

# Root Cause Analysis: The NSW Health Incident Management System

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Since the Harvard Medical Practice Study in 1991<sup>1</sup> and the 1995 Quality in Australia Health Care Study,<sup>2</sup> the extent of the problem of error in clinical care has been highlighted. Health services and governments have sought to put in place constructive solutions to address this. At the national level, the Australian Council for Safety and Quality in Health Care was established in January 2001. At the state level, NSW Health has developed two key documents, the Framework for Managing the Quality of Health Services in 1999 and, more recently, the Clinician's Toolkit for Improving Patient Care. In 2001, NSW Health also established the Institute for Clinical Excellence (ICE). Together with the Quality and Clinical Policy Branch, ICE has worked collaboratively to provide practical solutions for health services and clinicians on how to respond to the demands for help in addressing patient safety matters.

The ICE/NSW Health Patient Safety Program, based to a large extent on the Veteran Affairs (VHA), National Centre for Patient Safety (NCPS) program in the USA, is now introducing a state wide program of "Root Cause Analysis". The VHA was able to roll out a similar program to more than 180 facilities within 10 months, with a resultant 30-fold increase in incident reports and a 900-fold increase in reports of near misses or less serious adverse events. The NSW program is designed to support improved practice in both the clinical and non-clinical environment, where staff is able to undertake systematic root cause analysis to find the real cause(s) of problems.

This paper outlines the components of the NSW education and training program and highlights how incidents can be prioritised and then investigated by appropriately selected teams. Through systematic analysis and utilisation of practical tools, causation statements can be developed which assist in bringing about changes to prevent recurrence of similar events.

## INTRODUCTION

Patient safety and continuous quality improvement have been firmly on the health policy agenda for over a decade. The Harvard Medical Practice Study,<sup>1</sup> the Quality in

Australian Health Care Study,<sup>2</sup> the Institute of Medicine Report<sup>3</sup> and, more recently, the Douglas Report on events in a Perth hospital<sup>4</sup> outlined high levels of adverse events in health care institutions. The Australian Council on Safety and Quality in Health Care, the NSW Quality and Clinical Policy Branch and the NSW Institute for Clinical Excellence believe the high incidence of preventable adverse events in health care is a major issue for the population. To address these concerns, organisations need to focus on approaches that:

- Have a positive impact in improving patient and staff safety;
- Aid understanding of the causes underlying adverse events;
- Facilitate changes in the systems and processes to reduce the probability of such events in the future;
- Increase the knowledge about events, their causes, and strategies for prevention; and,
- Improve the safety of health care for the consumer and maintain the confidence of the public in the care and services provided.

To date it has been the norm for incidents arising in healthcare to be blamed on an individual. However, it is now clearly recognised that it is a combination of specific circumstances and the work environment that commonly combine to result in unwanted outcomes. It is acknowledged that people have not come to work to do a bad job or make a mistake. Today, it is known that the “root causes” of problems leading to incidents are usually found in the design of the system that permitted the event in the first place, and are rarely attributable to an individual.

Organisations with the right processes for the investigation and analysis of adverse incidents can create an environment that focuses on systems and not on individuals. To minimise error, we must have a healthcare system that makes it easy to do the right thing and difficult to do the wrong thing.<sup>3</sup>

## **CULTURE CHANGE**

To be successful, a change in culture across the health system is imperative for the implementation of this initiative. An approach that emphasises prevention, not punishment is required. Clinicians and managers need to be provided with the skills to identify and understand the deeper underlying factors in adverse events and translate them into corrective actions. This cultural change requires the following criteria:

- A commitment from the leaders of the organisation to quality improvement;
- The needs of patients/consumers, including open disclosure, be considered;
- A “quality culture” that emphasises empowerment, flexibility and multidisciplinary teamwork must be developed;
- Every clinician must take responsibility for patient safety;
- System improvements need to be the focus of corrective actions;
- Reliable, valid, timely and objective information necessary for decision making needs to be available to all who require it;
- Effective feedback processes must be in place;
- Monitoring and evaluation of performance must happen on a continuous basis; and,
- Management must commit to provide training and education to all staff, particularly on the use of “quality” tools.

Following a comprehensive literature review and consultation process, NSW Health has developed a model for a safety improvement program based to a large extent on that of the VHA in the United States. The VHA program was unique for health care

because of its focus on prevention, not punishment. The integration of human factor analysis and quality improvement methodologies was integral to their identification and elimination of system vulnerabilities.

“Root cause analysis” is the tool that is used by VHA and NSW Health to identify prevention strategies. As well, it defines processes to develop solutions, to test and implement them and then measure outcomes in order to improve patient safety. RCA has been a major factor in building a culture of safety within the VHA and in moving from a “blame” to a “just” culture. The NSW Health model, whilst based substantially on the VHA methodology, is also aligned to the Standards Australia Guideline for Managing Risk in the Healthcare Sector.<sup>5</sup> It relies strongly on the following principles:

**“Oversight” — Governance of the Process**

- Incorporates individual and team accountabilities;
- Defines committee structures and reporting mechanisms; and,
- Formulates and standardises policy.

**“Doing and learning” — The quality improvement and risk management process —**

- Prevention — such as credentialling, clinical guidelines and review of current and new procedures.
- Management of incidents — ensuring that particular types of incidents (including near misses and close calls) are identified, reviewed and analysed at an appropriate level and that recommendations are implemented.
- Audit and review of performance — including peer review, clinical indicators and variance analysis.

**“Knowing how” — Training and education —**

- Identification of training and education requirements.
- Communication of sentinel alerts, system learnings, the organisational safety process and skills training.

While the primary focus is on improving patient care, encouraging clinician participation and improving the work environment, RCA assists in the development of systems that:

- Identify and report incidents that occur, in a manner that encourages self-learning from the analysis;
- Lead to the investigation of serious adverse events and critical incidents in order to promote the redesign of systems as the main method for improving safety;
- Ensure action upon recommendations from these investigations;
- Ultimately improve patient safety and the individual’s health care experience;
- Support a culture where every clinician takes responsibility for patient safety and where reporting of events and problems are rewarded, not punished.

**ROOT CAUSE ANALYSIS — THE METHOD**

RCA reviews events to find the most basic reason(s) that can be readily identified and that are in management’s control to fix. RCA has the following characteristics:<sup>6</sup>

- It focuses primarily on systems and processes, not individual performance;
- It repeatedly digs deeper by asking “why”;
- It identifies changes that could be made in systems and processes -either through redesign or the development of new systems or processes;

- Its focus is non punitive;
- Its focus is on how to improve systems in order to prevent the occurrence of sentinel events;
- It digs into existing systems to find new ways to do things.

Rare situations arise where patient harm has resulted and it is found that individuals have acted with intention to harm, under the influence of drugs or in the full knowledge that they are not adhering to policy. This should not be handled through a quality improvement process, but managed via normal human resource investigation procedures.

The following process has been designed to support improved practice in both the clinical and non-clinical work environments and to help clinicians and managers to perform systematic root cause analysis to find the real causes of problems. It is recognised that RCA is only one of many processes that work together to improve patient care and that it is used principally when things have gone wrong! The steps involved in the RCA method include:

1. Reporting;
2. Prioritisation;
3. Investigation — including team selection, flow charting;
4. Cause and effect diagramming and determination of the root causes;
5. Developing causation statements, listing contributing factors, actions and recommendations; and
6. Implementation of recommendations and evaluation of effectiveness

### **1. Reporting**

Each Area Health Service in NSW will have its own mechanism for incident reporting. It is anticipated that, by late 2003, a state wide information system will standardise this mechanism.

### **2. Prioritising Incidents**

The Severity Assessment Code (SAC) below is a simple method that allows Area Health Services to quantify the actual and potential risk associated with an incident. By using the SAC score, all incidents/events are rated from 1 to 4, with 1 being the most severe. A rating of 1 will always require an investigation and notification to Area Executive and the Department of Health. A rating of 2 will require notification to the Area Executive and local assessment as to the level of investigation that may be required. Incidents that are rated 3 or 4 will be managed locally (Figures 1 and 2).

### **3. Investigation**

There are two fundamental challenges in the investigation process:

- To understand how and why an event occurred; and,
- To prevent the same or similar event from occurring in the future.

An identified problem is often the result of multiple causes, at different levels. This means that some causes affect other causes, which in turn create the visible problem. The process of RCA is somewhat analogous to clinical investigations, where symptoms and signs are further explored to identify underlying factors contributing to or causing the disease state.

Causes can be classified as one of the following:

Serious	Major	Moderate	Minor	Minimum
<p>Patients with death unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management or any of the following: Sentinel events reportable to Australian Council for Safety and Quality in Health Care</p> <ul style="list-style-type: none"> <li>Procedures involving the wrong patient or body part</li> <li>Suicide</li> <li>Retained instruments</li> <li>Unintended material requiring surgical removal</li> <li>Intravascular gas embolism resulting in death or neurological damage</li> <li>Haemolytic blood transfusion</li> <li>Medication error leading to death</li> <li>Maternal death or serious morbidity associated with labour or delivery</li> <li>Infant abduction or discharge to wrong family</li> </ul> <p>Requires notification under existing legislative reporting requirements</p>	<p>Patients with Major permanent loss of function (sensory, motor, physiologic or intellectual) unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following:</p> <ul style="list-style-type: none"> <li>Disfigurement as a result of the incident</li> <li>Absconded involuntary mental health patient</li> <li>Patient or staff assault requiring external involvement</li> </ul>	<p>Patients with permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following:</p> <ul style="list-style-type: none"> <li>Increased length of stay as a result of the incident</li> <li>Surgical intervention required as a result of the incident</li> </ul>	<p>Patients requiring increased level of care including:</p> <ul style="list-style-type: none"> <li>Review and evaluation</li> <li>Additional investigations</li> <li>Referral to another clinician</li> </ul>	<p>Patients with no injury or increased level of care or length of stay</p>
<p><b>Staff:</b> Death of staff member related to work incident or suicide, or hospitalisation of 3 or more staff</p>	<p><b>Staff:</b> Permanent injury to staff member, hospitalisation of 2 staff, or 3 or more staff experiencing lost time or restricted duty or illness</p>	<p><b>Staff:</b> Medical expenses, lost time or restricted duties or injury / illness for 2 or more staff</p>	<p><b>Staff:</b> First aid treatment only with no lost time or restricted duties.</p>	<p><b>Staff:</b> No injury or review required</p>
<p><b>Visitors:</b> Death of visitor or hospitalisation of 3 or more visitors</p>	<p><b>Visitors:</b> Hospitalisation of up to 2 visitors</p>	<p><b>Visitors:</b> Medical expenses incurred or treatment for up to 2 visitors but not requiring hospitalisation</p>	<p><b>Visitors:</b> Evaluation and treatment with no expenses</p>	<p><b>Visitors:</b> No treatment required or refused treatment</p>
<p><b>Services:</b> Complete loss of service or output</p>	<p><b>Services:</b> Major loss of agency / service to users, including cancellation of booked surgery, more than twice</p>	<p><b>Services:</b> Disruption to users due to agency problems</p>	<p><b>Services:</b> Reduced efficiency or disruption to agency working</p>	<p><b>Services:</b> No loss of service</p>
<p><b>Financial:</b> Critical financial loss &gt;\$1,000,000</p>	<p><b>Financial:</b> Major financial loss \$100,000 - \$1,000,000</p>	<p><b>Financial:</b> Moderate financial loss \$10,000 - \$100,000</p>	<p><b>Financial:</b> Minor financial loss &lt;\$10,000</p>	<p><b>Financial:</b> No financial loss</p>
<p><b>Environmental:</b> Toxic release off-site with detrimental effect. Fire requiring evacuation</p>	<p><b>Environmental:</b> Off-site release with no detrimental effects or fire that grows larger than an incipient stage</p>	<p><b>Environmental:</b> Off-site release contained with outside assistance or fire incipient stage or less</p>	<p><b>Environmental:</b> Off-site release contained without outside assistance</p>	<p><b>Environmental:</b> Nuisance releases</p>
<p><b>IF ANY OF THE ABOVE INCIDENTS ARE LIKELY TO EVOKE EXTERNAL INTEREST, CONSIDERATION MUST BE GIVEN TO REAPPRAISING THE SAC RATING FOR THAT INCIDENT.</b></p>				

Figure 1. Severity Assessment Code: all incidents are analysed against actual and potential outcomes.

CONSEQUENCE \ LIKELIHOOD	Extreme	Major	Moderate	Minor	Insignificant
Frequent (almost certain)	1	1	2	3	3
Probable (likely)	1	1	2	3	3
Occasional (possible)	1	2	2	3	4
Uncommon (unlikely)	1	2	3	4	4
Remote (rare)	2	3	3	4	4

**Figure 2.** Severity Assessment Code, scoring.

- Symptoms — these are not regarded as actual causes but rather flags of existing problems or the final outcome or event that occurred.
- First level causes — causes that directly lead to a problem.
- Lower level causes — causes that lead to the first level causes. While they do not directly cause the problem, lower level causes form links in the cause and effect relationships.

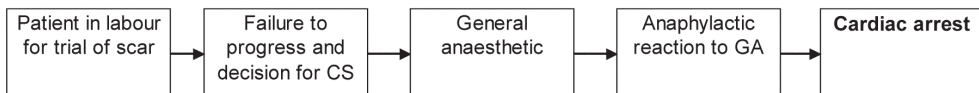
The lowest-level cause of a problem is called the root cause. It is “the evil at the bottom” that sets in motion the cause and effect chain that creates the problem(s).<sup>7</sup>

The NSW Health model has broken the investigation, cause and effect diagramming and actions into three separate meetings in its training program. This allows participants to more clearly focus on their objectives and complete the investigation in a timely manner.

***The sequence of events: Meeting 1***

The first key step taken by the root cause analysis team is to define the incident and determine the sequence of events that led to it. This involves the team mapping out the flow of what happened and when it happened, based on the initial understanding of the sequence of events and the known facts. An initial flow diagram is drawn up. This is an outline of the story of the key events, progressing chronologically from the first known fact, through the actual event being reviewed, and concluding with the final known event. Figure 3 is an example of the initial diagram that describes what has lead up to a disaster in an obstetric patient. In this story, the patient has undergone a failed trial of labour. A tired anaesthetist, who rarely does obstetric anaesthesia, reluctantly gives a general anaesthetic for the patient, who suffers anaphylaxis and a subsequent cardiac arrest.

Following the initial flow diagram, it is necessary to address each of these key events within the chain, asking “how and why” each condition existed, until there are either no more questions or no more answers. If the answer results in blaming an individual or group of individuals, another “why” question needs answering.



**Figure 3.** Initial flow diagram of events.

Based on the NCPS Triage Cards, NSW Health and ICE have developed a “Checklist Flipchart” to help identify system and process issues. At this stage in the process, the team familiarises themselves with the checklist flipchart questions that will help identify those who may need to be interviewed and assist in outlining other background information that needs to be collected. These may include records, policies and procedures, and equipment contributing to the event. The flipchart includes questions like:

- Were there issues related to patient assessment in this event?
- Were issues related to staff training or staff competency a factor in this event?
- Was equipment (or its use or lack thereof) involved in this event in any way?
- Was a lack or misinterpretation of information a factor in this event?
- Was communication a factor in this event?
- Were appropriate Policies/Procedures or guidelines, or lack thereof, a factor in this event?
- Was the failure of a safety mechanism or barrier designed to protect the patient, staff, equipment, or environment a factor in this event?
- Were specific patient issues a factor in this event.

Eventually, an expanded flow chart such as that shown in Figure 4 will be developed.

Following this step, unanswered questions may be resolved in interviews with those involved and identify information that still needs to be collected.

The team should not jump to conclusions, thinking they know the cause of an adverse event without doing any investigation. The natural tendency is to think in terms of a straight line from an adverse event to the preceding action and is influenced by “hindsight bias”. In reality, multiple decision points are encountered and must be

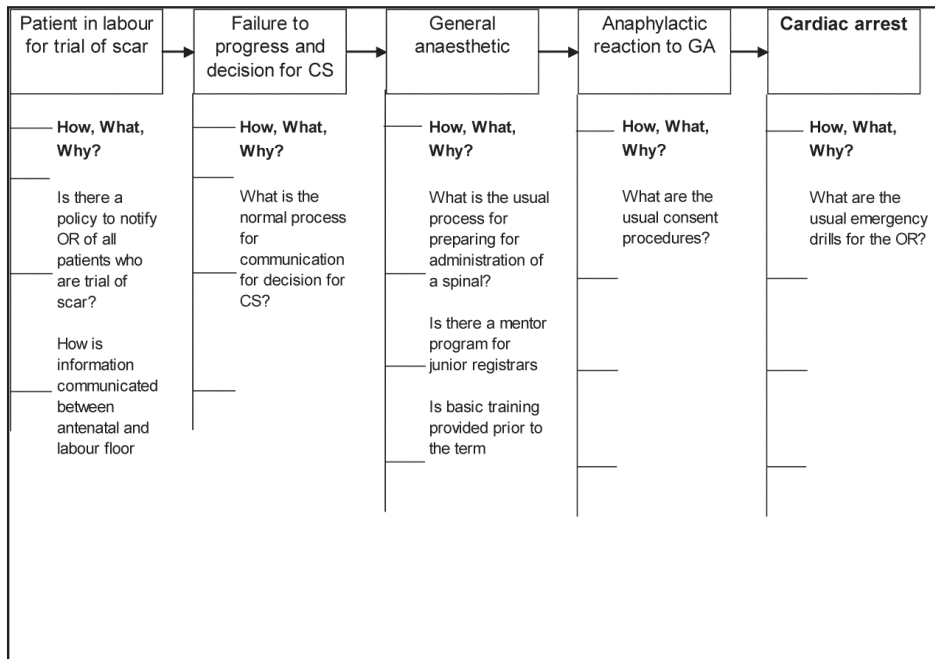


Figure 4. Expanded flow diagram.

dealt with. These environmental factors and decision points must be understood in order to identify the root cause or contributing factors leading to the adverse event. Thus, the importance of this stage of the process cannot be overstated. It identifies gaps in the story and sequence of events and assists in highlighting contributive factors and behaviours and provides the initial substance for the RCA, without which a team cannot proceed.

To finalise the first meeting, the team should agree on the following tasks:

- The questions that need to be asked and to whom;
- The additional information that needs to be obtained; and,
- Who is going to do each task.

#### 4. Determining the root causes

##### *Detailed flow diagram and Cause and Effect Diagram: Meeting 2*

After the interviews with staff identified at Meeting 1 have been completed and the additional information has been collected, the team needs to collate this information and ask “so what”, or “what is the relevance”, of each piece of information collected. This will help identify the symptoms or primary causes. This will lead to the root causes and contributing factors and what might be seen as the crucial “Barrier Points” where the event may have been prevented and can be set out in a detailed flow diagram, as in Figure 5.

The next step is the development of a cause and effect diagram, such as that in Figure 6. This assists the team in analysing relationships between a problem or symptom and its causes. It is a systematic way to combine the previous brainstorming, interviews and flowcharting tasks. The cause and effect diagram assists in:

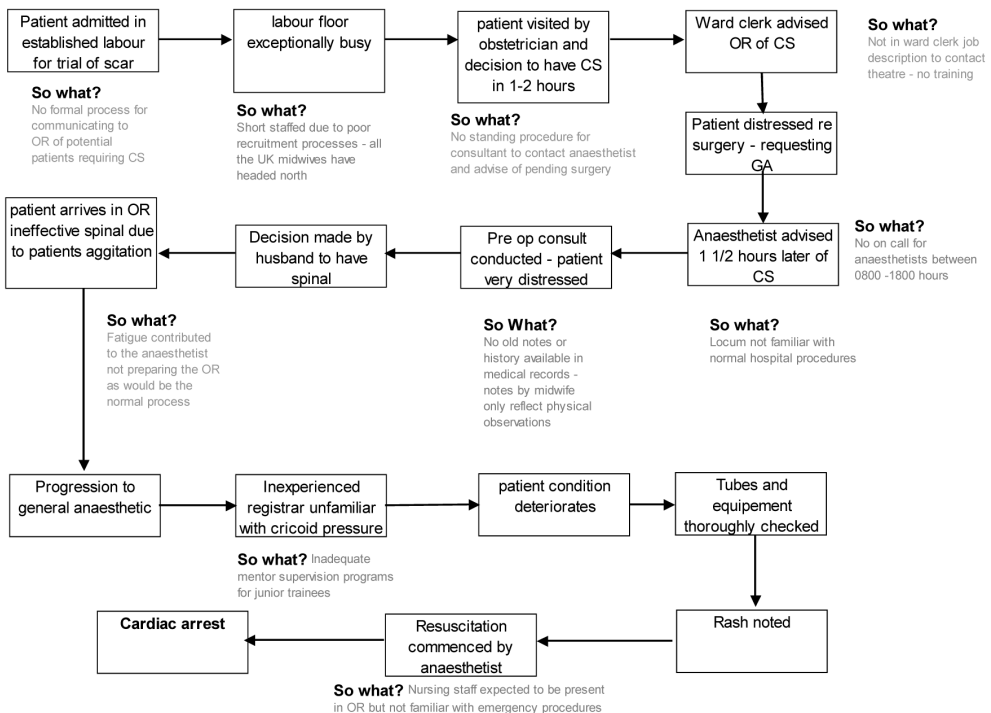


Figure 5. Detailed flow diagram.

- Clearly describing the problem for which the causes are sought — “What is the real problem we want to prevent?”
- Identifying the main categories of causes of the problem.
- Encouraging the team to dig deeper into each primary cause by repeatedly asking “What was this caused by or what did it result in?”, until the contributing factor root cause is identified.
- For each new answer to the question, ask the question again until no new answer results. (As a rule of thumb this often takes three to five rounds).

The cause and effect diagram is a four-step process:

1. Reviewing the event flow diagram and clarifying the problem statement — what is it you want to prevent occurring again?
2. Brainstorming a list of primary causes and choosing the most important.
3. Completing the causal chain for each of the primary causes or symptoms.
4. Concluding the investigation by developing root cause/contributing factor statements, actions and recommendations.

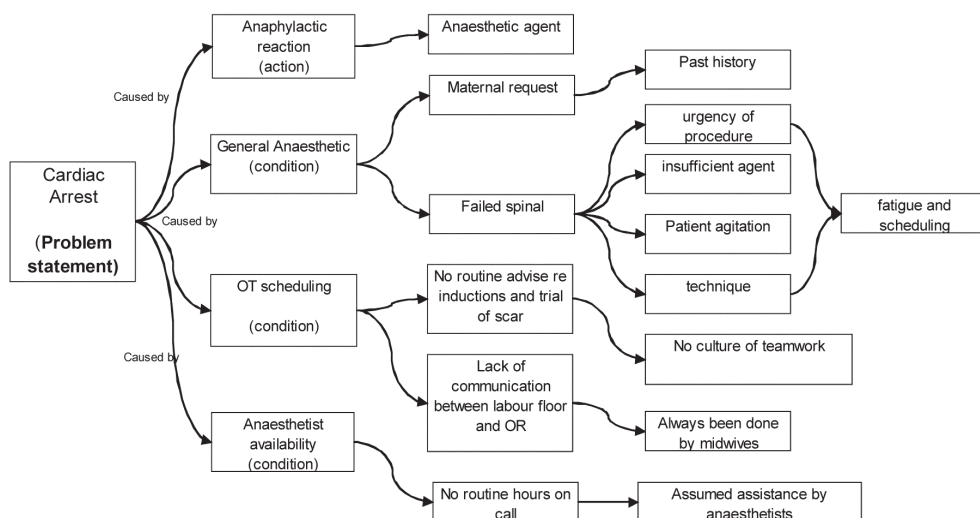


Figure 6. Cause and effect diagram.

### 5. Causal statements, actions and recommendations: Meeting 3

Once the cause and effect diagram has been completed, the team needs to develop root cause and contributing factor statements. These address why something occurred, not by whom it was caused. They should focus on what are the system vulnerabilities, not on individuals. The wording of causal statements has been described as cumbersome. We believe that this wording is crucial in that it prevents ambiguity and drives management to specific action that will prevent this incident in the future.

Root causes may include:

- Errors;
- Omissions;
- System deficiencies;
- Inadequate competencies;
- Poor communication or documentation;

- Inadequate facilities or equipment;
- Inadequate skill mix or availability of the health care team; and,
- Managerial inaction.

It is usual to identify more than one root cause; consequently, the team will need to prioritise the solutions to each cause.

### *Actions and Recommendations*

The key step to the RCA process is a decision on “actions and recommendations” to address the root causes that either directly or indirectly contributed to the event. Each root cause should be described and have the corresponding category from the checklist flipchart noted. The actions and recommendations will need to answer the question, “Will this prevent this incident in the future?” These actions may:

1. *Eliminate* the factor — remove, fix or replace a piece of equipment or put a measure in place to ensure the problem cannot recur.
2. *Control* the factor — checklists, cognitive aids, enhanced documentation, reduced disturbances. Or,
3. *Accept* the factor — place a warning notice or have reminders at team meetings and orientation etc, in effect acknowledging that there is an associated risk and accept it.

In addition, the team is expected to make recommendations about:

- What is the most effective remedial action?
- Who should be responsible for implementing the action?
- Outline a reasonable outcome measure for the action; and
- Set realistic target dates for measurement.

In our example, recommendations may include review of guidelines for “trial of scar”, protocols for communication between labour ward and operating theatres, when an urgent Caesarean section is possible, and the rostering of an anaesthetist specifically for obstetric patients during the day.

## **6. Monitoring and Evaluation**

While not specifically addressed in the training program, it is essential that organisations have a process in place that reviews the implementation of recommendations and their effectiveness. This should be undertaken by the management of organisations and reported regularly through Area Committees.

## **Conclusion**

It is recognised that there are many ways to improve the health care environment to make it safer for patients. The program that we have outlined on root cause analysis is one of these and concentrates efforts on improving patient safety through a focus on all types of errors. The causes of injury are rooted at the deepest organisational levels of clinical care and are difficult to observe and measure. Root cause analysis methodology provides an opportunity to reduce future injuries by identifying and addressing system related issues in health care. Through addressing clinical incidents in an environment that encourages reporting, thorough analysis of system vulnerabilities and making management accountable to ensure that recommendations are acted upon, Area Health Services not only stand to develop much more efficient services, but ones that will provide much greater customer satisfaction.

The training program provided by the Institute for Clinical Excellence has already

witnessed cultural change in places where RCA has been implemented. The end of 2003 will see over 2500 staff trained in the methodology. This should provide an immense impetus to cultural change and, even more importantly, lead to thousands of system improvements throughout NSW to provide a safer environment for patients. This process finally is using available information to put actions in place.

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