

SYDNEY WEST | **NSW**  **HEALTH**
AREA HEALTH SERVICE



**ANNUAL REVIEW OF
ROOT CAUSE ANALYSIS - 2007**

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY	3
2. BACKGROUND	4
3. VOLUME AND SUBJECT OF RCAS	4
3.1. RCAs by Network	4
3.2. RCAs by Facility	5
3.3. RCAs by Reason	5
4. PROCESS	6
4.1. Completion Times	6
4.2. Team Membership	7
4.3. PSO Role	7
5. OUTCOMES	7
5.1. Causal Statements	8
5.2. Recommendations & Outcome Measures	9
6. IMPLEMENTATION OF RECOMMENDATIONS	9
7. RISK REGISTER	10
7.1. Access & Patient Logistics	10
7.2. Cardiac Services	11
7.3. Imaging	11
7.4. Mental Health	11
7.5. Surgery & Anaesthetics	11
7.6. Women's & Children's Health	12
8. CONCLUSIONS	12

1. EXECUTIVE SUMMARY

During 2007, sixty-two (62) RCAs were commissioned by SWAHS. This was a 20% increase and continued the upward trend over the past four years. The major driver for this increase was 17 RCAs, which resulted from procedures carried out on the wrong patient or body part, the majority of which occurred in imaging. Five RCAs were related to suicide by a client of the mental health service. Four networks (APL, Cardiac, Imaging, W&CH) accounted for 2/3 of the RCAs.

In RCAs where the outcome was death, the management of the acutely deteriorating patient remained the major trigger for performing the RCA.

The average time taken to complete an RCA has further reduced in 2007 to 64 days and is now consistently below the DOH benchmark of 70 days. SWAHS has the best performance in NSW in this regard. Process improvements have been introduced throughout 2007 of which the most significant, was around re-defining the role of the RCA Team Leader.

Analysis of the causal statements and recommendations demonstrates a pattern consistent with previous years. Approximately 20% of the RCAs find no system issues on which to base recommendations.

The percentage of RCA recommendations implemented during 2007 has continued to climb, but 40% of recommendations remained outstanding at the time of writing this report. There is evidence that recommendations arising from more serious RCAs are being given a higher priority.

Significant clinical risks identified through the RCA process are now routinely reviewed for inclusion into the Clinical Risk Register. This process needs to be formalised in 2008. The 2007 RCAs predominantly highlighted risks already on the clinical risk register. Significant new risks to have been identified through this process included:

- Governance of ED patients around the time of transfer of care from the Department
- Complications of anti-coagulation therapy in catheter lab patients
- Provision of Area wide sub-speciality surgical services
- Production and compliance with neonatal policy

REPORT ON ROOT CAUSE ANALYSIS IN SWAHS RCAs COMMENCED IN 2007

2. BACKGROUND

In 2004, NSW Health introduced the Patient Safety and Clinical Quality Program (PS&CQP). Function 10 of this plan specifies that the Executive Director of Clinical Governance provides reports to the Chief Executive regarding the number, nature and outcome of Root Cause Analyses (RCAs) performed in the Area Health Service.

This is the 3rd consolidated annual report of SWAHS RCA activity. The information in this report is derived from the RCA database, maintained by the Clinical Governance Unit (CGU), and relates to RCAs commenced in 2007, as well as RCA recommendations falling due in 2007.

The report focuses on the nature and distribution of RCAs, performance benchmarks, the pattern of causal statements and recommendations, and how this informs the Area Health Service about clinical risk.

3. VOLUME AND SUBJECT OF RCAs

Sixty-two (62) RCAs pertaining to SAC 1 incidents were commenced during 2007. In addition:

- SWAHS also participated in a shared RCA with GWAHS, relating to an incident that occurred in a GWAHS facility.
- One RCA was commenced, but abandoned when the team identified that the incident was not a sentinel event, as originally reported.
- Seventeen additional investigations were completed by the Clinical Governance Unit (CGU), using the RCA methodology, but for non SAC 1 incidents.

This report will focus on the 62 completed SAC 1 RCAs.

In 2007, there was an average of five (5) new RCAs per month (range 2-9). The total represents the third consecutive annual increase since the introduction of RCAs in mid 2003.

3.1. RCAs by Network

In 2007, Cardiac Services, Surgical Services, Imaging, and Access and Patient Logistics (APL) generated similar numbers of RCAs which collectively made up approximately two thirds of the total.

APL, Surgery, Women's and Children's Health (W&CH) and Imaging were all responsible for more RCAs compared with the previous year. The large increase in Imaging RCAs is entirely related to wrong patient/site/side sentinel events. It is noted that the Department of Health (DOH), extended the definition of this sentinel event at the end of 2006, to include imaging procedures.

These increases have been partially offset by a significant reduction in the Mental Health RCAs. The most common cause for a Mental Health RCA is community suicide, which fell from nine (9) in 2006 to three (3) in 2007.

3.2. RCAs by Facility

More than half the RCAs in 2007 originated from incidents occurring at Westmead. In addition, Westmead has been responsible for the majority of the increase in RCAs over the past two years. "Community", has been included in the figure below, to best represent the location of the community suicides/homicides

3.3. RCAs by Reason

RCAs are performed for SAC 1 incidents. SAC 1 includes death - where there are concerns regarding the standard of care - and a handful of defined sentinel events.

In 2006-7 the triggers for RCAs were as follows:

Reason for RCA	2006	2007
Death (other than suicide)	28	37
Suicide	12	5
Homicide	2	0
Retained surgical material/instruments	0	3
Procedures on the wrong patient/side/site	2	17

The table demonstrates the increase in wrong patient/side/site incidents, which were related predominantly to imaging procedures, as well as two (2) cardiac procedures and one dental procedure.

The reduction in suicide has already been noted.

There was a 40% increase in deaths reported as SAC 1 events, which may be attributed to a number of factors:

- Identification of SAC 1 incidents through CGU comprehensive death audit.
- Participation of CGU staff in various Morbidity and Mortality meetings, enabling clinicians to raise their concerns directly through
- Increasing engagement of medical staff with IIMS.

For those RCAs in which death was the outcome, the primary cause has been coded within the RCA database. The distribution of primary causes is as follows.

Nature of Death	Number of deaths
Discharged from ED with Wrong Diagnosis	3
Admitted and Treated for Wrong Diagnosis	2
Delayed Response to Investigation - result not understood or acted on	1
Delay in response to documented deterioration	11
Related to adequacy of monitoring	1
During Procedure or directly related to an event during the procedure	4
Post Procedural Complication	0
Complication of Medical Management – Medication Error	1

Complication of Medical Management – Other	1
Following a Fall	2
Unexpected or Unexplained	6
Consistent with Disease Process	2

In 2007, as with 2006, the most frequent cause of conducting an RCA was a delay in response to a documented deterioration, associated with, or resulting in death.

The next most frequent category was “Unexpected or unexplained”. Along with “Consistent with Disease Process”, these two categories make up approximately 20% of the deaths and form the bulk of RCAs with an essentially negative outcome.

These RCA deaths were also coded based on the significance of the outcome.

Significance of RCA Incident	Number of deaths
No deviation from expected standard of care	10
Variation from expected standard of care, but with minimal impact on outcome	13
Variation from expected standard of care which had significant contribution to patient death	14

Clearly, this last category, which contains potentially preventable deaths, is the greatest cause for concern and should be the highest priority in relation to ensuring recommendations are implemented. It may also provide the greatest insight into risk. Of note is the fact that numbers in this group have been relatively stable over the past four years. The growth seen in 2007 in RCAs associated with death has been largely in the middle group. It might be inferred from this that obvious errors have been reported consistently, but that the increased identification of RCAs through death audit, M&M etc, has uncovered more marginal cases, where the significance of the incident has been less well defined.

4. PROCESS

4.1. Completion Times

For each RCA, key milestones are recorded, and for each milestone an internal benchmark has been set. The sum of these internal benchmarks is 70 days, which has been the NSW Health benchmark since August 2006. This benchmark applies to the interval between IIMS notification and submission of the final report to the DOH.

For the 62 RCAs commenced in 2007, the median time to completion was 59 days, with a mean of 64 days. This represents an improvement in performance compared with 2006. The most significant improvement occurred around the commissioning and organisation of the first RCA Team meeting.

	2005 Avg	2006 Avg	2007 Avg	Target (Days)	Cumulative Average	Cumulative Target
Commissioning	16	13	9	5	9	5
To 1st Meeting	17	11	7	9	16	19
To Last Meeting	30	19	18	28	34	47

To Team Report	25	10	9	7	42	54
To OIM	25	9	6	7	48	61
To DCO	20	7	6	7	54	68
To DOH	22	5	5	2	59	70
Total	154	74	64	70		

This achievement has only been possible through intensive support of the RCA process through the patient safety officers (PSOs), and through regular review and refinement of RCA procedures.

4.2. Team Membership

The sixty-two RCAs involved 263 team members. The median size of an RCA team was four (4) with a range of two (2) to seven (7).

Fifty-seven (57) RCAs had a nominated Team Leader who was not a CGU member. A PSO facilitated all 62 RCAs. The PSO allocated to each RCA was responsible for ensuring the team leader provides a draft report in a timely manner and the tone and content of the report reflected the required standard of report for submission to the Department of Health.

One hundred and twenty three (123) separate non-CGU staff participated on RCA teams and a quarter of these (i.e. 31) were involved in more than one team. Nine (9) non-CGU staff participated in five or more RCAs.

The organisation is now in a position where most RCA teams will have a mixture of some staff who are new to RCAs, some staff who have had previous experience, and at least one who has had extensive experience.

4.3. PSO Role

In order to maintain benchmarks and support the RCA team, PSOs have had to take a firm, controlling role in the RCA team. This has had the unintended side effect of the final report being regarded as the product of Clinical Governance rather than the RCA team and, by extension, a product of Clinical Operations. To address this issue, Clinical Governance has taken steps to ensure the role of team leader is strengthened, including ensuring that the Team Leader is nominated in advance rather than elected from the Team Members at the first meeting.

The fact that RCAs are privileged gives them a degree of independence. Managing the tension between this independence and the need to ensure consistency of approach and maintain standards in reporting has been a challenge.

5. OUTCOMES

Approximately 20% of RCAs conducted in 2007 had no recommendations with the RCA team concluding that the clinical outcome was not related to a deviation from an expected standard of care. This relatively high rate was similar to the previous year, and possibly related to the introduction of legislation relating to RCAs, which reduced

flexibility in responding to SAC 1 incidents. The remaining analysis is limited to the 50 RCAs, which resulted in recommendations.

Year	Number of RCA's	RCAs with no recommendations	% with no recommendations
2004	36	3	8%
2005	37	0	0%
2006	44	10	23%
2007	62	12	19%

5.1. Causal Statements

Fifty RCAs, generated 113 causal statements with an average of 2.3 causal statements per RCA. This is the same as in 2006. During the four years in which RCAs have been carried out, there has been a decreasing trend in the number of causal statements per RCA. This has been the result of a conscious effort to simplify RCAs, and has also resulted in a reduction in the number of recommendations per RCA.

All causal statements have been coded according to a human factors classification specified by the DOH. The results are contained in the table below. The trend has been highly consistent over four years.

Causal Class	2004	2005	2006	2007
Communication	24	34	34	35
Equipment	7	4	1	4
Individual Factors	0	1	0	3
Knowledge, skills and competence (KSC)	30	18	18	25
Patient Factors	5	6	3	3
Policies / procedures	21	27	15	20
Resources	2	4	2	9
Safety Mechanisms	0	2	1	1
Work environment / scheduling (WE/S)	10	15	7	13

If the analysis is limited to the most serious subset of RCAs – ie those resulting in death associated with a deviation from the expected standard of care – the pattern of causal factors does not change.

Locally, in SWASH, these human factors have been sub-classified into 31 sub categories, and the following table represents the most frequent. This grouping has also been relatively consistent over 4 years. Changes noted in 2007 were an increase in “Scheduling: insufficient for workload”, and “Policy known but not followed”.

Causal Class	2004	2005	2006	2007
Policy: No protocol or standard procedure	9	19	10	16
KSC: Policy known but not followed	4	6	4	15
Communication: Multiple teams not communicating effectively	5	19	6	12
Communication: Documentation missing or	5	8	10	11

inadequate				
WE/S: Insufficient for workload	5	5	1	10
KSC: Assessment of Severity of Patients Condition not Recognised	17	9	10	8
Communication: Delay in relaying important clinical information	10	4	11	7

5.2. Recommendations & Outcome Measures

The fifty RCAs generated one hundred and fifty seven (157) recommendations with an average of three per RCA (range of 1-10). As has been noted there has been a steady downward trend in recommendations per RCA.

The 50 RCAs generated 148 outcome measures (OMs). In comparison to previous years, all but one recommendation had a single outcome measure.

All Outcome Measures have been coded according to a locally developed classification. The results are contained in the table below.

Outcome Type	2007
Conduct Review/Audit: One off	13
Conduct Review/Audit: Recurrent	4
Facility/Equipment: Improved Utilisation	5
Facility/Equipment: New Allocation/Acquisition	5
New Procedure: Write/Amend Protocol or Guidelines	38
Notification: External	1
Other: Miscellaneous	4
Service: Amend Delivery Model for Existing Service	12
Staffing: Improve Supervision	3
Staffing: Improve Working Conditions	1
Staffing: Increase Staffing Levels	7
Staffing: Define, Evaluate & Enforce Competencies	13
Training: Education of Staff	30
Training: Update Educational Material/Manual	14

6. IMPLEMENTATION OF RECOMMENDATIONS

During 2007, 123 outcome measures fell due. These related to RCAs commencing in 2006 & 2007. Of the 123 outcome measures, approximately 40% were completed on time and a further 20% were completed but were overdue. The remainder were incomplete at the time of writing this report.

If the analysis is limited to the more serious RCAs – those where a deviation from an expected standard of care had been associated with death – the completion rate is approximately 75%, with only 25% remaining incomplete at the time of writing this report.

Completion of recommendations varies between Networks, with APL, Surgery and Cardiac Networks all having high non-completion rates.

During 2006, PSOs identified communication between CGU and the Networks responsible for implementing RCA recommendations, to be suboptimal, and new strategies were introduced to track the implementation of RCA recommendations. However, during early 2007 it was noted that despite improved communication between the networks and CGU, there were still delays in implementing RCA recommendations and in the reporting of their implementation. As a result of this, Clinical Governance assigned a Patient Safety Officer to each of the networks and a monthly meeting takes place between either the Network Director or Network Operations Manager in an effort to facilitate the implementation of the RCA recommendations. This has seen a marked reduction in the number of overdue or outstanding recommendations, especially from the Mental Health network which previously had over 30% of its recommendations overdue or incomplete at the time of the 2006 RCA Review.

Although the completion of recommendations is tracked and documented by CGU, it is still not possible to quantify the effectiveness with which implementation has occurred or the impact of the recommendations. A strong case can be made for selective audit to demonstrate the impact of selected key recommendations.

7. RISK REGISTER

In 2007 the first attempt was made to populate a clinical risk register based on pre-2007 RCA data. In addition, individual risk assessments were constructed for each of the Networks with high volumes of RCAs. The following section addresses the relationship between RCAs and risk identification.

7.1. Access & Patient Logistics

APL generated 10 RCAs all of which originated in ED. These RCAs highlighted the following risks:-

- Risk of missed diagnoses (egs AAA, # hip, appendicitis, ischemic gut, sepsis secondary to strep throat, dehydration & renal failure secondary to drowning and Pulmonary embolism).
- Risks associated with the environment in which care is provided. Two patients died on “NART” beds in Westmead ED and this practice of managing non-ambulant patients prior to ED assessment has now been significantly improved.
- Risks associated with governance of individual patients, especially around the time of transfer of care. This is a new risk which needs to be added to the risk register.
- New risks associated with Firstnet – primarily associated with mistaken online patient selection.

A common feature to many of the RCAs was paucity of clinical documentation and inappropriate triage assessment.

7.2. Cardiac Services

Cardiac Services generated 10 RCAs. One was a wrong patient echo and three others concluded the death was not preventable. Of the remaining 6 cases, one was cardiothoracic, four were cardiac cath lab procedures and one was related to choice of pacemaker. A recurrent issue for the cath lab procedures was the complications of anti-coagulation, which should be added to the clinical risk register as a medium risk.

7.3. Imaging

Imaging generated eleven (11) RCAs in 2007 – all relating to wrong patient or wrong site imaging procedures. This comprised five (5) plain X-rays, three (3) CTs, two (2) Ultrasounds, & 1 Nuclear Medicine scan spread over multiple facilities. Other than unnecessary radiation, no harm resulted to any of these patients. Patient mis-identification is clearly a serious problem, but these figures must be interpreted in the context of the high volume of procedures being conducted, and realistically this issue represents a low organisational risk. One of the common themes to emerge from these RCAs was the vulnerability associated with the patient identification process by porters. It should also be noted that a proportion of wrong sided incidents in imaging were not related to failure to apply the “Correct patient, correct side, correct site” policy, but to errors by the requesting doctor in completing the request form.

7.4. Mental Health

Mental Health generated five (5) RCAs, all related to suicide. There were four (4) community suicides and one (1) inpatient suicide. In general, the management of the patients who committed suicide in the community was considered appropriate, and generated minimal recommendations. The inpatient suicide, at St Josephs Hospital highlighted risks associated with the physical environment.

7.5. Surgery & Anaesthetics

Surgery & Anaesthetics generated ten (10) RCAs, two of which were from anaesthetics and the remainder surgery. Three (3) RCAs related to retained surgical material of some sort (sponge, IV central line guide wire, a component of a portacath). Two (2) RCAs related to delays in recognising coincidental medical problems in post surgical patients (AMI & PE).

One (1) incident related to the early surgical management of acute trauma. This is a risk previously recognised on the risk register, and continues to be an ongoing concern. A subsequent incident identified in early 2008 relating to the early response to trauma precipitated a formal reassessment of this risk.

One (1) RCA related to the provision of vascular surgery as an Area Wide service. This issue needs to be added to the risk register.

One (1) RCA related to the timeliness of Surgical consults. This precipitated a major audit of response to consults undertaken by CGU. This audit demonstrated that globally this risk is probably less critical than was first thought, however, it may be higher in some of the surgical sub-specialities, which have lower frequency of consult requests.

One (1) RCA highlighted the risk of inadequate monitoring in HDU. This issue had already been on the risk register and this incident, which resulted in a death, increased the level of risk. Of concern is the fact that a similar incident has recurred in 2008 despite the measures introduced from this RCA.

7.6. Women's & Children's Health

W&CH generated six (6) RCAs in 2007 – five (5) relating to obstetrics and one relating to neonatology.

The obstetric risks pertained primarily to the failure to respond to signs of increasing fetal distress. In two of these cases placental abruption was involved. The interpretation of CTG has already been identified on the risk register as a high risk and this remains the case.

One case related to a failure to strictly adhere to the protocol for managing cord prolapse. This seemed an isolated case and the relative infrequency makes this a lower risk.

The neonatology case highlighted the risk of variable or absent protocols in a Neonatal Unit. This is a longstanding issue, identified in multiple reviews of the NICU and remains a high risk. It should be formally added to the risk register.

8. CONCLUSIONS

In 2007 there has been a third consecutive annual increase in the number of RCAs performed. This was driven largely by a change in the definition by the DOH of the sentinel event pertaining to procedures carried out on the wrong patient or body part, and has resulted in a large increase in RCAs involving relatively minor incidents. In planning for RCAs in the future, we can expect the numbers to plateau at current levels

SWAHS administrative processes around RCA completion are robust, and reliably meeting benchmark performance. It is expected that this will continue.

Clinical Governance has, and will continue to refine the RCA process to ensure a high quality product for which there is ownership within clinical operations. This implies, for 2008, more detailed training, guidance & support for RCA Team Leaders, and strategic selection of RCA team leaders.

Increased interaction between Clinical Governance and Network Directors/NOMs has resulted in improved completion rates for RCA recommendations, particularly for the higher priority recommendations. However there is clearly room for further improvement.

While we can document the timeliness of completion of RCA recommendations, we need more information about effectiveness. Clinical Governance should undertake selected audits aimed at documenting this for those recommendations pertaining to high risk RCAs.

The process of moving from consideration of an individual incident to broader consideration of risk is relatively new and still evolving. There is a need for Clinical Governance to formalise the process of risk identification on an individual RCA basis,

and define the linkages with Clinical Operations and the Health Care Quality Committee (HCQC).

The RCA process is being continually refined and improved. Over the past three years RCA investigations have given rise to a wide range of important recommendations regarding system improvement and their implementation has required a major effort on behalf of responsible networks. This has undoubtedly had significant benefits. The credibility of this form of investigation is now established and widely accepted. There is no perfect form of investigation and there is no perfect investigation, but the utility of RCAs is demonstrated. What is needed now is to continue to refine this important tool so that maximum benefit continues to be gained from the time and energy that is invested in RCAs.

Deputy Director Clinical Governance
May 2008