Patient Matters Manual for Public Health Organisations

Chapter 19 – Pathology

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Note

Where a number appears at the bottom of an amended page [such as 252 (17/09/15) – amendment number, date] an alteration has been made or new section included. Amendment numbers are sequential, the date represents the date the source document was published on the Policy Distribution System (PDS).

Below is a summary of each policy document. To navigate to the complete policy document, click the hyperlink in the Table of Content or under each policy document title.

Blood Management

Document number PD2018_042 rescinds PD2012_016.

PURPOSE

The purpose of this Policy Directive is to support health services and health service staff to comply with their responsibilities as described in the Australian Health Ministers Conference (AHMAC) Statement on National Expectations for the Supply of Blood and Blood Products[1] by:

1. Providing policy and system direction for the use of evidence based best practice blood management guidelines for NSW Health facilities
2. Establishing a consistent, system wide approach to blood management in all facilities providing transfusion therapy
3. Minimising NSW patients exposure to risks associated with the clinical storage, prescribing, handling and administration of blood products in NSW facilities
4. Supporting health facilities to comply with the relevant National Safety and Quality Service Standards, and other accreditation requirements in relation to blood management.

MANDATORY REQUIREMENTS

NSW health services that provide transfusion therapy are responsible for:

1. Developing and maintaining effective systems to ensure safe, effective, appropriate and patient centred blood management processes and procedures
2. Adopting and implementing best practice procedures relating to blood management and the clinical storage, prescribing, handling and administration of blood products
3. Complying with the relevant National Safety and Quality Health Service Standards (NSQHS).

Health service staff involved in blood management and/or transfusion related activities are responsible for:

1. Complying with relevant blood management systems, processes and procedures, including those outlined in this Policy Directive
2. Providing safe, effective, appropriate and patient centred care.

It is recognised that some of the requirements in this policy such as the role of the Local Health Districts/Special health networks are not applicable to private health facilities. Private health facilities are expected to comply with the general principles described in this Policy Directive in compliance with the *Private Health Facilities Act 2007* (NSW) and the *Private Health Facilities Regulation 2017* (NSW).

IMPLEMENTATION

Chief Executives are responsible for:

- Assigning responsibility for implementing and complying with this Policy Directive and reporting on the implementation of this policy document as required
- Monitoring compliance with this Policy Directive by achieving and maintaining accreditation to the relevant NSQHS standard

1 Statement endorsed by the Australian Health Ministers' Conference, 12 November 2010 (see attachment 5.1)

Health service staff are responsible for:

- Complying with this Policy Directive

Clinical Excellence Commission is responsible for:

- Reviewing and ensuring the currency of this Policy Directive
- Supporting the implementation and evaluation of strategies related to this Policy Directive.

Cord Blood - Public and Private Cord Blood Banking

Document number PD2015_048 rescinds PD2005_394.

PURPOSE

Collection, storage and processing of cord blood in NSW is governed by the NSW *Human Tissue Act 1983* and regulated by the requirements of the Therapeutic Goods Administration.

This document provides direction to health services regarding public and private cord blood banking. It outlines the procedures to be followed by NSW Health staff for obtaining a woman's consent for and collection of cord blood for either donation to a public cord blood bank, directed donation to a family member requiring a haemopoietic stem cell transplant or for private storage for future personal use.

Failure to comply with the requirements of the NSW *Human Tissue Act 1983* may constitute an offence.

There are a number of options for cord blood banking available to women in NSW. It is important that women have access to relevant information on these options preferably in the antenatal period so that an informed choice can be made.

MANDATORY REQUIREMENTS

1. All consents to the donation of cord blood for its use in transplantation or other medical, scientific or therapeutic purposes (including research) must meet the requirements of the NSW *Human Tissue Act 1983*.
2. The collection of cord blood must not interfere with the delivery of the baby or placenta or any emergency procedure required.
3. If public or private patients in public hospitals wish to utilise a private cord blood bank, they must make their own arrangements for the collection of cord blood.
4. As a condition of permitting a private cord blood bank to undertake the collection of cord blood in a Public Health Organisation's premises, a mother is required to sign the request form provided at Attachment 1.
5. No employee of a Public Health Organisation may be involved in the collection of cord blood for private blood banking. Public Health Organisations must not be involved in the collection, storage or transplantation of cord blood for private blood banks.

IMPLEMENTATION

Chief Executives of Local Health Districts are responsible for:

- Ensuring that the contents of this policy are brought to the attention of relevant staff.

Cord blood bank collection staff (both public and private) must:

- Obtain consent to the collection and / or donation of cord blood by the woman (preferably in the antenatal period) and provide a copy to be placed on the woman's medical record at the commencement of labour
- Make their presence known to hospital staff when attending for collection and satisfy the Public Health Organisation's (PHO's) security requirements by presenting their company employee identification on arrival and

- Await the instruction of the doctor / midwife conducting the delivery for an indication that cord blood collection can proceed.

Individual patients who wish to have private collection of cord blood are responsible for:

- Making arrangements for the collection, storage and transfer of cord blood, with a collector from the private cord blood bank, a private obstetrician with visiting practitioner appointment to the hospital or another suitably qualified person and
- Ensuring that the private cord blood bank collection staff are notified of the commencement of labour.

Individual medical practitioners exercising their rights of private practice:

- May make arrangements with a private cord blood bank for the collection of cord blood at the request of their patients.

Private cord blood bank staff are responsible for:

- Ensuring that women complete the Request for Private Cord Blood Banking form (Attachment 1) antenatally and providing a copy to be included in the woman's medical record before the commencement of labour.

295 (10/12/15)

Medical Officers' Responsibilities regarding Drivers

Document number IB2023_055 rescinds IB2013_059.

PURPOSE

This Information Bulletin outlines the responsibilities of medical officers working in NSW Health with regard to drivers, and the relevant legislation that permits reporting by medical officers of concerns about drivers to Transport for NSW

KEY INFORMATION

NSW Health's policy is that the duty of confidentiality by medical officers to their patients must be preserved except where the patient consents to the disclosure of their health information, or where there is a lawful justification for disclosing the information without the patient's consent.

One context in which the disclosure of health information to third parties is permitted is following a medical assessment of a patient's fitness to drive. These assessments are generally done to assist the relevant licensing authority (Transport for NSW) to determine whether a patient is fit to hold a licence or conditional licence.

Information regarding this assessment process can be found on the Service NSW website. The website also includes a "Medical Condition Notification Form", which can be completed by a medical officer and submitted to Transport for NSW following assessment of a patient's fitness to drive, in consultation with the patient.

There may be circumstances in which a medical officer holds concerns about a patient's fitness to drive and/or that the patient is a potential danger to the public if permitted to drive in any circumstances or is permitted to drive without being subject to conditions. These concerns may arise following an assessment of a patient's fitness to drive or in other circumstances.

In this event, medical officers should encourage patients to either self-notify their medical condition to Transport for NSW or consent to the medical officer notifying Transport for NSW of the practitioner's concerns, for example, via the submission of a completed "Medical Condition Notification Form".

Where the patient does not comply with the medical officer's advice, legislation in NSW provides protections for medical practitioners who directly report concerns to Transport for NSW.

Section 275(4) of the Road Transport Act 2013 (NSW) provides as follows:

> *An individual does not incur civil or criminal liability for reporting to Transport for NSW, in good faith, information that discloses or suggests that—*
>
> *(a) another person is or may be unfit to drive, or*
>
> *(b) it may be dangerous to allow another person to hold, to be issued or to have renewed, a driver licence or a variation of a driver licence.*

The above provisions are **discretionary** reporting requirements only. There is no mandatory reporting requirement for medical practitioners in relation to drivers who may be unfit to drive or that present a risk to the public.

In considering whether to make a report to Transport for NSW, medical officers should ensure that:

- They are acting in good faith – that is, they are acting out of a genuine concern for the safety of the driver or the safety of the public.

- The health information they disclose to Transport for NSW is limited to information that is relevant to the issue of the driver's fitness to drive or that allowing the person to hold a licence may be dangerous.

Situations that may result in a medical practitioner reporting a patient to Transport for NSW include where the patient is:

- Unable to appreciate the impact of their condition,
- Unable to take notice of the health professional's recommendations due to cognitive impairment, and/or
- Continues driving despite receiving appropriate advice and is considered likely to endanger the public.

In the event that the medical practitioner decides to directly report a patient to Transport for NSW, it is good practice to advise the patient that the practitioner is doing so.

349 (22/12/23)

Forensic Drug and Alcohol sampling in Emergency Departments

Document number PD2021_010 rescinds PD2021_005.

POLICY STATEMENT

NSW hospitals are required by the Road Transport Act 2013 (Schedule 3), Marine Safety Act 1998 (Schedule 1), the Rail Safety (Adoption of National Law) Regulation and the Law Enforcement (Powers and Responsibilities) Act 2002 No 103 to provide a service 24 hours per day/7 days per week for the collection of forensic blood and urine samples for drug and alcohol testing. Currently this service is provided in emergency departments (EDs).

This Policy Directive provides additional information for authorised sample takers to assist them to meet the obligations of the stated legislation. Forensic sampling for legislation outside of this (for example sexual assault or drink spiking) is out of scope for this Policy.

SUMMARY OF POLICY REQUIREMENTS

This Policy **does not** replace the requirement for authorised sample takers (please refer to section 1.2 Key Definitions) to ensure they have a detailed understanding of their obligations and comply with legislative requirements.

Two different sampling kits are to be available in all NSW EDs to facilitate sampling– the blood testing for alcohol kit and the blood/urine testing for drugs kit (also known as the 'D' kit as the serial number on the certificate starts with a 'D'). NSW Police will bring an additional kit (also known as/referred to by Police as the 'B' or BAS kit) with them if that is required for sampling.

Authorised sample takers are to ensure the correct sampling kit is used to allow the samples and test results to be used as evidence.

Detailed instructions are available within each sampling kit and must be adhered to. The serial number of the kit is to be documented in the patient's health care record and the sample put immediately in the blue NSW Police security box located in the ED (unless sample is being taken in accordance with Rail legislation please refer to section 6 Rail Legislation).

Circumstances where taking a sample is not required are detailed in the attached procedure document in section 7.1

Appendix 1 provides a quick reference guide for hospitals/EDs in acknowledgement of the complexities of the various pieces of Legislation, sampling kits and sampling requirements.

336 (23/03/21)

Management of Sudden Unexpected Death in Infancy (SUDI)

Document number PD2019_035 rescinds PD2008_070.

PURPOSE

This Policy Directive outlines the mandatory requirements for management of Sudden Unexpected Death in Infancy (SUDI) in NSW Health facilities. It also outlines the role of NSW Health in the context of the NSW Government response to SUDI which includes the NSW Coroner and Police.

MANDATORY REQUIREMENTS

SUDI is a reportable death under the Coroners Act 2009[2]. Most SUDI deaths occur in the community and are brought to their local emergency department, however SUDI can also occur in hospital. NSW Health's role in management of SUDI includes that local health districts and specialty health networks must:

- Ensure that local policies that guide management of SUDI are easily accessible for staff. This includes emergency departments as well as other areas that SUDI may occur such as maternity, paediatrics and intensive care. Information for staff on how to access locally networked paediatric services should be included.
- Ensure that adequate resources and education are provided so that staff can meet the needs of the infant and the parents/carers, and that parents/carers have access to expert medical advice, nursing care and social work. If necessary, these can be accessed via locally networked paediatric services. In some instances the situation may warrant transfer of the infant to a higher level facility.
- Nominate a hospital contact who will coordinate the SUDI response for example a social worker or nurse. This health professional will provide support to the parents/carers and coordinate completion of documentation required by NSW Health. A list of roles and responsibilities of agencies and staff involved in the SUDI response is at Section 6.1 Response to Sudden Unexpected Death in Infancy (SUDI) - Roles and Responsibilities.
- Ensure that the infant's medical history is completed by a senior medical staff member and documented in the health care record. A checklist to support this is at Section 6.2 Medical History Guide – Sudden Unexpected Death in Infancy. A copy of the infant's health care record must be forwarded to Forensic Medicine (NSW Health Pathology) within 24 hours of the infant's death.
- Ensure that support is available for staff who provide care to infants and parents/carers who have experienced SUDI. If necessary, this can be accessed via locally networked paediatric services.
- Ensure there are processes to maintain the quality of care and patient experience of SUDI cases. This includes incident notification, documentation, case discussion that includes the perspective of parents/carers and staff and implementation of any identified improvement opportunities.

IMPLEMENTATION

Local health district chief executives are responsible for:

- Assigning responsibility, personnel and resources to implement this policy.

2 NSW Health Policy Directive Coroners Cases and the Coroners Act (PD2010_054 section 5)

- Establishing mechanisms to ensure the mandatory requirements are applied, achieved and sustained as usual processes in the instance of a SUDI. This should include nomination of an executive sponsor.
- Ensuring that any local policy reflects the requirements of this policy and is written in consultation with the hospital executive, clinical governance unit and clinical staff.

326 (30/07/19)

Non-Coronial Post Mortems

Document number PD2013_051 rescinds PD2005_008.

PURPOSE

Non-coronial post-mortems are governed by the Human Tissue Act 1983 (the Act) which makes specific provisions for obtaining consent and authorisation for the conduct of a non-coronial post mortem and the subsequent use of organs and tissues removed at post mortem and retained for other purposes (eg. for scientific research or teaching purposes).

This Policy Directive provides guidance for Local Health Districts (LHDs) Speciality networks and NSW Health Pathology Services on the procedures that must be in place to support families and clinicians in:

- Providing information to families regarding non-coronial post mortems
- Obtaining written consent and the authorisation of a designated officer for a non-coronial post mortem and the retention and subsequent use of organs and tissue removed at post mortem for other purposes
- Disposing of, or returning tissue removed at post mortem to the next of kin for disposal
- Determining attribution of the costs of post mortems
- Meeting the requirements relating to the post mortem report including the retention periods for post mortem records.

MANDATORY REQUIREMENTS

Facilities where non-coronial post mortems are undertaken must ensure:

- Compliance with the requirements of the Act in relation to obtaining consent and authorisation prior to post mortem being undertaken and in relation to using tissue taken at post mortem for other purposes (such as scientific research or teaching)
- One or more designated officers are available for authorising the post mortem and/or the subsequent use of tissues removed
- That staff who approach families for consent for the above procedures have appropriate knowledge about the post mortem process and the training to provide that information in a clear and sensitive manner
- That the standard state-wide forms attached to this policy directive are used wherever indicated by this policy directive.

IMPLEMENTATION

Chief Executives of LHDs and Specialty Networks must ensure that:

- All relevant staff are made aware of their obligations in relation to this Policy Directive
- Documented procedures are in place to support the Policy Directive.

Staff involved with non-coronial post mortems:

- Must comply with this policy statement as it relates to the work they undertake.

Destitute Persons - Cremation or Burial

Document number PD2008_012 rescinds PD2007_051.

1. Introduction This policy directive rescinds Policy Directive PD2007_051 due to the inclusion in that Policy Directive of Police forms, and references to them, which are no longer to be used. This Policy Directive deals with the cremation or burial of the bodies of deceased destitute persons in the State of New South Wales as set out in this document.

Coroners Cases and the Coroners Act 2009

Document number PD2010_054 rescinds PD2009_083.

PURPOSE

To provide:

(a) medical practitioners, health care workers and managers in the public health system with specific information about the Coroners Act 2009; and

(b) medical practitioners, nurses and midwives, health care workers and administrators with direction and guidance about reportable deaths to the NSW Coroner.

MANDATORY REQUIREMENTS

Each NSW Health Agency must have effective systems and procedures in place to report deaths to the Coroner in accordance with the Coroners Act 2009 and this Policy Directive.

IMPLEMENTATION

Roles and Responsibilities

Chief Executives must ensure that:

- the principles and requirements of this policy are applied, achieved and sustained;
- all staff are made aware of their obligations in relation to this Policy Directive;
- documented procedures are in place to support the Policy Directive;
- there are documented procedures in place to effectively respond to and investigate alleged breaches of this Policy Directive.

Hospital Managers and Staff have responsibility to:

- report Anaesthetic deaths to the Director-General via the Report of Death Associated with Anaesthesia/Sedation form (section 7.1);
- provide copies of medical records to the pathologist or medical officer conducting a post mortem (section 9.3);
- provide the Coroner's Office with a completed "Report of Death of a Patient to the Coroner" (form A) along with original or copies of medical records (sections 6; 9.3).

Coronial Checklist

Document number IB2010_058.

PURPOSE

To advise the NSW health system of a checklist that has been drawn up for use in determining whether a death should be reported to the coroner.

KEY INFORMATION

The NSW Health Department has recently issued Policy Directive PD2010_054 Coroners Cases and the Coroners Act 2009. A Coronial Checklist has been developed for optional use as an aid in determining whether a death should be reported to the coroner. All forms (those annexed to the Policy Directive PD2010_054 and the Coronial Checklist) can be obtained from SALMAT either by Electronic Print On Demand (ePOD) or by purchase order from Health Support Services, Better Health Centre.

113 (02/12/10)

Accreditation of Pathology Laboratories in NSW Health

Document number PD2017_011 rescinds PD2017_005.

PURPOSE

NSW Health Pathology is required to ensure that the accreditation of pathology laboratories is maintained. By maintaining accreditation it is expected that laboratories will meet uniform standards of practice, competently perform tests / examinations and produce accurate and reliable results for the tests for which they are accredited.

MANDATORY REQUIREMENTS

The Commonwealth requires that for a pathology service to attract Medicare benefits the pathology laboratory is to be accredited for the kinds of services that are being provided.

The standards used to assess accreditation for pathology laboratories are Standards for Pathology Laboratories developed by the National Pathology Accreditation Advisory Council ("NPAAC"). These set out the minimum standards acceptable for good pathology practice in Australia. It should be noted that the NPAAC Standards also require the laboratory to be certified to *AS ISO 15189: Medical laboratories – Requirements for quality and competence* and other Australian and International Standards.

The Commonwealth has chosen the National Association of Testing Authorities (NATA) to act on its behalf to undertake the accreditation and certification of laboratories.

Full information on the Commonwealth's requirements for obtaining accreditation are in the Medical Benefits Schedule Category 6 – Pathology Services which can be obtained from http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Downloads201605

IMPLEMENTATION

- The NSW Health Pathology Chief Executive is responsible for ensuring pathology laboratories in NSW Health are accredited.
- The Sydney Children's Hospitals Network Chief Executive is responsible for ensuring pathology laboratories at The Children's Hospital at Westmead are accredited.

326 (15/05/17)

Managed Point of Care Testing (PoCT) Service

Document number PD2018_028 rescinds PD2015_028.

PURPOSE

The purpose of the Managed Point of Care Testing (PoCT) Service Policy Directive is to describe the requirements for a quality assured pathology service using devices located near the patient. More rapid access to test results provided through the use of PoCT devices can increase clinical effectiveness and contribute to improved patient outcomes. However the result provided by the devices must be accurate, reliable and relevant. This Policy Directive outlines the requirements for the safe and effective management and use of PoCT. Devices must be fit for their intended purpose and be used by competent individuals on the correct patient. Results become part of the patient record. The expected outcomes for this Policy Directive are to ensure that:

- PoCT pathology testing is deployed in NSW Health facilities in an accurate, effective and clinically reliable manner supporting safe and optimal care for patients.
- clear standards for the introduction and management of PoCT that maximise patient care and patient safety are provided.
- any associated medico-legal and financial risks are minimised by supporting all operators in implementing PoCT appropriately including those without a laboratory background.
- patients and staff do not suffer avoidable harm or loss.
- staff using PoCT are trained, competent and use safe work practices.
- equipment including facilities and environmental conditions are safe for users.
- compliance with International Standards ISO 15189 and ISO 22870 and any other relevant regulatory requirements so that supervising laboratories achieve and maintain National Association of Testing Authorities Australia (NATA) accreditation for PoCT.
- principles of quality management and continuous improvement for PoCT are applied.

MANDATORY REQUIREMENTS

The mandatory requirements are described in the Procedures at Attachment 1.

IMPLEMENTATION

Effective clinical governance is an essential component of PoCT. This Policy Directive describes a co-operative framework involving both NSW Health Pathology services and local healthcare facility staff.

The multidisciplinary PoCT Clinical Advisory Committee provides governance oversight.

The NSW Health Pathology Operational Team where the PoCT device is situated provides operational oversight of the PoCT Service including laboratory assigned supervision. The local healthcare facility performs testing at the point of care.

Customer Service Charters must specify:

- appropriate use of devices.
- roles and responsibilities for managing the PoCT service.
- measures for compliance with the requirements of this Policy Directive and any other relevant requirements.

NSW Health Pathology provides an electronic management solution for PoCT devices to support clinical governance and accreditation objectives by:

- electronically transmitting a patient result to the Laboratory Information System (LIS) in which they then become part of that patient medical record.
- monitoring both operator and device performance.
- allowing for remote management of devices including preventing device operation if the competency of the operator has not been assessed or reassessed within appropriate intervals.
- supporting e-learning for ongoing competency assessment.

Public Health Organisations (PHOs) and NSW Health Pathology must ensure that all relevant staff comply with this Policy Directive.

326 (19/07/18)

Transport of Pathology Specimens to Laboratories

Document number PD2023_001 rescinds PD2018_020.

POLICY STATEMENT

NSW Heath Pathology provides specialist pathology services for NSW Health organisations, NSW Police, private pathology providers, community based medical practitioners and private hospitals. It ensures a consistent state-wide approach to the safe and timely transport of all pathology and forensic specimens in compliance with relevant regulatory requirements.

SUMMARY OF POLICY REQUIREMENTS

Pathology specimens must be transported by the NSW Health Pathology Transport Service to NSW Health Pathology's on-site laboratory or to the appropriate laboratory providing the required diagnostic testing.

Other transport services can only be used to transport specimens to the appropriate laboratory providing the required diagnostic analysis in the following circumstances:

- Where the NSW Health Pathology Service is not operating
- Where there is no on-site NSW Health Pathology laboratory
- When the NSW Health Pathology laboratory is closed.

To ensure the integrity of specimens and the safety of staff and transport personnel, specimens must be appropriately handled, prepared, stored, packaged, labelled and transported in compliance with all legislative and regulatory requirements and this Policy.