

**Independent review of the circumstances surrounding
four serious adverse incidents that occurred in the
Oncology Day Beds Unit, Bristol Royal Hospital for
Children on Wednesday, 3 January 2007**

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Reviewer**

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Contents

Executive summary	6
Section 1: Introduction	8
Terms of reference	9
Acknowledgments	9
Methodology	10
Reliability of evidence	10
Serious adverse incidents	11
Observations	11
References	12
Section 2: Medication safety	13
Intravenous catheters and cannulas	13
Heparin	14
Heparin as an agent to keep intravenous catheters and cannulas patent	14
British national formulary for children	15
NHS advice on intravenous catheter and cannula patency	16
Manufacturers of intravenous catheters and cannulas advice on patency	16
Dangers associated with the use of heparin flushes	16
NHS litigation authority data	17
National patient safety agency data	18
Observations	19
References	22
Section 3: Anaesthesia	27
Frequency of drug errors in anaesthetics	28

Observations	29
References	31
Section 4: ODB working environment	33
Controlled drugs cupboard in ODB treatment room	33
Controlled drugs cupboard in BRHC Theatre four	35
Comparison of controlled drugs cupboards ODB and Theatre four	35
Trust policies	35
Trust development and administration of policies	36
Trust policies dissemination and modifications	37
Trust policy on checking injectable medicines	37
Trust policy on checking injectable medicines to children	39
Anaesthetist awareness of medicine code	39
Medicine code chapter 11 update	40
Visual similarity of heparin ampoules at the Trust	40
Human factors	42
Drug errors within the Trust	44
Frequency of heparin related incidents in Trust	45
Heparin purchased by Trust	45
Observations	45
References	50
Section 5: Chronology of events leading to the PSI	53
Wednesday morning 3 January 2006	53
Wednesday afternoon 3 January 2006	53
Pressure to start theatre list	53
CPA1 pre-anaesthesia procedures	54

Conflicting views	54
CPA1 procedure for drawing up drugs into syringes	55
Anaesthetising patients	56
Recovery of patients	56
Wednesday evening 3 January 2006	56
Thursday morning 4 January 2007	57
Check of controlled drugs cupboard	57
ODB immediate clinical investigation	57
ODB investigations and prognosis post 4 January 2007	57
Affects of the patient safety incident	58
Trust investigation into PSI's	59
Observations	59
References	62
Section 6: Miscellaneous issues	63
Verbal double check safety protocols	63
Technology	67
Attempts to reduce look-alike labelling	68
Risk assessments	69
Observations	70
References	71
Section 7: conclusions and recommendations	74
Patient safety incidents	74
System failures	75
CPA1 safety culture	75
Human and organisational factors	76

Heparin	76
ODB Controlled Drugs Cupboard	77
Trust policies	78
Operational practices	79
Communications	82
Trust investigation of PSI's	82
Technology	83
Disregarding safety warnings	83
Learned bodies conclusions and recommendations	84
Department of Health conclusions and recommendations	85
References	88
List of plates	
Plates	
Appendices	

Executive Summary

Background

On the 13 February 2007 Dr Jonathan Sheffield, Medical Director, United Bristol Healthcare NHS Trust (Trust), Bristol, commissioned the author of this report to review the circumstances surrounding four identical serious patient safety incidents (PSI's) that had occurred in the Oncology Day Beds Unit (ODB), Bristol Royal Hospital for Children (BRHC). This report sets out the conclusions that I have reached and my recommendations as to how such events might be prevented in the future.

The starting point for the Trust and Reviewer is that patient safety is paramount. As a result, the Trust immediately took action to prevent a recurrence of the incidents. The Review has confirmed that those actions were appropriate and have been included in the recommendations section of this report for completeness. However as the Review progressed a number of other issues were identified that affect the whole Trust or are worthy of consideration by national bodies and recommendations have also been made in that regard.

Patient safety incidents

On Wednesday, 3 January 2007 four patients were admitted to the ODB, BRHC to undergo diagnostic tests that afternoon. As young children do not tolerate invasive procedures very well when awake the tests were to be carried out under general anaesthesia.

One of the drugs to be administered by the Consultant Paediatric Anaesthetist (CPA1) was the anticoagulant drug '*Hepsal*' (Heparin, at a concentration of 10 International Units per millilitre in 5ml). However, on the following morning during a routine check of the ODB Controlled Drugs Cabinet it was discovered that four ampoules of '*monoparin*' (Heparin, at a concentration of 5,000 International Units per millilitre in 5ml) were missing. It was then reasoned that CPA1 could have inadvertently administered the wrong concentration of heparin to each of the patient's he had anaesthetised the previous day. Thus each patient could have received a dose of heparin significantly greater than the one intended

A clinical investigation was immediately embarked upon by the medical staff on the ODB where upon it was discovered that each patient had received a significant overdose of heparin. As a result of these four PSI's one patient underwent an in-depth investigation, a second patient had their treatment schedule slightly modified, while the other two patients required no changes to their regimes. At the time of writing none of the patients appear to have suffered any long term problems as a result of their overdose of heparin. Nevertheless the seriousness of these four PSI's cannot be overstated.

Professional practices

CPA1 is a highly experienced and respected anaesthetist who had no reason to doubt that his professional practices were anything other than safe. Particularly as he had successfully managed the Wednesday afternoon ODB Theatre List for over three years. However, CPA1's professional practice appears to have been compromised on the day the four PSI's occurred by a number of endogenous and exogenous system factors. The evidence strongly suggesting that the four PSI's that occurred were caused through inadvertent human error and systems failures.

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Section 1: Introduction

The United Bristol Healthcare NHS Trust (Trust) provides an outpatient service for children at the Oncology Day Beds Unit (ODB), Level 6 at the Bristol Royal Hospital for Children (BRHC). On Wednesday, 3 January 2007 four patients were admitted to ODB to have diagnostic tests that afternoon. As young children do not tolerate invasive procedures very well when awake the tests were to be carried out under general anaesthesia.

One of the drugs to be administered by the Consultant Paediatric Anaesthetist (CPA1) was the anticoagulant drug '*Hepsal*' (Heparin, at a concentration of 10 International Units per millilitre in 5ml). However, CPA1 inadvertently administered '*monoparin*' (Heparin, at a concentration of 5,000 International Units per millilitre in 5ml). Therefore each patient received a dose of heparin significantly greater than the one intended. However, as none of the patients displayed any adverse physiological symptoms following the administration of the heparin neither CPA1 nor any of the other healthcare professionals attending the patients realised that a serious patient safety error had been made each time an anaesthetic had been administered.

During Wednesday evening the two children who had undergone bone marrow aspirates bled more than normal from the site where the tissue sample had been taken. As a consequence the Mother of one child and the Father of the other phoned BRHC Ward 34 for advice as the ODB was closed. The parents were told to apply a pressure dressing to the area which they did and the bleeding eventually stopped. This information was however not passed on to ODB so the staff had no knowledge that two of their patients had experienced excessive blood loss.

On the morning of Thursday, 4 January 2007 the parents of the two patients who had experienced the excessive bleeding the previous evening reported their concerns to staff on ODB. Initially the bleeding was not thought to be indicative of anything serious as it had stopped by the time the two patients arrived at the ODB. However when four ampoules of *monoparin* could not be accounted for during a routine check of the '*Controlled Drugs Cupboard*' (CDC) it was realised that a serious patient safety incident (PSI) could have taken place.

A clinical investigation was immediately embarked upon by the medical staff on ODB to determine if any of the patients who had been anaesthetised the previous afternoon had been inadvertently administered an overdose of heparin. It was subsequently discovered that each patient had received a significant overdose of that drug. As a result of these serious PSI's one patient underwent an in-depth investigation, a second patient had their treatment schedule slightly modified, while the other two patients required no changes to their regimes. At the time of writing none of the patients appear to have suffered any long term problems as a result of their overdose of heparin. However the seriousness of this PSI cannot be overstated.

Terms of reference

In order to ensure that the maximum amount of learning would be drawn from the four PSI's it was decided by the Trust's Medical Director (Dr Jonathan Sheffield) as Lead for Patient Safety to invite the author of this report to undertake an independent Review of the events with a remit to:

- '(1) Investigate the specific incident occurring on the Paediatric Day Unit.*
- '(2) Subsequent to the investigation, make suggestions to the Trust's Policies and procedures regarding the administration of intravenous drugs particularly in the Anaesthetic and Operating Rooms.*
- '(3) To present those suggestions and advice to the Anaesthetists in the Trust for discussions and implementation.'*

Acknowledgments

I would like to express my sincere thanks to the following persons external to the Trust for the assistance that they have provided during this Review.

Sir Liam Donaldson, Department of Health; Spokesperson, GMC; Kevin Cleary, David Cousins and Isabel Nesbitt, NPSA; Ruth Symons, NHSLA; James Patterson, Healthcare Commission; Howard Stokoe, PASA; Dominic Bell, The General Infirmary at Leeds; Hilary Cass and Deni Kadirov, The Royal College of Paediatrics and Child Health; Charles McLaughlan and Edwina Jones, The Royal College of Anaesthetists; David Whitaker, The Association of Anaesthetists of Great Britain and Ireland; Gordon Urquhart, John Hancock and Russell Nugent, Wockhardt UK Ltd; Simon Rule, The British Committee for Standards in Haematology; Clive Powell, Association British Healthcare Industries; Ian Maclean and Brian Wixted, DMC Medical Ltd; Gerry Gallagher, Shama Wagle and Sejal Ami, BNF publications; Jan MacDonald and Hannah Street, MHRA; Michael Murphy, NHS Blood and Transplant; Spokesperson, NICE; Clive Jackson, National Prescribing Centre; Colin Waller, Vygon (UK) Ltd; Heather Racknell, Kimal; Andrew Smith, Royal Lancaster Infirmary; Maggie Mort, Institute for Health Research, University of Lancaster; John Calvert, Swansea NHS Trust.

I should also like to thank the Trust staff who assisted me during the Review and in particular all those who agreed to be interviewed for the forthright answers they provided in response to the questions put to them. From my first contact with the Trust all the staff have been open and cooperated fully with the author. Additionally, as issues have come to the attention of the author, possible recommendations have been discussed so that they could be addressed by the Trust and other interested parties as soon as possible.

Prior to commencing the interviews, the author visited the site where the PSI's took place in order to gain first hand knowledge of the physical characteristics of the premises and to be taken through the different sequences of actions that was believed to have taken place. I would like to thank all those

concerned for their assistance during my visit for it was very useful and helped to increase my understanding of the evidence that was presented.

I would like also like to thank the Anaesthetists, Operating Department Practitioners, Surgeons and Nurses at St Michael's Hospital for their patience and help while I undertook a very brief ethnographic based study in two of their operating theatres. The insights which I gained from that research proved to be of considerable help when formulating the recommendations made in this report and in particular the context in which some of them will have to be implemented.

Methodology

One of the conditions specified for undertaking this review was that the methodology used would be rigorous. To that end the methodology adopted in this review broadly conforms to that devised by the National Patient Safety Agency (NPSA).

Thus, as recommended by the NPSA and others^{1, 2, 3} this report draws upon a number of sources of information including, the verbal statements of witnesses who were interviewed, confidential internal reports, confidential medical records, publicly available documents and a limited amount of research carried out by the author.

The interviews with Trust staff were conducted using the '*Cognitive Interview*' technique, i.e. free recall and a semi-structured questionnaire was employed. The mapping of data has been undertaken using a '*Narrative Chronology*'. An explanatory synthesis of the data was undertaken utilising the extensive professional knowledge base available at the Trust.

While many of the other techniques discussed in the NPSA '*Root Cause Analysis Toolkit*' could have been utilised to investigate these serious PSI's it is the opinion of the author that the time required to use them would have been disproportionate to their exploratory value. That is, they appeared to have little probative merit and therefore were unlikely to have produced any additional insights in to these four PSI's other than that which has been achieved.

A review of the circumstances surrounding the PSI's using the NPSA '*Incident Decision Tree*' model leads to the conclusion that the incident was caused by a '*System Failure*' (Appendix 1). This determination is strongly supported by the evidence presented to the author and discussed in this report.

Reliability of evidence

It should be noted that the PSI's that are the subject of this review occurred several months before the author was able to interview those involved. Thus, when questioned many of the healthcare professionals associated with these incidents had no clear recollections regarding the specific events that took place that day. The only reliable evidence available to the author relating to

the circumstances surrounding the incidents has been that obtained from documentary sources.

The verbal evidence provided by many of the witnesses is for the most part generic and often based upon indistinct memories of what they believe occurred at the time.

Serious adverse incidents

Reason⁴, Turner and Pidgeon⁵, Toft and Reynolds⁶ and others have comprehensively argued that the precursor conditions required for the creation of any serious adverse incident may lie cloaked in the social and technical fabric of an organisation for many years before an untoward incident occurs. Similarly, an organisation's culture, i.e. the commonly accepted way of behaving within any given organisational settings, does not spring into existence overnight as an established phenomenon. It takes time for the complex sets of individual and collective perceptions to develop and coalesce into a system of commonly shared values.⁷

Therefore the actions that individuals take within an organisation are determined by the understanding that they have of any particular situation. People try to make sense of their organisational settings and then act in the belief that the assumptions that they have made are facts⁸.

Moreover there was not just one patient but four to whom a general anaesthetic was administered by CPA1. *'It is therefore imperative to understand the organisational setting in which the adverse incident[s] took place'*.⁹

The different organisational contexts in which the PSI's noted above took place will be described in the following sections.

Observation

The length of time taken from when the serious PSI's occurred and the Review took place lead to witnesses' accounts of the circumstances surrounding the events becoming more anecdotal than factual. Thus, it is possible that some of the lessons that could have been learnt from these PSI's may have been unintentionally overlooked by witnesses.

References

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http://www.npsa.nhs.uk/health/resources/root_cause_analysis?contentId=2665
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- 3 Gilbert, N (Ed), *Researching Social Life*, 2nd edition, Sage, 2001
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- 6 Toft, B. and S. Reynolds, *Learning for disasters a management approach*, (3rd edition), Palgrave Macmillan, 2005,
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Section 2: Medication safety

The vast majority of medications administered intravenously to patients by healthcare professionals worldwide are done safely. Regrettably inadvertent drug errors do occur to adults and children on occasions due to human fallibility and systems failure.^{1,2,3,4,5} The NPSA have reported that between January 2005 and June 2006 the *National Reporting and Learning System* (NRLS) received approximately 800 reports each month of errors relating to injectable medicines. During this period 25 patients lost their lives and there were 28 incidents of serious harm. The NPSA also noted that:

'Research evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine'.⁶

Moreover, one recent study into medication errors in the United Kingdom came to the conclusion that:

'Our study shows that errors in the preparation and administration of intravenous drugs remain a concern in the United Kingdom, 25 years after the problem was first highlighted'.⁷

One common system induced cause for medication errors is that the labelling of different types of drug ampoules, doses and dilutions can be very similar in appearance (see Plates 1 & 2). Therefore it is perhaps not surprising that there are occasions when even the most conscientious of healthcare professionals, particularly if in a hurry, stressed or fatigued, will inadvertently select the wrong medication and administer it to a patient^{8,9,10}.

Reason and Mycielska have suggested that such human errors:

'...are the price we pay for being able to carry out so many complex activities with only a small investment of conscious attention'.¹¹

While Leape came to the conclusion from his research in the field of inadvertent medical errors that:

'Physicians and nurses need to accept the notion that error is an inevitable accompaniment of the human condition, even among conscious professionals with high standards. Errors must be accepted as evidence of systems flaws, not character flaws'.¹²

Intravenous catheters and cannulas

Because of their medical condition some patients require an intravenous catheter (tube) to be surgically implanted into one of their large veins (typically the jugular, subclavian or femoral vein) under a general anaesthetic. Such a catheter is known as a central venous catheter (CVC) or *Hickman Line*. This is in contrast to a peripheral line for which a cannula is employed usually in a vein in the arm or hand.

Intravenous catheters and cannulas are designed so as to provide healthcare professionals with an easy access path to a patient's cardiovascular system, for treatment or diagnostic test purposes. Besides providing easy access to a patient's cardiovascular system these devices also significantly reduce the amount of distress that patients might otherwise experience as their skin does not have to be pierced on each occasion that access is required.

Heparin

The drug heparin is an anticoagulant and is one of the agents used to prevent a patient's blood from clotting. It has been highlighted in a recent report to the Chief Medical Officer (CMO), Sir Liam Donaldson, as an effective treatment for, amongst other medical conditions, the prevention of venous thromboembolism in hospitalised patients.¹³

Heparin is therefore clearly a useful medicine in the battle against ill-health. However, medication errors involving anticoagulants are a serious problem and the NPSA recently published '*Patient Safety Alert 18*' to advise healthcare professionals on the dangers associated with such drugs.¹⁴

Heparin as an agent to keep intravenous catheters and cannulas patent

Besides being used as a prophylactic heparin's anticoagulant properties are also used in an effort to keep intravenous catheters and cannulas unobstructed by blood clots or '*patent*'. The reason that these medical devices need to be kept free of blood clots is because if they should become blocked then they must be changed as the patient can no longer receive the treatment or have the diagnostic tests that they require. Thus changing an intravenous catheter in a patient, particularly one that has been implanted in a child, is a task to be avoided if at all possible. Therefore conventional wisdom dictates that intravenous catheters and cannulas should be '*flushed*' with a weak solution of heparin in an effort to ensure they remain patent for as long as possible.

However, there does not appear to be any evidence to demonstrate that a '*heparin flush*' is any more beneficial in keeping a range of intravenous catheters and cannulas patent than flushing them with a 0.9% sodium chloride(saline) injection, particularly in adults.^{15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26,}

^{27, 28, 29, 30, 31, 32, 33, 34, 35, 36} Moreover, the British Committee for Standards in Haematology (BCSH) in their publication '*Guidelines on the insertion and management of central venous access devices in adults*' have stated that '*Flushing with heparin versus normal saline remains controversial*'.³⁷

Therefore having read the BCSH statement regarding the contentious nature of heparin flushes I secured a telephone interview with Dr Simon Rule, Chairman, BCSH Task Force for Haematology and Oncology, who is a Consultant Haematologist and Senior Lecture at University of Plymouth University. I asked Dr Rule, '*If the BCSH believe that using a heparin flush is controversial for an adult is it not more controversial to use them on children*'.

To which Dr Rule replied '*While I do not think it is more controversial - it is certainly as controversial.*'

One of the reasons for the controversy regarding the efficacy of heparin flushes in children is the lack of research in this area. There are of course significant ethical dilemmas in carrying out such studies on children and therefore the reluctance of the medical profession to pursue them is understandable. However, two studies in *The Cochrane Central Register of Controlled Trials*, one for neonates³⁸ and the other in paediatric population,³⁹ came to the conclusion that saline was just as effective as heparin in maintaining the patency of peripheral lines using cannulas. One study published in 2006 on the '*Treatment of Catheter Occlusion in Paediatric Patients*' came to a similar view.⁴⁰ As did a 1993 study entitled '*Improving practice through research: the case of heparin vs saline for peripheral intermittent infusion devices*'.⁴¹

With regard to research undertaken to establish the efficacy of intermittent heparin flushes verses 0.9% saline, in central venous and arterial catheters to maintain patency, at the time of writing I have only found one peer reviewed paper regarding a paediatric study in which it is noted that:

'Prevention of occlusion of central venous access devices is also critical. To date, no data conclusively show heparin flushes to be superior to saline flushes'.⁴²

There have been however at least five adult studies, including the BCSH guidance, which argue that a flush with 0.9% saline is just as effective as a heparin flush in keeping central venous and arterial catheters patent^{43, 44, 45, 46, 47}

British national formulary for children

As the four PSI's being reviewed concerned children I asked the Royal College of Paediatrics and Child Health if they offered any guidance on the use of heparin flushes and they referred me to the *British National Formulary for Children* (BNFC). The BNFC kindly sent me a copy of their latest reference document published in 2006 entitled '*BNF for children*'. The section devoted to '*Heparin*' flushes' contains the following statement:

'For maintaining patency of peripheral venous catheters, sodium chloride 0.9% injection is as effective as heparin flushes. However, heparin flushes do have a role in maintaining patency of arterial catheters and implanted central venous access devices'.⁴⁸

Subsequently I telephoned the BNFC to ask them precisely what role it was that heparin had to play in maintaining patency of the devices noted in their guidance. The Editorial Assistant at the BNFC to whom I spoke said that the question that I had asked had never been put to them before and he would make enquiries.

A short while later (11 April 2007) I received an E-mail from the BNFC stating that:

'...your comments have prompted us to consider a fresh review of the evidence for the use of heparin flushes to maintain patency of catheters and cannulas, and we will further discuss this issue with our clinical experts for both BNF and BNFC'.

NHS advice on intravenous catheter and cannula patency

Given the evidence regarding the unproven efficacy and hazardous nature of heparin flushes I contacted the NPSA, *Medicines and Healthcare Products Regulation Agency* (MHRA), *NHS Purchasing and Supply Agency* (PASA), *NHS Prescribing Centre*, *National Institute for Clinical Excellence* (NICE) and the *Healthcare Commission* (HC). Each organisation was asked if they provided explicit guidance on the use of heparin flushes and they all replied that they did not.

Manufacturers of intravenous catheters and cannulas advice on patency

To ascertain whether or not the manufacturers of intravenous catheters and cannulas issued any central guidance on the use of heparin flushes to keep their products patent I contacted their lead trade body the *Association of British Healthcare Industries* (ABHI). The ABHI stated that they did not offer any guidance on behalf of their membership on heparin flushes.

For the sake of completeness I also contacted the manufactures of all the intravenous catheters purchased by the Trust. Of the three manufacturers concerned only Vygon (UK) Ltd produced any guidance on heparin flushes. In the section entitled '*Heparin Lock Procedure*' of their document '*Catheter Care and Maintenance*' which covers a wide range of intravenous catheters and was published in 1999 it is stated that:

'Most units use 2-5ml of heparinised saline of a strength of 10-100units/ml for flushing. Some units have found plain saline sufficient to maintain patency, whereas other units have found this unsuccessful'.⁴⁹

The other two manufacturers from whom the Trust purchases catheters, *BD* and *Kimal Plc*, do not offer any guidance on the use of heparin flushes to keep their products patent.

Dangers associated with the use of heparin flushes

There is evidence that when heparin is used in flushes serious harmful reactions may be seen in patient's.^{50, 51} Other evidence has shown that heparin is incompatible with a number of commonly used drugs and can also affect the results of bloods tests if it is present in an intravenous catheter or cannula when a sample is taken. Such an event occurred with two of the patients blood tests involved in this Review following the discovery of the missing *monoparin*.⁵²

Of additional concern however is that the '*Incorrect selection, preparation and administration of heparin products*' has been identified by the NPSA as one of the top 15 risks associated with the use of all anticoagulants and these PSI's reinforces that finding.⁵³

Another example of the dangers associated with the use of heparin and the way in which it's labelled occurred in 2004 at a hospital in London. Vials containing several administration of the drug were on two separate occasions administered to two different patients. This resulted in the patients receiving 25,000 units of heparin rather than the intended dose of 5,000 units and required medical intervention to remedy the situation. Fortunately neither incident resulted in any long term harmful effects. However, on another occasion, the authors note that this same error in the same hospital '*...resulted in death from cerebral haemorrhage*'.⁵⁴

On February 6, 2007 the Baxter Healthcare Corporation in the United States of America (USA) issued an '*Important Medication Safety Alert*' in which they made the following statement:

*'Baxter is aware of fatal medication errors that have occurred when two heparin products with shades of blue labelling were mistaken for each other. **Three infant deaths resulted when higher dosage heparin Sodium Injection 10,000units/mL was inadvertently administered instead of lower dosage of HEP-LOK U/P 10 units/mL***'.⁵⁵ (Emphasis in original, for an example of vials involved see Plate 3.)

A report by the *Institute for Safe Medication Practices* (ISMP) regarding this tragedy noted that three other children may also have been affected by the same mistake but was not now in any danger.⁵⁶ The tragic errors that were made in this incident however are compounded by the fact that a similar error occurred at the same hospital in 2001.

This earlier incident occurred over a two days period when an 18 month old infant's intravenous catheter should have been flushed with 90 units of heparin but instead was inadvertently flushed with 90,000 units, 1000 times the intended dose. Following the child's death several months later due to brain cancer his parents complained to the media that while the heparin mistake was not responsible for his death it had increased his suffering. They also highlighted the fact that following the accident to their son that the hospitals staff had promised them that it would '*...not happen again after her family's ordeal*'.⁵⁷

NHS litigation authority data

In an attempt to ascertain if there had been any similar PSI's the author of this report asked the NHS Litigation Authority (NHSLA) if they could answer the questions below. The author's questions are in plain **bold** type the NHSLA's answers are in '*italic*':

'Please note that the database from which this information is taken was designed primarily as a claims management tool, rather than for research purposes; we cannot therefore guarantee that the coding used is 100% consistent.'

'How many claims are there where an anaesthetist has administered the wrong concentration of Heparin when flushing any patient's peripheral or central venous line? What is the total cost to date of such claims?'

'There are 16 claims on the database where there is an allegation of the wrong dose of Heparin having been given (usually described as 'overdose'). There is no identification of the status of the person administering the medication or of the means of delivery.'

'The total paid to date on these claims, including damages and costs, is £1,125,950.'

'How many claims are there where Heparin has been the medicine responsible for the harm to a patient? What is the total cost to date of such claims?'

'21 claims allege a failure or delay in administering Heparin, and a further 17 allege that Heparin was somehow involved in the incident but the data is insufficiently detailed to determine the precise course of events.'

'The total paid to date on these claims, including damages and costs, is £981,380 and £533,545 respectively.'

'How many cases are there where an anaesthetist has administered the wrong drug to a patient intravenously? What is the total cost to date of such claims?' No answer.

'What percentage of all claims does intravenous medication errors by anaesthetist's form? What is the total cost to date of such claims?' No answer.

'The database does not provide sufficient detail to determine who administered the medication or by what means. I'm afraid therefore, that it is not possible to provide the numbers, costs or percentage breakdown that you request in questions 3&4.'

National patient safety agency data

In an attempt to ascertain if there had been any PSI's similar to the ones that are the subject of this report, the author also asked the NPSA if they held any data on incidents using the categories 'heparin flushes' AND 'anaesthetists'. The NPSA replied as follows:

'There are very few [data] relating to anaesthetics and I cannot see

any specifically involving wrong drug administration by an anaesthetist. That said this data was a small cut so perhaps a wider search of the NRLS would need to be undertaken to gain a full picture'.⁵⁸

In subsequent conversations with the NPSA it has become clear that, as with the NHSLA database, they cannot provide data on incidents using the joint category 'heparin flushes' AND 'anaesthetists' because the taxonomy and structure of the NRLS data does not readily allow for the provision of information using such specific data categories. However, as already noted above, the NPSA have identified heparin as a significant contributor to PSI's and issued an 'Alert'

Thus, as it had proved difficult to obtain information using the joint categories 'heparin flushes AND anaesthetists', under the terms of the 'Freedom of Information Act' the author requested the NRLS to provide information on 'Medication errors in the speciality of Anaesthetics' from 1st January 2006 to 31st December 2006.

The NPSA replied as follows:

'...Our search was limited to medication incidents reported from anaesthetic areas in acute hospitals for the period of time requested.

'Incidents involved anaesthetists, other medical staff, nurses and operating theatre practitioners and assistants. It was not possible for us to identify specific reports that only involved incidents involving anaesthetists.

'Although the numeric data is limited for this reason, we have tried to provide a range of examples of the different types of incidents that will help inform your work and your report on the incidents involving anaesthetists and heparin injections...'.⁵⁹

A total of 502 PSI's were identified by the NRLS during the one year period specified these include 5 deaths, 2 serious and 17 moderate harm incidents to patients. However heparin did not feature any of these events. An analysis of the PSI's was kindly undertaken by the NPSA 'Safe medication Practice' and can be found at Appendix 3.

Observations

Injectable medication errors are a major cause of patient safety incidents and one of the root causes of those events is the similarity in the labelling and the packaging of different drugs, doses and diluents.

Thus, as countless numbers of people have pointed out '*...it is completely unrealistic to believe that human error can be totally eliminated. Errors occur and should be expected and anticipated*'.⁶⁰ Therefore it is imperative that '*...the design of packaging and the labelling of medicinal products ... make it*

easy to use them correctly and difficult to use them incorrectly”.⁶¹

There is evidence to suggest that a *'heparin flush'* is no more effective at keeping an intravenous catheter or cannula patent in an adult or child than a flush using an appropriate dose of *'0.9% saline'*. The use of heparin as a flush is also deemed to be controversial by the BSH. The use of a *'heparin flush'* can lead to a range of unwanted side effects, unreliable blood tests and cause complications if employed with a number of commonly used drugs. The use of saline on the other hand does not appear to carry any of the risks associated with heparin.

No advice is provided to Trusts from any of the NHS organisations contacted regarding the use of *'heparin flushes'* however the risk to children of having surgically implanted intravenous catheters removed earlier than otherwise would be the case if only saline flushes were to be used is unknown. Thus appropriately qualified healthcare professionals need to make a determination as to the risk and safety benefits of the continued use of heparin flushes per se. To that end and as a direct result of the PSI's under Review the BNF and BNFC are going to reassess the advice they provide on the use of that product. The BNF and BNFC however are not in a position to offer the NHS the authoritative guidance that could be provided by NICE if they were to be directed to undertake a review of the costs and safety benefits of *'heparin flushes'*.

The dangers associated with large inadvertent overdoses of heparin are well documented however the evidence reviewed above demonstrates that PSI's similar in nature to the ones which are the subject of this Review do reoccur and in some times in the same hospital. This has also proved to be the case with respect to this Trust see section 4 for details. Such events demonstrating, as argued by the author on numerous occasions, that if the circumstances surrounding an unwanted event are allowed to replicate themselves then it is highly likely that another similar unwanted event will take place regardless of geographical location or time, i.e. an *'isomorphic failure'* can occur⁶².

The lead trade body for the manufacturers of intravenous catheters do not offer any advice on behalf of their members regarding how their products should be kept patent. The one manufacturer contacted who did offer advice about keeping their products patent reiterated that the evidence regarding the efficacy of heparin flushes was equivocal.

The NHSLA database shows 54 claims with regards to heparin related PSI's and the amount of money paid to date approximately £2,600,000. However, the NHSLA could not ascertain who had administered the heparin or its means of delivery. This is because the taxonomy and data structure of the NHSLA database does not readily allow the provision of such specific information.

Similarly, the NPSA could not provide data on the frequency of PSI's with the joint categories of *'heparin flushes AND anaesthetists'* nor when the more

general category of '*Medication errors in the speciality of Anaesthetics*' was used. This is because the taxonomy and data structure used by the NRLS database does not readily allow for the provision of such specific information.

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Section 3: Anaesthesia

Anaesthesia is without a doubt a huge boon to the human race. Without the developments that have been made in the field of anaesthesia countless numbers of people around the world would not have been able to have the life saving surgery that they required. However, the anaesthetic gases and drugs administered to patients' besides helping to save lives are also potent and therefore life threatening if used inappropriately. As a consequence anaesthetists have long been in the vanguard for patient safety¹. Thus, while the overwhelming majority of drugs administered intravenously by anaesthetists worldwide are done so safely there are occasions when errors are made inadvertently and the wrong drug, dose or diluent is administered to a patient².

It should be noted that in the United Kingdom anaesthetists are considered to be individual practitioners who work primarily on their own.³ However, whilst anaesthetists are solely accountable for the anaesthetising of their patients and any other drugs administered by them they do not work in complete isolation. Typically they will have an Operating Department Practitioner (ODP) or an Anaesthetics Nurse (AN) working with them as an assistant. In addition, there are also other medically qualified personnel working in the Operating Theatre at the same time who are not directly involved with the treatment being provided to the patient.⁴

In an attempt to manage patient safety within the health-care profession, one of the techniques used is that of verbal double-checking safety protocols, sometimes referred to as '*witnessing*', the expectation being that if one person misses an error the other will detect it. However while anaesthetists do not have to carry out a verbal double-checking safety protocol for majority of the drugs they administer intravenously there are a number of occasions when they do informally use such a protocol. For example, when they administer controlled drugs such as morphine or medicines like antibiotics. Therefore anaesthetists do in fact carry out a number of verbal double safety checks with other staff as a matter of course at the present time albeit not in a formal structured manner.⁵

Administering a general anaesthesia to a patient has three phases. The first phase is known as '*Induction*' and this is where a patient is put to sleep by the anaesthetists either with an intravenous injection of an anaesthetic drug or the inhalation of an anaesthetic gas. The anaesthetist may also intravenously administer a range of other drugs at this time such as for pain relief or a muscle relaxant⁶.

The second phase of anaesthesia is termed '*Maintenance*' and during this stage the anaesthetist maintains a balance of medications while carefully monitoring the patients breathing, heart rate, blood pressure, and other vital functions. It is also common during the provision of general anaesthesia for the patient to be given a range of drugs intravenously so as to maintain stable vital functions and to help prevent or decrease pain or nausea after the procedure.⁷

Thus, if the '*Induction*' and '*Recovery*' phases of anaesthesia are likened to the takeoff and landing stages of an aircraft flight respectively then the *Maintenance* element of anaesthesia can be considered to be the similar to the main part of a flight. Thus the anaesthetist typically has plenty of time to undertake the tasks required during this phase unless there is an emergency.⁸

The last phase of a general anesthetic is '*Recovery*'. This is when the intravenous or inhalation anesthetic is stopped and the patient is allowed to wake up. To facilitate this process the anesthetist may on occasions also intravenously administer drugs to reverse the affects of drugs previously given to the patient during the procedure. Once awake the patient is closely monitored to ensure that they are not suffering any ill-effects from the anesthesia.⁹

Frequency of drug errors in anaesthetics

While there are a number of peer reviewed studies that have been carried out, research looking at the frequency and types of errors made by anaesthetists tend to be limited to an individual or group of hospitals, the provision of anaesthesia in a particular context, a particular country or do not address the overall frequency of incidents. Furthermore there are few studies that contain denominator data so that the frequency of the errors reported in papers can be calculated. Moreover, the results of some studies appear to draw contradictory conclusions, for example, in a study of adverse drug errors in anaesthesia in Norway it was reported that:

'Drug errors are uncommon, and represent a small part of anaesthesia problems but still have the potential for serious morbidity'.¹⁰

Whereas, the researchers who conducted a study on the frequency and nature of drug administration errors during anaesthesia in New Zealand stated that there was:

'A drug administration error of some type was reported for every 133 anaesthetics, one error involving IV boluses of drug was reported for every 200 anaesthetics...Our data demonstrate a relatively high rate of drug administration error in anaesthesia, and suggest substantial scope for improvements in safety through better procedures and equipment'.¹¹

The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists were contacted to ascertain whether they had any information on the frequency of intravenous drug errors in anaesthesia and both organisations replied that they had not. The reason for this is that neither organisation has the funds available to develop a system to capture and analyse such data.¹²

It has not proved possible, at the time of writing, to find authoritative national or international studies that can be used as an accurate statistical benchmark

with regard to the frequency with which anaesthetists inadvertently administer the wrong drug, dose or diluent to a patient intravenously.

However, to get a rough feel for the potential average error rate for anaesthetists making inadvertent intravenous medication errors we can take the highest frequency error rate identified in this report, i.e. the New Zealand study of 1 error per 200 anaesthetics for the administration of an intravenous bolus. This is because the error is of a similar type to the one made by CPA1 in the PSI's under review. The 200 anaesthetics can then be multiplied with a rough estimate of the average number of drugs given in one anaesthetic, i.e. five or six.¹³ This calculation then provides a rough worst case estimate of about 1 error per 1000 drug administrations. This error rate is approximately one third the numbers of medication errors cited in a study by Krause *et al*,¹⁴ when like anaesthetists just one nurse carried out medication checks prior to administration.

Thus, it would appear that on 'average' anaesthetists have a very good safety record with regard to drug administration errors however this excellent safety record could also be in part due to the under reporting of incidents by them.¹⁵ As for example was reported in the 'South West Anaesthetic Drug Error Survey' (SWADES) where:

'A majority of errors (63%) were not reported to the hospital critical incident reporting system. The reasons given for non-reporting were; mistake of no consequence to patient (49%); no confidence in reporting system (28%); forgot (11%) and personal mistake (7%)'.¹⁶

If the results of the SWADES survey were to be reflected nationally and internationally then a different picture might begin to emerge regarding the assumed low frequency with which anaesthetists make intravenous drug errors. More importantly while an error committed by one anaesthetist did not harm a particular patient it is not a reason for failing to report that the error occurred. Particularly when the SWADES report states that:

'Only a small proportion of errors were reported to the hospital critical incident system despite 80% being associated with potential for permanent patient harm'.¹⁷

Hence, the evidence appears to suggest that a significant amount of potentially 'free' learning may be lost, i.e. errors are actually being made but there is no harm to the patient. However, where an error physically takes place, regardless of whether the patient suffers harm or not, such an event is a 'hit' not a 'near miss' and it is disingenuous to treat it like one.

Observations

Anaesthetists have a long history of being concerned with patient safety. For example in 1974, 26 years before the publication of 'An organisation with a memory: Report of an expert group on learning from adverse events chaired by the Chief Medical Officer'¹⁸ in the UK and the US publication 'To err is

human'¹⁹ both seminal works with regard to patient safety, The Association of Anaesthetists of Great Britain & Ireland established a Safety Committee to study such matters. However errors do occur in anaesthetics and on these occasion's lives are put at risk or patients suffer injury or death because the wrong drug, dose or diluent is inadvertently administered intravenously by an anaesthetist.

To reduce such errors research has been carried out to determine what the factors are that can lead to patients being inadvertently harmed during anaesthesia. There is however a dearth of studies on the frequency of errors made during anaesthesia where denominator data has been collected. As a consequence it has proved impossible to state with any certainty the average frequency rate with which anaesthetists make intravenous drug errors. However a 'ball park' figure has been arrived at which appears to suggest that, in general, anaesthetist's error rates are low when compared to the study reviewed in this report.

It should be noted on the other hand that there is also tentative evidence to suggest that many of the errors made by anaesthetists are not reported by them to official NHS sources. Thus the approximated error frequency rate for anaesthetists developed from the literature in this report may be completely erroneous and 'real' error rate might be far higher.

It is also a cause for some concern that the failure of some anaesthetists to report errors will mean that many lessons from PSI's are going unlearned. This could result in patients being inadvertently harmed unnecessarily. For an error which did not harm a patient in one set of circumstances and therefore thought not worthy of reporting, in other less forgiving conditions, could lead to a significantly different outcome.²⁰

The administration of a general anaesthetic has three phases, *Induction, Maintenance and Monitoring* and *Recovery*.

Anaesthetists do not routinely undertake verbal double-checking safety protocols but there are some circumstances in which such safeguards do have to be undertaken. Section 6 provides a discussion on the advantage and disadvantages of utilising such a protocol.

The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists do not possess a PSI recording system.

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Section 4: ODB working environment

'The ODB is a 10 bed unit caring for Haematology, Oncology and Bone Marrow Transplant (BMT) patients aged 0-20 years, as well as adult BMT patients. It is open from 8am to 6pm Monday to Friday while out of hours patients attend the Accident and Emergency Department.'

'The Unit has an experienced team of 10 nurses led by a Sister and one Senior Staff Nurse. There are also two doctors designated to look after patients.'

'Patients are seen on the ODB for a range of treatments such as outpatient chemotherapy and a range of diagnostic tests including a number which continue throughout the treatment of some patients. Patients are reviewed by both nursing and medical staff.'

'A Theatre List is undertaken within the Treatment Room on ODB every Wednesday afternoon so that if a child requires an invasive procedure like a lumbar puncture or bone marrow aspirate there is no need for them to leave the department. It was while attending one of these theatre sessions that the four patients whose PSI is the subject of this review inadvertently received an overdose of heparin'.¹

Controlled drugs cupboard in ODB treatment room

The *monoparin* (strong heparin) was originally stored in the Treatment Room CDC for research purposes in 2005. The research programme ended in May 2006. Later in 2006 a renal oncology patient who had a surgically implanted *Vas-cath* (a type of intravenous catheter) required *monoparin* to keep the device patent. That patient's last treatment in the ODB was on 11 December 2006 several weeks before the PSI's took place. However, as it was recognised that there would be patients admitted to the ODB who would require *monoparin* as part of their treatment regimen the remaining ampoules were not returned to the pharmacy.²

Plate 4 gives a view of the Treatment Room in the ODB where the Wednesday afternoon Theatre List is undertaken. As can be observed the room is quite small and two cupboards can be seen attached to the wall. At the time the PSI's took place only the white lockable storage cupboard seen in Plate 4 was present. Plate 5 shows the original CDC in the Treatment Room unlocked and with its door wide open. It should be noted that this cupboard is no longer used as a CDC but as a secure cabinet for the storing of drugs used by the anaesthetist undertaking the Wednesday afternoon Theatre List. As can be observed there are three open shelves for the storing drugs.

Controlled drugs however were not the only items that were stored in the CDC. For example, as the anaesthetic drugs to be used by CPA1 are not controlled Nurse 1 (N1) was asked why they were stored in the CDC. N1 replied *'There was only one secure cabinet so they were put in there for safe keeping'*. Similarly, quantities of *Lignocaine* and other non-controlled drugs

including the *monoparin* were also stored in the ODB CDC to keep them secure.

The OBD CDC however was also a place where valuables such as a ring, money, or watches would be left for safe keeping. Such inappropriate usage, it can be argued, eventually resulted in the perceived status of the CDC being lowered from that of high security storage for controlled drugs to a safe place to keep items of value. It has also been reported that such usage increased access to the CDC by extraneous staff.³

The apparent cognitive down grading of the security status of the CDC can be seen in the fact that ODP1 reported that he had sometimes found it difficult to find who on ODB had the key to the CDC. Not being able to locate the CDC key meant that ODP1 could not start laying out the anaesthetic drugs for the Wednesday afternoon Theatre List and thus delays could occur. Finding the situation unsatisfactory ODP1 stated that in the end:

'What made me go to my clinical co-ordinator in Theatres and say that they had to sort out the issue [was] that the controlled drugs were in the general drug cupboard and this particular day, what made it an issue, was the fact that the keys for that cupboard were left in the lock of the fridge ... which is contrary to all policies. No one seemed to be actually in charge of the keys I reported this situation because I wanted the practice to stop.'

Subsequently, in a telephone interview the Theatres Clinical Co-ordinators (TCC1) stated that he *'...had raised ODP1's concern during a telephone conversation with a Senior Staff nurse on ODB [who] said that they knew about ODP1's concern and this had been raised as an incident'*.

However, when interviewed by telephone regarding the situation described by ODP1, N1 said that she *'was not aware of the incident and had not seen any written documentation to support the complaint'*.

In a further telephone interview with ODP1 regarding N1's comments he stated that when he could not find who had the key to the ODB Treatment Room CDC:

'I went looking for the CDC key and found it in the lock of the fridge in which they keep the suxamethonium which is at the back of the Treatment Room. It was one of a bunch of three keys. I did not report this to the ODB staff at the time as I thought I would do it through my Theatres Clinical Co-ordinator, which is what I did when the list was finished'.

However, when ODP1's account of the circumstances surrounding his search for the ODB Treatment Room CDC key was related to N1 she stated that:

'The only time the CDC key is part of a bunch of three keys is when those keys are taken off the Units big bunch of keys and handed over

to the people doing the Theatre List. Therefore it could not have been [one of the ODP nursing staff] who left it in the fridge lock'.

Controlled drugs cabinet in BRHC Theatre four

Plate 6 shows a picture of the cupboard in Theatre Four unlocked and with its door wide open. Theatre Four is where CPA1 spent the majority of his time as an anaesthetist. As can be observed in the left hand corner of the cupboard there is a small inner lockable cabinet. It is in this cabinet that all the controlled and hazardous drugs for use in Theatre Four are kept - including on the day of my visit a box of *monoparin*. This was despite my guide to Theatres assurance prior to his opening the CDC that there would be no *monoparin* present as he had previously ordered the drugs removal.

In fact the *monoparin* had been removed as directed but a patient with a Vas-cath had been subsequently admitted. As the patient was being treated on a daily basis a member of staff had replaced the drug in the CDC without telling anyone.⁴

Comparison of controlled drugs cupboards OBD and Theatre four

Comparing Plate 5 with Plate 6 it can be observed that one difference between the two CDC's is that the cupboard in Theatre Four has a small inner cabinet that can be locked. It is within that inner lockable cabinet that all the hazardous and controlled drugs for Theatre Four are stored. On the other hand the whole of the lockable cupboard in the ODB Treatment Room is the CDC. Therefore, while two keys are required to obtain access to controlled or hazardous drugs in Theatre Four only one key was required to gain access to the same drugs in the OBD Treatment Room.

The reason for the two different types of CDC's is that when the new BRCH hospital was being built the Trust was informed that the cupboards with the small lockable inner cabinet were no longer manufactured. Thus, the Trust sought to purchase lockable cabinets that met the relevant specification for Controlled Drug Cupboards, i.e. British Standard 2881 (BS2881). However the standard does not require that a CDC should be a lockable inner cabinet within a lockable cupboard.

Thus, the Trust purchased the type of CDC found in the OBD for the whole hospital as it meets the requirements of (BS2881). Theatres on the other hand do have the inner lockable type of CDC's because they were brought from the old hospital when the move took place in 2001.⁵

Trust policies

The document '*Framework for the management of Trust policies*' (October 2006) states that Trust '*...policies are deliberately global statements setting out clear expectations and are the Trust regulations that must be adhered to*'...'.⁶

Thus all Trust wide policies apply to:

*'All staff employed by the Trust
'Personnel working in the Trust under honorary contracts
'Students working on placement in training in the Trust
'External Contractors on site'.⁷*

Moreover, the Trust document *'Statement of Principal Terms and Conditions of Employment'*, i.e. each member of staffs contract of employment with the Trust, states in Section 18 that *'You [the employee] are required to comply with our Policies and Procedures as may from time to time be in force'*.⁸

It is therefore quite clear that there are no exceptions to Trust wide policies and that a failure to do so can result in disciplinary action⁹. However, in order for Trust personnel to observe this stricture they must first be aware of the policies that apply to them. To that end Pharmacist (P2) gives a short presentation on safe prescribing which includes the Trust's *Medicine Code* and how to access it on the Trust *'Document Management System'* (DMS) to Doctors on their *'Induction Course'*. Similarly it is also brought to the attention of Nurses on their *'Induction Course'*.

Trust development and administration of policies

The framework document is extensive in its coverage of the development and administration of Trust policies. However, it does not specify the feedback (monitoring) mechanism that must be used by policy makers to ensure that they can identify which members of staff are aware of their policies and those who are not. Moreover, the position is the same when there are changes to a policy or a policy is discontinued. This situation exists because members of staff are not required to indicate explicitly, for example by signing a register, that they have read the appropriate policies or changes to them.¹⁰

Similarly there is no requirement at the present time for staff to explicitly demonstrate that they have revisited crucial policies such as the Trust's *Medicine Code* periodically in order to ensure that they are up to date with its contents.

Thus, whilst there is an explicit procedural framework for the management of Trust policies the individuals who make policy have no knowledge whether the policies they have disseminated have been read and understood by all those members of staff who are required to implement them.¹¹

It is interesting to note that a similar situation occurred in New Zealand with regard to a guideline that required healthcare professionals to undertake a verbal double-checking safety protocol before administering injectable drugs. Merry and Smith observing sometime after the guideline had been published in a Medical Council newsletter that *'...a subsequent survey (involving anaesthetists) revealed that only a minority of practicing clinicians were aware that the guideline existed'*.¹²

Trust policies dissemination and modifications

The Trust policy framework document states that the dissemination of all new policies and amendments to existing policies are to be placed on the Trust DMS and that *'The specific groups etc it applies to receive a specific communication'*¹³. The assumption being that all those who receive such a communication will read it and then cascade that information to all those who need to be aware of a new policy, amendment or the discontinuation of an old policy. This assumption however appears to be without foundations in some quarters.

For example, one respondent reported that:

'...changes to Trust policies are a bone of contention I sometime get as many as 30 or 40 e-mails saying policies have been changed – they send all the policy even if only one line has been changed or a review has simply been undertaken with no changes – I do not have time to read them all so I simply delete them from my system... – however if there is a change which clearly effects my area of responsibility then I make sure that it is disseminated to all the staff via Ward meetings – I do audit some of the policies that are relevant to the Department but it would make life much easier if where there are specific changes to policies were flagged up'.¹⁴

Another respondent said that there was *'... no specific formal system for making sure that anaesthetists are aware of changes to UBHT policies'*.¹⁵ A third respondent when asked how they would find out if there was a change in the Trusts *Medicines Code* (policy) said *'We would be told, perhaps a memo or a note in the communications book'*.¹⁶ Similarly, a another respondent to that question said *'Sometimes in communications book'*.¹⁷

Additionally, a demonstration of how to access policies on the Trust DMS was given to the author by a senior member of the medical staff. It took several attempts by CPA4 before he could find the policy that had been specified (Chapter 11 of the *Medicines Code*). This was in spite of the fact that he had worked at the Trust for some considerable time, was familiar with the DMS and was also a member of the *Medicines Advisory Group* which approves such policies.

It was also noted by several respondents that policies can be very long documents CPA3 observing that sometimes *'...its 60 pages long and there will be one sentence in it that's actually important '*,

Trust policy on checking injectable medicines

The development and administration of the Trust's *Medicine Code* conforms to the Trust's framework and management policy document noted earlier. The *Medicine Code* consists of a number of chapters. Of particular relevance to these PSI's are Chapters 9, subsection 4.2 and Chapter 11, subsection 2,

bullet point 1. The former chapter deals primarily with adults and the latter solely with children.

Subsection 9.4.2 '*Medical Checking*' states that:

*'All other injectable preparations, chemotherapy and Controlled Drugs must be checked by **two** appropriate professional individuals, **one of whom must be the administering practitioner**. Where medicines are second checked, the second checker must independently work out any calculation, and second check all aspects of the checking procedure'. (Emphasis in the original)*

Subsection 9.4.3 states: '*For paediatric administration see separate policy*'.

Subsection 9.4.4 states: '*In the event that qualified staff undertake solo administration they are responsible for their actions in doing so*'.

Thus, the intention of the Trust's *Medicines Code* appears to be clear. Where injectable drugs are to be administered to children, practitioners must follow the additional requirements set out in a separate paediatric policy. Where injectable drugs are to be administered to an adult they must be checked by two qualified medical practitioners except where a practitioner decides to or has to undertake the solo administration of a drug or drugs. In these cases subsection 9.4.4 can be invoked by the qualified practitioner to provide relief from subsection 9.4.2. Subsection 9.4.4 was specifically incorporated into the *Medicines Code*, because it is argued, that there are circumstances:

'...recognised nationally via the Association of Anaesthetists of Great Britain and Royal College of Anaesthetists that frequently in the Operating Room it is not possible to double-check'.¹⁸

However, at the time of writing I have not found a body of literature to justify such a position¹⁹. For example in a study on preventable mishaps during anaesthesia undertaken by Cooper *et al* at Harvard it was reported that:

'When prompted with the question, "At what stage of anaesthesia is a problem most likely to occur", interviewees were usually of the opinion that induction or emergency, or both, were the most critical periods. Yet, nearly half of the incidents were reported to have occurred during the maintenance period. This could mean that many errors occur, or proceed to a point where they are recognized as incidents, during the time when problems are least expected. The induction – emergency preconception may be a trap'²⁰.

This view is also supported by the evidence of a much earlier study undertaken by Chopra *et al* when it was noted that, '*Forty-five percent of all reported significant observations [errors] were made during maintenance of anaesthesia*'.²¹

It is therefore of interest to note that The Association of Anaesthetists of Great Britain and Ireland in their monograph *'Fatigue and Anaesthetists'* state that *'Anaesthetists are most at risk of microsleeps and loss of vigilance during the maintenance period of an anaesthetic.'*²²

As noted above the *'Maintenance'* phase of anaesthesia is when anaesthetists have the most time to undertake tasks such as the intravenous administration of drugs unless there is an emergency. It should also be noted that the errors made by CPA1 in the PSI's under review occurred before the *'Induction'* of anaesthesia and there was no emergency (See section 5).

Trust policy on checking injectable medicines to children

As noted above practitioners who wish to administer injectable drugs to children must refer to a separate medicines policy, i.e. Chapter M11 *'Prescribing and Administration of Medicines in Children'*. Subsection 11.2 of that Chapter entitled *'Administration of Medicines to Children'* states:

*'Medicines Code, Chapter 9: Administration of medicines, gives details of the general policy relating to administration of medicines within UBHT. In addition the following policy statements **must** be followed:*

*'All medicines given to children **must** presently have a second check. (This requirement is being revised in order to identify situations in which a single check is appropriate and those where the requirement for a second check will be retained.)'* (My emphasis)

Thus the instruction that all medicines to be administered to children, regardless of a practitioner's medical status, qualifications, the type of medicine or route of administration, must be subject to a second check appears to be unequivocal. All medicines to be given to children must be double-checked prior to their administration.

Anaesthetists' awareness of medicine code

As noted earlier in order for an instruction to be implemented all those to whom it applies must be aware of it. However, when the CPA1 was asked whether or not he was aware of the instructions contained in Chapters 9 and 11 of the Trust's *Medicine Code* he replied: *'I have never seen the policies - never brought to my attention'*

Similarly, CPA2 when asked about the content of Subsection 11.2 replied:

'Only when you [the author] showed me - I was aware of the first one [i.e. 9.4]'
Likewise CPA3 replied:

'First time I knew was when [Dr X] mentioned you [the author] and the drugs policy - I knew about 9.4 after the heparin incident and 11.2 from you today'.

Furthermore when asked about whether or not the general body of anaesthetists would be aware of the instruction contained in Chapters 9 and 11 of the Medicines Code a Senior Manager (SM1) involved with clinical governance replied: '*I know for certain they do not know*'.²³

Medicine code chapter 11 update

The instruction in bullet point one subsection 11.2 of the *Medicines Code*, i.e. '*...all medicines given to children must presently have a second check*' came about as the result of an update to Chapter 11 by the BRHC *Medicines Working Party* (a subcommittee of the BRHC *Clinical Risk Committee*). When asked about the instruction in bullet point one during a telephone interview a representative of the working party, Pharmacist 1 (P1), noted that at the time Chapter 11 was being updated there had been a discussion taking place about the nature of verbal double checks on medicines.

One of the issues mooted at the time of the update was whether the nursing staff in BRHC should be allowed to administer a limited range of oral drugs to children without undertaking a verbal double-checking safety protocol. Thus, to ensure that nurses did not inadvertently undertake the solo administration of oral drugs to children before a formal determination had been made by the Trust the instruction in bullet point one was added to subsection 11.2. of the *Medicines Code*.

P1 also stated that the potential implications of adding bullet point one to subsection 11.2 of the *Medicines Code* had not been considered by his working party with respect to medically qualified doctors. Nor, in so far as he was aware, any of the other committees, including the *Medical Steering Group*, which ratified the updated Chapter 11 before being published on the Trust DMS.

At a presentation of the updated *Medicines Code* given to members of the Anaesthetics Department at an '*Audit Presentation Meeting*' on the 20 September 2005 by CPA4 bullet point one of subsection 11.2 was not mentioned. This was because CPA4 had not recognised the implications of the additional bullet point in 11.2 since it had not been emphasised in any way, such as for example by being printed in bold type or underlined. As a result this important change to the *Medicines Code* was not discussed at the meeting. Hence members of the *Anaesthetics Department* remained unaware of its existence, as noted above, until it was brought to their attention during the course of this review.

Visual similarity of heparin ampoules at the Trust

As noted earlier errors do occur in the administration of a medicine because different drugs, doses and diluents can have very similar perceptual features. Such as for example, ampoules of different drugs, doses or diluents being of the same size and labels looking alike. The ampoules of heparin that CPA1 inadvertently administered to the four patients involved in this review had these characteristics.

Plate 7 shows a range of heparin products that are regularly purchased by the Trust. It can be seen that the packaging or livery for each group of products is similar. However, Plate 8 shows that the packaging of *monoparin* (strong heparin) and *Hepsal* (weak heparin) are really quite different. The text of the registered trademark *monoparin* is dark blue in colour and the box has a distinctive green line and states 25,000 I.U. in 5ml on the front. The proprietary name *monoparin* is also printed on three sides of the box.

The text of the registered trade mark of *Hepsal* on the other hand is red in colour and the dose of 10 units per ml can be seen on the front of the box. The proprietary name *Hepsal* is also printed on four sides of the box again in the colour red. In Plate 5 the distinctive red and white livery on the side of a box of *Hepsal* can clearly be seen on the middle shelf of the cupboard. Thus giving an indication of how conspicuous the outer packaging of the product is.

Plate 9 however shows the similarity between the visual appearance of *monoparin* and *Hepsal* ampoules when removed from their outer packaging and laid in their respective plastic trays.

There is however a perceptual difference between the *monoparin* and *Hepsal* ampoules. The *monoparin* ampoule has a red spot plus a green and red band around the top while the *Hepsal* ampoule has two white bands and a white spot. The bands however are solely for use by the manufacturer. They allow the manufacturer to determine the contents of an ampoule before it has a label attached to it. While the spots are there to indicate the place a medical practitioner should place her or his thumb in order to break off the top of an ampoule prior to use so as not cut themselves. Clinicians are not trained or ever expected to use the bands or spots as an identification cue regarding the contents of any ampoule of medicine²⁴. Thus for all intents and purposes medical practitioners are 'blind' to them as a method of identifying the contents of an ampoule.

Plates 10 and 11 allow a visual comparison to be made between *monoparin* and *Hepsal* ampoules. The information on the labels of each ampoule is printed in black on a *Pantone Yellow* background the same as in Plates 1 & 2. As the scale in front of the two ampoules shows the text providing the information on the labels regarding the contents is small. Thus, even at fairly short distances there are strong perceptual similarities between the two different concentrations of heparin.

It is important to note however that this form of labelling for medicine ampoules was not introduced by the pharmaceutical industry but specified by the NHS in 1991 in an attempt to prevent medication errors.²⁵

The rationale for having the two colour NHS specification was because it was thought that multicolour coding might lead to medical practitioners using the colours as a short-cut to identify the drug in an ampoule rather than reading the label. Furthermore, as the manufactures of drugs had no convention as to what colour represented which medicine it was believed that a change to multicolour coding was an accident just waiting to happen. Hence, the switch

to the yellow and black arrangement for the labelling of ampoules with that particular colour combination 'affects conspicuity to a surprising degree'²⁶

The proposal for the NHS specification for ampoule labels was accepted by the National Pharmaceutical Supply Group following:

'...a detailed study undertaken by the Centre of Responsibility for Pharmaceutical Procurement based in North East Thames Regional Health Authority and consultation with the Association of Anaesthetists of Great Britain and Ireland, The Hospital Pharmacist Group of the Royal Pharmaceutical Society, the Association of the British Pharmaceutical Industry and the National meeting of the NHS Regional Quality Controllers'.

However, once the NHS specification was being utilised for ampoule labelling it was recognised that different highly potent drugs looked very similar since there were no visual clues to differentiate them. Indeed, the only way for a healthcare professional to ensure that they are about to administer the correct medicine, if the label has been produced to the NHS specification, is to read the label correctly. However, as noted earlier, it has been recognised for sometime that even the most diligent healthcare professional can miss an error that is clearly before their eyes and administer the wrong drug, dose or diluent.

Webster making the observing that:

*'...it seems unlikely that labels will be read every single time a drug administration is made. What will tend to happen is that colour, shape and size will dominate as the features used to discriminate [syringes and ampoules].'*²⁷

Human factors

Similarly to Webster, Nott has concluded that:

*'It is a fallacy to assume that mistakes cannot happen as long as the label is read. Psychological factors are involved which makes the standardisation of labels dangerous...the phenomenon of "in-filling" can easily occur, i.e. we have expectations of seeing or reading a particular event or name but only see part of it and our brains fill in the rest.'*²⁸

Abeysekera et al observing that:

*'Although some have advocated that all ampoules should be identical to ensure the label is read carefully, it is recognised that humans tend to see what they expect to see, and words are not usually recognised by what is written but by their shape (Poggenorf effect).'*²⁹

While Dawson and Arkes, has observed that:

'...physicians and non-physicians alike tend to seek only evidence that can be used to confirm hypotheses... [This] confirmatory bias not only causes one to seek predominantly confirmatory evidence but influences data interpretation as well'.³⁰

Pines has also argued that *'Confirmation bias is a pitfall in emergency care and may lead to inaccurate diagnosis and inappropriate treatment care plans'.³¹*

The USA based ISMP also warning healthcare professionals that:

'Confirmation bias refers to a type of selective thinking whereby one selects out what is familiar to them or what they expect to see, rather than what is actually there. Many errors often occur when practitioners, due to familiarity of certain products, see the one they think it is rather than what it is. It is human nature for people to associate items by certain characteristics. It is very important for the health care community to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems'.³²

Further support for the role of confirmation bias being a part of the aetiology that can result in an iatrogenic event taking place can be found in the research undertaken by Merry et al who state that administration errors in anaesthetics are frequently made because *'...people see what they expect to see'³³*.

The United States Federal Aviation Administration (FAA) making the same point in relation to aviation stating that on occasions *...'crewmembers see what they expect to see rather than what is actually accomplished or indicated'.³⁴*

Additionally, it has also been suggested by Reason that many errors are the result of a 'slip'. A slip occurs when a person fails to carry out the actions that they had intended and *'...are commonly associated with attentional or perceptual failures'.³⁵* Interestingly it has also been suggested that such absent-minded errors: *"...are a characteristic of a highly skilled or habitual activities. In short, they are a problem for the expert, not the novice."³⁶*

Leap also draws our attention to the fact that there are:

'A variety of factors [that] can divert attentional control and make slips more likely...Psychological factors include other activities ('busyness') as well as emotional states... [may be caused by] a host of external factors [including] interpersonal relationships and many other forms of stress'.³⁷

Indeed, there has been a great deal of research conducted on stress in healthcare settings which has revealed that all those who work in such environments are often subjected to excessive amounts.^{38,39} It is therefore of

interest that Leape argues that:

'Although it is often difficult to establish causal links between stress and specific accidents, there is little question that errors (both slips and mistakes) are increased under stress'.⁴⁰

In a similar manner Nguyen and Bibbings argue that:

'It is accepted and proven that errors lead to accidents and that stress can lead to errors. It follows logically, therefore, that stress must also contribute to accident causation'.⁴¹

Moreover, they also suggest that the stress factors that increase the likelihood of an error occurring include, the pressure of workloads, distractions, interruptions, insufficient staffing levels and fatigue. And while some *'medical staff seem to deny the effect of stress and fatigue on performance'*, there appears to be a body of evidence to suggest the opposite.⁴² Thus, such factors should not be dismissed as they may play a part in creating the right conditions for the adverse affects of other human errors to flourish.⁴³

One empirical example where some or all of the influences discussed above may have played a part can be drawn from a study undertaken by Krause et al.⁴⁴ Conducted over 46 weeks and 129,234 administered medications, the observed error rates for the administration of 1000 medications by two nurses was 2.12, and for one nurse 2.98. However, while there was a significant statistical improvement using two nurses to check drugs the error rate was still greater than two per 1000 doses. Therefore as the staff involved in that study did not deliberately select the wrong, drug, dose, diluent or route they must have been convinced that the action they were about to take was the correct one.

Thus as Merry et al note *'...errors are inherent in any human activity and cannot be avoided simply by resolve – indeed, the person will often not even realize that an error has been made'.⁴⁵* Particularly if, as Ferner argues, *'... the person giving the drug is unaware of the existence of a similarly packaged preparation [is present, in which case] the patient may be put at risk'.⁴⁶*

Drug errors within the Trust

A review of all the reported PSI's within the Trust showed that medication related events were the most frequent accounting for 18% of all incidents in 2006. However, it should be noted that data from the NRLS shows this figure to be comparable to other similar acute teaching NHS Trust's.

With regard to medication errors made by anaesthetists within the Trust a search was conducted of the data held on the Trust's database *'Ulysses'*. The search revealed that the taxonomy and data structure used by the database did not readily allow the provision of such specific information. But by using a more labour intensive method of inspecting reported medication errors, i.e. selecting likely PSI's and then read the details of those cases it was found that

'There were a total of 14 errors involving anaesthetists and drugs...' including the four currently under review since the database was installed in 2000 -2001⁴⁷.

Frequency of heparin related incidents in Trust

In an attempt to ascertain how frequently heparin featured in medication errors at the Trust a second search was conducted of the Trust's PSI database. The search revealed that heparin was implicated in 63 or 1.2% of the 5261 medication errors reported to date.

Besides the four PSI's that are the subject of this review, of particular note is an incident report that provided the following information:

*'Patient given incorrect strength heparin by accident. Heparin 5000 IU/ml discovered in box with heplock 10 IU/ml...All children with IV lines insitu had bloods taken for clotting. 2 came back elevated...Error discovered after the event on subsequent checking of drugs. Flushed with Heplock because line was needed to be kept patent'*⁴⁸.

The circumstances in which the PSI above occurred are not exactly the same as in the PSI's being reviewed at the present time but they are quite similar.

In another PSI a very significant overdose of heparin was administered by a surgeon who used almost all the heparin contained within four 5,000 IU/ml in 5ml ampoules, i.e. 100,000 IU in 20ml, to flush a patients implanted intravenous catheter even though the person assisting him in the operation queried its use at the time.⁴⁹

However like the NHSLA and NPSA databases the number of incidents where *'heparin flushes [AND] anaesthetists'* have been specifically involved could not be ascertained. This was because, as noted above, taxonomy and data structure used by the Trust's database does not readily allow for the automatic provision of information using such specific data categories. It should also be noted that the *'Summary'* data held on each of the incidents that have been identified is very sparse and that on many occasions the *'Outcomes'* area of the form contains no information.

Hepsal purchased by Trust

A review by P1 regarding the amount of *Hepsal* purchased by the Trust last year found that a total of £8,740 had been spent and that if it were all to be replaced by *'0.9% saline'* the saving would amount to £5,529. Thus there would only be a small saving on costs if *'heparin flushes'* were to be replaced with saline. The potential safety gain could however be considerable.

Observations

The Treatment Room is used for a range of clinical purposes during the week

and not solely for the ODB Theatre List held on Wednesday afternoons. Although the patient requiring *monoparin* had ceased to attend ODB the drug was retained for use with other patients.

Allowing the continued storage of items other than statutorily controlled drugs in the ODB CDC and access by extraneous staff appears over time to have lowered the cupboards perceived security status. Indeed, the key to the CDC being found unattended in the lockable refrigerator within the Treatment Room, it can be argued, is symptomatic of such a situation.

Although an instruction had been previously given by a senior member of the BRHC staff, CPA2, that all *monoparin* should be removed from all CDC's in Theatres, upon inspection a box containing the ampoules of the drug was found in Theatre Four's CDC. This was because a patient required the drug on a daily basis to keep their Vas-cath patent and a member of staff had replaced the stock of *monoparin* with out telling anyone.

Although CDC in the OBD Treatment Room and in Theatre Four are used for the same purpose, only one key is required to access controlled and hazardous drugs in the former, but two in the latter. Thus, although the lockable drugs cupboard in Theatre Four might be open neither CPA1 nor any of his colleagues could have retrieved controlled or hazardous drugs like *monoparin* unless they had consciously unlocked the second inner cabinet to gain access.

The reason that there are two different types of CDC's at BRHC is because the CDC's with the inner lockable cabinet were brought from the old hospital and fitted in Theatres. However, one way in which that process could have been emulated is if there had been two wall cabinets. One cabinet used solely for controlled drugs and the other for high risk or dangerous drugs.

A failure by staff to follow Trust policies can result in disciplinary proceedings.

Currently there is no feedback mechanism in place to ensure that the originators of Trust wide policies can identify which of the relevant Trust staff is or is not aware of their policies. There is also no requirement for individual members of the Trust's staff to revisit crucial policies like the *Medicines Code* periodically to ensure that they are up to date with the contents or a method for explicitly recording that they have done so. This kind of situation has also occurred on at least one other occasion overseas.

The current system in place for informing staff of Trust wide policies and any changes to them does not appear to work in the way intended. This is because the methodology currently used for informing staff does not appear to be user friendly. This results in staff under certain conditions selectively ignoring some of the communications that they receive. Particularly as some policies can be 60 pages long and there is no information as to what specific changes, if any, have been made. Furthermore some members of staff do not appear to be aware that there is a formal system in place to inform them of

new or changes to Trust policies. Additionally, navigating the current DMS system can be challenging and time consuming.

The evidence discussed in this report implies that the circumstances that might prevent anaesthetists from carrying out a verbal double-checking safety protocol prior to administering an intravenous drug may not be as frequent as is thought at the present time and thus feasible. Furthermore, just because there are occasions when anaesthetists and other healthcare professionals cannot carry out a verbal double-checking protocol prior to the administration of an intravenous drug it does not mean that they should not carry them out when they can. Particularly given the safety argument discussed in section 6 of this report.

The Trust's policy on the administration of drugs to children is unequivocal in that they must always be subjected to a double check. However such double checks have never been carried out by CPA1 or many if not all of his colleagues. Thus strictly speaking CPA1 and his colleagues have, for some considerable period of time, albeit unwittingly, broken the terms of their Contract of Employment.

The evidence presented in this Review demonstrates that neither CPA1 nor, in so far as the author could ascertain, were any of his colleagues aware of the limitations placed on their professional conduct by subsection 11.2 of the Trust's *Medicines Code*. However, the long standing legal principle of '*ignorance of the law is no excuse*' would appear to apply as the members of the Anaesthetics Department had been informed of the update to the Trust's *Medicines Code* and it was available for them to read on the Trust's DMS. Nevertheless it would appear that the anaesthetists to who subsection 11.2 of the trust *Medical Code* applies may not have done so.

It was not the intention of the BRHC Medicines Working Party that bullet point 1 of subsection 11.2 of the Trust's *Medicines Code*, regarding the verbal double-checking of drugs before their administration to children, should apply to medically qualified doctors. But given the ratified text of the updated chapter 11 it does.

The reason this occurred was because the significance of the change to anaesthetic practice that bullet point 1 of subsection 11.2 of the Trust's *Medicines Code* made was not recognised by CPA4 who gave a presentation of the updated *Medicines Code* to the Anaesthetics Department. This was because that particular passage in the *Medicines Code* had not been emphasised by the use of bold text as had occurred in other parts of that document.

The outer packaging of *monoparin* and *Hepsal* are significantly different and it would be very difficult to confuse them under normal Treatment Room lighting levels. However, once the ampoules of *monoparin* and *Hepsal* are removed from their outer packaging their visual appearance is similar and very much easier to confuse. Particularly, if it is not known, that a hazardous drug is present.

The different coloured bands and spots on the ampoules of *monoparin* and *Hepsal* are for the manufactures use and not clinicians. Thus whilst physically present they are not consciously processed by the person about to administer the medicine as a means to identify the contents of the ampoule.

The 1991 NHS specification for the labelling of ampoules is responsible for the colour and format of the labels on the ampoules of *monoparin* and *Hepsal* looking so similar. However, as noted later in section 6 of this report the NHS specification has been superseded by guidance from the MHRA which prevents the labels of ampoules on new pharmaceutical products following that layout. But as evidenced by the PSI's which are the subject of this Review there are pharmaceutical manufactures that are still using the format.

There are a range of factors within the working environment and the systems of work that people use which promotes human error. Exhorting people to be more careful will not prevent these unconscious human biases from functioning. For as argued by Toft⁵⁰ the structural and dynamic properties of the working environment play a central role in the making of inadvertent human errors. Thus, the operating environment and system of work to be used by people needs to be designed so as to reduce, in as far as is reasonably practicable, the likelihood that individuals will unintentionally succumb to such mechanisms.

The total number of medication errors at the Trust is comparable to other similar healthcare institutions. The Trust's PSI database could not automatically provide the data requested by the author with respect to the total number of medication errors by anaesthetists. This was because the taxonomy used by the Trust's database for categorising PSI's does not readily allow for the provision of such information. However it did prove possible to determine that in addition to the four PSI's that are the subject of this Review there have been at least 10 other occasions when anaesthetists have made drug errors since the database was established in 2000 – 2001.

The Trust like the NHSLA and NPSA was unable to readily provide data on '*heparin flushes* [AND] *anaesthetists*' directly because of the taxonomy and data structure used by the computer systems databases. Additionally, the summary of an incident provided by the '*Ulysses*' database had very little data describing what had occurred during the event. Frequently the '*Outcomes*' field was blank while one PSI that had occurred in 2004 contained the phrase '*Incident being investigated*'. Thus the reports generated have not been particularly insightful.

However, the search did reveal that 63 PSI's or 1.2% of all medication errors at the Trust were heparin related. It was also discovered that one PSI had occurred with features similar to the PSI's that are the subject of this Review. Another PSI demonstrated that even when warned there are some surgeons who take no notice and continue with their treatment even though it places their patient in harms way.

If the total amount of heparin purchased by the Trust were to be replaced by saline there would be cash savings of £5,529 which is negligible in terms of the Trust's medicines budget. While the risks to patient safety could be improved if such an action were to be taken by the Trust medical research does not currently support the wholesale abandonment of heparin products. Thus further research is required by an appropriate medical body to ascertain the efficacy of heparin as a flushing agent.

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Section 5: Chronology of events leading to the PSI

Wednesday morning 3 January 2006

The ODB Treatment Room had one CDC and it was there that the drugs required to anaesthetise patients on the Wednesday afternoon ODB Theatre List were stored along with the controlled and other hazardous drugs. As noted above, a check was made of all the controlled medicines stored in the CDC every 24 hours. Therefore sometime during the morning of Wednesday 3 January 2007, the staff involved could not remember the exact time, a check of the drugs in the CDC was undertaken by Nurse 2 (N2) and Nurse 3 (N3). N2 noting that:

'We check the controlled and dangerous drugs against the stock listed in the Controlled Drugs Book. Having finished the check we sign the book and if there is a discrepancy it is reported to the Unit Sister'.

When N3 was asked could the *monoparin* ampoules have been removed from their box and left on a shelf in the CDC? She replied, *'No, all drugs are always kept in their packaging – never been out of their box in all the years I have checked'.*

The controlled drugs check did not reveal any discrepancies in the stock of the CDC and the *monoparin* ampoules were in their box when N2 and N3 completed their audit.

Wednesday afternoon 3 January 2006

Sometime between 11.30hrs and 12.00 noon the four patients who were to have diagnostic test that afternoon were admitted to the ODB for their pre-operative examinations.

Patient 'A' was to have a bone marrow aspirate and lumbar puncture, patient 'B' a bone marrow aspirate while the other two patients 'C' and 'D' were to have lumbar punctures. As young children do not tolerate such invasive procedures well when awake the investigations were to be carried out under a general anaesthetic. CPA1 who was to anaesthetise the patients was very experienced and had managed the once a week ODB Treatment Room Theatre List for over three years.

Pressure to start theatre list

Coming directly from the *Cardio-Catheter Unit* without a break CPA1 arrived late on ODB noting at interview that he *'...was in a bit of a rush' [and] under pressure to get the list started'*. The reason that CPA1 was under pressure is because he and all the other staff on ODB do not wish to add to their patient's

and their parents stress by keeping them waiting. ODP1 making the additional point that *'...the later it is [i.e. starting the list] then the more chance they have [children and parents] of being stuck in traffic jams on the way home'*. Hence, the pressure to start the Wednesday afternoon Treatment Room Theatre List is driven by the desire to make the life of patient's and their parents as stress free as possible under the circumstances.

It should also be noted that CPA1 had been working since 07.45hrs that morning without any rest breaks or making time to have lunch. But when interviewed CPA1 said that he had not felt fatigued or tired at the time. However, when asked if anything had caused him an emotional upset that day he replied that he had been given the date of a funeral that he was to attend.

CPA1 pre-anaesthesia procedures

Having arrived at ODB CPA1 went straight to the Ward to carry out his pre-operative examination on each patient to ensure that they were fit enough to be anaesthetised. Having completed his examinations CPA1 then went to the ODB Treatment Room to check out the anaesthetics machine and prepare the drugs that he would require for the session.¹

CPA1 laid out one anaesthetics drug tray for each patient on which he wrote their name. Next he placed the three syringes, one for each drug that he was going to administer, on each patient's anaesthetics drug tray. The drugs to be administered to each patient were then taken out of the CDC and placed on the trays. The drugs to be administered were *'Propofol, to put them to sleep - wash out line with saline [and] heparin to keep the line patent'*. The drugs were also to be administered by CPA1 in that order.

When CPA1 was asked whether his drugs were located in the same place as always in the CDC that afternoon he replied:

'Propofol always kept in cabinet [CDC] – saline was all over the place – weak Hep [Hepsal] in three places- in cupboard other side of room – sometimes in Controlled Drugs Cupboard - sometimes draw compartment of trolley – sometime not in a box'.

CPA1 went on to note that the *'heparin was on the second shelf but not in a box - but four ampoules in a plastic tray'*.

Not being aware that there was any *monoparin* in the CDC CPA1 took the plastic tray of what he perceived to be four ampoules of *Hepsal* out from the CDC and placed one ampoule on each tray.²

Conflicting views

When N1 was asked to your knowledge as *Hepsal* ever has been kept in the CDC? She replied its *'Never been kept in the cupboard'*. Similarly, when asked if it was possible that the 5ml *'heparin flushes'* could have on occasions

been stored in the CDC. N 2 replied '*I have never known it*'. Nurse 3 (N3) replied '*No*' and Nurse 4 (N4) also said '*No*'

On the other hand when queried as to whether he had ever seen a box of *Hepsal* in the CDC ODP1 stated that:

'I am just saying that a box of Hepsal will be in amongst the other collection of drugs - it might have been put in there [the CDC] inadvertently - in so much as over the other side of the room they have saline and Hepsal in a cupboard - one scenario would be that I would get it [Hepsal] from where I can find it - put it on the side then at the end of the list either I or somebody just puts it in the cupboard – so its fluid – rather than officially kept in there but either way it has definitely been in'.

Similarly when asked if he had seen *Hepsal* in the OBD CDC on previous occasions CPA1 replied '*...that's a very definite yes*'.

CPA1 procedure for drawing up drugs into syringes

When CPA1 was asked how he had checked the drugs to be drawn up into the syringes to ensure that they were the ones he intended to administer CPA1 replied:

'I check the drug as I draw it up so I read the ampoule then draw the drug up. I did not expect to find strong heparin - I was not aware any was stored there - I expected to see the right drug'.

Therefore having selected what he perceived to be were the correct drugs for the Wednesday afternoon Treatment Room Theatre List CPA1 drew them up into their respective syringes.

The process of drawing up the contents of an ampoule used by CPA1 was that he first read the label on the ampoule, then broke off the top, after which he drew up the contents into the syringe. CPA1 then discarded the remains of the ampoule by placing them in a '*sharps*' box placed there for that purpose. CPA1 noting that he used:

'...different syringes for different drugs, for Propofol I use a syringe which is appropriate for the volume I need to give, which is variable...Depending on the size of the child. The heparin and the saline are always given in the same dose. The heparin always comes in ampoules of 5mls so I have always put that in a 5ml syringe. The normal saline comes in a 10 ml ampoule so therefore I put that in a 10 ml syringe. So I have an ampoule of 5mls a syringe of 5mls an ampoule of 10 mls a syringe of 10mls so without having to sit down and write labels you know exactly what drugs are in the syringes and the Propofol is white like milk so its easy to get that right'.

With regard to CPA1 undertaking a verbal double-checking safety protocol had he wished to do so. CPA1 was assisted by ODP1 and there were other members of the ODB clinical staff, including a medical consultant, available to double check the drugs to be administered if he had called upon them to do so. However, CPA1 was under the impression, like many if not all his colleagues, that he was not required to carry out such a check as he was not aware of bullet point 1 subsection 11.2 of the Trust *Medicines Code*.

It should also be noted that for a verbal double-checking safety protocol to have identified that CPA1 had selected the wrong concentration of heparin the verbal double safety check would have needed to have been carried out before he drew the contents of the ampoules up into the syringes. This is because once the wrong concentration of heparin had been drawn up and the ampoules disposed of there were no visual clues to inform someone doing a verbal double safety check of what the actual strength of heparin in the syringe was. Similarly, if CPA1 had labelled the syringes, each check would have been against a label showing the concentration of heparin that the syringe should have contained and not what it did contain.

Anaesthetising patients

Once ready the list was started. CPA1 anaesthetised each patient in turn and in doing so the wrong concentration of heparin was inadvertently administered.

Three of the patients the CPA1 anaesthetised had Hickman Lines while the fourth patient had been fitted with an intravenous cannulae. CPA1 noting that, *'The one without the line had less heparin than those with a line'* but could not specify how much less.

As noted earlier because none of the patients displayed any adverse physiological symptoms following the administration of the *monoparin* CPA1 did not realise that he had made an error. Similarly, none of the other healthcare professionals attending the patients realised that anything was amiss for the same reason.

Recovery of patients

All the patients had their diagnostic investigation completed between approximately 13.30hrs and 15.30hrs with each procedure appearing to have been uneventful. CPA1 did not leave ODB until after the last patient had woken up. Once awake and showing no adverse symptoms each patient was discharged from ODB either to home or as in the case of patient C back to Ward 34, BRHC.

Wednesday evening 3 January 2006

On Wednesday evening the parents of the two children who had undergone bone marrow aspirates became concerned for their welfare as there appeared to be more bleeding than normal from that site. Because the ODB was now

closed the Mother of patient A and the Father of patient B telephoned Ward 34, BRCH, to report the problem. They were both told to apply a pressure dressing which they did and the bleeding stopped. However, this information was not communicated to ODB as the patient's parents concerns were not documented in the Ward communications book. Thus the clinical staff on ODB were completely unaware of the parental concerns that had been expressed about bleeding experienced by their children.³

Thursday morning 4 January 2007

Although not required to attend ODB on Thursday 4 January the mother of patient A brought her daughter in to the Unit at approximately 09.15hrs. Patient A's mother then informed the staff about her concerns the previous evening with regard to the excessive bleeding that had occurred at the site of her daughter's bone marrow aspirate. Upon examination by a staff grade doctor it was found that patient A's bleeding had stopped but that the dressing was soaked in blood.

As a result it was decided to apply clean dressings not only to the site of patient A's bone marrow aspirate but also to the site of the lumbar puncture which she had also undergone. Patient A was then discharged to home. However, while still in the main Reception Area on Level 2 of BRHC patient A vomited. Consequently, she was immediately brought back on to the ODB for observations, her condition quickly improved and she was then discharged to home a second time.

Check of controlled drugs cupboard

Approximately 30 minutes after Patient A left ODB two nurses, N3 and N4 while undertaking the daily check of the drugs stored in the Treatment Room CDC, discovered that four ampoules of *monoparin* were missing. This fact was reported to N1 who then realised that patient A's excessive bleeding could have been caused by an inadvertent overdose of heparin. It was also realised at this point that all the patients on the previous days Treatment Room Theatre List could also have received an overdose of the drug.⁴

ODB immediate clinical investigation

A clinical investigation was embarked upon immediately by the medical staff to determine whether any of the patients had suffered an overdose of heparin. It was subsequently discovered that all the patients who had been anaesthetised by CPA1 on Wednesday 3 January 2007 had inadvertently received a significant overdose of heparin.

ODB investigations and prognosis post 4 January 2007

During the clinical investigation of patient A it was discovered that she had suffered a bleed into '*...the sub-dural space post LP [Lumbar Puncture]*'.⁵ However, further in-depth investigations revealed that there was no need for any neurological intervention or other treatment with regard to the heparin

overdose. Patient A appears to have recovered from her PSI with no long term medical problems expected due to the overdose of heparin she experienced.^{6, 7, 8}

Patient B who also experienced excessive bleeding at the site of his bone marrow aspirate was found not to require any neurological intervention or other treatment with regard to the heparin overdose. Patient B appears to have recovered from his PSI with no long term medical problems expected due to the overdose of heparin he experienced.^{6, 7, 8}

Patient C was an inpatient on Ward 34, BRHC. On examination it was found that she had experienced some back pain following her Lumbar Puncture and there was a small bruise at the site. Further investigation found she had had a small bleed at the site of her Lumbar Puncture but this did not require any neurological intervention or any other treatment with regard to the heparin overdose. Patient C appears to have recovered from her PSI with no long term medical problems expected due to the overdose of heparin she experienced.^{6, 7, 8}

Patient D's clinical examination proved to be normal as was his coagulation test and no further action was required. Patient D appears to have recovered from his PSI with no long term medical problems expected due to the overdose of heparin he experienced.^{6, 7, 8}

Affects of the patient safety incident

Although none of the patients involved in these PSI's appear to have suffered any long term harm as a result of their experience a considerable amount of worry and stress was endured by all those involved. First there were the patients who had to bear the consequences of the error, next the patient's family and friends and finally there was CPA1 whose inadvertent errors caused the PSI's.

It should be noted that apart from criminals, such as Dr Harold Shipman, healthcare professionals do not want to harm their patients. In fact just the opposite, they spend all their entire working lives trying to alleviate the suffering of others. Thus, when the action of a healthcare professional inadvertently put a patient at risk of injury or actually causes them harm they are, as CPA1 stated '*mortified*' by what had taken place. This is not to excuse what occurred but to recognise that the errors were unintentional and has had a profound negative affect on CPA1.

The doctor/patient relationship is undoubtedly built upon a bond of trust between the two parties. Unfortunately one of the effects of a PSI as N1 observed is that:

'The trust that existed between the staff and the families of the children involved in the incident has been damaged – but because the families talk to each other there has also been some damage to their trust in us as well. Don't forget we have these families for years and years the damage in that sense is incalculable'.

Additionally PSI's put extra stress on all the staff in the department involved because as N1 observed they *'...also cause a huge amount of additional work'*. It should also be noted that the reputation of the healthcare professional involved, the department, medical speciality concerned, Trust and the medical profession as a whole can also be damaged as a result of a PSI.

Trust investigation into PSI's

With respect to the investigation of the four PSI's which are the subject of this Review. A Senior Manager (SM2) at BRHC observed that there was no formal process for the investigation of such events. As a result some confusion had arisen over the division of responsibilities regarding the investigation of the PSI's between the Trust Risk Management Team and BRHC.⁹ Nurse 5 (N5) noted that:

'There are no explicit procedures for what we should do with this serious type of event. The incident form was faxed off immediately to Trust Headquarters as required but then we did not know what to do'.

Similarly a BRHC Risk Co-ordinator (RC1) pointed out that *'...the Trust Risk Management Team take over high profile cases so that there is some times confusion between the two teams.*

While another SM1 noted that *'...there was no person in charge of the incident [and as a result] often we don't know what's going on as we are not informed'*. In a similar vein RC1 stated there was *'...no feedback from the Trust so did not know what was going on'*.

Observations

At the time of the Treatment Room CDC check by N2 and N3 on Wednesday morning 3 January 2007 the number of *monoparin* ampoules stored in their box was correct.

CPA1 arrived late on ODB and felt under pressure to start the Treatment Room Theatre List in an attempt to keep any anxiety felt by the patients or their parents as low as reasonable practicable. CPA1 had been working since 07.45hrs without taking any rest breaks or having his lunch. He had also recently been informed of the date of a funeral that he was to attend.

Not being aware that *monoparin* was stored in the CDC CPA1, as he had done on previous occasions, took out an unboxed plastic tray from the second shelf containing what he believed to be four ampoules of Hepsal. He then placed one ampoule on each patient's anaesthetic tray ready to be drawn up into a syringe.

However NI, N2, N3 and N4 have all stated that, to their knowledge, *Hepsal* was never stored in the CDC and that all drugs are kept in the manufacturers'

box. On the other hand ODP1 has stated that like CPA1 he had on occasions found plastic trays of unboxed *Hepsal* in the CDC.

CPA1 believing he had read the labels correctly drew up the contents of each ampoule of *monoparin* (25,000 I.U. in 5ml) into the patient's syringes. After which he discarded the ampoules in the 'sharps' box. As noted in Section 2 and 4 where the ampoule labels of different drugs, doses or diluents are similar there is a danger that they can be confused and consequently wrong medicine can be inadvertently administered. Moreover CPA1 did not conduct the verbal double-checking protocol as required by bullet point 1 of subsection 11.2 of the Trust's *Medicines Code* as he was unaware of it.

Once the pre-operative procedures in the Treatment Room had been completed the Theatre List was started. As each patient was anaesthetised they were inadvertently administered an overdose of heparin by CPA1. One of the reasons why heparin in high concentrations appears to be so dangerous is because even when an overdose 500 times greater than that intended was inadvertently administered none of the patients demonstrated any physiological reaction to the insult. Indeed once the patients recovered from their procedures with apparently no adverse symptoms they were discharged from ODB either to home or BRHC Ward 34. Thus, because of heparin's pharmacological effects a serious PSI went undetected for some considerable time.

On Wednesday evening 3 January 2007 the parents of patients A and B were concerned about their children's welfare because the site of the bone marrow aspirate was bleeding more copiously than their previous experience. As ODB was closed they each rang BRCH Ward 34 for advice. They were told to apply pressure dressing to the site which they did and the bleeding stopped. However, this information was not conveyed to the staff on ODB the next morning so they were unaware that two of their patients had experienced excessive bleeding during Wednesday night.

Patient A's mother was so concerned about the bleeding the previous evening that although her daughter did not have an appointment to attend the ODB on the morning of Thursday 4 January 2007 she took her in for an examination. The examination by a staff grade doctor revealed that the excessive bleeding had stopped but not that patient A had been subjected to a significant overdose of heparin. And, although Patient A did have a vomiting episode she was subsequently found to be fit enough to be discharged to home.

Approximately 30 minutes after patient A had left ODB it was discovered by two nurses undertaking the daily check of the CDC in the Treatment Room that four ampoules of *monoparin* (strong heparin) were missing. It was then realised that all the patients on the Wednesday afternoon Treatment Room Theatre List could have been administered an overdose of heparin inadvertently.

An immediate clinical investigation was embarked upon which discovered that CPA1 had inadvertently administered a significant overdose of heparin to each patient.

The initial results of the medical examinations of patients A and C suggested that additional investigative procedures should be performed to ascertain the extent to which they had been affected by the heparin overdose. These in-depth tests revealed that no neurological interventions or other treatments were required. The prognosis for all four patients with regard to the heparin overdose is good and no long term medical problems are expected.

The affects of a PSI are wide ranging and encompass the patient, their family and friends, the healthcare professional who makes the error and his or her colleagues all suffer in various ways. A significant amount of extra work is also created and the stigma associated with a PSI may cause significant reputational damage.

Once the PSI's were discovered the Trust Risk Management Team was informed by BRCH this created some confusion as to what actions they should then be take. The uncertainty of what actions BRCH should take occurred because there is no explicit PSI protocol which defines the structural and functional relationships between the Trust Risk Management Team and the BRCH Risk Management Team.

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Section 6: Miscellaneous issues

Verbal double-checking safety protocols

One way in which the risk can be reduced of patients being administered the wrong drug, dose or diluent intravenously is through the use of an explicit appropriately configured verbal double-checking safety protocol. The expectation being that if one person misses an error the other will detect it. However, there is no doubt that such verbal double-checking safety protocols do occasionally fail and therefore they are not a panacea.¹ For example, one problem with the use of a verbal witnessing protocol is that the *'Two members of staff may rely upon the other to be rigorous, resulting in neither giving the task their full attention'*.²

Similarly, Linden and Kaplan observe that:

'Unless carefully configured to prevent it, in a system in which two people are responsible for the same task, neither person is truly responsible. Paradoxically, such safety procedures may provide less, rather than more assurance'.³

Nevertheless there are a number of powerful arguments why all healthcare professionals should undertake verbal double-checking safety protocols at all times particularly when administering intravenous medicines. In a *'Medication Safety Alert!'* published by ISMP it is argued that:

'Research shows that people find about 95% of all mistakes when checking others. Mathematically, the benefit of double checks can be demonstrated by multiplying this 5% error rate during the checking process and the rate in which errors occur with the task itself (the checking error rate X the task error rate). For example, if a pharmacy dispensing error rate is 5% (based on research finding), and a double check occurs before medications are dispensed, then the actual chance of a dispensing error reaching the patient is 5% of 5%, or only 0.25%'.⁴

Moreover, there is some empirical evidence to indicate that the use of verbal double-checking of drugs by healthcare professionals can reduce the risk of an error being made when medicines are being administered. For example, in the study undertaken by Krause *et al* and discussed earlier in a different context, it was reported that observed error rates for the administration of 1,000 medications by two nurses was 2.12 but for one nurse 2.98. Thus, there is a statistically significant safety improvement through using two nurses to check medicines instead of one.⁵

The Department of Health monograph *'Building a Safer NHS for Patients improving medication safety'* has also reported that in:

'A study of more than 1 million dispensed items in British hospitals identified 178 errors (0.018%). The error rate was 0.01% when the dispensing of pharmacists and technicians was double-checked, compared with 0.035% when there was no double-check. 9 errors resulted in patient harm'.⁶

Similarly, a retrospective study of medication errors in a large UK paediatric hospital over a five year period revealed that:

'The introduction of a policy of double checking all drugs dispensed by pharmacy staff led to a reduction in errors from 9.8 to 6 per year'.⁷

Additionally, following research undertaken by the NPSA designed to learn from medication errors in the NHS it was very recently recommended that healthcare organisations should *'...use segregated storage, alert labelling and double-checking systems in medicine policies and procedures to help minimise mis-selection...'*⁸

Furthermore, the Department of Health monograph *'Building a Safer NHS for Patients improving medication safety'* also points out that:

'Ideally, all intravenous drug administrations should be checked by two qualified practitioners. This check should also include confirming the route of administration to the patient'.⁹

Further support for the use of verbal double-checking safety protocols can be found internationally and from a variety of healthcare sources including those who practice anaesthesia.^{10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21} For example, following a systematic review of the literature on evidence-based strategies for preventing drug administration errors during anaesthesia the research team involved came to the conclusion that *'...labels should be checked with a second person or device before a drug is drawn up or administered'.²²*

While in a letter to the journal *Anaesthesia* it was recommended that to reduce the risk of anaesthetists inadvertently administering the wrong drug, dose or diluent to a patient due to the look-alike phenomenon that *'It is distinctive difference in labelling that are required and, to avoid bias, a second person must read the label too'.²³*

That the safety and quality of a clinical service can benefit from the use of an explicit, appropriately configured verbal double-checking safety protocols, can be drawn from the fact that *The Human Fertilisation and Embryology Authority* (HFEA) has made such protocols (witnessing) mandatory in UK. The HFEA stating that:

'Centres [Assisted Conception Units] shall have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.'

'These checks shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.

'Witnessing protocols shall ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process in order to prevent mismatches of gametes or embryos at any point of the laboratory or treatment process.

'Use of electronic systems (such as bar coding and radio frequency identification) shall be suitable for use in the context of assisted conception'.²⁴

Thus, while a verbal double-checking safety protocol is not a perfect solution to the inadvertent intravenous administration of the wrong medicines to patients, there is evidence to suggest that there is support for the use of such a protocol within the medical profession.

The *Expert Group on Safe Medication Practices* (EGSM) was established by The Council of Europe Committee of Experts on Pharmaceutical Questions in 2003. In the EGSM report published in March 2007 entitled '*Creation of a better medication safety culture in Europe: Building up safe medication practices*' it states that criteria below should be applied to ascertain if a suggested intervention can be considered to be '*Best practices for preventing medication errors*':

'Benefit: If the safe medication practices were more widely implemented, it would save lives endangered by the medicine use process, reduce disability or other morbidity, or reduce the likelihood of adverse drug events.

'Evidence of effectiveness: There must be clear evidence that the practice would be effective in reducing the risk of harm resulting from the medicine use process, systems or environment of care.

'Generalisability: The safe medication practice must be able to be implemented in multiple applicable care settings (i.e., inpatient or outpatient settings) and/or for multiple conditions.

'Feasibility: The necessary technology and appropriately skilled staff must be available to most health care sites. Most are widely applicable regardless of size of settings or financial capabilities.

'Cost: Cost might to be considered as a component of the feasibility criterion'.²⁵

The use of an explicit appropriately configured verbal double-checking safety protocol meets all the criteria specified by EGSM.

Because of the potential for explicit appropriately configured verbal double-checking safety protocol to save lives the author asked the *General Medical*

Council, British Medical Association, Royal College of Anaesthetists, The Association of Anaesthetists in Great Britain & Ireland, The Royal College of Paediatrics and Child Health and the Department of Health if they had issued any guidance to their members regarding the use of such a procedure prior to the administration of intravenous drugs or diluents to patients. They all replied that they had not. Their line of reasoning for not issuing such advice was because they either do not see their role as issuing such detailed procedural clinical guidance to their members or because it is assumed that NHS Trusts will have local policies dealing with such matters.

It should however also be noted that the CMO observed that such protocols were ‘...an important issue which warrants further consideration’.²⁶ And that none of the professional medical membership organisations that I contacted expressed a view that the introduction of a mandatory explicit appropriately configured verbal double-checking safety protocol prior to the administration of intravenous medicines would be an anathema. Their sole concern was to ensure that the clinical judgement of their members must always be the deciding factor as to whether the circumstances prevailing at the time of administration of an intravenous medicine permitted such a check to be carried out.

The Royal College of Anaesthetists, The Association of Anaesthetists in Great Britain & Ireland and The Royal College of Paediatrics and Child Health kindly agreed to ask senior members of their respective organisations to informally review the recommendations that have been made in this report with regard to the use of a verbal double-checking safety protocols. Thus their responses, which can be found in Appendix 4, while the views of experts in their respective fields do not necessarily reflect those of the organisations to which they are affiliated.

Frequently analogies are drawn between the medical profession and the commercial aviation industry. However, there is at least one major difference between the two professions in terms of their operating procedures. All aircrews globally must undertake verbal double-checking safety protocols so as to provide the safest service possible to their passengers but the same does not apply the medical profession. Indeed, anecdotally there appears to be strong resistance to such a move by a substantial group of doctors and yet in both cases the professionals involved have the lives of others in their hands.

The commercial aviation industry has a remarkable record for safety. In part this has come about through the constant upgrading of their operating procedures - including the universal adoption of mandatory verbal double-checking safety protocols. Bennett and Stewart observing that:

‘There is a broad agreement among aviation trainers that such routines as monitor and cross-check and CRM [Crew Resource Management] have helped improve aviation safety generally...’²⁷

In a recent report on aviation safety it was observed that in 2006 major aviation accidents worldwide declined at a record rate with less than 0.4 major accidents per million departures. This was despite an increase of 5.2% in volume. The report also noted that if aviation safety rates are to improve still further that:

'...to reduce the rate even more and to keep the accident rate coming down, we must address human error. We must acknowledge it, educate all aviation personnel on it and devise ways, both technical and non-technical, to address it. Only by doing this will we be truly able to make aviation safer by reducing the risk of an accident'.²⁸

The same can be said of the errors which lead to iatrogenic disease. Thus without the introduction of an explicit, appropriately configured verbal double-checking safety protocols, error rates in the preparation and administration of medicines are not going to fall significantly. This is because even though aircrews use verbal double check safety protocols they still have major accidents caused through the same kind of human errors which led to the four PSI's that occurred on ODB.

Technology

The stringent conscious application of a persons mind to the task in hand can help reduce the risk of the wrong drug, dose or diluent being inadvertently administered intravenously to a patient. As can the use of verbal double-checking safety protocols however technology can also be put to good use.²⁹ For as observed by anaesthetists Merry et al *'Conventional methods of injectable drug administration in anaesthesia make little use of technology to support manual checking...'*³⁰

In an attempt to rectify that situation Merry and his colleagues developed an *'Integrated Injectable Drug Administration and Automated Anaesthetic Record System'* (IDAARS). The object of the system was to improve patient safety through the reduction of drug administration errors and provide a process for the easy and accurate keeping of anaesthetic records.

IDAARS has been developed over the years and essentially consist of a physical and rule based methodology for organising the area where an anaesthetist works along with a barcode reader attached to a computer. Pre-filled syringes using colour and barcoded labels are used where ever possible. When an anaesthetist is required to administer a particular drug to a patient the appropriate syringe is scanned by the barcode reader. The drugs name and class appear in large font on the computer screen and the name of the drug is spoken by a pre-recorded voice. The system also makes a complete automated anaesthetic record including physiological data and clinical notes.³¹

In a clinical study using an improved version of the IDAARS published in 2004 Webster et al concluded that:

'...this study provides evaluative evidence in the clinical setting, which supports that from a previous simulator-based study, that the new drug administration system has the potential to reduce drug error in anaesthesia, thus addressing one aspect of the important and costly problem of iatrogenic harm in health care'.³²

Similarly, in a study published in 2003 by Turner, Casbard and Murphy into the use of barcode patient identification technology as a means of improving the safety of blood transfusions, it was found that:

'The baseline audit revealed poor practice, particularly in patient identification. Significant improvements were found in the procedure for the administration of blood following the introduction of barcode patient identification, including an improvement from 11.8 to 100 percent in the correct verbal identification of patients ($p \leq 0.001$)...'³³

Improvements were also found in a number of other important factors such as the number of patients correctly identified before blood samples were collected and the number of blood samples labelled correctly.

However, while technology could have an important role to play in the safe delivery of healthcare the caveat issued by the US based National Coordinating Council for Medication Error Reporting and Prevention should be kept in mind *'While technology can reduce medication errors and enhance patient safety it also has the potential to cause new types of unintentional errors'.³⁴*

For example McDonald reports that:

'...a diabetic patient admitted to a teaching hospital was mistakenly given the bar-coded identification wristband of another patient who was admitted at the same time. When a laboratory result that documented the diabetic patient's severe hyperglycemia was entered into the other patient's electronic medical record, the latter patient seemed to have a very high glucose level and was almost given what could have been a fatal dose of insulin. This near miss shows that computer systems, although having the potential to improve safety, may create new kinds of errors if not accompanied by well-designed, well-implemented cross-check processes and a culture of safety. Moreover, computer systems may have the pernicious effect of weakening human vigilance, removing an important safety protection'.³⁵

Attempts to reduce look-alike labelling

In an attempt to reduce the risk of the wrong drug, dose or diluent being inadvertently administered to a patient due to look-alike characteristics MHRA have issued new guidance with regard to the labelling and packaging of medicines.³⁶ Furthermore, the MHRA, PASA, NPSA and British Generic

Manufactures Association (BGMA) are currently engaged in negotiations that are aimed at reducing the incidence of look-alike drugs being produced in future.³⁷

In a similar vein, where ever appropriate PASA is using the purchasing power of the NHS in its negotiations with pharmaceutical manufacturers to persuade them to modify the livery of their products so that they do not label or package different drugs, doses and diluents that look-alike.³⁸

The NPSA are also currently involved in a design research project with the Helen Hamlyn Centre and are undertaking a period of consultation on a draft guidance booklet, *'Design for Safety: Labelling and packaging guidelines for injectable medicines'*.³⁹

Moreover, Wockhardt, parent company of CP Pharmaceuticals Ltd who manufactured the two different concentrations of heparin involved in this PSI are so concerned about the type of error made that they have now made changing the livery on all their heparin products a top priority. Although they had already done a significant amount of work on potential changes to the livery designs the procedure is to be speeded up. Examples of the proposed new livery for the two heparin products involved in this review can be seen in Plates 12 and 13.

Encouragingly there also appears to be some interest by manufactures of medical devices in attempting to provide a solution to the problem of look-alike medicines. During the course of this review DMC Medical Ltd a supplier of anaesthetic syringes got in touch with CA1 at Bristol Royal Infirmary. The reason the company contacted CA1 was to inform him that they have developed a range of anaesthetic syringes where the colours of the plungers are the same as the International Colour Coding Syringe Labelling System.

The proposed colour code plunger anaesthetic syringe system would save anaesthetist from having to manually apply the appropriate colour label to their syringes when they draw up drugs. This would reduce the risk of the wrong label being applied to a syringe. However, it still requires the anaesthetist to ensure that the drug that they draw up into the syringe is the correct one for that colour. Thus while not a complete solution it is a helpful step.

Risk assessments

The NPSA state that:

'Risk management is the process of identifying, assessing, analysing and managing all potential risks.'

'Decisions made within an organisation, and within practice, should take into account potential risks that could directly or indirectly affect patient care. If risks are properly assessed, the process can help all NHS organisations, teams and individuals set their priorities and

improve decision-making to reach an optimal balance of risk, benefit and cost'.⁴⁰

To that end the NPSA have developed several risk assessment tools for healthcare professionals including a '*Risk assessment tool for the preparation and administration of injectable medicines in clinical areas*'. This and the other the tools they have developed can be found on the NPSA website.⁴¹

Observations

The evidence suggests that use of an explicit appropriately configured verbal double-checking safety protocol prior to the intravenous administration of a medicine to a patient could have significantly reduced the risk of the four PSI's taking place. Moreover this particular intervention also meets all the criteria suggested by the EGSM for best practice to prevent medication errors. However further research in this area would be helpful.

The evidence suggests that the technological developments in the field of anaesthetics that have been discussed in this section could have significantly reduced the risk of the PSI occurring if it had been available. No technology regardless however can be made completely foolproof and thus the vigilance of healthcare professionals will always be the key to patient safety.

Attempts are being made to reduce the risk of look-alike drug labels and packaging by a number of NHS organisations and the BGMA however progress appears to be slow and the NHS specification for the labelling of drug ampoules is still being used by a number of pharmaceutical companies.

The NPSA have developed a number of risk assessment tools including a '*Risk assessment tool for the preparation and administration of injectable medicines in clinical areas*'.⁴²

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Section 7: conclusions and recommendations

The conclusions that have been drawn from the evidence presented above are noted below in plain text, while recommendations are shown in ***bold italic***.

The recommendations made below are intended to address the range of issues revealed by the evidence presented during the course of the Review. However, the recommendations that have been made should not be considered to be a definitive set of actions that will guarantee the safety of patients who are administered intravenous drugs under all circumstances. Medicine, technology and clinical management practices change and therefore given that no one can prespecify their own ignorance constant vigilance and a robust safety culture will always be required if such accidents are to be prevented in the future.

Patient safety incidents

The immediate and direct causes that underlie the four patient safety incidents that have been the subject of this Review are as follows:

The security status of the CDC in ODB Treatment Room appears to have been cognitively down graded from high security to a safe place to keep things. Thus, an unconscious state of complacency seems to have been created regarding the contents of the CDC by many of those who accessed it.

CPA1 was in a rush to start the Wednesday afternoon ODB Treatment Room Theatre List. He had not been able to have a rest break and had recently been given some distressing news these are all factors which are known to promote inadvertent human error.

CPA1 did was not aware that *monoparin* was stored in the CDC.

CPA1 had seen the drug that he intended to use to keep the patients intravenous catheters and cannula patent (*Hepsal*) unboxed in the CDC on previous occasions.

CPA1 did not read the labels on the ampoules of *monoparin* correctly, i.e. he saw what he expected to see rather than perceiving the information that was physically present.

CPA1 undertook the preparation of all the drugs for all four patients in one batch thus creating the potential for the systemic failure which then occurred.

CPA1 did not carry out a verbal double-checking safety protocol because he was not aware that the Trusts *Medicines Code* required him to undertake one before the administration of medicines to children.

System Failures

The evidence presented to the Reviewer strongly suggests that the four patient safety incidents that occurred during the ODB Theatre List on Wednesday 3 January 2007 were caused by inadvertent human error and systems failure. The specific conclusions and recommendations with regard to these four PSI's are detailed below.

CPA1 safety culture

Levitt and March have observed that:

'Routines are based on interpretations of the past more than anticipations of the future. They adapt to experience incrementally in response to feedback about outcomes'.¹

Therefore since CPA1 had been successful at his profession for over thirty years; he had also managed the Treatment Room Theatre List for more than three years, thus he would have had no reason to question either his behaviour or the procedures that he adopted. To CPA1 his professional practices were at least as safe as any other anaesthetist.

However Miller warns that:

'Failure teaches leaders valuable lessons, but good results only reinforce their preconceptions and tether them more firmly to their "tried-and-true" recipes'.²

Thus, success can lead to people being unaware that they are unconsciously becoming complacent and that their safety culture is being affected. The importance of any organisation creating and maintaining a robust safety culture is clearly spelled out by the Department of Health where it is suggested, *'People may come and go, but an effective safety culture must persist'.³* Unfortunately, CPA1's safety culture appears to have been compromised by a number of inherent human and external system factors.

Recommendation 1

This report or a redacted version of it should be made available to all members of staff via the Trust Document Management System so that they can learn from these PSI's.

Recommendation 2

The Trust should make this report available on its website so that all those who have an interest in patient safety worldwide can learn from these four PSI's.

Human and organisational factors

There are numerous factors both known and unknown within humans, their systems of work and the operating environment that promotes inadvertent human error. It is therefore important that such factors are, where ever possible, designed out of the healthcare systems.

Recommendation 3

The Trust should ensure that all Divisions are aware of the drug Alerts and Risk Assessment Tools produced by the National Patient Safety Agency and that they are employed to their full advantage to increase patient safety.

Heparin

The Trust PSI database was unable to readily provide accurate information on whether there had been any previous heparin related PSI's similar to the four which are the subject of this Review. The difficulty was due to the way in which PSI data is structured and the taxonomy utilised by the database. However it did prove possible to identify one PSI similar to those being reviewed and that a significant number of drug errors (1.2%) of all medication errors to date have been caused through heparin related incidents.

Recommendation 4

The Trust should seek to modify the data structure and taxonomy used by the PSI database so that more detailed data can be captured and analysed so as to improve the potential numbers of lessons that could be drawn from such events.

Recommendation 5

The Trust should ensure that the lessons learned from each PSI are inculcated into the practice and procedures of all relevant departments. This could be accomplished by maintaining a list of all such lessons and periodically auditing departments against them.

Recommendation 6

The Trust should undertake a review of all the different concentrations of heparin used and minimise the number of different types purchased

to as few as reasonably practicable. (See NPSA Alerts 18 and 20)

CPA1 was unaware that ampoules containing heparin at a concentration of 5,000 IU/ml in 5ml (*monoparin*) were stored in the ODB CDC. This in part led to the PSI's occurring. Moreover patients can be administered significant overdoses of heparin with potentially injurious consequence without the insult causing any immediate physiological effect. Thus masking that a PSI has occurred and delaying remedial actions until the drugs pharmaceutical effects on the body are well established.

Recommendation 7

High concentration heparin should not be stored in patient treatment areas, apart from Operating Theatres, but prescribed by a doctor, collected from the Pharmacy and immediately administered to the patient or patients. Any remaining stock of high concentration heparin should be immediately returned to the Pharmacy.

The savings to be made if the Trust were to replace all its *Hepsal* with saline would result in a relatively small cash saving. While the reduction in the risks to patients from staff inadvertent administering an overdose would be significant. However, medical research at the present time does not appear to support the withdrawal of heparin products for children with central venous lines. However, since heparin has been responsible for a significant number of PSI's and is clearly a danger to patients further research should be carried out by the Trust to determine where '*heparin flushes*' should continue to be used and where it would be appropriate to change to saline.

Recommendation 8

The Trust should appoint an appropriately medically qualified member of staff to make recommendations to the 'Medicines Steering Group' as to the circumstance where 'heparin flushes' might safely be changed to saline.

ODB Controlled Drugs Cupboard

There is conflicting evidence about whether *Hepsal* ampoules, the drug which should have been administered to the patients, had occasionally been placed in the CDC. Similarly, there is also conflicting evidence as to whether the *Hepsal* ampoules could have been left on a shelf out of their box. Given that there is no explicit proof to support either set of assertions it is impossible to make a determination as whether *Hepsal* was or was not occasionally to be found in the ODB CDC. However given the fact that extraneous persons had access to the CDC, it can be argued, that it is possible that *Hepsal* on some occasions could have been put in the CDC by such individuals.

Recommendation 9

Only controlled drugs must be stored in a CDC and only authorised persons should have access to it.

Recommendation 10

When any non-controlled drug is found in a CDC it must be reported to the identified Lead for Clinical Governance of that Division.

Recommendation 11

Any person found accessing a CDC who is not authorised must be reported to the identified Lead for Clinical Governance of that Division.

Recommendation 12

Where there is a requirement for non-controlled drugs or other items to be stored securely a lockable cupboard should be purchased for that purpose.

Trust policies

Currently there is no requirement that Trust staff explicitly record that they have read, new policies, changes to existing policies or acknowledge that a policy has been discontinued. Thus, policymakers have no assurance at the present time that all their policies are being implemented by the relevant staff.

Recommendation 13

The Trust should develop a monitoring system for explicitly recording when members of staff have read new policies, amendments to existing policies and communications that a policy has been discontinued.

Recommendation 14

The Trust should make it a requirement of employment that all staff explicitly record when they have read new policies, amendments to existing policies or acknowledge that a policy has been discontinued.

The current communication system in use to inform specific groups that there is new policy, changes to an existing policy or a policy has been discontinued is not user friendly.

Recommendation 15

The Trust should redesign their policy communications system so that new policies have a summary sheet of no more than two pages highlighting the crucial issues in the policy. Changes to existing

policies should state what the changes are and where in the policy they are located. Where a review of a policy has been carried out but no changes have been made this should be clearly stated in the communication. The estimated time to read the full policy document should be recorded on the first page of the summary.

The Trust policy that double checks must be carried out on all medicines given to children is unequivocal. However it would appear that CPA1 and his colleagues have not followed that instruction because they were unaware that it existed. This was because CP4 who presented an overview of the updated *Medicines Code* to his colleagues did not realise the importance of that subsection because it had not been emphasised in the document. It was not however the intention of the working party which updated the policy that it should be applied to medically qualified doctors. Nevertheless it does.

Recommendation 16

The makers of Trust wide policies on clinical issues should before submitting their policy or policy amendments for ratification ensure that the whole document is read by senior colleagues of all the medical specialities concerned who have not been involved in its production.

Recommendation 17

All members of staff should be periodically reminded that Trust wide policies can be found on the Document Management System.

Recommendation 18

All members of staff should be reminded periodically that it is a provision of their contract of employment that they must comply with the Trust Policies and Procedures and that ignorance of them is no excuse.

Recommendation 19

Trust policy documents should not emphasis any particular segment of the text as being of particular importance as some readers may only read the emphasised sections and not the complete document.

Operational practices

Having worked without a break from 07.45hrs Wednesday 3 January 2007 CPA1 arrived late on ODB because his previous list had gone on longer than intended and therefore was under pressure to commence his Theatre List at 1.30pm. He had also been informed that morning of the date of a funeral he was to attend. As noted earlier pressures of work, emotional upsets and unrecognised fatigue are human factors that have also been observed in many other patient safety incidents.

Recommendation 20

Anaesthetists managing the Wednesday ODB Treatment Room Theatre List who have not had a rest break since commencing work should delay the start time of the list in order to have one.

Recommendation 21

Where an anaesthetist has had a rest break but arrives late on ODB the start time of the list should be delayed so that all the necessary pre-operative procedures can be undertaken without undue haste.

The only times that CPA1 accessed the CDC in the ODB Treatment Room was when he removed the drugs he required to undertake the Wednesday afternoon Theatre List. Consequently he was unfamiliar with the contents of the CDC and thus not aware that *monoparin* ampoules were held in stock.

Recommendation 22

A list of all the medicines stored within a CDC or secure cabinet containing hazardous drugs should be displayed on the inside of the cupboards door.

Recommendation 23

When patients are not to be anaesthetised in Theatres all the drugs to be administered intravenously should be prepared by the Pharmacy and collected by the ODP or anaesthetist. If for operational reasons that should not prove to be possible the drugs should be package by Pharmacy and delivered to where the anaesthesia is to be provided with strict instructions that only the ODP or anaesthetist may open the package. (See NPSA Alert 20)

All the patients were to receive exactly the same three drugs in the same order. Therefore CPA1 prepared all the drugs and syringes to be used that afternoon in one batch. Once CPA1 was convinced that the drugs he had selected were correct his subsequent checking process for drawing the drugs up into their respective syringes did not identify that he had selected the wrong concentration of heparin, i.e. he saw what he expected to see and this created the potential for the systemic failure that occurred. However, if CPA1 had prepared the drugs for each patient separately, i.e. just prior to their arrival in the Treatment Room it is possible that the error might have been identified before the last patient was anaesthetised.

Recommendation 24

In order to prevent a systemic failure when several patients are to receive exactly the same drugs as part of their anaesthesia they should not be drawn up as batch. (See NPSA Alert 20)

As the contents of each ampoules was drawn up into a syringe CPA1 placed the discarded ampoule in the 'sharps' box.

Recommendation 25

Subject to a satisfactory risk assessment once the contents of an ampoule have been drawn up into a syringe the ampoule should be placed on the anaesthetics tray for that patient and not discarded. This is so, in as far as reasonably practicable, there is a physical record of what drugs the patient has had administered intravenously and hence can be checked at any time. Ampoules should only be discarded once the operation is over and the anaesthetist is confident that the patient is recovering satisfactorily from the anaesthesia.

At present anaesthetists only undertake verbal double-checking safety protocols in specific instances. However, had such a protocol had been employed at the time of the four PSI's it is not 100% certain, but highly probable, that CPA1's error in selecting the wrong concentration of heparin would have been discovered. Human errors are ubiquitous consequently the recommendations with regard to this conclusion are of a similar character.

Recommendation 26

The Trust should draw up an explicit appropriately configured verbal double-checking safety protocol for the preparation, drawing up and intravenous administration of drugs. (See NPSA Alert 20)

Recommendation 27

All members of Trust staff should, subject to their clinical judgement, carry out the verbal double-checking safety protocol drawn up by the Trust when preparing drugs for the administration of intravenous drugs to patients and at the point of administration. (See NPSA Alert 20)

Recommendation 28

Where a verbal double-checking safety protocol is not undertaken, because in the clinical judgement of the healthcare professional administering the drug it would be unsafe to do so, then the reason must be documented in the appropriate medical record. Such exceptions must be reported to the identified Lead for Clinical Governance of that Division.

Recommendation 29

A written record should be made in the appropriate medical record by the person who prepared the medicine for intravenously administration and the person who witnessed it. A similar record should be kept with regard to the physical administration of the medicine. The recording of the names in both cases should be in uppercase letters and with their signature in near proximity.

Recommendation 30

In the case of anaesthetists the 'Anaesthetic Record' should be redesigned to incorporate an area where the person who prepared the medicine for intravenously administration and the person who took part in the protocol can record their names. A similar record should be kept with regard to the physical administration of the medicine. The recording of the names in both cases should be in uppercase letters and with their signature in near proximity.

Recommendation 31

Operating Department Practitioners and nurses should be trained to assist anaesthetists with verbal double-checking safety protocols for the preparation, drawing up and administration of intravenous drugs.

Communications

The parents of Patients A and B telephoned Ward 34 BRCH on Wednesday evening with concerns about the excessive bleeding from the site of the bone marrow aspirate. This information was not passed to ODB.

Recommendation 32

Out of hours telephone enquires to Ward 34 BRCH regarding patients who are being treated on ODB should be recorded in writing along with the action taken and the information forwarded to ODB as soon as possible.

Although an instruction was given by a member of the BRCH senior management team to remove all *monoparin* from the CDC's in Theatres the stock was subsequently replaced by a member of staff without telling any body.

Recommendation 33

BRCH senior management should ensure that when they issue a direction that a drug should no longer be readily available in Theatres or any other location that all members of staff receive written notification of the decision.

Recommendation 34

The Pharmacy should be informed of any decision to remove drugs from patient treatment areas so they can ensure that the medicine concerned is not released for use unless it is prescribed for immediate use.

Trust investigation of PSI's

A delay in interviewing the personnel involved in these serious patient safety incidents, due to operational exigencies, may have led to details being forgotten. It is therefore essential that all those associated with serious PSI's provide a detailed written account of their involvement while it is still fresh in their minds if potential lessons are not to be lost.

Recommendation 35

As soon as possible, but within 24 hours, all the healthcare professionals present at a serious PSI must submit a written statement of their involvement to the identified Lead for Clinical Governance within that Division.

Following the Trust Risk Management Team being informed of the four PSI's by BRCH there was confusion as to what actions should then be taken by them. The confusion occurred because there is no formal serious PSI protocol that explicitly defines the structural and functional relationships between the Trust Risk Management Team and the BRCH Risk Management team.

Recommendation 36

The Trust should provide all Divisions with a protocol that explicitly maps out the structural and functional relationships between them and the Trust Risk Management Team in the event of a serious PSI.

Recommendation 37

In the first instance all information regarding a PSI must be channelled through the identified Lead for Clinical Governance of the Division concerned. This is so that a determination can be made as to whether or not the Medical Director and the Trusts Risk Management Team need to be alerted.

Technology

A significant reduction in the risk to patient's from a similar type of PSI as the ones discussed in this report could be achieved through the use of technology. However technology is not infallible and therefore the vigilance of healthcare professionals will always be the key to patient safety.

Recommendation 38

The Trust should explore the possibility of using the developments that have been made in anaesthetic technology as a means to improving patient safety.

Disregarding safety warnings

The Trust PSI database identified an incident where a surgeon refused to take any notice of his assistant that his use of heparin was endangering the safety of his patient.

Recommendation 39

Where a member of staff wilfully disregards an appropriately qualified colleagues warning that she or he is putting a patient's safety at significant risk then an internal Review should be undertaken to determine if the Trust's 'Code of Expectation of Staff' has been violated.

Learned bodies conclusions and recommendations

The medical speciality of anaesthetics has long been in the vanguard of patient safety. However there appear to be few peer reviewed studies that provide denominator data so that the frequency rates of intravenous medication errors within this medical speciality can be accurately calculated. This prevents direct comparison with anaesthetic practices nationally and internationally. Hence, identifying precisely what anaesthetic practices could yield the lowest possible rate of errors in varying circumstances is difficult to establish.

Recommendation 40

The Editorial Boards of 'The British Journal of Anaesthesia' (The Royal College of Anaesthetists) and 'Anaesthesia' (The Association of Anaesthetist in Great Britain and Ireland) should encourage the submission of papers on intravenous drug errors during anaesthesia that contain denominator data so that the frequency rates per 1000 drug administrations can be calculated.

There is tentative evidence to suggest that for a variety of reasons anaesthetists may not inform official NHS reporting systems of the majority of inadvertent errors being made by them. Thus the actual risk of an anaesthetist making an error which could affect the safety of a patient might be far higher than previously thought. Moreover, important lessons that could save lives may not be learnt and disseminated.

Recommendation 41

The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists should strongly recommend to their members that all errors which physically occur are reported to the appropriate 'Adverse Incident Reporting System' (AIRS).

Recommendation 42

The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists should consider whether the failure of a Member to report an error he or she has committed to the appropriate

AIRS is a breach of professional good practice and therefore a matter for disciplinary action.

The evidence discussed in this report demonstrates that there is great potential for the saving of lives by the use of verbal double-checking safety protocols in anaesthesia.

Recommendation 43

The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists should strongly urge to their members to adopt the recommendations made in this report with respect to the use of verbal double-checking safety protocols in anaesthesia.

Department of Health conclusions and recommendations

There are numerous factors both known and unknown within humans, their systems of work and the operational environment that promotes inadvertent human error. It is therefore important that such factors are, where ever possible, designed out of the healthcare systems.

Recommendation 44

The Department of Health should direct the National Institute for Health Research, Research Centres for Patient Safety and Service Quality to undertake or commission research into the individual, group, organisational and cultural factors that can lead to patient safety incidents.

Recommendation 45

The Department of Health should direct the National Institute for Health Research, Research Centres for Patient Safety and Service Quality to undertake or commission research into the risks and safety benefits surrounding the use of appropriately configured explicit verbal double-checking safety protocols.

Injectable medication errors caused by look-alike pharmaceutical products are a significant national and international problem. It is also well known that it is not feasible to completely eliminate human error. Therefore the labelling of drug ampoules and the outer packaging in which they are stored must be designed by manufactures of pharmaceutical products so as to reduce the risk of look-alike errors to as low as reasonably practicable. This would undoubtedly save a very significant number of lives worldwide. However until this objective can be achieved, as noted earlier, the National Patient Safety Agency have produced guidance on how the risks associated with look-alike drugs can be reduced (*Alert 20; promoting safer use of injectable medicines*).⁴

Recommendation 46

The Department of Health should direct The Medicines and Healthcare products Regulatory Agency, as a matter of urgency, to work with the national regulators of medicines worldwide to ensure that the manufacturers of pharmaceutical products are not permitted to produce look-alike drug packaging and labelling.

There are significant risks to the wellbeing of both children and adult patients if they are inadvertently administered a significant overdose of heparin. However there is no compelling medical evidence or advice from any quarter to suggest that a 'heparin flush' is more effective at keeping intravenous catheters and cannula patent in many cases than a saline solution. Therefore the efficacy of heparin flushes, in terms of their cost and safety benefits to the NHS, should be investigated as soon as possible by the appropriate national body. This is because if the evidence discussed in this report is an accurate reflection of the situation generally then the numbers of patients being put at risk nationally and internationally for no benefit is considerable and should be urgently addressed.

Recommendation 47

The Department of Health should direct the National Institute for Clinical Excellence, as a matter of urgency, to undertake a cost and safety benefit analysis of the 0.9% saline and heparin flush methods used to maintain the patency of peripheral, central venous and arterial indwelling catheters so that authoritative guidance can be provided to the whole of the NHS as to their relative efficacy.

Attempts are being made to prevent pharmaceutical manufactures producing drugs with look-alike labelling and packaging. The pace is slow however and there are still companies that are licensed to produce drugs whose labels are still being printed to the NHS specification.

Recommendation 48

Subject to European Union regulations on medicines, the Department of Health should direct The Medicines and Healthcare products Regulatory Agency, to issue an instruction to all pharmaceutical manufacturers that the NHS specification for ampoule labeling must not be used on any of their products by the end of 2007 otherwise the products license will be withdrawn on the grounds of patient safety.

The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists, due to funding problems, do not possess a reporting system that will allow the capture of data on inadvertent errors made by anaesthetists. However, such a joint reporting system could encourage anaesthetists to provide more data on errors that occur during anaesthesia than at present. The specialised analysis that could be drawn from that data could be used to supplement and support the information produced by the NRLS.

Recommendation 49

The Department of Health should consider providing the necessary funds to The Association of Anaesthetist in Great Britain and Ireland and The Royal College of Anaesthetists for the provision of a joint Patient Safety Incident Reporting System.

The National Patient Safety Agency were asked if they could provide information on the frequency of PSI's which fitted the joint categories of 'heparin flush' AND 'anaesthetist'. Similar to the NHSLA such information could not be provided because the data structure and taxonomy utilised by the National Reporting and Learning System does not readily allow the provision of such information.

Recommendation 50

The National Patient Safety Agency should seek to modify or change the data structure and taxonomy utilised by the National Reporting and Learning System so that more specific details than those recorded at present regarding the circumstances surrounding a PSI can be captured and analysed. Thus reflecting the findings of the Department of Health's monograph 'Safety First A report for patients, clinician and healthcare managers'.⁵

The NHS Litigation Authority have 54 claims on their database with respect to heparin related patient safety incidents and paid have paid approximately £2,600,000 to date in compensation and legal costs. They could not however ascertain the circumstances under which the heparin had been administered because the taxonomy and data structure utilised by the NHSLA Claims Management System does not readily allow the provision of such information.

Recommendation 51

The NHS Litigation Authority should seek to modify or change the taxonomy and data structure utilised by its Claims Management System so that more specific details than those recorded at present regarding the circumstances surrounding a PSI can be captured and analysed.

Finally, as the recommendations in this report demonstrate:

'No single act will significantly reduce the incidents of IV errors; there needs to be a coordinated approach from practitioners, regulators and the pharmaceutical industry'.⁶

References

- 1 Levitt, B and J. March, 'Organizational Learning', *Annual Review of Sociology*, Vol.14, 1988, pp.319-40
- 2 Miller, D. 'The Icarus paradox', in Carnall, C.A., *Strategic Change*, Butterworth-Heinemann
- 3 Department of Health, 2000, op cit, p.35
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- 5 Sir Ian Carruthers OBE and Pauline Philip, *Safety First – A report for patients, clinicians and healthcare managers*, Department of Health, 15 Dec 2006, p. 26
- 6 Taxis, K and N. Barber, op cit, p.346

List of Plates

Plate 1 Example: similar labels for different medical products

Plate 2 Example: similar labels for different concentrations of same drug

Plate 3 Example: Baxter Heparin Safety Alert 6 February 2007 vials

Plate 4 Treatment Room in the OBD

Plate 5 ODB Controlled Drugs Cabinet – post PSI's

Plate 6 Control Drugs Cupboard in Theatre Four

Plate 7 Range of heparin products purchased by Trust

Plate 8 Comparison: outer packaging *monoparin* and *Hepsal*

Plate 9 Comparison: *monoparin* and *Hepsal* ampoules respectively

Plate 10 Example: *Hepsal* and *monoparin* ampoules respectively

Plate 11 Example: *Hepsal* and *monoparin* ampoules respectively

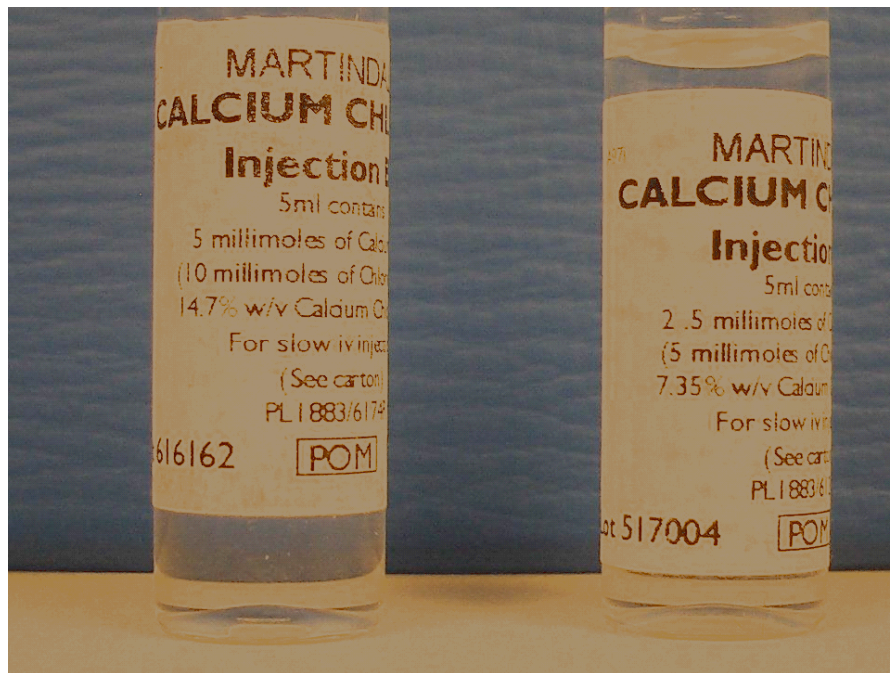
Plate 12 Example: hypothetical new livery style for high strength heparin

Plate 13 Example: hypothetical new livery style for *Hepsal*



Source: National Patient Safety Agency

Plate 1: Example of similar labels for different medical products



Source: National Patient Safety Agency

Plate 2: Example similar labels for different concentrations of same drug



Source: Baxter

Plate 3: Example Baxter Heparin Safety Alert 6 February 2007 vials



Source: Illustration and Design, UBHT Education Centre

Plate 4: Treatment Room in the OBD



Source: Illustration and Design, UBHT Education Centre

Plate 5: ODB Controlled Drugs Cabinet – post PSI's



Source: Illustration and Design, UBHT Education Centre

Plate 6: Control Drugs Cupboard in Theatre Four



Source: Illustration and Design, UBHT Education Centre

Plate 7: Range of heparin products purchased by Trust



Source: Illustration and Design, UBHT Education Centre

Plate 8: Comparison outer packaging *monoparin* and *Hepsal*



Source: Illustration and Design, UBHT Education Centre

Plate 9: Comparison *monoparin* and *Hepsal* ampoules respectively



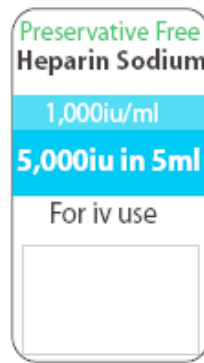
Source: Illustration and Design, UBHT Education Centre

Plate 10: Example *Hepsal* and *monoparin* ampoules respectively



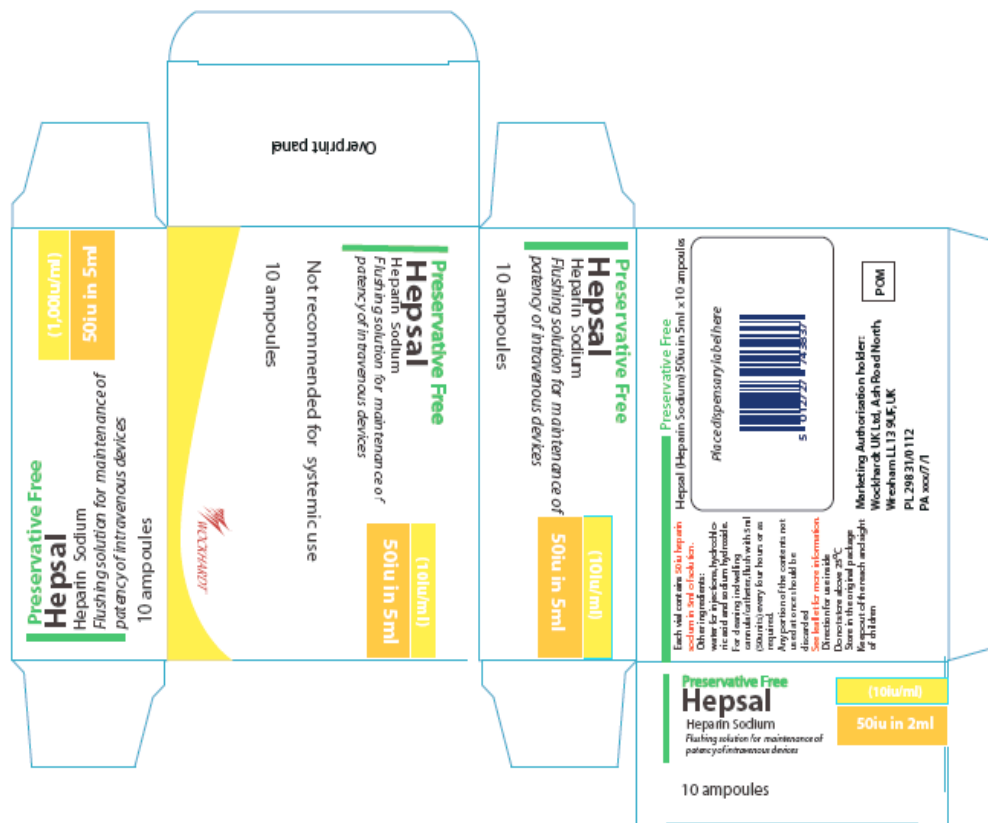
Source: Illustration and Design, UBHT Education Centre

Plate 11: Example *Hepsal* and *monoparin* ampoules respectively



Source: by kind permission of Wockhardt UK Ltd

Plate 12 Example: hypothetical new livery style for high strength heparin



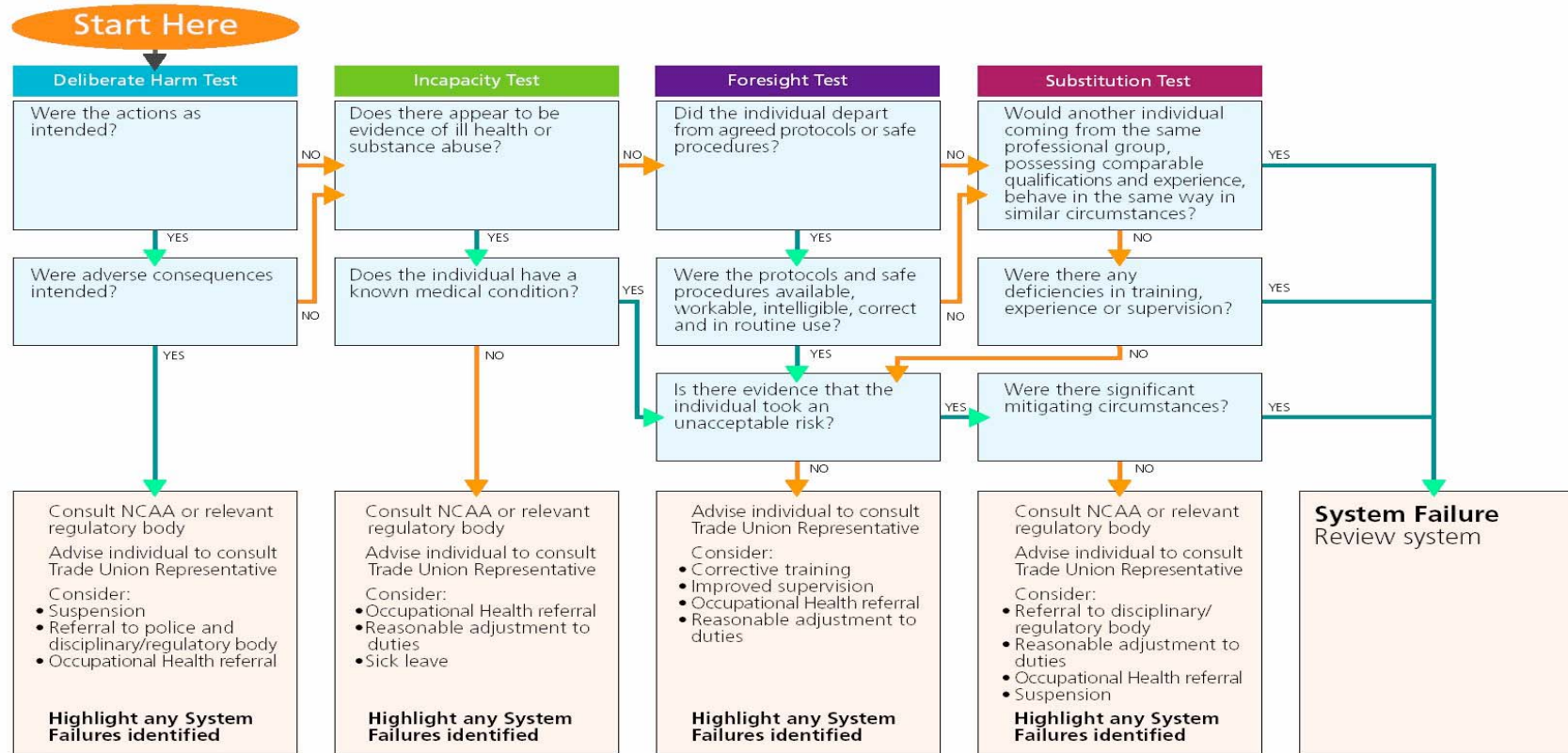
Source: by kind permission of Wockhardt UK Ltd

Plate 13 Example: hypothetical new livery style for *Hepsal*

Appendix 1

INCIDENT DECISION TREE*

Work through the tree separately for each individual involved



* Based on James Reason's Culpability Model

Appendix 2

From the Chief Medical Officer, Sir Liam Donaldson



Our reference: **PO177/2007**

11 June 2007

Professor Brian Toft

Sent by E-mail - brian.toft@ntlworld.com

Dear *Brian,*

Richmond House
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www.dh.gov.uk/cmo

Thank you for your letter of 10 May 2007 outlining the details of the patient safety review you are currently undertaking on a serious dosage error with heparin. The issues you raise are important ones and serve to underline the continued importance of improving the safety of medicines management in day-to-day practice.

As you would be aware from your literature review, there are a number of pieces of national and international safety guidance that highlight the important role of checking mechanisms as a means of reducing risks to patients. In the United Kingdom, for example, the Royal Pharmaceutical Society of Great Britain produced revised guidelines in March 2005 on *The safe and secure handling of medicines: a team approach* which provide a set of principles that will enable providers to devise safe and secure systems appropriate to their needs. In paragraphs 10.10.5 and 10.10.6, there are references to one-nurse administration and second nurse checks. Although there is no explicit requirement to use verbal double-checking of administration, it is expected that healthcare organisations put in place locally relevant policies and Standard Operating Procedures based on guidance such as this.

The Department does not have a specific role in issuing guidance of this kind. However, we have worked closely with the National Patient Safety Agency (NPSA) and the Welsh Assembly Government to produce a programme of work for the National Health Service in April 2007 on safe medication practice. This comprised five safety alerts on high-risk areas, two of which were concerned with safer use of anticoagulants and injectable medicines.

The NPSA guidance on anticoagulants recommends the use of 1,000 unit per ml heparin products in clinical areas and the subsequent removal of higher strength products such as those involved in the incident that you are investigating. The Alert on injectable medicines incorporates a multi-professional, safer practice standard for prescribing, preparing and administering injectable medicines in clinical areas. This includes the recommendation that, following risk assessment to identify those products that represent the highest risk to patients (for example sodium heparin products), consideration must be given to the use of safer products and systems, for example, double-checking.

You write to draw specific attention to the opportunities to strengthen checking mechanisms, in particular the use of verbal double-checking. You have highlighted an important issue which warrants further consideration. As I am sure you would agree, the use of checking mechanisms is quite a complex area. There is little research evidence on the patient safety benefits of double-checking medicines administration and there are concerns among some professionals that the introduction of a poorly performed checking system may increase errors. The area of verbal double-checking requires more research and careful risk assessment. I recall that your own work on involuntary automaticity specifically mentions verbal-challenge response protocols and the possibility that this can lead to staff believing the treatment they are about to administer is safe when potentially it is not.

I am pleased to note your success in encouraging the Royal College of Anaesthetists, The Association of Anaesthetists in Great Britain & Ireland and The Royal College of Paediatrics and Child Health to consider any recommendations, which might emerge from your review. I would also suggest, if you have not already done so, that the emerging findings and recommendations from your review are discussed with the NPSA to inform any work that they might take forward in this area. I am therefore copying this letter to Martin Fletcher, the new Chief Executive of the NPSA to facilitate this link.

Thank you for taking the time to write to me.

Yours sincerely

A handwritten signature in black ink, appearing to be 'L. Donaldson'.

**SIR LIAM DONALDSON
CHIEF MEDICAL OFFICER**

Cc: Mr Martin Fletcher, Chief Executive, NPSA

Appendix 3

National Patient Safety Agency

Summary report Medication Incidents in Anaesthetics

A search of medication incidents reported to the NPSA via the National Reporting and Learning System was carried out from 1st January 2006 to 31st December 2006.

The search was limited to medication incidents reported from anaesthetic areas in acute hospitals for the period of time requested.

Incidents involved anaesthetists, other medical staff, nurses and operating theatre practitioners and assistants. It was not possible for us to provide incidents that only involved anaesthetists.

A total of **502** incidents were identified, and analysed.

Table 1 Stage during medication process where the incident took place.

Medication process	Incidents Reported
Administration / supply of a medicine from a clinical area	374
Prescribing	58
Preparation of medicines in all locations / dispensing in a pharmacy	31
Monitoring / follow-up of medicine use	27
Advice	5
Other	7
Total	502

Table 2 Medication error type

Type of medication error	Incidents Reported
Wrong / unclear dose, strength, quantity or frequency	173
Omitted medicine / ingredient	70
Wrong drug / medicine	58
Patient allergic to treatment	34
Adverse drug reaction (when used as intended)	19
Wrong / transposed / omitted medicine label	22
Wrong method of preparation / supply	9
Wrong route	19
Wrong storage	15
Contra-indication to the use of the medicine in relation to drugs or conditions	12
Wrong / omitted / passed expiry date	10
Wrong formulation	9
Mismatching between patient and medicine	7
Other and unknown	45
Total	502

Table 3 Degree of harm

Degree of harm	Number
No Harm	397
Low	81
Moderate	17
Severe	2
Death	5
Total	502

Example reports

Incidents with a reported outcome as death

Adverse Drug Reaction

- Induction of anaesthesia followed by bradycardia leading to cardiac arrest. Excessive slowing of a heart affected by atheroma in a patient given propofol, remifentanyl & suxamethonium.

Adverse Drug Reaction

- Following induction of anaesthesia, patient had cardiac arrest and resuscitation was unsuccessful. This was the second such event in a week. Individual removed from clinical duties and investigation by Trust and RCoA followed. Anaesthetic room too small hampering movement of staff around the patient.

Wrong drug

- A critically ill patient had an intraoperative cardiac arrest, and therefore, intravenous fluids were administered quickly as part of the resuscitation. It was noted after the patient was stable that a rogue intravenous bag of fluid had been infused. The 500mls bag of 5% Glucose with 0.4% Lignocaine was administered via infusion at speed instead of 500mls of Voluven (plasma expander) 6% for infusion. The patient died 48hrs later with clotting and suspected liver problems.

Omitted medicine/dose

- Patient had low BP from admission despite numerous fluid boluses, and increasing inotropic support. Adrenaline rate increased but BP started to fall, adrenaline syringe found not running. BP dropped from 78 systolic down to 54 systolic, bolus of adrenaline given. Dr present at time, no response, BP + HR both dropping further. No pulse - CPR commenced, despite 55 mins resuscitation CPR, adrenaline, atropine and fluids, no response / output regained.

Wrong dose

- High blood sugar (20) noted on anaesthetised patient intraoperatively. This was an emergency procedure in a young girl with spontaneous intracranial bleed and signs of raised intracranial pressure. Insulin was handed to a busy anaesthetist not familiar with the preparation of insulin infusions. Concentration on vial stated insulin 100 units / ml in 10ml. Anaesthetist read 100 units in 10ml and consequently drew up 5ml and diluted to a total of 50ml incorrectly labelling the syringe insulin 1 unit / ml. The concentration was in fact 10 units / ml. infusion was started at 4ml / hr. Anaesthetist realised mistake 15 minutes later as he casually checked half empty vial. Infusion was stopped and new syringe was correctly made up. Blood sugar was checked and found to be 10, so no harm. However patient died 12 hrs later for other reasons.

Wrong dose

- Administered dose of ketamine infusion in error. Consultant anaesthetist asked reporting SHO to make up a Ketamine infusion 25mg in 50ml of N / Saline to be given over 2 hours, and to sit with the patient. In error, SHO made up an infusion with 250mg Ketamine in 50ml N / Saline and commenced infusion. Soon after, patient complained of feeling ' spaced out ' and unpleasant sensations. Discontinued infusion, re - examined vials, discovered error and disconnected infusion, aspirated line and flushed it with N / Saline. Called Consultant anaesthetist to explain what had happened. Came to review patient and informed patient of error. Consultant and reporting SHO calculated that the actual dose given was 5mg Ketamine i.e., 1ml of the infusion. (No harm).
- Wrong strength of morphine ordered 30mg instead of 10mg . Wrong strength was accepted by 2 checkers and entered into CD book. Drug checked by two people, the anaesthetist and ODP who gave to two patients - twice daily drug check did not pick error up. (No harm).
- 'Drug error - 10mg iv bolus of midazolam given in error instead of 1mg bolus (No harm).
- Patient under anaesthesia had 40mg tenoxican. A second patient was planned to be given the same treatment (but inadvertently gave the 1st patient half of 2nd patients dose. Busy teaching clinical attachment person when this happened. Noticed immediately by the anaesthetist
- 'Patient received cocaine solution 4 times the maximum dose. Surgeon was unaware of the dose he had given. Patient experienced cocaine intoxication in PACU. (Low Harm).
- Administering medication vancomycin. Input incorrect calculations into volume pump which resulted in the dose being administered too quickly. Dose checked with senior sister, although calculated correctly, administered incorrectly (Low harm).

Omitted medicine

- Verbal handover in recovery room was that whilst in operating department patient did not receive any analgesia, this was verbally confirmed by second anaesthetic nurse. On return to ward patient unsettled, anaesthetic sheet checked. (No harm).
- Patient known NIDDM. Put on Insulin Infusion. No Dextrose infusion running. Last BM was taken at 06:30 (4.3) Went to review patient in preparation for theatre, noticed insulin, asked for BM , which was 2.8. (No harm).
- The ward staff failed to administer a pre med which was prescribed a day before and requested to the staff nurse present then. They also failed to administer patients own anti hypertensive medications as prescribed. The patient was badly rheumatoid, a high risk and for a major surgical procedure. (No harm).

Wrong drug

- Injection of 3ml (mg) ephedrine in error for bupivacaine via epidural catheter. (No harm)
- 'Epinephrine given instead of ephedrine. Drugs both in identical boxes. (No harm).
- The patient was about to get a spinal by the Doctor. The patient was sitting at the side of the trolley. The Staff Grade Anaesthetist gave what he thought was Cefuroxime but it was 500mg of Thiopentone. (Low Harm).
- The patient went to sleep and got a General Anaesthetic instead of the spinal . The Staff Grade Anaesthetist had drawn up the drug himself , and mixed up the vials. (No harm).
- 'Anaesthetist gave patient 25mgs of pethidine instead of the intended 25mgs of fentanyl. (No harm).
- Incorrect anaesthetic given to patient, rescued immediately. No harm The patient 'came to' physically - however I await to see if she will remember the incident . Seen patient. at 12.00 on 13.1.06 she remembers the experience of not being able to breath , I explained to her my error , she was reassured and has accepted my explanation and apology (Low harm)

Drug allergy

- Patient that was known to be allergic to penicillin given Augmentin iv by an anaesthetist (No harm).
- Patient prescribed antibiotic when documentation clearly stated that patient was allergic to that medication (No harm).

Wrong formulation

- 'Whilst HDU nurse was collecting patient from recovery, she noticed his epidural contained 5mg diamorphine in 0.25% bupivacaine, but the prescription clearly stated it should have been 5mg preservative free morphine sulphate. (No harm).

Wrong route

- During below - knee amputation , under combined spinal - epidural anaesthetic, I inadvertently administered ephedrine 15mg in normal saline 5mls down the epidural catheter (mistook syringe for chirocaine 0.25%). 10ml normal saline given as diluent. consultant .informed, entry in patient notes (No harm).
- Anti - d was given by Dr intravenously when prescribed intramuscularly drug information leaflets advises against intravenous delivery. Manufacturer contacted who advised potential risk of shock when given intravenously with no reduction in efficacy. Patient transferred to recovery under close observation for 1.5 hours, remained well transferred to F9, informed of incident. (No harm).

- Carboprost (Hemabate) used to treat haemorrhage given to patient by doctor IV instead of by deep IM injection (Low harm).

Adverse Drug Reaction

- Sudden Cardiovascular collapse with bronchospasm after induction of anaesthesia. Anaphylaxis to either Thiopentone or Suxamethonium. Patient had no history of allergy to medication. No significant medical history. SPO2 35% , BP 60 / 40 at least 2mins. Two SHO's and consultant anaesthetist present. (Low Harm).
- Severe allergic reaction to Atracurium resulting in widespread rash and severe bronchospasm. Full eventual recovery. (Low harm).

Wrong/transposed or omitted medicine label

- Patient transferred from theatre with syringe driver running but no label on the syringe to say what was on it. (No harm)
- 'Pt arrived from ward & on inspection of glucose potassium infusion it was noted that insulin syringe was not labelled. (No harm).

Wrong method of administration

- 'Patient receiving amiodarone infusion.600mg diluted to 50mls of 0.9% Sodium Chloride. Amiodarone incompatible with Saline. Treatment commenced / drawn up on at 0100hrs 1 / 6 / 06. Error spotted 1600hrs 1 / 6 / 06. Prescription date 30 / 5 / 06 . D / W on called pharmacist, potential complications of precipitation and thrombosis. D / W on call ICU registrar , nil ordered , other than change to oral prescription infusion discontinued as medical and pharmacist advice and converted to oral prescription. (No Harm).

Patient has intravenous sliding scale 10% glucose infusion prescribed for management of insulin dependent diabetes. The infusion of insulin was started alone with no IV glucose in a patient who was nil by mouth. On arrival in Theatre at 11:00hrs the patient had had 2 units of insulin and blood glucose of 7.6mmol / L .

Appendix 4

Responses by members of learned bodies to the draft report

The responses to the draft version of this report obtained from senior members of the learned bodies discussed in section 6 can be found below. It should be noted however that the opinions expressed do not necessarily represent the views of the organisation to which the members are affiliated.

Royal College of Paediatrics and Child Health

This is a very detailed and rigorous report which spans not only the direct circumstances of the incidents but also makes generic points about safety culture and healthcare processes. In complex care pathways, such as were apparent for these children, teamwork and excellent communication are fundamental to delivering high quality, lowest-risk care. In these incidents, an anaesthetist was under pressure to work fast, without break and was unsupported in delivering complex care. The rapidity of daycare work maybe a factor in this. The "sole working" of anaesthetics is less common to paediatricians; in this situation it appears vital for the team (paediatrics, nurses, administration, anaesthetists, etc) to have joint meetings on the management of children passing through their unit.

In general, whilst acknowledging that flushes of IV cannulae have been undertaken without checks for years, there is a need to see these prescribed or subject to a PGD (Patient Group Direction) and to have a double-checking mechanism. However, new guidance cannot be developed from a single Trust-level report, and it is clear that further work is needed to review national guidance on this. The RCPCH would be happy to be consulted on any national initiative to address this, and this would need to be taken out of the context of this specific set of circumstances. We would endorse the need for a broader review of similar incidents to be undertaken, and would suggest that the NPSA and NHSLA should lead on this work.

Dr Hilary Cass

Director of PGME & Deputy Medical Director, Great Ormond Street Hospital

Registrar to Royal College Paediatrics and Child Health

Royal College of Anaesthetists

The College welcome's Professor Toft's thorough report which, although aimed primarily towards a specific safety incident, highlights some broader key areas. Anaesthesia as a specialty has always regarded patient safety areas as fundamental to good practice and this paper initiates deeper consideration of important issues such as the double-checking of drugs. This is a particular area which the College feels should be researched in more depth and we would be happy to contribute to the work.

The Royal College of Anaesthetists has been closely involved in patient safety concerns since its formation and recent work on safer syringe labelling together with audits of practice to advise safety focused guidelines, show how a representative organisation can improve the safety environment. However, we believe it is through collaborative working between healthcare organisations that the best form of integrated approach develops to ensure that risks are reduced and practice improved. It is for this reason that we have recently formed stronger links with the National Patient Safety Agency (NPSA) to improve the potential for learning from anaesthesia related critical incidents, such as the one detailed in this report. From

this initiative we would also suggest that the work of this paper together with other related initiatives, specifically that of Prof Alan Merry, should be taken forward with all key stakeholders, primarily the NPSA.

Mr Charlie McLaughlan
Director of Professional Standards
Royal College of Anaesthetists

Association of Anaesthetists of Great Britain & Ireland

The Association of Anaesthetists of Great Britain & Ireland (AAGBI) has read Professor Toft's report with great interest. His detailed investigation of the events surrounding the administration of an overdose of heparin to four children leads him to a number of recommendations relating to drug preparation and handling. Some of these recommendations are based on reliable data; many are based on simple common sense; we are however concerned lest a few may have unintended adverse consequences. We certainly support those relating to the labelling, packaging and storage of injectable drugs. The AAGBI's strapline for its 75th Anniversary this year is "75 years advancing patient safety", and it holds safety as being of paramount interest and importance in the practice of anaesthesia, intensive care and pain medicine.

The AAGBI is of the view that some of Professor Toft's recommendations – in particular, those relating to double-checking of drugs during preparation and administration – should be subject to careful, prospective study before implementation. We have met with Professor Toft, and he has expressed his support for such an approach. In particular, the practicality, cost, time implications, risks, benefits and contribution to overall patient safety of the recommendations should be assessed before pilot studies confirm whether they are not only effective but also deliverable. The AAGBI thinks that the double-checking of drugs should be assessed in tandem with studies of the prefilling of syringes ("ready to administer" drugs) and bar-coding approaches in order to determine which technique or combination of techniques best serves patient safety. The AAGBI would be happy to work with the National Patient Safety Agency, Department of Health, Royal Colleges and other bodies in developing robust, effective and workable guidelines based on the excellent work and draft recommendations contained in Professor Toft's report.

Dr William Harrop-Griffiths
Honorary Secretary
Association of Anaesthetists of Great Britain & Ireland