A robust clinical review process: the catalyst for clinical governance in an Australian tertiary hospital

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ABSTRACT

Objective: To determine if a robust clinical review process can influence an organisation's response to adverse patient outcomes.

Design and setting: Retrospective analysis of the activity and outputs of the Clinical Review Committee (CRC) of a university-affiliated tertiary hospital from 1 September 2002 to 30 June 2006.

Main outcome measures: Engagement of clinicians (number on CRC, number interviewed for the clinical review process, number of specific referrals from clinicians); and numbers of cases reviewed, system issues identified, recommendations made to the hospital board, and ensuing actions.

Results: A multidisciplinary CRC with 34 members established a robust clinical review process and identified 5925 cases for initial case review. Of these, 2776 (46.8%) fulfilled one or more of the specified criteria for adverse events and progressed to detailed review; 342 of these (12.3%) were classed as serious or major. A total of 317 staff (11%) were interviewed, and 881 system issues were identified, resulting in 98 specific recommendations being made to the Clinical Board and implementation of 81 practice changes (including seven hospital-wide projects) to improve patient care.

Conclusion: A robust, multidisciplinary clinical review process with strong links to managers and policymakers can influence an organisation's response to adverse patient outcomes and underpin a clinical governance framework.

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High-profile patient safety inquiries[1,2] and persistently high levels of preventable adverse events in health care systems[3-5] have led governments to revolutionise their approach to the delivery of safety and quality in health care.[6-8] A key component of this revolution has been the adoption of "clinical governance",[6,9] which requires structures and processes that integrate financial control, service performance and clinical quality in ways that engage clinicians and generate service improvement. Good clinical governance ideally shares the responsibility for averting adverse events between clinicians and managers. This includes shared ownership of both the issues and implementation of solutions.

In the Australian Capital Territory, a public review of neurosurgical services at the Canberra Hospital[10] recommended that adverse events be identified and monitored to prevent harm to patients. In response to this review, a senior hospital executive decided that both clinicians and managers should be involved in developing a process to not only identify and investigate adverse events but also to create solutions to minimise their recurrence. A multidisciplinary committee was formed to oversee the development and implementation of a hospital-wide clinical review process and to provide the hospital's Clinical Board with recommendations for reducing the incidence of adverse events.

Here, we report the development and implementation of this clinical review process and its impact on the hospital's response to adverse patient outcomes.

METHODS

We undertook a review of documents pertaining to the set-up and maintenance of the Clinical Review Committee (CRC) and recommendations made to and subsequent actions from the Clinical Board during the period 1 September 2002 – 30 June 2006. We assessed the degree of hospital staff engagement in the clinical review process by using the surrogate measures of CRC membership, the number of specific referrals made by clinicians, the number of departmental committees undertaking clinical review, and the number of staff interviewed during investigation of incidents. Other outcome measures were the numbers of cases reviewed, system issues identified, recommendations made to the hospital board, and ensuing actions.

CRC establishment and governance

A senior clinical leader was appointed Chair of the CRC by the General Manager, and, together with the Deputy General Manager, appointed a multidisciplinary committee of 12 representative members from September to November 2002. During the first year, the hospital Executive affirmed its commitment to the clinical review process by funding a dedicated team of four skilled clinical nurse reviewers to provide a consistent, objective and timely approach to the process.

A CRC Executive of five members was established to ensure that the weekly CRC meeting only dealt with appropriate cases (severe or significant adverse events) and was not distracted by daily operational matters. The CRC delegated authority to this Executive to prioritise cases by severity of the adverse event, identify the method of case review, and deal with daily operational matters.

The clinical review process

CRC members adapted the clinical review process from the process at another institution,[11] which, at the time, did not have a multidisciplinary approach to clinical review or the same hospital structure. The main change made to this process was the introduction of a six-tier system of case review, so that intensity of the review was dependent on the severity of the adverse event, allowing more cases to be reviewed without diminishing the review outcomes.

Cases were identified for initial review using predetermined flags (Box 1). The clinical reviewers would then screen the medical records of flagged cases for the presence of one or more specified adverse events (Box 2), which were developed from a review of published adverse event data,[11,12] national core sentinel events[13] and aggregated CRC data after 12 months. If a case involved one or more of the specified adverse events, it was tabled at the CRC Executive meeting and evaluated against a severity assessment code (SAC).[14] Along with other predetermined criteria relating more specifically to the nature of the case, the SAC determined the method of review (Box 3). The review aimed to determine if any system issues led to the adverse event.

The CRC was afforded "qualified privilege" under the *ACT Health Act* (1993), which encouraged frank discussion of the adverse

event during the review process. However, qualified privilege did not prevent the CRC from publishing its findings and recommendations to a wider audience, including the Coroner, the Community and Health Services Complaints Commissioner, patients, and their relatives; nor did it prevent the ACT from supporting the national open disclosure policy.[15]

CRC recommendations

When system issues were identified, CRC reviewers, in consultation with the staff members (clinicians and managers) directly or indirectly involved in the adverse event, developed and presented recommendations to the Clinical Board. This peak decision-making body's role was to accept, reject or modify these recommendations and appoint a senior clinician or manager to ensure they were enacted through policy and practice changes or targeted quality improvement projects.

Over time, common system issues became evident and were aggregated to facilitate prioritisation of clinical improvement initiatives. From cases deemed to have had a serious or major patient outcome (based on the SAC), 16 broad categories of system issues were identified and modified after review of the literature[16,17] (Box 4). These system issues were ranked annually by frequency and reported to the Clinical Board, to advise of clinical priority areas requiring attention.

1 Cases detected by Clinical Review Committee (CRC) flags

CRC flag*	2002–2003	2003–2004	2004–2005	2005–2006
Specific case referral	29	115	120	175
Unplanned transfer to ICU	184	109	139	111
High-level incident report	48	57	122	172
Hospital readmission within 72 h	561	240	280	295
Hospital death	475	438	465	473
Unplanned return to operating theatre	78	198	154	145
Medical emergency team referral	nc	nc	326	416
Total cases detected by CRC flags	1375	1157	1606	1787
Total cases moving to further review	414	666	1023	673
Total cases identified as serious or major (SAC 1 or 2)	nc	59	89	194

ICU = intensive care unit. nc = not collected. SAC = severity assessment code.
* Cases could fall under more than one flag. ◆

RESULTS

From September 2002 to June 2006, 179 750 inpatients and 1 370 092 occasions of service were screened, capturing 5925 cases involving adverse patient outcomes; many were captured under more than one criterion. Of these events, 2776 (46.8%) progressed to detailed review and, of these, 342 (12.3%) were classed as serious or major (SAC 1 or 2). Investigation of these 342 cases identified at least two system issues associated with each, with a total of 881 system issues being identified.

Staff engagement

Over the 4-year period, the committee grew from 12 to 34 members as a result of active and strategic recruitment, through the Chair and Deputy General Manager meeting with 29 clinical directors and nurse managers. The new appointments were made deliberately to increase hospital representation and to penetrate the clinical review process deeper into the institution. Additional junior medical officers, registrars, midwives, clinical nurse consultants, and senior staff members became CRC members. More recently, a consumer representative has been appointed. Throughout the 4 years, there was a sustained average weekly CRC meeting attendance of 20 people (60%).

From 2002 to 2006, the number of specific referrals made by clinicians directly to the CRC increased sixfold from 29 to 175 (Box 1), and the number of local morbidity and mortality committees increased from eight to 16. The number of these groups reporting their activity and findings to the CRC increased from two to nine. During the

2 Initial adverse event screening criteria that trigger further review

Australian national core sentinel events[13]

- Procedure involving the wrong patient or body part (including wrong site)
- Suicide of a patient in an inpatient facility
- Retained instrument or other material after surgery (or procedure) requiring re-operation or further procedure
- Intravascular gas embolus resulting in death or neurological damage
- Haemolytic blood transfusion reaction resulting from ABO incompatibility
- Medication error leading to death of a patient reasonably believed to be due to incorrect administration of drugs
- Maternal death or serious morbidity associated with labour or delivery
- Infant discharged to the wrong family

Other triggers

- Death of patient who had been generally healthy during or immediately after surgery for localised problem
- Death unrelated to natural course of illness and differing from immediate expected outcome of patient management
- Death or disability associated with misuse or malfunction of a device
- Transfer of patient from general care to coronary care, neonatal intensive care, intensive care
- Patient attempting suicide, resulting in serious disability or admission to intensive care unit
- Major and permanent loss of function (sensory, motor, physiological, or intellectual) or disfigurement unrelated to natural course of illness and not present on admission
- Unplanned removal, injury or repair of organ during surgery or invasive procedure
- Death meeting criteria but not referred to the Coroner's office
- Diagnostic error — missed, delayed, misdiagnosis
- Abnormal laboratory, medical imaging, physical findings or other tests not followed up or addressed
- Inadequate observation process prior to patient deterioration or death or medical emergency team referral
- Clerical administration error related to patient information (eg, incorrect name, unique patient identifier)
- Poorly planned discharge from hospital
- Non-adherence to clinical policy, procedure or guideline impacting on patient outcome
- Admission to hospital as a result of clinical management at another hospital
- Admission to acute hospital as a result of outpatient management or procedure
- Adverse outcome associated with patient transfer or retrieval ◆

3 Clinical Review Committee (CRC) review process — levels of review*

Level of review and type of adverse event	Method of review
Level 1: External opinion	
Actual or potential significant/sentinel/critical incident	• Referral for external opinion considered when: ➢ Opinions differ among craft group of clinicians ➢ Clinical incident occurs within small specialised unit ➢ Craft group of clinicians request an external opinion
Level 2: ACT Clinical Audit Committee (CAC) interdivisional (joint) review	
Any incident involving more than one health agency in the ACT	• Review conducted under auspices of the ACT Health CAC • Clinical record review, staff discussions, literature review • Depending on severity, could involve assembly of a representative team to conduct interviews at other sites, or collation of reviews from either site • Presentation to CAC and CRC; system issues gathered
Level 3: CRC extended review	
Actual or potential significant/sentinel/critical clinical incident in accord with severity assessment coding process and Significant Incident Policy	• Coordinated by clinical reviewers; assembly of small multidisciplinary team not directly involved in incident; identification of team leader • Clinical record review, and staff interviews using the "how", "what", "why" methodology • Additional information gathered (guidelines, benchmark data) • Sequence of events elucidated; actual or potential breaks in care management identified; and, where relevant, recommendations determined in collaboration with clinicians • Presentation to CRC for endorsement; system issues gathered
Level 4: Review and presentation to CRC	
Incident involving more than one clinical unit — "not significant" in accord with severity assessment coding process and Significant Incident Policy	• Clinical reviewers conduct clinical record review +/–staff discussion to gather additional information • Presentation to CRC • Actual or potential breaks in care management confirmed; and, where relevant, recommendations determined in collaboration with clinicians
Level 5: Single unit review	
Incident involving only one clinical unit — not "non-significant" in accord with severity assessment coding process and Significant Incident Policy	• Clinical reviewers conduct clinical record review +/–staff discussions to gather additional information, or send to local morbidity and mortality committee to review • Outcomes of review presented to CRC Executive • Where clinical improvement changes are suggested, presented to CRC for endorsement
Level 6: CRC Executive	
Any case reviewed by the clinical reviewers that fulfils the screening criteria	• Clinical record review; level of review (1–5) determined by CRC Executive • Referral to other committees if required

ACT = Australian Capital Territory. * A review may be escalated to another level at the discretion of the CRC Executive. ◆

4-year period, 27 extended reviews (Level 3; see Box 3) were performed, involving interviews with 317 (11%) of the 2854 hospital staff: consultants (70), registrars (43), resident medical officers (20), nursing staff (168), allied health staff (9), ward staff (3) and hospital administrators (4).

Actions

Ninety-eight recommendations were made to the hospital's Clinical Board, of which 81 (83%) have been implemented or continue to be enacted through hospital-wide projects. The actions taken have been far-reaching; examples are detailed in Box 4.

Four of the 16 categories of system issues emerged as the most frequent: clinical assessment and management; clinical guidelines/policy procedure; communication between staff; and skills/education. The most frequently recurring system issues were seen to require large-scale projects to implement hospital-wide changes. These long-term projects include Early Recognition of the Deteriorating Patient; Clinical Handover; Respecting Patient Choices; Review of Resuscitation Processes; Management of the Mentally Ill Patient with Significant Medical Comorbidity; and After-Death Management. Most of these projects have been implemented as hospital-wide programs; for example, the Early Recognition of the Deteriorating Patient project involved development of a new observation chart, an education program, and installation of a track and trigger system. This initiative demonstrated clear changes in clinical practice (increase in the frequency of documentation of observations and calling of the medical emergency team) and an improvement in patient outcome.[18]

DISCUSSION

The implementation of a hospital-wide clinical review process in our tertiary hospital has demonstrated that all serious adverse events can be detected in a systematic way using predetermined detection flags and screening criteria. With seven methods of detecting clinical incidents, no significant adverse event has been identified outside the CRC processes. The close relationship with the hospital's Clinical Board has enabled the CRC to bridge the gap between frontline clinical staff, policymakers and managers, by ensuring that system issues identified in serious adverse events are acknowledged and result in actions and hospital-wide projects to improve patient care.

The role of the independent clinical reviewers has been important in the success of this clinical review process. They have been able to work collaboratively with all clinicians, including senior consultants, and, being located in the hospital's independent Clinical Practice Improvement Unit, have been able to provide impartial and objective reports. Their independence has also facilitated objective feedback to the clinicians, CRC and Clinical Board.

Another potentially important determinant in engaging clinical staff in the review process has been the driving of CRC activities and development of CRC processes by

4 Frequency of systems associated with adverse events and examples of actions taken

System associated with adverse event	2003–2004	2004–2005	2005–2006	Examples of actions taken
Clinical assessment and management	35%	57%	34%	• Early Recognition of the Deteriorating Patient project • Failure to Attend Outpatient Clinic project • Electronic Incident Reporting System • Installation of a medically staffed retrieval system for critically ill patients in the Australian Capital Territory • Review of trauma criteria to include women > 20 weeks' gestation • Improved process for management of acute postoperative patients • Management of acute eye injury — eye triage information review
Clinical guidelines/policy procedure	20%	43%	23%	• After-Death Management processes • Coronial Management project • Percutaneous transluminal angioplasty pathway • Procedural sedation guidelines • Conflict resolution guidelines • Inpatient review policy • Addition to therapeutic guidelines of dosing for renal patients • Management of fever in paediatric patients in emergency department guidelines • Guidelines for the Management of Upper Gastrointestinal Haemorrhage
Communication between staff	37%	42%	26%	• Clinical Handover project • Formal notification of patient deaths to their general practitioners • Electronic discharge referral form
Skills/education	33%	27%	22%	• Review of Resuscitation Processes • Chest drain device change and development of training package • Mandatory Schedule 8 and patient-controlled analgesia (PCA) training • Junior medical officer (JMO) training to include neonatal resuscitation • Cardiotocograph monitoring standards reviewed and education session implemented • Development of relevant night-duty staff to facilitate maintenance of clinical skills
Patient observation process	19%	25%	9%	• Changes to post-anaesthesia care unit chart • Development of integrated hospital observation chart • Review of postprocedural observation charts
Documentation	20%	24%	13%	• Review of pre-operative checklist to include "accountable items" • Request for admission form to include relevant clinical information • Outside correspondence retained; now scanned with medical record and available to staff
Coordination of care	17%	16%	20%	• Management of the Mentally Ill and Medical Patient – Comorbidity Working Group
Staff supervision	7%	14%	9%	• Structured morning medical and surgical handover with JMOs, registrars and consultants, including a teaching session
Human resources/staff allocation	8%	11%	4%	• Increased JMO numbers after hours
Equipment	5%	8%	8%	• New PCA pumps procured to mitigate accidental overdose or misadventure with older-style pumps • Inclusion of large-diameter covered stents for timely vascular procedures • Tracking register for sterilised bronchoscopes • Mechanical ventilators that directly monitor end-tidal carbon dioxide to detect early failure of ventilation
External factors	4%	8%	5%	• Memorandum of understanding between Greater Southern Area Health Service and ACT Health for review of patients
Other factors	6%	8%	6%	• This category has been revised to "Patient flow, access block and outliers"
Physical environment	4%	4%	8%	• Redesign of computed tomography scanning workflow practices • Review of the psychiatric patient admission area
Communication between staff, patient and family	3%	2%	7%	• Respecting Patient Choices program
Security/design	0	1%	1%	• Roadside hazard lights to warn when transporting critically ill patients from the helipad
Patient site/identification	0	1%	3%	• Evaluation of implementation of the Correct Patient, Correct Site, Correct Procedure Policy ◆

clinicians, allowing them to "buy into" the CRC and its activities. The CRC has also been able to give feedback to clinicians, morbidity and mortality committees, and the hospital Executive on its findings, and together developed recommendations for the Clinical Board. This allowed for engagement of clinicians (nurses, doctors, allied health workers) in developing recommendations, which facilitates ownership and makes it more likely they will be enacted.[19]

Introduction of the systematic clinical review process has not been without difficulties. Its set-up and maintenance has been time-consuming and dependent on a small number of enthusiastic people. Some craft groups did not initially embrace the clinical review process, but the resistance to take part has declined over time. This change in behaviour occurred through active participation (eg, CRC membership) and also through an understanding, gained from face-to-face meetings, that adverse events are investigated consistently and independently in accord with transparent processes.

The qualified privilege conferred on the CRC appears to have helped with acceptance of the clinical review process. Previously, clinicians were reluctant to discuss adverse events[9] for fear of reprisal (defamation, litigation). However, with the knowledge that documents relating to CRC investigations were not admissible in a court of law, only rarely did clinicians refuse to take part. With the clinical review process now embedded in the hospital culture, clinicians have welcomed a consumer representative onto the CRC and the introduction of open disclosure.

The CRC was slow to develop rigorous reporting of identified system issues. In the first 2 years, it was difficult to report to the Clinical Board in a meaningful way, due to lack of grouping or prioritisation of identified system issues. Over time, a data dictionary has been developed to enable accurate grouping of identified system issues, which has been essential for the development of hospital-wide projects.

Despite the apparent success of the CRC, this study only reports surrogate markers for engagement of clinical staff in the clinical review process. The failure to conduct interviews with participants and non-participants in the CRC process weakens the evidence for good clinical engagement. Also, in the absence of a CRC database in the early days, much of the data collection was performed manually, increasing the risk of missing data and incorrect analysis.

The CRC, through its multidisciplinary group of clinicians and links with the Clinical Board, has had a visible impact on patient care. The multi-tiered investigative process has been a practical solution to the overwhelming number of cases identified for initial screening, without compromising review outcomes. We see the success of the CRC as twofold: the engagement of clinicians in the process,[20] and the development of actions overseen by the peak decision-making body. The consistent methods used for case review of similar incidents, the independent nature of the dedicated reviewers, the penetration of the CRC into the institution and the local university curriculum, and the visible actions that have arisen from the reviews represent some of the evidence of its success.

The clinical review process is itself continually under review, and substantial resources have been invested to not only support the CRC's processes, but also for clinical improvement projects driven by clinicians. While the system continues to mature, it has led the development of the clinical governance framework in our institution that is now being used territory-wide.

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COMPETING INTERESTS

None identified.

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