(290A)

**QUEENSLAND**

***COMMISSIONS OF INQUIRY ACT 1950***

**BUNDABERG HOSPITAL COMMISSION OF INQUIRY**

**STATEMENT OF JOHN GREGORY WAKEFIELD**

1) I, **JOHN GREGORY WAKEFIELD, Executive Director of the Patient Safety Centre,** of c/- Block 6, Royal Brisbane Hospital, Herston in the State of Queensland, acknowledge that this written statement by me is true to the best of my knowledge and belief.

2) This statement is made without prior knowledge of any evidence or information held by the Inquiry which is potentially adverse to me and in the expectation that I will be afforded procedural fairness should any adverse allegation be raised against me

## A MY EXPERIENCE

3) A copy of my Curriculum Vitae is **ATTACHMENT 'JGW1'**.

4) I have had 17 years experience as a clinician and medical administrator in the public and private sector both in Australia and overseas. My specific experience in patient safety over includes:

   a) As Deputy Director of Medical Services at the Princess Alexandra Hospital ("PAH") between July 2001 and May 2004, I co-developed a Patient Safety System. The system provided a coordinated and transparent approach to the identification of patient safety risks and implementation of corrective actions.

   b) Fellowship with the Veterans Health Administration ("VHA") National Centre for Patient Safety ("NCPS") in the United States from January to April 2004. The VHA are recognised as world leaders in improving patient safety. I undertook the fellowship to learn more about the challenges in implementing a safety system in the largest public healthcare system in the United States. The VHA is approximately 4 times the size of Queensland Health ("QH") During this time, I worked on a variety of projects including Correct Site Surgery, Medical Team Training, Patient Safety for Leadership, Bar-Code Medication Systems, Patient Safety Curriculum, RCA Training and HFMEA.

   c) Attending several courses run by the VHA in the United States and Australia. I provided support, including acting as a facilitator in group exercises, for the VHA in a Root Cause Analysis ("RCA") training program it ran for the

Australian Council for Safety and Quality in Healthcare ("ACSQH"). RCA is a multi-disciplinary team-based systems analysis of a serious event

d) Director of Safety, Quality and Risk Management at the PAH between June 2004 and November 2004.

5) In May 2005, I was permanently appointed to the position of Executive Director of QH's Patient Safety Centre ("PSC") **ATTACHMENT 'JGW2'** is a copy of the position description for the position of Executive Director of the PSC. It sets out my responsibilities.

## B THE PROBLEM THAT NEEDS TO BE ADDRESSED

6) Improving patient safety is a major national and international health reform agenda.

7) Despite the fact that most health care is delivered safely, large studies in many first world countries, including the landmark "To Err is Human" report from the Institute of Medicine in the United States in 1999, have highlighted the unacceptable rate of adverse events in healthcare .

8) The Quality in Australian HealthCare Study ("QAHCS") was published in 1995. It was based on investigations in various South Australian and New South Wales Hospitals. It found:

   a) 16.6% of patients that are admitted to Australian hospitals are harmed as a result of the health care that they receive This harm is often referred to as an adverse event.

   b) Half of these adverse events are considered preventable.

   c) 75% of adverse events are due to human error.

9) It is estimated that 50,000 patients suffer a permanent disability and 18,000 preventable deaths occur per annum in Australia as a result of adverse events.

10) The direct cost of adverse events (that is, patient harm) in Australia is estimated to be $4 billion per annum

11) There is no evidence to suggest that the Queensland public health system is any better or worse than any other health care system in the first world in relation to preventable patient harm.

### The Major Causes of Patient Harm

12) QHACS and other studies have found the top five causes of harm to patients as a result of adverse events are:

   a) Medication adverse events

b) Pressure ulcers

c) Surgical complications

d) Health care associated infections

e) Falls

**The Major Contributing Factors to Patient Harm**

13) The major underlying factors contributing to adverse events identified in the QAHCS include:

a) Inadequate communication with patients and between healthcare providers. Examples include absence of structured medical handover and failure to provide a discharge summary.

b) Lack of awareness by clinicians of the risks of healthcare interventions.

c) Acceptance of poor outcomes as an inevitable consequence of healthcare by clinicians. This is sometimes referred to as "normalisation of deviance".

d) Work designs that do not allow for human failings. Work designs focus on policy and procedure instead of engineering safety into systems to reduce reliance on memory and vigilance

e) Lack of standardisation of key processes and equipment. An example of this would be the use of six different infusion pumps in the same hospital with six differing methods of programming and orientation requirements.

f) Lack of standards. The absence of standards around many key clinical processes leads to marked variation in practice.

g) Unclear roles and responsibilities. Many errors are caused when orientation, education and supervision fails to establish clear accountabilities for clinicians.

h) Lack of real leadership commitment to safety: Whilst the performance of leadership is assessed only on activity and budget, safety will not receive leadership priority.

i) Patient Safety not being seen as a priority or a high risk to the organisation: In aviation, safety is 'mission critical'. In other words, failure threatens all passengers, crew and therefore business survival. In health, harm is often seen as an inevitable consequence of healthcare and safety systems as an optional extra. The 'icing on the cake'.

## C WHAT WORKS IN HEALTHCARE TO IMPROVE SAFETY

### Lessons from Other High Risk Organisations

14) Other high-risk organisations ("HROs"), such as aviation, mining and nuclear power have dramatically improved safety over the past thirty years by developing and applying an understanding of how "human factors" affect performance. "Human factors" is a relatively new science addressing how humans interact with each-other and their work environments

15) Strategies used successfully by HROs, and more recently being applied to healthcare, aim to develop an organisational culture of safety. These include:

a) Crew Resource Management (Team Training) and a focus on effective communications, for example, structured pre-operative briefings, debriefings and patient handovers.

b) Human factors work design including using:

i) "Forcing functions". These are engineered barriers making it difficult to do the wrong thing. For example, providing pre-diluted potassium so that concentrated potassium cannot be given intravenously in error.

ii) 'Knowledge in the world'. Providing information, policy, procedure or other decision support that is readily accessible where the clinical decision is made. For example, warfarin bedside dosing guidelines or decision support linked to electronic prescribing. These are also referred to as 'cognitive aids'.

iii) Standard operating procedures for key high risk procedures. For example, a standard checking and marking process to prevent wrong site, side or patient surgeries.

iv) Simplifying and standardising key processes. An example would include using the same medication chart in every hospital in Queensland.

v) Redundancy: This means having more than one fail-safe in place to trap errors For example, aeroplanes always have one more engine than is required to fly.

vi) Simulation. With modern high-fidelity simulators, it is possible to recreate real-life situations for individuals and teams to gain experience and have performance assessed in a 'safe' environment. Commercial pilots must pass an annual simulator competence test to continue to fly.

vii) Incident and 'near-miss' reporting systems focussed on learning not punishment. An example is the aviation reporting system which guarantees no action by the employer against any employee that reports an incident or near miss.

viii) Legislation to provide protection for staff involved in reporting serious incidents and privilege from disclosure for the team conducting the analysis. This does not remove individual accountability in coronial, civil or criminal matters. However, it does provide for a 'safe' place for staff to contribute to learning and prevention. Aviation and recently rail accident investigations are protected by this legislation in Queensland. Increasingly, jurisdictions in Australia and overseas are passing this legislation for healthcare. New South Wales is the most recent example, as a direct result of a recommendation from the Walker Inquiry into the Western Sydney Area Health Service failures.

**Experience in Healthcare**

16) It is not possible to eliminate all medical errors as humans will always make errors. Therefore, the goal for patient safety is to minimise preventable patient harm caused by healthcare. The focus is on creating systems that trap errors before they lead to harm

17) Elimination of litigation is not the goal of patient safety as only 2% of adverse events ever result in litigation.

18) The prevailing method healthcare managers (and often professional peers) in first world countries have used (and continues to influence current systems) in dealing with adverse events in the health system is to blame and punish the individual. Not only has this failed to address the problems, it has created a culture of fear, where staff are afraid to report when things go wrong. This precludes healthcare organisations from identifying vulnerable systems that pre-dispose to harm.

19) The evidence suggests that most adverse events are caused by a series of system errors that set up a competent clinician to fail.

20) Over the last five years, health systems in the first world have started to move towards adverse event analysis for learning rather than punishment. Accordingly, investigations into adverse events are increasingly conducted as a systems analysis that looks at 'what happened?', 'why did it happen?' and 'what can be done to prevent it?' rather than 'who was responsible?'

21) Over the past decade, an increasing body of international evidence has supported certain interventions to current health care systems that have been shown to improve safety Some of these are listed below:

a) Effective clinical incident management focussed on learning and prevention rather than punishment.

b) A coordinated approach to identifying and addressing key safety risks at an organisational level Top leadership support is essential for this to be successful

c) Ward-based clinical pharmacy services

d) Standardised communication tools and processes, for example, Standard medication charts, fluid order charts and structured briefings. Having the same chart in every hospital significantly reduces the opportunity for error

e) Electronic medical records with decision support.

f) Smart intravenous pumps, which calculate drug doses and have dose limits programmed in to prevent over- and under-dosing.

g) Computerised physician order entry ("CPOE"). Ordering of pathology, radiology and medicines by computer, such that the minimum information is mandatory, decision support can be incorporated, and follow up of results can be assured with automatic reminders.

h) Bar-coded medication administration systems. These systems enable the patients and the individual drugs to be bar-coded to avoid wrong patient, wrong dose incidents which are very common.

i) Hand washing by clinicians between individual patient encounters

## H NATIONAL HEALTH REFORM IN PATIENT SAFETY

22) The ACSQH was formed in 1999 by the Australian Health Ministers Advisory Committee ("AHMAC"), to provide national leadership and reform around safety and quality.

23) In April of 2004, the Health Ministers released a Joint Communique with the following commitments:

a) Implement Correct Site Surgery Protocol by Sept 2004.

b) Incident Management Systems in all hospitals by Jan 2005

c) Patient Safety Risk Management Plan in all hospitals by end 2005

d) Sentinel Event reporting to State/National level by end 2005.

e) Common medication chart in all public hospitals by June 2006.

f) Pharmaceutical review of medication cycle by end 2006

g) All patients admitted to hospital to receive a copy of the ACSQH's *"Ten Tips To Safer Healthcare"*.

24) In September 2004, the Health Ministers added a commitment to implement the Open Disclosure Standard nationally.

## I QH INITIATIVES TO ADDRESS SAFETY AND QUALITY PROBLEMS

**Prior to the establishment of the PSC**

25) Between early 2001 and the end of 2004, a range of state-wide initiatives to address unintentional patient harm were developed and implemented by QH as part of the Quality Improvement Evaluation Program ("QIEP"). These included projects targeting the high risk areas of medications, falls, pressure ulcers and infection. The Clinicians Development Program ("CDP") was one of the projects.

26) From about late 2002, the PAH received funding through the CDP to implement a patient safety project ("the project").

27) I was part of the Patient Safety Committee at the PAH that put together the proposal for the project. After it was established, I was part of the Safety and Quality Committee which oversaw it.

28) The project was based upon the VHA NCPS model of utilising systems analysis techniques modified from industry to assess serious clinical incidents and near misses, in order to identify system deficiencies. This is followed by implementation of corrective actions with appropriate tracking of actions and outcomes. The PAH worked in collaboration with Dr Jim Bagian, Director of the NCPS, to develop and implement the project.

29) The resources provided to the PAH by CDP were used to recruit, train and support three AO6 Patient Safety Officers as technical experts to provide support to clinicians and management in the divisions of medicine, surgery and mental health.

30) The Patient Safety Officers at the PAH provided training to staff in patient safety, reviewed and risk-rated all reported clinical incidents, assembled multidisciplinary teams for RCA, provided technical and administrative support to the team, and supported the divisional executives in addressing key actions raised. They also provided support to Divisions in tracking actions and outcomes, and provided support in certain key initiatives such as correct site surgery and a emergency department/mental health project.

31) Between January 2003 and December 2004, the PAH conducted 50 RCA's on serious adverse events, with over 200 corrective actions implemented.

32) In June 2004, I returned from my fellowship with the VHA to take up the position of Director of Safety, Quality and Risk Management at the PAH. During my time in that position, I was successful in attracting permanent funding from the PAH administration for the Patient Safety Officers and Medication Safety Officer.

**Establishment of the PSC**

33) In August 2004, I helped to organise a patient safety workshop with the aim of engaging QH senior executives and the Minister for Health in consideration of

funding a state-wide Patient Safety Program based on the VHA model. Dr Bagian was guest speaker at the workshop.

34) Dr Mark Waters, the appointee to the position of Senior Executive Director of the Innovation and Workforce Reform Directorate ("IWR") attended the conference.

35) Following the workshop, Dr Waters asked me to prepare a submission to the Director-General to create a PSC based on the VHA model. **ATTACHMENT 'JGW3'** is a copy of the *"Proposal for a Queensland Patient Safety Program"* that I prepared with the assistance of Dr Andrew Johnson and Dorothy Vincenzino.

36) After the initial submission was approved, it was decided that the pre-existing highly successful QIEP project areas of medication safety and CHRISP should be incorporated into the original model as programs with permanent funding.

37) The PSC was established in January 2005 and I was appointed Acting Executive Director at that time.

**Subsequent to the establishment of the PSC**

38) The PSC is made up of 3 Units, the Safety Improvement Unit, Centre for Healthcare related Infection Surveillance and Protection ("CHRISP") and Safe Medication Practice Unit.

39) **ATTACHMENT "JGW4"** is the PSC Operational Plan for 2005-2006, the PSC organisational chart and the organisational charts for the Safety Improvement Unit, Safe Medication Practice Unit and CHRISP.

40) The role of the PSC is to:

a) Take a lead role in the planning, implementing, managing and evaluating of patient safety initiatives and programs across Queensland Health

b) Work with clinicians and managers at the "coal-face" as part of a broader system to prevent and address patient harm.

c) Set safety priorities at the statewide level – at patient/clinician, managerial and policy levels.

d) Analyse data from a variety of sources (for example, eICAT, iPharmacy and PRIME) to identify key vulnerabilities for the primary purpose of developing safer systems of care.

e) Facilitate community understanding of the potential for adverse events, encouraging and supporting patients to play an active role as a defense against adverse events.

f) Promote and monitor research into patient safety.

41) **Safety Improvement Unit ("SIU"):**

a) This newly formed unit aims to reduce preventable adverse events by:

i) Improving the capacity of DHS to establish and maintain effective local incident management programs.

ii) Coordinating and standardising these processes to ensure that benefits are shared across all HSD's.

iii) Planning and implementing key clinician-led safety initiatives at a state-wide level

b) **ATTACHMENT 'JGW5'** is a copy of the 2005-2006 Operational Plan for the Safety Improvement Unit.

c) The SIU undertakes the following projects and programs in pursuit of these aims:

i) Incident Management Policy development incorporating Sentinel Event monitoring and reporting.

- QH has had an Incident Management Policy since June 2004 (**ATTACHMENT 'JGW6'**). Many Districts reported being unable to comply due to inadequate training and resources.
- The PSC has assumed responsibility for supporting HSDs in the implementation of this policy. It is doing so by undertaking the activities listed in paragraphs (d) to (f) listed below.
- The policy is currently being reviewed by the PSC. There has been extensive consultation with the HSDs with 3 zonal workshops conducted since April 2005. The HSDs have raised a number of issues in relation to the current policy including:
  - Lack of initial training in standardised process for incident analysis, particularly RCA
  - Lack of resources to support implementation of the policy.
  - The purpose of central reporting of sentinel events.
  - The Queensland Health Sentinel Event List
  - Qualified Privilege for Root Cause Analysis.
- A draft internal summary report in relation to sentinel event reporting is **ATTACHMENT 'JGW7'**

- A workshop with key stakeholders, including representatives of HSDs, will be conducted by mid September 2005 to finalise an amended policy. The amended policy will then be submitted to the QH Safety and Quality Board ("SQB") for approval.

ii) Safety Culture Survey:

- In order to evaluate the impact of the PSC, all HSD's will be surveyed in order to establish a baseline measure of the perceptions of staff as to their attitude and behaviours in relation to patient safety.

- Evidence from other industry suggests safety culture is closely aligned to safety outcomes

- The survey will be repeated in 2-3 years to determine the impact of the PSC's initiatives

iii) PRIME: Web-based Clinical Incident Information System:

- PRIME facilitates the improved management of reported incidents. It provides a consistent state-wide approach to the notification, tracking and analysis of incidents at local clinician, managerial and state-wide levels.

- Between January and July 2005, the PSC provided funding to all 37 HSDs to support the implementation of PRIME. Local project officers were supported by three change managers who were based at the Sunshine Coast, Royal Brisbane Hospital and Townsville HSDs.

- It is anticipated that PRIME software will be fully deployed in all HSDs by December 2005 and PRIME will be fully implemented by March 2006.

iv) Patient Safety Officers:

- On 1 July 2005 the PSC provided funding for 26 full time equivalent Patient Safety Officer ("PSO") positions to service all 37 HSDs. Some HSDs will be serviced by a part-time PSO.

- The PSOs will provide support to clinicians and management in ensuring that incidents are consistently managed according to best practice, and that lessons learned lead to improvement.

- There is a standard position description for Patient Safety Officers (**ATTACHMENT 'JGW8'**).

- Once the PSOs are recruited, which is anticipated to be by September 2005, the PSC will provide initial training to them. The PSC will also provide ongoing support and training to the PSOs

v) Training in RCA and other reactive and pro-active risk assessment tools. This training will be conducted on a HSD by HSD basis commencing in September 2005. It will take approximately 9 months for the training to be provided to all HSDs. It is also anticipated that several RCA workshops will be conducted to ensure that all HSDs have trained personnel by October 2005.

vi) Human Error and Patient Safety ("HEAPS") Training. This program has been running for 3 years with over 4000 staff trained. This training raises awareness of the reasons errors occur and provides individuals with strategies aimed at improving the response to errors. The PSC's aim is to ensure that within 5 years every QH clinician and manager has undergone this training.

vii) Coronial Data Management with the purpose of:

- Working with the Office of the State Coroner to ensure that coronial recommendations are considered for implementation on a state-wide basis. Previously QH often did not receive coronial reports All coroner's reports now go to the Chief Health Officer ("CHO"). A representative of the PSC works with the CHO to:
  - Review the reports.
  - Assess the recommendations contained in the reports in conjunction with the relevant HSD.
  - Consider the need for implementation of recommendations at a state-wide level based on the coroner's recommendations.
  - Provide feedback to the State Coroner regarding the recommendations
  - Improve the quality of information provided to the coroner by QH when a reportable death occurs. A pilot of a coronial discharge summary is currently away.

d) The SIU also undertakes specific safety programs in high-risk areas:

i) Pressure Ulcer Prevention:

- Under QIEP, guidelines for risk assessment and prevention of pressure ulcers were developed.
- The SIU is currently negotiating with HSDs to form a Pressure Ulcer Prevention Collaborative to sustainably embed key interventions at a clinical unit level. This means that the PSC will establish a forum to bring clinical leaders together to translate the theory into practice realities. The PSC will support them in this endeavour.

ii) Falls Prevention

- Under QIEP, guidelines for risk assessment and prevention of falls were developed.

- The SIU is currently negotiating with Public Health and the HSDs to form a Falls Prevention Collaborative to sustainably embed key interventions at a clinical unit level.

e) Targeted Safety Projects:

i) Ensuring Intended Surgery Protocol (**ATTACHMENT 'JGW9'**).

- This is designed to address the problem of wrong site, side or patient surgeries. The solution to this problem is a simple series of preoperative checks akin to pre-flight check in aviation.

- Is a Ministerial commitment through AHMAC.

- Piloting of the project took place in late 2004 as part of QIEP. The Protocol came into force on 17 March 2005.

- The PSC took over the project in January 2005. A Reference Group of key stakeholders, including the Royal Australasian College of Surgeons has been formed. A senior surgeon, Dr Ian Dickinson, and President of the Peri-operative Nursing Association of Queensland, Ms Ruth Melville, are working with the PSC to provide clinical leadership to the project. Three Workshops have been run by the PSC for local clinical leaders to assist implementation. This is being followed up with HSD visits and evaluation of compliance and impact on incorrect surgeries.

ii) Open Disclosure Pilot Project:

- Open Disclosure is the practice of providing a full explanation and expression of regret to a patient/carer as soon as possible after an adverse event. It is known to be associated with a significant reduction in litigation risk.

- I represent QH on the National Steering Committee for Open Disclosure.

- 7 HSDs have been selected to pilot the National Standard. A business case for the pilot has been developed and will be submitted to the SQB in August 2005. The methodology is based on the United State's Institute of Healthcare Improvement Collaborative approach which is led by clinicians.

- **ATTACHMENT 'JGW10'** is a copy of the *"Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Health Care"*

42) **Safe Medication Practice Unit:**

a) **ATTACHMENT 'JGW11'** is a copy of the 2004-2005 Business Plan for the Safe Medication Practice Unit.

b) This unit develops and supports implementation of medication safety initiatives across the following four main areas:

i) High Risk Medicines and Processes

ii) Medication Continuum

iii) Medication Review

iv) Electronic Medicines Management Strategy

c) The statement of Danielle Ann Stowasser dated 15 August 2005 sets out in detail the role and activities of the Safe Medication Practice Unit.

43) **CHRISP**

a) CHRISP provides and supports surveillance, economic and behavioural systems and processes designed to minimize preventable infection-related harm.

b) **ATTACHMENT 'JGW12'** is a copy of the 2004-2005 Operational Plan for CHRISP

c) I have seen an unsigned version of the statement of Dolly Olesen. It sets out in detail the role and activities of CHRISP.

44) The functions of the Safe Medication Practice Unit and CHRISP existed within QH before the PSC was created. The Safety Improvement Unit deals with many issues that were not previously effectively addressed at a State-wide level by QH prior to the establishment of the PSC.

45) The PSC allows for a coordinated state-wide approach to improving patient safety. The PSC adds value to the three individual units by providing:

a) Shared governance at state and national level. Representation of the SQB and various national committees.

b) Efficiency of data analysis and shared data-sets

c) Consistent approach.

d) HSD relationship single point of contact.

e) Shared resources and expertise.

**Impediments to the Implementation of Safety and Quality Agenda in QH**

46) Previously, the confidentiality provisions in the *Health Services Act 1991* impeded QH staff from reporting adverse events. This situation has been remedied by amendments to the *Health Services Act 1991* earlier this year.

47) However, 2 impediments remain:

a) There are inadequate protections for people who report adverse events and team members conducting RCA's. Reporters of adverse events can face action by the employer in relation to reported events.

b) Information and documentation collected by the RCA team members during an analysis are discoverable in subsequent civil or coronial proceedings. This may impact upon the amount of information provided to investigators and therefore the lessons that can be taken away from the incident.

48) Other jurisdictions, such as New South Wales, have implemented legislative protection for individuals that report adverse events and the teams that investigate them.

49) Dr Steve Buckland, the previous Director General agreed to preliminary work on drafting changes to the *Health Services Act 1991* in line with the New South Wales changes. The QH Legislative Projects Unit is currently working on this project.

**Bundaberg Health Service District**

50) According the PSC's records, only 1 sentinel event from the Bundaberg HSD was notified under the *"Incident Management Policy"* between 1 July 2004 and 1 June 2005. That sentinel event involved the suicide or unexpected death of a mental health patient.

**Telehealth**

51) As Director of Medical Services at BBH, I collaborated with Royal Brisbane Hospitals Telehealth to study the impact of virtual ward rounds from a metropolitan centre. My recollection was that it was not considered to be a practical solution.

52) In my view, Telehealth is not a solution in its own right. It is one way of bringing the doctor to the patient There are many other considerations, not least of which is whether the patient should be moved to the doctor. Often, the telephone is just as good an option and much easier to use. The challenge is usually the system of support (that is, specialists at the other end with time and responsibility for the care), rather than the technology

Signed at **Brisbane in the State of Queensland** on **16 August 2005**.

**JOHN GREGORY WAKEFIELD**
**Executive Director of the Patient Safety Centre**
**Queensland Health**