STATE
CORONER
VICTORIA

1st February, 2003
Case No: 1908/00

RECORD OF INVESTIGATION INTO DEATH WITHOUT INQUEST

FINDINGS

The death of Taylor Ainalidis occurred on 21st June 2000 at the Royal Children's Hospital from 1(a) cardiorespiratory failure 1(b) failure of anaesthetic rebreathe bag 11 Contributory factors congenital heart disease (Tetralogy of Fallout).

Summary of circumstances

Master Taylor Ainalidis, aged 3 weeks, was admitted to the Royal Children's Hospital with several episodes of hypertension and hypoxaemia. He was diagnosed with a congenital heart condition called Tetralogy of Fallout and surgery was recommended. The surgery was performed at the Hospital and during the resuscitation process a *`Sanbrook'* Rebreathe Bag and circuit was used (Model SANMB50 which was manufactured by Datex-Ohmeda Pty. Ltd.). There was a problem with the bag, in that the folds of the bag stuck together, and the oxygen delivery to the infant was compromised. The infant was unable to be resuscitated.

The autopsy report, complied by Dr. Peter Campbell for the Coroner, initially indicated that *`no anatomical cause for failure of resuscitation following surgical repair is apparent at*

postmortem. The surgical repair was satisfactory and the shunt was patent.' Subsequently, in August 2002 an additional report by the pathologist stated *`it would appear most likely that the cause of the collapse was failure of adequate ventilation during the suctioning procedure.'*

Detail of the circumstances, product information and TGA Report

The clinical summary in the *`Medical Practitioner's Deposition for a Death Reported to the Coroner'* indicates inability *`to achieve chest movement with a bagging circuit during mechanical ventilation via endotracheal tube was interpreted as a blocked endotracheal tube.'* Apparently this interpretation resulted in the *`removal of the endotracheal tube and replacement but the original tube was not blocked and enquiries indicated that the stickiness of the bag may have been the cause.'* The summary concludes:

> *`The outlet of the bag of the bagging circuit may have become sticky preventing deflation when filled with oxygen from a compressed gas supply. In the meantime, reopening of the surgical wound, drainage of the then discovered pneumothorax and placement of an epicardical pacing lead were performed along with attempted resuscitation with drugs but cardiac output and oxygenation could not be re-established.'*

Master Taylor was born at 37 weeks gestation and shortly after his birth he was diagnosed with Tetralogy of Fallout.

Apparently, the rebreathe bag was actually manufactured by Sanbrook Rubber Company as a sub-contractor to Datex-Ohmeda Pty. Ltd. of Homebush, New South Wales. Datex-Ohmeda provided a Product Information Sheet to the TGA, which is dated 6th September 1999. The information sheet states:

> *`3. This is not a long life product and therefore should only be used whilst the rubber shows no sign of stickiness or softening.*
>
> *4. Due to the many variables such as shelf storage and exposure to water, heat and cleaning agents in hospitals, it is not possible to give any life span expectancy for this product.'*

The Report of Therapeutic Goods Administration (TGA) also confirmed the clinical summary as being the following:

> *`inability to achieve chest movement with a bagging circuit during mechanical ventilation via endotracheal tube was interpreted as a blocked endotracheal tube, however the original tube was not blocked as previously thought, and enquiries indicate that the stickiness of the bag may have been the cause. The outlet of the bag of the bagging circuit may have become sticky preventing deflation when filled with oxygen from a compressed gas supply?...'* [1]

[1] Report, 13/12/2001

The bag was tested by TGA, who concluded that there *`appears to be degradation of the rubber causing stickiness and softening of the device. Testing revealed this stickiness prevented the bag from inflating.'*

TGA also noted that the instructions for use do not recommend *`autoclaving as a means of sterilisation and that the device should only be used while it shows no sign of stickiness and softening.'* Importantly, the TGA Report comments that the *`bag was firmly stuck together prior to use and this should have been noticed when the device was being cleaned and sterilised prior to being placed in the Intensive Care Unit.'*

The TGA Report also notes that the Hospital no longer uses this type of device and that the bag has not been supplied by the manufacturer since June 2000 (it had been used at the Hospital since 1978). Apparently there had been one other instance of a bag having been found stuck together.

There is no indication, in any of the evidence in the Coroner's Brief, that the Sanbrook Rebreathe Bag was checked for serviceability before it was used. However, it is noted that the TGA Report states:

> *`The bag involved was firmly stuck together prior to use and this should have been noticed when the device was being cleaned and sterilised prior to been (sic) placed in the Intensive Care Unit.'*

There is also no indication in the material of any system at the Hospital to check all equipment that may have a limited life or may be subject to deterioration over time.

Conclusion

The death of Master Taylor Ainalidis occurred at the Royal Children's Hospital on 21st June 2000, principally as a result of the failure of the anaesthetic *`Sanbrook'* rebreathe bag immediately after a procedure to correct a congenital heart disease (Tetralogy of Fallout).

The particular Rebreathe Bag and circuit used (Model SANMB50) was manufactured by Datex-Ohmeda Pty. Ltd.). There was a problem with the bag, in that the latex folds of the bag stuck together, and the oxygen delivery to the infant was compromised. The infant was unable to be resuscitated.

The bag was of a reusable type with recommended cleaning procedures by the manufacturer. These procedures were not followed by the Hospital. The manufacturer's instructions also warned of the potential problem with stickiness in the bag. The problem with the particular bag being used on Master Taylor was not identified by the staff working at the Hospital.

The bag has subsequently been recalled by the manufacturer and the Hospital now does not use bags of the reusable type.

COMMENTS AND RECOMMENDATIONS

The need to follow manufacturer's instructions and provide supporting systems

The death of Master Taylor is an example of the apparent failure, of those working within the health sector at the Royal Children's Hospital, to follow the manufacturer's instructions and check the bag device before use for the problem of stickiness. The manufacturer's instructions are clear and concise and warn of the risk of problems developing with the material used in the product. Whilst, on the material in the Coroner's Brief, it is not possible to say definitively whether or not the manufacturer's instructions were available to the relevant staff at the Hospital, what is clear is that they were not followed.

It is not possible to say precisely where in the chain the failure to identify the problem actually occurred. Suffice to say there were opportunities at all levels to intervene and identify the problem with the bag. This could have been done during cleaning (whenever that occurred) or, at the other end of the process, immediately before use with the patient.

It is noted that the TGA Report states:

> *`The bag involved was firmly stuck together prior to use and this should have been noticed when the device was being cleaned and sterilised prior to been (sic) placed in the Intensive Care Unit.'*

It also appears that the manufacturer's instruction did not recommend autoclaving as a method of sterilisation. The Hospital used this method. However, the manufacturer recommended a different process - sodium hydrochloride based sterilants.

The problem of failure to follow manufacturer's instructions within the health sector is not isolated to this case. By way of example, in 1996 Mr. Eric Jones[2] died at the Alfred Hospital, when he was asphyxiated whilst being restrained because he was agitated. There was extensive training and other information supplied by the manufacturer about the particular restraining device, which warned of the risks and indicated that it was unsuitable for agitated patients. Whilst the information was in the Hospital Stores area it was not supplied to Hospital staff that had to work with the device.

Where a particular product is being used, and the consequences of failure of the product (or inappropriate use) may well result in death or serious injury, it is essential that careful assessment of the potential problem areas is made before the product is permitted to be placed in the ward for use with patients. Thus detailed inspection and audit systems need to

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[2] Coroner's Case No: 3226/96 (Finding attached)

be in place in the Hospital's stores area to ensure the product is generally assessed for suitability, and particular units are checked for defects. Involvement of the Hospital's Risk Management Group in this assessment process is essential.

Realistically, clinical and nursing staff are often under considerable pressure and therefore it is essential that the assessment and checking processes before a product is available for use are rigorous and systematic. No doubt clinical staff often rely on the very availability of the product on the ward as an indicator that it must have been checked. Sometimes, under pressure human errors are made, and a product that is faulty has potential to be used with, as we have seen with Master Taylor, disasterous consequences. Systems need to be in place to reduce these types of errors.

In spite of the necessity for rigorous, systematic pre-use checking processes, clinicians also need to be made aware of potential problem areas with products. Therefore it is also essential that information and training about the potential problems be provided to all staff that are required to work with the particular product. This would include clinicians, nurses, maintenance and staff required to clean the product prior to use. With a greater degree of knowledge and information about potential for product failure throughout all areas of the hospital, any unit that slips through the earlier assessment and checking process is more likely to be identified.

Regular and documented audit of the systems in place is necessary to ensure that products are assessed and checked, staff are informed, trained and aware about potential problems with products that are used within the Hospital. The audit process needs to ensure that errors in the systems are proactively looked for and, where identified, redressed.

Recommendation 1

That the Royal Children's Hospital consider establishing a system to ensure that, where a mechanical or life supporting product has potential to fail catastrophically (with a risk that it may result in death or injury) that:

- *products are carefully evaluated for patient safety and potential problems are identified before introduced into the ward area for application to patients;*
- *product information and related training material is provided to all relevant staff (this would include clinicians using the equipment in the Hospital, etc) and is readily available with the product;*
- *updated product information is regularly and pro-actively sought from the manufacturer;*
- *products are regularly audited and checked for safety, suitability and compliance with original specifications;*
- *maintenance or cleaning processes comply with the manufacturers specifications (in the event that different processes are used they are checked with the manufacturer);*
- *regular, detailed audit of the systems are undertaken and documented.*

The involvement of the Hospital's Risk Management Group in the process is essential.

Recommendation 2

That the Royal Children's Hospital consider establishing a system to ensure that, where a mechanical or life supporting product has potential to fail catastrophically (with a risk that it may result in death or injury), adequate training on the use and maintenance of the product (and risk factors) is provided to all relevant staff who are likely to use the equipment in the Hospital (this would also include clinicians, whether on staff or visiting).

The training also requires an audit procedure.

Graeme Johnstone
State Coroner

STATE
CORONER
VICTORIA

26th April 1999
Case No: 3226/96

RECORD OF INVESTIGATION INTO DEATH OF ERIC JONES

(held at the Coronial Services Centre, Southbank on 28th and 29th April 1998 and 1st and 29th March 1999)

The death of Eric Jones occurred on the 30th October 1996, at the Alfred Hospital from 1(a) Postural Asphyxia; 1(b) Restraint Device; 1(c) Delirium Post Drug Overdose in the following circumstances:

1. Mr. Jones was admitted to the Alfred Hospital on 19th October by ambulance after being discovered unrousable on the floor at David and Kyle Kerry's house at 14 Rooding Street, Brighton. It appeared that he had overdosed on drugs. Initially he was treated in the Intensive Care Ward and later transferred to Ward 4 East after his condition stabilised. During his time at the Ward he became difficult to manage and was restrained by shackles on 24th October. The shackles were removed and a `Posey Poncho' vest type restraint (Model Number 3611) applied on 25th October. The `Posey Poncho' vest restraint basically remained in situ until his death.

   At 1.15 am on 30th October Mr Jones was discovered hanging over the cot sides of his bed. He had strangled in the Posey Restraint.

   The Posey `Poncho' type restraint was contra indicated for a patient who was agitated.

2. Detective Senior Constable Donald Gallahar was unable to discover the precise type of drugs that Jones had taken prior to his Hospital admission. He summarised the result of his inquiries thus:

   > *`...It has been ascertained that the deceased was on numerous types of prescription drugs, that included, `Valium', `Normison', `Rivitrol', Panadeine Forte', `Aropax', `Norvasc', `Plendil' and `Rohypnol'. The deceased had also used, `Amphetamine', however it has not been established if the deceased was a habitual user nor is it known if at any time the deceased used `Heroin'. It has been established that the deceased had recently begun to consume amounts of `Vodka' mixed with prescription drugs in company with recent acquaintances...'*

   The Detective Senior Constable, was unable to precisely establish Jones' movements prior to being discovered on the floor in the house. Gallahar stated:

   > *`It is believed that the deceased attended at the premises of David and Kyle KERRY, for the duration of the day and evening of Friday the 18th of October, 1996. It is further believed that after withdrawing said monies the deceased returned to the premises at 14 Rooding Street, and whilst there, consumed a mixture of Alcohol and either prescription drugs or restricted drug/s, possibly including Amphetamine/Heroin. Preliminary medical evidence revealed that at some stage during this night the deceased lapsed into unconsciousness.*
   >
   > *It is not known who was actually present at this premises on this night nor whether it was known by these persons that the deceased had actually lapsed into unconsciousness or was asleep. What is known is that no medical assistance was requested until the evening of Saturday the 19th of October, 1996. It is believed that medical assistance was only requested after a phone call between 5.30 p.m., and 6.00 p.m., had been made to the mother of Elizabeth SMITH, Joyce Ellen SMITH...by Kyle KERRY, stating that the deceased was asleep, could not be woken, had been that way since the previous night, and had a bad colour...'*

   Following the arrival of the ambulance Mrs. Kerry was the only person present with Mr. Jones. Evidently she was evasive and uncooperative. Both David and Kyle Kerry had extensive criminal history (both in Victoria and interstate). Apparently David Kerry was being investigated by police for the trafficking of Rohypnol. After the incident both the Kerrys left their home in Brighton and have not been found.

After Mr. Jones' arrival at the Hospital the drug screening test indicated:

> *`...19th October 1996 2145*
> *Urine drug screen*
> *Methadone and metabolites, opiates, benzodiazepines and an unidentified compound (probably paroxetine) were detected...'*

Blood serum indicated paracetomol.

3. Detective Senior Constable Gallahar also summarised Jones' history:

> *`...The deceased was a 33 year old single male. He was from a dysfunctional family, mother Heli JONES, residing in Sydney, and father Murray Russell JONES, residing in South Australia. He had one other sibling, a sister Andrea, 35 years old. From the age of 14 years, the deceased was fostered out to his direct relative, HALDMA. In 1988, HALDMA, moved from Melbourne to Mallacoota, and the deceased remained in Melbourne. The deceased at this stage was gainfully employed by the Victorian Railways and had been so since 1981. In 1991, the deceased took a redundancy package and received a lump sum payout of between $15,000.00 to $20,000.00. It appears that the deceased's life both physical and mentally took a drastic turn for the worse, in 1992, after suffering a serious assault which required treatment at the Melbourne Psychiatric Hospital, Richmond. It was at this Hospital that he met and developed a relationship with Elizabeth SMITH, which lasted on and off to his death.*
>
> *In the ensuing 4 years, the deceased attended numerous Doctors, including Doctor Mark GLASMAN, Doctor BARKLEY, and Doctor Simon COOPER, and was prescribed a variety of drugs as per prescription for on-going psychiatric problems. The deceased in May 1996, left a stable place of residence in Brunswick and began to move residence on a frequent basis.*
>
> *SMITH, states that this transitory lifestyle coincided with an increase of prescription drug abuse by the deceased and was further enhanced by the forming of the friendship with the KERRYs' when the deceased moved to Brighton for a short time. Since leaving the Railways Department in 1991, the deceased was not employed and relied on social benefits, monies sent to him via HALDMA, and his payout from the Railways.*
>
> *In 1992, the deceased received a suspended sentence for various offences which related to drug involvement, but nil further Police involvement known from the date of that appearance...'*

Mr. Jones did not have regular contact with either his parents or sister.

4. On admission to the Alfred Hospital Dr. Stephen Salerno stated:

> *`...On 20 October 1996 the abovementioned patient was admitted to the Alfred Hospital with an altered conscious state believed to be secondary to a drug overdose. He was assessed, resuscitated and admitted to the Intensive Care Unit, where he was ventilated and received management for his poor neurological state, rhabdomyolysis and aspiration.'*

As Mr. Jones improved over the next two days he was transferred to the general ward on 22nd October. He was assessed on 23rd October by Drs. Salerno and Steven Kypraios and:

> *`...found to be disorientated to time and place and stated that he still wanted to kill himself. In light of this statement and his past medical history a psychiatric review was arranged.'*

On 24th October Mr. Jones was still confused although oriented to place. Salerno stated:

> *`He was later reviewed by psychiatry and their suggestions noted and recommendations put into place. I was called later that afternoon concerning a fall that the patient had sustained. In light of this and other falls that had occurred earlier in the day, the patient still expressing ideas of self harm and the increased aggression, it was necessary that the patient have a psychiatric special nurse and be restrained till calm and no longer a danger to himself.'*

On 25th October Mr. Jones' rhabdomyolysis was found to be improving although he was still *`confused, disoriented and in a fluctuating mental state.'* Later on 28th October he was found to be:

> *`...medically stable, orientated to day and place. His chest was clear and his antibiotics ceased.'*

Dr. Salerno played no further part in his management. He was unable to say as to whether Jones' actions resulting in his death were likely to be deliberate or otherwise.

5. Dr. Steven Kypraios, who was also involved in the earlier decision to restrain Jones, stated:

> *`...On the morning prior to his death he was placed in a Posey restraint lying flat in bed with the cot sides up. When I saw him on the round on the 29 October 1996 he was confused and disorientated in time and place was not struggling with the restraint or attempting to climb out of bed.'*

Dr. Kypraios had the day to day responsibility for Jones' treatment and management of his restraint. Kypraios, who had also worked in a geriatric hospital, was not aware of specific risks with the use of restraints. He had not been aware of any deaths. There was no information provided to the doctor about the risks associated with the use of restraining devices.

Dr. Kypraios gave evidence that:

> *`...It is fair to say, doctor, isn't it, during his time in the ward his behaviour and condition fluctuated?---Yes.*
> *Appeared calm sometimes and then, for apparently irrational reasons, became quite agitated at others?---yes.*
> *That was an ongoing pattern?---No, the pattern changed – well, the pattern did change during his admission. He was more aggressive, more physically aggressive, and more abusive towards the beginning of his stay. Towards the middle and the end of his stay he was quite conducive and quite cooperative, although he remained confused and his verbal outlook fluctuated. At times he was very quiet at other times he verbalised quite irrational*

thoughts and so on. But his physical agitation was more of an issue towards the beginning of his admission.'

In addition, Dr. Kypriaos posed the essential problem, when he answered the following question:

`...I just want to ask you this: in the circumstances in which Mr. Jones was in, say, the 24 hours prior to his demise, if you had left him wholly unrestrained, how would you regard yourself as having discharged your duty and obligations to him? --- I would have felt that I had left him in a dangerous position because he was still getting up, trying to walk and falling over.'

Clearly without restraint Mr. Jones was at risk of falling. With restraint, as he was still attempting to get up, he was at risk of becoming entangled in the restraining device. It was this risk that required careful and constant management.

Dr. Kypriaos stated that as Jones was in an acute confusional state and disoriented his expression of some suicidal ideation was not necessarily an indication of intention.

6. On 28th October the nursing notes indicate that Mr. Jones was:

`...calmer now but still confused. Being restrained for his safety...Able to walk (?)...Ataxic. Remains incontinent...Patient got out of chair with restrainer on...'

Also on 28th October the Psychiatric Liaison nurse notes:

`...Ward staff particularly concerned at his level of risk given confusion and risk of falling. Restrained in his bed when visited this evening. His confusional state fluctuated throughout today, spilling his food tray allover the floor, being naked and sitting naked from the waist down in the middle of the corridor.

Overall he has greatly exhausted the human material resources of the ward, as he has constantly pushed the buzzer for his nurse (plus calling out)...It is clear that he remains effected by his delerium and his level of frustration with this environment is increasing, with each perhaps feeding the other...'

By 29th October various nursing notes indicated Mr. Jones was *`settled...and eager to participate';* appears *`calmer this morning'; `Delirium improving.'* However one note for the morning of 29th states:

`...restrained and chair shackled to bed to prevent pt getting up with chair attached and tipped over...'

Nurse Lisa Cummins, who was caring for Jones on the pm. shift, 29th October, commented:

`...Mr. Jones was withdrawn and unpredictable in his behaviour. His ataxia had worsened since I last cared for him on Friday 25th October. He required two nurses to transfer from the chair to the bed. He was unable to stand or walk by himself, however he frequently made attempts to do so.

Mr. Jones had been restrained on the previous shift After assessing him and discussion with the nurse who had cared for him on the morning shift and reviewing his file it was decided to continue restraining him for his own safety. The restrainer had been used for the previous five days.

A posey restrainer continued to be used. This was used in both the chair and bed.

...Mr. Jones did not appear agitated so I did not give him his prescribed haloperidal which was ordered only if the patient was agitated...'

Nurse Cummins last saw Jones at 8.30 and 9pm and observed him to be asleep.

Observations of the patient in the hours immediately prior to the death occurred at the following intervals: 1600, 2000, 2130, and 2200 (29th October); 0030 and 0115 (30th October). The opportunity for the patient to be observed by nursing and other medical staff includes a mixture of `observations' of the patient's vital signs, medical checks, psychiatric assessment and observation, delivery of oral medication, monitoring intravenous lines, bathing, meals and checking of the patient by nursing staff. During the afternoon shift of 29th October no nursing notes were made.

On 30th October Nurse Felicity Quirk checked Jones at 0030 and the 0115 observation was the final emergency call. In her statement she indicated that she observed Jones in his bed when passing his room.

Nurse Quirk, made her notes after the incident. Quirk who was trained at the Alfred Hospital did not see the `Posey' information sheets.

7. Dr. Ruth Vine, Deputy Chief Psychiatrist, Victoria indicated that within the Psychiatric System physical restraints are rarely used as, under the Victorian *Mental Health Act 1986* (Section 81) there must be continual visual monitoring. In the *Mental Health Act* there is also a specific statutory requirement for review every 15 minutes and medical review every four hours. Also there are guidelines issued by the Chief Psychiatrist in June 1996 – *`Victoria's Mental Health Service: Medical Restraint Clinical Practise Guidelines'*

   The Alfred's Medical Services Policies and Procedures Manual – Restraint and Seclusion of Patients, June 1994 provides that the Hospital has a *`duty of care'* to ensure patients' *`safety and protect them from harm.'* The Manual deals with various types of restraint from pharmacological intervention, seclusion to body restrainers. It further provides that:

   `...There is occasionally a ``responsibility'' to take measures which would not normally be taken in the community, in order to fulfil the duty of care.'

   The Manual stresses the importance of assessment, planning, constant (and regular) review and documentation. With Physical Restraints the Manual provides:

   `...5.1.1 Use Purpose designed appliances.
   5.1.2 Apply correctly and securely

5.1.3 Frequent observation – minimum every 2 hours. Specific instructions regarding the frequency of observation should be documented in the individual's management plan.
Check skin integrity/circulation.
Check application of appliance, re-adjust as needed.
Observe the effects on patient's behaviour.
5.1.4 Re-appraise the need for continued application of physical restraint at least at the beginning of each nursing shift and document decision, patient response and any adverse effects noted.'

Nurse Quirk, who was caring for Jones shortly before his death, had not read the relevant section in the Manual.

8. The `Posey Safety Poster[3]', apparently not seen by most of the staff managing Mr. Jones, provides a timely *`WARNING' – 1. Always monitor patients frequently!...3. The inappropriate and/or incorrect application of restrictive products may result in serious injury or death.'* It is noted that the poster and instruction videos were provided to the hospital but not used.

   Other relevant `Warnings' in the `Safety Poster' are:

   `Check our facility's policy and procedures before using any products. Follow the manufacturer's instruction sheet included with each product.'

   And:

   `Keep patients in staff line of sight whenever possible and monitor their condition frequently. Accidents can happen in a matter of minutes.'

   The `Posey Safety Poster' provides a clear illustration (by way of line drawing) of how Mr. Jones may have met his death. It also warns under the heading *`Bed Products'*

   `...For example, physical restraints may be needed to prevent falls if the patient's bed mobility presents a risk of harm (i.e., physical injury). Under these conditions, restraints are beneficial and acceptable, if used properly.

   Always use the proper size product. If the patient is uncomfortable, agitated, restless or aggressive, consult the proper medical authority so other treatment can be considered. Patients who struggle against restrictive devices may damage skin integrity or become entangled - resulting in suffocation and death.'

   Beside the line illustration of the bed related incident:

   `...Straps should always be snug, but should not interfere with breathing. You should be able to slide your open hand (flat) between the device and the patient. If too loose, the patient could climb over, under, around, through, or between the side-rails and become suspended in the device, resulting in chest compression, strangulation and death...'

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3 Copy attached to this finding. First published 1992.

The `Safety Poster' also provides warnings from the US Food and Drug Administration – *`Potential Hazards with Protective Restraint Devices'* which states:

> *`...Due to increasing reports of injuries and deaths associated with the incorrect use or patient restraints, the FDA is warning health professionals to make sure these devices are used safely. The devices include safety vests, lap and wheelchair belts, and body holders.*
>
> *Incorrect use of these devices has involved using the wrong size for a patient's weight, errors in securing restraints, and inadequate patient monitoring. Such mistakes have resulted in fractures, burns and strangulations. Injuries and deaths have been reported in health-care facilities as well as in patient's homes.*
>
> *The FDA recommends these steps to reduce the risk of injury or death:*
>
> - *Follow good nursing and basic patient-care practices*
> - *Monitor patients frequently and remove restraints often.*
> - *Apply and adjust devices properly to maintain body alignment and patient comfort.*
> - *Allow the use of restraints only by prescription and for a strictly defined period.*
> - *Define and communicate a clear institutional policy on the use of restraints, covering such issues as appropriate conditions for use and length of time to use restraints.*
> - *Display user instructions in a highly visible location and in foreign languages as necessary.*
> - *Keep accurate patient records on the use of the device, including the reason for use, the type selected and the length of time it should be used.*
> - *Follow local and state laws regarding these devices...'*

The `Safety Poster' also deals with the necessity for in-service training and beside the illustration of a patient lying in a bed:

> *`7. Aggressive or agitated, or restless patients requiring increased monitoring and systematic review and evaluation of both physical and psychological status. If there is a history of sliding down or a danger that the patient could become suspended in the restraint, resulting in chest compression and suffocation, the medical authority should be notified immediately so that an acceptable alternative intervention or product can be used.'*

An additional warning provides:

> *`Just as patient behavior is not 100% predictable, no product is 100% foolproof under all circumstances. Patient safety requires periodic assessment and frequent monitoring. A product that worked successfully in the past may prove inappropriate as the patient's overall function and health decline. Sudden mood swings may cause patients to exhibit agitated and aggressive behaviour. Use common sense in the application of any Posey product - if the patient begins to slide down or struggle there is potential for entanglement or physical harm...'*

9. It appears that Mr. Jones attempted to hoist himself over the raised cot sides of his bed and thereby was asphyxiated with the restraint. Whether he was able to loosen one of the ties of the restraint thereby permitting sufficient slack to enable him to maneuver over the edge or the ties were not sufficiently firm at the time of the incident is not known. It is noted that Nurse

Quirk stated that she checked the straps and positioning of the restraint on one of her previous rounds (2120 on 29th October).

Dr. Kypraios, who was in charge of Jones' medical management, was not aware of the risk associated with restraints. Nurse Quirk was also not fully aware of the risks – she had not read the Hospital's Manual as it related to the use of restraints and did not see any of the safety information that was supplied with the product.

In the light of the stringent provisions for observation provided under the *Mental Health Act 1986* (although the Act did not strictly apply to Jones[4]), the Chief Psychiatrist's Guidelines and the clear warnings about risk provided by the J.T.Posey Company management by the Alfred Hospital was less than optimal. It must be noted that there is a distinction between the use of physical restraints for the purpose of assisting in clinical management for non-psychiatric related treatment and in the use under the provisions of the *Mental Health Act 1986.* However, in reality from a risk perspective, with patients who may become agitated (whether being treated under the Mental Health Act or only for clinical problems), the risk may well be similar.

It must be noted that, although Mr. Jones was being treated for the clinical effects of overdose, he was also being seen by psychiatric staff for problems with aggression and suicidal ideation.

The two previous incidents with restraints in the days prior to the death were timely warnings of the fact that Mr. Jones was seriously at risk of injury. They were not adequately heeded.

Although the Hospital's Manual provided information on management of restrained patients when compared with the observation regime and material provided in the *Mental Health Act 1986*, the Guidelines and J. T. Posey Company's poster and videos it was less than adequate. The training program adopted by the Hospital, using experienced staff to teach other staff by way of demonstration, was flawed as the manufacturers instructions and warnings were obviously not used and some staff were not aware of the Hospital's own procedures on restraints.

There was inadequate training for staff using restraints; the product information on risk factors (although provided with the restraints) was not supplied to staff; the system of observation was not adequate; the documentation of observations was not adequate. As the Doctor in charge of the patient's management was not aware of the risk factors with the use of restraints it follows that other staff did not receive adequate warnings or guidance.

Because of the deficiencies in training and dissemination of manufacturer's information within the hospital system there appeared to be a general lack of understanding of the risk associated with the use of physical restraining devices.

Contribution

4 As Mr Jones was not admitted an an `involuntary patient' under the Mental Health Act.

Mr. Jones contributed to his own death[5]. Dr Steven Kypraios[6] and the Alfred Hospital also contributed to the death[7].

Recommendations and Comments

I propose to forward the Findings, Recommendations and Comments to the Attorney General as a matter of information. I will also send the Findings to the:

- Commonwealth Minister for Health,
- Minister for Health (Victoria),
- Chief Psychiatrist for Victoria,
- Secretary, Department of Human Services,
- Chief Executive Officer, Therapeutic Goods Administration (Commonwealth Department of Health & Family Services),
- Australian Patient Safety Foundation (South Australia),
- Medical Director, the Alfred Hospital,
- Association of Medical Directors of Hospitals,
- College of Emergency Medicine,
- Royal College of Surgeons,
- College of General Practitioners,
- Royal College of Physicians,
- Australian Medical Association,
- Australian Nursing Federation,
- Australian College of Nurse Management,
- Health Services Union,
- Royal College of Nursing,
- Managing Director, J.T.Posey Company, and
- The Director, The Accident Research Centre, Monash University,

General – death and injury associated with the use (or failure to use) restraining devices

The issue of death and injury following the use of physical patient `restraining devices' generically known as `Posey' restraints is of concern. Conversely, the failure to use restraining devices also

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5 Although it is probable that he did not understand the consequences of his actions Jones has causally contributed in accordance with the ruling in the Supreme Court Appeals Decision in Keown v Khan.

6 The doctor's contribution should be seen in the context of overall management of the patient and lack of sufficient knowledge of the risks of injury/death associated with restraints. Thus he failed to instruct nursing staff about the risks and provide adequate guidance.
The hospital did not provide the doctor with the `Posey' restraint information which may well have assisted him in understanding the risks.

7 The Alfred Hospital failed to ensure that all staff (including medical) received adequate training, manufacturers information and that its systems to manage the risk of injury for the patient whilst in the restraint were adequate.

may be a problem. In the areas where restraining devices are used on psychiatrically disturbed patients there are strict controls specified in the *Mental Health Act 1986.*

In Victoria there have been an additional two known deaths from strangling using restraining devices. Those deaths occurred in 1988[8] and 1997.[9] The comments by Coroner Klestadt in Lowe (forwarded to the then Victorian Health Department) are particularly pertinent relating to the use of restraining devices and the risks.

Other deaths have occurred during the application of restraining devices – e.g. a possible head injury from a fall while being restrained on a hospital trolley;[10] A patient removing a bed restraining device and falling resulting in a head injury.[11]

The failure to use restraining devices, in appropriate cases, may have also have caused injury or contributed to death. See for example an incident, which occurred in a 1991 case where the cause of death was `unascertainable' and Deputy State Coroner Wilmoth found:

> *`...Even if Mrs. Branch had been restrained by a seat belt, she could possibly have overturned the wheel chair, resulting in injury. Although (the nurse) made a reasonable decision to use the shower chair, which lacked a seat belt, it was not the ideal decision to have made. However, it is clear that (the nurse's) options were severely curtailed as a matter of practical reality by the availability of only two shower chairs with seat belts.'* [12]

In that case there was a hospital policy to use shower chairs with seat belts. The nurse left the patient for a short time (about 10 seconds). During this time the patient fell from the chair and was injured. The coroner found that as the cause of death was likely to be `natural' the *`chain of causation was not so inexorably linked as to establish the nexus between the fall and her death.'*

Deaths and injuries may have occurred during the use of a restraining device manufactured by J.T.Posey & Company or by a device manufactured by others generically (and incorrectly) known as a `Posey' restraint. Caution needs to be exercised when referring to a device involved in any incident as a `Posey' restraint as it may not have been manufactured by J.T.Posey & Company (this includes data from the United States).

The J.T.Posey & Company has extensive in-service training videos and product information sheets warning of the risks associated with the use of the various models of restraining devices. That information was available to the Alfred Hospital prior to the death of Mr. Jones. Apparently this information was not widely used in the Hospital. It is noted that the President of the J.T.Posey Company, Mr. Ernest Posey, who came to Australia from the United States, gave evidence at the inquest and provided the Court with substantial training material on his Company's products.

The J.T. Posey Company vests that were supplied to the Alfred Hospital (and of the model type involved in this incident) included instruction and warning information. That information was not

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8 See D.A.Lowe - Coroner's case number 3484/88 (finding attached).

9 See: Coroner's case number 3500/97 - this case is still under investigation.

10 M.McNally – Coroner's case number 0054/90. In this case the deceased had a pre-existing head injury. `Neuropathological examination was unable to determine if the worsening of the (pre-existing) haemorrhage was due to the fall or if it in fact caused the fall...'

11 See: R.Hewat - Coroner's case number 0990/93.

12 See: H.M.Branch – Coroner's case number 161/91

provided by the Hospital's stores section with the vest to the medical and/or nursing staff responsible for the management of the patient. No witness called during the inquest had seen this information.

The J.T. Posey (`Poncho') vest used on Mr. Jones was not suitable for patients who were struggling or agitated. In the days prior to the death the patient had been shackled, was agitated and had been involved in two incidents with restraints. Although his condition was seen to be improving, as there was a risk of death or injury with a restrained patient, the observation plan was less than adequate.

At the Alfred Hospital there was no structured induction or in-service training for the use of restraining devices and management of patients when they were under restraint. There was a protocol *`Medical Services Policies and Procedures Manual – Restraint and Seclusion of Patients'* dated June 1994. One nurse who had been at the Hospital for about 10 months had not read the manual. She managed the patient in the last hours of his life.

In the case under investigation there was neither documented management plan nor instruction to nursing staff as to what procedures to follow with the patient. The Alfred Hospital's protocol document provides for the following of management plans. The Hospital's general observation regime may well be inadequate in view of the protocols established under the *Mental Health Act 1986*, the Chief Psychiatrist's Clinical Guidelines and from product information delivered with J.T.Posey's restraints.

It is noted that information supplied by Therapeutic Goods Administration (Commonwealth Department of Health & Family Services) has identified 125 incidents involving injury and death following the use of `restraining devices'. Those incidents were obtained from the Emergency Care Research Institute database in the United States. Some of the abstracts of those incidents identify the restraints as being manufactured by `Posey.' It is also noted that in the United States the use of restraining devices is controlled under the Ominbus Budget Reconciliation Act 1987.

Mr. Michael Flood, Program Manager from Therapeutic Goods Administration, explained that restraints are considered as therapeutic devices under the Therapeutic Goods Act 1989 (Commonwealth) but are exempt from listing. However, even though exempt from listing, the Therapeutic Goods Administration still has a requirement to investigate injuries from restraints. In the event that a device is placed on the list (and is categorised as being in an area of high risk of injury) it is evaluated before going on to the market.

In conclusion, clearly there are significant risks with the use of restraining devices. If a careful evaluation of the clinical circumstances requires the use of such devices as this, and other cases have shown, strict and well-structured systems must be in place to reduce the risk. Those who are being restrained, because of the very need to use such devices, are not likely to be in a position to protect themselves.

Recommendation 1

In view of the risk associated with inappropriate (or lack of use in appropriate cases) of restraining devices the Victorian Department of Human Services consider working with all relevant Health Care Networks, Nursing Associations, Medical Colleges and Nursing Homes to ensure that:

(a) All restraining equipment is audited (and regularly reviewed);

(b) Up to date and relevant manufacturer's information is provided with equipment;

(c) Where practicable a standardised protocol is developed (with adequate focus on risk management – including illustrations of at risk situations);

(d) Where practicable a standardised training package is developed and regularly delivered (including re-training);

(e) All incidents (including near misses) with restraining devices should be immediately reported to those in charge of clinical management of a patient with a view to assessing the applicability in a particular case; and

(f) All incidents (including near misses) with restraining devices should also be reported to Hospital/Nursing Home management and investigated with a view to assessing the applicability in a particular case. Countermeasures may well be needed following investigation of a particular incident or series of incidents.

The deaths (and the strict provisions of the Victorian Mental Health Act 1986) illustrate the high level of care needed and risk associated with the use of these devices.

The findings and comments in this and other cases should not necessarily be used to limit use of restraints in appropriate circumstances - but to assist with the recognition of the level of risk and management systems that are needed to reduce the risk.

All staff (both medical and nursing) should have a sound working knowledge of the legislative requirements, risks, organisational protocols/guidelines and manufacturer's instructions when using restraining devices with patients.

Recommendation 2

That Therapeutic Goods Administration (Commonwealth Department of Health & Family Services):

(a) disseminate the findings and recommendations in this case to all relevant agencies within the Commonwealth and other States and Territories for consideration;

(b) consider further researching the issue of injuries/deaths associated with the use of restraining devices (and/or failing to use) with a view to determining whether:

- *restraining devices need to be listed;*
- *other controls/countermeasures are necessary; and/or*
- *an incident reporting system is needed.*

Graeme Johnstone
State Coroner
29th March 1999

Messrs. Paul Scanlon QC and Frank Saccado (on 1st March) for the Alfred Hospital,
Mr. David Beach for J.T. Posey & Company,
Dr. David Neal for the family, and
Senior Constable King Taylor, Assisting the Coroner.