Bundaberg Hospital Commission of Inquiry

Statement of Michael Ian Cleary

Attachment MIC-17

QUEENSLAND HEALTH RESPONSE TO RECOMMENDATIONS CONTAINED IN THE MAHAR REPORT

1. Cardiac Services Planning

- Consideration is given a Statewide Cardiac Services plan to be developed by Queensland Health.

Actions to date:

- Queensland Health is working on a comprehensive state-wide plan with enhancement of services already begun, including $700,000 for the development of a heart failure service to be jointly managed by the Prince Charles and Royal Brisbane.

2. Access to Tertiary Care for Acute Coronary Syndrome

- Consideration is given to a review of patients awaiting transfer to cardiac services and those waiting for management of acute coronary syndromes.

Actions to date:

- Clinical Coordination Centres have been established in Brisbane and Townsville to allow an immediate point of contact to arrange appropriate urgent referrals.
- TPCH has established an internal process to monitor and where necessary escalate this issue when waiting times for urgent angiography exceeds the capacity to manage effectively.
- Collaboration between TPCH and Royal Brisbane & Women's Hospital (RBWH) has facilitated patients accessing care in a timely fashion across both sites.
- Additional funding ($1.4million) has been provided to TPCH to allow an additional 400 procedures to be undertaken annually.
- Additional funding has been provided to RBWH to allow an approximate additional 500 procedures to be undertaken annually.

3. Approach to new high cost therapies

- Recommend that a Standing Committee be established to look at new and ongoing technologies.

Actions to date:

- The establishment of a Standing committee will require further consideration to remain consistent with national standards as:

- The Commonwealth Department of Health has an infrastructure (Medical Services Advisory Committee) that undertakes this activity.
- Queensland Health has four members on this Committee who are able to provide advice back to the Department.
- The Technology Assessment Team exists within Queensland Health that provides advice to the Department on new and emerging technology.

4. Matching selection criteria and funding for ACIDs

Consideration is given to convening a specialist panel to determine appropriate selections criteria for ACIDs having regard to resources available and current medical evidence.

Actions to date:

- The Zonal Manager, Central Zone has convened a specialist clinical panel to review the selection criteria with a view to developing agreed clinical guidelines and selection criteria.
- Additional funding has been provided to TPCH to increase activity from 145 cases per year to 166 cases per year.

5. Sustainable Services and coordination of Cardiac Services between providers

- Recommend that the cardiac services provided between RBWH and TPCH be reviewed with a view to developing greater coordination/consultation of services across the two sites.

Action to date:

- The respective Directors of Cardiology at RBWH and TPCH are liaising closely in relation to coordination of clinical services.
- A proposal has been developed and submitted to the Zonal Manager, Central Zone to establish a unit to review and coordinate interventional cardiology across both sites.

6. Cardiac Surgical workload Distribution

- Consideration be given to creation of pooled waiting lists for public patients referred to TPCH for cardiac surgery.

Actions to date:

- Surgical allocations at TPCH have been revised so that new referrals are allocated to the surgeons with the shortest waiting list.

7. Standard of referral for Cardiac Services

- To improve the referrals and communication between Cardiologists and Cardiac Surgeons.

Action to date:

- The District has recently finalised the appointment of an Acting Director of Cardiac Surgery to follow the retirement of the existing Director. The Directors of Cardiology and Cardiac Surgery have agreed to establish appropriate communication and referral arrangements.
- TPCH has completely reviewed its referral processes. This involves the development of a comprehensive referral form which includes patient risk factors and morbidity screening. There is also a tracking process in place to monitor actions taken following referral.

8. Clinical Leadership

- Every effort should be made to appoint a world-class clinical leader to the TPCH as Director of Cardiology.

Actions to date:

- The formal appointment of Dr Darren Walters to the position of Director of Cardiology has been completed.

9. Waiting List Management

- A specialist has been convened to develop and implement guidelines including definition of categorisation for waiting lists for cardiological care across the state.

Actions to date:

- The Zonal Manager, Central Zone has convened a specialist clinical panel to develop agreed guidelines for the management of waiting lists used to monitor patients requiring angiographic procedures. Finalisation of the criteria is currently underway.

10. Date Management

- Recommend that appropriate data management systems for cardiac services be implemented.

Actions to date:

- TPCH has recently undertaken a comprehensive review of information services requirements within the District and is currently reviewing priorities against recommendations of this review.

Bundaberg Hospital Commission of Inquiry

Statement of Michael Ian Cleary

Attachment MIC-17A

EMAILED
DAN BERGIN
Copy SDLO, MCREDMS

Queensland Government
Queensland Health

EXECUTIVE SERVICES STAFF
MIN / DG / GMHS / DDGP&O / FILE
EMAIL:- MIN SDLO DLO EXDG
EMMC MCM

A BRIEFING TO THE A/SENIOR EXECUTIVE DIRECTOR HEALTH SERVICES DIRECTORATE

BRIEFING NOTE NO:	N/A
REQUESTED BY:	Senior District Liaison Officer, Queensland Health
DATE:	22 October 2004
PREPARED BY:	Dr Michael Cleary, Executive Director Medical Services, The Prince Charles Hospital Health Service District (TPCHHSD), contact 3350 8220
CONSULTATION WITH:	Ms Jenny Walsh, Nursing Director, Cardiology Program, TPCHHSD, contact 3212 5884
CLEARED BY:	Gloria Wallace, District Manager, TPCHHSD, contact 3350 8224
DEADLINE:	22 October 2004
SUBMITTED THROUGH:	Dan Bergin, Zonal Manager, Central Zone, contact 3234 0825
SUBJECT:	**Advice regarding patients who died whilst on the Waiting List at The Prince Charles Hospital**

COMMENTS A/SED HEALTH SERVICES:

DR JOHN SCOTT
A/Senior Executive Director
Health Services Directorate

/ /

PURPOSE:

To inform the Acting Senior Executive Director Health Services (A/SEDHS) of the details of patients raised by the Opposition Health Spokesman on Thursday 21 October 2004 who were said to have died whilst on the waiting list at The Prince Charles Hospital (TPCH) and inform the A/SEDHS of management strategies being used to address the cardiology waiting list for patients referred to TPCH for specialised cardiac procedures from other Queensland hospitals.

BACKGROUND:

Management Strategies

Patients are referred to TPCH for the management of acute coronary syndromes. Patients needing treatment are revascularized either by Percutaneous Coronary Intervention (PCI) or bypass surgery. A number of these patients are being treated at other Queensland Health hospitals. These patients are managed on a priority basis. This requires that the patient's clinical condition is assessed using a standardised clinical assessment tool and placed on an Interhospital Transfer Waiting List.

TPCH has a comprehensive process in place to manage the Interhospital Transfer Waiting List so that cases are treated on a clinical needs basis. The process has three components.

The specific arrangements for patients with Acute Coronary Syndromes is as follows:

- The District has a written protocol in place outlining the process to be followed.
- All cases are coordinated by the Nurse Manager for the Acute (after hours) or the Cardiac Catheter Lab Booking Office (during office hours).
- Written referrals together with ECG's and other investigations are requested from the referring hospital.
- Referrals are received and reviewed by the admitting Cardiology Registrar.
- Referrals are assessed using a clinical risk stratification tool (TIMI Score). This allows clinical priority to be determined.
- Decision regarding the prioritisation of cases is made using the TIMI Score, whether the patient is having specialised drug treatments and how long the patient has been waiting

At times of high demand for services there is an escalation process in place within the hospital. This process is summarised below:

1. Number of patients on the Interhospital Transfer Waiting List is less than nine:

    - Nurse Unit Mangers and Cardiology Registrars are alerted by the Bed Manager and a review of the clinical management of the existing inpatients occurs. Extra ward rounds are conducted and patients are assessed for possible discharge or transfer for a non-cardiology ward.

    - Prioritisation of existing inpatients with an evaluation of appropriateness of transfer back to referring hospital will be discussed with the treating consultant.

    - An internal review of bed availability is done hospital-wide. The appropriateness of placing cardiology patients into non-cardiology beds is examined.

2. Number of patients on the Interhospital Transfer Waiting List exceeds nine:

- The Director of Cardiology is briefed on the patient's clinical details and current status. The Director of Cardiology then contacts the Directors of Cardiology at the Royal Brisbane and Women's and Princess Alexandra Hospitals to assess if these hospitals are able to treat any of the patients on the Interhospital Transfer Waiting List.

3. Number of patients on the Interhospital Transfer Waiting List exceeds fifteen:

    - The Executive Director Medical Services (EDMS) is contacted and briefed on the situation. The EDMS contacts the EDMS at the Royal Brisbane and Women's and Princess Alexandra Hospitals to assess if these hospitals are able to treat any of the patients on the wait list.

    - The EDMS briefs the District Manager on the situation.

The Hospital has an effective bed management process in place.

- Each morning the Nurse Manager on duty advices the Program Management Teams and District Executive by email using a standard report of issues that arose overnight, current bed occupancy and expected admissions and discharges. If beds are available patients on the Inter Hospital Transfer Waiting List are scheduled for transfer.

- A hospital bed round conducted each day at 10:00 am. This round is attended by Program Nursing Directors, Nurse Managers and Unit Managers. At the conclusion of this round a daily bed plan is formulated and implemented. If further patients from the Inter Hospital Transfer Waiting List can be accommodated these are scheduled for transfer.

- Where issues arise where there is a supply/demand mismatch in relation to hospital beds, the EDNS and EDMS are contacted and assist with the resolutions of the issue.

Current issue:

Following notification of the limited details of the patients who died on waiting lists at TPCH, the District undertook a comprehensive process to identify the specific patients. This included running reports from HBCIS reviewing the waiting list and reviewing the Interhospital Transfer Waiting List

Eight of the nine patients notified to the District could be identified. It is noted that one of the eight patients identified had slight difficult different demographics to those that were provided.

There was one patients who could not be identified from the data provided.

A summary of the cases is outlined below:

Patient A:
71 year old female who died while being urgently transferred by the Royal Flying Doctor Service (RFDS) from the Intensive Care Unit (ICU) at Rockhampton Hospital to ICU at TPCH. No delays noted in care provided.

Patient B:
78 year old male died while being urgently transferred by RFDS from Bundaberg Hospital to TPCH. No delays noted in care.

Patient C:
88 year old female died prior to transfer. Transfer arranged for two days after original referral

Patient D:
64 year old man with multiple medical problems who died prior to transfer

Patient E:
80 year old male who died prior to transfer. Transfer arranged for three days after original referral

Patient F:
76 year old male who died while waiting for an elective procedure.

Patient G:
67 year old male died while waiting for an elective angiogram. Patient was listed as Category 1 and was scheduled to have the procedure within 30 days.

Patient H:
Unable to identify patient.

Patient I:
76 year old male who died while waiting for an elective angiogram. Patient had multiple medical problems and was reviewed by a cardiac surgeon who advised he was NOT a candidate for cardiac surgery.

Details of patients are outlined on Attachment 1.

KEY ISSUES:

Cardiac disease in Australia is a leading cause of death with approximately 30% of all deaths relating to cardiovascular disease.

Patients with cardiac disease have an incidence of sudden cardiac death. This incident relates to their underlying heart disease. It is therefore critical that waiting lists are actively managed and coordinated to minimise any adverse incidents. TPCH has a comprehensive waiting list management system in place to ensure that patients are prioritised appropriately as outlined above.

RELATED ISSUES:

- TPCHHSD formally investigated concerns that three specific patients died while waiting for treatment at TPCH in January 2004. The investigation report was provided to the then Acting General Manager Health Services.

- TPCHHSD is currently formally investigating concerns that two specific patients died while waiting for treatment at TPCH.
- It is noted that both of these formal investigations (established under the Health Services Act) were instigated by TPCHHSD as part of an internal quality and patient safety improvement process.

- TPCHHSD established a Mortality and Morbidity Review Committee to monitor patient safety issues within the District. This Committee reviews patient deaths reported to it through the District's Australian Incident Monitoring System (AIMS) and any other matters referred to it.

BENEFITS AND COSTS:

N/A

ACTIONS TAKEN/ REQUIRED:

That the A/Senior Executive Director Health Services note the contents of this brief.

ATTACHMENTS:

Details of Patients – Attachment 1.

Patient A

Background:

- 71 year old lady
- Impatient at Rockhampton Hospital
- Related medical problems
  - diabetes
  - high cholesterol
  - high blood pressure
  - chronic lung disease

14.07.2004

- Admitted Rockhampton with myocardial infarcts. Improved after initial treatment.

15.07.2004

- At 10:00am contacted TPCH to arrange transfer. Placed on Interhospital Transfer Waiting List.

15.07.04

- Subsequently became profoundly unwell and was admitted to ICU Rockhampton. Patient improved overnight.

16.07.2004

- At approximately 10:00am Rockhampton Hospital contacted TPCH who advised that they would arrange an ICU bed and advise of transfer arrangements as soon as possible.

- At approximately 11:00am TPCH advised Rockhampton Hospital that an ICU bed was available and that the patient should be transferred as soon as possible.

- At approximately 7:00pm when being transferred from Rockhampton Hospital to an RDFS aircraft, the patient suffered a catastrophic deterioration and was returned to Rockhampton Hospital for specialist care.

- At approximately 9:10pm died at Rockhampton Hospital despite active resuscitation.

Comment:

- Patient's care was appropriate in terms of the transfer arrangements and presentation.
- ICU bed arranged within one hour of initial contact.
- RFDS retrieval arranged for patient as a priority.
- This patient was reviewed by TPCH Mortality & Morbidity Review Committee on 4th August 2004, who noted situation and commented that:
- The patient had suffered a myocardial infarct with the background of diabetes and poor left ventricular function.
- Initial treatment and transfer were appropriate
- Patient was prioritised on basis of clinical urgency.

Patient B

Background:

- 78 year old man
- Inpatient at Bundaberg Hospital
- Related medical problems
  - heart disease
  - high cholesterol
  - previous heart attacks
  - chronic renal failure

29.04.2004

- Admitted to Bundaberg Hospital with myocardial infarct after 18 hours of chest pain at home.
- Treated with thrombolysis with improvement.

07.05.2004

- At approximately 2:30pm contacted TPCH who recommended transfer as soon as possible with a plan to perform an angiogram in the evening of 07.05.2004.

07.05.2004

- At approximately 5:00pm, while the RFDS still were transferring the patient (the RFDS team were still at the hospital when this occurred) he deteriorated and died.

Comment:

- This patient was reviewed by the Executive Director of Medical Services who considered that all arrangements were appropriate and transfer was arranged urgently. Note: Patient died 2 ½ hours after initial contact was made with TPCH.

- Patient care was appropriate in terms of transfer arrangements and prioritisation.

- RFDS retrieval arranged for patient as a priority

Patient C

Background:

- 88 year old lady
- Inpatient at Caboolture Hospital
- Related medical problems
  - high blood pressure
  - Paget's disease
  - Gastrointestinal bleeding
  - Chronic coronary artery disease
  - Haemoptysis

21.02.2004

- Admitted to Caboolture Hospital with a myocardial infarct after presenting at Kilcoy Hospital.

23.02.2004

- Fax sent to TPCH requesting further assessment.

24.02.2004

- Patient referral reviewed and patient listed for transfer to TPCH on 27.02.2004.

27.02.2004

- Caboolture Hospital advised patient deceased prior to transfer which was planned for that morning.

Comment:

- Patient died on the morning of his planned transfer.

Patient D

Background:

- 64 year old man
- Inpatient at Caboolture Hospital
- Related medical problems:
  - Ischaemic heart disease
  - Myocardial infarct (1995)
  - High blood pressure
  - High cholesterol
  - Stroke (1993)
  - Peripheral vascular disease
  - Below knee amputation - both legs
  - Aorto bi-femoral bypass

10.02.2004

- Admitted to Caboolture Hospital with myocardial infarct

11.02.2004

- At approximately 10:30am the Cardiology Registrar at TPCH contacted the medical officer at Caboolture Hospital. The TPCH registrar provided advice in relation to further treatments and requested the Caboolture Hospital fax a referral to TPCH on the specified fax number in line with the hospital protocol. At 8:30pm on 11.02.2004 the fax had still not been received.

12.02.2004

- The bookings office at TPCH contacted Caboolture Hospital to determine if the referral had been sent as it had not been received by the following morning.

- At approximately 10:00am the patient details were forwarded to the TPCH's cardiology registrar by email.

- Patient died at Caboolture in the early hours of the morning.

A review of the situation identified that the fax from Caboolture Hospital was sent to the wrong fax number at TPCH (The Cardiac Investigations Unit reception area rather than to the fax used for urgent bookings in the Bookings Office).

Comment:

- The communication error has been reviewed and a revised protocol established.
- The patient was referred to TPCH on 11.02.2004 and died in the early hours of the morning of 12.02.2004.
- Had the fax been received earlier, there would have been arrangements made for transfer of the patient during the 12.02.2004 or the subsequent days.
- The fact that the fax was delayed in reaching the Bookings Office did not materially affect the outcome, as the Bookings Office at TPCH followed this matter up with Caboolture Hospital as a priority the following morning.

Patient E

Background:

- 80 year old man
- Inpatient at Nambour Hospital
- Relevant medical problems:
  - Chronic obstructive lung disease
  - hearing impairment

19.02.2004

- Presented to Caloundra Hospital with chest pain, shortness of breath and a cough. Treated for heart failure and discharged home 23.02.2004.

24.02.2004

- Admitted to Nambour Hospital with a myocardial infarct. He improved following treatment.

27.02.2004

- Referred to TPCH for care and assessment. Booked for procedure 01.03.2004

- Patient wished to stay at Nambour until his daughter came up to care for his wife (who has dementia).

- Patient would not be transferred over the weekend as elective angiography is not undertaken on Saturday and Sunday. Scheduled for transfer Monday 01.03.2004.

- Patient deceased prior to transfer on 01.03.2004.

Assessment:

- This patient was reviewed by the Executive Director Medical Services who considered transfer arrangements appropriate.

- Patient died on the day of transfer.

Patient F

Background

- 76 year old man
- Inpatient at Mackay Hospital
- Related medical problems
    - End stage heart failure
    - Pneumonia
    - Sick sinus syndrome (pacemaker inserted)
    - Acute valve replacement

29.06.2004

- Referral received from Mackay Hospital for an opinion regarding further management.
- Review by cardiologist however cardiologist did not document date of review or a clear management plan or categorise the patient other than "elective".
- Staff in bookings Office planned an elective admission "on Wednesday" as requested. Booking made for 18.08.2004.

09.07.2004

- Second referral received from Mackay Hospital by a second cardiologist who arranged a private OPD appointment for 18.08.2004 (Note to second cardiologist did not consider that transfer for an angiogram was required.

12.07.2004

- Patient died at Mackay Hospital. The chart in Mackay contain a "Not for Resuscitation" order.

Comment:

- Patient was referred for an opinion regarding appropriate further management.
- Patient booked for an elective procedure.

Patient G

Background:

- 67 year old man
- outpatient of TPCH
- Related medical problems:
  - previous cardiac surgery (1995)
  - diabetes
  - high cholesterol

21.07.2004

- Referred to TPCH for OPD cardiology review.

24.08.2004

- Reviewed in OPD where noted he had been well for 7 years following his previous cardiac surgery. Recently he had experienced some shortness of breath and chest tightness at work.

- Listed as Category 1 patient. Angiogram booked for 24.09.2004.

13.09.2004

- Out of hospital cardia arrest at home. QAS responded but was not able to be resuscitated.

Comment:

- Patient was reviewed by TPCH Mortality & Morbidity Review Committee on the 13th October 2004. They noted the situation and commented that:

  - Long history of ischemic heart disease
  - Planned treatment in line with hospital procedures
  - Unexpected death at home

- Patient care was appropriate in terms of prioritisation and planning of procedure.

Patient I

Background:

- 76 year old man
- Outpatient at TPCH
- Relevant medical problems:
  - Ischemic heart disease
  - Cardiomyopathy
  - Diabetes
  - Acute stenosis
  - High blood pressure
  - High cholesterol
  - Leg ulcers
  - Previous cardiac surgery
  - Peripheral vascular disease
  - Protein loosing nephropathy

28.11.2003 to 16.12.2003

- Admitted to TPCH with heart failure – Note: Long inpatient stay.

09.12.2003

- Booked for elective angiogram as Category 2 patient (booked for 20.04.2004).

06.01.2004 to 13.01.2004

- Admitted to TPCH with myocardial ischaemia. Cardiac surgeons reviewed patient and advised he was NOT a candidate for cardiac surgery.

10.02.2004 to 16.02.2004

- Admitted to TPCH with shortness of breath, cough and thought to have a chest infection complicated by heart failure.

09.04.2004

- Died at home

Comment:

- Patient was a well known patient at TPCH with multiple medical problems.
- Between the time he was booked for an angiogram and the day of his death, he had 3 prolonged inpatient admissions.
- The cardiac surgeon had reviewed the patient and advised he was NOT a candidate for surgery before he had had an angiogram.
- Although he was scheduled for an angiogram at 4 months from being booked (not within the recommended 3 month period), no concerns about this were raised by cardiologists. This is probably because he was not a candidate for surgery.
- Patient was listed as a Category 2 patient however, given his clinical background and the fact he was not a candidate for surgery, he may have been of lesser urgency i.e. Category 3 (the District is not able to confirm this as his treating specialist has taken urgent sick leave and is currently in hospital).

Bundaberg Hospital Commission of Inquiry

Statement of Michael Ian Cleary

Attachment MIC-17B

PAH ODM

32340583

ORIGINAL GIVEN TO DR A GALBRAITH 11/8 AT 12.30 PM TO PHONOS TO DR WALTERS

The Prince Charles Hospital
Health Service District

FILE COPY

Enquiries to: Peter Palmore
Director, Human Resources
Telephone: 3350 8841
Facsimile: 3350 8915
Our Ref:

Dr Darren Walters
Senior Medical Officer
Cardiac Adult Medicine
The Prince Charles Hospital Health Service District

Dear Dr Walters

I am in receipt of a report relating to an incident that is alleged to have occurred on Sunday 9th February 2003. Specifically, it is alleged that:

- you obtained a 'Serolimus-Eluting Stent device' from the Holy Spirit Northside Hospital.
- you utilised this particular stent in a procedure performed within the facilities of The Prince Charles Hospital.

It is to be noted that these alleged actions contravene my written direction of 28 August 2002 indicating that "...under no circumstances has approval been granted for the use of Sirolimus-Eluting Stent devices" (see attached copy).

If proven, these actions may constitute a breach of the *Queensland Health Code of Conduct*, Principle 1, 'Respect for the law and system of government'. After giving careful consideration to all evidence available to me so far in respect of these allegations, it appears that you may be liable for disciplinary action pursuant to section 87(1)(d) and / or (f) of the *Public Service Act 1996* in that you appear to have contravened, without reasonable excuse, a direction given to you by a person with authority to give the direction.

In accordance with the principles of natural justice, no determination has been made, or will be made, until you have had the opportunity to formally respond to the allegations.

Accordingly, you are required to reply to these allegations, in writing, within fourteen (14) days of the receipt of this letter, by stating whether you admit or deny the allegations made against you and by furnishing any explanation in relation to this matter.

(3)

If you do not respond, or if your response is received later than fourteen (14) days from the date of receipt of this letter, I will make a decision on the material currently available to me.

The Employee Assistance Service offers a confidential counselling service to all employees of Queensland Health and you may wish to discuss with them your situation. To make an initial appointment, please contact Megan Kreis on telephone number 3212 5691.

Should you have any queries in relation to this process please do not hesitate to contact Peter Pamore, Director, Human Resources on telephone number 3350 8841.

Yours sincerely

Deb Podbury
District Manager
The Prince Charles Hospital Health Service District

10/2./2003

23 rd February 2003.

Ms Deb Podbury
District Manager
The Prince Charles Hospital
Health Service District
Rode Rd
Chermside. 4032.

Dear Ms Podury,

I am in receipt of your letter detailing an alleged incident that occurred Sunday 9th February 2003. Specifically alleging that:
I obtained a Sirolimus –Eluting Stent device" from the Holy Spirit Northside Hospital and utilized this in a procedure performed within the facilities of the Prince Charles Hospital.
It is alleged that this act contravened a direction given to me by you in a Memorandum dated 28/8/02.

I would like to say that I was shocked and anxious that the allegation had been made.

The events that occurred on that day were as follows.
The Emergency Room House Officer contacted me at home early that Sunday morning. It was my day-off and I was not rostered on call. The wife of a longstanding colleague presented unwell with chest pain. The Resident officer was unable to determine the diagnosis with certainty. The Night Registrar was unable to attend directly being "busy" elsewhere. I was specifically requested to attend the patient by my colleague who was clearly concerned regarding his wife's condition. The patient was fully privately insured. I attended her in the Coronary Care and determined her to be critically ill with an ST elevation acute myocardial infarction. I immediately requested the Catheter Lab to be activated. I performed emergency infarct angioplasty. The patient was diabetic. T o provide the best indicated medical practice available and to afford the patient the best possible outcome, I made a request to the Nurse Manager to borrow a drug eluting stent form the Holy Spirit hospital. There has been frequent exchange of stock, equipment and staff between the hospitals since it opened. In the past I have transferred patients to Holy Spirit Northside, as suggested by the Medical Superintendent Dr Michael Cleary, so they could receive The Sirolimus stent. In the clinical setting of a critically ill patient, it was my opinion that a transfer would result in an unreasonable delay and place the patient at increased risk. For this reason the option was not pursued. I was not aware my actions could be considered illegal and I was transparent in my activities. The stent was implanted and the patient has done well as a result. Johnson & Johnson recovered the cost of the stent directly from the Health fund. In summary I rendered life saving therapy to a critically ill patient in the setting of an emergency and performed best medical practice at no cost to the hospital. (Refer to Stable, Mission Statement).

(6)

With respect to the directive dated 28 August 2002.
This is a memorandum that I had considered be well dated and invalidated by your subsequent directions. I have been working in concert with you and Johnson & Johnson at a State level via the Queensland Angioplasty Group, and at a National Level with the representatives of the Commonwealth Medical Advisory Group to progress on this issue. I was my impression that your original direction had progressed.

The reason that I thought your directive was no longer a current are as follows.

I had received no direct communication from you since attached email 11 November 02. I was also in receipt of an email from Dr Prado (Assistant Executive Director of Medical Services) dated 13 November 2002 that had outlined his belief that policy change in relation to this matter, was on the horizon.

Since then I received a copy of a letter dated 9 January 2003 notifying the Investigators (including myself) that the ENDEVOUR trial of the E-Sirolimus (ABT-m578) stent had been approved by the Ethics Committee. The process for approval is required to be signed –off by the District Manager and I was repeatedly assured that you were happy for us to proceed with the implantation of these drug-eluting stents. This is a multi center registry.

I received a copy of a letter dated 3 February 2003, notifying the investigators (including myself) that the " marketing 2 Registry of the use of Cypher Sirolimus-Eluting stents in **public patients"** was also approved. The process for approval is required to be signed – off by the District Manager and I was repeatedly assured that you were happy for us to proceed with the implantation of these drug-eluting stents. This is a multi center registry.

Since the memorandum dated 28 August other correspondence had also rendered the memorandum as you had sent it as not current in my understanding.
The Commonwealth Medical Services Advisory Committee had in-fact met in June 2002 and determined that the results of long term clinical trials and follow up data was available and this showed an unequivocal benefit from this new technology.
The Therapeutic Goods and Administration had approved the stents and they were freely available to patients. They are the single most common stent placed in private practice Australia wide.
From our discussions dated 11 November 2002 via email you acknowledged that access for public patients to this newer treatment was particularly "related to cost".
This was acknowledged and we in the Cardiology community lobbied successfully to have a Registry created and funded by Johnson & Johnson to specifically allow some equity of access access to this treatment for **public**, i.e. "non-insured " patients. This is a marketing Registry of limited scientific merit designed to help bridge the gap between public and private health care in this area. Implantation of these stents in private patients has continued unhindered in other hospitals as near as the Royal Brisbane Hospital and

Princess Alexandra Hospital.Again leading me to make a reasonable assumption about my ability to treat patients with the stent.

I did not seek to enroll the patient in the trials though I could have, simply because the patient was privately insured and funded by her insurance company for the treatment. I thought it might, **unnecessarily deprive a public patient** of their opportunity for enrolment, as numbers for entry into the registry are limited. I was under the impression that this type of patient was not the type of patient who should be enrolled in the trial. (See trial protocol). I was attempting to ensure equity of access without imparting a cost burden to the hospital.

Further it had been the express policy of the Executive Director of Medical Services, Dr Cleary to seek to encourage privately insured patients to utilize their insurance and be admitted privately when in the Prince Charles Hospital. This increased hospital revenue. It also ensured that in the setting of weekly rationing of resources, public patients would not unnecessarily be deprived of appropriate care by a privately insured patient who elected to "go public".

In the setting of a life-threatening emergency, I had to synthesize all of this information and place the life of the patient at the highest priority.

In addition, having just returned from holidays I was thrust into a situation in which the Director of Cardiology had been taken unexpectedly ill. He was handling the matter of the drug eluting stents personally. An Acting Director who was on holidays was filling this role. An Acting- Acting Director was in place for less than a week who had no intimate knowledge of the issue. The usual lines of communication from executive to the coal-face of clinical practice were severely disrupted over an extended period.

I have at all times co-operated fully with executive directives. I have demonstrated an ability to work with administration to progress the introduction of new treatments and technologies. I worked with the Cardiac catheter laboratory to provide a basis for business and health planning.

Since this case I have put in further drug-stents in a public patient as part of the Endevour trial. This did not draw any comment.

I feel that I have been a victim of misunderstanding. I feel that clear direction had not been provided in an up to date and timely fashion on this issue. This had lead me to make a reasonable assumption . I would respectfully request that a clear directive be made as to in whom these stents might be placed. Can they be implanted in both public and private patients? Are they to be implanted in trial patients alone? Can private patients enter the public registry? Is there a possibility of implanting these stents in a patient whom for reasons of confidentiality or otherwise decline to enter the registry but would still wish to receive the treatment? These questions need to be clearly addressed and place the memorandum dated 28 August 2002 as a directive that is no longer relevant or valid in its original form.

There is a misunderstanding in this situation related to a dated memorandum that had been contradicted by your own actions. This was clearly an issue that was and is, in a state of considerable flux. This led me to make reasonable assumptions about my ability to deliver the best care to my patient in an emergency setting. A setting that to my mind would constitute extra ordinary circumstances. This matter could have been resolved without need to resort to an allegation that a breach of the Code of Conduct had occurred. I believe that the above response shows that I did not intentionally contravene a current directive.

I would hope that with the principles of natural justice a determination would be made that I did **not intentionally, without reasonably excuse**, contravene a direction give to me by a person with the authority to give that direction. I remain hopeful that my excellent record of service to Queens land Health and my professional reputation remain untarnished by this unfortunate episode.

I believe that satisfactory resolution of this issue can be achieved on the conditions that:
-My explanation be found acceptable.
-It is found that **I have not** breached the Code of Conduct or found to be of diminished professional competence.
-I not be the subject of disciplinary action.
-Negative, adverse or unfavorable remarks not be entered on my personal record in relation to this matter.
-I not be the subject of future punitive or disciplinary action in relation to this matter.
-My continued employment in Queensland Health and at The Prince Charles Hospital not is placed in doubt as a result of the incident.

I am of the firm belief that this matter can be settled to the satisfaction of both parties so that we may continue to work together to achieve our mutual goals of providing the best possible medical care to our patients in a fiscally responsible fashion.

Yours Sincerely,

Darren Walters

PAH ODM Hand-delivered to office.
24/2/03.

The Prince Charles Hospital
Health Service District

Queensland Government

Queensland Health

Enquiries to: Deb Podbury
District Manager
Telephone: 3350 8224
Facsimile: 3350 8825
Our Ref: DP:jg

Dr Darren Walters
Senior Medical Officer
Cardiac Adult Medicine
The Prince Charles Hospital Health Service District

Dear Dr Walters

I refer to my letter of 10 February 2003, and to our subsequent discussion on 22 February 2003 in relation to an incident that is alleged to have occurred on Sunday 9th February 2003 relating to the use of a Serolimus-Eluting Stent device.

You will recall that I was particularly concerned with the allegations made as they appeared to contravene my written direction of 28 August 2002 in relation to the use of Sirolimus-Eluting Stent devices.

I note from both your formal response to my letter and from our discussion that you do not deny using the device. However, I understand that you consider there were specific and extenuating circumstances that led to your decision to utilise the particular stent in question. These include:

- Confusion in relation to the position of the District in relation to the procedure; and
- The serious nature of the illness and the timeframe in which to provide appropriate care.

As we discussed, there are certain requirements and standards of behaviour to be achieved by all staff employed within Queensland Health. I understand that you are aware of this, and are committed to work within these requirements and standards.

I understand the circumstances that led to your decision and I accept that there were significant mitigating factors. However, as discussed, I do not believe that there should have been confusion in relation to my instruction regarding the use of these stents or that my actions could have led you to form this view. Notwithstanding this, and based on your response and the discussion held with you, I have decided not to pursue any further action in relation to this issue. Accordingly no disciplinary action will be taken against you in this matter and no record of this issue will be maintained on your personnel file. I consider this matter to be now closed.

(10)

As we discussed, I request that in future if there is an issue that you are unsure of in relation to your work practice, that you seek clarification from an authorised senior person within the District.

I would like to thank you for meeting with me and I look forward to a positive working relationship in the future.

Should you have any queries in relation to this issue, please do not hesitate to contact Peter Patmore, Director, Human Resources (07 3350 8841) or myself at your convenience.

Yours sincerely

Deb Podbury
District Manager
The Prince Charles Hospital Health Service District

24/2/2003

MEMORANDUM

Queensland Government
Queensland Health

The Prince Charles Hospital
Health Service District
Rode Road, Chermside Q 4032

To: Dr G Stafford
Chair Cardiac Services
Dr N Bett
Director Cardiology
Mr P Lee
Nursing Director, Cardiac Servicews

Copies To: Ms C Burns
Executive Director Nursing Services
Dr M Cleary
Executive Director Medical Services

From: Deb Podbury
District Manager

Tel No 3350 8224

Fax No.: 3350 8825

Date: 28 August 2002

File Ref: M02-102 05.01.8
DP:jg

Subject: **Drug Eluting Stents - Sirolimus**

I wish to inform relevant staff that under no circumstances has approval been granted for the use of Sirolimus-Eluting Stent devices.

The current recommendation from the Commonwealth Medical Services Advisory Committee (February 2002) recommends that in the absence of long term clinical trial follow up data the use of treated stents remains essentially experimental and as such should be subject to Ethics Committee approval.

We are awaiting further advice from Queensland Health in relation to this matter.

Deb Podbury
District Manager

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Bundaberg Hospital Commission of Inquiry

Statement of Michael Ian Cleary

Attachment MIC-18

Hi Josh

Queensland Government
Queensland Health

MEMORANDUM

To:	Dr Peter Pohlner, Cardiac Surgeon, The Prince Charles Hospital		
Copies to:	Dr Michael Cleary, Executive Director Medical Services Peter Patmore, Director Human Resource Services		
From:	Deb Podbury District Manager, TPCHHSD	**Contact No:** **Fax No:**	07 3350 8224 07 3350 8825
Subject:	Alleged Breach of Code of Conduct		
Folio:	M03-086		

I refer to your memorandum of 2 July 2003 relating to the scheduling of a patient and I apologise if I did not clarify appropriately the specific details of the alleged breach of the Queensland health Code of Conduct 2003.

Please find attached copies of a formal memorandum from Dr Michael Cleary and an email from myself, both of which I believe would be considered as formal directives in relation to the "non-approval" of the procedure relating to this patient.

In light of these directions, I believe your decisions around scheduling this procedure and discussions with the patient's parents were a breach of these formal directives. Principle 1.3 of the Code of Conduct provides that all *Queensland Health staff must comply with all reasonable, lawful directions given by a staff member in authority*, and I consider that your actions may not have been consistent with this Principle.

Whilst I do not propose to take any further action in relation to this matter, I do require you acknowledge that it is unacceptable to wilfully disregard a lawful instruction.

In terms of the services provided by this District, I would like to further clarify that any decision in relation to the introduction of expanded or new services within this District rests with the District Manager. However, I would be very happy to develop with clinicians a clear policy and process in relation to approval for service expansion and/or introduction of new service/technologies.

I am happy to meet with you to clarify any issues you may have in relation to this matter.

Deb Podbury
District Manager
The Prince Charles Hospital Health Service District

8/7/03

Attachments:
1. Memo from Dr Michael Cleary, Executive Director Medical Services dated 20th June 2003
2. Email from Deb Podbury, District Manager dated 24th June, 2003

MEMORANDUM

Queensland Government
Queensland Health

The Prince Charles Hospital
Health Service District
Rode Road, Chermside Q 4032

To: Ms D Podbury, District Manager TPCHHSD

Copies To: Dr M Cleary, EDMS
Ms C Burns, EDNS
Dr G Stafford, Chair Cardiac Services

From: Dr P Pohlner, Cardiac Surgeon **Tel No:** 3350 8024
Fax No: 3350 8651

Date: 2 July 2003 **File Ref:**

Subject: **Alleged breach of Code of Conduct**

Following your phone call of 30.06.2003;
I am puzzled how, as you alleged, I "breached the Code of Conduct" in relation to scheduling Jacob Norton for operation on 03.07.2003.

I would be grateful if you would clarify how the alleged "breach" occurred, and the implications for the patient, his family, and myself as a result.

In order to avoid further potential procedural pitfalls, we as clinical health providers, together with administrators, need to understand and fulfil due process, if that is the issue, to facilitate optimal patient care.

P. Pohlner

Peter G POHLNER
Cardiac Surgeon

MEMORANDUM

Queensland Government
Queensland Health

THE PRINCE CHARLES HOSPITAL
HEALTH SERVICE DISTRICT

To: Dr Pohlner, Cardiac Surgeon
Dr Justo, Paediatric Cardiologist
Dr Haas, Staff Specialist, Paediatric ICU
Ms M Wheeldon, CNM Critical Care

Copies to: Dr J Murray, Chair, Critical Care Services
Dr G Stafford, Chair, Cardiac Services
Dr A Galbraith, A/Director Cardiology
Dr D Mullany, Director ICU

From: Dr Michael Cleary
Executive Director Medical Services

Contact No: (07) 3350 8220
Fax No: (07) 3350 8867

Subject: Proposed use of an LVAD in a paediatric cardiac case

Date: 20 June 2003

File Ref: MC:cm 50

I note that a two-month-old child P429 was booked for a Ross Procedure on the 19th June 2003.

I am advised that there is a possibility that this child may require a left ventricular assist device (LVAD) post-operatively and that this care would be provided in the Paediatric Intensive Care Unit (PICU). This practice is outside the current scope of practice in Paediatric Intensive Care Unit at The Prince Charles Hospital.

On a previous occasion I advised that:

1. Paediatric Intensive Care Unit at The Prince Charles Hospital was not delineated to provide post- operative extracorporeal cardio-pulmonary support services (eg LVAD).

2. Paediatric patients requiring limited post-operative support of this type can be maintained in the operating theatre on bypass for short periods.

3. Paediatric patients that may require post-operative extracorporeal cardio-pulmonary support (eg LVAD), are to be referred to interstate units at an appropriate time (based on clinical need) for management.

I also indicated that should the paediatric team believe that post operative extracorporeal cardio-pulmonary support services be evaluated that a formal business case be developed for consideration by the District Executive.

An urgent meeting was arranged to discuss this specific case on the 18th June 2003 with Dr Haas, Dr Pohlner, Dr Mullany, Dr Cleary, Ms Burns, Dr Murray and Dr Galbraith. An apology was received from Dr R Justo.

The following information was provided at the meeting.

1. The Prince Charles Hospital has not undertaken an LVAD procedure in a paediatric patient. I note that Dr Pohlner described how the device was used over 10 years ago, and before the new generation of LVAD's became available.

2. The procedure represents an extension to the existing paediatric service provided at TPCH and as such represents a new service for paediatric patients.

3. The impact on the services at the hospital would be significant if the procedure were to proceed and may necessitate cancellation of all but emergency cardiac surgery while the child was being treated, because of the demands on perfusionist staff.

4. Protocols, policies and work unit instructions were not in place in PICU or other areas of the hospital to support the use of the LVAD in the paediatric environment.

5. Staff training in the Paediatric Intensive Care Unit, and in the operating theatre in relation to this service has not been sustained, developed or was not in place.

6. The LVAD had not been maintained in optimal condition and was now more than 15 years old. I was advised that when it was last used in 1995/96 there were significant problems with its use.

Because of the above the procedure scheduled on 19/6/03 was postponed until further notice.

In reviewing this matter three principles were considered:

1. Did the proposed care constitute a change in the scope of services provided at TPCH.

2. Are the proposed changes consistent with accepted clinical practices?

3. Are policies, procedures and work unit guidelines including appropriate consent procedures in place to support patient care?

I am concerned that:

1. Staff will not be indemnified in relation to this procedure.

2. That formal advice in relation to the proposed procedure was not provided in advance of the patient being booked for the procedure. The timeframe to allow for an appropriate review of the circumstances for paediatrics was therefore limited.

In conclusion

1. The clinical management of this specific patient must be made in the context of TPCH existing policy arrangements and be based on a recognition that TPCH is not designated to provide post- operative LVAD support to paediatric patients. Given this position, I recommend that the patient should be referred to an interstate unit as soon as possible if a procedure is contemplated that could result in the child requiring an LVAD post operatively.

2. That I support a proposal being developed for submission to the General Manager Health Services, Queensland Health for the establishment of a Paediatric LVAD Service.

I look forward to further progression of this issue with you as a matter of urgency.

Michael Cleary
Executive Director Medical Services

19th June 2003

From: Deb Podbury
To: Haas, Nikolaus; Justo, Robert; Pohlner, Peter
Date: Tue, Jun 24, 2003 5:07 pm
Subject: Introduction of Service

Rob, Peter, Nik

I acknowledge the Business Case and your work on its development to date.

I have discussed this issue with the Central Zone Manager and will be discussing it further with Dr Steve Buckland, General Manager Health Services, tomorrow. The Executive Director Medical Services and Executive Director Nursing Services will support you in any further preparatory work required in relation to the further development of the Business Case and approval process.

I wish to reconfirm Dr Cleary's indication to you that until such time as the Business Case, training and protocols are in place, the introduction of this service is not approved.

If you wish to discuss this further I will make myself available to meet with you.

Deb

CC: Burns, Cheryl; Cleary, Michael; Phillips, Suzanne