

Identifying Design Deficiencies through Anaesthetic Incidents

A. J. Sellen¹, J. W. Senders² & W. J. Russell³

SUMMARY Detailed analysis of a sample of 261 anaesthetic incidents showed that almost half of them were associated with weaknesses in engineering design. Many of these incidents may have been avoided if a defensive approach were taken to the design or manufacture of the anaesthetist's equipment or environment. Feedback from incident reporting is an effective way to probe the weaknesses of the present anaesthetic management and give a guide to how to achieve improvement.

1 INTRODUCTION

The Australian Incident Monitoring System (AIMS) was established in 1988 by the Australian Patient Safety Foundation to identify and understand the factors contributing to errors, incidents, and accidents in anaesthetic practice. AIMS is an anonymous, self-reporting system. Anaesthetists are asked to fill out an AIMS form whenever they are involved in an "anaesthetic incident" defined, for the purpose of the form, as "any unintended event in anaesthesia which reduced, or which, if not detected in time, could have reduced the safety margin for the patient". Participation in AIMS is entirely voluntary, and the amount of information given by any anaesthetist who fills out a report varies widely. Each form contains space for the reporter's free-form description of the incident, plus a series of structured check boxes and fill-in-the-blank type questions attempting to elicit details about what happened, when it happened, and why.

By 1996, the AIMS study had collected over 5,000 incidents from over 100 Australian hospitals or group

practices. Current estimates are that over 600 anaesthetists have access to the system. Preliminary analysis of the first 2,000 incidents resulted in a symposium issue of the journal *Anaesthesia & Intensive Care* (Vol. 21, No. 5, Oct. 1993 pp 501-695). That collection of papers was influential in raising awareness amongst anaesthetists of the pervasiveness of human error in the operating room, and of the various ways in which errors may be expressed.

This paper presents a further analysis of some of the AIMS data. In this analysis, we were struck by the observation that, in many of the AIMS reports, the reporters seemed to be particularly self-blaming or "intra-punitive". We found this despite that in many of these cases, it seemed that poor engineering or deficient design of equipment used by the anaesthetist contributed to the incident.

We set out to examine this observation more closely with three goals in mind:

1. To re-classify and re-analyze a subset of the AIMS database in order to estimate the contribution of design deficiency in anaesthetic incidents.
2. To assess the extent to which the reporting method of AIMS reflects and reveals these design deficiencies, and suggest ways in which it might do

¹ Rank Xerox Research Centre & MRC Applied Psychology Unit, Cambridge, U.K.

² E.M.S.C.O. Consulting, Toronto, Canada

³ Dept. of Anaesthesia and Intensive Care, Royal Adelaide Hospital, Adelaide, S.A.

this more effectively.

3. To outline some design guidelines and suggest measures which might reduce the occurrence of incidents due to design deficiency.

2 THE "CAUSE" OF AN INCIDENT

Assessing and attributing the cause of incidents, accidents, or events involving a human error is far from straightforward. Incidents and accidents can be viewed as having causes at many different levels.

There is the "direct cause" which defines the action that was directly responsible, or that could have been directly responsible for negative consequences. For example, one could analyse an incident in anaesthesia where a patient was given the wrong drug and trace back through the events to find that the wrong ampoule was selected (and subsequently drawn up and administered).

But one need not stop there. Indeed, both the people involved in the incident, and those who analyse the circumstances surrounding the incident after the fact, often find *reasons* for these direct causes. Reasons attempt to specify what caused the deviating action to occur. For example, in the wrong drug case, we may find that the anaesthetist was tired, that there were distractions, that the ampoule looked very similar to the ampoule that should have been selected, and so on.

In terms of improving patient safety, knowing the direct cause of an incident may not help prevention. All one can say is, had the deviating action not occurred, the incident would not have occurred. However, knowing the indirect causes of an incident may be more effective in prevention because there is often a systematic and predictable relationship between these indirect factors and the incident.

2.1 Attribution of Causes

Reasons or indirect causes differ from direct causes because they are more bound up with the issue of attribution or blame to the individual. Examples of this include haste, inattention, failure to follow procedure, and bad judgment. Alternatively, sometimes indirect causes are attributed to the conditions imposed upon an individual, for example, the state of the environment in which the individual is working. This could include the actions of another person, poor lighting, noise, a cluttered work environment, faulty equipment, or poor equipment design. If the individual self-attributes the causes this can be regarded as "intra-punitive". On the other hand, if attribution is external to the individual, this is "extra-punitive".

Most errors or incidents are the result of multiple fac-

tors. In the AIMS reports, it is rare to find incidents where the causes can be clearly blamed only on the individual, or only on the circumstances surrounding the individual. To illustrate, consider the following two examples of incidents taken from the AIMS database. In the first instance, 20 ml. of the anti-clotting agent heparin was given instead of 20 ml. of the intended narcotic fentanyl:

Syringe swap incident. Induction for cardiac surgery. Fentanyl & heparin in adjacent 20 ml syringes. Usually use 40 ml fentanyl, but patient given 20 ml fentanyl + 20 ml heparin. Labelling adequate! Preoccupied with late surgical start; (usually heparin & metaraminol syringes are separated from others on work-top. Geographically.) - This precaution overlooked. No problems with clinical care. No excess pre-bypass blood loss. Keep cool, maintain normal fastidious approach.

The tone of the report is clearly self-blaming. Reasons for the incident include being preoccupied, failing to follow usual procedure (in keeping the heparin physically separate from the fentanyl), falling back on an old habit (in that two 20 ml. syringes of fentanyl were normally drawn up), and failing to take care.

An extra-punitive reporter might have looked to the external circumstances: Despite adequate labelling, under conditions of stress (caused by starting late), two drugs which are both colourless liquids can be easily confused, especially in view of previous habits. In another example, the tone of the report is still intra-punitive not in the sense that it is self-blaming, but rather in that the reasons for the error are attributed to an individual rather than to external circumstances imposed on that individual:

During pre-anaesthetic check of equipment, one-way valve on expiratory limb misassembled with cage and valve stuck downside of gas outlet. Corrected problem and told anaesthetic sister to be vigilant and instruct staff to be more careful with these valves. (Two other cases of this problem occurred at my institution where haste and poor communication mitigated against proper equipment checking...)

It is difficult to know the true causes of the misassembly in this incident. Perhaps poor judgment, inadequate knowledge, haste, and lack of attention were factors. However, note that in this example, the reporter knew of two other similar cases. In light of this, it is interesting that the reporter did not point to poor design of the valve as a contributing factor, given that it appeared that more than one person had misassembled the valve in the past.

2.2 Two Kinds of Remedy

The distinction between intra and extra-punitive factors is important because it leads to different kinds of remedies. In the case of intra-punitive factors, the analyst would look at aspects of the anaesthetist's

behaviour and try to change it. Many of the reporters in AIMS do this. They blame themselves or their assistants for the misassembly, misconnection of equipment, or for other erroneous acts. They then suggest more care or vigilance, or suggest ways to change behaviour such as improved training, improved work-rest schedules, or new procedures.

Adopting an extra-punitive perspective is to assume that people will make errors despite all precaution, all motivation, and all effort to avoid them, simply because it is a natural state of behaviour that people will err. This approach looks instead to factors in the external environment ie the workplace, which either permit, or in the worst case, actually encourage, erroneous action. This is an engineering perspective, which seeks to find the remedy in factors such as the design of the equipment involved.

2.3 Error-Sensitive Design

In the rest of this analysis we will adopt an engineering and design approach to the analysis of anaesthetic incidents, and in suggestions for their prevention. This is not to discount approaches which seek to change behaviour through improved training, and so on. Rather it is to attempt to reduce incidents by attempting to create a more benign environment — one which takes into account the natural tendencies of human beings to err. By adopting this kind of approach, a valve which can be misassembled is an accident waiting to happen and is a completely inappropriate state of affairs which can often be easily remedied. It should no more be possible to misassemble a valve than to use a front door key to start an automobile.

This approach to incident analysis and prevention places responsibility on the designer of the equipment, and the physical environment in which the anaesthetist must work for the conversion of errors into injury to a patient. If design permits or encourages a foreseeable error or class of errors, and if an alternative, equally effective design would not do so, then the responsibility rests on the designer, not on the user. Often correcting the design deficiencies requires no complex design decisions to be made, but only common sense and a sensitivity to the possibility of human error. This recognition of error in design has been well recognised (Norman & Lewis 1986).

A design deficiency may be any aspect of design of equipment or of the physical work environment that:

- permits something to be done wrong;
- encourages something to be done wrong;
- permits an improper procedure to continue without alerting people that it is improper.

3 CLASSIFICATION OF INDIRECT CAUSES

Because of our initial assessment that reporters had a tendency to be self-blaming in specifying the indirect causes or reasons for the incidents that they reported, we made a separate and independent classification of a subset of the AIMS data. We first examined together a subset of about 200 AIMS reports and arrived at a mutual classification scheme of 5 general categories of cause which we felt captured the range that emerged (described below). This was based mainly on the free-form narratives written by the reporters.

We then selected a different random sample of 250 incident reports from the database. Using our prescribed definitions, each report in that subset was classified by two authors (JWS & AJS) independently as to the major contributing causes. Because some of the reports contained multiple incidents, the total number of incidents classified was 261. Each of the 261 incidents was classified as stemming from one or more of the five classes described below. Most fell into only one category, but a few of the more complex incidents fell into more than one, so they are not, strictly speaking, mutually exclusive.

3.1 Five Categories of Indirect Causes

The five categories were defined as follows:

1. Design Deficiency

An incident which was triggered by a characteristic of equipment or work environment which could reasonably have been designed in such a way as to have prevented the incident, or which could have aided in its detection. In our definition, design deficiencies do not include: equipment failures due to wear-out, poor maintenance or incorrect specification of equipment needed (failure to have correct equipment available). We do include compatibility and integration of different pieces of equipment.

Examples:

1. *Three-legged drip stand pulled over onto Datex Cardiocap (monitor) at end of case. I am uncertain as to how this happened. These stands are intrinsically unstable. More 5 legged versions are urgently required. I feel certain that the reported incidents of this occurrence represent the tip of the iceberg.*
2. *Inability to produce satisfactory ventilation with Bird respirator, although $E_T\text{CO}_2$ & SaO_2 levels were within normal limits Ohmeda Volume monitor indicated lower than expected tidal volume. Problem solved by finding that cage over the inspiratory side one-way valve in the circuit had popped off & the disc valve was misplaced. This was replaced and no further trouble experienced. Not known when the cage became displaced.*

3. *Just starting case, took blood pressure. Nurse pressed inflate instead of auto BP button. Didn't realize not auto for 25 min !! N₂O/O₂ relaxant & enflurane + IPPV. Fortunately next BP almost the same.*
4. *Elective CABG routine case. Ten minutes earlier came off bypass smoothly but still labile BP. Sudden loss of ECG/art.bp/cvp traces on monitor. Separate SaO₂ & E_TCO₂ still OK. Pump technician had left a bag of pump blood on top of monitoring unit not adequately clamped which gradually dripped into electricals until short circuit occurred. Fully draped patient difficult to get to a peripheral (arm) pulse to check BP (approx 80/40 at time). Only measurable by auscultation of Korotkov sounds and peripheral pulses palpable (cold+++). Alternative monitoring unit available 15 mins later.*

2. Equipment Failure.

Describes equipment which is inherently defective and includes all those cases in which a machine worked improperly or failed to work because of some hidden flaw which was the result of age, improper maintenance or, occasionally, improper choice of materials. This category differs from the first category in that it is not that it fails to accomplish its intended purpose, but rather that it works exactly as intended until it fails to work at all. In other words, its functional design is correct but it does not have the requisite reliability because of choice of materials and components.

Examples:

1. *Failed to ventilate with an adequate tidal volume on Bird MK8 ventilator. Hand ventilated — OK. Checked for leaks — circle circuit OK. Expiratory control (pressure activated) was found to be cracked & broken. Replaced.*
2. *Datex Cardiocap (monitor) working properly all day, then screen went blank. Power to Sony printer still maintained. We tried switching it off & on again, and we changed power points, but screen still blank. So we changed monitoring leads to another Cardiocap.*

3. Idiosyncratic

Includes all cases where the incident was triggered by the unpredictable or unforeseeable reaction of the patient either to the nature of the surgical procedure or to the drugs used by the anaesthetist interacting with the particular physical or pathological state of the patient.

Examples:

1. *Excision & grafting burns under ketamine/diazepam with N₂O/O₂ via nasal cannula. Pulse oximeter 20 month old male. Late in procedure and with no apparent precipitating event, patient developed laryngospasm. SaO₂ fell to 20%. Responded to CPAP with*

100% O₂ via bag & mask (Mapleson F) & suctioning of airway. Occurred on 2 further occasions though much less marked & quite transient. (unusual with ketamine).

2. *Dural tap on attempted insertion of epidural needle. Patient being prepared for caesarean section under epidural anaesthesia. Patient had severe kyphoscoliosis & probable spina bifida occulta. It is possible to identify spina bifida with Xray studies and this may have helped but I feel it is difficult to justify such studies in pregnancy.*

4. Human Error

Includes cases involving either a choice and correct execution of an incorrect intention; or an incorrect execution of a correct intention (mistakes or slips). These are cases which are not triggered by or accounted for by the particular design or configuration of the equipment in use. Many of them are cases of poor judgement and decision-making.

Examples:

1. *At end of procedure (laparotomy), appendix at 2 am — teaching registrar and disconnected patient, having reversed without washing out N₂O with 100% O₂. Distraction!*
2. *At end of laparoscopic cholecystectomy, nurse went to turn off power to camera and video monitor. Turned off wrong switch and cut power to the anaesthetic monitor*

5. Procedural

Includes all cases in which institutional rules permitted things to be done which should not have been permitted or prevented things from being done which should have been available. The policies, rules, and standard procedures of the institution may make the completion of correct intentions difficult or impossible, or may make them more prone to error.

Examples:

1. *A healthy patient undergoing elective Caesarean Section (LSCS). Two previous LSCS had been uneventful. Induction was performed after pre-O₂ for 5 mins. She was given thiopentone 300 mg & sux 100 mg IV. Cricoid pressure was applied. Hypnosis occurred but after 30 - 45 secs there was no twitching suggestive of sux activity. The patient had good muscle tone. An attempt was made to intubate. This was slightly difficult due to increased muscle tone & movement, but successful. The patient continued to move oxygenation fell to about 88% & she gagged on the tube. Once correct placement of the tracheal tube was confirmed she was given vecuronium & ventilated. The rest of the anaesthetic & surgery was uneventful. Problem:*

inactivated *sux* probably due to being left at room temp on several occasions. (new policy to either have fewer amps of *sux* in drawer or for small Eski cooler to be used in future).

2. During induction, more thiopentone was required. The syringe on the anaesthetic machine was used to give the drug. Subsequently, it was discovered there were 2 thiopentone syringes on the machine (one was obscured). It is difficult to say whether the syringe used was from the previous patient or from the left-over of the present patient. Both syringes were then discarded. It is not a drug identification problem but more a syringe identification problem. Prevention: All drugs on the machine top must be discarded by anaesthetic nurse before start of next case. If anaesthetist wants certain syringes to be kept it is his/her responsibility to put them aside elsewhere.

Upon completion of the independent classification, a Kappa statistic (see Siegel & Castellan, 1988) was computed to indicate the measure of agreement between the two judges in assigning the individual incidents to the named categories. The value of Kappa calculated was 0.77 which is significant with $p < 0.001$. The 95% confidence interval for this value was found to be from 0.69 to 0.84. This indicates that the two judges were able to reliably assign the incidents to the five categories specified above, and were in strong agreement with each other.

The results of this classification are shown in Table 1. From our perspective, the most significant finding is that, on average, 48% of the incidents fell into the "Design Deficiency" category. In other words, almost half of the incidents appeared to be permitted, or even encouraged, by the particular way in which the anaesthetic equipment and work environment were arranged.

Another interesting finding was the frequency with which the incidents were assigned to the category "Idiosyncratic". An average of 37% of these incidents were classified as falling into this category with the two raters agreeing on 86 of the 97 cases in the sample. The reports do not suggest any corrective strategy except for the use of this information in raising awareness of the possibility of such cases occurring.

Equipment failure was found to be the major contributing factor in less than 4% of the cases. It should be noted that a very large fraction of things which might ordinarily be called equipment failure have been attributed to poor design rather than failure due to wear or improper maintenance.

4 INTERNAL VS. EXTERNAL ATTRIBUTION OF BLAME

An assessment was made about the causes of the 261

Table 1

The mean percentage of 261 reports assigned to each of 5 categories of contributing causes.

	Mean % Assigned to Category
Design Deficiency	48
Equipment Failure	4
Idiosyncratic	37
Human Error	9
Procedural	6

incidents. To do this only that subset of reports which both assessors had classed as stemming from design deficiency were considered. Of the 261 incidents, 118 were incidents on which this same judgement had been independently made. We then considered the check boxes that the AIMS form provided under the heading "Factors Contributing to Incident". This list provided 26 different factors and choosing more than one option for each incident was permitted. Of the 26 factors available, we classified 8 as being clearly "intra-punitive" or self-blaming (e.g., "distraction", "haste", "inattention"). We then classified 11 as being "extra-punitive" or attributable to other people, things, or circumstances (e.g., "inadequate assistance", "communication problem", "sick patient", "equipment problem") The remaining 7 factors could not be classified as clearly intra- or extra-punitive, either because the terminology was ambiguous (e.g., "lack of facility"), or because the options were deliberately open-ended (e.g., "other stress", "other factor"). These were left out of further analysis.

Using these definitions, we then analysed the extent to which this subset of 118 incidents classified as stemming from design deficiencies were specified by the reporters as being attributable to intra or extra-punitive factors (see Fig. 1). There were 9 reports where no factors were checked. Of the remaining 109, there were 70 in which at least one intra-punitive factor was ticked, and 31 in which *only* intra-punitive factors were ticked. In all, there were 78 incidents in which at least one extra-punitive factor was ticked, and 39 containing *only* extra-punitive factors. Thus, a total of 39 of the 109 reports contained a mixture of both (shown in Fig. 1).

Although this subset of 109 incidents was judged by us to be attributable to factors imposed upon an individual, 64% of these were judged by the reporters to be at least partly attributable to themselves, and in 28% of the cases the reporters were entirely self-blaming.

It is also interesting to note that, of the 78 reports in which extra-punitive factors were ticked, the majority of them (58) contained factors which were directly indicative of design deficiencies, as opposed to being due to the actions of other people, or circumstances beyond the reporter's control. These were approximately equally distributed amongst the subset of reports containing only extra-punitive factors, and the subset which had a mixture of intra and extra-punitive factors.

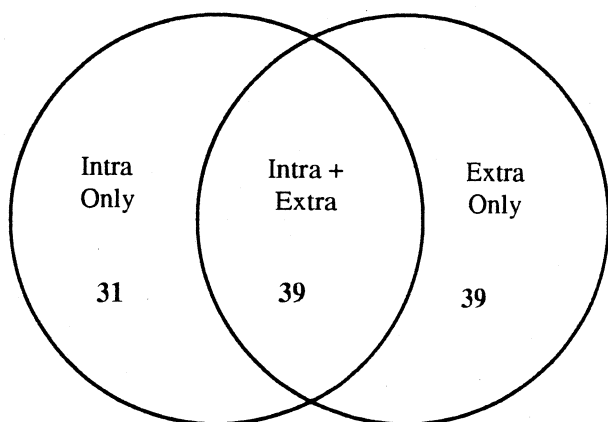


Figure 1: A schematic diagram of the number of reports containing intra- and extra-punitive contributing factors.

From this analysis we can surmise that there are two different influences on the reporters as to their choice of contributing factors. One is their propensity to assign blame and responsibility to themselves. The other is an awareness of the possibilities of redesign of the equipment. It is reasonable to assume that, as in all professional groups, there is some knowledge of engineering. Evidence for this view is found by examining the choices listed under the heading "Suggested Corrective Strategies" for the same sample of 109 reports. Of the people who ticked no intra-punitive factors, 24 (62%) recommended Equipment Design Improvement. Of those who had some of each, 16 (41%) recommended Equipment Design Improvement, and of those who listed only intra-punitive factors recommended this 35% (11) of the time. Thus, as one might expect, the more self-blaming the reporter, the less likely was the suggestion for design improvement. There was a statistically significant difference between those who were only intra-punitive and those who were only extra-punitive ($p=0.027$ Fisher one side)

5 ANALYSIS OF THE DESIGN CATEGORY

One benefit of taking a design perspective to the analysis of these anaesthetic incidents is that it can help to

extract the emotional issues of blame that may impede practical, preventative action. Instead, we can focus on the nature of the design deficiencies with which anaesthetists have to contend and use these to suggest design improvements.

With this in mind, we looked more closely at the 118 incidents agreed upon as stemming from design flaws, and attempted to describe and classify these in more detail. In doing so, we arrived at 12 different sub-categories of Design Deficiency. They are not intended to be mutually exclusive, and we do not claim that they are exhaustive. Rather, they are intended only to provide a structure to describe the ways in which a design can be flawed, thereby pointing to ways in which it can be improved upon.

These categories are defined as follows:

1. Disconnects

Disconnections of gas lines in the anaesthetic apparatus appear to occur either spontaneously or from inadvertent contact.

Emergency neurosurgical procedure. 10 mins after scalp incision. Ventilator alarm sounded. Disconnection between angle piece & catheter mount detected. Rectified before any other alarm sounded.

2. Problems with tracheal tubes

The design of the tube permits incorrect placement to remain undetected until the adverse consequences are reflected in some other physiological indication.

Loose tracheal tube mount., and misplacement of tube into right main bronchus. I was just relieving registrar for lunch when I noticed above. SaO₂ 91-93%, FiO₂ 0.33, ETCO₂ 37. (problems picked up by experience & healthy dose of clinical awareness).

3. Problems with alarms

Alarms sound when they should not, fail to sound when they should, are difficult to discriminate from one another, or are otherwise badly designed.

One hour into a partial hepatectomy a man 74 years old The Cardiocap monitor suddenly failed. No NIBP arterial line ECG, SpO₂ CO₂. felt carotid pulse OK. Had not noticed Cardiocap running on battery — not mains power. No warning when battery exhausted. needs flashing light on battery unit when in operation.

Anaesthetic ventilator on equipment precheck, checking ventilator for leaks etc. starting enabled the alarm, which could then not be silenced. Resulted in call to Biomed who had to disconnect power supply to shut it up. Otherwise it functioned OK.

4. Problems with syringes

Syringes difficult to discriminate by either visually or tactually.

Inadvertent administration of thiopentone during maintenance phase of anaesthesia, mistaking the 10 mls of straw coloured thiopentone solution for 10 mls of straw coloured cephalosporin solution. After establishing anaesthesia, request from surgeon for 2 antibiotics. These prepared & syringes labelled. Gentamycin dose given. Then required to help scout nurse apply diathermy plate onto patient under sterile drapes. Resumed anaesthetic duties & started to give the cephalosporin in divided doses— error made in picking up unlabelled thiopentone syringe while correct syringe lay with label down & not visible. Error detected when label on correct syringe (with 10 ml solution) noted.

5. Problems with absorbers

Absorbers permit misassembly with consequent leaks.

Leaking circle absorber. After filling and replacing container with soda lime, a leak occurs at the top or bottom seats the problem is due to the poor design of the equipment and occurs about once each week to me. Problem found prior to start of case.

6. Problems with IV drips

The lines from multiple IV sources are not discriminable either visually or tactually or permit misassembly.

Epidural infusion (bupivacaine 0.1% & fentanyl 2 mg/ml) accidentally connected to IV infusion. Received 1 ml of solution over 5 minutes. Error recognised by midwife & corrected. No specific factors in causation except haste (busy labour ward & theatre).

7. Sticky valves

The design of the valves is inherently flawed in that, under the conditions of normal use, the valve fails to close or to open reliably.

One hour into otherwise uncomplicated (R)hemicolecotomy rising EtCO₂ & bizarre capnograph. Inspiratory yellow-flap-valve on circle absorber head stuck in partly open position indicated re-breathing. Valve changed while using an alternative machine and problem solved.

Adjustable pressure relief valve would not release gas (despite appearing to function normally, i.e. able to be turned open, "feel" of return spring working; not obviously sticking).

8. Unsuitable materials

The materials used in the construction of the equipment is inherently unsuited to that use resulting in

breakage and corrosion.

Leaking tracheal tube cuff. Large person 84 kg but small nasal passages. 7.0 mm nasal RAE tube. Unable to pass nose cavity. 6.0 Sheridan tracheal tube passed successfully, but cuff leak detected. Tube replaced via oesophageal dilator with same kind of tube — cuff burst again.

9. Poor functional design

More general problems of poor equipment design. It is not that the equipment fails but rather that it works exactly as intended and does not accomplish its ostensible purpose. Examples include: loose knobs, three footed stands that fall over, battery problems, lack of sufficient feedback.

Hypoxic gas mixture due to free flow control knob on rotameter. (a common problem). Assumed to have been reset when accidentally knocked.

10. Permissible misassembly

The design of equipment permits incorrect actions to be executed and to remain undetected

Sick anaesthetist relieved just after intubation by another anaesthetist. Patient transferred immediately into theatre from induction room, and on the way, bag in theatre noted to be tight & not emptied by spill valve. On arrival in theatre, passing anaesthetist called in to check back of machine as primary anaesthetist busy ventilating. Scavenging piping noted to be misconnected. Tubing was connected back into itself in scavenger interface. Scavenger tubing from APL patient valve connected into ventilator scavenging connection. No high pressures delivered to patient.

11. Confusion

The distinguishing characteristics of two or more controls, containers, labels or names are not effective in encouraging detection or identification of an incorrect choice.

During busy resuscitative efforts of a patient with a ruptured abdominal aortic aneurysm with leaking aorto-caval shunt, 250 mg of protamine was given instead of 25 mg as requested by the surgeon. The ampoule read 10 mg (in 1 ml) 10 ml amp. Erroneous mistakes for 10 mg in 10 ml. Perhaps ampoules are too large if 25 mg is a commonly used dose.

12. Poorly designed work environment

The work place allows normal human activity in the course of normal procedures to disrupt the functioning of equipment.

Resection abdominal aortic aneurysm. Surgical assistant leaned on drip stand (3 legged) & both right and left stands near patient's head fell over. Both three legged drip stands

(Left with blood warmer mounted) pulled by attached drapes. Radial artery line pulled out. (At this stage aortic clamp had been on about 2-3 mins). Blood warmer flooded floor. Arterial line reinserted in R radial artery & patient came to no harm.

The percentage of incidents falling into each category is shown in Table 2.

6 PREVENTION THROUGH "DEFENSIVE" DESIGN

What can we say about human error which a designer could use in order to maximize the safety of a device? The first and most important thing is that people will not always follow instructions or procedures. Some evidence suggests that the probability that people will follow procedure as prescribed is about 0.5. Steps will be omitted; steps will be transposed in time; steps which do not form part of the procedure will be inserted. There is no reason to believe that the data derived from a wide variety of industrial situations ranging from chemical plant operations to nuclear power plants should be any different in the operating room. Indeed the AIMS data provide ample evidence of this similarity.

Designers need to adopt defensive design. This means:

1. The designer should assume that any of the steps required for the intended use can be omitted by a

user.

2. The designer should assume that even if steps are not omitted, they may be done out of order.
3. The designer should assume that active effort on the part of the user to accomplish the goal of assembly and use by means not included in the intended procedure.
4. The designer should assume that despite all precautions above, errors will still occur, so devices need to provide effective feedback to alert the user to the fact.

In addition, The ways in which design deficiencies can be addressed as a general principle are:-

1. The primary approach should be that wrong action should not be permitted. However, this is not always possible. If a wrong action can occur, it should be clearly flagged. This could be that the wrong action is permitted but system disabled or that the wrong action is permitted but system alerts. These are robust warnings but even this may not be possible. However, as a minimum a wrong action may be permitted but discriminability enhanced.
2. Current designs should improve feedback. One example of this is the identification of the muscle relaxants as the dominant drug group in drug errors which has led to a successful trial of an

Table 2
The frequency and percentage of each category
(Note that categories are not mutually exclusive)

	Frequency in Sample	Percentage of Total Sample (n = 262)	Percentage of Design Subset (n = 118)
Disconnects	17	6.5	14.4
Problems with tracheal tubes	13	5.0	11.0
Problems with alarms	12	4.6	10.2
Problems with syringes	14	5.3	11.9
Problems with absorbers	3	1.1	2.5
Problems with IV drips	2	0.8	1.7
Sticky valves	13	5.0	11.0
Unsuitable materials	9	3.4	7.6
Poor functional design	27	10.3	22.9
Permissible misassembly	23	8.8	19.5
Confusion	25	9.5	21.2
Poorly designed work environment	12	4.6	10.2

exclusive relaxant syringe with a red plunger at hospitals in Adelaide.

To some extent the awareness of the need for defensive design may help the process. Until recently the female 19mm scavenging conical taper, which may securely mate into the slightly larger common 22 mm breathing taper, was widely used. Now the 30 mm taper is being encouraged and this avoids the misconnection risk.

However, more can be done. eg alarms should always arm when the device is turned ON. Today many ventilators still have separate low pressure disconnect alarms.

A design deficiency is present if: the design is such that there is no inherent way to self-detect the error during the action; a wrong action is permitted, and the system is neither disabled nor alerts the user to the fact in any other way foreseeable and preventable if taking into account the possibilities.

JOHN W. SENDERS

John W. Senders graduated A.B. in experimental psychology from Harvard College, and was later awarded a PhD in quantitative psychology from the University of Tilburg. He has been Aviation Psychological Psychologist at the USAF Aero-Medical Laboratory; Lecturer in Psychology at Brandeis University and Professor (now Emeritus) of Industrial Engineering at University of Toronto. He was also Research Professor of Engineering & Psychology at University of Maine. He is currently Lecturer in Intellectual Property law at Osgoode Hall Law School of York University. His current research interests include the nature and source of human error and perceptual confusions, error in medicine, and the mathematical analysis of the distribution of visual attention. Professor Senders was supported in part of this work by the Anaesthesia Patient Safety Foundation (USA).

ABIGAIL J. STEVENS

Abigail J. Stevens PhD. is a Cognitive Psychologist with training in Human Factors Engineering. She has a special interest in the role of errors and accidents in anaesthesia. At the Xerox European Research Laboratory in Cambridge, England, she uses psychological research and in situ studies of organisation to design new technologies such as videoconferencing, computer input techniques, portable reading devices, computer help systems, and technologies helping prospective memory. Prior to working at Xerox, she has worked at Apple, Bell Northern Research, the Computer Systems Research Institute, University of Toronto (as a member of the Toronto Telepresence Project), and the MRC Applied Psychology Unit on Cambridge. She is a special lecturer at the University of Nottingham and a former research fellow of Darwin College, University of Cambridge.

W. JOHN RUSSELL

W. John Russell FANZCA, FRCA, PhD, DIC. is the Director of Research & Development in the Department of Anaesthesia & Intensive Care at the Royal Adelaide Hospital. He has had a long interest in anaesthetic equipment and has published widely in this area, including a book on Australian anaesthetic equipment which has recently gone into its second edition. He was a founding member of the Australian Incident Monitoring Study when it began to collect anaesthesia incidents. He is on several Australian standards committees and is currently chairman of HE3 and the Health Coordinating Committees. In addition to Australian Standards, he also is involved with International Standards for anaesthesia and intensive care equipment and is chairman of ISOTC121 Subcommittee 8 which handles medical suction.

"Medical devices should be safe and effective when used as intended." (FDA rule). We would add... "And at least safe when used in any other way."

REFERENCES

1. Norman DA & Lewis C 1986 Designing for error. In Norman DA & Draper SW Eds. User Centered System Design: New Perspectives on Human-Computer Interaction Hillsdale, NJ. Erlbaum Associates
2. Runciman WB, Sellen AJ, Webb RK, Williamson JA, Currie M, Morgan C, Russell WJ. Errors, Incidents and Accidents in Anaesthesia. *Anaesthesia & Inten. Care* 1993;21:506-519
3. Siegel S. & Castellan NJ. *Nonparametric Statistics for the Behavioural Sciences* 1988 New York McGraw-Hill