

Lookback Policy

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Functional Sub group Clinical/ Patient Services - Governance and Service Delivery
Clinical/ Patient Services - Incident management
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Summary The policy is to ensure a consistent, coordinated and timely approach for notification and management of potentially/affected patients when necessary.

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Author Branch Quality and Safety

Branch contact Quality & Safety Branch 9424 5923

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Public Health Units, Public Hospitals

Audience All staff, including managers, clinicians

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Environmental Health Officers of Local Councils, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Private Nursing Homes, Tertiary Education Institutes

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Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

LOOKBACK

POLICY

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1) Introduction

Lookback is a process that is triggered when a notification of a clinical incident or concern from any source leads to the need for the notification, investigation and the management of a group of commonly affected patients. The clinical incident may arise from complications or errors relating to diagnostics, treatment or products that patients have received.

For the management of a lookback process concerning communicable/infectious diseases, refer to PD2005_203: Infection Control Management of Reportable Incidents and/or PD2005_162: HIV, Hepatitis B or Hepatitis C - Health Care Workers Infected. The NSW Health Notifiable Diseases Manual provides guidance to Public Health Units to respond to notifications of the diagnosis of Scheduled Medical Conditions as prescribed by the Public Health Act 1991. Such conditions are therefore outside the scope of this policy.

The purpose of this policy is to ensure a consistent, coordinated and timely approach for notification and management of potentially/affected patients when necessary.

For the purpose of this policy, the term “health services” refers to Public Health Organisations and the Ambulance Service of NSW.

This policy documents the steps, including the communication strategy, that are to be undertaken by the health services when a lookback is initiated.

Health services are required to develop their own local policies and procedures, consistent with this policy, to address any potential lookback exercise.

What is a lookback?

The lookback process is triggered when a group of patients are affected by a common clinical incident that may be related to time, place, and treatment. The group of patients may have been recipients of a faulty medical device or equipment and/or inappropriate/inadequate treatment or diagnostics. The process involves:

- Identifying, tracing, communicating, and providing appropriate ongoing advice to, and/or management of, the group of patients.
- Notification to appropriate bodies involving the Department and formation of a communication strategy.
- Notification to the wider public.

2) Objectives

The objectives of this policy are to:

1. Assist the health services with the timely management of appropriate and relevant care for affected groups of patients.
2. Establish a standard approach to notification of patients, families/carers, health administrators and the public of clinical incidents involving potential injury, damage, loss or other harm to groups of patients.

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3. Ensure that communication with, and support for, all affected and potentially affected patients, their families and/or carers occurs in a timely manner.
4. Ensure that communication with the Minister for Health, the Director-General and the public occurs in a consistent and timely manner.
5. Ensure that the health services have established and consistent processes in place when a lookback exercise is undertaken.

3) Roles and Responsibilities

3.1 The Department is responsible for:

- Dissemination of information and notification to health services of the clinical incident or concern.
- Assisting the health services with the lookback process and coordinating communications where more than one health service is involved.
- Assisting the health services with the development and management of communication strategies.
- Allocating an executive to work with the health services at all stages of managing the lookback.

3.2 Chief Executive is responsible for:

- Initiation of the lookback process.
- Coordination with any other involved health services.
- Decisions on public notification, media management and advising the Director-General and the Minister.

3.3 Director of Clinical Governance is responsible for:

- Development and documentation of local lookback policy and procedures.
- Actioning and management of the lookback process.
- Conducting an evaluation and review as required when a lookback has been completed and reporting the results to the Health Care Quality Committee.
- To liaise with clinicians involved in the lookback.

3.4 Clinicians are responsible for:

- Liaise and act in accordance with the Director of Clinical Governance and expert group throughout the lookback.
- Apply Open Disclosure principles (Open Disclosure Policy Directive PD2007_040) when communicating with patients, families and/or carers.

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- Maintain records of the confirmation that the discussions of a lookback event with their affected patients have taken place.

4) Steps

The following steps are to be included in any local lookback process.

4.1 Step 1 - Immediate Action

Identify the members of an Area Team to form a steering group; lead by a member of the Area Executive that includes the Director of Clinical Governance, and the local public relations/media unit. A relevant Director, or delegate from the Department will be allocated to work with the Area Team at all stages of the lookback.

Within 24 hours of recognition of the triggering event, the steering group is to decide on the immediate responses that include:

- Undertaking a risk assessment to determine the immediate facts and nature of the risk to patients /carers.
- Addressing and managing issues of notification to the Department via a RIB in accordance with PD2007_061 Incident Management Policy and recorded in the IIMS.

This information contained within the RIB is to include:

- 1) Urgency
 - 2) Need for Department notification
 - 3) Determining who has been affected
 - 4) Process for determining risks
- Agree on the formation of an Expert Advisory Group comprising experts in the area of concern, relevant clinicians, and department/directorate heads to devise and implement a detailed patient action plan.
 - Agree on a media and patient communications management plan. The aim is to be proactive in public disclosure whilst managing the manner in which affected patients receive the information and how media questions will be answered.

Communications management

Full public disclosure following the principles outlined in PD2007_040 Open Disclosure Policy should be the guiding principle for communications management throughout the lookback process and should ideally occur as soon as possible following the discovery of the triggering event and include:

- Being open with information as it arises from the lookback.
- Ongoing liaison with the media throughout the lookback process.

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- Preliminary notification being made public where a situation requires additional time for the discovery of accurate information to be provided to patients and the wider public.

Media management

The health service media unit is the primary point of contact for news organisations and requests for interviews or information should be directed through the unit.

The lead member of the Area Team should ensure that the health service media unit advises the Department Media Unit at the earliest possible time. The health service and Department Media Unit are to develop and collaborate on a communication strategy for the media and the general public at all stages of managing the lookback.

The health service media staff will:

- Nominate a spokesperson for public and media communications.
- Determine key messages.
- Minimise the delay in response to the public and the media
- Develop questions and answers in advance
- Work with the Area Team to develop a strategy for notification of external organisations such as appropriate medical colleges and any other affected organisations. It is appropriate that the Area Team in accordance with advice from the Department and health service media units conduct such notification.

4.2 Step 2 - Expert Advisory Group

An expert advisory group is to be convened as soon as possible and at the latest within 5 calendar days of the triggering event to advise on a detailed action plan with timeframes. Close communication with the Director of Clinical Governance must be maintained until all action is complete.

If there is no risk to patients, the lookback process is complete. The expert advisory group will communicate this to the Director of Clinical Governance. In these circumstances, the near miss should prompt the organisation to review and investigate issues associated with the event to ensure future patient safety.

4.3 Step 3 - Action Plan and Implementation

Identifying and tracing affected patients, families and/or carers

The health services are responsible for the identification and tracing of the affected patients and must allocate appropriate resources to ensure that this is undertaken.

Patient communication and support

The expert advisory group should provide advice to the Director of Clinical Governance in determining the person/s best suited to communicating sensitive news with affected

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patients their families and/or carers. The health service should document the details of actions according to local policy and procedure.

Strategies in communication and support for patients should include:

- Identifying immediate and ongoing management needs of patients their families and/or carers.
- Ensuring that patients understand the processes for ongoing management and have written advice/fact sheets concerning this.
- Ensure that relevant fact sheets containing information on the lookback are published on the health service inter/intranet website.
- Ensuring adequate resources are in place to provide the level of service required.

All information should be given in accordance with the PD2007_040 Open Disclosure Policy and privacy principles PD2005_593 Privacy Manual (Version 2) – NSW Health. Initial communication should be direct, either face-to-face or via telephone, where the patient must be given the opportunity to ask questions.

The following should be included in the patient communication and support plan:

- A designated point of contact for patients their families and/or carers.
- Regular and ongoing information updates provided to patients their families and/or carers.
- Affected patients are offered a written apology by the health service.
- Establishment of a toll free telephone hotline for patients and families/carers to ask any questions and to obtain information.
- Affected patients who need additional consultation have these appointments expedited to allay any anxieties or concerns that they may have.

Patients their families and/or carers should not incur any cost from any additional consultations required:

- Provision of follow-up at no cost to patients their families and/or carers.
- The health services offer to pay for any additional consultation (eg General Practitioners or Specialists Medical Practitioners) for affected patients, arising out of the lookback.
- Affected patients who have had to pay for additional consultations are reimbursed for these expenses.

Group meetings should not be undertaken for reasons of confidentiality of patient information and protection to the privacy of those involved. Every attempt should be made to inform all patients involved at approximately the same time and, where possible, in advance of any media attention of the issue.

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The health service is to form teams consisting of counsellors and mental health clinicians to offer/provide counselling and psychological support to all affected patients their families and/or carers. Appointing an independent body to conduct counselling services during the lookback process should be considered.

Staff communication and support

A communication and support plan should be devised for staff. This should include communication and support for:

- All staff who are managing the lookback process.
- All staff working in the area of concern.
- All other staff that may be affected.

Record keeping

The health service is to maintain records of the confirmation by treating clinicians that the discussion of a lookback event with their affected patients has taken place.

4.4 Step 4 - Evaluation or Review of Lookback:

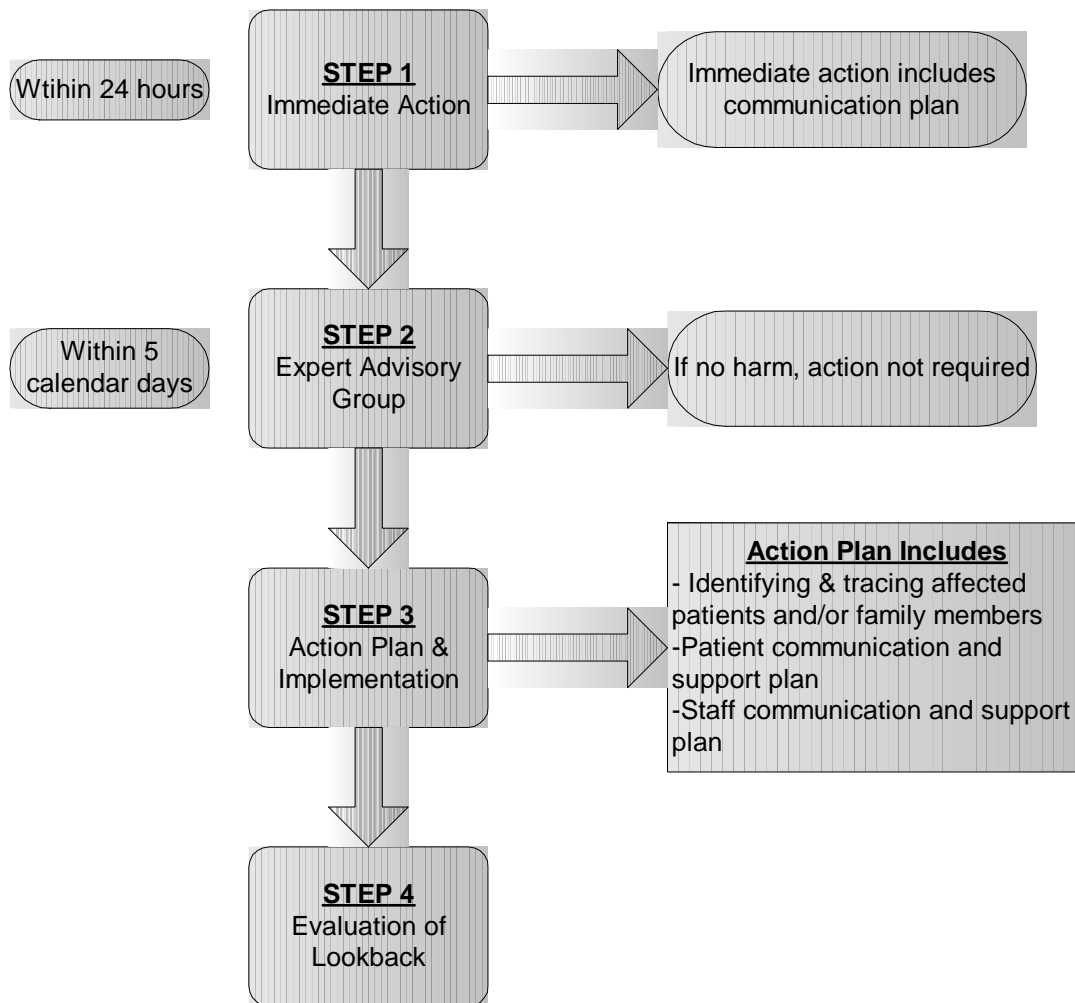
Directors of Clinical Governance are required to evaluate the management of the lookback to assess the efficiency and effectiveness of the process. Key measures should be assessed and strategies for further improvement should be implemented and reported to the Chief Executive as required.

Directors of Clinical Governance are to:

- Implement strategies to prevent this or similar events from recurring.
- Communicate lessons learned from the lookback process to the Department and other health services.

Evaluation reports, including performance measures, are to be reported to the Health Care Quality Committee.

4.5 Summary Diagram of Steps:



5) Performance Measures

The following process performance measure is to be developed and reported to the Chief Executive by the health service.

- Documented local policies and procedures consistent with this policy are in place in each health service.

Key measures showing compliance with this policy must be reported as part of the lookback evaluation.

- All patients who are of immediate risk to be contacted within 2 weeks
- Patients are to be contacted within 2 months of the triggering event, in the event that further information/investigations are required to evaluate risk to patients and such risk is eventually detected.

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6) Definitions

Ambulance Service of NSW

The Ambulance Service of NSW as defined in the Health Services Act 1997.

Area Health Services

Organisations constituted under the Health Services Act 1997 that are principally concerned with the provision of health services to residents within a designated geographic area.

Clinician

A health practitioner or health service provider regardless of whether the person is registered under a health registration act.

Department

NSW Department of Health.

Health Services

For the purposes of this policy the term "health services" refers to Public Health Organisations including Area Health Services and the Ambulance Service of NSW.

IIMS

The NSW Health Incident Information Management System (IIMS). This system incorporates the Advanced Incident Management System (AIMS) software application as its underlying database.

Lookback Process

The lookback process is triggered when a group of patients are affected by a common clinical incident that may be related to time, place, and treatment. The group of patients may have been recipients of a faulty medical device or equipment and/or inappropriate/inadequate treatment or diagnostics. The process involves:

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- Notification to the wider public.

Near Miss

Any event that could have had adverse consequences but did not and is indistinguishable from an actual incident in all but outcome. A near miss is further categorised as:

- Actual harm with no adverse outcome: an incident occurred and ran to completion but resulted in no harm.
- Arrested or interrupted sequence: the incident was intercepted prior to causing harm.

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- Hazardous event or circumstances: the incident involved a dangerous state or the possibility of harm occurring.

Open Disclosure

The process of providing an open, consistent approach to communicating with the patient and their support person following a patient related incident. This includes expressing regret for what has happened, keeping the patient informed, and providing feedback on investigations, including the steps taken to prevent a similar incident occurring in the future. It is also about providing any information arising from the incident or its investigation relevant to changing systems of care in order to improve patient safety.

Public Health Organisations (PHO)

This term refers to an area health service, statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services as defined in the Health Services Act 1997.

For the purposes of this policy, the relevant statutory health corporations and affiliated health organisations are set out in Appendix B of PD2007_061 Incident Management Policy.

Reportable Incident

An incident identified according to PD2007_061 Incident Management Policy that requires direct notification to the Department under existing legislative reporting requirements or Departmental policy directive.

7) Further Reading

GL2007_007: Open Disclosure Guideline

http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_007.pdf

PD2005_162: HIV, Hepatitis B or Hepatitis C- Health Care Workers Infected

http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_162.pdf

PD2005_203: Infection Control Management of Reportable Incidents

http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_203.pdf

PD2005_593: Privacy Manual (Version 2) – NSW Health

http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_593.pdf

PD2006_007: Complaints or Concern about a Clinician

http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_007.pdf

PD2006_014: Notification of Infectious Diseases under the Public Health Act 1991

http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_014.pdf

PD2007_061: Incident Management Policy

http://www.health.nsw.gov.au/policies/pd/2007/PD2007_061.html

PD2007_036: Infection Control Policy

http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_036.pdf

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PD2007_040: Open Disclosure Policy

http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_040.pdf

NSW Clinical Governance Directions Statement

<http://www.health.nsw.gov.au/quality/clingov/pdf/cgudirstat.pdf>

NSW Notifiable Diseases Manual

<http://www.health.nsw.gov.au/infect/diseases.html>

Professor Debora Picone AM
Director-General