

Human Error and 'Non Compliances': Causes & Prevention

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DBA**



Any of these sound familiar?

- Procedural 'non compliances'
- Calculation errors
- Batch Records...not 'right first time'
- Pressing the 'wrong button'
- Poor decision making



The list is endless and the impact ?

Potential Consequences?

- Risk to patient. Mistakes go unnoticed
- Risk to your 'licence to do business'
- Reputations and legacies destroyed
- Lack of confidence and trust
- Massive cost and waste



Three-day-old baby 'died after overdose of sugar in hospital'

JACK LEFLEY

A PREMATURE baby died of massive brain damage hours after being given a huge sugar overdose, an inquest heard today.

Jada Pilkington Asanye's condition deteriorated after she was given an intravenous feed bag at Chelsea and Westminster Hospital, Westminster Coroners Court was told.

Born after 26 weeks, she was three days old when she died at the hospital a year ago today. The solution in the bag had been mixed at Guys and St Thomas' hospital, the court heard.

Reading from the post-mortem report, Dr Josephine Ashmead Wyatt said the level of sugar in Jada's blood had been "a contributing factor in her death".

She told the court the causes of Jada's death were massive brain damage, prematurity and the sugar levels in her blood caused by the feed bag, adding: "To have inadvertently had a feed bag with too much glucose exacerbated everything." Earlier the



Tragic: Jada Pilkington Asanye and her mother Lorraine



court had heard how Jada was given a bag containing 36.6 per cent sugar, when it was meant to contain seven per cent sugar.

Jada's mother Lorraine Pilkington sobbed as she told the court she wanted to know how and why her baby died. Jada's twin brother died of natural causes shortly after his birth.

Deputy Coroner Dr Shirley Radcliffe also heard from Dr Shu-Ling Chuang, the consultant paediatrician at Chelsea and Westminster hospital. She

told the court that after being given the feed bag Jada's blood levels were "abnormally high" and the consultant had "not encountered levels of that nature".

Asked if delayed blood test results would have changed Jada's treatment, she said: "By that stage the baby had so much sugar in her blood system that it would not have altered our management or the final outcome."

Jada's situation deteriorated and her life support machine was turned off less than 24 hours

after she had been fed. Dr Chuang said there was a lack of evidence over any link between hyperglycaemia (raised sugar level in the blood) and brain haemorrhaging in premature babies.

Ms Pilkington, and Jada's father Edward Asanye, have vowed to take legal action. Miss Pilkington, 43, from Victoria, said before the inquest: "We are devastated by the entirely avoidable death of our baby and want to make sure this never happens again." The inquest continues.

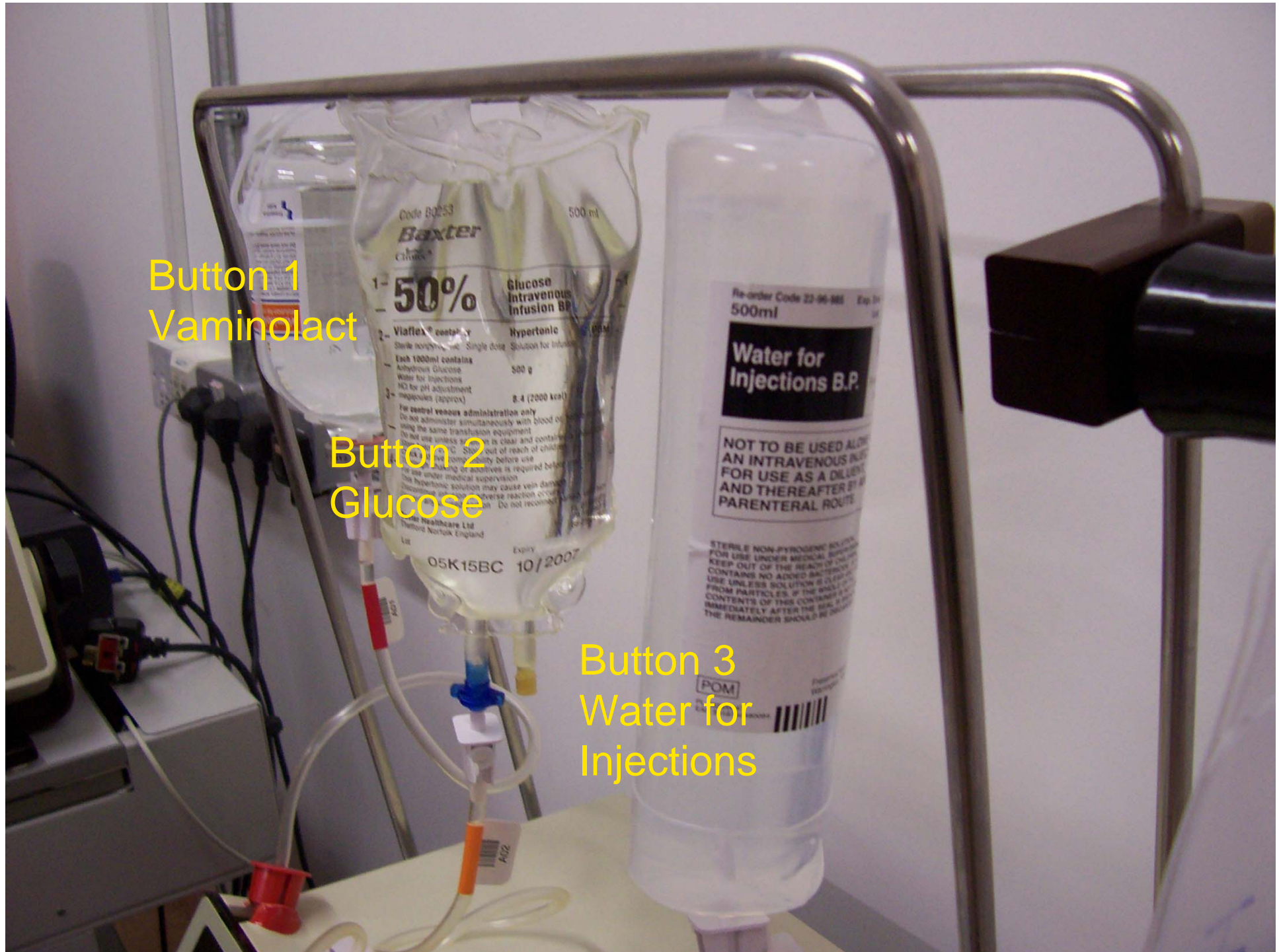
Accident Causation

Product	Volume	Weight	Batch number & expiry date		
Aminoacids, glucose and electrolytes					
Vaminolact	27.4 ml	28.0 g			
Water for Injection	111 ml	111 g			
Glucose 50%	24.2 ml	28.7 g			

Button 1
Vaminolact

Button 2
Glucose

Button 3
Water for
Injections



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Why should you listen to me?!

Because I've seen lots of mistakes...

- **31 years global experience**
- **Microbiologist and 'psychologist'!**
- **Senior positions in Manufacturing, QA, QC and Corporate**
- **Life long passion for error prevention**





Why David Begg Associates?

- **Provided consultancy and training services to the pharmaceutical industry for nearly 25 years**
- **720 clients in over 40 countries**
- **400 years combined experience**
- **We've seen a lot of mistakes!**



Human Error: Some Simple Facts

- **96% of workplace errors involve human factors**
- **Deming estimated that 93% of mistakes and defects were due to systems created by 'management', not the operator or worker**
- **Most human errors are the result of predicatable characteristics and patterns of behaviour**



We ALL Make Mistakes!!









*Prospects for pharmaceutical
companies in China?*

FANTASTIC!!!

*Providing you learn
from the mistakes
of others!*



Human Error Reduction: 'Best Practices'



'Best in Class' Attitudes and Practices

Let's learn from the experts!

- **Nuclear**
- **Aviation and Aerospace**
- **Motor industry (Toyota)**
- **Military**
- **Academia**



10 Essential Elements

- **Understanding of human 'behaviour'**
- **'Positive' attitude to human error**
- **TOTALLY open and blame free culture**
- **Drive out complexity**
- **Focus on 'User Centred Design for *everything***
- **Robust 'System Defences' to stop errors getting through**
- **Reliable 'Error Reporting Systems'**
- **Remove error causes *before* error happens**
- **Invest in 'Education and Learning' not training**
- **Help people to be 'Responsible' and 'Accountable'!**



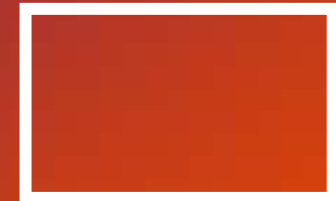
10 Essential 'Characteristics'

- Each one described
- You evaluate your company practices
- Scale
 - ★ ***None = 0***
 - ★ ***Exists but does not meet all criteria = 1-9***
 - ★ ***Exists and meets all criteria = 10***
- Record your score on the sheet provided




Number 1: Understand Human Behaviour

- Brains designed for SPEED, not accuracy
- Most decisions based on emotion not hard facts or figures
- Limited attention span (30-40 minutes for 'logical' brain)
- Breaking old habits is very hard
- Easily distracted
- Damaging effects of stress and fatigue



Best In Class - Practices

- Design equipment, processes and procedures to be 'brain friendly'
- Standardised approach to structured, fact based decision making and problem solving
- Actively break old habits *before* introducing new ways of working
- Lateral thinking tools and techniques
-  Reduce stress and fatigue!!

Number 2: 'Positive' Attitude to Error

- **Accept we all make mistakes!**
- **The Thomas Edison attitude 'mistakes are unique 'learning opportunities''**
- **Every mistake is a 'free lesson'**
- ***Always* focus on cause and not consequence, prevention and improvement not punishment**



Learning from mistakes...

' You don't learn from successes; mistakes are what shapes us. We treasure mistakes'

Jim Press. Toyota USA



Best In Class - Practices

- **Education = Drives behaviour**
 - ★ ***'Mistakes drive improvement'***
 - ★ ***Making the same mistake twice IS bad!***
 - ★ ***EXPERTISE and understanding of products, processes and the needs of the PATIENT***
- **Managers that 'walk the talk'**
- **Performance measure that drive the RIGHT behaviour**



Best In Class - Practices

- **EVERY** incident reported, prioritised, investigated and resolved in hours!
- Suffer short term pain for long term gain!!
- Share 'lessons learnt' openly and quickly



Number 3: Totally Open and Blame Free Culture

What we know about blame cultures?

- **Generate atmosphere of fear**
- **Dangerous**
- **Mistakes go unnoticed**
- **Errors repeated at massive cost**
- **Nothing improves**



EVERY ONE LOSES



Best In Class - Practices

- **Management education and practice**
- **'Every one does the best they can'**
- **Performance measures that drive continuous improvement**
- **No 'silo' working. Teams fully integrated**
- **Focus on systems not people**
- **Culture of candour and transparency**



Number 4: Drive Out Complexity

- **Complexity causes errors and mistakes**
- **Simplicity is the sign of intelligence
Complexity is the sign of the 'lazy' thinker.**
- **There is no such thing as 'necessary' complexity. Complexity is not natural, it is created!**



- **Actively drive out complexity**



Best In Class - Practices

- **Focus on 'Core Purpose' and remove everything else**
- **Early involvement of users and listen to those at the 'sharp end'**
- **Only use proven technology that serves the people and the process**
- **Standardise when ever possible**
- **Employ a 'fresh pair of eyes'**



And some more...

Make sure you don't add complexity

- **Deviation and CAPA system**
- **Change Control system**
- **Audit and self inspection program**

Must focus on keeping things SIMPLE!



An example – SOP's

- **Instructions start on page one**
- **More pictures and diagrams, less words = Fewer pages**
- **Face to face review meetings**
- **Fewer check signatures**



Number 5: User Centred Design

For EVERYTHING:

- **Plant**
- **Equipment**
- **Processes**
- **Procedures**



Best In Class - Practices

Early on in design ask the following

- **What could go wrong?**
- **Can we improve ergonomics?**
- **How can we simplify?**

.....MULTI DISCIPLINARY TEAM



Deployment of UCD in Equipment Selection

- **In Factory Acceptance Trials (FATs) ensure operational staff look at key UCD requirements**
- **Ensure that UCD is incorporated in Installation Qualification**
- **Use computational modelling, e.g. in an isolator can an individual physically perform the tasks when restricted by a glove port or half suit**



Hints for Design Engineers

- **Prevention of 'Accidental Activation'**
- **Standardise whenever possible**
- **Abuse resistant**
- **Coding**
- **Grouping**



Abuse Resistant!!

Take account of

- **Frustration**
- **Fatigue**
- **The 'novice'**
- **Reality in the work place**



Deployment of UCD in Documentation Design

- Typical batch records 20 to 30 pages
- Batch records for complex processes up to 250 to 400 pages long
 - ★ *10 to 20 entries per page not uncommon with up to 100 seen in some cases*
- Potential for from 200 to 40,000 opportunities for error in a record



And more..

- **Typical Right First Time (RFT) in industry ranges from 70 to 95%**
- **At best an error rate of 50,000 per million (electronics industry looking at 1 per million or better)**



How to Improve Document Design

For every item in a batch record consider

- ★ *What is its purpose*
- ★ *Why is it there?*
- ★ *Who needs the information*
- ★ *How is the information used*
- ★ *Is it available elsewhere*
- ★ *Alternatives to words?*



Ask yourself is it:

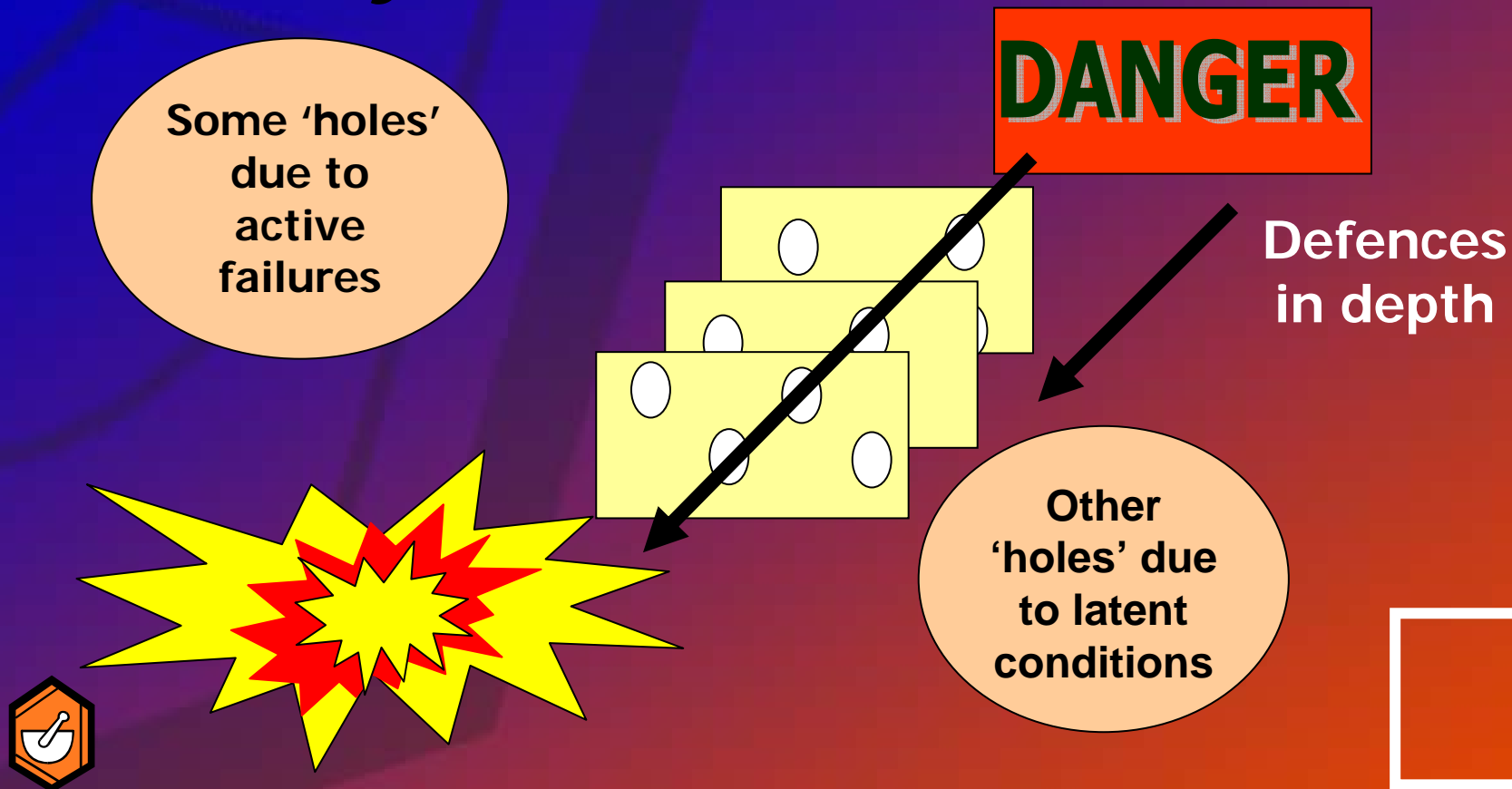
1. Compliance requirement?
2. Legal requirement?
3. Essential 'how to do'?
4. Financial?
5. Operational efficiency?

Remove 4 and 5 and put elsewhere!



Number 6: System Safeguards

The 'Swiss Cheese' Approach: Building in safety measures



Key Systems Safeguards

- Deviation and CAPA
- Change Control
- Documentation (Policies, SOPs, Batch Records)
- Technical Agreements
- Planned Preventative Maintenance
- Audit and Self Inspections
- Quality Control
- Validation
- And what else??



System Safeguards that...

- Capture
- Flag up
- Contain
- Remove

*To drive **long term improvement**, not
short term fire fighting*



A point to consider

Quality Systems are there to protect the patient and drive continuous quality improvement

....in reality many systems do the complete opposite



Number 7: Reporting Errors

Reporting Systems that are:

- **Available to all**
- **Quick and easy to use**
- **Acted upon**
- **Positive feedback to reporter**



Number 8: Remove Risk Increasing Factors

Structural:

- **Lighting/Noise**
- **Inconsistent process**
- **Poor procedures**

Stressors:

- **Workload**
- **Pressure**
- **Interruptions**



Best In Class - Practices

Focus on PREVENTION

- **Operator led RIF assessments**
- **Sharing of information**
- **Adoption of best practice**
- **Company auditors!!**



Number 9: Investment in Education and Learning, NOT 'Training'

Education that:

- **Explains the WHY (the BIG PICTURE)**
- **Uses good 'adult learning' practices**
- **Encourages good habits...breaks BAD ones
(*'de-training'*)**
- **Makes people more aware of 'consequences'**
- ***NEVER STOPS***



Best In Class - Practices

- Talk about **patients** not customers or 'stake holders', **medicines** not products or batches
- Poster campaigns
- Direct contact with patient groups
- Keep people 'risk aware'



Education

- **Risk Aware...'*follow the drum*'**
- ***REALLY* understand the WHY**
- **Influences behaviour...no matter how much pressure**
- **Passion!**



Number 10: Responsibility and Accountability

People who are 'able to respond' and 'held to account'

- **Clearly defined**
- **Have authority (some without 'position')**
- **Are supported not 'hung-out-to-dry' when things go wrong**



Some Final Thoughts

- **Lets learn from the best, not reinvent the wheel**
- **Please LEARN FROM OUR MISTAKES!**
- **EVERY mistake is preventable**
- **Think beyond the person**
- **With a little thought and investment everyone wins!**



