Ex 355

Bundaberg Base Hospital – Review of Systemic Issues

The HRC has undertaken a review of the investigation conducted by QH of Clinical Services at BBH. The purpose of our review was to consider the scope of investigation as well as any recommendations arising from the investigation, which directly relate to systemic issues identified by the HRC. The aim is to identify a) those issues which have been adequately dealt with and b) those issues which require further enquiry by the HRC.

The systemic issues identified in complaints received by the HRC are as follows:

1. Scope of surgical practice
2. Premature discharge (*)
3. Consent (*)
4. Infection rates
5. Monitoring complication rates
6. Pathology (*)
7. Complaint handling
8. Communication
9. Documentation

(*) Issues not addressed in QH investigation

Terms of reference (relevant)

1. Included was an analysis of the clinical outcomes and quality of care across all services at BBH and compared with benchmarks from other states or other like hospitals and identifying areas requiring further review or improvement.

2. Also to review the risk management framework as it relates to the provision of direct services at BBH to determine effectiveness.

3. Examine the way in which the Service Capability Framework has been applied at BBH to determine that the Scope of Practice is appropriately supported by clinical services.

Scope of Surgical Practice

HRC Concerns
The HRC will be examining the scope of surgical practice at BBH and the processes for referring patients who are scheduled for major surgery to tertiary hospitals.

Review team analysis:
During his employment, Dr Patel was involved in the care of one thousand four hundred and fifty seven in-patients (1457). Fifteen percent (15%), or two hundred and twenty one patients who: died, were transferred, or had an outcome which was identified as 'adverse' were brought to the attention of the review team. Dr Woodruff identified that in these cases, Dr Patel operated outside his scope of expertise or outside the scope of the hospital on 3 occasions. Dr Woodruff identified that in a further 5 cases, Dr Patel 'maybe' operated outside of that scope.

Update – Dr W's recent evidence.

The review team identified that there is an emphasis upon production within health service delivery. Some of the hospital funding is linked to activity and waiting list performance which leads to a focus on finance. Such focus and increase on workloads can impinge adversely on safety and quality. The performance assessment of local management was based heavily upon budget integrity and ability to keep services going, with safety and quality of services receiving lesser emphasis.

Clinical Services Capability Framework (CSCF):
The CSCF is a framework that outlines the minimum support services, staffing, safety standards and other requirements required in both public and private health facilities to ensure safe and appropriately supported clinical services. The review team identified that:

- The CSCF had been applied to BBH, however, it was quite broad in its indicative range of procedures where significant and complex abdominal and thoracic surgery were grouped together with less major surgery such as caesarean section;
- There are some procedures detailed within the indicative surgery list which should not be performed in a facility such as BBH and others which reasonably could be; and
- The CSCF lacks clarity in relation to specific surgical procedures. The Credential and Privileges process would require significant change to allow for specific procedures to be defined based on Clinical Services Capability.

Review team recommendations:

Bundaberg Health Service District at a local level:

- Ensure decisions regarding service profile are clearly communicated to hospital staff so as to clearly define scope of service;
- Ensure that all medical staff are provided with written clinical privileges upon appointment, consistent with the service capability of the facility and their credentials; and
- Ensure the CSCF is used only as a guide to decision making. There is a need for Management within a hospital to take a holistic view of the services when applying the current framework in specific instances.

Queensland Health at a broader level

- Review the indicative range of procedures described within the Surgical Complexity section of the CSCF document to ensure greater homogeneity of complexity of the listed procedures;
- Develop objective mechanisms for monitoring ongoing clinical performance of medical practitioners to determine whether their practice is within acceptable standards. This may include periods of supervised or formative assessment; and
- Develop, implement and support statistical process control and 'cusum' methodologies, to assist with monitoring individual clinician performance and clinical services in key clinical areas of practice.

HRC Recommendations

One overriding concern in reading the Review Report and its accompanying recommendations in relation to scope of practice issues is that it is based on a review of 15% of cases. In other words, 85% of cases were not examined. Therefore, the conclusion drawn by the report that Dr Patel

operated outside of the scope of the hospital on 3 occasions could be misleading and lead to flawed recommendations.

While the Commission is in agreement that decisions regarding scope of practice cannot be made simply by broadly applying the CSCF, and must be made on a case by case basis, BBH is also an example of where this process has been undertaken, abused and the public have suffered as a result.

Therefore, an additional recommendation is that:

- In cases that warrant individual discussion, and are outside of the general guidelines of the CSCF, a policy should be implemented which sets out the process for making such decisions. For example, a provider should not be able to make a lone decision that a certain type of procedure is to be undertaken.

An additional concern that the Commission has is that in simply reiterating current structures (such as the CSCF) or comparing BBH to other Queensland facilities, the acceptance of possible 'mediocre' care could be maintained. Therefore, the Commission would recommend that:

- The Scope of Practice at BBH be directly compared to a similar hospital in both Queensland and interstate.

Complaint Handling

HRC Concerns

Another area of concern relates to the issue of complaints handling at BBH. It seems that BBH did not have its own Patient Liaison Officer. The HRC will be examining whether at the BBH there was a culture that welcomed complaints, and whether complaints were responded to openly, fairly and appropriately. The issue as to whether information from the complaints was fed back into quality improvement practices at the BBH will also be examined.

Review team analysis

The Review team identified that there was clear evidence that BBH had responded promptly to develop local procedures in response to the Queensland Health policy directives. However, a number of difficulties had been identified:

- inadequate staffing/resourcing;
- inadequate training and support;
- failure to close the loop (referral of high, very high and extreme risks to the relevant executive director rarely led to a report which documented investigation findings, provided actions or feedback to DQDSU or reporting staff;
- directors did not provide clear advice on what reports they required to monitor safety and quality performance;
- a tendency to have an individual and punitive approach to staff that reported incidents, rather than a system-focused approach which encouraged reporting and used incidents as an opportunity to learn;
- reluctance to report incidents as there was a perception that executive management did not listen to concerns raised by clinicians. This was made worse as they were reportedly rarely seen in the clinical areas;

- there appeared to be a varied understanding of what was a reportable clinical incident amongst staff; and
- It appeared that the complaints processes were not consistent with open disclosure principles.

In addition, there appeared to be no link between the complaints and clinical incident management processes. For example, there were many examples of patient complaints which were later shown to be clinical incidents that had not been reported through the incident management system, including an instance of incorrect surgery by Dr Patel.

Review team recommendations

Bundaberg Health Service District at a local level

- Ensure that a plan to implement effective clinical incident and complaints management that is consistent with Queensland Health policy is developed. This should include implementation of the incident management information system (PRIME) with consideration of designated consumer liaison and patient safety officers to support the district.
- Ensure that all documents raising complaints or concerns are dated and signed by the staff member raising the complaint or concern are returned to them for signing and date at the time the document is first presented.

Queensland Health at a broader level

- Provide comprehensive training and support in clinical incident and complaints management to Bundaberg Health Service District. This should include standardized Root Cause Analysis (RCA) methodology.

HRC Conclusions

The Commission is of the opinion that these recommendations will go a long way toward implementing a comprehensive complaints process. However, to be effective, they need to be implemented alongside a proactive cultural, leadership and change management process at BBH. It is no good to have a policy which encourages individual initiative in complaint handling if a culture of blame still exists.

Communication & Documentation

HRC concerns
The HRC will examine whether there was adequate channels of communication (both verbal and written) between providers and between departments.

The HRC will review the adequacy of documentation of adverse clinical incidents / surgical complications.

Review team analysis

Committees

? outline

The review team identified that there were a total of 21 committees in existence on the District Communications Strategy Map & Terms of Reference in April 2005. However, the map supplied by the District does not clearly the accountability and reporting relationships of the various committees. In May 2005 the total number of committees recorded was 13 following a review. It was noted by the review that similar information, if not the same, is discussed at various committees. It was reported by many staff that there were too many committees, significant overlap in the functions and potential for issues to "fall through the cracks". It was reported, and evident from reviewing the minutes, that when safety and quality issues were raised, that there was rarely feedback of decision and documented actions. Further, there was little evidence of any outcome. The agreed action column frequently has 'Nil' recorded.

Orientation

At an individual level, the appointment of interstate executives without adequate orientation led to appointees who were unfamiliar with legislative, policy and administrative processes.

Culture

There appeared to be a medical culture of tolerating problems rather than addressing them. Several doctors withdrew, some did nothing, others hid patients, or arranged alternative surgical support rather than providing clinical leadership to address the problem together with their nursing colleagues.

Dr Patel's bullying behaviour gave rise to fear and polarized staff groups. There was no minimal commitment to facilitate the multidisciplinary review of patient care and adverse events. This resulted in a focus on interpersonal issues rather than what was best for patient care.

The review team acknowledged serious deficiencies in communication in respect of patient management. In particular:

- There was an absence of contemporary interaction between members of the clinical team;
- There was no system of contemporary review of the patients' care particularly those involving adverse outcomes.

Review team recommendations

Bundaberg Health Service District at a local level

- Establish a clear process for the multi-disciplinary review and management of clinical incidents consistent with the Queensland Health Incident Management Policy;
- Ensure the format of the After Hours Nurse Managers' Bed Status Report is standardized so that all Nurse Managers provide accurate, pertinent and timely advice to the Executive in a consistent way;
- Review the District Communications Strategy Map & Terms of Reference for committees to minimize duplication and to reduce the number of committees attended by individual staff;
- Review the committee structure and their Terms of Reference to minimise duplication and to establish clear accountability;
- Consider the establishment of a single multidisciplinary committee to address patient safety and quality issues, monitor and evaluate actions and provide feedback to staff. District policies must clearly articulate the responsibility and accountabilities of all clinical staff to report incidents;

- Ensure that feedback to referring committees or staff occurs in a meaningful format which assists in organisational improvement;
- Ensure that all minutes of meetings clearly document key points of discussion, agreed action, accountable officers and timeframes.
- Ensure that items remain on meeting agendas until there is documented completion of agreed action by the accountable officer;
- Review reporting relationships for the Nursing Service to incorporate the existing Assistant Director of Nursing position and also to provide a reporting relationship for Clinical Nurses who are sole practitioners.
- Review the Assistant Director of Nursing position as a matter of priority;
- Ensure that all medical staff receive adequate orientation to the District on the commencement.
- Ensure one complete Personnel File is maintained in the Human Resources department;
- Ensure that all documents raising complaints or concerns are dated and signed by the staff member raising the complaint or concern or returned to them for signing and date at the time the document is first presented.

Queensland Health at a broader level

- Work with Bundaberg Health Service District to develop peer clinical networks with a focus on clinical performance, service improvement, benchmarking and shared learning.
- Develop and implement an orientation process for key executives,

HRC Conclusions

Again, these recommendations would go some way to developing streamlined communication within the District. The HRC makes the following, additional recommendations for consideration:

- Staff training (bullying, harassment, leadership);
- Dr Woodruff found that to be effective, a team requires effective communication between each member which is encouraged, uninhibited and constructive. The Commission recommends that a review and analysis of current communication processes and patterns is undertaken at BBH. To be effective, this review will need to address communication which is based in policy (theory) and that which is accepted and cultural (reality); and
- Development of policies for feedback to BBH following patient transfer to other institutions;

Once again, the Commission is of the opinion that to be effective, all of the above recommendations need to be implemented alongside a proactive cultural, leadership and change management process at BBH.

Risk Management Framework

HRC concerns

Infection Rates
The HRC will examine whether there was adequate monitoring of infection rates at BBH. Issues such as how individual incidences of infection are recorded and then reported and who is, or

should be, responsible for this task will be examined? Other issues raised in this regard are what systems were in place to alert hospital management or Queensland Health officers in relation to high rates of infection?

Management of Dr Patel (as it relates to systemic issues)
On 2 July 2004 the ASPIC minutes suggested that wound dehiscence rates were high. This has also been reported to Executive Council. This had been followed up by Dr Patel and the Infection Control Nurse. It had been reported back to the committee that this had been a definitional issue and, as a result of further review, the Infection Control Nurse had indicated that she was satisfied with the results of the audit.

The review team stated that this information in addition to the previous concerns would have suggested external peer review of the cases and consideration of restriction of clinical privileges of Dr Patel.

Complication Rates
The HRC will examine whether there was a system in place to monitor surgical complication rates.

Management of Dr Patel (as it relates to systemic issues)
Dr Miach provided Mr Martin (Acting DDON) and Dr Keating a report which he had compiled which outline a 100% complication rate (6 out of 6 patients), that had undergone Tenkhoff Catheter insertion by Dr Patel. Mr Leck asked Dr Keating to follow it up. Dr Miach refused to refer his patients to Dr Patel.

The review team found that given that several senior clinicians had expressed concerns regarding the patient outcomes from Dr Patel's surgery, consideration could have been given at this stage to obtaining formal external peer review.

Review Team Analysis
The Review Team defined Risk Management as the 'systemic application of management policies, procedures and practices to the task of identifying, analysing and assessing, treating and monitoring risk' (Management Advisory Board's Management Improvement Advisory Committee, 1996). And further that 'Clinical Risk Management', is a systematic approach by health services to improve patient safety through the identification, prioritisation and treatment of risks.

It was confirmed that there was no process in place wherein clinicians in BBH regularly validate complication codes.

The initial process to screen for adverse events was to review Dr Patel patients from Hospital Based Clinical Information System (HBCIS), looking at deceased and transferred patients (this was a screening tool only and was not intended to review all deceased or transferred patients that had come in contact with Dr Patel).

The review team identified a number of relevant committees which may have had relevant records to consider and also identified a number of sources of relevant documents for review eg. Adverse and sentinel event forms.

Key underlying systems issues identified by the review team believed to have contributed to the events in relation to Dr Patel

Organizational level (relevant points only):

- There is an emphasis on production within health service delivery. Some of the hospital funding is linked to activity and waiting list performance which lead to a focus on finance. Such focus and increase on workloads can impinge adversely on safety and quality.
- There is no objective mechanism for monitoring the ongoing technical ability of a medical practitioner to determine whether their practice is within acceptable standards. The absence of any formal guidance to help senior clinical staff and executives determine the appropriate process when concerns are raised about a clinician's performance, causes confusion and uncertainty in dealing with this situation.

Health service district (workplace) level:

- The local committee structure is complex and lacks clear accountability systems for the reporting and management of patient safety and quality issues.
- There appears to be insufficient resources and expertise to adequately support the safety and quality requirements of the hospital.
- There appears to be a culture at BBH which does not support the open reporting and analysis of clinical incidents.

Team Level

- There was no established process for the multidisciplinary review and management of clinical incidents. The executive are charged with investigating events and the process lacks openness and transparency, which has led to a lack of trust between staff and management.
- There was no standard process and support for multidisciplinary peer review, audit and quality improvement at clinical unit level.

Individual Level

- There appeared to be a medical culture of tolerating problems rather than addressing them. Several doctors withdrew, some did nothing, others hid patients, or arranged alternative surgical support rather than providing clinical leadership to address the problem together with their nursing colleagues.

Dr Woodruff's Clinical Case Review
As a part of Dr Woodruff's clinical case review he noted the following:

Effective patient care is a team effort. The team works effectively when communication between each member is encouraged, uninhibited and constructive. There were serious deficiencies at BBH in this respect. There was no system of contemporary review of the patient's care particularly those involving adverse outcomes. Constructive and contemporary review among those involved in a patient's care, if necessary with input from other experienced senior clinicians, would go a long way towards improving outcomes. Ideally from the perspective of healthcare outcomes alone such a review would be confidential and conducted

within a culture which encouraged the open disclosure, discussion and analysis of adverse outcomes, clinical events and near misses. Feedback of such formative data to the multidisciplinary team (nurses, doctors and allied health) should be resourced and supported.

Analysis of clinical outcomes and quality of care

The review team analyzed the available sources of data in relation to quality of care issues at BBH and they found that there was significant limitations on the validity of various reports that track clinical indicators. They concluded that it was rarely possible to obtain useful information to assist management decision-making. In addition to this, at BBH data is sourced from medical record coding which has not received clinical validation.

Surgery

Adverse event recording was reported on trended graphs, produced by DQDSU (District Quality & Decision Support Unit) which were not well developed and only recently commenced. The surgical ward reported much higher numbers of incidents than other clinical areas. They concluded that this was either due to a better reporting culture in the area or heightened awareness due to concerns about Dr Patel. However, they stated that it was not possible to draw valid conclusions from comparison of 'reported incident numbers'.

Infection rates were reported through the CHRISP (Centre for Healthcare Related Infection Development Services Coordinator Surveillance Prevention) eICAT Surgical Site Infection Process, which provides 6 monthly reports across a range of indicators. Dr Whitby, Medical Director of CHRISP suggested that there was no significant change in the infection rates collected and reported through CHRISP at BBH. General surgical data is not collected from BBH (or from many hospitals) due to the short length of hospital stay for common surgery. Long stay operations are usually complex and are classified as 'dirty'. As a result, inpatient Surgical Site Infection Surveillance is not collected in either of these general surgical groups. Due to the small numbers and the problems with post-discharge surveillance, it is not possible to make any conclusions.

Risk Management Framework

Limited training had been provided in 2003 by QH Risk Management Co-ordinator to BB Health Service District to assist staff to comply with the risk management policies but no formal training in Root Cause Analysis methodology was provided. No resources were allocated to maintain these policies. The DMS and DQDSU raised concerns with the District Executive that there was not sufficient funds to support these activities but no extra resources were provided.

There is no single committee delegated with the responsibility for clinical safety and quality. It was reported that there were too many committees, significant overlap of functions and potential for issues to 'fall through the cracks'. Further there was little evidence of any outcome of the preceding discussion or of any decisions made.

Prior to Dr Patel, there had been an electronic information system to support surgical audit data collection and reporting (OTAGO). Dr Patel ceased using this system and indicated to the DMS that it was no longer required. Dr Patel conducted monthly audits with junior medical staff, surgical consultant colleagues did not attend and there was little opportunity for peer review. It was reported that Dr Patel went to great lengths to prevent his patients and clinical management being reviewed by peers.

Incident Reporting

BBH had procedures in place for incident report and sentinel event reporting, approved in November 2004. Risk management procedures were initially approved in Feb 2002 and revised in November 2004.

DQDSU utilizes an Excel spreadsheet for the recording of clinical incident data – various reports are then produced which are currently of little value. BBH Health District is currently in the process of implementing the state-wide, web-based incident management information system (PRIME).

There was varied understanding by staff of what a reportable clinical incident was.

Barriers to reporting clinical incidents were:

- Little point reporting as nothing changed
- Leadership not actively encouraging reporting for 'learning'
- Lack of feedback of outcome to reporting person/unit
- Culture of blame and history of punitive approach to reporter
- Fear of reprisal
- Seen as nursing business
- Multiple forms

Findings and analysis
Clinical indicator reports are not embraced by clinicians

Risk Management Framework at BBH was examined. It was found that the clinical governance Committee Structure was complex and there was no single committee responsible for Safety and Quality Issues. Lack of follow through and flow of information when incidents or concerns were raised and feedback to staff required improvement

Incident reporting systems were in place, but there were problems with the availability of resources of the Safety and Quality Unit, staff training and support, lack of aggregated data reports to the executive to monitor safety and quality. No clear link with complaints management process and incident reporting.

Morbidity and Mortality audits
Little evidence of hospital wide mortality audit and departmental clinical audits were available, particularly in general surgery.

Review Team Recommendations:

Bundaberg Health Service District at local level

- Develop and implement a clinical governance framework which effectively tracks accountabilities for clinical performance, and is subject to regular compliance monitoring. QH should support this process by developing a state-wide clinical governance framework;
- Ensure that safety and quality is afforded priority in funder/provider contracts. This will require QH to examine health funding incentives;

- Ensure a plan to implement effective clinical incident and complaints management that is consistent with QH policy is developed. This should include implementation of the incident management information system (PRIME) with consideration of designated consumer liaison and patient safety officers to support the district;
- Establish a clear process for the multidisciplinary review and management of clinical incidents consistent with the QH Incident Management Policy;
- Ensure that a process is established for coded data on clinical outcomes (particularly complication codes) to be audited with input from clinicians;
- Consider the establishment of a single multidisciplinary committee to address patient safety and quality issues, monitor and evaluate actions and provide feedback to staff. District policies must clearly articulate the responsibilities and accountabilities of all clinical staff to report incidents; and
- Ensure the Measured Quality Indicators are followed up with the Measured Quality Program Team once 2004/05 data is available.

Queensland Health at a broader level:

- Develop, implement and support statistical process control and 'cusum' methodologies, to assist with monitoring individual clinician performance and clinical services in key clinical areas of practice;
- Provide input into the review processes of the ACHS specifically consideration to amend the current clinical indicator reporting and benchmarking to enhance validity and clinician acceptability;
- Further develop the Measured Quality Program to provide risk-adjusted and statistically valid performance data for outcomes of clinical services;
- Provide comprehensive training and support in clinical incident and complaints management to BBH health service district. This should included standardized Root Cause Analysis methodology; and
- Develop objective mechanisms for monitoring the ongoing clinical performance of medical practitioners to determine whether their practice is within acceptable standards. This may include periods of supervised practice or formative assessment.

HRC Conclusions
The Commission makes the following recommendations in relation to monitoring complication rates and infection rates:

At BBH Level

- It appears that there is no standard process for multidisciplinary peer review in place (either internally or externally) at BBH. A process for establishing peer review should be implemented and monitored at BBH;
- Implement a solution to the limitations identified in the report regarding the validity of reports to track clinical indicators;
- According to the review there was significant limitations to obtaining reliable data about infection rates in both short and long stay patients. The Commission that this situation be rectified to allow adequate collection and utilisation of this data.
- The Commission would like feedback on the current status of the implementation of PRIME, including any issues relating to resources and training;

- Implement a policy for accountability of the allocation of resources in managing change. For example, where deficiencies are identified by the District, what process is in place to appeal for further resources and how is the equitable distribution of resources ensured?
- Once again, the Commission believes that recommendations are required which recognise and deal with the culture in place at BBH. It appears that a culture exists at BBH which tolerates problems rather than addressing them. A cultural shift which supports open reporting must be implemented. Therefore, recommendations which address the communication, culture, leadership and change management process at BBH must be considered if lasting positive change is to occur.

Queensland Health at a wider level

- If a policy exists which outlines the procedure for revising and/or withdrawing clinical privileges it should be reviewed. If there is no policy in place which guides district manager's decisions in this regard, one should be implemented.

Issues not addressed in QH investigation

Premature discharge
HRC concerns
The HRC identified concerns in relation to the issues of early discharge and inadequate patient follow-up. The HRC in this regard will review the BBH's discharge and follow up policy and procedure documents and the availability of relevant resources.

Recommended action:
- HRC to review BBH cases that identify premature discharge as a complaint issue, to determine the significance of this issue.
- Discuss with independent adviser cases where premature discharge is a complaint issue;
- Request a copy of policy and procedure documents on discharge planning; and
- Following review of relevant evidence, consider what further action necessary.

Consent
HRC concerns
The HRC will also be looking at the processes that were in place at the BBH for obtaining patient consent and whether the patient consents obtained were appropriate.

Recommended action:
- HRC to review BBH cases where consent is a complaint issue to determine the significance of this issue;
- Discuss with independent adviser cases where lack of consent is a complaint issue;
- Request a copy of policy and procedure documents on consent processes; and
- Following review of relevant evidence, consider what further action necessary.

Pathology
HRC concerns
The HRC is also concerned by the number of complaints where the complainant was unclear about whether their surgery was undertaken due to the presence of disease. The HRC will be examining whether adequate diagnostic investigations were conducted at the BBH.

Recommended action:

- HRC to review BBH cases that identify lack of indicative pathology prior to surgery as a complaint issue, to determine the significance of this issue.
- Discuss with independent adviser cases where lack of indicative pathology is a complaint issue;
- Request a copy of policy and procedure documents on pre-operative processes (pathology); and
- Following review of relevant evidence, consider what further action necessary.