaborate to develop a laboratory workforce with the skills to adapt to changing laboratory testing technologies. i. We will review career paths for our pre-analytical workforce. j. Our Anatomical Pathology (AP) Stream will: k. Develop workload assessment tools for scientific and technical staff to determine and implement appropriate levels of medical, scientific and technical and support staff. l. Extend technical and scientific staff activities, including macroscopic dissection and cut-up. m. Revise the activities of trainee pathologists to better reflect the obligations inherent in specialist AP practice and to better train them for this role. n. Promote a respectful and cooperative workplace culture.
	7.2.3 Develop business and customer service opportunities	a. We will develop business opportunities and competitive advantage to support rural and regional services and sustain small laboratories – including private referrals from GPs and community services. b. We will develop business opportunities and competitive advantage for specialised and subspecialty services to support service growth and sustainability.
7.3 Commissioner of choice	7.3.1 Implement genomics service key priorities	a. We will establish state-of-the art genomics capability to position NSWHP as a preferred provider that provides cost-effective, timely and clinically-appropriate genomic testing. This would also reduce costly and uncoordinated outsourcing of genomics services. b. We will establish a formalised facilitation role in genomic testing for patients in NSW Health to ensure safety, governance and appropriate control of genomic data and resources. c. We will leverage the Australian Government's Medical Research Future Fund's Genomics Futures funding wherever it aligns to our objectives.

8. Being reliable, accountable stewards of community resources is an important foundation for us

Our goals:

- We are great stewards of public resources and investments

Our lead strategies	CSP recommendations	How we will achieve these recommendations
8.1 Mature governance models	8.1.1 Enhance clinical governance	a. We will continue building our incident management and improvement science capability using our Clinical Governance Framework (Kaiser Permanente model).
8.2 Collective stewardship	8.2.1 Reduce duplication, costs and better use resources	a. We will create a sustainable asset management plan for Point of Care Testing (PoCT). b. We will consolidate complex or specialised public health testing and reduce costly and uncoordinated outsourcing of testing.
	8.2.2 Implement public health key priorities	a. We will delineate the role of our current and planned biobanking facilities to support public health activities and research.

2. Introduction

Pathology is the branch of medicine that deals with the essential nature of disease[1] – especially with the structure and functional changes in tissues and organs of the body that cause or are a response to disease.

It is an important part of clinical services delivered in Australia's public hospitals and one of the essential inputs into health care.

This first Clinical Services Plan (CSP) for NSW Health Pathology (NSWHP) outlines the strategic direction for NSWHP services to 2025.

NSWHP includes:

- more than 60 hospital labs
- more than 200 collection centres
- seven clinical discipline streams
- six statewide services, including:
  - Genomics
  - Point of Care Testing (PoCT)
  - Biobanking
  - Perinatal Post Mortem Service
  - Public Health Pathology, and
  - the Forensic & Analytical Science Service (FASS).

Established on 31 May 2012, NSWHP is a health service provider and part of the Health Administration Corporation. The NSWHP Board was appointed in December 2012.

Four pathology networks (Pathology West, Pathology North, South Eastern Area Laboratory Services, South Western Area Pathology Services) and FASS were brought together in July 2017 to create NSWHP.

The networks were dissolved and transitioned to a new organisation structure to better reflect a single statewide pathology service. The seven clinical streams progressively established from May 2014 were also restructured with formal appointment of clinical leads who were allocated time to undertake the role.

A key rationale for a single statewide NSWHP service was to scale efficiencies from:

- a single information technology (IT) system
- common analyser platforms
- standardised work practices
- standardised processes (e.g. credentialing, quality management)
- statewide procurement practices
- rationalisation of non-urgent testing[2].

[1] Dorlands (2008)
[2] Paxton Partners (2012) *NSW Health Pathology Structure and Governance Arrangements*

It was envisaged that a statewide NSWHP service would also improve clinical service planning and lead to more efficient and effective delivery of pathology and forensic services.

Clinical services planning has involved key stakeholders to “improve the effectiveness of services and their responsiveness to changing patient and clinical needs[3]”.

The aim of this CSP is to provide a rigorous and evidence-based foundation to ensure future pathology services meet the needs of NSW residents, and NSWHP delivers safe and effective services that are sustainable in both staff and financial resources.

2.1. Context of the CSP

Local Health District (LHD) and hospital CSPs have focused on acute, emergency and subacute services for many years. Pathology has not had early, effective engagement and communication between LHDs in planning.

Current public pathology services across NSW reflect decades of decision-making driven by local hospital and LHD perspectives rather than a whole-of-system perspective including pathology. At times this has resulted in sub-optimal integration of pathology services in location, design and capacity.

This whole-of-system perspective is now possible with a single NSWHP service. A key objective of the NSWHP CSP is to utilise the NSW Ministry of Health service modelling and planning tools; and work in close engagement with the Ministry, LHDs and SHNs to plan and align pathology and hospital-based clinical services.

2.2. Scope of the CSP

This CSP applies to all services provided by NSWHP, including:

- Clinical streams:
  - Pre and Post Analytical Services
  - Haematology
  - Transfusion
  - Immunology
  - Chemical Pathology
  - Microbiology
  - Anatomical Pathology
- Clinical services:
  - Public Health Pathology
  - Genomics
  - Point of Care Testing (PoCT)
  - Biobanking

[3] NSW Health (2012) *Proposed Business Model for a Statewide Public Pathology Service*

- Perinatal Post-Mortem and related services
- The Forensic & Analytical Science Service (FASS).

Key enablers, such as information technology, logistics, workforce, PoCT and assets, will be considered and included in strategies. Detailed operational planning for implementation of these key enablers is not part of this CSP.

2.3. Objective of the CSP

The NSWHP CSP outlines the strategic direction for developing clinical and forensic services to 2025 and beyond.

The CSP considers:

- what services will be required
- how services should be configured and delivered
- how to ensure clinical timeframes, patient safety and clinical quality standards are maintained to ensure high quality, safe services.

2.4. Planning principles

Clinical service planning is an iterative process that responds to changes in the communities' needs and models of clinical service delivery.

The NSWHP Planning Principles were applied in 'Future Directions for Pathology Services' (2017) and guide the CSP to ensure planned service changes are consistent with NSWHP values and priorities.

NSW Health Pathology Planning Principles

- consider the best interests of NSW as a whole
- focus on patients
- deliver safe, accessible and culturally appropriate services
- deliver the best outcome in clinical quality, efficiency and effectiveness
- achieve services that are sustainable, contestable and value for money
- be feasible, affordable and optimise use of resources.

Proposed service changes must consider the following desirable principles:

- planning will review activity data, scan literature for future pathology trends and consult with key stakeholders to develop strategic initiatives for future service delivery.
- support the right workforce and workforce models
- utilise the right technology and innovative technology where appropriate
- promote innovation in service delivery
- contribute to the quality use of pathology
- deliver agile and flexible services
- enhance the value of NSW Health Pathology for patients, staff and NSW Health.

3. Planning and policy framework

3.1. NSW Health

The Clinical Services Plan (CSP) is guided by:

- the NSW Premier's Priorities
- the NSW State Health Plan: *Towards 2021*, and
- the NSW Health Strategic Priorities (shown in Figure 3.1).

The NSW State Health Plan brings together NSW Health's existing priorities, plans, programs and policies to deliver 'the right care, in the right place, at the right time'.

The Leading Better Value Care (LBVC) program provides a key planning and policy direction for NSW. LBVC introduces ways of delivering care to positively impact on the health and experience of care of patients. Importantly, it works towards reducing cost and increasing the return on current investments.

This is achieved through:

- focusing on patients by adopting a patient experience and health outcomes approach
- focusing on value rather than volume
- addressing future demand and fiscal pressures through efficient and effective care and services.

The NSW Ministry of Health *Role Delineation Guide* is a framework that provides a consistent language across NSW to describe the minimum support services, workforce and other requirements for clinical services to be delivered safely[4].

Pathology services are a core clinical service in the Role Delineation Guide, which makes provision for core services 'on-campus' for clinical reasons (e.g.: intensive care) as well as 'off-campus'.

An off-campus facility can be credited with having a core service if there is equivalent functional access and patient care is not compromised by that service being offsite.

The essential consideration is that the requirements of the clinical service are met, and not whether the core service is provided on or offsite. This is particularly the case with pathology services.

[4] NSW Ministry of Health (2015) *Guide to the Role Delineation of Health Services*

Figure 3.1 NSW Health Pathology Planning Framework

3.2. NSW Health Pathology

The NSW Health Pathology (NSWHP) Strategic Plan *Towards 2025*, developed in 2018, outlines our purpose, guiding principles and values.

These are also directly aligned to NSW Health's eight strategic priorities to ensure our contribution to achieving broader health system goals.

The overarching purpose of NSWHP is 'creating better health and justice systems' as illustrated in Figure 3.2 and our guiding principles – caring, connecting and pioneering - are presented in Figure 3.3.

Future Directions in Pathology Services (2017) outlined the principles and priorities that shape future NSWHP service models, including the role of the seven clinical streams.

This document has been used to help inform the development of NSWHP's strategic plan – *Towards 2025* – and this Clinical Services Plan.

Clinical Stream Service Development Plans have also helped inform the overall development of this CSP. In turn, the CSP will inform future development of key NSWHP plans including asset strategic, logistics and workforce plans.

Figure 3.2 - Our purpose

Figure 3.3 - Our vision and aspirations

3.3. Health facility guidelines

The Australasian Health Facility Guidelines has been developed to facilitate design of physical spaces for hospitals and health facilities. Section 550 presents health facility briefing and planning guidelines for pathology units[5] and are due for review in 2019.

The Pathology Unit Health Planning Unit (HPU) guideline outlines requirements for planning and design of hospital pathology units in a generic sense. It recognises that scale and complexity of pathology units will depend on factors such as the role delineation level of the specific unit, networking arrangements, operational practices and the location of the unit.

The HPU does not provide guidance on specific requirements in terms of dimensions and inclusions to guide design of labs of varying sizes or levels of complexity of services on-site.

The HPU is designed to provide the building blocks for a pathology unit of any size and describes the key activities that take place within the pathology unit:

- specimen collection services through fixed locations, mobile services (e.g. phlebotomy) and outreach services (e.g. home based)
- specimen reception
- specific analytical tests
- preparation of reagents and instruments
- calibration of quality control activities
- calculations, reporting and interpretation of results
- preparation of back-up facilities to cover instrument breakdown
- preparation for specialised procedures
- equipment maintenance
- supporting Point of Care Testing (PoCT)
- ordering supplies, receipt and storage.

3.4. Planning process

The NSWHP CSP aligns with the NSWHP Strategic Plan: *Towards 2025* and will guide our directions and decisions to 2025 and will be reflected in subsequent Operational Plans and Strategic Program Plans.

NSWHP has developed clinical service plans for key statewide services, including a Genomics Strategic Plan, and a PoCT Strategic Plan.

External clinical service planning expertise was engaged to ensure suitable approaches were taken to develop new service models for the future that align with the broader NSW acute hospital system.

Planners reviewed a range of activity data, future focused literature (a summary is in Appendix 4) and undertook extensive consultation with

[5] AHIA (2016) Part B – *Health Facility Briefing and Planning, 0550 – Pathology Unit*

NSWHP Clinical Streams, Clinical Operations and Forensic & Analytical Science Services (FASS).

Consultation and validation with internal and external stakeholders for *Towards 2025* provided significant input into the priorities specified in the CSP.

4. Our future role

NSW Health Pathology (NSWHP) is leading the evaluation and transformation of public pathology services as NSW Health's preferred provider and commissioner of an integrated, statewide pathology service for NSW.

Access to vital forensic and analytical sciences services will be enhanced by redesigning and modernising laboratory services models across NSW.

The focus is services not just tests

The focus of a single, connected and integrated NSWHP will be delivery of high quality, innovative services that support clinical decision making and provide advice for patients and more direct access to information and results, no matter where they present in the system.

This is a significant change from the current model focusing on collection of specimens and provision of testing geographically tied to the site where patients present. This changed focus will mean considering where services should be provided rather than the emphasis being on where the test is run.

This broader service role includes a greater role for pathologists and scientists as customer advocates, connecting patients to the broader health system.

NSWHP will build a more integrated statewide pathology service. Laboratories will be better connected with pathology support services, such as specimen collection centres, to provide a single statewide network of pathology services and expert advice to support high quality outcomes and experiences.

NSWHP will harness new technology and science to reimagine laboratories in terms of what they can provide and how they will operate. Service models will be updated to embrace new technology and ways of working to better meet customer needs. Staff will be equipped and developed to deliver these new service models.

There will be greater integration of service delivery between labs and across former regional networks to remove artificial boundaries and provide a truly statewide service. It is expected there will be an increase in multidisciplinary service provision and reduction in the traditional boundaries between pathology sub-specialties and Clinical Streams as technology platforms change.

Collection services within hospital facilities will be developed to provide greater flexibility for patients in location, scheduling and comfort. Community based collection locations will be enhanced to reduce attendance upon hospital campuses. Home based collection services will support patients treated in the community.

This new approach will require enhanced customer engagement technology. This technology will allow patients and collection staff to feel supported for collection visits and to be empowered with accurate and timely information on their tests and discussion of results with treating clinicians.

NSWHP envisages an enhanced role in screening and monitoring of general health conditions and chronic diseases, enabling integration of primary and secondary care for these patients, and greater presence in the community.

A statewide integrated service will connect and leverage the capacity of all laboratories and enable services and expertise to be enhanced and equitably accessed across the state. It also provides for business continuity for service delivery. In this model, pathologists and scientists will maximise their role as customer advocates, increase direct clinical engagement and enhance the clinical use and interpretation of pathology diagnostic results and data.

Developments in information technology and biotechnology show that bioinformatics will be the pathway to precision medicine. As custodians of a huge volume of patient and system-wide health data, NSWHP is well placed in the role of connecting patients to better care.

Genomic developments will blur traditional boundaries between pathology specialties, as well as disrupt diagnostic requires and clinical responses, and boundaries between pathologists, physicians and surgeons. Genetic analysis will be a feature of core activities within traditional pathology specialties.

By 2025, with key enablers (Statewide LIMS, single test catalogue, harmonised testing platforms, middleware, and statewide quality systems, integrated inventory management system) in place, NSWHP's services will be truly networked on a statewide basis. This will enable equity of access to uniform high-quality clinical diagnostics for all patients in NSW no matter where they live.

Networking NSWHP pathology laboratories enables large hubs to provide specialised services for smaller laboratories which do not have sufficient patients or clinicians to support efficient and effective service provision. This networking is enabled by an agile and efficient logistics and courier system. Networking laboratories supports equitable access to specialised testing that NSW patients deserve and expect and enables the practical implementation of the proposed service models.

Conversely, digitalisation in laboratories brings opportunities to redistribute workload and utilise geographically isolated professional expertise. It will also optimise the reporting capacity of regional and rural staff who can report for services provided by laboratories in metropolitan and other regional/rural sites.

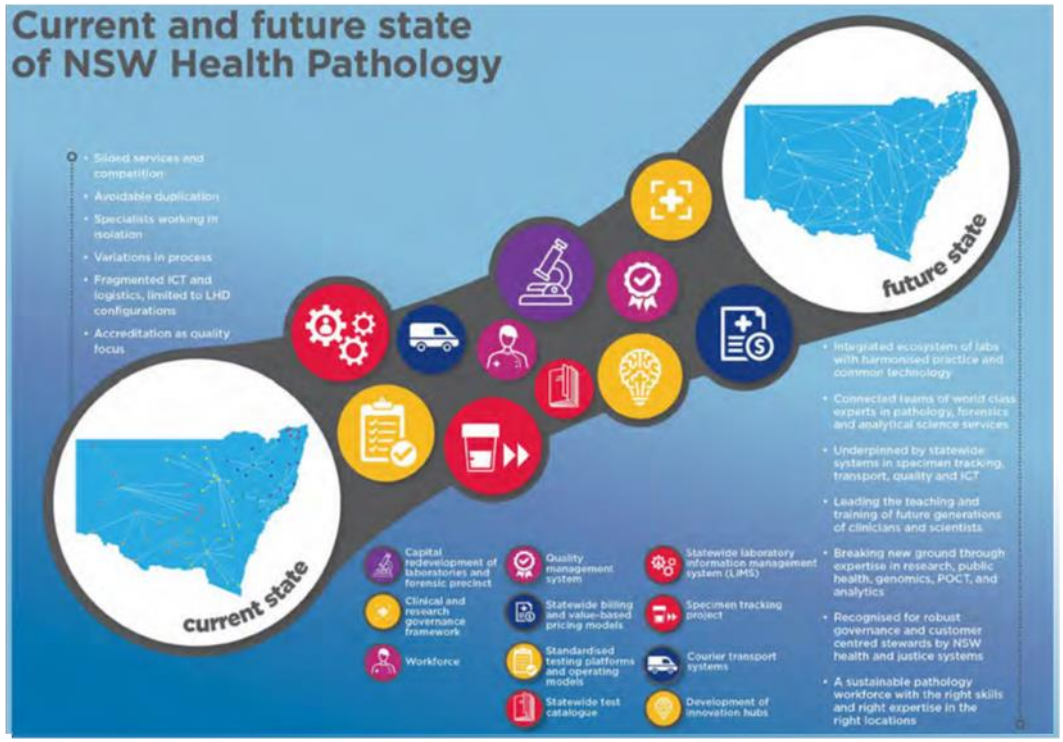
Future pathology services will reach out to customers with more mobile and flexible access. Investment in a customer friendly online portal to allow clients to book a collection time online, download fact sheets and check on opening times/locations will be a key part of providing more timely and flexible services in the future.

Due to generational change and shifts in expectations of health consumers, including requesting clinicians, NSW patients and

communities more direct relationships with service providers and more direct access to, and individual ownership of, health data is required. A sustainable pathology workforce with the right skills and right expertise in the right locations is crucial to the delivery of service models outlined in the CSP.

Over the next five years and beyond, NSWHP will:

- invest in new technology and science to reimagine what pathology services can provide and how they operate.
- utilise information technology to unify statewide information systems, test directories and platforms to enable standardised testing systems and processes, as well as an ability to flex workloads across our networks.
- expand access to specialty pathology services to improve patient outcomes and experiences.
- leverage and expand access to our clinical expertise across the state to enhance support for our clinical peers.
- enable better value in diagnostic pathology service provision through streamlined and consistent service models and enhanced local engagement with LHD and Network services.
- align infrastructure, equipment and workforce in a new structure of pathology services.
- lead the way in teaching, training and research in pathology to deliver better outcomes for the community.



NSWHP will move from this current state to a future model best presented in the diagram above.

5. Current and projected demand for pathology services

5.1. Current health pathology services

Pathology investigations are an integral part of the clinical decision-making process. They support high quality patient care by providing information and expert medical opinion to facilitate accurate and timely diagnosis of diseases and management of patients.

NSW Health Pathology's (NSWHP) work is mostly provided within the NSW Health public health system in the provision of emergency, acute and sub-acute inpatient care and other non-inpatient and clinic services.

NSWHP customers include:

- NSW Health Protection for disease surveillance, outbreak investigation, infection prevention and antimicrobial resistance
- General Practitioners (GPs)
- Community health centres
- Aboriginal Community Controlled Health Services
- Sexual health clinics
- Selected private hospitals
- NSW Police, and
- The NSW Justice system.

The key disciplines or sub-specialties of pathology are to the right. With technology development, there is increasing overlap between these specialties or disciplines and future laboratories will be based around technology platforms rather than solely on traditional specialties.

Disciplines of pathology[6]

Anatomical Pathology, including:

- Histopathology; diagnosing disease by analysing solid tissue samples and reporting on cellular and structural changes.
- Cytopathology; examining separated cells (rather than solid tissue) including fluids and tissue smears to diagnose disease and determine disease post-mortem.

Chemical Pathology: examining chemical changes in blood and body fluids to detect disease and/or check the functional status of organs and tissue to detect conditions like diabetes, high cholesterol and nutritional disorders.

Forensic Pathology: examining human tissue after death, focusing mainly on determining cause of death in sudden or unexpected death.

Genetic Pathology: diagnosing genetic conditions or determining predisposition to future disease using tissue, blood and body fluid samples, including:

[6] RCPA (2018) *Pathology Australia*

- Clinical cytogenetics; microscopic analysis of chromosomal abnormalities (e.g.: to detect Down Syndrome)
- Molecular genetics; using the tools of DNA technology to identify mutations (changes) in genes.

Haematology: study of blood and bone marrow to identify abnormalities, including to diagnose and treat blood cancers (e.g.: leukaemia), anaemia, bleeding disorders and management of blood transfusions).

Immunopathology: involving tests of the immune system. (e.g.: tests for 'allergy antibodies' to various substances or measurement of different classes of antibody proteins to determine the state of the immune system's defence mechanisms).

Microbiology: diagnosing disease caused by infectious agents such as bacteria, viruses, fungi and parasites (e.g.: HIV/AIDS, hospital acquired infection, Legionnaires' disease, tuberculosis and whooping cough).

NSWHP acknowledges that developments in precision medicine, including genomics and proteomics, are expanding the scope of our services. In addition to the traditional role of providing diagnostic information and interpretation, NSWHP is increasingly involved in preventive medicine services and identifying prognosis and treatment options as part of multidisciplinary teams.

5.2. Profile of demand for NSW Health Pathology services

Key services provided by NSWHP to NSW communities include:

- specimen collection including blood
- specimen reception, registration of pathology requests, data management and reporting
- diagnostic testing for inpatients including Emergency Departments (EDs), Intensive Care Units (ICU), coronary care, operating theatres and wards; and outpatient and ambulatory care clinics
- transfusion testing and provision of blood products
- diagnostic testing services to community health centres and sexual health clinics
- consultation liaison with local clinicians, advice on interpretation of results
- involvement in direct patient care including multi-disciplinary teams and direct patient care such as fine needle aspiration and biopsy
- public health services, including testing and monitoring of disease in the community
- diagnostic testing for the justice system
- forensic medicine, criminalistics & environmental sciences, including examinations to determine cause of death, illicit drug, toxicology and DNA analysis. DNA analysis, etc
- human biospecimen biobanking
- research and innovation
- teaching and education, both undergraduates and postgraduates at many tertiary institutions.

5.3. Trends in activity for NSWHP services

In 2017/18 NSWHP received almost 9.5 million pathology requests, representing a 3.8% increase from 2016/17.

The majority (94%) of requests came from patients attending hospitals and collection centres. This is presented by Local Health District (LHD) boundaries in Table 5.1. These requests came from public and private patients, including privately referred outpatients within public hospitals and patients referred to collection centres by GPs.

The remaining 6% was from private hospitals and other agencies and does not include Point of Care Testing (PoCT) conducted outside NSWHP laboratories.

Table 5.3 NSW current and projected population by LHD, 2011-2031

Local Health District	2011 ERP	2016	2021	2026	2031	% growth 2016-2031	% pa growth 2016-2031
Albury Wodonga	49,451	52,100	54,470	56,550	58,340	12.0%	0.8%
Central Coast	322,657	339,550	357,250	374,850	391,050	15.2%	1.0%
Far West	31,127	30,740	30,220	29,510	28,700	-6.6%	-0.4%
Hunter New England	875,573	920,370	962,390	1,001,800	1,038,920	12.9%	0.9%
Illawarra Shoalhaven	385,295	404,660	423,130	440,600	456,790	12.9%	0.9%
Mid North Coast	207,490	218,180	227,980	237,050	245,080	12.3%	0.8%
Murrumbidgee	237,495	241,910	244,870	246,220	246,030	1.7%	0.1%
Nepean Blue Mountains	348,345	375,980	396,790	418,020	440,780	17.2%	1.1%
Northern NSW	288,241	301,600	313,820	325,010	335,310	11.2%	0.7%
Northern Sydney	853,162	910,260	966,340	1,015,340	1,069,690	17.5%	1.2%
South Eastern Sydney	848,378	911,510	970,370	1,016,160	1,071,930	17.6%	1.2%
South Western Sydney	875,763	966,450	1,057,080	1,176,170	1,284,700	32.9%	2.2%
Southern NSW	196,840	208,770	220,020	230,870	240,990	15.4%	1.0%
Sydney	581,936	639,530	706,850	766,530	832,790	30.2%	2.0%
Western NSW	270,775	279,200	286,410	292,300	297,530	6.6%	0.4%
Western Sydney	846,001	947,460	1,079,650	1,217,460	1,348,350	42.3%	2.8%
Total	**7,218,529**	**7,748,270**	**8,297,640**	**8,844,440**	**9,386,980**	**21.1%**	**1.4%**

5.4. Key demand drivers

Overseas studies show that 70% to 80% of all health care clinical decisions involve a pathology investigation. Pathology provides source information for 90% of all diagnostic health care records[7].

Demand for NSWHP services arise from three sources:

a. activity in NSW public hospitals, particularly emergency, acute and sub-acute inpatient care and non-inpatient and clinic services.
b. health protection, supporting public health surveillance, outbreak investigation, infection prevention and antimicrobial resistance.
c. other providers, including selected private hospitals, GPs, community health centres, Aboriginal Community Controlled Health Services, sexual health clinics, NSW Police and the NSW Justice Department.

As most NSWHP service requests are ordered by public hospitals and health services we can assume that demand for NSWHP diagnostic services will rise in line with demand for the NSW health system.

Key drivers are population growth and ageing, and increasing prevalence of chronic and complex conditions within the NSW population.

Demand for these services is expected to increase at a rate of between 1.9 to 2.1% per annum over the period to 2031 (discussed in Section 5.5.2). Demand from GP referrals to collection centres on and off hospital sites is expected to grow at similar rates.

5.4.1. Population growth and ageing

Population growth and ageing drives demand for acute inpatient and ED services within the NSW Health system (discussed in Section 5.5.1). Other factors expected to drive increases in volume and complexity of NSWHP diagnostic testing include.

5.4.2. Chronic disease

Chronic diseases are the leading cause of illness, disability and death in Australia, accounting for 90% of all deaths in 2011[8]. Chronic diseases have become increasingly common and now cause most of the burden of ill health.

Chronic disease is categorised in four major disease groups - cardiovascular, cancer, chronic obstructive pulmonary disease (COPD) and diabetes. These four disease groups account for three-quarters of all chronic disease deaths, with cancer services a major driver of volume and complexity growth throughout pathology services. In addition to the increasing prevalence of acute health conditions, regular diagnostic testing of patients living with chronic disease is also growing. There is

[7] Forsman (1996) UK Department of Health

[8] AIHW (2011) Key indicators of progress for chronic disease and associated determinants, Data Report PHE142

increasing complexity in diagnostic medicine, particularly in guiding the use of new therapeutic agents.

There are groups of Australians who have above average prevalence of chronic disease, including Aboriginal people, migrants and people affected by social determinants of health who experience significantly poorer health status and health outcomes compared to the general community.

5.4.3. Impact of technology

Technology has a significant impact on pathology services. It facilitates earlier and different clinical interventions in support of acute clinical care, monitoring disease, and in expanding realms of wellness, risk mitigation and lifestyle management. Technological advances grow the number of new tests, and the cost and complexity of those tests. A good example is the proliferation of diagnostic tests to support the more targeted identification and management of cancer treatments.

Technologies with the greatest potential and ongoing impact are molecular diagnostics, near patient testing, image analysis, automation/robotics, genomics and information management.

Molecular pathology tests with potential clinical use is expanding rapidly. Investigations for circulating tumour cells and cell free DNA may soon find a role in the treatment of solid malignancies. DNA tests in oncology can detect small numbers of tumour cells, but the clinical and diagnostic use of such tests is yet to be established.

Continued improvements in biosensor technology and miniaturisation are increasing the ability to test for many analytes at or near the patient. Computerised image analysis has the potential to radically change, and in some cases, eliminate, manual clinical microscopy in urinalysis, haematology, immunohistochemistry, cytology and histology. Analysis of computerised images can be undertaken by pathologists and scientists from any location across NSW and will enable patients to receive timely care from wherever they enter our services.

Genomic technology is also transforming the way healthcare is delivered. Genomics can provide greater accuracy in determining disease risk, assessing diagnosis and prognosis, and inform selection of therapeutic options for care.

Automation is increasing in genomics with introduction of high throughput platforms, such as micro-arrays and next generation sequencing, which enable convergence of many genetic tests to a single platform.

Genomic developments are also resulting in overlap and blurring of the boundaries between traditional pathology specialties for example histology and cytology.

Genetic analysis will be a feature of core activities within traditional disciplines such as urinalysis, haematology, immunohistochemistry, cytology and histology

Robotics will diminish repetitive manual tasks, such as specimen transport, processing and aliquoting. Image management systems will archive diagnostic gross and microscopic images along with traditional

text descriptions and diagnosis. Telepathology will link smaller labs with expert pathology consultants in other NSWHP sites.

5.4.4. Development of new guidelines, protocols and evidence

Healthcare research and innovation is increasing guidelines and protocols leading to significant increases in pathology tests.

Examples include:

- protocols for population screening for cancers such as breast, cervical and bowel cancer; and
- development of best practice guidelines in patients receiving anticoagulant warfarin, which has resulted in regular INR testing for bleeding disorders.

Pathology activity will increase due to:

- recognition of new diseases
- sub-classification between similar diseases
- quantification of prognostic markers within a disease
- introduction of new tests and services, and
- increases in the number of tests requested for each episode of care (many more tests can be done on the same specimen).

5.4.5. Clinical care and access to therapeutics

There is increasing use of pathology testing to support therapeutic drug regimes in hospitals. This requires regular monitoring to ensure appropriate patient selection and effective dosing of drugs.

Pathology is a central component of clinical decision-making and treatment selection for an increasing number of malignant tumours. For example, genetic testing for breast and lung cancers will guide clinical management, choice of treatment modalities and may indicate prognosis. Microbiology molecular testing can provide faster and more explicit indications of infectious agents allowing more targeted antibiotic regimes, rather than previous broad-spectrum drugs. Flow cytometry and cytogenetics enables clinicians to be more specific in classifying and characterising leukaemia and determining the therapeutic regime and treatment plan.

5.4.6. Public health policy requirements

Community disease outbreaks, such as influenza, measles and whooping cough, result in spikes in diagnostic testing activity. These spikes may be of a predictable, seasonal or unpredictable epidemic nature. The importation of exotic diseases, escalation in disease prevalence or development of emerging disease is of public health and community concern.

5.4.7. Preventative medicine

Increasing numbers of tests will be ordered in the future to identify potential risk for individuals and families and to monitor general health and wellbeing (in the General Practice environment). Health services will be looking for more options to manage health conditions outside of the hospital environment.

5.4.8. Treating clinician practice

Quality use of pathology reduces excessive, inappropriate and unnecessary testing, and encourages appropriate testing activities. Patient care is compromised by unnecessary testing as much as neglected or unordered testing. There will always be variation in ordering pathology tests by clinicians or institutional practices. Ensuring appropriate ordering of tests via education, audit, expert assistance and feedback is an ongoing strategy within the public hospital sector. Learnings gained from unexpected hospital deaths will also inform clinical practice into the future.

5.4.9. Increasing reliance upon forensic science and forensic medicine to provide answers that support grieving families and solve crime

Trends in crime, including the manufacture, use and importation of illicit substances, arson, sexual assault and homicide, coupled with changes in policing priorities that emphasise forensic intelligence, are key drivers of demand for our forensic sciences. Rapid developments in DNA technologies, increasing sample submissions from crime scenes, the ability to access expanded applications on the National Criminal Investigation DNA database and legislative change such as the Early Appropriate Guilty Plea, all drive our forensic sciences to provide rapid, high quality results that enable crimes to be solved.

Answers provided by forensic science and forensic medicine will be relied upon to support families as well as informing and alerting the community in respect of both justice and health related impacts upon society. Forensic medicine will continue to be a key clinical link between the NSW health and justice systems.

5.5. Future demand for NSWHP services to 2025

5.5.1. Population growth and ageing

Population growth and an ageing population are the major drivers of health and pathology service demand in NSW. The population of NSW is projected to grow about 21% between 2016 and 2031 from 7, 748,270 in 2016 to 9,386,980 in 2031 (1.4% per year).

There is substantial variation across NSW with Western Sydney Local Health District (LHD) projected to grow as high as 2.8% p.a. between 2016 and 2031, and 2.2% p.a. in South Western Sydney LHD. However, rates of population growth are lower in rural NSW, and in Far West LHD, the population is expected to decline.

People aged over 65 years are frequent users of the NSW public hospital system and pathology services. Their numbers are projected to increase at a rate of 3.4% per annum over the period 2016 to 2031, as indicated in Table 5.4 (on page 45).

Table 5.3: NSW Current and Projected Population by LHD, 2011-2031

Local Health District	2011 ERP	2016	2021	2026	2031	% growth 2016-2031	% pa growth 2016-2031
Albury Wodonga	49,451	52,100	54,470	56,550	58,340	12.0%	0.8%
Central Coast	322,657	339,550	357,250	374,850	391,050	15.2%	1.0%
Far West	31,127	30,740	30,220	29,510	28,700	-6.6%	-0.4%
Hunter New England	875,573	920,370	962,390	1,001,800	1,038,920	12.9%	0.9%
Illawarra Shoalhaven	385,295	404,660	423,130	440,600	456,790	12.9%	0.9%
Mid North Coast	207,490	218,180	227,980	237,050	245,080	12.3%	0.8%
Murrumbidgee	237,495	241,910	244,870	246,220	246,030	1.7%	0.1%
Nepean Blue Mountains	348,345	375,980	396,790	418,020	440,780	17.2%	1.1%
Northern NSW	288,241	301,600	313,820	325,010	335,310	11.2%	0.7%
Northern Sydney	853,162	910,260	966,340	1,015,340	1,069,690	17.5%	1.2%
South Eastern Sydney	848,378	911,510	970,370	1,016,160	1,071,930	17.6%	1.2%
South Western Sydney	875,763	966,450	1,057,080	1,176,170	1,284,700	32.9%	2.2%
Southern NSW	196,840	208,770	220,020	230,870	240,990	15.4%	1.0%
Sydney	581,936	639,530	706,850	766,530	832,790	30.2%	2.0%
Western NSW	270,775	279,200	286,410	292,300	297,530	6.6%	0.4%
Western Sydney	846,001	947,460	1,079,650	1,217,460	1,348,350	42.3%	2.8%
Total	**7,218,529**	**7,748,270**	**8,297,640**	**8,844,440**	**9,386,980**	**21.1%**	**1.4%**

In 2016, people aged over 65 years represented 16% of the total NSW population, and are projected to account for 20% in 2031. The rate of increase in the older population group is consistently high across all LHDs.

Table 5.4: Resident Population Aged over 65 Years by LHD 2011 - 2031

Local Health District	2011 ERP	2016	2021	2026	2031	% pa growth 2016-2031	% pa growth 2016-2031
Albury Wodonga Health - Victoria	7,363	8,780	10,370	12,160	13,600	55%	3.7%
Central Coast	60,606	69,300	79,170	90,810	101,280	46%	3.1%
Far West	5,528	6,260	6,910	7,590	7,950	27%	1.8%
Hunter New England	149,627	173,910	198,680	225,830	248,970	43%	2.9%
Illawarra Shoalhaven	68,242	79,030	90,180	103,070	114,430	45%	3.0%
Mid North Coast	43,800	51,120	58,830	67,360	74,270	45%	3.0%
Murrumbidgee	40,999	47,370	53,480	59,980	64,890	37%	2.5%
Nepean Blue Mountains	40,590	53,290	65,170	77,240	87,560	64%	4.3%
Northern NSW	55,882	64,860	75,250	86,370	95,400	47%	3.1%
Northern Sydney	126,035	144,380	162,050	182,280	204,190	41%	2.8%
South Eastern Sydney	115,855	133,220	150,440	169,980	190,430	43%	2.9%
South Western Sydney	100,779	126,720	154,600	188,310	220,620	74%	4.9%
Southern NSW	33,690	41,030	48,320	56,260	63,130	54%	3.6%
Sydney	67,918	79,660	92,930	108,240	125,030	57%	3.8%
Western NSW	43,810	50,850	57,430	64,440	70,140	38%	2.5%
Western Sydney	88,180	110,980	136,420	165,530	195,630	76%	5.1%
Total	**1,048,904**	**1,240,760**	**1,440,230**	**1,665,450**	**1,877,520**	51%	3.4%

5.5.2. Trends in public hospital activity in NSW

There is a very high correlation between demand for acute hospital services, such as Emergency Department (ED) presentations and acute inpatient admissions, and demand trends for pathology services.

While development of a service activity projection methodology is embryonic for NSWHP, the acute hospital system has used projection methodologies for many years. Local health districts and networks use these tools to project future demand and create scenarios to inform clinical service and infrastructure development.

The NSW Ministry of Health has developed the *HealthAPPAnalytics* projection modelling tool using historical trends of hospitalisation and projected population growth and ageing, trends in length of stay and separation rates to develop projections of inpatient separations and bed-days.

Using these tools, the total volume of acute inpatient separations in NSW is projected to increase by 27% (or 1.9% per annum) over the next 14 years from 1,260,224 in 2016/17 to 1,599,610 in 2030/31.

Overall growth projected between 2017 and 2031 varies from 46% for Western Sydney to just 1% for Murrumbidgee LHD.

Table 5.5: Current and Projected Acute Hospital Separations by LHD 2016/17 – 2030/31

	Separations			% Change	% Change pa
LHD	2016/2017	2025/26	2030/31	2017-2031	2017-2032
Central Coast	61,963	66,779	73,046	18%	1.3%
Far West	5,746	5,751	5,928	3%	0.2%
Hunter New England	162,987	182,514	197,590	21%	1.5%
Illawarra Shoalhaven	59,902	68,815	74,816	25%	1.8%
Mid North Coast	57,230	60,600	65,827	15%	1.1%
Murrumbidgee	52,103	49,528	52,546	1%	0.1%
Nepean Blue Mountains	61,122	72,122	80,262	31%	2.2%
Northern	69,934	80,408	87,193	25%	1.8%
Northern Sydney	106,407	117,886	129,532	22%	1.6%
South Eastern Sydney	112,936	132,141	145,356	29%	2.1%
South Western Sydney	152,708	183,324	208,454	37%	2.6%
Southern	31,320	35,654	39,081	25%	1.8%
Sydney	105,972	128,539	143,560	35%	2.5%
Sydney Children's Hospitals Network	45,715	57,543	63,501	39%	2.8%
Western	60,998	64,420	68,190	12%	0.8%
Western Sydney	113,181	144,939	164,728	46%	3.3%
Total	**1,260,224**	**1,450,963**	**1,599,610**	**27%**	**1.9%**

Source: Flowinfo V17, HealthAppAnalytics

Includes: Acute Care Type, NSW Public Hospitals, Acute Psychiatry delivered in Acute Setting

Excludes: Chemo,Renal Dialysis, Unqualified Neonates, ED Only, Hith, Psychiatric and Subacute Care Type

Annual rates of growth are quite substantial for LHDs in western Sydney ranging from 2.2% p.a in Nepean LHD, to 2.6% in South Western Sydney LHD and 3.3% in

Western Sydney LHD. By comparison projected growth rates for Far West, Murrumbidgee, Mid North Coast and Central Coast LHDs are 1.5% p.a or lower.

Projected rates of growth in acute hospital separations are greatest for NSW Public Principal Referral Hospitals as illustrated in Figure 5.1.

Rates of growth vary between -2.5% p.a. in Far West to 4.1% p.a in Western Sydney (refer Table 5.6).

A similar rate of increase is projected for ED presentations in NSW over the same period. Total ED presentations are projected to increase by 30% (approx. 2.1% per annum) from 2,742,961 in 2016/17 to 3,555,269 in 2030/31.

Figure 5.1: NSW Acute Activity by Peer Group – Actual and Projected 2016/17 to 2036

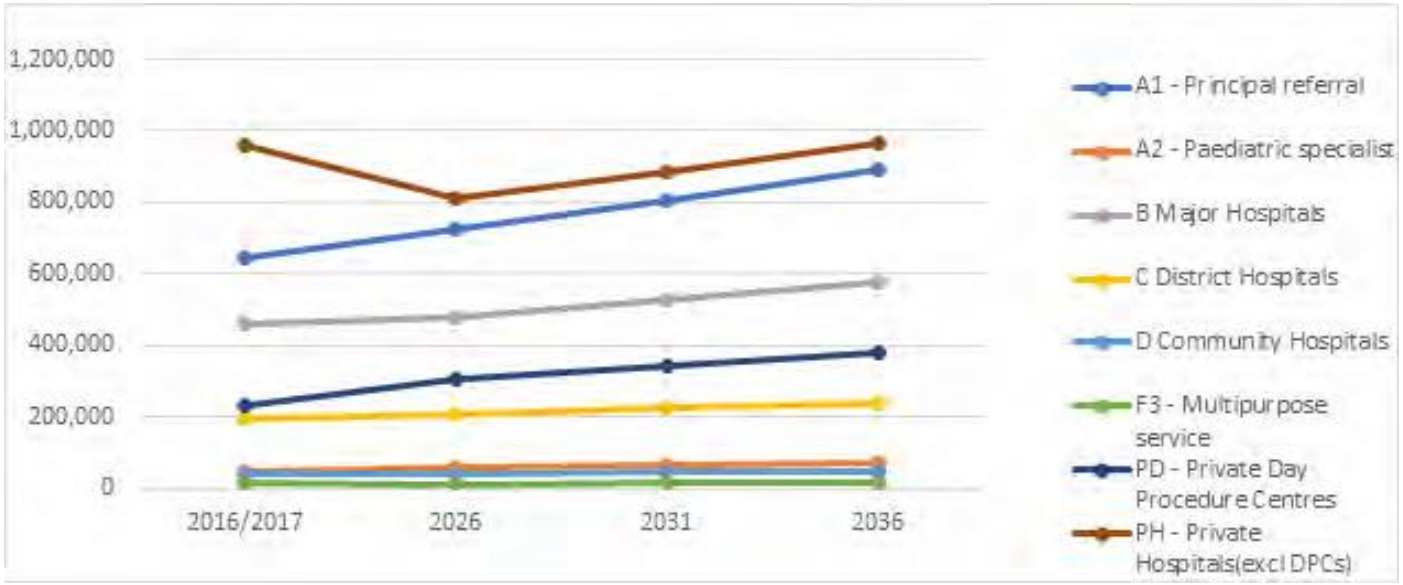
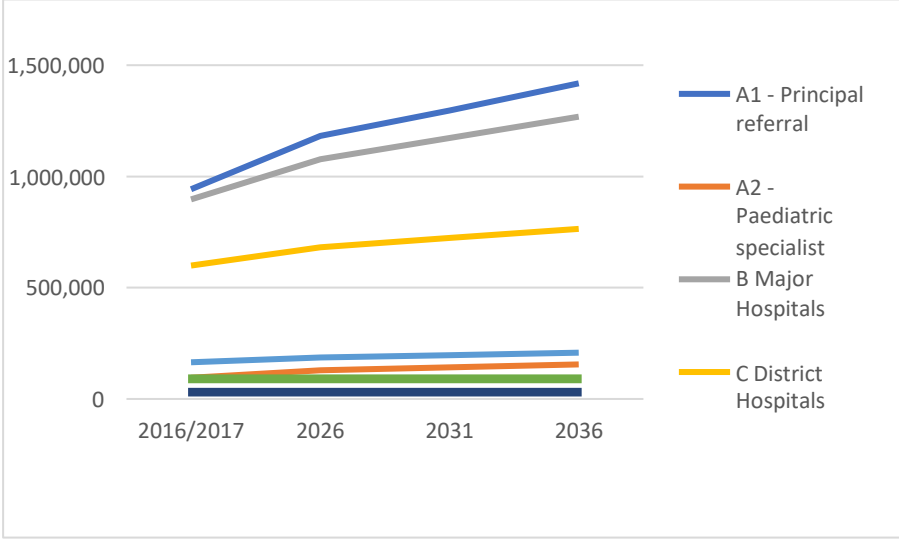


Table 5.6 Current and projected ED presentations by LHD 2016 -2031

	ED Presentations			% Change	% Change pa
LHD Of Hospital Name	2016/2017	2025/26	2030/31	2017-2031	2017-2032
Central Coast	131,516	150,178	162,009	23%	1.7%
Far West	28,138	18,486	18,431	-34%	-2.5%
Hunter New England	410,499	468,507	497,829	21%	1.5%
Illawarra Shoalhaven	153,100	178,565	190,354	24%	1.7%
Mid North Coast	122,647	138,645	147,597	20%	1.5%
Murrumbidgee	146,482	141,364	145,244	-1%	-0.1%
Nepean Blue Mountains	122,002	151,817	165,723	36%	2.6%
Northern	199,149	227,096	241,703	21%	1.5%
Northern Sydney	209,753	256,668	279,523	33%	2.4%
South Eastern Sydney	220,440	272,668	295,647	34%	2.4%
South Western Sydney	271,185	357,808	404,069	49%	3.5%
Southern	105,892	127,934	136,331	29%	2.1%
Sydney	160,246	222,360	245,778	53%	3.8%
Sydney Children's Hospitals Network	94,685	128,856	141,546	49%	3.5%
Western	184,740	188,416	195,666	6%	0.4%
Western Sydney	182,487	253,910	287,819	58%	4.1%
Grand Total	**2,742,961**	**3,283,278**	**3,555,269**	**30%**	**2.1%**
Source: EDAA 17, HealthAppAnalytics					

Figure 5.2 NSW ED activity by peer group – actual and projected 2016/17 to 2036



Source: CaSPA accessed December 2018

5.5.3. Interim projection of demand for NSWHP services

Growth in pathology demand aligns with growth in hospital activity, and in many cases, has grown faster than hospital demand due to the increasing reliance on pathology to inform clinical diagnosis and monitor ongoing treatment responses and requirements. Introduction of a larger range of diagnostic tests means more tests per patient per presentation.

For NSWHP, total pathology requests increased by 3.8% in 2017/18 compared to the previous year (2016/17) as indicated in Table 5.1.

This correlates with a projection of pathology activity in Australia in the recent workforce study by the RCPA[9].

This study used two measures of demand drivers to identify future demand growth:

- Total Medicare Benefits Scheme (MBS) billed service items for the MBS pathology service grouping 2011 to 2016 adjusted for weighted service volume for Anatomical Pathology using Relative Time Units[10] (RTUs) service grouping.
- trends in total workforce size 2011 to 2016.

The trend in demand growth of billed items was 3.8% per annum and was used as the high scenario for demand growth in the workforce study.

The trend in workforce size was 3.4% per annum and was used as the low scenario.

It is recommended that a system-wide, interim overall projection of NSWHP statewide activity be estimated at between 3 to 4% per annum. Activity projections for specific hospital laboratory redevelopments should be linked to projected increases in acute hospital activity for that hospital or LHD because there is significant regional variation in projected growth rates across NSW.

There is also the potential for significantly higher rates of growth driven by further technological advances - such as growth in biomarker tests deriving from precision medicine research being translated into clinical practice -and further developments in genomics and proteomics.

It should be noted that hospitals and LHDs are developing clinical service plans that move away from traditional inpatient models of care towards ambulatory care and home-based care. This will influence historical trends for pathology services. Projections need to align with LHD projections and consider the effects on pathology services.

NSWHP's projection methodology will use historical trends, consultation with pathology clinical streams and managers, as well as reviews of literature describing the future trends in services to develop projections.

[9] RCPA (2018) *Australian Pathologist Workforce Study 2018*

[10] RCPA System to convert Medicare items into time needed by a pathologist to report the case

6. NSW Health Pathology services overview

6.1. Organisation and management of our services

NSW Health Pathology's (NSWHP) current organisational structure is presented in Figure 6.1. The key governance structures are the Board and the Strategic Leadership Team (SLT).

Key members of the SLT in terms of management and planning of clinical services include:

- Executive Director, Strategy & Transformation (strategic, operational and capital planning, clinical service design for the Statewide Clinical Streams, analytics and benchmarking performance)
- Chief Medical Information Officer/Executive Director, Statewide Clinical Services (clinical leadership, digital strategy, innovation) and ICT
- Executive Director, Clinical Operations (strategic leadership for pathology operations)
- Executive Director, Clinical Governance & Quality
- Executive Director, Medical Services
- Executive Director, Scientific & Technical Strategy
- Executive Director, Forensic & Analytical Science Service
- Executive Director, Corporate Governance.

In terms of clinical service planning and delivery, the clinical streams and statewide clinical services are responsible for making recommendations to the NSWHP Executive for service directions. Operations Directors are responsible for operationalising strategic priorities (including accepted service directions from the Clinical Streams) and for day-to-day operational management.

Local Pathology Directors at each Local Health District (LHD) are responsible for clinical governance and together with the Operations Director, provide leadership and lead communication with LHD Executive and senior clinicians. Local Pathology Directors and Operations Directors report to the Executive Director, Clinical Operations.

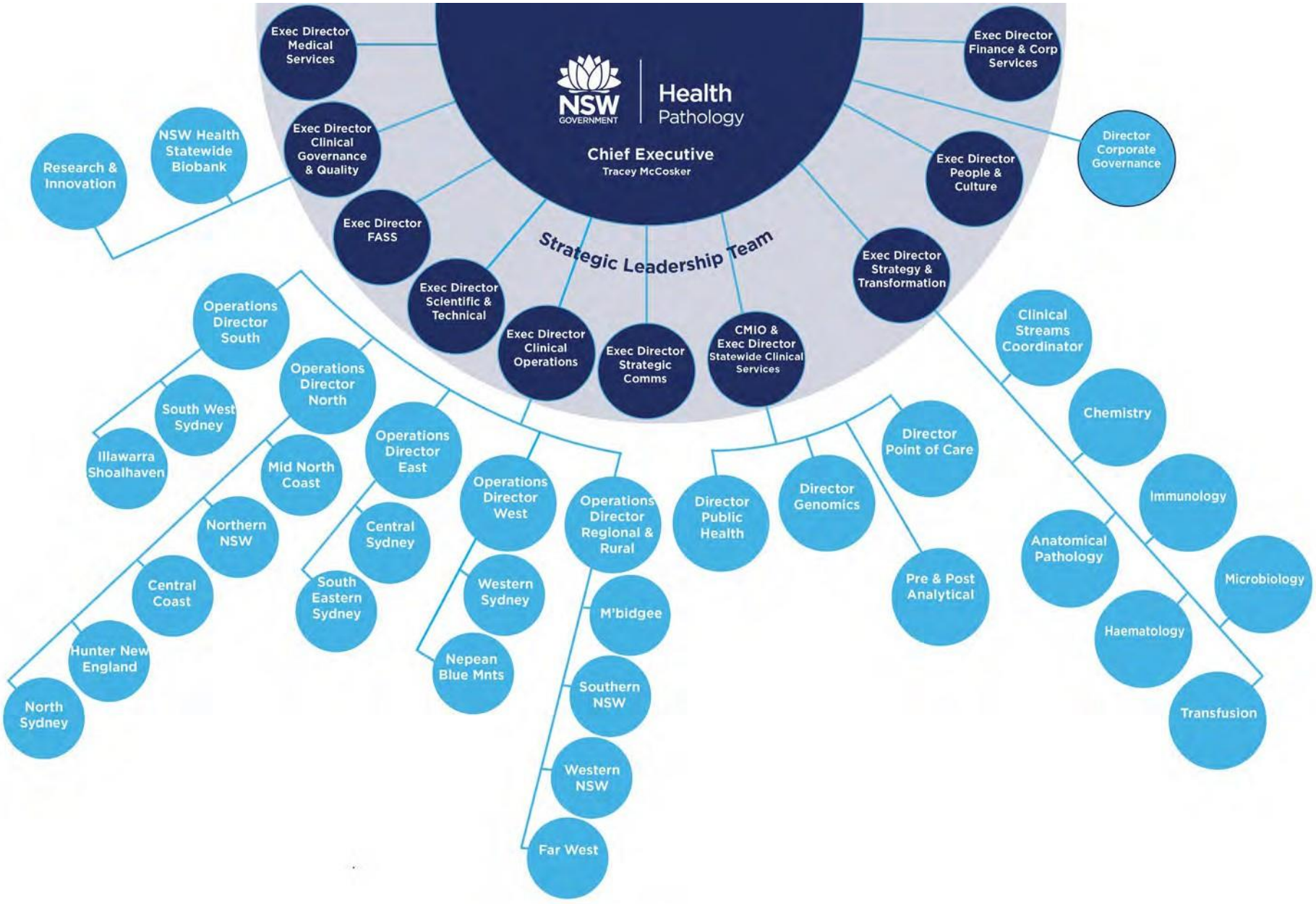
The five Operations Directors have geographically based areas of responsibility and are assisted by Operations Managers in day-to-day operation of their sites. Laboratory Managers are responsible for the running of laboratory services, which may include an entire laboratory or perhaps an individual discipline-specific department such as microbiology.

This structure is mirrored in the Forensic & Analytical Science Service where the Chief Forensic Pathologist, Branch Directors and Operations Leads, along with Laboratory Managers and Team Leads undertake these functions.

In large laboratories, each discipline department has a Clinical Director, a pathologist who has a clinical governance responsibility (and often for specialties at smaller sites where there is no pathologist in that specialty).

In many cases, Senior Medical Officers have dual clinical and diagnostic roles and close associations with the clinical services where they are based. Within specialities, scientists oversee service provision in their laboratories.

Figure 6.1 – NSWHP Organisational Chart, October 2019



6.1.1. Organisation

6.1.2. Clinical streams and statewide services

NSWHP has created discipline clinical streams to lead clinical service planning discussions in haematology, chemical pathology, transfusion, immunology, microbiology and anatomical pathology.

There are also newer service realms of Pre and Post Analytical, Point of Care Testing (PoCT), Genomics and Public Health Pathology.

The Forensic & Analytical Science Service (FASS) is the only specialty public sector provider of forensic services in NSW, providing a statewide service in both Forensic Medicine and the Forensic & Environmental Sciences.

Each of these is described below.

Clinical streams

Pre and Post Analytical (P&PA)

Pre and Post Analytical services are the glue that ensures the effectiveness of NSWHP services. They are custodians of the patient specimen up to handover to the laboratory. P&PA maintains the NSWHP Test Directory, manages distribution of test results and is responsible for patient care in NSWHP facilities or while undergoing sample collection.

It is responsible for collection, transport and delivery of high-quality patient specimens to over 60 testing laboratories and delivery of timely, accurate and comprehensible results to requesting clinicians. For tests not performed at the site receiving the sample, P&PA staff pack and transport specimens to the relevant laboratory for testing.

Services provided include:

- phlebotomy/specimen collection,
- couriers
- pre-analytical request registration and specimen processing
- dispatch of tests to specialist labs for testing
- delivery of test results and reports
- customer engagement.

Services also include advocacy for the service, clients and customers. Staff also manage patient and client inquiries, although this is often performed by dedicated customer service staff in larger centres.

There are collection services at 100 sites in LHDs, as well as 48 community collections centres across the state. Phlebotomy services support inpatients in public and private hospitals and aged care facilities, as well as outpatients in clinics and community collection centres. There is also a home collection service provided in many areas.

Chemical Pathology

Chemical Pathology is the pathology discipline that detects changes in substances in blood and body fluids (electrolytes, enzymes and proteins) as a consequence of disease. In addition, it detects and measures tumour (cancer) markers, hormones, poisons and therapeutic and illicit

drugs. Changes in the presence or level of these substances may be an indicator of the presence, cause or severity of a disease and the progress of treatment.

Chemical pathology produces the highest volume of specimen testing in pathology, including many of the most requested tests, for example, electrolytes and liver function tests.

Most chemical pathology tests are part of the routine ‘core’ laboratory tests undertaken in a high throughput laboratory setting. This is essential for immediate patient care and is available in all public hospitals, delivered by either on-site laboratories or through Point of Care Testing devices. Some specialised testing areas in Chemical Pathology are for inherited metabolic diseases, trace metals and environmental monitoring, drugs of abuse, and nutrition. These are usually referred to NSWHP’s larger tertiary hospital laboratories.

Haematology

Haematology is a clinical specialty concerned with the cause, diagnosis and treatment of diseases that affect the blood and blood-producing organs.

- haematology services manage;
- patient sample testing
- storage and management of full blood counts (FBC)
- blood films
- routine and special coagulation
- flow cytometry
- haemoglobinopathy testing
- haematological genetic testing
- pathology services in support of bone marrow and organ transplantation.

The Haematology Clinical Stream covers pathology services ranging in complexity from routine time-critical tests provided in labs at all levels of the health system, such as full blood counts, to very specialised services provided only in tertiary hospital settings such as genetic testing and bone marrow transplantation (BMT) support.

Haematology has heavy involvement and integration between laboratory diagnostic testing and clinical care. Haematologists are involved in laboratory testing related to diagnosis and monitoring of therapy. They provide clinical advice and treatment directly to patients. They also assist clinicians with haematological support for other specialty practice. This includes consultation and support for a broad range of haematological conditions, and anticoagulation reversal in acute and critical care settings.

Transfusion

Transfusion services manage patient sample testing, storage and management of fresh blood and blood components at the pre-transfusion stage, as well as antenatal and post-natal haematology testing. Consultation and support for transfusion services is provided in a broad

range of medical and surgical settings, particularly in acute and critical care settings.

Transfusion services are provided at all NSWHP laboratories. In addition, management of blood in some hospitals where there is no laboratory, as well as for NSW Ambulance and the Royal Flying Doctor Service is also provided. There are defined pathways for referral of transfusion samples for testing from small to medium to large laboratories.

Anatomical Pathology

Anatomical (or anatomic) pathology is the branch of medicine that involves the study of human organs and tissues and has a large role in cancer diagnosis. Anatomical pathology is vital where a sample of tissue or tissue cells is taken from the patient to provide diagnosis and allows clinicians to give the most appropriate advice and treatment to their patients.

It has roles in:

- determining the cause of disease
- the effect(s) these diseases have on the body and specific organs or tissues
- the choice of treatment to be given
- prediction of prognosis, and
- determining cause of death.

There are two main subdivisions within anatomical pathology. The first is histopathology which involves examination of sampled fragments of tissues. This is often aided by special staining techniques and other associated tests, including histochemistry, immunohistochemistry and in-situ hybridization. The second is cytopathology which exams single cells. Services include fine needle aspiration of biopsy specimens and electron microscopy - a separate sub-discipline which supports both histology and cytology. A common cytology test is the cervical smear.

Anatomical pathologists are also involved in performing non-coronial post-mortem examinations including pre-natal post-mortems.

Microbiology

Microbiology is the study of the cause of infectious diseases. This can require microscopic or genomic examination of a patient's samples or detection of organisms from patient specimens. Microbiology also explores the susceptibility of organisms to antibiotics to help decide on treatment.

Services provided by Microbiology include:

- general bacteriology
- virology
- mycology
- mycobacteriology
- parasitology
- serology

- Nucleic Acid Amplification Testing (NAAT) and other molecular-based tests (which overlap all pathogen-based groupings)
- short incubation/ near patient testing/ point of care testing (overlaps with some of the above groupings), and
- testing for organisms of public health significance e.g. legionella that involves pathogen genomics and environmental samples e.g. water.

Immunology

Immunology specialises in disorders of the immune system, including autoimmune disorders such as rheumatoid arthritis, lupus, Crohn's disease and coeliac disease. Production of antibodies (proteins produced in response to a foreign organism or substance) is central to the body's ability to fight infection. Without adequate levels of antibodies, the body's defence is lowered but high levels of antibodies can be indicative of autoimmune disease. Services include tests to establish whether someone is immunodeficient.

Services provided by immunopathology include:

- autoimmune serology
- specialised immunochemistry
- allergy testing
- immunogenetics (particularly HLA – a human leukocyte antigen is a gene complex that assists in regulation of the immune system)
- cytokine testing, and
- flow cytometry.

Immunopathology overlaps with other disciplines:

- HIV testing (with microbiology),
- flow cytometry (overlap with haematology),
- endocrine testing (overlap with chemistry),
- complex therapeutic monitoring (overlap with therapeutic drug monitoring),
- Human Leukocyte Antigen (HLA) and other genetic testing (overlap with genomics / molecular),
- some individual tests also cross disciplines (such as latent tuberculosis and H pylori – a common digestive tract infection)

Statewide services:

Genomics

The NSWHP Statewide Genomics Service covers rare diseases, cancer and pathogens (described below), and translational research to promote development of new clinical models of care and diagnostic services. NSWHP currently performs over 80,000 genetic and genomic tests annually, such as clinical exome sequencing for rare disorders, gene panels for rare cancer syndromes and tumour profiling, and sequencing infectious organisms.

Genetic testing has traditionally been provided by molecular genetics and cytogenetic laboratories. However, current technology advances are merging these disciplines into a single discipline of genomics. Fellowship

training programs run by the Royal College of Pathologists of Australasia (RCPA) are merging to reflect this change, with a single Fellowship in Medical Genomics replacing separate training programs in Cytogenetics and Molecular Genetics.

Tests are mostly performed in tertiary or specialised labs depending on the complexity of testing, prevalence of abnormalities for which testing is performed and co-location with other services. Future structures for genomics should further promote the merging of these laboratories where this has not already occurred.

There are four broad categories of genomic testing:

1. **Cancer genomics:** (Includes Molecular Genetics and Cytogenetics)
- Familial cancer predisposition testing (inherited risk)
- Tumour profiling:
  - solid tumours (associated primarily with Anatomical Pathology)
  - haematological tumours (associated primarily with Haematology)
  - predictive selection of therapeutic drugs (relationship with oncology)

There is overlap between these groupings in terms of technology.

2. **Rare diseases**: (includes Molecular Genetics and Cytogenetics)
- inherited conditions (e.g. Cystic Fibrosis, Haemochromatosis, population specific conditions)
- rare conditions e.g. a single genome or exome test
- primarily in genetics clinics and expanding application in cancer and cardiac clinics.

3. **Pathogen genomics:**
- strong links to public health surveillance and hospital outbreaks, food and water testing, legionella, salmonella etc
- likely to replace traditional methods of microbiology analysis when developed further:
  - culture free analysis of specimens
  - metagenomics (mixed pathogen analysis of primary specimens.

4. **Genomics Statewide Exome/Genome Data Facility:**
- this is an initiative with Hunter Medical Research Institute (HMRI) and operated by NSWHP Genomics Statewide Service. Further funding for a second instrument and operational funding from the NSW Ministry of Health became available in March 2019
- data distribution network (run as a distributed service)
- will provide high throughput sequencing for cancer and rare diseases as well as pathogen genomics in time.

Biobank

NSWHP opened the Statewide Biobank at Royal Prince Alfred Hospital (RPAH), Camperdown in November 2017 and operates the facility and its services in partnership with NSW Health's Office of Health and Medical Research (OHMR).

The Biobank has large scale robotic technology which can store and process over three million human biospecimens including tissue, blood, DNA and tumour cells. Highly specialised automated equipment reduces the time taken to manage and retrieve samples.

This the first and largest statewide biobank of its kind in Australia and it provides a variety of temperature-controlled storage environments for research biospecimens, including -196ºC cryogenic vats, -80ºC freezers and a large scale -80ºC robotic Biostore which can process and store over three million human biospecimens including tissue, blood, DNA and tumour cells.

NSWHP has been the recipient of significant financial resourcing by NSW Ministry of Health (MOH) to develop Public Health Pathogen and Rare Disease Genetic testing.

Point of Care Testing (PoCT)

PoCT enables diagnostic testing to be performed at or near the site of patient care in a clinically acceptable timeframe.

The NSWHP PoCT service provides advice, support and strategic direction in the implementation of PoCT within NSW Health and is the largest POCT service in Australia.

The service:

- supports laboratories to manage PoCT performed on their hospital campus
- provides onsite training, maintenance and regulatory compliance assistance for LHD staff
- assists governance over the selection of compatible and endorsed PoCT equipment
- provides outreach support for PoCT delivered at sites where there is no laboratory onsite
- improves access to pathology services by Aboriginal and isolated communities.

As health care moves from hospital to community based care, and the greater focus on prevention rather than treatment, the role of POCT will grow.

Public Health Pathology

Public health is defined as “the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society[11]”. It is part of the ‘one health’ concept, defined as an approach to designing and implementing programs, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes (WHO).

[11] Acheson, 1988; WHO

NSWHP laboratories produce results for both individual patient care and for protecting the general population's health. Public health has application to all areas of pathology and medicine, although the most obvious are in microbiology and infectious diseases.

There are legislative requirements around provision of laboratory results monitoring public health at state (e.g. notifiable infectious diseases list), national (e.g. quarantinable diseases list) and international (e.g. International Health Regulations) levels. All NSWHP laboratories have a role in identifying diseases of public health importance, although specialised tests are performed in a limited number of NSWHP laboratories.

Major technological advances in pathogen genomics (the genetic sequencing of micro-organisms) have led to the translation of research into laboratory practice. In 2018/19, the NSW Ministry of Health provided an initial $2.4 million and a further $1.9 million recurrent funding for whole genome sequencing for pathogens of public health importance (e.g. legionalla, tuberculosis, food borne diseases and antibiotic resistance) at the NSWHP-Institute of Clinical Pathology and Medical Research (Westmead) laboratory. This forms a component of the NSWHP Genomics Strategy.

Perinatal Post-Mortem Service (PPMS)

Perinatal anatomical pathology is a highly-specialised area of pathology practice, with the quality and clinical utility of reports requiring a degree of expertise/experience of the pathologist, scientist and technical staff.

Perinatal post-mortems are performed to understand and determine the likelihood of recurrence in subsequent pregnancies and impact to families and potentially the healthcare system.

NSWHP developed a new Perinatal Post-Mortem Service in partnership with The Children's Hospital, Westmead. Three centres of excellence operate in NSWHP at John Hunter Hospital, Prince of Wales, Randwick and The Children's Hospital Westmead. This partnership enables a consistent approach to perinatal post-mortems across NSW with standardised business and clinical guidelines, a shared performance monitoring system, centralised data collection and a shared approach to training and workforce sustainability.

The PPMS Care Coordinator supports families during a difficult and sensitive time by providing family-focused care and consultation with relevant health care teams to identify the cause of death, providing answers to the families.

Forensic & Analytical Science Service (FASS)

NSWHP's Forensic & Analytical Science Service (FASS) plays a major role in helping NSW create better health and justice systems. It provides a range of expert scientific and pathology services to the NSW criminal and coronial justice system, NSW Roads and Maritime Services, Corrective Services NSW, NSW Health and other organisations. FASS provides the following services:

- Forensic chemistry, illicit drugs analysis, drugs and driving toxicology, specialised consultancy and advice as well as education, training, research and development.

- Forensic toxicology
- Forensic biology and DNA
- Forensic medicine
- Forensic chemical criminalistics (specialised analysis for ignitable liquids, explosives, trace evidence and gunshot residue.)

The forensic & environmental sciences team provides environmental health testing in:

- water microbiology
- legionella isolation
- clinical and environmental toxicology
- trace inorganics

Forensic Medicine employs a multi-disciplinary team of experts, including forensic pathologists, radiologists, radiographers, forensic post-mortem technicians, nurses, social workers and specialist administrative staff.

Complex coronial post-mortem examinations can only be performed by highly specialised forensic pathologists who are supported by a team of forensic social workers, forensic technicians, radiographers and administrators at one of three dedicated Forensic Medicine locations in Sydney, Newcastle and Wollongong. As required, Forensic Medicine also consults with forensic odontologists who work under the request and direction of the Coroner and NSW Police.

In addition, the services of t forensic anthropologists may be retained for cases involving unidentified human remains.

Forensic medicine plays a major role in the State's Disaster Victim Identification responses following major incidents involving the loss of life.

6.1.3. Regional operations and networking within local health districts (LHDs)

Operational services are provided under the leadership of five Operations Directors with responsibilities over the following footprints:

- **West**: Western Sydney and Nepean Blue Mountains LHDs
- **East**: Sydney and South East Sydney LHDs and Sydney Children's Hospital.
- **South**: South Western Sydney and Illawarra Shoalhaven LHDs.
- **North**: Northern Sydney, Central Coast, Hunter New England, Mid North Coast and Northern NSW LHDs.
- **Rural and Regional**: Western NSW, Southern NSW, Murrumbidgee and Far West LHDs.

A Local Pathology Director has been appointed in each LHD. Each LHD has a dedicated pathology support team focused on building stronger relationships with local clinicians and delivering on local service needs.

Local Pathology Directors are responsible for:

- governance of testing performed at their sites
- contributing to the Site Pathology Support Team
- building and maintaining strong customer relations
- addressing clinical and operational issues, and
- providing support and guidance to site Clinical Directors to facilitate better communication between NSWHP and the LHD.

6.2. Overview of NSW Health Pathology service environment

6.2.1. Local health districts and specialty networks

NSW Health Pathology (NSWHP) provides pathology services to Local Health Districts (LHDs) and Specialty Health Networks (SHNs) in NSW within the scope of the local Service Level Agreement.

These services include:

- clinical advice
- pathology collection services and diagnostic testing for most public hospitals (including ED, inpatient and outpatient services), community health and other ambulatory clinics including sexual health clinics

Sydney Children's Hospital receives pathology services via a shared services arrangement with NSWHP Randwick laboratory located on the Prince of Wales campus. The Children's Hospital Westmead and St Vincent's Network provide their own pathology services.

6.2.2. Profile of laboratories across NSW

NSWHP currently has laboratories in 61 NSW public hospitals (listed in Appendix Four). NSWHP laboratories use service delivery models, such as networking arrangements, to ensure there is equal access to services required at each site and patient care is not compromised by services being located off-site. In some instances, these laboratories provide diagnostic testing for co-located private hospitals.

Each laboratory is accredited by the National Association of Testing Authorities (NATA) and the Royal College of Pathologists Australasia (RCPA) and categorised according to the National Pathology Accreditation Advisory Council (NPAAC) and classification system. This system is currently being reviewed and the categorisation of laboratories in Appendix Four is subject to change.

6.2.3. Laboratory Information Management Systems (LIMS)

A key component of the NSWHP service profile is the Laboratory Information Management System(s) (LIMS). LIMS enable:

- recording of all requests for all tests linked by patient identification
- online, real-time bi-directional linking of automated analytical instruments to the LIMS
- sample tracking and workflow management
- worksheet generation for manual tests
- automated validation of test results
- real-time recording of quality control data
- electronic delivery of results to clinical users and where appropriate patients/health consumers
- implementation of decision support systems to enhance clinical outputs
- support of data analysis for audit, clinical risk management, disease surveillance and epidemiology
- provision of relevant information to enable billing
- statewide Inventory Management System.

In NSW, there are currently five legacy LIMS in operation. Each of the four previous pathology networks had developed separate LIMS, each with varying architecture using different nomenclature and methods of counting the various diagnostic tests. A key initiative for NSWHP is to develop a single statewide LIMS for NSW. This will provide significant benefits, including service improvements, safety and quality improvements, better patient care and reduction in costs.

6.3. Key enablers

Key enablers are crucial in shaping and ensuring sustainable delivery of pathology services required by NSW residents and health services to meet future needs.

6.3.1. Information Technology (IT)

Information Technology (IT) is transforming delivery of pathology services worldwide, including diagnostic and personal health information services, and how and where these services can be provided. While new laboratory technology and the knowledge and expertise of pathology staff is crucial, information technology advances are the key enabler that bring these developments into production.

There are four key enablers to NSWHP's IT strategy:

- **Standardisation**

A single, statewide NSWHP LIMS will lead and assist in the standardisation of systems and processes across the state - unifying previously disparate information systems, policies and procedures, test directories and platforms.

Successful implementation of these standardisation and harmonisation initiatives will bring greater agility between facilities, consolidation of key services and in some instances, will enable greater, and more timely access to diagnostic technologies, particularly in rural and remote areas.

NSWHP will drive standardisation across several initiatives, including:

- test orderable and reportable coding
- instrument and reagent procurement and implementation
- laboratory workflow development, and others.

These initiatives are underpinned by statewide ICT systems. Ultimately a standard baseline build for all ICT supports laboratory buildings, instruments, staffing and related systems. Local customisations would be then overlayed on these standards.

- **Digital transformation and automation**

Processes in pathology already appear highly automated and digital. The majority of our orders are electronic, many large laboratories are heavily automated, and for most orders a set of electronic results are posted to the patient's Electronic Medical Record (EMR).

There are, however, many residual manual processes in microbiology, anatomical pathology, and genomics, that can benefit from automation or digital transformation. Introduction of Whole Slide Images (WSI) and using digital images of specimens for microscopic interpretation in

anatomical pathology (replacing glass slides using a microscope) is a significant digital transformation.

Digital processes allow NSWHP to separate parts of the value chain (collection, processing, diagnostics, reporting) to different physical locations, often allowing additional flexibility in the work process (e.g. pathologist reporting from a remote location). This improves services by enabling easier access to expertise from anywhere in the state, but also creates more flexibility with the ability to distribute workload more evenly – particularly in the event of disruptions to service at a given site.

Digital processes rely on and require standardisation which enables common training and certification, and enables a single quality process, including audit.

- **Miniaturisation, the Cloud and the Internet of Things (IOT)**

Miniaturisation and simplification of device operation is allowing pathology instruments to be located closer to the patient, with many tests now available at, or near, the point of care. With further developments in miniaturisation, the range of tests available will increase and instruments will become small enough, reliable enough and inexpensive enough to be deployed at the patient's home, worn by the patient – or even embedded within the patient (the concept of the 'instrumented self').

Miniaturisation and device operational simplification will lead to more distributed devices, each carrying out a smaller number of tests. This is a challenge to our current model of operation (smaller number of large devices conducting many tests), including the way ICT systems interface to instruments. The challenge of acquiring data from many devices and being able to push data to these same devices, ie managing many devices in a common way, is a future need.

Public cloud services allow a new and flexible set of off-the-shelf technology components at very large (even global) scale. Some cloud providers offer IOT toolsets designed for broader implementation of managed PoCT devices.

The Proactive Sepsis Management project is a pilot project to significantly reduce sepsis deaths by leveraging IOT and real-time analytics for a faster sepsis diagnosis, reducing time to antibiotics, resulting in a significant reduction in patient deaths.

The business problem this project is attempting to resolve is two-fold:

- develop a secure, scalable and manageable IOT diagnostics pipeline for the secure transmission of data from medical devices not directly connected to existing clinical applications, such as patients electronic Medical Records (eMR)
- leverage Artificial Intelligence (AI), Machine Learning (ML) and real-time analytics to produce a dynamic risk stratified list of at-risk sepsis patients in the emergency department waiting room, for action by emergency department clinicians.

NSWHP is currently piloting an IoT managed device which allows connection of our current point of care devices along with adding in data acquisition and management of other vital sign devices.

- **Big data, metadata, stream data and application of analytics and artificial intelligence**

NSWHP is a repository of data regarding the patient journey, their diagnosis and outcomes. Combining this with other clinical repositories provides opportunities for insights into how pathology can be best used to improve health outcomes and experiences. NSWHP currently carries out analytics on the metadata of the tests ordered and performed within the system – primarily for reporting to our LHD customers for service level reporting and outcomes (e.g. what is most commonly or best ordered for a given clinical presentation).

This 'big data' set is not routinely analysed internally, but is often requested by university researchers looking for insights into particular conditions or diseases.

Standardisation provides an opportunity to mine this data for clinical insights in a far more structured way. With high volumes of results overall, and a mix of results from individual patients, a stream analytics approach (applying analytics tools to the identification and analysis of data from multiple sources which are related to a single patient) will directly benefit clinicians in real time. NSWHP has developed an Atlas of Variation – a data driven application providing analysis and insights into pathology ordering variation within emergency departments that improves services and outcomes for patients. The Pathology Atlas of Variation will be expanded to include Intensive Care Units and test results in the coming year.

6.3.2. Logistics

Logistics refers to the planning, procurement and control of the flow and storage of goods and services from request to use. NSWHP inherited manual and resource intensive logistics systems impacted by fragmented computer systems that inhibited flows between laboratories.

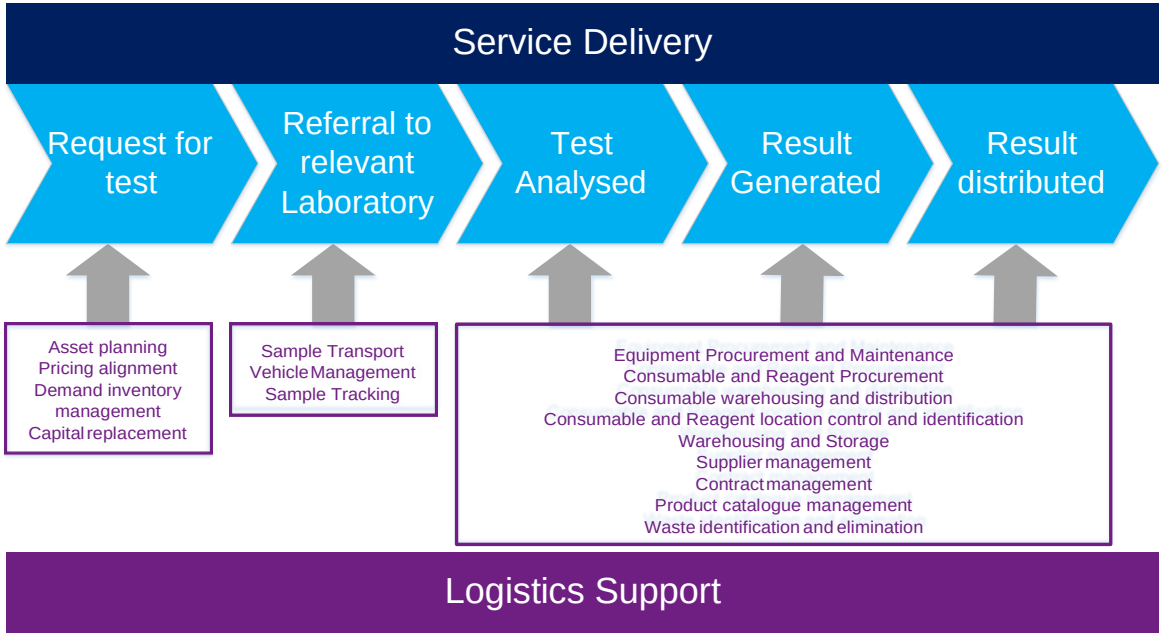
Statewide oversight and optimisation of the specimen courier network and integrated specimen tracking systems is required and underway. Some storage areas and warehouses were overstocked due to laborious manual ordering systems creating wastage due to out-of-date consumables but will soon be replaced by a statewide electronic inventory management system.

NSWHP's logistics framework delivers the required services to the 'right customer, in the right place, at the right time, at the right price' including clinical couriers and the flow of goods.

This requires efficient flow and stewardship of both physical material and data. Our growing capacity to manage, distribute, integrate, assemble, interpret and analyse data is pivotal to achieving the lead strategies in our Strategic Plan: *Towards 2025*.

Information, materials, systems and processes must integrate across the supply chain to enable the secure, efficient and effective delivery of pathology services as illustrated in Figure 6.3.

Figure 6.3 Logistics Support for Clinical Service Delivery



In November 2015, NSWHP contracted a consultant to undertake a review of logistics processes at NSWHP 'to identify strategic improvement opportunities and to create a logistics strategy and roadmap for implementation[12]'.

Following this review, NSWHP is now implementing the key components of a statewide logistics service.

These include:

- implementation of specimen tracking systems in real time, from pickup to delivery to enhance traceability and chain of custody
- review and optimisation of courier routes to support time critical test results and sample transport; and,
- implementation of an inventory management system to facilitate improved procurement of reagents and consumables, and wastage within smaller laboratories

Development of a single NSWHP Asset Register and integrated Asset Management System was a key initiative in 2018/19.

Development of the Asset Facilities Management (AFM) Online will provide an up-to-date asset register of all NSWHP assets, indicating which equipment is obsolete or nearing the end of its serviceable life and/or no longer delivering value for money. This will be followed by a statewide review of the condition of all NSWHP laboratories and enable prioritisation of laboratory upgrades considered on a statewide basis along with overall NSWHP asset redevelopment requirements.

6.3.3. Workforce

NSWHP employs over 4500 people (approximately 4000 FTE) across multiple sites. Of the NSWHP workforce, 44% are employed in technical roles, 27% in scientific roles, 16% in administrative/ hospital support roles, 6% in medical roles, 2% in nursing roles and 5% in other roles. For the purposes of this plan, these roles are referred to as our main job families.

The NSWHP workforce is relatively stable with an average tenure of 11 years. More than 21% of the workforce has attained 20 years' service or longer. Five percent of all staff are 65 years or older and are eligible to retire. The distribution of this over 65 workforce varies across our main job families and sites. Thirty percent are aged 55 or older. The current retirement rate (i.e., the proportion of those retiring compared with the total number of staff who are eligible to retire with reference to superannuation preservation age) is 4%.

6.3.4. Safety and quality

The NSWHP Clinical Governance Framework, Quality and Patient Safety Operational Plan has seven priority areas. The current focus is to embed a clinical governance reporting structure throughout NSWHP and

[12] TNT, Sydney 2016, NSW Health Pathology Logistics Review and Preliminary Business Casefor Identified Opportunities, TNT Sydney.

includes review of current quality and patient safety KPI's to increase focus on high risk areas, including transfusion, critical results notification, specimen traceability and supervision. Standardised processes and templates for incident management and reporting are under development.

The methodology and system development this CSP is advocating is designed to refine and advance capability to reduce error in patient care. This includes the identification, limitation, mitigation or removal of diagnostic error.

6.3.5. Education and training

Education and training within NSWHP has been predominantly delivered locally within the former pathology networks, based on existing procedures and workflow, and has not yet been systematised on a statewide basis. Further standardisation of procedures and analysers across the state provides an opportunity to move to a more systemic approach to training and education.

NSWHP is currently aligning generic position descriptions to the NSW Public Sector Capability Framework and mapping occupation-specific competencies to the National Competency Framework for Scientific / Technical groups. When complete, this will provide a strong basis for both recruitment and on-boarding of staff, as well as a basis for assessment of development needs of existing and future workforce.

Currently, attraction of medical trainees to pathology training positions is, in part, limited by reduced exposure to pathology content within medical undergraduate programs. This is compounded by a drift toward clinical trainee positions as a preference over laboratory pathologist roles. Pathologist trainees have historically been aligned within LHD networks, rather than managed through a statewide training program.

Management and leadership capabilities are developed through a Frontline Managers Program, external agency leadership programs and our own Emerging Leaders program. Ongoing alignment with the Health Education and Training Institute (HETI)'s Leadership Framework (and potential future leadership and management frameworks) will augment the NSW Public Sector Capability Framework and provide a platform for management and leadership development.

6.3.6. Research and innovation

Research and innovation are part of NSWHP's core business. It will continue to be integrated into existing pathology and forensic governance and organisational structures and developed as key aspects of organisational culture. We aim to be an innovative research powerhouse led by an interconnecting network of leading specialists and partners in translational research where discoveries move rapidly from the lab to the community.

NSWHP's Research and Innovation Advisory Committee is driving the research and innovation agenda, translating research into outcomes through implementing initiatives that help build research capacity, enhance research collaborations, further embed research and innovation in our culture, and develop services for research.

NSWHP's Research Governance Office offers guidance and support to NSWHP researchers on ethics and governance and has set up a transparent process that supports:

- internal, investigator-led research,
- research collaborations between NSWHP and non-NSWHP researchers, and
- efficient and effective testing services for non-collaborative, non-NSWHP, research.

NSWHP will continue to establish tighter links with external clinicians, local health districts, medical research institutes and universities, providing support to collaborative research that helps us achieve our pioneering ambition of discovering (and testing) new services and adopting new models of care for future generations.

Through its performance, change management and project management teams, NSWHP is taking a proactive approach to bring new ideas to life through engaging with our most important asset, our people; discovering opportunities, understanding problems, and identifying solutions that are of benefit to all pathology stakeholders.

This grass roots systemic approach will provide a strong foundation for developing and moving ideas into new realities.

7. The case for change: key issues and challenges

7.1. Identifying core business

There is substantial agreement that provision of diagnostic services, utilising clinical and scientific expertise, and provision of critical public health and forensic services to NSW are primary obligations for NSW Health Pathology (NSWHP).

Diagnostic services are largely provided to patients within the public hospital services of Local Health Districts (LHDs) and the public health and forensic services to a broader NSW community.

This is recognised in NSWHP's Instrument of Establishment which identifies NSWHP as a Division of the Health Administration Corporation "established to provide specialist pathology and forensic services, including clinically integrated diagnostic, disease monitoring and forensic and scientific analysis expertise[13]."

NSWHP operates on behalf of the Secretary of NSW Health as the preferred provider and commissioner of pathology, forensic and analytical science services, with the responsibility to:

- deliver better health and justice systems through an integrated whole-of-state model of service;

[13] HAC (2018), *NSWHP Instrument of Establishment*

- develop and implement rigorous clinical and corporate governance frameworks that provide sustainable, responsive, efficient, high quality pathology, and forensic and analytical science services;
- operate services with transparency and clear accountabilities ensuring that organisational performance and financial management meet the objectives of the NSW Public Health System;
- develop organisational teaching, training, research and innovation capacity to support staff development; new diagnostic capabilities; forensic analysis methods and models of service delivery; and to enhance patient outcomes and experiences;
- build strong relationships with the NSW Public Health System, NSW Department of Justice, NSW Police Force and other key stakeholders and contribute to the achievement of NSW Government priorities.

Diagnostic services are just on part of NSWHP's complex service for NSW communities. This service includes a major role in many areas, such as:

- partnering in integrated patient care:
- providing clinical expertise to support serious medical conditions including operating the largest stem cell processing lab and the only TGA-certified laboratory for organ and tissue donation in Australia
- using world leading forensic analysis to help NSW Police solve crimes and operating the most advanced forensic DNA processing facility in Australasia
- protecting the health and safety of the community, such as testing for infectious diseases
- informing better clinical practice and quality use of pathology through big data analytics and literacy
- developing future generations of clinical and scientific workforce by providing the most complex care in diagnostic medicine, and involvement in broader clinical care; and education and research on public hospital campuses. Staff consider this a major contributor in workforce satisfaction, attraction and retention.

Provision of these key functions, and engagement with local clinicians and LHDs in research collaborations and involvement in integrated care, provides a point of difference, and important strength, for NSWHP in comparison with the primary focus of the private pathology providers.

There is increasing recognition that NSWHP's role in in teaching, research and innovation is one of the major "value add" aspects of the public pathology service.

7.2. Community expectations and customer demand

There is an increasing demand for access and ownership of personal health data. Citizen empowerment means that NSWHP customers, including patients and clinicians, and the wider community, are expecting rapid and direct delivery of information and results in the form most suitable to them.

The community will demand easier, more streamlined access to collection services. At present patients attend collection centres, only knowing location and opening hours of our collection centres via a paper request form or on our website, without prior detailed test pre-requisites and no ability to book online. Patients might not know they have a choice of collection centres regardless of their doctor's location.

Investment in an online portal to access information relevant to client services and collection facility access, including online booking, fact sheets/ patient information materials in a range of formats, opening times and collection centre locations will be a key part of providing faster, flexible and more convenient services.

Investment in collection services which are mobile, able to attend a customer's home, neighbourhoods and key community events, will improve access to pathology services, particularly for hard to reach or potentially vulnerable members of our communities.

7.3. Impact of technology

Introduction of new technologies is transforming pathology and eroding the boundaries between various pathology disciplines. In some cases, it is even blurring the boundary between diagnostic pathology services and direct clinical care. These new and disruptive technologies include:

7.3.1. Miniaturisation and near patient testing

Continued improvements in biosensor technology and miniaturisation are increasing the ability to test at or near the patient. This is expected to come from additional new devices and not from expanded tests on existing device platforms.

Diagnostic devices are getting smaller. Point of Care Testing (PoCT) devices offer high quality, accurate, reliable diagnostic testing performed at or near the site of patient care – but does not totally replace traditional laboratory testing. Patient proximity and time of treatment is central to PoCT, enabling rapid results and faster decision-making about patient care, treatment options and need for referral.

PoCT devices are expanding the reach of diagnostic testing beyond the traditional settings of Emergency Departments and Intensive Care Units to ambulatory care settings, other inpatient units within hospitals and to community settings, such as nursing homes and ambulance vehicles.

Given that testing may be performed by various clinical staff, using multiple devices, in many locations outside the laboratory environment, this decentralisation of testing presents several IT challenges.

Some new modalities of testing are being introduced directly on to PoCT platforms where in the past, tests on PocT devices were derived from existing static laboratory instruments.

Miniature devices are likely to include wearable technologies and injectable or ingestible sensor devices. It is likely that some existing PoCT will be replaced by this type of technology, particularly where continuous monitoring is required.

Miniaturisation of technology may also extend to sampling devices and requirements, meaning less sample volume may be required, less time

needed to reach sensors and ultimately less time for results to be reported.

This combined with easier use of technology will increase the application for PoCT environments.

7.3.2. Automation

Modern clinical laboratories have a continuous work-flow process that reduces specimen wait times, ensures accurate and timely electronic reporting of results and reduces biohazard exposures for laboratory staff. Accurate results can be obtained in a matter of minutes for over 84 laboratory test analytes performed on samples in one, or at most two, small vials of blood. The efficiencies of this testing and the workflow is often relying on automation.

Automation in the pathology laboratory is defined as the use of automated equipment and information technology. Automation and robotics transfer, processes and analyses samples within the laboratory. In the pathology laboratory, automation systems transfer specimens within and between devices and electronically transfer, analyse and process information related to testing of patient specimens. These systems also transfer, analyse and process quality controls, calibrators, standards and images. Many specimens are being processed from start to finish without human intervention.

Automation, via robotics, will significantly reduce the amount of time spent on repetitive tasks, such as specimen transport, processing and aliquoting; and reduce handling and transcription errors. It will enable scientists to direct their knowledge and expertise to diagnostic service, client support, quality assurance and laboratory improvement activities rather than low skill, repetitive and manual tasks. Automation may also allow the location and retrieval of a single vial of blood in a large refrigerated specimen repository for additional or repeat testing in a very short time.

The rate of change in automation can be expected to increase over the next 10 years. This is being driven by the capability of the technology, service demand and cost pressures.

Automation within laboratories may increase in response to higher volumes of testing, expectations of faster turnaround time, staff shortages, cost savings, device maintenance requirements and shorter and fewer down times and error reduction.

Laboratory automation requires computer systems that interface with instruments and devices; and robotics with LIMS and/or middleware. The LIMS automates many tasks that would otherwise require manual intervention. An integrated data-management system may identify specimens that require intervention by a scientist and allow results that fit pre-programmed auto-validation guidelines to be reported immediately.

In the pre-analytical area, automated track systems exist that may receive, centrifuge, sort and aliquot specimens, and they can load specimens into instrument-specific racks or directly onto analytical instruments. Within laboratories, automation systems may act within one or across many instruments, the most common being auto-samplers. Automation may include some algorithms or software methodologies to

enable, expedite and increase the efficiency and effectiveness of diagnostics or research. Where these applications are already installed, they are generating significant cost reductions and improving accuracy. Automation is a key feature in the performance of some large volume, high throughput, urgent testing.

7.3.3. Digitisation

Digital technologies provide opportunities for diagnostic testing to become more efficient and scalable, more accurate with less subjectivity; and specimen analysis more reproducible, and tasks less cumbersome. Subspecialisation could be more accessible over a broader geography and assist in the deepening of that specialisation.

Digitisation and computerised image analysis has the potential to radically change traditional workflows and workload management within pathology disciplines, including anatomical pathology, microbiology, immunology and haematology.

There are four key steps in the digital imaging process:

- image acquisition (capture)
- viewing, display or transmission (sharing) of images
- manipulation and annotation (editing), and
- storage and management (saving).

Slide digitisation opens the possibility of developing Artificial Intelligence (AI)-based pathology algorithms. Using computer vision, combined with deep learning, this would provide pathologists with decision-support and quality control tools, resulting in more accurate, rapid and objective diagnosis.

It is also possible that image analysis is initially complemented by genomic analysis and tissue mass spectrometry before being replaced by fully automated versions. Analysis of circulating tumour cells and circulating cell-free DNA will also increasingly and rapidly impact on what pathologists currently do. There may be less dependence on ‘tissue’ image analysis as much less invasive and possibly, equally or more useful opportunities develop for diagnosis and monitoring of cancer and assessment of relapse.

In Haematology, the application of automation and digital imaging to cell morphology replaces or complements manual microscopy. This creates an automated digital workflow for morphological cell analysis, enabling labs to work more efficiently with improved connectivity while improving accuracy and reliability.

In Anatomical Pathology, digital whole-slide imaging (WSI) allows capture and visualisation of the entire tissue sample on a slide, as opposed to the narrow field of view of microscopy. After macroscopic evaluation of blood, fluid or tissue in the digitised pathology laboratory, the WSI process takes place. After the slices are prepared, an electron microscope, or mass spectrometry analysis, digitalises the sample for further analysis with the help of various scanning solutions. A variety of digital products are available for migrating the entire workflow of anatomical pathologists from manual to digital.

Working with digitised slides can significantly reduce the time currently taken in transport of tissue specimens.

It makes possible computerised quantitative analytics, speedier image search and slide retrieval and reduces the barriers between hospitals and regions. It will facilitate sending slides and data for consultation and second opinions and provide virtual pathology services at remote sites. While there may be someone looking at tissues through a microscope, the interpretive reporting will generally be carried out in front of screens rather than next to microscopes.

7.3.4. Molecular Pathology

The list of molecular pathology tests with potential clinical utility is expanding rapidly. Molecular pathology and cytogenetics specialists use advanced technology to investigate genes and chromosomes particularly in diagnosis of cancer, where a sub classification of cancer can be identified, and inform treatment decisions.

Molecular genetic testing involves performing analysis of a nucleic acid target such as DNA or RNA. This may involve several different techniques including polymerase chain reaction (PCR), restriction digestion, sequencing and microarrays, as well as cytogenetic karyotyping, histocompatibility testing and fluorescence in situ hybridisation (FISH).

Developments in proteomics may be more important than DNA in transforming pathology and will give rise to an enormous range of biomarker assays. Machines that use PCR (thermal cyclers) provide rapid influenza diagnoses have been introduced in many of the major laboratories across NSW. The same techniques are also used to look for genetic evidence of bacteria or viruses, providing a quicker way of testing for infections than conventional methods.

Molecular diagnostic machines are now a core component of major laboratories in metro, and increasingly, regional, NSW. Demand for molecular testing is growing significantly with the growth in personalised healthcare and rapid expansion of molecular discoveries in cancer diagnosis and treatment. Molecular laboratories will require a large footprint in a limited number of specialised labs.

7.3.5. Genomics and Precision Medicine

Genomic technology is transforming the way healthcare is delivered. Genomics plays a role in nine of the 10 leading causes of death, including heart disease, stroke, diabetes and Alzheimer's disease. Cancer is essentially a disease of the genome.

Systems approaches to medicine are beginning to provide patients, consumers and physicians with personalised information about each individual's unique experience of health and disease.

This is described as precision or ‘P4’ medicine - predictive, preventive, personalised and participatory[14].

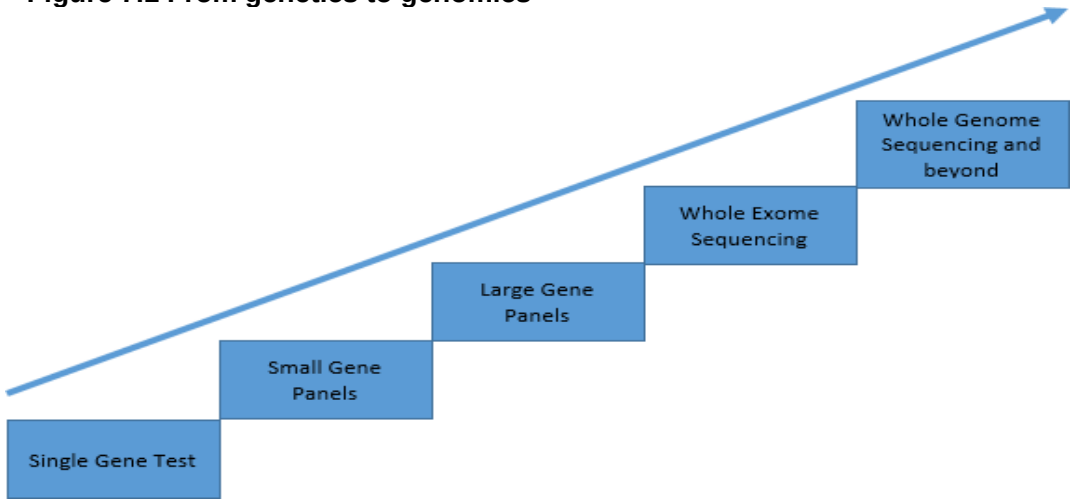
Precision medicine is being increasingly enabled by genomics (and other ‘omics’ technologies, such as transcriptomics and proteomics). This will enable more cost-effective healthcare by treating causes rather than symptoms. A deeper understanding of the molecular and cellular origins of disease and health in each individual patient is likely to change the way diseases are classified.

Traditional genetics testing consisted of testing a single gene or a very small number of genes (less than five) that had been previously associated with a particular genetic disorder or syndrome. This approach was most useful when a clinician was already fairly certain that a mutation in one of the genes being tested was causing the specific condition.

However, in many cases the patients required testing multiple potential genes over a long period of time, to identify the definitive cause of the condition and provide a diagnosis. This places a large cost on the system providing the testing and more often than not failed to provide a definitive diagnosis. Commonly quoted diagnostic rates for this approach for rare genetic disorders as a group are in the order of 10-20%.

Development of Massively Parallel Sequencing (MPS) also called Next Generation Sequencing (NGS), allows greater levels of sequencing and potentially diagnostic information to understand the reason/s for a rare genetic disorder which was previously not readily identifiable. It has

Figure 7.1 From genetics to genomics



[14] Hood. L, Balling. R, Auffray. C *Revolutionising medicine in the 21st Century through systems approaches*. Biotechnol J 2012;7(8):992-1001.

allowed for greater knowledge about genes and their complex relationships to human disease.

Genomics can provide greater accuracy in determining disease risk, assessing diagnosis and prognosis, and informing the selection of therapeutic options for care. This improved precision in care may avoid unnecessary treatments and provide savings for the healthcare system while at the same time presenting new options for clinical management.

Disruptive changes in technology are currently driving the development in genomics. The best example of this in the sequencing of the human genome, a task that took $1 billion and eight years to complete in 2003 that can now be provided for around $1,500 in 2019.

The increasing level of automation in genetics, with introduction of high-throughput sequencing platforms, will enable the convergence of many genetic tests to a single assay. The next challenges include collection of patient metadata, or 'phenotype', to inform complex genomic analysis and the workforce to interpret and provide an informative report that accurately describes the data and its application to the clinical management of a patient.

The application of genomics to the study of bacteria and viruses with epidemic potential and pathogens of critical relevance to hospital epidemiology not only offers new and important insights into their transmissibility and virulence but also can offer significant improvements in public health.

Recent investment by NSW Health has enabled collaboration between translational researchers and clinicians and networking across different sites; providing a unique opportunity for implementation of genomic surveillance of pathogens into communicable disease control.

7.3.6. Biobanking

NSWHP is now breaking new ground to reshape how pathology and forensic services are delivered in the future. This includes investing in disruptive innovation in areas such as biobanking.

Biobanks are vital to modern medical research and this facility will help accelerate NSW's health and medical research efforts in finding and treating the causes of illness and more effective treatments. They provide unique support for large-scale population studies to help track health trends across the state and disease-specific studies, such as cancer, heart disease, dementia and diabetes.

Researchers across NSW can store and access a wide range of samples to advance their research programs. Specimens are deposited and retrieved from the cold storage facility through a dedicated processing laboratory. A data linkage service is being developed to link collections stored at the Biobank with relevant clinical and health system administrative datasets. Adoption of common data structures will also assist a planned central specimen locator portal for researchers looking to find specimen types for their research in NSW.

The statewide biobank brings together local health districts and specialty networks, universities, medical research institutes and industry to

strengthen research collaborations and networks across the state and beyond.

NSWHP will continue to pursue opportunities in biobanking and collaboration in research to improve the way disease is detected, diagnosed and treated. The service will use NSWHP's integrated collection services across our extensive network of laboratories and collection centres; and fully automated barcode tracking systems to ensure traceability and custody control of samples.

7.3.7. Connectivity and the Internet of Things

Connectivity is the primary driver of diagnostic solutions in a range of healthcare locations. NSWHP, in partnership with third party technology providers, to develop connectivity solutions that enable testing in locations like ambulances or hospital in the home environments via bi-directional messaging.

These solutions allow real-time results to be viewed by clinical staff in a central location or decision makers elsewhere. The ability to send information back to the device allows software updates and configuration settings can be applied by system support staff without the need to disrupt services by recalling the technology.

7.4. Core laboratory concept

The core laboratory is the key change in the design and operation of laboratories over the past decade. It is a section of the laboratory characterised by a high degree of automation facilitating rapid results delivery for high volume tests as well as specimen reception/pre-analytical services. Platforms that have traditionally been part of separate laboratory specialties come together in the core laboratory, which is under the day-to-day management of the core laboratory manager. Scientists and pathologists from individual disciplines remain responsible for quality control and specialised reporting whether testing is performed in the core laboratory or other relevant specialty-specific areas.

The key benefits of this service configuration include economies of scale achieved by testing that is high volume, relatively low complexity, with a workflow capable of utilising automation and is scalable over a range of laboratory sizes, while meeting clinically relevant result turnaround times.

NSWHP is currently in the process of developing a core laboratory concept, including how this may best operate in NSW laboratories and what the implications may be for workforce.

7.5. Workforce

The predicted shortage of pathologists and medical scientific workforce in Australia, particularly in rural and remote locations, is a significant risk to sustainability of clinical pathology services. Core issues are an ageing workforce and a shortage of qualified pathologists and scientists.

This is further compounded by issues such as:

- high staff turnover
- training and recruitment of blood collection staff
- administrative and reception staff

- retention and replacement of staff
- costs of on-the-job training
- pathology being an unpopular residency choice for medical staff, and
- recruitment of qualified people in rural and remote areas.

NSWHP has the largest and most diverse pathology training network in Australia and is uniquely placed to provide the most comprehensive training program for medical, scientific and technical staff. Our training program should respond to changes in technology, service configurations and clinical service innovations to ensure our pathology workforce has the necessary skills and knowledge to adapt. It is critical for NSWHP to plan to address these issues to ensure we can sustain services in a changing environment.

The full impacts of technological advancement, contestability, health reforms and demographic trends over the next decade are not yet known, and will require new approaches to workforce issues.

7.6. Commissioning of pathology services

NSWHP is transforming the model of public pathology in NSW by establishing a structure that demonstrates the competitiveness of public pathology and establishes NSWHP as an intelligent commissioner for services across the supply chain of pathology delivery.

In 2018 the Secretary of NSW Health updated the NSWHP instrument of establishment to confirm delegation to act as a commissioner of services in pathology and forensics on behalf of NSW Health. In undertaking this stewardship function, NSWHP aims to ensure the broader system has access to high quality, patient-centred and value-for-money diagnostics.

As a commissioner, NSWHP will collaborate with LHDs to determine how pathology and forensics can be best planned and provisioned by models of service that achieve better outcomes and experiences for patients and clinicians.

NSWHP will undertake commissioning studies based on patient and clinical needs to determine a model of service that best responds to those requirements. NSWHP will perform this function, managing conflict of interest through appropriate structuring of the governance and evaluation process. The commissioning study will consider opportunities to leverage the capability and capacity of the broader pathology market. Where leverage possibilities are identified in the market, a market sounding may be conducted against a clear public-sector comparator as the baseline.

8. Conceptual framework for planning laboratory service models

During development of the first NSW Health Pathology (NSWHP) Clinical Services Plan (CSP) there was early recognition of the need to provide the foundation for a more systematic and evidenced-based approach to pathology service planning. This led to development of the Conceptual Framework for Laboratory Service Models.

8.1. Rationale

Until NSWHP was established in 2012, public pathology laboratories operated in geographic silos. Unintended consequences of this model were a level of duplication of services, and growth in demand and capacity without assessing the sustainability and affordability to the system.

Configuration of pathology services across NSW and the role, scope and capacity of individual laboratories in public hospitals reflects decades of decentralised clinical service planning. The range of services available at individual pathology laboratories on hospital sites has been planned to meet the requirements of the local hospital or health service and the strongest planning requirement was to meet the delineation level required to meet the core service requirement of the clinical services for that hospital.

This conceptual framework for laboratory service models in NSW aims to establish clear statewide guidelines to indicate what pathology services can be expected to be provided on-site at each tier of the NSW hospital system. This is within the context of a rational networking of services on a regional, and for some specialised tests, statewide basis.

NSWHP's laboratory service models will guide service and capital planning in NSWHP, as well as inform Local Health Districts (LHDs) in developing their hospital Clinical Service Plans. These would provide clear expectations on the appropriate level of diagnostic services a laboratory at each of these levels can provide in the future.

8.2. Guiding principles

Development of the conceptual framework was guided by a set of CSP planning principles:

- **Service and patient focus**

The primary focus in developing this conceptual framework of pathology services across NSW public hospitals is identifying the clinical services required at each level of the system. For example, what is the minimum set of tests required within four hours to respond to the acute or life-threatening illness of patients presenting at hospital Emergency Departments (ED)s?

- **Future focus (following implementation of key enabling initiatives)**

Service models should be what NSWHP expects future service delivery to look like in 2025 based on future capabilities made possible by projected developments rather than accurate descriptions of current practice. The implementation of the proposed service models is predicated on the successful implementation of key enabling initiatives over the next three to five years.

These include:

  – a single LIMS
  – ICT systems and middleware to support the single LIMS
  – a single statewide test catalogue
  – standardised testing platforms

  - new technology in laboratories e.g.: automation, robotics, miniaturisation/ near patient testing
  - proposed networking across laboratories supported by results of review of logistics, transport/ courier systems, laboratory supervision and digitisation, and
  - a unified approach to quality and safety.

- **Networking of services**

Implementation of the key enablers will enable NSWHP to implement a statewide integrated service model that connects and leverages the capacity of existing laboratories across all locations.

Networking NSWHP's laboratories across the regions enables large hubs to provide specialised tests for lower role delineation level laboratories that would not have the critical mass of throughput for efficient and effective provision of these tests.

This networking is enabled by an agile and efficient logistics and courier system. Such networking enables practical implementation of the proposed service models.

- **Alignment with hospital clinical service planning**

This CSP aims to achieve greater engagement of pathology service planning within acute hospital clinical service planning and vice versa. Planning acute clinical services in public hospitals is guided by several guides and tools. The Guide to Role Delineation outlines levels of clinical care appropriate at each tier of the system; and planning tools project future requirements for acute inpatient bed requirements, ED treatment spaces, chemotherapy and renal dialysis chair requirements etc.

The NSWHP Laboratory Service Models Framework uses Role Delineation Levels to link laboratory test profiles and service models with the level of complexity, and range, of acute clinical care delivered at the hospital where they are located. This enables clear alignment with acute hospital clinical service planning.

The Framework presents a hierarchy of laboratories guided by the six Role Delineation Levels for hospital services across NSW. NSWHP has added a seventh tier, Specialised Laboratory(s) to represent tests that would be provided at one site in NSW or a very limited number of sites only, and includes the possibility of providing these tests at an Innovation Hub. Major regional laboratories (Level 5) act as rural/regional hubs processing samples from small networked labs, and are considerable distance from a Level 6 laboratory.

The hierarchy of laboratories in the Framework is:

1. Point of Care Testing (PoCT) only
2. Small Laboratory / PoCT (equivalent to Level 3 hospitals)
3. Medium Laboratory (equivalent to Level 4 hospitals)
4. Major Regional Laboratory (Level 5)
5. Tertiary Laboratory (Level 6)
6. Specialised Laboratory(s).

- **Evidence based**

Pathology service planning will require development of a range of planning tools, including planning methodologies, parameters and guidelines. These will support the assessment of needs and ability to tailor local service requirements to both fit in with system or network-wide requirements and effectively support local clinical practice.

Consideration of key pathology service planning parameters includes identification of:

- key tests required at different tiers of hospitals to support urgent and acute clinical services delivered on-site
- maximum turnaround times for urgent tests in ED, ICU, operating theatres and maternity
- maximum turnaround times for less critical send-away tests
- minimum volumes for test throughput for expertise and proficiency
- minimum volumes for test throughput for cost efficiency (critical mass) including cut-off points where costs and risks of transport outweigh benefits of performing tests on-site
- special tests to meet public health requirements
- test profiles required to underpin registrar teaching (particularly in specialties with combined clinical and laboratory training programs)
- tests that require significant/frequent input from pathologists who need to be situated in/near a clinical environment
- criteria governing where PoCT devices should be provided:
  - where clinically appropriate turnaround times are unable to be met by an onsite laboratory
  - where after hours services can be provided more safely and efficiently using these platforms to avoid the need to extend hours of opening of a laboratory
  - where the need for laboratory infrastructure can be obviated using a PoCT platform.

- **A dynamic model**

NSWHP recognises this Framework must be dynamic and reviewed on an ongoing basis, as technology will continue to shift the boundaries as to how services are delivered and what is possible at each level over time.

Proposed test profiles will need to be reviewed to reflect the findings from current reviews and working groups (e.g. digital morphology, Microbiology working groups) which are expected to result in changes to system architecture in terms of analysers and platforms.

- **Groupings of diagnostic tests**

The Framework aims to group tests (as much as possible) by type of test and homogeneity in terms of complexity (similar to the Diagnosis Related Groupings in coding) to provide information as concise as possible.

The Frameworks uses National Association of Testing Authorities (NATA) groupings in describing the on-site test capability of Australian pathology labs and then groups further to reduce the total number of

categories while maintaining homogeneity in type and complexity of tests.

- **Inclusion of the Core Laboratory Concept**

The Framework groups tests together where they are delivered in the Core Laboratory (defined as a contiguous section of the laboratory that includes automated instrumentation supported by scientific or technical staff under the direction of a local manager). All laboratories have a core laboratory. As a principle, if a test can be provided in the core laboratory it should be provided from within the core laboratory.

- **Consideration of PoCT devices within the framework**

PoCT devices will be used at all tiers of the system. At the lower role delineation levels of the Laboratory Service Models Framework, there is no on-site laboratory and all tests are performed using PoCT. At each higher level of the system, use of PoCT is an important component of the overall provision of diagnostic testing, and most of these tests are undertaken outside of the laboratory environment.

- **A baseline or default framework for planning**

The aim is to develop a minimum baseline or default guide that will inform the process of pathology service planning across the state in a more systematic approach. It will provide the foundation, or **starting point**, in planning individual laboratory services in NSW.

The aim is not for a one size fits all approach to laboratory service models. Laboratories have developed their service profile over many years based on local needs and individual clinical expertise. Consideration will be given to networking arrangements within a specific region and the profile of clinical services delivered on-site, health needs and geography.

The diagram below illustrates how planning will be sequenced, starting from this baseline conceptual framework, and then overlaid with the detail of regional networking, LHD operational requirements and local hospital clinical service requirements.

Figure 9.1 Sequencing the clinical service planning

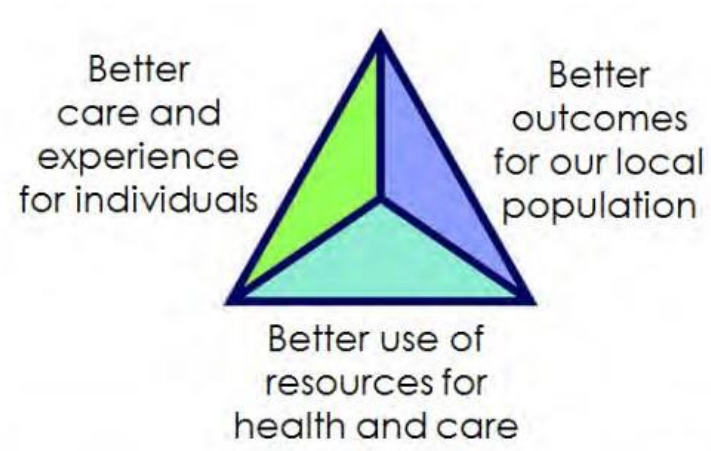
The first iteration of the Laboratory Service Models has focused on the tests provided at NSW laboratories and does not yet include:

- other key services provided by NSWHP including;
  - blood collection
  - blood transfusion
  - consultation liaison
  - involvement in clinical care and Multi-Disciplinary Teams
  - provision of Bone Marrow Transplant and cell processing
  - fertility services
  - non-invasive perinatal testing.
- services provided to private hospitals, clinical trials, and environmental agencies.
- **Managing the implementation: Transformation with care and connection**

NSWHP will transition to new service models with care and connection with stakeholders. Discussions relating to the progressive implementation of the new Laboratory Service Models must align with:

NSWHP values: RITE (Respect, Integrity, Teamwork and Excellence).

- Organisational strategy (Strategic Plan and the Clinical Services Plan objectives)
- NSWHP Change Management Policy.
- Agreed Change and Redesign methodology (ACI Redesign methodology, AIM and other suitable models for change and redesign).
- NSW Ministry of Health Workforce planning policies and procedures
- Goals of Leading Better Value Care.
- **Triple AIM (Institute for Healthcare Improvement)**



Source of framework: The Institute for Healthcare Improvement Triple Aim framework

Transformation with care principles and requirements will be discussed with the NSWHP Joint Consultative Committee and stakeholders to ensure there is alignment to and confidence in these principles and requirements.

8.3. Baseline test profiles for laboratories

The Laboratory Service Models Framework has developed draft test profiles for labs at each tier of the NSW hospital system as presented in the attached Framework (Appendix Five).

The draft test profiles for laboratories had input from the clinical streams and was reviewed by an expert panel, Operations Directors and Local Pathology Directors at each LHD to identify operational implications and provide feedback on test profiles and specific categories that required refinement. Ongoing consultation with LHDs will ensure suitable adaptations to the baseline models to meet local needs.

Implementation of the Laboratory Service Models Framework

In reviewing or planning the future role and test profile of a specific hospital laboratory the following will be considered:

- networking arrangements within a specific network and local clinical requirements
- the profile of clinical services delivered on site
- health needs and geography.

Changes to service models will align to Lead Strategies in the NSWHP Strategic Plan and/or Clinical Service Plan priorities.

Design and implementation of change will align to the NSWHP Change Policy.

8.4. Workforce implications

In the same way that historic service models have developed idiosyncratically across NSW in response to local needs and individual expertise, workforce configuration at laboratories developed in similar ways.

NSWHP will undertake a workforce planning project to review workforce configuration within the various tiers of NSWHP laboratories and explore opportunities to develop workforce profiles to meet future laboratory service models.

There is also a need to look at how jobs may change in the future. With ongoing introduction of new technologies into the laboratory and broader hospital environment, boundaries are blurring between the disciplines/specialties and there is the potential for development of more multipurpose roles.

The Core Laboratory model and further introduction of near patient testing within hospitals are areas of focus.

9. Key clinical service and infrastructure priorities

Clinical Service Plans outline the key clinical service priorities for relevant services[15] and clinical service directions drive non-infrastructure and infrastructure priorities.

In this inaugural NSW Health Pathology (NSWHP) Clinical Service Plan (CSP), key clinical service and infrastructure priorities in 2019 are generally focussed on ensuring key statewide service enablers will be implemented over the next five years to ensure the future vision of a single, connected and integrated NSWHP service. The Key Priorities in Section 9.1 below detail the major enabling programs of work to be undertaken to achieve this.

In addition, the key clinical service directions and priorities of the NSWHP Clinical Streams and presented in Section 9.2 below. These have been documented in the Clinical Stream Service Development Plans during 2018/19. The key clinical service directions and priorities for the NSWHP statewide services are presented in Section 9.3 below.

A key issue for NSWHP is that it does not own the external laboratory infrastructure and this limits access to the NSW Capital Works Program for major redevelopment of pathology laboratories past their economic life and/or in need of major redevelopment to provide increased capacity or to address issues of functionality. NSWHP has had to rely on the process of Local Health Districts (LHDs) redeveloping hospital services and the cost of upgrading pathology laboratories was included in the capital budget of hospital redevelopments.

However, funding for some laboratory redevelopment and major technology upgrades have been sourced through the NSW Health Strategic Asset Management Plan for works in excess of $250k. Funding requests for 2019/20 include the LIMS, the Innovation Hub, Transfusion and Clinical Chemistry tenders and laboratory automation and digitisation.

9.1. Major statewide pathology infrastructure projects

9.1.1. Statewide Laboratory Information Management System (LIMS)

The LIMS platform will consolidate the multiple existing LIMS aligned with former pathology networks and drive significant efficiencies in NSWHP. The project will also assess the feasibility of expanding the LIMS into the Forensic and Analytical Science Service (FASS) environment as well as developing a new Forensic Medicine Information System (FMIS) to support the statewide service.

9.1.2. Standardised testing platforms

The Clinical Streams are leading tenders for laboratory analysers to standardise testing platforms, (and test methodologies, nomenclature and work practices) and adopt more innovative technology.

Haematology and coagulation analysers are underway with electrophoresis, specialised immunochemistry, transfusion medicine,

[15] NSW Ministry of Health (2017) Guide to Service Planning

chemistry and immunoassay expected to be completed by early 2020. Planning is underway for flow cytometry, molecular microbiology and anatomical pathology. The tender, procurement and implementation processes for all major equipment is due to be completed by 2023.

9.1.3. Development of innovation hub(s)

The concept of innovation precincts is being considered within major health campus redevelopments in NSW; and NSWHP has been developing an Innovation Hub proposal which will include:

- research, development and training in an advanced simulation and innovation space and ICT centre
- specialised 'wet' laboratory processing tests and off-site processing laboratory
- specialised genomics laboratory
- consolidated corporate functions
- logistics support services.

We will continue to explore opportunities to build innovation partnerships with NSW Health Research and Innovation hubs and precincts, and other agencies.

Specimen processing will consolidate a critical mass of expertise and equipment. For example, processing of samples with slow turn-around-times and not reliant on co-location on acute hospital campuses. This provides future expansion zones on acute campuses for the essential space required for housing clinical pathology staff and maintaining collaboration with other clinicians.

9.1.4. The Forensic & Analytical Science Service (FASS) and the forensic precinct

FASS's equipment requirements are as diverse as its service delivery profile. Test analysis equipment for assessing DNA, illicit drugs and alcohol, and public health parameters is highly specialised, sophisticated, and costly.

A key risk and challenge faced by the network is the lack of redundancy and internal backup equipment in place to address equipment downtime. FASS has been working to mitigate this risk through the development of service continuity plans.

To maintain FASS service delivery in the future, the organisation has developed 10 to 15 year capital replacement programs outlining the strategic asset requirements of each unit.

Units such as the Drugs and Toxicology Unit are developing service enhancement plans to provide quality forensic and analytical science services and innovative models of service delivery and practice.

Each focus area of the laboratory is undergoing redesign to eliminate unnecessary handling, remove duplication of processes and streamline workflows. Expected capital investment recommendations include a drive towards greater automation and equipment that can assist the laboratory in eliminating any risks (health and quality). For other assets, FASS has addressed capital costs by utilising funding from other sources, including a recurrent capital subsidy from the NSW Ministry of Health.

The Forensic Precinct at Lidcombe has future redevelopment opportunities identified in master site planning. A scoping and planning process is currently underway to assess the existing aged infrastructure on the Lidcombe site and will determine options for co-locating all FASS laboratories and associated functions and consider options for the most appropriate use of space on the campus. Funding will be required to progress any future development.

9.1.5. Specimen tracking project

The Statewide Specimen Tracking Program aims to ensure a robust chain of custody for the handling of specimens across NSWHP and addresses program governance, policy directive implementation, ICT, specimen tracking governance, processes, communications and change management, and implementation.

Work is underway to scope and design the future specimen tracking capability for NSWHP.

Short terms goals include identifying and implementing opportunities for improvement based on current ways of working, while longer term, a technology solution is being designed to reduce the current reliance on manual processes to track specimens.

9.1.6. Statewide test catalogue

A new, single catalogue is being assembled to provide a uniform repository to list tests and investigations carried out across NSWHP sites and will inform NSWHP staff, customers and stakeholders about pathology and forensic services.

A single test catalogue is an important prerequisite for many future IT and service developments, such as direct LIMS-to-LIMS communication, better client focused reporting capabilities, common operating protocols, enhanced specimen tracking, a statewide LIMS, and billing system. This catalogue will be a dynamic repository continually maintained and developed by NSWHP.

9.1.7. Courier transport systems

The courier and logistics network transports specimens to and between laboratories and is critical to NSWHP service delivery.

Configuring the specimen transport network in an agile and efficient way is a key enabler to ensure effective implementation of other clinical and organisation plans and ensure that service levels evolve with stakeholder expectations.

9.1.8. Clinical Governance Framework

NSWHP will focus on building incident management and improved scientific capability utilising the Keiser Permanente model described in the NSWHP Clinical Governance Framework.

Further development and refinement of quality and patient safety data use, including triangulation and use of statistical process control charts will facilitate a response to unwanted variation.

9.1.9. Quality management

A single Statewide Quality Management System (QMS), (the Quality Manual) is being developed, moving from the current multiple disparate QMS existing across the operational areas.

ICT systems to support the QMS will be standardised and planning for this large piece of work has commenced in collaboration with NSWHP ICT and the Clinical Excellence Commission. Standardisation of quality documents and audits tools will be undertaken.

9.1.10. Statewide billing project

The billing systems in place across NSWHP mirror the current LIMS configuration with multiple systems in place in line with the former network configuration.

NSWHP has partnered with eHealth to develop a statewide billing solution to replace legacy billing systems across five operational areas. We will pilot the Stafflink-based solution at West/Rural and Regional in 2019, and plan to implement the solution statewide in the next two years.

9.2. Clinical stream vision and priorities

Each NSWHP clinical stream has developed a vision and service development plan that describes their key priorities to be targeted over the next five years.

These priorities have been aligned under five overarching strategies:

- service delivery
- service configuration
- technology
- workforce
- clinical engagement

The specific issues as they relate to each clinical stream are detailed in the following pages.

9.2.1. Pre and Post Analytical

By 2025 technology will drive significant developments in Pre and Post Analytical services in:

- ordering and managing the journey of samples and test results
- the changing landscape of how and where diagnostic tests are provided
- significantly greater involvement of patients and customers in this process.

The single LIMS and statewide test catalogue will significantly change the pre and post analytical environment. Standardised laboratory testing platforms and integration of pre-analytical specimen processes will automate the specimen journey within core laboratories.

Patients and customers, including specialists and General Practitioners (GPs), will be active and engaged participants in ordering and receiving

diagnostic services from NSWHP. With developments such as My Health Record and increased consumer interest in managing their own health care, patients will want to be an equal and active participant in monitoring and receiving their diagnostic data. Delivery of results utilising more customer focussed modalities such, as mobile apps, will improve the ability to deliver service to all customers.

Key priorities

- **Service delivery**
  - develop electronic ordering of requests through a trial e-ordering system for hospital outpatients and investigate options for a standardised, statewide e-orders system for inpatients and community patients.
  - explore innovative models of care in non-traditional settings such as colocations with HealthOnes and Service NSW, cruise ships, airport arrivals and home collections.
- **Service configuration**
  - develop a collection model for the 21st Century beginning with development of specifications for community collection centre kiosks and trialling of patient booking system.
  - work collaboratively with other Clinical Streams to develop a model of service that integrates pre-analytical specimen processing/transport system into a service driven core laboratory.
  - develop a model to respond with mobile “pop-up” clinics due to increased demand in capacity to respond to emergent public health response.
- **Technology**
  - Establish an electronic tracking system that integrates with the single LIMS that results in one system tracking movement of specimen from collection to archiving.
- **Workforce**
  - review organisational structures within the pre-analytical area and develop a structured career path for the workforce.
- **Clinical engagement**
  - engage with Local Health Districts (LHDs), clinical practitioners and patients to develop customer focussed services.

9.2.2. Transfusion

On-site transfusion services will continue to be required at most acute hospitals to provide immediate access to blood products during emergency, acute and trauma situations.

The future development of a single LIMS, together with future developments in the use of remote release blood and smart fridge technologies will enable networked laboratories to support facilities without a 24/7 laboratory service to provide type-specific blood in acute situations.

Key priorities

- **Service delivery**
  - implement new technology to manage blood and blood transfusion services including smart blood fridges and remote release of blood products. New laboratory technology to harmonise

- **Service configuration**
  - improve transport of blood and ensure minimal wastage of blood products.
- **Technology**
  - implement new laboratory technology to harmonise and improve testing services across NSW.
- **Workforce**
  - develop a framework for training the next generation of transfusion laboratory staff and sustaining workforce.
- **Clinical engagement**
  - engage with LHDs to ensure safe and effective use of blood.

9.2.3. Haematology

Routine Haematology will continue to be performed on-site at all laboratories, however optimal service delivery of specialised Haematology testing is under review.

It is anticipated there will be more laboratory automation and use of digital technology to improve workflow and delivery of services; and possible separation of work into wet laboratory and dry laboratory, with the intention of the dry laboratory component being digitalised.

With the statewide NSWHP service in place, the goal is to develop integrated, seamless Haematology services across NSW with improved access for rural and regional patients via telemedicine and digital technology, increased levels of crossover and collaboration between disciplines and specialties.

Essential, time-dependent diagnoses will be maintained in laboratories across NSW public hospitals through access to machines capable of faster, high volume delivery of results in the core laboratory environment.

Information technology will be an important component of Haematology services enabling access to Big Data, Artificial Intelligence and cloud technology and greater connectivity, ensuring equity of access to diagnoses in rural settings. Haematologists will be the curators of data and have a greater role in interpretation and involvement in clinical care including multidisciplinary teams.

Future diagnostic Haematology services will have greater use of Point of Care Testing (PoCT) and Genomics, and the boundaries between these will be reduced.

Key priorities

- **Service delivery**
  - integrate PoCT and laboratory-based testing across the state to improve the service delivered to clinicians and patients.
- **Service configuration**
  - develop standardised operating procedures to optimise laboratory services across the state.
  - develop a model of service using new technology to improve service configuration.

- **Technology**
  - implement a digital morphology system and roll-out new haematology, coagulation and flow cytometry analysers across the state to standardise testing.
- **Workforce**
  - develop a laboratory workforce model that ensures training of the next generation of laboratory staff and sustains the workforce.
- **Clinical engagement**
  - engage with LHDs and clinicians to develop laboratory services that meet the expected clinical demand.

9.2.4. Chemical Pathology

High-volume chemical pathology tests are generally considered part of the ‘core laboratory’ setting where testing analysers are close to specimen reception, haematology and transfusion.

These core chemical pathology tests are essential for immediate patient care in all acute care public hospitals and further development of the ‘core laboratory’ concept will have a big impact on provision of chemical pathology tests in NSWHP laboratories.

Laboratories at tertiary referral hospitals also provide core services but also more specialised testing services such as therapeutic and illicit drug testing, inherited metabolic disorders, endocrinological, vitamin, trace metal and porphyria testing. Networking and linkages that have occurred within the statewide organisation have ensured there is now minimal unnecessary duplication of services in tertiary hospitals. Evaluation of new technology and development of new tests is an ongoing process in chemical pathology, particularly in evolving areas, such as the use of molecular biology techniques and rapidly advancing fields of genomics, proteomics and metabolomics.

Key priorities

- **Service delivery**
  - create statewide standards for testing platforms, reference intervals, operating procedures and high-risk result alert thresholds to improve statewide services.
  - develop new service delivery models across multiple customer settings to improve customer experiences.
- **Service configuration**
  - streamline workflows to increase operating efficiencies, particularly integration of relevant testing for all disciplines within the core laboratory setting.
- **Technology**
  - embrace new technologies, such as Mass Spectrometry, proteomics, genomics and metabolomics, to ensure we remain as leaders in the discipline.
- **Workforce**
  - create a sustainable chemical pathology workforce, including chemical pathologists, clinical scientists and technical staff.

- **Clinical engagement**
  - Establish a framework for collaborative research between chemical pathology and other clinical and laboratory specialties, including FASS, universities and other research institutes.

9.2.5. Microbiology

The past two decades have seen significant advances in diagnostic microbiology, driven by advances in technology and molecular medicine such as automation, nucleic acid amplification tests (NAATs) and pathogen and human genomics.

In summary:

- there will be a continuing transition over the next five years from the traditional labour-intensive procedures to high throughput automated systems and molecular-based platforms.
- the impact of technology development within microbiology will drive consolidation of some diagnostic testing, such as specialised and “reference” confirmatory tests in fewer sites, while enabling increased decentralisation for other tests.
- new technology has enabled a paradigm shift that will see the placement, wherever possible (based on operational and service needs, and availability of validated and fit for purpose equipment) of short incubation, high throughput, automated machines in some core laboratories that will replace traditional procedures

The Microbiology Clinical Stream has established working groups to review trends in service delivery models and to identify the potential impact on configuration and delivery of Microbiology services across NSW. Standardisation of diagnostic algorithms, methods and reporting is an important strategic principle to reduce variation and heterogeneity in practice. Recommendations from these working groups will play a vital role in advising the direction for Microbiology services across NSWHP over the next five years and beyond.

Key priorities

- **Service delivery**
  - develop a service model that actively adopts technology to deliver patient focused services.
- **Service configuration**
  - utilise near patient testing platforms and automation of culture-based testing to re-configure laboratory services.
  - expand the concept of a core laboratory by inclusion of microbiology testing through the implementation of short incubation, “random access” molecular microbiology systems
  - enhance integration of pathogen and host genomics with microbial-diagnostics (whole genome, microbiome) through establishment of a statewide microbiology bioinformatics capability.

- **Technology**
  - develop a framework for implementing high-volume automated culture testing systems at selected laboratories.
  - consider the application to laboratory workflows and testing of artificial intelligence.
- **Workforce**
  - develop a laboratory workforce with the skills to adapt to changing laboratory testing technologies.
  - ensure service reconfiguration enhances training of the next generation of scientists and pathologists
- **Clinical engagement**
  - engage with LHDs and clinicians to develop laboratory services that meet the expected clinical demand and collaborate on research projects.
  - enhance support for quality and safety activities in Infection Prevention and Control, Antimicrobial Stewardship, Hospital Outbreak Management and Public Health.

9.2.6. Anatomical Pathology (AP)

The drive towards individually targeted therapies is expected to continue to increase the level of detail needed in individual AP reports, particularly in cancer treatments, that depends on identification of specific tumour attributes and detailed grading and staging. There is already a need to integrate somatic genomic findings within AP reports, for instance in neuropathology, where the classification, prognosis and treatment of some tumours depends on molecular findings as well as morphology.

Digital technologies provide an opportunity for diagnostic testing to become more efficient and scalable, more accurate and with less subjectivity. Digitisation of pathology labs has the potential to make reporting more reproducible and the work of pathologists less cumbersome.

The AP Clinical Stream has done extensive work to obtain uniformly collected and reliable data on activity and growth, and visited laboratories to understand local circumstances and challenges. There has been an ongoing revision of medical staffing levels which has been necessary due to growth in workloads and the medical labour-intensive nature of AP. Areas of clinical risk and potential solutions have been identified. Introduction of new technologies and their potential for improvements in service delivery are continuing to be explored.

Key priorities

- **Service delivery**
  - enhance report delivery. Electronic transfer of results to clinician's preferred device in their preferred format.
  - uniform reporting of cancer cases consistent with RCPA protocols for Structured Reporting of Cancer.
  - ensuring timely access for patients to genomic tests in cancer.

- **Service configuration**
  - develop standardised operating procedures to optimise laboratory services across the state.
- **Technology**
  - introduce new enabling technologies such as whole slide imaging and use of a digital microscope rather than the current optical microscope for most routine reporting.
  - re-evaluate how technical laboratory processes, such as tissue processing and slide production, immunohistochemistry and in-situ hybridisation can be best provided.
- **Workforce**
  - determine and implement appropriate levels of medical, scientific and technical and support staff with the development of workload assessment tools for scientific and technical staff
  - extend technical and scientific staff activities, including macroscopic dissection and cut-up.
  - revise the activities of trainee pathologists to better reflect specialist AP practice and improve training.
  - Promote a respectful and cooperative workplace culture.
- **Clinical engagement**
  - improve access to expert primary diagnosis or second opinion consultation within NSWHP AP departments by developing and identifying specific subspecialty expertise.

9.2.7. Immunology

Immunopathology teams navigate high levels of uncertainty which is twofold - from within the tests, and from within the disease. Immunology tests are non-linear and require high levels of supervision.

Immune disease can be difficult to diagnose. Immunopathology laboratories guide clinicians who are often unfamiliar with complex test results in complex medical conditions. Immunopathology tests are needed for the minority of patients. People with immunologic illnesses undergo extensive testing, and management can be challenging as many immune disorders are very rare.

Immunopathologists have a liaison role where they translate information, from the complex science of the testing done, into patient management advice. This requires immunopathologists to be part of a team with skilled scientists who understand the methodologies and results.

Laboratory service configuration considers: the importance of the liaison role, the relatively low volume of testing (e.g. when compared to routine chemistry and routine haematology), and the requirement of sufficient caseload and case mix to maintain experience. Currently these are met well with seven laboratories dispersed across NSW.

Every immunology laboratory is a specialist laboratory and should have access to high proportions of senior scientific staff. Within immunopathology there will be experts in the field(s) of autoimmunity, immunochemistry, cellular phenotyping (including, but not limited to, flow cytometry), allergy, and molecular testing.

Key priorities

- **Service delivery**
  - integrate PoCT and laboratory-based testing across the state to improve the service delivered to clinicians and patients.
- **Service configuration**
  - realise opportunities of both large (assessment of new technologies) and small (contracted research work).
  - realise our current opportunities as NSWHP has access to the largest number of samples from people with immune disorders in Australia.
- **Technology**
  - adopt new technologies and standardise work practices across the state to improve the delivery of services.
- **Workforce**
  - establish a career pathway for scientists that explicitly includes roles of quality, test development, research and teaching.
- **Clinical engagement**
  - improve our liaison with clinicians, including guidance and provision of homogenous result formats, and pooled expertise for interpretative guidance.

9.3. Statewide service initiatives

9.3.1. Genomics

National and State governments within Australia have recently shown high interest and strong support for the development of Genomic Medicine.

A National Health Genomics Policy Framework was released in November 2017 and this was followed by an implementation plan in November 2018. In parallel to these frameworks the Genomics Futures Mission was announced as part of the 2018 Federal Budget. This initiative has allocated $500 million over the next 10 years for development of Genomic Health in Australia. The first program of this initiative was announced as a Reproductive Carrier Screening Program (called Mackenzie's Mission) with $20 million given to a three-year pilot study.

NSW Health also released a Genomics strategy in 2017 and an implementation plan in 2018. The NSW Ministry of Health has established a Genomics Steering Committee and five subcommittees; Translation Medicine, Service Planning, Community Engagement, Workforce and Information Technologies. In addition, the Ministry has provided an initial $2.4 million and a further $1.9 million recurrent funding to provide whole genome microbial sequencing which is relevant to public health and includes antimicrobial resistance mapping.

These initiatives provide great opportunity to develop an infrastructure that will increase the use of genomics in health and benefit patients and residents of NSW in many ways. The Clinical Services Plan will align the genomics service provided by NSWHP with the high expectations for the role of genomics in the health system of the future.

Key priorities

- further align NSWHP Genomics initiatives with the NSW Health Genomics Strategy including research and translation medicine.
- establish state of the art genomics capability within NSWHP to be a preferred provider, that provides cost effective and timely clinically appropriate genomic testing and at the same time reducing costly and uncoordinated outsourcing.
- establish the formalised facilitation role of NSWHP in genomic testing for patients in NSW to ensure safety, governance and appropriate control of genomic data and resources.
- leverage Medical Research Future Fund (MRFF) Genomics funding wherever aligned to the objectives of NSWHP.
- consolidate complex genomic testing at a small number of sites within NSWHP and provide centralised data requirements from a cloud-based service to leverage economies of scale.
- formalise inclusion of The Children's Hospital, Westmead Genomics within NSWHP Genomics and potentially NSW Newborn Screening.

9.3.2. Point of care testing (PoCT)

NSWHP's PoCT service ensures consistent and quality assured delivery of PoCT regardless of the location of testing.

Delivery and support have evolved since 2013 and can be categorised in the following service models:

- PoCT where there isn't a NSWHP laboratory in close proximity (same campus)
- PoCT where there is a NSWHP laboratory in close proximity.

Where there isn't a laboratory nearby, the PoCT team directly supports the people doing the testing. Where there is a laboratory close, the PoCT team assists the laboratory to support the people doing the testing.

In future models, as PoCT moves closer to a patient's home and other hospitals outside of healthcare centres, it is anticipated the PoCT team will also support NSWHP staff to deliver PoCT in locations like NSWHP collection centres, Aboriginal communities and their health organisations and mobile screening stations.

PoCT strategic/operational plans are aligned to this Clinical Services Plan. The key strategic initiatives are listed below.

Key priorities

- embed standardised PoCT service delivery into the core function of all NSWHP laboratories

- ensure ICT interfacing to LIMS, eMR and other result display systems is resourced so that statewide service implementation for new technology is not delayed
- resource pilot initiatives that provide community value or improved quality/reliability of PoCT
- Create a sustainable asset management plan for PoCT
- develop the customer service and business development capability of NSWHP PoCT Service staff
- participate in NSW, national and international PoCT service initiatives to strengthen the position of NSW public pathology
- identify relevant business development opportunities

9.3.3. Information Technology

With over 300 projects on the go, our ICT team drives everything from large-scale statewide initiatives, such as the Lab Information System (LIS to LIS) cloud-based genomics, providing access to electronic pathology results via HealtheNet, pathology results at clinicians' fingertips anytime anywhere; to keeping our laptops and laboratory systems running.

Laboratory Information Management Systems (LIMS) are the central system for clinical settings with integration to testing instruments, processing and the capture and reporting of results. These systems have evolved alongside related hospital systems and in some cases are closely integrated to them. The diversity and fragmentation of existing systems adds complexity to statewide initiatives for test/data standardisation, financial and performance reporting and consolidated billing. It also reinforces the boundaries which exist between networks, creating a further barrier to collaboration

Key priorities are outlined in our Strategic Vision Document 2015-2020 for ICT and include the LIMS, and to develop IT solutions (Internet of Things) that supports a range of initiatives, including the Statewide Pathology Test Catalogue, pathology discipline middleware, billing systems, electronic ordering.

9.3.4. Public Health Pathology

Public Health is our newest statewide service and is a key part of the value NSWHP brings to the health system.

Our public health experts work across a range of areas including:

- disease outbreaks
- laboratory investigations for notifiable diseases
- responses to emerging diseases
- monitoring public health trends
- public health research and education
- supporting emergency preparedness.

Key priorities

- align provision of public health laboratory work across NSWHP laboratories. This includes human pathogen testing in NSWHP hospital laboratories, and environmental testing in NSWHP-FASS.

- work with the Clinical Streams, particularly the Microbiology Clinical Stream, to ensure provision of appropriate and cost-effective laboratory services relevant to public health.
- establish a NSWHP state-of-the-art pathogen genomics laboratory
- establish a Public Health Pathology Advisory Committee to guide public health activities in NSWHP.
- consolidate complex or specialised public health testing.
- reduce costly and uncoordinated outsourcing of testing.
- maintain direct linkages with NSW Health Protection and other NSW Health agencies to ensure coordinated approaches to public health issues.
- maintenance, and where required, capital replacement of high-level biosecurity facilities (e.g. NSW P4 laboratory, AQIS and TGA approved laboratories).
- ensure NSWHP LIMS continue to enhance electronic notifications of relevant public health laboratory results to NSW Health.
- ensure that the NSW Genomics strategy around IT ('cloud' storage, analytics etc) supports public health pathogen genomics development
- leverage research funding through the Office of Health and Medical Research in the NSW Ministry of Health, NHMRC and other funding agencies (e.g. Medical Research Future Fund) to enhance the role of NSWHP in public health
- identify emerging trends in pathology that support public health initiatives e.g. metagenomics, antimicrobial resistance testing, PoCT etc
- delineate the role of current and planned NSWHP biobanking facilities in supporting public health activities and research.

9.3.5. Perinatal Post-Mortem Service (PPMS)

NSWHP leads the Perinatal Post-Mortem Service in partnership with Children's Hospital Westmead. The service operates as three centres of excellence including the John Hunter Hospital and Prince of Wales, NSWHP-Randwick and The Children's Hospital, Westmead. PPMS is performance-based, family-centred and improves access for regional and rural families.

Prior to the development of the PPMS it was estimated that only 25% of stillborn babies had a post-mortem examination[16]. The NSW Maternal and Perinatal Mortality Review Committee recommended an aspirational target of 100% of families offered a perinatal post-mortem examination.

The service interfaces with diagnostics services such as genetic testing and medical imaging. There is an opportunity for some examinations to utilise less invasive diagnostic tests, such as MRIs.

[16] NSWHP (2016) *NSWHP Perinatal Post Mortem and Related Services: Service Model of Care*

Key risks to ongoing quality and sustainability of the new service model identify the need to:

- enhance service capacity to provide a greater ability to respond to demand and maintain appropriate turnaround times
- ensure a sustainable future workforce of suitably qualified and experienced paediatric pathologists, scientist and technical staff (who are prepared to work in the post-mortem area of pathology)
- improve access to perinatal post-mortem examinations in regional and rural settings
- improve integration of the service with referring service and Maternal Fetal Medicine Units
- development of integrated ICT systems and reporting tools, and
- standardised business models, policies, procedures and clinical processes.

9.3.6. Forensic & Analytical Science Service (FASS)

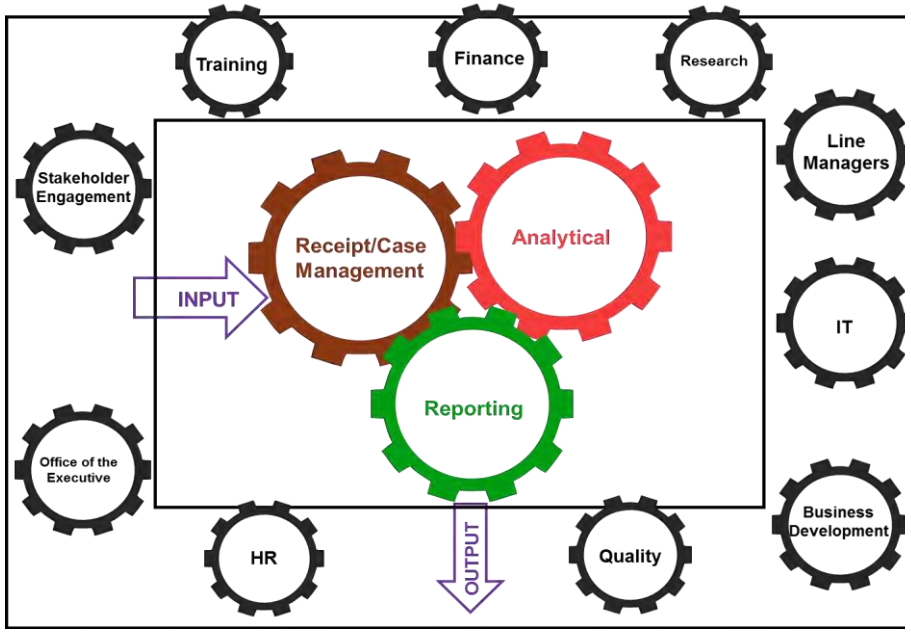
The Forensic & Analytical Science Service (FASS) has identified its key priorities to 2025, including:

- **Enhanced Service Delivery System**

FASS will develop an enhanced service delivery model based on interconnected functions across all disciplines and laboratories providing timely forensic and scientific information relevant to our stakeholders.

The system relies on discipline integration and connected science to optimise forensic and analytical services. FASS will identify internal synergies and opportunities to capitalise on system inter-reliance.

Figure 9.1 - FASS Stylised Enhanced Service Delivery System Model



- **Alignment with the ESDS**

The rapidly evolving scientific landscape has created a discordance between workforce skills (based on historical positions and practice) and emerging operational best practice.

FASS will undertake a detailed understanding of current capabilities and develop a strategic roadmap to enable an enterprising workforce that collectively will drive our ESDS.

9.3.7. Logistics

Work is progressing on development of a NSWHP Transport Control Hub that oversees a network of specimen transport using GPS analytics to allow NSWHP to log, in real time, the location of all samples and transport vehicles.

The service will be able to identify route changes to meet urgent ad hoc requests for sample transport. The number of samples transported will be reduced due to improved lab-to-lab communications and digitisation of test data.

NSWHP is investing in enhanced inventory storage, replenishment and stock control infrastructure and systems across all NSWHP laboratories. Modifications to the ORACLE inventory management module will provide for perpetual inventory functionality, enabling real-time stock-on-hand visibility and replenishment of high velocity and value consumables.

NSWHP procurement services will change to support the agility of equipment replacement due to increasing speed of technological change.

NSWHP will have a long-term financial plan to support asset replacement supported by inclusion of capital funding within the NSWHP cost of service. NSWHP equipment contracts will allow us to respond to changing technology allowing us to upgrade our equipment as required.

9.3.8. Workforce

Designing the workforce of the future will require significant and coordinated service planning to understand future service needs and inform workforce planning.

Fundamental to workforce redesign will be service reconfiguration. This work will be critical in ensuring we have sufficient skilled and trained staff now and in the future. While natural attrition and career progression will assist in reshaping the organisation and its workforce, other strategies such as appropriate career transition, accelerated advancement opportunities and succession planning will also need to be implemented.

Further work will be done to build partnerships and collaborative efforts with educational institutions both within and outside NSW Health. There is considerable work to be done to further build strong partnerships with the Health Education and Training Institute (HETI), vocational education and training institutions, tertiary education institutions and relevant professional bodies and associations.

Some progress has been made since NSWHP's creation in this area and it will be important to continue to advocate for pathology staff who are generally under-represented in terms of focus and attention paid to their specific education needs.

NSWHP will:

- actively pursue options to increase the available supply of qualified and skilled staff
- improve and better target our recruitment strategies and practices
- increase our focus on developing our staff at all levels and provide greater opportunities for staff to access and participate in training and development programs
- support our ageing workforce by introducing greater flexibility in work arrangements (where appropriate) and transition to retirement programs
- review and project staffing needs and gaps to address the impending workforce shortages and ensure succession planning fills identified gaps
- increase our efforts to build partnerships and collaborative efforts with educational institutions
- ensure that clinical service and workforce planning are highly integrated to enable us to identify and respond to our future service and workforce needs
- support equitable employment opportunities for Aboriginal people.

9.3.9. Education and training

Building capability of all employees

To achieve the planned change over the coming five to seven years and to achieve our outcomes as an extraordinary public pathology service, we will build upon the core knowledge, skills and abilities of employees.

Employees will need to:

- develop their capability to respond and commit to change
- work effectively as teams across existing and historic boundaries
- provide exceptional customer service
- communicate and uphold our values
- learn and adopt new technology and ways of working
- continuously improve our service and achieve outcomes.

Alignment and developmental needs assessment against capability frameworks such as the NSW Public Sector capability framework will assist us to plan and deliver this broader development.

Continuing education will be coordinated to meet ongoing competency and capability development needs, through events such as scientific and technical symposiums and targeted workshops.

Leadership and management capability

Our managers and clinical leaders will effectively lead change and support their teams by developing their leadership and people

management capabilities (see NSW Public Sector capability framework and NSW Health Leadership framework).

We will continue to develop our leaders and managers through internal programs (e.g. Emerging Leaders) as well as securing opportunities available through external partnerships (e.g. HETI, Clinical Excellence Commission, TAFE NSW, Australasian College of Health Service Management.

9.4. Major laboratory redevelopments

Major redevelopments are occurring in many laboratories, including:

- Liverpool
- Westmead
- Randwick
- Nepean
- Campbelltown
- Tweed Heads
- Blue Mountains
- Maitland
- Mudgee
- Cooma
- Bowral, and
- Griffith.

For each of these redevelopments, NSWHP Service Planners, Operations Directors and Local Lead Pathologists are working with the local hospital, Local Health District (LHD) and Health Infrastructure (HI) in planning the design and space requirements for pathology services.

These projects are funded by the NSW Ministry of Health and managed by HI. They provide an opportunity to redesign laboratories in line with more contemporary flexible laboratory designs incorporating new technology and service models described in this CSP.

Some LHD sites have had multiple recent capital redevelopments where pathology laboratories have not been included. Consequently, these laboratories are finding it increasingly difficult to address the growing demands while working within fragmented laboratory spaces. Some laboratories do not have enough room to accommodate replacement next generation analysers and emerging technologies.

In addition to these LHD-led redevelopments, NSWHP recognises the need to review the condition, capacity and functionality of all laboratories in NSW. It will determine the relative priority for new investment in updating outdated and dysfunctional infrastructure. To this end, the Condition of Labs Audit will assess the condition of laboratories and equipment within labs. This will entail measuring capacity against current activity and functional relationships with key services using statewide assessment tools.

The need for investment will be identified and projects prioritised. Projects under $10 million will be undertaken as minor capital projects. Projects requiring a greater capital investment may be proposed for funding as part of Super Project User Groups.

Service redevelopment - RACI

RACI is a process that visually summarises:

- what is the broad process we're trying to follow?
- what is everyone's role?
- where are we in the process? (who has carriage of it now?)

It clearly delineates:

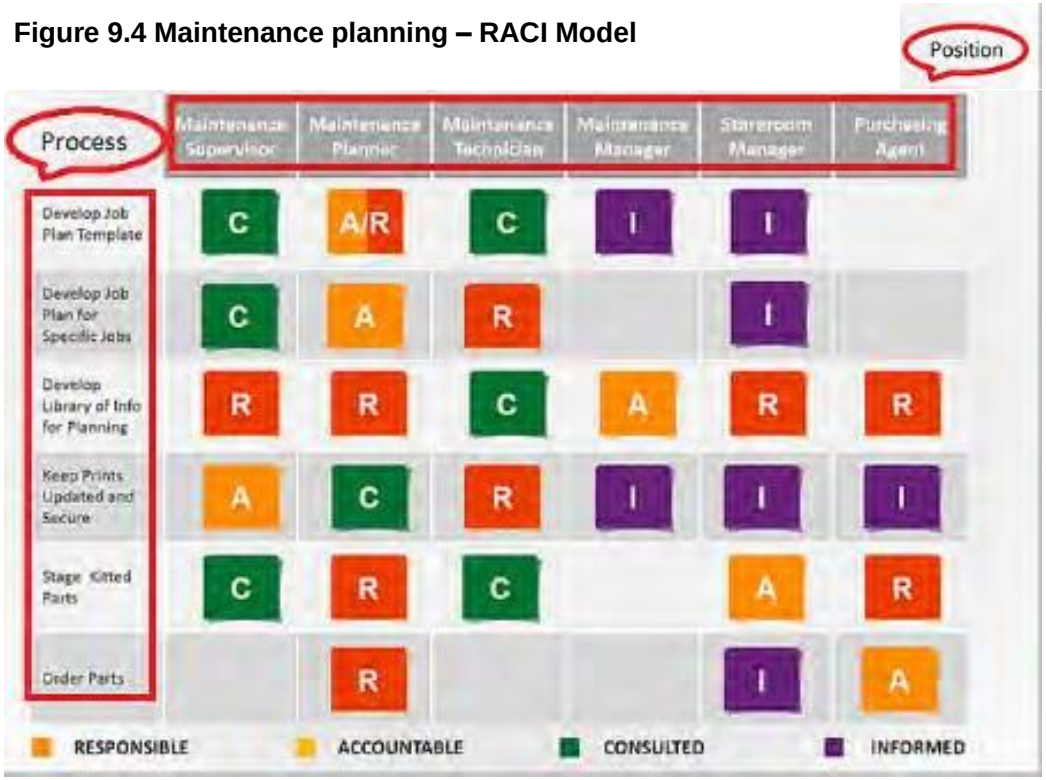
- which position is doing the do (R – Responsible),
- who is the sponsor/has the budget (A – Accountable),
- who needs to be providing input/involved (C – Consulted),
- who needs to be advised about what's going on (I – Informed).

A very basic example is presented at Figure 9.4.

NSWHP will introduce this and other project management tools to monitor and inform the progress of laboratory redevelopments and major planning projects.

RACI Model Reference":
https://blog.triaster.co.uk/blog/raci-matrix-template-for-business-process-improvement

Figure 9.4 Maintenance planning – RACI Model



10. Clinical services planning to support future pathology service models

This CSP has laid the foundations for a statewide approach to planning pathology services.

There is much work to do to build on these foundations and develop a more rigorous and robust approach to pathology services planning and are presented below.

10.1. Ongoing development of pathology service models

The Laboratory Service Models Test Profiles presented in this CSP (as outlined in Section 9.2 above and Appendix Five) comprises the baseline test profiles only for various laboratory tiers. This Framework requires further, comprehensive description of Pathology Service Models and a methodology developed to introduce and implement the Framework laboratories.

10.2. Laboratory design guidelines

There is a subsequent, urgent need to for the development of statewide guidelines to support service and facility planning at all levels of the system.

This will ensure that:

- pathology laboratories on these sites are upgraded in sync with the plans to upgrade clinical services at these locations
- provision of the required space, capacity and expertise to match the proposed Emergency Department (ED), Intensive Care Unit (ICU), operating theatre, cancer services and overall acute inpatient bed capacity, and
- optimal location of the laboratory in terms of the key functional relationships between pathology and clinical services.

It is anticipated that the development of these guidelines would inform future updates to the Australian Health Facility Guidelines for Pathology Units.

10.3. A potential future methodology for projecting NSWHP demand

There is a need to develop a more sophisticated modelling of projected NSWHP activity taking into account a broader range of demand drivers and the impact of case mix (diagnosis/disease groupings) on NSWHP volume and complexity.

This work has not been possible until now due to multiple Laboratory Information Management Systems (LIMS) and nomenclature used across different regions to describe and count tests.

Modelling of NSWHP activity data will aim to identify relationships hospital activity data as well as factor in the effects of innovations such as Point of Care Testing (PoCT) and increased automation to enable more sophisticated projection methodology of demand. This is turn will be used to plan laboratories. It is expected that increases in volume of tests will not result in significant growth in laboratory space or workforce.

11. Next steps for NSWHP

This is the first Clinical Services Plan (CSP) for NSW Health Pathology (NSWHP) and has laid the foundation for a more rigorous approach to the planning and development of pathology clinical services in NSW. There is much work to be done to further develop service models and planning methodologies to support effective and optimal configuration of NSWHP services across the State to best meet the customers, and ultimately, NSW population needs to 2025 and beyond.

These next steps are presented below, in order of priority:

1. Consult with clinicians

Continue system-wide engagement with clinicians based on the NSWHP CSP.

2. Consult with local health districts, the Ministry of Health and Health Infrastructure

Consult with each individual Local Health District's (LHD) service planners and other key stakeholders, including the Local Pathology Directors about the NSWHP CSP.

Discuss the planning framework, proposed hospital redevelopments, current networking arrangements, etc. Also consult with the NSW Ministry of Health and Health Infrastructure (HI) over the proposed development of new service models for NSWHP.

3. Further refine the laboratory services models test profiles

Consult with Operations Directors and Local Pathology Directors to socialise the proposed Laboratory Service Models Framework. Discuss how services can be best provided using this framework across the existing regional, and broader statewide, networks particularly when ICT and logistic barriers are no longer limitations.

Further refine the Framework following completion of key clinical redesign projects in Flow Cytometry, Digital Morphology and the deliberations of key Microbiology working groups.

4. Develop Laboratory Design Guidelines

Develop Laboratory Design Guidelines to inform the current facility planning of laboratory redevelopments across NSW.

5. Further define the role and operations of the Core Laboratory

Complete a Core Laboratory Project to define the core laboratory concept, workforce implications, change in workplace culture, and design. Implement change pathways to support this.

6. Develop pathology planning parameters and benchmarks

Continue to develop benchmarks and planning guidelines for pathology services.

7. Develop comprehensive laboratory service models

A comprehensive description of Pathology Service Models would cover the full range of services provided by NSWHP at each tier of the system

including the whole process from specimen collection to report delivery and would include the engagement of Pathologists in clinical care and consultations.

8. Workforce implications of laboratory service models

Undertake an initial project to review the potential impact of the Laboratory Service Models and CSP recommendations on the workforce.

9. Develop projections methodology

Develop a model for identifying the relationship between acute hospital inpatient case mix and pathology requests to develop a methodology for projecting future NSWHP activity demand.

10. Conduct condition of laboratories audit

Develop an audit mechanism and undertake a statewide review of functionality and state of repair of all laboratories. A priority listing of labs requiring redevelopment will then be established.

11. Liaise with The Children's Hospital, Westmead regarding exploring opportunities for collaboration and share NSWHP service frameworks

The Children's Hospital, Westmead (CHW) has an important role in the provision of pathology services, including a significant Genomics capability. There are already strong links between NSWHP and CHW and it is important that future service models align and are complementary in role and design.

12. Implement recommendations

This Clinical Services Plan (CSP) has made several recommendations that are aligned to the NSWHP Strategic Plan – *Towards 2025* and will form the foundation of service design discussions with customers, stakeholders and staff.

Our recommendations are listed in Section 1.9.

NSWHP will review and prioritise the recommendations into our annual operations plan to ensure implementation over five years.

Operational plans are developed annually and cascaded down into Director's operational plans, detailing responsibilities and timeframes; and enable planning for budget or program management.

All NSWHP business cases, briefs, operational plans and work plans will reference the relevant Strategic Plan, *Towards 2025*, lead strategies and/or CSP recommendations.

Appendix One: List of acronyms

ACSQHC	Australian Commission on Safety & Quality in Health Care
CHW	The Children's Hospital at Westmead
CSP	Clinical Service Plan
CSR	Central Specimen Reception
DNA	Deoxyribonucleic Acid
ED	Emergency Department
eMR	Electronic Medical Record
FASS	Forensic & Analytical Science Service Full
FBC	Blood Count
GPs	General Practitioners
HDU	High Dependency Unit
HI	Health Infrastructure
ICT	Information Communication Technology
ICU	Intensive Care Unit
LBVC	Leading Better Value Care
LFT	Liver Function Test
LHD	Local Health District
LIS	Laboratory Information System
LIMS	Laboratory Information Management System
MoH	Ministry of Health
MPS	Massive Parallel Sequencing
MRFF	Medical Research Future Fund
NAAT	Nucleic Acid Amplification Testing
NSWHP	NSW Health Pathology
PCR	Polymerase Chain Reaction
PoCT	Point of Care Testing
PoWH	Prince of Wales Hospital
PPMS	Perinatal Post Mortem Service
RCPA	Royal College of Pathologists of Australasia
RNA	Ribonucleic Acid
RNSH	Royal North Shore Hospital
RPAH	Royal Prince Alfred Hospital
SCHN	Sydney Children's Hospital Network
SHN	Specialty Health Network
WGS	Whole Genome Sequencing
WSI	Whole Slide Imaging

Appendix two: Aboriginal impact statement

Summary

The NSW Health Pathology (NSWHP) Clinical Service Plan (CSP) aligns with the NSW State Plan and the NSWHP Strategic Plan – *Towards 2025*.

These plans have a strong commitment to closing the health and justice gaps for Aboriginal and Torres Strait Islander communities.

Our lead strategy is to keep people healthy and safe and we will ensure our communities get reliable and meaningful answers every time - regardless of who they are or where they live.

Those at increased risk or facing unacceptable inequities in health and justice, such as Aboriginal and Torres Strait Islander People, are priority communities for us.

The CSP is focusing on improving access to pathology services for vulnerable and at risk people and where patients and clients should have access to high quality, innovative diagnostic services to support clinical decision-making regardless of where they are in NSW.

Investment in collection services which are mobile, able to attend at customer's home, neighbourhoods, Aboriginal Community Controlled Health Organisations, and key community events, will improve access to Pathology services. Technological innovation will allow online appointment bookings and SMS reminder messaging.

Cultural safety is a key goal and to support that facility design and employment participation by Aboriginal and Torres Strait Islander are included as strategies.

The CSP will be measured against key performance indicators that measure our goals - including measurements of access by Aboriginal and Torres Strait Islander people to pathology testing, as well as the workforce participation of Aboriginal and Torres Strait Islander people.

The health context for Aboriginal people

NSWHP is a clinical support service across NSW and demand and access to services arises from the activity of NSW public hospitals in their provision of emergency, acute inpatient, sub-acute care and other non-inpatient and clinic services and the tests that are requested for these patients.

NSWHP provides its services for selected private hospitals, GPs, community health centres, sexual health clinics, NSW Police and the Justice Health system.

Proposed service changes and decisions outlined in the CSP must follow these principles:

- consider the best interests of NSW as a whole
- focus on patients

- deliver safe, accessible and culturally appropriate services
- deliver the best outcome in clinical quality, efficiency and effectiveness
- achieve services that are sustainable, contestable and value for money
- be feasible, affordable and optimise use of resources.

NSWHP will work closely with local health districts (LHDs) and related agencies to provide services that improve the health and justice outcomes for Aboriginal and Torres Strait Islander people, in metropolitan, regional and rural areas and increase access to pathology services outside traditional service locations.

The potential impact of this CSP on Aboriginal people and our approach to mitigating any potential undesired effects

NSWHP will undertake systematic assessment of barriers and enablers to accessing pathology services that support early diagnosis of health issues for Aboriginal and Torres Strait Islander people.

This will support programs that improve the health of Aboriginal and Torres Strait Islander People.

The CSP will drive policy that reduces disparities for Aboriginal and Torres Strait Islander people and increase equity in service access, and we will actively monitor and evaluate outcomes.

Pathology services are undergoing rapid change and introduction of new technology that will increase access to pathology services in metropolitan, regional and rural areas.

Point of Care Testing (PoCT) and home collection will reduce institutional and design barriers to Aboriginal and Torres Strait Islander people accessing pathology testing.

NSWHP is focusing on improved logistics and working with LHD to ensure that networked hospitals provide services as close to home as possible, but with access to equitable diagnostic and treatment services wherever patients are living.

Engagement with Aboriginal people

The NSWHP Aboriginal and Torres Strait Islander Recruitment and Retention Program supports our organisation to grow and develop our Aboriginal and Torres Strait Islander workforce.

This aligns with NSW Health's Aboriginal Workforce Plan and planning tools. The NSWHP program is structured around the six key priority areas contained in the framework.

Our program is focused on strategies to make NSWHP an employer of choice for Aboriginal and Torres Strait Islander people and close the gap on Aboriginal disadvantage.

The Manager for Aboriginal Workforce Development and the NSWHP Aboriginal Workforce Development Unit are working together to achieve strategies and outcomes which include:

- increasing employment opportunities
- supporting and developing our current indigenous staff
- providing culturally safe and respectful workplaces through cultural redesign and cultural awareness training for all staff
- improving provision of NSW Health Pathology services to Aboriginal communities.

We are committed to engaging with Aboriginal and Torres Strait Islander people in the review and design of our services.

Work is currently underway to develop a specific framework for this to ensure it is culturally competent and reduces bias and harmful attitudes in research to improve services for Aboriginal and Torres Strait Islander people.

Appendix three: Literature review

A literature search revealed little in the way of pathology-specific clinical service plans or planning parameters/benchmarks, guidelines and methodologies.

The search did, however, produce a range of useful journal articles to inform the development of the Clinical Services Plan (CSP).

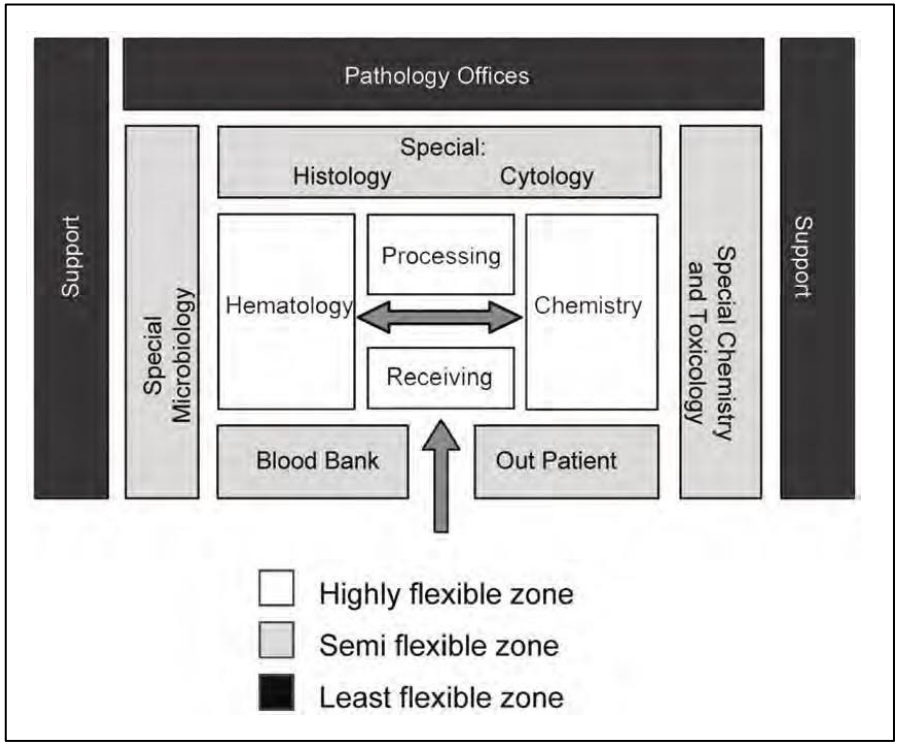
These include the articles by Battisto and Plebani – a full summary is available on request from NSW Health Pathology.

1. **Battisto, Dina (2009) *Change in Clinical Labs in Hospitals*, Informedesign Vol 03 Issue 09**

Battisto utilised survey research and case study research to explore changes in clinical labs in a variety of hospitals.

Key themes

- technological development
- physical environment
- workflow
- quality in laboratory medicine.



Conceptual diagram of the clinical laboratory

Source: Battisto Dina (2009) Change in Clinical Labs in Hospitals, Informedesign Vol 03 Issue 09

2. **Plebani M (2018) Clinical laboratory: bigger is not always better, Diagnosis 2018; 5(2): 41-46**

Plebani reviewed the relationship between volume and costs and volume and quality in the clinical laboratory setting.

Key themes

- the relationship between volume and costs is not linear and numerous variables influence the end cost per test.
- quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process is correctly performed, thus ensuring valuable decision making and effective patient care.

3. **Lippi G, Plebani M (2017) The add value of laboratory diagnostics: the many reasons why decision-makers should actually care, J Lab Precis Med 2017;2:100**

   Forsman RW (1996) Why is the laboratory an afterthought for managed care organisations? Clin Chem 1996;42:813-6

Key theme

Laboratory diagnostics contribute only 1.4 - 2.8% towards the overall budget of most healthcare systems, while laboratory data may be influencing up to 70% of clinical decisions.

4. **Lundberg GD (1998) Changing physician behaviour in ordering diagnostic tests, JAMA 1998; 280:2036**

Lundberg reviewed quality cycles in pathology services

Key themes

Quality of pathology must ensure that the appropriate test is requested, that the correct, uncompromised specimen is collected, that the sample maintains integrity in transit to the testing location, that the right result is produced and that the result is understood and used correctly for the benefit of the patient.

5. **Reitz**

Rietz defines a ‘Core Laboratory’ as a shared resource, often expensive, containing capabilities (tools, techniques, people skills) that can be shared by many users and is applicable to multiple experiments or studies.

Core Laboratories are designed to deliver workflow efficiency and create economy of scale, such that the larger they are, the lower the cost due to greater volumes of work, fewer workers and lower costs of quality control reagents and so on.

6. Hood. L, Balling. R, Auffray. C Revolutionising medicine in the 21st Century through systems approaches. Biotechnol J 2012;7(8):992-1001

This article discussed genomics and precision medicine.

key themes

- systems approaches to biology and medicine are now beginning to provide patients, consumers and physicians with personalised information about each individual's unique health experience of both health and disease at the molecular, cellular and organ levels.
- the development of Precision Medicine has been made possible by three worldwide trends:
- the ability of systems biology and systems medicine to decipher the biological complexity of disease via the enablers of genomics, proteomics, other "omics", data sciences, computing capacity and AI
- the digital revolution's radically enhanced capabilities for collecting, integrating, storing, analysing and communicating data and information, and
- consumer access to information and interest in managing their own health.

Appendix four: List and profile of NSW laboratories

NSWHP Region	LHD	Labs	NATA category	Pathology Disciplines on site	Hospital Peer Group	Hospital Total NWAU 2017/18[1]
East	SE Sydney	Randwick	GX	T, H, C, M, AP, G	A1	83,818
		St George	GY	T, H, C, M, AP	A1	58,805
		Sutherland	B	T, H, C, I	B1	22,410
	Sydney	Sydney	B	T, H, C	A3	8,340
		RPAH	GX	T, H, C, M, I, AP, G	A1	88,034
		Concord	GX	T, H, C, M, AP	A1	39,585
		Canterbury	B	T,H,C	B2	16,849
		Balmain		PoCT only	F4	
South	SW Sydney	Liverpool	GX	T, H, C, M, I, AP	A1	81,246
		Bankstown	B	T,H,C	A1	32,575
		Fairfield	B	T,H,C	B2	17,691
		Campbelltown	B	T,H,C	B1	32,752
		Camden		PoCT only	D1b	374
	Illawarra SH	Bowral	B	T,H,C	C1	6,491
		Wollongong	GY	T, H, C, M, I, AP	A1	55,517
		Shellharbour	B	T,H,C	C1	7,658
		Shoalhaven	B	T,H,C	B2	15,211

West	W Sydney	Westmead	GX	T, H, C, M, I, AP, G	A1	95,856
		Blacktown	B	T,H,C	B1	42,049
		Mt Druitt	B	T,H,C	C1	5,553
		Auburn	B	T,H,C	B2	10,969
	Nepean BM	Nepean	GX	T, H, C, M, AP	A1	61,730
		Blue Mountains	B	T,H,C	C2	3,925
		Lithgow	B	T,H,C	C2	2,255
North	N Sydney	RNS	GX	T, H, C, M, I, AP, G	A1	77,010
		Ryde	B	T,H,C	C1	9,644
		Hornsby	B	T,H,C	B1	18,614
	Cent. Coast	Gosford	GY	T, H, C, M, AP	A1	46,967
		Wyong	B	T,H,C	B2	19,917
	Hunter NE	JHH	GX	T, H, C, M, I, AP, G	A1	78,774
		Calvary Mater	GY	T,H,C	A3	17,454
		Belmont	B	T,H,C	C1	7,895
		Maitland	B	T,H,C	B2	15,960
		Manning (Taree)	B	T,H,C	B2	13,850
		Tamworth	B	T,H,C, M, AP	B1	20,851
		Armidale	B	T,H,C	C1	7,045
		Glen Innes	B	T,H,C	D1a	1,213
		Inverell	B	T,H,C	C2	2,275
	Mid North Coast	Coffs Harbour	GY	T, H, C, M, AP	B1	25,306
		Macksville		PoCT only	C2	2,219
		Kempsey	B	T,H,C	C2	3,960
		Port Macquarie		Serviced by Laverty Pathology	B1	22,454

	Northern NSW	Grafton	B	T,H,C	C1	7,916
		Lismore	B	T, H, C, M, AP	B1	27,793
		Tweed	B	T, H, C, M	B1	24,546
		Murwillumbah		PoCT only	C1	3,483
Rural & Remote	Southern NSW	Goulburn	B	T,H,C	C1	7,334
		Cooma	B	T,H,C	C2	1,795
		Moruya	B	T,H,C	C2	3,533
		Queanbeyan	B	T,H,C	C2	3,307
		SERH (Bega)	B	T,H,C	C1	7,712
	Murrumbidgee	Wagga Wagga	B	T, H, C, M, AP	B1	27,507
		Griffith	B	T,H,C, M, AP	C1	6,646
		Tumut	B	T,H,C	D1a	937
		Cootamundra	B	T,H,C	D1a	1,172
		Deniliquin	B	T,H,C	C2	1,491
		Young	B	T,H,C	C2	1,395
		Dubbo	B	T, H, C, M, AP	B1	18,309
		Orange	GX	T, H, C, M, AP	B1	22,435
	Western NSW	Bathurst	B	T,H,C	C1	8,249
		Mudgee	B	T,H,C	C2	2,022
		Forbes	B	T,H,C	C2	1,480
		Cowra	B	T,H,C	C2	1,918
		Bourke	B	T,H,C	F4	
		Walgett	B	T,H,C	MPS	
	Far West	Broken Hill	B	T,H,C	C1	5,301

T=Transfusion, H=Hamatology, C=Chem Pathology, M=Microbiology, I=Immunology, AP=Anatomical Pathology, G=Genomics

Note: Micro has only been indicated in those labs which perform on-site MC&S

[1] National Weighted Activity Units for Acute Separations excluding chemo, dialysis, unqual. Babies, sub-acute, psych

Appendix five: Test profiles for laboratory service models

Please note, this should be read in conjunction with the NSW Health Pathology Clinical Services Plan (CSP).

Colour coding

In developing this conceptual Framework or guide to what pathology tests may be expected to be provided at each tier of the NSWHP system, colour coding of cells was developed to identify which tests may be provided onsite, and whether these should be provided from within the core laboratory.

Shades of green represent essential tests to be provided on site, with lime green indicating provision within the core laboratory and olive green indicating tests to be provided in the core laboratory if appropriate automated equipment is available. The lightest shade of green indicates the minimum range of tests that are essential to support clinical services at the lower tiers of the hospital system.

Orange coding denotes tests that may be provided on site due to reasons of geography (distance from nearest higher-level laboratory, location in NSW, specific individual expertise of pathologist).

Some non-core laboratory tests which are suitable to be provided from within the core laboratory at lower tiers (e.g. Factor VIII, anti-XA) are coded navy blue. These may be tests that are done manually in laboratories with more specialised expertise but can be done on analysers in smaller laboratories.

Specialised tests that will only be provided in a limited number of locations (yet to be determined) are coded purple.

Figure 8.2 - Colour coding for laboratory service models test profiles

Category
Minimum test menu (includes core and non-core test) eg FBC,COAG, LFT, XM
Core Lab Tests (eg Malaria ICT, Therapeutic Drug Markers)
Core Lab tests if on automated equipment (eg General Microbiology / serology)
Undecided requiring more consultation
Site specific tests
Non Core Lab tests but do them in a Core Lab if the Lab is smaller (eg special Coags)
Specialised test menu tests (eg Immunology, AP, mycology, parasitology)

Combined Test Profiles for NSWHP Lab Tiers - Version 1.0

27-Mar-19

MASTER COPY

Category
Minimum test menu (includes core and non-core test) eg FBC,COAG, LFT, XM
Core Lab Tests (eg Malaria ICT, Therapeutic Drug Markers)
Core Lab tests if on automated equipment (eg General Microbiology / serology)
Undecided requiring more consultation
Site specific tests
Non Core Lab tests but do them in a Core Lab if the Lab is smaller (eg special COAGS)
Specialised test menu tests (eg Immunology, AP, mycology, parasitology, Genomics)

NOTES ON USE OF THE LAB SERVICE MODELS FRAMEWORK

a) This is a Baseline or Default Model. There will be exceptions for individual labs due to local circumstances eg geography / clinical expertise
b) The focus of the framework are the services required to support best clinical care for patients who present, not on the platforms provided
c) This framework is designed to reflect lab service models in the future rather than a mapping of current service delivery
d) As such, it is predicated on the implementation of key enabling architecture including; single LIMS, Statewide Test Catalogue, ICT systems to support the single LIMS, enhanced logistics and courier systems, single middleware, unified approach to safety and quality
e) The framework is dynamic and will be updated to reflect ongoing reviews and implementation of new technology
f) Identification of the appropriate tests to be delivered on-site at each tier is based on expert opinion and best available evidence
g) PoCT will be available at all tiers of the hospital system
h) The Lab Tiers align with NSW Health Role Delineation Levels
i) Delivery of tests across all Lab Tiers is enabled via networking of lab services
j) Over the coming year, Clinical Streams and Statewide Services will be examining system architecture that may influence test profiles and the distribution of these

Services	PoCT Only	Small Lab (L3)	Medium Lab (L4)	Major Metro Lab (L5/6)	Major Regional Lab (L5/6)	Tertiary Lab (L6)	Specialized Lab/s	Comments
Clinical Services normally provided on site	**Acute Inpatient**	**Acute inpatient, ED, COU**	**Acute Inpatient, ED, Obstetrics, ICU/CCU**	**As for L4 plus NICU, Oncology, Renal Dialysis, Stroke Unit**	**As for L4 plus, NICU, Oncology, Renal Dialysis, Stroke Unit.**	**As for L5 plus all tertiary Specialties**	**Limted number of L6 Labs or Special Hub**	
Pathologist Consults								
Diagnostic Tests:								
Immunohaematology								
Blood group antibody screening								
Identification of blood group antibodies								
Determination of compatibility of donor units								
Red cell phenotyping		Rh/Kell only						Limited range of antibodies in the smaller labs
Storage & distribution of blood & blood components								
Blood grouping incl.ABO, RhD by manual								
Blood grouping incl.ABO, RhD by automated								
Direct Antiglobulin Test (Poly & monospecific)								
Investigation of transfusion reactions								Preliminary investigations only in smaller labs
Antibody elution								
Antibody titration								
Haematology								

FBC + Diff								Diff not available on PoCT
Visual examination blood films								visual examination requires specialised staff, but this will all be impacted by future rollout of digital morphology
ESR								
Monospot								
Automated retics								
Malaria ICT screening								Kits shared over sites to reduce expiration of kits
Malaria ID morphology								Low volume, specialised test. We have a designated reference centre
Bone Marrow morphology examination								Tertiary lab undertaking BM assessment, based on availability of Haematologist
Kleihauer								Result required within 72 hours wherever babies delivered, via stains in L4/5 labs and by flow cytometry in L5/6 labs
Limited haemostasis related tests (INR, APTT, +/- fibrinogen, D-dimer, DOACs)								
Extended haemostasis related tests								
ADMTS13, fibrinolysis								
VWD								
Thrombophilia screen								
Platelet Function Analysis Screening								
Platelet Function Complex Tests								
Flow Cytometry								Immunophenotyping
Progenitor cell storage & processing transplant procedures								
Tests for haemoglobin variants and thalassemia								
Screening test for G6PD deficiency								
Red cell enzyme assays								
Molecular genetic studies including BCR-ABL								
APT								

Chemical Pathology								
General Chemistry								
Analytes in general use in cardiac, liver function, lipid, renal, proteins, BHCG & other	Limited range	Limited range						Smaller labs provide a basic (core) suite of tests as agreed for that Tier
Blood gases, glucose & electrolytes	Limited range	Limited range						
CO-oximetry								
Therapeutic Drug Monitoring								
Toxicology definitive testing by LCMS								
Thyroid Function (TSH only)								
Thyroid Function Extended panel								
Hormones								
Iron studies								
Vitamin B12 and folate								
Protein peptide tumour markers								
Glycohemoglobin's								In smaller labs will be done via PoCT
Snake Venom detection								Will be site specific. Need to test for snake venom where there are snakes, and need a reference lab
Proteins, qualitative & semi quantitative analysis; electrophoresis & immunoelectrophoresis								
Haem related pigments and precursors								
Trace elements								

Hormone receptor assays								
Sweat electrolytes								
Maternal markers of foetal wellbeing								
Vitamin assays								
Markers of Bone metabolism								
Trace elements in solid tissues								
Biogenic amines								
Calculi								
Special enzyme assays								
Caeruloplasmin								
Hormone receptor assays								
Amniotic fluid analytes for foetal lung maturity								
Amniotic fluid analytes for foetal abnormalities								
C-1 esterase inhibitor								
Solid tissue enzymes								
Body Fluid analysis								
Breath tests								
Faecal chemical analysis								
Reducing substances and/or other sugars in urine or faeces								
Tests not otherwise covered above								

Microbiology								
Bacteriology								**NOTE: This section is under review and will be impacted by recommendations flowing from current Working Group**
Urine screening								Via dipstick
Microscopic examination of clinical specimens URINE microscopy								Urine microscopy, urine antigen
Microscopic examination of clinical specimens CSF microscopy								Model proposed should have a KPI of less than 1 hour TAT
Preparation of films for microscopic examination CSF GRAM STAINS								Urgent gram stains
Preparation of films for microscopic examination GENERAL GRAM STAINS								Blood Culture incubation
Inoculation of cultures - URINES		Due to distance						
Inoculation of cultures - GENERAL								Automated Micro (Keistra etc)
Identification of organisms including antibiotic sensitivities – URINE								
Identification of organisms including antibiotic sensitivities – GENERAL								Not include Fungus, TB
Detection of bacterial antigens by non-culture non-molecular techniques								Examples of such Non Molecular procedures include - Broth, Microdilution, Serum Bacteriocidal Concentration.
Specialised antibiotic procedures								
Parasitology								**NOTE: This section is under review and will be impacted by recommendations flowing from Fecal Pathogens Working Group Report**
Preparation & examination of films								
Definitive identification of parasites								
Limited identification of parasites								
Detection of parasitic antigens by non-culture non-molecular techniques								Cryptosporidium and giardia
								Cryptococcus EIA

Miscellaneous tests								Helminth Culture, amoebic culture, PCR for Schistisoma. Toxoplama, Microsporidia & Acanthamoeba
Virology								
Viral culture								
Detection of viral antigens by non-culture non-molecular techniques								
Mycology								**NOTE: This section is under review and will be impacted by recommendations flowing from current Working Group**
Microscopic examination of clinical specimen								Culture & identification for fungi including dermatophytes and susceptibility testing (where indicated)
Culture of specimens								Identification of complex fungal pathogens by non-phenotypic method
Identification of fungi								
Susceptibility to antifungal agents								
Detection of fungal antigens by non-culture non-molecular techniques								
Mycobacteriology								
Microscopic examination of clinical specimens					Micro & rapid molecular only			All services mentioned for principal culture & ID of mycobacteria & susceptibility testing where indicated
Culture for isolation of mycobacteria								
Definitive identification of isolates								
Susceptibility testing								
Serology of Infection								**NOTE: This section is under review and will be impacted by recommendations flowing from current Working Group**
Limited (Blood Borne Virus) serological testing								Specialised serology, Viral serology, Parasitic serology, Fungal serology
Extended serological testing								
Specialised or uncommon serological testing procedures								
Detection and characterisation of microbial DNA/RNA								**NOTE: This section will be impacted by rollout of NAAT testing over the next 5-10 years across NSW**
Detection and characterisation of bacterial DNA/RNA				C.diff				Any other specialized PCR testing to pathogens under item 69494.
Detection and characterisation of parasitic DNA/RNA								Rapid molecular detection for invasive fungal infections – specific or panfungal PCR AND other specialised molecular sequencing platforms.
Detection and characterisation of fungal DNA/RNA								
Detection and characterisation of viral DNA/RNA								
Detection and characterisation of mycobacterial DNA/RNA								
Tests on Clinical Non-Human Specimens								
Environmental investigations								
Investigation of nosocomial infections (MRSA/VRE)								
Dialysis waters								
Miscellaneous								
Semen analysis (post vasectomy)								
Semen analysis								
Vet Testing								

Anatomical Pathology								
Histopathology								
AP reporting								
AP cutup								
Tissue processing								

Immuno HistoChemistry								
Frozen section								
Paraffin-ISH (Chromogenic)								
Enzyme Histochemistry (nerve/muscle biopsies)								
FISH								
Cytology								
Gynaecological (cervical screening)								
Gynaecological (other than cervical screening)								
Non-gynaecological								May reflect individual pathologist expertise
Electron Microscopy								
Autopsies								
perinatal								Up to 12months
Paediatric / Adult								

Immunology								
Immunochemistry Testing								
Alpha 1 acid glycoprotein								
Alpha 1 Antitrypsin level								
Alpha 1 Antitrypsin genotyping								
Complement C1								
Complement C2								
Complement C3								
Complement C4								
All other complement								
Total Haemolytic Complement								
AH50								
sC5b-9								
C reactive protein								See also chemical pathology
Haptoglobin								See also chemical pathology
Immunoglobulin A Level								See also chemical pathology
Immunoglobulin G Level								See also chemical pathology
Immunoglobulin M Level								See also chemical pathology
Immunoglobulin D Level								
Immunoglobulin G Subclass Levels								
Free Light Chains								
Prealbumin (TTR)								
Rheumatoid Factor								
Urine alpha / beta microglobulin								
C1 Esterase Inhibitor Function								
Serum / Urine EPG/IEPG								See also chemical pathology
Beta 2 Transferrin								See also chemical pathology
Serum Amyloid A (SAA)								
Quantiferon TB								
Autoantibody Testing								
Autoantibodies								Rheumatic, vasculitic, other, Hepatic, gastro, nerve, muscle, skin, endocrine
Renal biopsies (DIF)								
Skin biopsies (DIF)								

Allergy testing								
Flow cytometry								Quantitative T,B,NK lymph subsets, HLA B*27, Neutrophil oxidative burst. Refer to Haematology.
Other assays								includes DQ genotyping, anti-HLA Ab, IGRA

Genomics three broad sub-specialties: Cancer, Rare Diseases, Pathogen Genomics							
Cancer Genetics (includes Molecular Genetics & Cytogenetics)							
Familial cancer predisposition testing (inherited risk) by NGS							Single lab
Tumour profiling by NGS and non-sequencing approaches including FISH, targeted PCR, microarray:							Limiter number of tertiary labs, likely three, colocation of cytogenetic and molecular genetic capabilities preferable
Solid tumours (associated with AP primarily)							Limiter number of tertiary labs, likely three, colocation of molecular and cytogenetic capabilities preferable
Haematological tumours							Limiter number of tertiary labs, likely three, four including CHW, colocation of molecular and cytogenetic capabilities preferable
Rare Disease (includes Molecular Genetics & Cytogenetics)							Co-location of Molecular and Cytogenetic capabilities preferable in most cases
Includes 1,000's of individual disease settings							
Reproductive testing including Prenatal (invasive and non-invasive (NIPT,NIPD)), carrier screening)							Limited number of tertiary labs, likely three (including CHW)
Panel NGS sequencing and standard approaches							Limited number of tertiary labs, likely three (including CHW)
Microarray testing/ Karyotyping							Limited number of tertiary labs, likely three (including CHW)
Acute care genomics (NICU/PICU setting)							Limited number of tertiary labs, likely two (including CHW)
Pathogen Genomics							
Public health & hospital outbreaks							Limited number of tertiary labs initially two
Food & water testing legionella, salmonella							Limited number of tertiary labs 1-2
Culture free analysis of specimens							Limited number of tertiary labs 1-2, initially
Metagenomics (mixed pathogen analysis of primary specimens e.g. microbiome)							Limited number of tertiary labs 1-2, initially
Genomics Statewide Exome / Genome Facility							
Data production for clinical and research applications							Virtual single lab structure across two sites operated by NSWHP Genomics
Cloud based analysis tools for complex interpretation and reporting							Cloud-based State service being developed

NSW HEALTH PATHOLOGY
CLINICAL SERVICES PLAN
2019-2025

Version 2: 2021

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