AYRSHIRE AND ARRAN NHS BOARD

CRITICAL INCIDENT REPORTS:

HEALTH & SAFETY AT WORK ETC ACT 1974 (HSWA)

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Ayrshire and Arran internal investigations into critical incidents report major failings of healthcare. These incidents fall within the scope of the Health and Safety at Work etc Act 1974 as it applies to patient safety. The incidents demonstrate major breaches of the Act. The relevant enforcement code identifies the majority of cases as requiring consideration of prosecution of the NHS Board.

1. Summary

This report is a collation of published Critical Incident Reports (CIR) and Significant Adverse Event Reports (SAER) from Ayrshire and Arran NHS Board (A&A). It extracts the Board's findings across the hospitals on problems identified by their investigation teams. These findings are then compared with the statutory requirements of the Health and Safety at Work etc Act 1974, the primary UK-wide legislation applying to patient safety, to identify what enforcement action if any was appropriate. The comparison is done using the default regulator, the Health and Safety Executive (HSE) enforcement code (EMM), and using the conviction of Mid Staffordshire NHS Trust as a recent example of its application to patient safety.

Of the 86 reports over 46 relate to fatalities where the failures reported may have been a factor. In **49** of the cases the HSE's EMM determination is to consider **prosecution** for breaches of HSWA. Additionally, in 65 of the cases there is a determination of issuing legal enforcement notices. It appears that so far there has been only one prosecution and subsequent conviction of A&A. This is in respect of report DB66. This seems to only have come about because the parents of the deceased repeatedly pressed the COPFS for action, initially understanding that only a FAI was being considered. Two years after the death the HSE was called in. A further two years elapsed and A&A was convicted. The Sheriff referred to the death as a 'never event'. However it appears that in the intervening period there had been a similar death that should have been avoided, report DB89. So far the FAI on DB66 has been refused

2. Introduction

The UK-wide Health and Safety at Work etc Act 1974 (HSWA) applies to patient safety. It requires that effective measures are taken to secure their safety under section 3(1) and associated regulations such as the Management of Health and Safety at Work Regulations 1999 (MHSWR). The regulations require that proportionate measures are taken to secure health and safety. The hazards and risks associated with healthcare are very high and accordingly, as with other high hazard sectors, it requires a high standard of precautions. Section 18 of the Act requires effective regulation to ensure that dutyholders comply with the legislation.

MHSWR requires effective management arrangements to control the risks. As part of this, there is the need to monitor and review the precautions and management arrangements. This is taken as including the investigation of incidents, which review the frontline failures and the effectiveness or otherwise of the organisational arrangements for managing the risks. The review process is required to inform the need to improve the planning, organisation, and control of risks, and the monitoring of performance.

3. Background

This section gives the immediate background to the Critical Incident Reports and the enforcement action considered on the incidents referred to. It gives the (1) Reports, their (2) Context in respect of the Health and Safety at Work etc Act 1974, their (3) Reporting, the (4) Enforcement Criteria, the (5) NHS and Scottish Government, and the (6) Actions.

3.1 Reports

The Critical Incident Reports (CIR) used in this report are published on the Ayrshire and Arran website at http://www.nhsaaa.net/publications/reviews.aspx

A sample of CIR reports relating to other NHS Scotland boards are accessible via http://www.bbc.co.uk/news/uk-scotland-19717332 . This relates to the BBC Scotland programme 'How safe is your hospital?' of 26 November 2012.

The reports are redacted. This is inevitable but the amount of redaction is heavy, excessive and unnecessary. In some cases it makes it very difficult to work out what the incident was, the consequences, what the issues are, or the appropriate learning and enforcement action. However in most cases it is possible to work out the main issues with confidence and the appropriate enforcement action to be considered. This often necessitates reading the recommendations and then going back to the remaining information on the incident to make sense of the report.

CIR at Ayrshire and Arran were the subject of a major investigation by the Scottish FOI Information Commissioner in 2011/2012. The Commissioner Kevin Dunion was highly critical of A&A, finding the most serious failings in records management and information recovery he had seen in his nine years in office. The investigation was prompted by the concerns expressed by Mr Rab Wilson. The Commissioner went further and expressed wider concern at the NHS board's handling of investigation reports into very serious incidents, the inadequate governance, and the lack of their use in learning to prevent further incidents.

The reports are from across most parts of the acute hospitals – mental health, medical, surgery, maternity and 'others'. All areas show examples requiring consideration of prosecution and enforcement notices.

3.2 Context: Health and Safety at Work etc Act 1974

The Health and Safety at Work etc Act 1974 applies to both employees and the public including the safety of patients. The intent is given in section 1, and expanded in section 3(1). Other regulations such as the Management of Health and Safety Regulations 1999 apply. Some incidents covered by HSWA are also required to be reported by the Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations (now) 2013 (RIDDOR). There is an exemption for such

as those under medical treatment. There is widespread misunderstanding in the NHS and government that because an incident is not RIDDOR it is not HSWA, that is a critical error. NHS boards are required to have a competent person (under regulation 7 MHSWR 1999) to advise them on how to comply with HSWA. From the CIR at A&A they are rarely referred to or apparently involved. The vast majority, and arguably all, of the CIR come under HSWA and have implications for compliance. This has not been understood by the NHS boards, with the Act almost never referenced.

The two highest profile cases in recent years of prosecutions of a NHS hospital have been those relating to the deaths of Gillian Astbury at Mid Staffordshire NHS Foundation Trust and to Nicola Black at Ayrshire and Arran, neither of which were deemed RIDDOR. Yet both involved major breaches of HSWA.

The Act requires effective precautions to be in place to prevent deaths and other harm. It does not require any harm to have actually occurred (Regina v The Board of Trustees of the British Museum 1993, which I understand as a Decided Case would be considered 'highly persuasive' in Scottish courts. It should be extremely difficult to argue against such a fundamental principle of major UK legislation). The emphasis on prevention is widely misunderstood. The prosecution is on the failure to have the required measures in place to prevent harm so far as is reasonably practicable.

3.3 Reporting

UK-wide research shows the large number of avoidable deaths occurring in NHS acute hospitals. The current figure being used by the Secretary of State for Health has revised the figures upwards. Additionally there are a high number of deaths in mental health units as emphasised by the Equalities and Human Rights Commission report 'Preventing Deaths in Detention of Adults with Mental Health Conditions' (4 March 2015). The report is on there being over 120 deaths of non-natural causes each year in mental health units and in police custody in the UK. As well as HSWA, avoidable deaths are covered by the Human Rights Act 1998, the European Commission on Human Rights and some can come under the Corporate Manslaughter and Corporate Homicide Act 2007. The UK estimate is that there are well over 12,000 avoidable deaths occurring each year in acute hospitals in regard to physical healthcare. That equates to over 1,200 in Scotland when considering both physical and mental health. Also that does not address deaths related to community care or social care. Scotland has not investigated the matters. For A&A with about 8% of the Scottish population it would suggest about 100 Reasonably Preventable Premature Deaths (RPPD) each year in A&A hospitals. There is nothing like this number of RPPD showing in the CIR. The CIR that are published are all undated but it suggests only about a ten year are

reported, approximately 10% of what should be expected. It is widely known that such incidents do not necessarily appear in internal statistics and reports.

At A&A there is hardly any reference to the Health and Safety Executive (HSE). In the unique absence of an independent healthcare regulator in Scotland, HSE is the default regulator. HSE is not resourced to undertake the role. They were not consulted by the Scottish Government when what regulator there was, was abolished (that itself resulted in a breach of legislation). The HSE's written view is that it is for the Scottish Government to set up the required fully independent (and effective) regulator such as is required both here and in the rest of the UK.

One reason for the under-reporting will be the absence of awareness that HSWA applies including at the levels of departments, NHS boards, NHS Scotland, the Health and Social Care Directorate and the Scottish Government. Senior ministers have refused to commit to healthcare in Scotland complying with the Act, and certainly not to the standards required. The Ministers and the Scottish Government in 2011 abolished the independent healthcare regulator (IHR) that should have been promoting and ensuring compliance with the legislation. A current high profile case has been the Vale of Leven Hospital Public Inquiry. This was into 30 to 50 RPPD associated with poor infection control. Compliance with the Act at the hospital should have prevented the deaths and set up the right precautions for this and other hospitals across Scotland. However the then Cabinet Secretary for Health on briefing the chair of the inquiry omitted reference to HSWA as the main legal standard that applied. This was repeated in the submission to the inquiry by Scottish Ministers and the Scottish Government's Legal Directorate. The law has been excluded from the public inquiry.

The approach to patient safety in Scotland is based on guidance. It is not based on law. That is a major determinant of perception and actions to prevent harm. If speed limits were only 'guidance' and there were no police or cameras to regulate speeding, then it would make a difference to road safety. When the hazards and risks are high then the standards and regulation have to be high. They are not in Scottish healthcare. It is the legal requirement that they are in place.

CIR from across other NHS Scotland boards shows that A&A is not atypical. The Scottish-wide intent and policy is set by NHS Scotland, the Health and Social Care Directorate and Scottish Ministers. None of them make it clear that the Act applies, that it must be complied with to a high standard, and that compliance will be regulated. There are incidents reported across all of Scotland that show major non-compliance with HSWA and consequent avoidable harm.

3.4 Enforcement Criteria

HSWA is UK-wide legislation and it is a reserved matter irrespective of the delivery of health and social care being devolved. Whilst dutyholders may be seen to break the law, the UK-wide policy is that regulatory actions should be proportionate to the potential consequences. The UK enforcement criteria on HSWA are given in HSE's Enforcement Management Model (EMM). This compares the particular situation with what the hazards and risks are, and the gap between what the law requires and what the situation shows. These factors determine the initial assessment on what enforcement actions should be considered and then may be taken. The enforcement action will range from verbal and written advice on requirements, to the more serious statutory enforcement notices, and prosecution. This means that there is an established validated and justified system to make enforcement actions proportionate, consistent, and transparent. It codifies the approach of an experienced regulator based on an understanding of the hazards, the risks and the law.

The enforcement criteria of EMM can, and indeed should have been applied to the CIR reports. This would determine the need for a regulator to investigate further and collect evidence for prosecution. The evidence of the A&A internal investigations presented in the reports is of major failings to provide adequate healthcare. In the majority of cases they also report on failures to comply with HSWA to secure safety as far as could be expected. In the CIR there are usually very serious failings and they often relate to deaths. The majority of the incidents by EMM state that prosecution should be considered. A larger percentage state that statutory enforcement notices should have been issued. This is as near an objective approach to enforcement as can be given at the current time.

Of the incidents reported there seems to have been only one where a prosecution was considered and a conviction took place. This was not at the instigation of the NHS or initially the HSE. It was only after two years of pressing by the family of the deceased to progress the case, that COPFS notified HSE and asked them to investigate the death. (The family then asked why the Fiscal Deputes previously involved had not pursued the health & safety route at the time, but no satisfactory answer was given). There is not the awareness of the application of the Act to patient safety throughout healthcare in Scotland, and that is the case at all levels including government ministers. The Act has applied to patient safety for forty years and compliance has been regulated, but in Scotland it currently is not. HSE are rarely involved, the reliance having been that there should have been a fully independent healthcare regulator to secure patient safety. But in Scotland there is nothing. On potential prosecutions, frontline healthcare staff may make errors in compliance with the Act. But these are made in the context of healthcare in

Scotland not having in place legally compliant effective systems, management and resources to prevent the avoidable harm

There are a very large number of very serious incidents at A&A that should have required actions by a fully independent and effective regulator. This should have been to address serious failing across this NHS board but also across all of healthcare in Scotland. The failings are not only about frontline failures but the wholesale failure to have the legal requirements embedded in the sector and the effective management to deliver them. The one prosecution that did take place concentrated on the frontline failures and did not address the management arrangements (e.g. MHSWR) of the board nor the legal responsibilities on those setting the policy on healthcare in Scotland. As the prosecution only addressed the 'surface'issue it permitted similar failings in this and other boards to continue. There was no real learning form this CIR or from the others in regard to the underlying issues of disregard of HSWA.

The EMM or equivalent enforcement code cannot have been applied to the CIR at A&A. That is a failure in regulation and enforcement. It needs to be addressed.

(Note: Whilst in HSE policy I was involved in the development of the Enforcement Code EMM, I also initiated its application to health topics. I am very familiar with the EMM theory and application, and know what it should do in the matter of healthcare and CIR. The policy used my experience as a HM Inspector and regulator of health and social care).

3.5 NHS Scotland and Scottish Government

The Act applies across all sectors. However healthcare is Scotland is the one sector where it has not been recognised or regulated. The consequences will be in the region of 2,000 avoidable deaths each year in Scotland permitted by non-compliance with the Act. The Act is not present in the intent and plans of the Scottish Government, and it abolished the regulation of healthcare in 2011. The legal responsibilities under the Health and Safety at Work etc Act 1974 apply to senior management at NHS Boards. However there are also duties on those involved in setting the policy for NHS Boards. This comes from NHS Scotland, the Health and Social Care Directorate and the Scottish Ministers. This regrettably has been to disregard the legal responsibilities in regard to the protection of the public in Scotland, and with such severe and on-going consequences.

Two Scottish First Ministers and three Scottish Cabinet Secretaries for Health have refused to commit to implement HSWA to the standards required to secure patient safety, to set the requirement that healthcare in Scotland has an effective plan on compliance, and they have also refused to reinstate the independent healthcare regulator.

As a current comparison, the Morecambe Bay inquiry report of 3 March 2015 into the avoidable deaths of nine babies and a mother, states that it 'is highly damning of the regulatory system'. Scotland does not even have a regulatory system to seek to prevent such occurrences. It is not possible on the evidence produced by A&A to say exactly how the maternity units compare, however the failings identified at both have commonalities. The CIR on the A&A unit show evidence for a potential 5 prosecutions in 9 reports, some involving deaths and other avoidable harm. They are sufficiently serious in nature as to warrant further investigation in the light of those reported at Morecambe Bay.

3.6 Actions

The position of healthcare in Scotland not having the intent, the effective plans, the regulation or the enforcement on the Act is not one that is tenable. This is law-breaking on a very large scale with the highest consequences and there is no effective intervention being taken. The law needs to be recognised and understood as to what it means. There needs to be actions across all healthcare in Scotland to bring it up to standard and prevent avoidable harm. There needs to be effective regulation including enforcement.

4. Conclusion

4.1 The A&A Critical Incident Reports demonstrate major failings in healthcare. Their own report recommendations show that there were reasonably practicable measures that could have been taken to both comply with the Act and to prevent harm to patients so far as was reasonably practicable either in the specific cases or other foreseeable cases. The majority of the incidents reported show major breaches of the Act. The Health and Safety Executive's Enforcement Management Model applies to these cases to show the enforcement action that should be considered. Here they show a large number of reports that should be considered for prosecution and statutory enforcement notices. This has not been done to the standard required. Cases can still be taken.

4.2 The performance of the Ayrshire and Arran NHS Board requires a formal investigation as a minimum for its compliance with the Act. This should cover frontline risk controls, management arrangements, and the organisational culture.

4.3 Inspecting a sample of 200 critical incidents from across the Scottish NHS boards has shown that A&A is not atypical of the failures of healthcare in Scotland to comply with the Act. In view of the highly serious consequences of healthcare failures, the matter requires investigation. NHS Scotland, the Health and Social Care Directorate, and Scottish Ministers set the policy for healthcare in Scotland and all the NHS boards. The policy has been to disregard the binding legislation that would secure patient safety. They have not required healthcare providers in

Scotland to comply with the law. They have abolished the regulator that should have been there to promote and verify that the law was being complied with. These are a major breach of their legal and functional responsibilities.

In view of the major failings of healthcare in Scotland to comply with the law and the severe consequences, the legal responsibilities of these bodies require a full investigation.

5.1 Appendix 1: Table of EMM Enforcement Actions

5.2 Mental Health				
Report Number	**Subject**	**Enforcement Notice**	**Consider Prosecution**	**A&A Investigation Comment**
DB06	Fatal	Yes	**Yes**	Suicide prevention policy inadequate
DB07				NFA
DB30	Abscond	Yes		Heavy often excessive redaction on reports
DB35	Abscond	Yes	Unclear	Risk Assessment (RA), Fragmented management
DB36	Fatal	Yes	**Yes**	RA, Wrong ward COPFS involved
DB39	Abscond	Yes		Inadequate management of case and of clinical services
DB40	Fatal?	Yes	**Yes**	Redaction, A&E management
DB43	Fatal	?	?	Very heavy Redaction makes unclear
DB44				Heavy redaction
DB45	?	?	?	Illegible
DB55	?	Yes	**Yes**	'Absence of any structured approach to risk

				management'
DB56	?	Yes		RA, lack of continuity of care
DB58	Fatal	Yes	**Yes**	Case management
DB59	Fatal	Yes	**Yes**	Condition not managed
DB66	Fatal	Yes	**Yes**	HSE conviction. Two years before was referred to HSE. Conviction of A&A after 4 years.
DB70	?	?	?	OTT redaction. Precautionary approach on transferred psychosis patients. Improved and dynamic RA.
DB85	Para-suicide	Yes	**Yes**	RA, Poor controls Poor transfer system
DB89	Fatal	Yes	**Yes**	Similar to DB66
DB94	Fatal	?	?	Redaction, unclear
5.3 Medical				
DB02	Fatal	Yes	**Yes**	RA,' lack of organisation-wide policy'
DB05	Fatal	?	?	Redaction, unclear
DB09	Abscond ?	Yes	?	Redaction, unclear

DB13	Fatal	Yes	**Yes**	Inadequate policy
DB14				Learning point
DB15	Fatal	Yes	**Yes**	Inadequate liaison with contractors
DB17	Fatal	Yes	**Yes**	Inadequate process
DB24	Fatal	Yes	**Yes**	Poor tracking, no safety net
DB28	Fatal?	Yes	**Yes**	Poor tracking, no safety net. No systems audit.
DB41	Fatal	Yes	**Yes**	Inadequate care management & patient vital signs. .**'Urgent review of all nursing care & practice'.**
DB42				Learning point
DB61	Fatal	Yes	**Yes**	'No ILTS' Immediate Life Threatening Symptoms'
DB64	Fatal	Yes	**Yes**	Poor comms shift handover, care plan
DB67	Fatal	Yes	**Yes**	Inadequate assessment & observing
DB68	Fatal	Yes	**Yes**	Poor care management
DB71	Fatal		?	
DB72	Infections	Yes		Inadequate infection control

				procedures
DB73	Fatal	Yes	**Yes**	Poor care management & lack of learning
DB74	Fatal	Yes	**Yes**	Inadequate RA & care management
DB77	Fatal	Yes	**Yes**	Inadequate process
DB78	?	?	?	Redaction. Unclear. Inadequate care.
DB80	Delay	?	?	Misread X-ray serious complications Incorrect response
DB82	Fall	Yes	**Yes**	'**Improve fundamental elements of nurse practice'. 'Clinical process not fit for purpose'**
DB86	10 Fatal	Yes		H1N1 infection learning
DB87	Fatal	Yes	**Yes**	Inadequate policy
DB90	Fatal	Yes	**Yes**	Inadequate monitoring & management of patient's vital signs
DB92	Fatal	Yes	**Yes**	Medication not administered
DB93	Fatal	Yes	**Yes**	Heavy redaction. Poor comms absence of records on patient.

DB96	Process			Staffing levels & escalation.
DB97	Cancer	Yes	**Yes**	Records not checked
SAER 000001	Fatal	Yes	**Yes**	Inadequate ward assessment. Untrained Homecare staff unable to deal with case.
SAER 00004	Fatal	Yes	?	Heavy redaction
5.4 Surgical				
DB03	Fatal	Yes	**Yes**	Many failures. Poor care, lack of monitoring & management patient vital signs.
DB04	Fatal	Yes	**Yes**	Many missed chances to assess & treat patient
DB12	Fatal	Yes	**Yes**	Lack of care, plan missing. 'Systematic audit of nursing practice on care planning'.
DB18	Fatal	Yes	**Yes**	A&E pressures, policy not followed.
DB23	Process	Yes		Unnecessary CT scan
DB26	Fatal	Yes	**Yes**	OTT redaction. PR unlikely. Reactive approach to patient

				care
DB27	Fatal			OTT redaction. Update process.
DB31	Fatal	Yes	**Yes**	Inadequate policy, RA.
DB34	'Wrong Part' removal	Yes	**Yes**	Systems failure
DB37	Fatal	Yes	**Yes**	Untrained staff
DB60	Rare condition			Change process NFA
DB63	Action Plan only	?	?	Incomplete process on discharge, comms and responsibilities of junior doctors.
DB75	Fatal	?	?	OTT redaction. Missing observations & records
DB81	Fatal	Yes	**Yes**	Lack of line management. Untrained Homecare staff.
DB83	'Wrong Part' removal. 'Near hit'	Yes	**Yes**	Almost repeat of DB34. Systems still inadequate
DB88	Fatal	Yes	**Yes**	Poor monitoring & management of patient vital signs.
SAER 00002	Harm	Yes	**Yes**	OTT redaction.

				Catheter in artery not vein, inadequate systems
SAER 00003	n/k	Yes	?	Unreadable. Poor patient transfer, poor radiology image, poor comms
SAER 00005	Fatal	Yes	**Yes**	OTT redaction. Discharge docs and medication not given. No protocol 'criteria-led discharge',
5.5 Maternity				
DB10	Stillborn	Yes	**Yes**	Sensitivity. Inadequate out of date process, untrained staff.
DB11	Fatal	Yes	**Yes**	Failure to deliver right care, training, possible equipment failure comms.
DB16	Harm	Yes	**Yes**	Instructions not followed. Policy missing.
DB20	Harm	Yes	**Yes**	OTT redaction. Medication error.
DB21	Harm	Yes	**Yes**	Missing policy. Instruction's not followed, 'standards routinely not complied with'. Lack of CIR review process for

				maternity. Lack of learning.
DB57	Harm	Yes	?	OTT redaction. Unclear care planning. Rota fragmented. ‘ Urgent review of induction and labour protocol’.
DM62	?	?	?	OTT redaction. Inadequate comms.
DM79				Improved process
DB84	Stillborn			Improved recording
5.6 ‘Other’				
DB19	Fatal	Yes	**Yes**	En-route to intensive care, lift stuck, slow rescue, care compromised.
DB38	‘Near Hit’	Yes		Duplicate patient numbers, risk of wrong treatment, multiple risks.
DB47	Process			Improved equipment setting instructions
DB48	Staff	Yes		Locum radiologist errors. Actually in normal range **10-15% radiology errors.** Competence management system (CMS)

DB69	Staff	Yes		Culture of small groups. CMS.
DB76	Process			Inadequate equipment
DB91	Process	Yes		No report, plan only. Staff not trained in new equipment.
Total 86		65	49	Some decisions could not be made or unclear due to redaction
		Three-quarters	Over half	

5.2 Appendix 2 Mental Health Reports

1. **DB06** Fatality

- Suicide prevention policy inadequate
- Policy, guidance and procedures not fit for purpose
- Inadequate health and safety manual.
- Inadequate staffing levels
- Lack of clinical psychology input into acute in-patient psychiatric wards.
- Risk assessment procedure defective. Staff drawn to making incorrect risk assessment
- Patient incorrectly classed as not a suicide risk
- Suicide prevention policy out of date, not reviewed at due date, not on ward
- Clinical Guideline Management of Missing Persons policy not appropriate, inadequate

EMM Outcome: Prosecution Consider . Enforcement notices

2. DB07 Not HSWA

3. DB30 Patient absconded Excessively redacted.

Enforcement notices

4. DB35 Patient Absconded Excessively redacted, confusing report.

- Staff not recording information
- Inadequate shift handover
- Poor procedures for high risk areas
- Confused management structure and accountability on mental health
- Constant reorganisation probably led to the failures
- Accommodation poor for patients & staff'

Enforcement notices

5. **DB36** Fatality Patient absconded. Excessively redacted

- 'Wrong ward for patient with mental health issues'
- Self-harm not addressed
- Known mental health issues but not referred to psychiatric liaison team
- Consultants in Emergency Medicine should not have sole clinical judgement on patient with on-going mental health issues
- Expert opinion that criteria for detention under Mental Health Act met, but patient was not detained
- Minimum staffing level at A &E, so used bank staff
- Bank nurse unfamiliar with A & A procedures
- No summary risk assessment, no documentation on decision not to detain

Prosecution considered. Enforcement notices

5. DB39 Abscond

- Wrong ward
- Professional boundaries between staff and patients blurred
- Role of lead clinician unclear,
- Responsible Medical Officer (RMO) not fully involved in care
- RA on intimate relationships on ward should be clear
- Missing persons policy not followed
- Injuries but not recorded
- Problems with patient and medical management. Eight consultant doctors not accept responsibility for patient
- On return patient not properly assessed
- Need for RA and care plan revised, but were not, no record of
- Injuries assessed by unqualified member of staff
- Decision-making on patient care made at too low a level of grade and competence
- Placement of patients should be on 'assessment need' not bed availability
- Inadequate individual and over-arching management of clinical services
- Complex cases not appropriate for a locum consultant

- Many care plans unsigned and undated
- Poor quality statements by staff
- Record keeping failures
- Patients incorrectly given maximum dose, prescribed contrary to medical policies
- No policy on managing patient relationships

Enforcement notices

6. DB40 Fatal Very heavy redaction

- Lack of clarity on patient discharge
- Inadequate process on staff workload and redistribution when away, cases put on hold
- Lack of clarity on patients who attend A&E regarding mental health issues
- Assessment is weighted towards physical health not mental health
- Records undated, patient's name missing, not signed, procedure on appointments missed not recorded
- Delays on letters

Not clear

7. DB43 Suicide Very heavy redaction

- Patient had self-harmed. Some difficulty in assessing patient's state because of intoxication
- Mental health assessment identified a low risk of repeat self-harm
- No beds at _____(redacted)
- Patient subsequently attempted hanging, brought in to Intensive Care Unit but died of injuries
- Report states assessment and care appropriate

Not clear

8. DB44 New patient caused risk to ward Heavy redaction

- Report says precautions and response reasonable

Not clear

9. DB45 ? Extremely poor photocopy, illegible, insulting

- Improved communications with ___police? (redacted) on a patient arrested
- Inadequate assessment at A&E of mental health issues
- 'Assessment and care adequate'

Not clear

10. **DB55** Absconding Excessive redaction

- Lack of clarity on ward role
- Poor accommodation – inadequate and inappropriate, mixed gender ward
- Lack of role clarity
- No clear admission criteria, referral process, or assessment structures
- Ward confusion
- Communications, policies lapsed
- Inconsistency on patient observations
- **Particular concern is the apparent absence of any structured approach to risk assessment or risk management**
- Inadequate senior and junior medical psychiatric staff
- Very limited psychological input
- Lack of structured supervision
- Responsibilities of RMO unclear and other roles, ward management and lead consultant
- Need to improve clinical and professional supervision
- Lack of robust and coherent approach to patients (individual and ward level)
- 'Containment' not 'caring'
- What risk assessment that had been done were not followed
- Poor recording of observations
- No patient crisis plans
- Unilateral changing of care plans
- Medical notes disordered, and incomplete
- Inconsistent approaches to ward procedures and the management of patients
- Reactive management not proactive
- Issues not addressed promptly, or effectively
- Inadequate communications within ward
- Mandatory training lapsed

Prosecution considered. Enforcement notices

11. DB56 Heavy and inappropriate redaction

- RA not updated , and controls not verified
- Not proper transfer of responsibility for patient
- Incident A&E delay in treatment, problems with communications between ward staff and A&E
- Lack of continuity in care
- Changed medication with potential of adverse effect o n patient

Enforcement notices

12. DB58 Fatal

- Whilst on pass and not return by due time
- Care plan not updated
- Lack of range of inputs into care and preparedness of discharge

- Missed opportunity for multi-disciplinary team (MDT) to act
- No nominated staff to co-ordinate overall care
- Staff needed additional training on management of the increasing number of patients with difficult social skills and interaction 'disability'

Enforcement notices

13. **DB59** Fatal Heavy redaction

- Omission of monitoring patient's condition
- Missed identifying risk factors. It should have prompted an ECG as soon as possible
- Observation changed form general to constant
- No ECG given, which was required
- Blood pressure, pulse, temperature, and hydration should have been monitored weekly but no record of them taking place
- Licensed dose of medication exceeded. Authority for this should lie with the patient's psychiatrist. However it was done by another consultant
- Significant error on patient's medicine prescription sheet
- Omissions on documents placed on patient's notes, risk factors omitted
- Patient should have had monitoring temperature, blood pressure, pulse, respiratory rate, oxygen saturation for 5-10 minutes for one hour then half-hourly then half-hourly until ambulatory
- Staff unclear on purpose of observing patient
- When on constant observing duties staff should take a break every two hours. Instead staff actually moved to another patient often with no breaks taken
- Risk factors on co-morbidity not considered in hospital or community
- Staff not recognise seriousness of patient's condition. There was information on the FACE system
- Medications administered without knowing the care plan, use of medication, dosage, side effects, precautions, contra indicators

Prosecution considered. Enforcement notices

14. **DB66** Fatal Heavy redaction

- Patient on constant observation plan. But they were not kept within visual or hearing at all times
- Contributing factor was the lack of a system to manage personal possessions that could be used in suicide
- Leadership inadequate
- Inadequate communications
- Poor understanding of risk, which led to 'avoidable event'
- Risks not recorded, information came from patient's parents. Written risk of suicide in records but not in written shift handover

- Risk of suicide not conveyed. It was thought that the risk was of absconding. The latter would rely on the ward being secured
- No record of a named nurse
- Patient not checked on mood
- Parent's message not passed on, a missed opportunity to check her state
- FACE system not positively/ proactively accessed
- No routine RA on ward regarding suicide risk
- Self-harm items not removed, despite attempted suicide being the cause of the admission
- Patient personal property procedure not followed
- No process for ensuring risk from objects removed
- Guidelines on 1:1 care patients in acute hospitals (Clinical Guidance 163) not used
- Policy on inpatients not used
- Guidelines for implementing named nurse not used
- Safety notice policy not implemented
- Generic RA not done
- A&A Health and Safety Department had to repeatedly prompt this unit for the RA to be done
- Clinical statements undated
- Remedial actions not done
- (Hospital considered that as not RIDDOR not HSWA, not need HSE. Board convicted four years later under HSWA)
- Extremely poor attitude of some staff. Example given- 'Such events will always happen'

Prosecution. Enforcement notices

15. DB70 ? Heavy redaction

- Consultant not have case notes
- Patient not taking medication
- Seen by six different doctors but not by the designated one
- Was not a crisis team at the time, just being set up
- Absence of protocol for transfer of psychotic patients
- Should be entered on first episode psychosis pathway
- Need to properly RA and keep updated particularly important in this case Report unclear on enforcement needs

16. DB94 Suicide Heavy redaction

- No carer's assessment (not considered a factor by A&A)
- 'No global view of patient's behaviour and care provided'
- Need for improved communications between clinicians and escalation of care
- 'Appropriate care given'

17. **DB85** Para-suicide Extreme redaction

- Out of area patient, information and other communications not adequate on condition
- RA on environment not up to date
- Control or elimination of risk not done

Prosecution considered. Enforcement notices

18. **DB89** Death Similarities with DB66

- Avoidable death, suicide
- Patient RA not adequate
- RA on environment not adequate, and not control measures
- Multi Disciplinary Team (MDT) not make contemporaneous notes
- Needed agreement of RMO on decisions
- Records system needs reviewing
- Staff were making records for other staff (e.g. Junior doctor for consultant, nurse for other nurses)
- Medical and nursing notes on patient recorded on separate patient records
- Use of FACE system requires retraining for staff. Staff not understand risk assessment tool for patients
- Staff not comply with guidelines of custody of patient's property
- Suitability of current site needs reviewing
- RA not kept up to date
- FACE record inaccurate. Entry made by nurse who was not at the meeting
- Investigation team found 62 outstanding risks on the ward
- Unacceptable risks to patients on ward _____ redaction
- Staff trained in RA having difficulty ion recording on FACE
- Consultants not checking junior doctors MDT records

(Lessons not learnt from previous incidents)

Prosecution considered. Enforcement notices

19. DB94 Fatal Unclear. Very heavy redaction

- Patient seen by police at home and they considered them to be a high suicide risk. Taken to A&E for assessment. Patient assessed and not considered detainable under the Mental Health (Scotland) Act 2003
- Police still considered them to be a risk to themselves, detained them for their own safety
- Patient attended outpatients but discharged from Crisis Response Team
- System needed for patients who rapidly escalate symptoms
- Formal cares assessment needed when patients show sustained crisis
- Explanation for non-detention under the Mental Health Act needs to be given to patient and family and carers
- Overview of patient's condition needed

Not clear

5.3 Appendix 3 Medical

1 **DB02** Fatality. Notified to HSE as a late RIDDOR when was required to notify without delay. Quoted incorrect regulations, should be the Management of Health and Safety at Work Regulations 1999 (MHSWR), over zealous redaction. Investigation team reported -

- Risk assessment (RA) documentation missing
- Lack of clarity on need for RA
- Incident contributed to death
- Lack of organisation-wide policy on RA
- RA not done, not account for patient
- Investigation recommendation ' work on policy and implement across whole organisation'
- Lack of RA led to inadequate precautions and factor in death
- Adverse incident policy and supporting procedures defective on staff actions
- Staff statements not signed or dated
- No statement from doctor on duty
- Roles and responsibilities of staff not fulfilled on incident reporting
- Confusion over whether incident clinical or other factor
- Delay gathering information
- Need actions by general manager and Clinical Governance Directorate
- Need to strengthen links between A&A Health and Safety department and Clinical Governance Directorate. (HSWA applies to care)
- Serious gap in RA regarding patients

Prosecution considered, Enforcement Notices

2. DB05 Fatality Badly redacted. No action
3. DB09 Redaction makes unclear, left ward, attack of staff? Refer to recommendations.

- Inadequate RA, gap
- Inadequate RA procedures
- Inadequate night security for patients and staff
- Lack of understanding of role of security
- Lack of procedure for when patient attacks staff (except for A&E and mental health)

Enforcement Notices

4. **DB13** Fatality Heavy redaction

- Standard of care of patient with head injuries not to standard
- SIGN – Scottish Intercollegiate Guideline Network) not followed
- If had head injury policy require cotside for patient
- Inadequate policy(Falls Management Guidelines)
- Needed RA to address transfers and escort in arrangements
- Lack of clarity on what is a clinical incident
- Lack of clarity on what is a reportable incident
- Record keeping inadequate
- Patient not examined after fall, required by SIGN and responsibilities
- Advanced Nurse Practioner did not respond to paging, failure of system. Second attempt to contact not made.
- CT scan not undertaken within 1-2 hours as required by SIGN.
- Incorrect escorting arrangements
- Safety briefing did not report the incident
- 'Failure in care and record keeping'
- Neurological observation not carried out as required. Should be every 30 minutes for first two hours and hourly for the following four hours.
- Medical assessment required but not carried out
- Local guidance on falls management not followed, and it specifically requires observations.

Prosecution considered. Enforcement Notices

5. DB14 Learning

6. **DB15** Fatal Infections.

- Ingress of contaminated dust
- No RA on risks from adjacent building work
- Air supply for protective isolation requires HEPA filtration (High-efficiency particulate arrestance). None of units at A&A filtered. Investigators say that this is standard practice in Scotland.
- Inadequate liaison between contractors and hospital
- Inadequate controls with windows open

Prosecution consider. Enforcement notices.

7. **DB17** Fatal

- Poor unclear process on control of DVT risk and condition
- Patient should have been assessed and placed on clinical pathway
- Precautions would have prevented death

Prosecution considered. Enforcement Notices

8. **DB24** Fatal

- Missed diagnosis
- Delay of four months
- Very poor service
- Condition found but no action taken
- Poor tracking of patient and condition
- Known problems
- No safety net
- Poor handover on admin issues
- Inadequate procedures for clinical follow up on results
- Inadequate flagging up systems
- X-ray reporting not matched to clinical priority
- Poor tracking of reports

Prosecution considered. Enforcement Notices.

9. **DB28** ? Very heavy redaction

- Not admin system to track the clinical investigations requested but not reported.
- Failure to issue a report as required. Consequently secretary not know was outstanding.
- No secure system to track requests
- X-rays known to be occasionally not reported
- Not a fail-safe radiology system on unreported investigations
- System fails to danger
- Critical gap in system of A&E, and other assessment areas
- Safety net is needed for poorly designed systems such as radiology
- Not an audit of systems
- Absence of minimum data requirements. Such as Royal College of Radiologists standards and Ionising (Medical Exposures) Regulations 2000.
- Critical findings not emphasised for priority

Prosecution considered. Enforcement Notices.

10. **DB 41** Fatality

- Incorrect treatment and management
- Test results not communicated. Led to lack of medical and nursing care
- Communications failures between clinical areas and hospitals
- Delay in tissue viability review
- Poor pain control
- Poor observation of patient

- Poor monitoring and management of patient's vital signs (temperature, fluid balance)
- Poor recording
- MEWS (Monitoring Early Warning Signs) had a poor score but not acted on
- Care poor and reactive, not proactive
- **'Require an urgent review of all nursing care and practice'**
- Retraining needed on clinical observation, recording and actions to be taken.
- Inadequate system of tracking patients on transfer
- Many charts incomplete e.g. fluid balance(15, 10 complete), some had no entries ; nutrition charts (8 complete, 26 incomplete)
- Poor monitoring on Waterlow Score (tissue viability)
- Treatment mismatch condition
- X-ray result disregarded
- Home-made clinical records form and badly entered data
- No pain management plan
- Medical records not meet guidance of statutory bodies
- Patient tracking poor

Prosecution considered. Enforcement Notices

11. DB42 Learning. NFA

12. DB61 Fatal.

- NHS 24 approach to ILTS. Call handler incorrectly excluded Immediate Life-Threatening Systems
- Difficult diagnosis
- GCS – Glasgow Coma Scale measure of consciousness
- Improved protocol for access to medical records by primary and secondary care

Unclear

13. **DB64** Fatal

- Only part of A & E record transferred to ward. Missing blood results, and summary of treatment
- Poor documentation
- Inadequate verbal advice
- Poor shift handover
- Electronic records not accessed by nursing and medical staff to check results
- Infusion administered by SHO whereas unlicensed preparation requires a consultant's prescription
- Infusion commenced without checking blood results
- Neither medical or nursing staff picked up on patient's abnormal ECG trace

Prosecution considered. Enforcement Notices.

14. **DB67** Fatal

- Mental health issues, observation missed (hanging?)
- Inadequate triage
- Needed basic questioning on patient's mental health
- Observation policy needed from mental health services
- Risk assessment not done on room used for patients who could have mental health issues
- System for assessing, triaging and observing patients with mental health issues inadequate
- Room unsuitable for mental health patients
- A & E not have a policy for observation of patients with mental health issues
- A & E staff do not record mental health issues as they do not consider that they are competent to do so
- No guidance for A & E staff on assessing or treating mental health patients
- Not been any training in mental health triage
- Manchester Triage System is heavily weighted towards physical needs and few indicators on mental health risk
- Designated room contained ---------- (redacted)
- RA for room and patients inadequate
- Inadequate communications between ambulance to A & E on patient

Prosecution considered. Enforcement Notices.

15. **DB68** Fatal Heavy redaction

- Missed diagnosis
- Missed malignancy on CT scan
- Delay in diagnosis for seven months and condition then not treatable
- Three opportunities missed to treat cancer
- Poor recording on patient and follow up

Consider **prosecution**. Enforcement Notices

16. DB71 Fatal

- Incorrect reporting and observations. Not use GCS (Glasgow Coma Score), used poorer system
- Questionable clinical skills
- Confusion over use of joint medical and nursing notes (atypical approach)

Report unclear on effect of using atypical approach. N/k prosecution. Enforcement Notices

17. DB72 C-difficile infections, no deaths.

- Four cases of type 027, highly virulent and high transmission risk
- Use of 'guidance' (not the legal requirements of HSWA, COSHH and MHSWR)
- Patients should be isolated within two hours. Clinical and prophylaxis policy needs review
- Audit of infection control policy required

Enforcement Notices

18. **DB73** Fatal

- Problems on monitoring and managing MEWS
- Nursing notes not to professional standard
- Clinical management procedure of patients with head injuries not applied properly
- Absence of certain –redacted- observations between fall and death. Not in MEWS data
- MEWS not done, and contrary to policy
- Patient assessment inadequate
- Considerable delay from requesting medical assistance after the fall and being provided. This even after patient noted to be deteriorating for several hours.
- There had been a similar event elsewhere in A & A, and learning had not occurred here.

Prosecution considered. Enforcement Notices.

19. DB74 Fatal

- Inconsistency on bedrail policy
- Should have been bedrails but not used
- No moving and handling assessment
- Slips, trips and falls assessment inaccurate
- Underestimation of risk, factor in death

Consider **Prosecution**, but probably not.

20. **DB77** Fatal

- Delay in action on X-ray
- Lack of robust control system for transfer of responsibility referring consultant to responsible consultant
- A & E prioritisation system confusing, ambiguous for other departments

- Urgent referral missed (regarding respiration)
- Systems failure
- Results not properly accessed
- 'P' marking ambiguous and confused staff.
- Report filed without action

Prosecution considered. Enforcement Notices

21. DB78 n/k. Heavy redaction.

- Discharge letter did not clearly highlight where follow up required, and who by.
- Consultants need to inform patients of unexpected findings
- Patient care not what it should be
- Avoidable communications errors

22. DB80

- Misinterpretation of X-ray
- Emergency department incorrect response to X-ray
- SIGN guidelines on management of head injuries not followed. Should be CT scan and in this case within 8 hours
- Fracture not noticed
- Led to significant complications

Enforcement Notices

23. DB82

- Weakness in nursing on RA of individual patient
- The 1:1 care of patients in acute setting needed revision
- Training needed on MEWS
- Training needed on clinical management of patients with head injury
- Need review of use of behavioural charts for the elderly, and link to care planning
- Need to 'improve fundamental elements of registered nurse practice'
- 'Other' clinical processes not fit for purpose

Enforcement Notices

24. DB86 Ten deaths relating to 2009 H1N1 influenza. Learning

- Difficult to find clear guidance for clinicians on use of anti-viral medication for patients who had received influenza immunisation

- Limited facilities in Scotland for certain intensive care patients

25. **DB87** Fatal

- Toxic shock, difficult diagnosis
- Delay in medication
- Missed dose
- Record keeping not to professional standards
- Inadequate local guidance on suspected sepsis
- Inadequate medical input
- Antibiotic not given, or no record of. Not known why
- Only summary of care recorded and end of shift. This retrospectively after patient's death
- Should have been early diagnosis of sepsis from established quantitative measures
- Need for dedicated medical input in high dependency unit
- Too high a workload on medical staff. Leading to unsafe practice

Prosecution considered. Enforcement Notices

26. **DB90** Fatal

- Another sepsis shock
- Failings on MEWS, disregarded urine output
- Failing to record fluid balance
- Inadequate management of patients and sepsis
- Inadequate experience of new 'Emergency Response Team' ERT
- If MEWS done properly it would have resulted in a full medical review
- Instead further delay in administering antibiotic
- MEWS missed
- Wrong ward for patient. Should have been on ICU or High Care
- MEWS severely underscored – critical error
- Poor medical handover
- Fundamental errors on MEWS recording and frequency
- Lack of clear guidance on frequency of MEWS recording after escalation to medical review
- Treatment not appropriately escalated on signs of sepsis
- Three medical reviews but the Emergency Response Team not informed of patient
- Issues not discussed at night/day handovers, with consultant on call, or HDU
- Medical staff misunderstood the availability of beds in HDU
- ERT not proactively identify patients with high MEWS scores across wards

Prosecution considered. Enforcement Notices.

27. **DB92** Fatal

- Patient did not receive medication for nine days (27 doses)
- Safety briefs inadequate
- Registered nurses need medication management
- Need identified named nurse responsibilities for patients and their pathway of care
- Problems with pharmacy Standard Operating Procedure (SOP) on the ward top-up service dealing with when medicines not supplied
- Prescribers to check effectiveness of their prescription
- Need for joined up working of nurses and pharmacy staff on the ordering and supply
- Bank staff need reminding of professional standards of care
- Medication supplied to ward but not administered
- Pharmacy visited ward but not top-up or check on medicines. Patient repeatedly failed to get medication
- Ward staff said difficult to ensure that medication is administered at the correct time
- There was not a system to ensure patient's medication sent on when they moved to another ward
- Failure to reorder medication
- Low staffing level due to bank staff not being available
- On another day, twice as many patients to care for, being 15 rather 7/8
- Continuing problems on staffing
- Medication out of stock at p[pharmacy. Bit not flagged up to clinical pharmacist
- Staffing problems at pharmacy
- Repeated failures to administer medication on ward
- On this patient, it took 11 days for a prescriber to take responsibility for ensuring medication administered
- No safety briefs taking place on wards
- System for ordering medications not effective
- On reception patient was not medically clerked for 7 hours. This contributed to missed dose

Prosecution considered. Enforcement Notices

28. **DB93** Fatal Unclear, heavy redaction

- Misdiagnosis
- Inadequate communications between healthcare professionals
- Blood results and other records not with patient on transfer

Prosecution considered. Enforcement notices

29. DB96 Brief Report Medical staffing levels, systems of escalation regarding priorities and delays. N/A

30. **DB97** Desktop Review

- Missed cancer radiology report
- Similar to another incident/ SAER
- Radiology chest X-ray report 'carcinoma likely urgent CT scan is recommended'. Report filed without action.
- Discharging doctor did not check radiology report
- Ambiguous marking 'SS' on radiology report

Prosecution considered. Enforcement Notices

31. **SAER 00001** Fatal Very heavy redaction

- Inconsistent approach to prevention, assessment, identification, and management of _____ (redacted)
- Poor communications regarding hospital community staff
- Shortfalls in systems and processes
- RA not account for patient's pre-existing co-morbidities
- Nutritional assessment incorrect, should be higher concern
- No facility to weigh patients on-ward, or to deal with bed-bound patients
- Nutritional assessment tool defective and not necessarily reflect patient's condition
- Too long before patient's initial RA, 7 hours
- Initial RA rating too low (again not allow for pre-existing condition), missed special risk.
- If RA done correctly it would have prompted earlier and more intervention
- Further errors on records and monitoring any deterioration
- Charts not available at bedside
- Delay in measures to protect patient
- Staff had high workload
- Nutritional assessments procedure not followed
- Discharge plan inadequate
- Defective process for restarting homecare, not updated
- Poor homecare assessment records. Used free text rather than guiding prompts
- No formalised process for transfer of information into hospital from district nursing team. Implications for restart on return home.
- Inadequate training for homecare staff
- District nursing fell short of acceptable standards
- No formal structured record for assessment , RA and care planning
- Little evidence of robust care planning and communications of the plan to home carers
- Home care records not kept safe. Led to discontinuity in care plan

Overall lack of understanding of roles and relationships between care in hospital, district nursing and social services at home service

Prosecution considered. Enforcement Notices

32. SAER 00004 Fatal Very heavy redaction

- No recommendations given on particular death
- Need for clear patient management when consultant not on ward. With nurse in charge and middle ranked doctor reviewing patients every two hours
- Triage timescales regularly breached for more urgent cases. Whilst blue (four hours) was met 100% at both Crosshouse and Ayr; the yellow (urgent, one hour) was missed in about 20% cases and orange (very urgent) missed in the majority of cases, about 70%, at both hospitals. Red, immediate, was missed in 98% and 87% of cases respectively. According to the table, it stated that on average patients rated as requiring immediate attention were waiting on average about 25 minutes. Very urgent took about an hour.

Enforcement Notice

5.4 Appendix 4 Surgical

1 **DB03** Fatal Very poor copying and redaction.

- Nursing notes documented but not in medical notes
- Generally documentation poor. No current care plan and no evaluation of care
- Patient issues not fully addressed
- No evidence of pain scoring
- Staff not respond to drop in patients vital signs
- Medical staff not informed of deterioration in saturation respiratory rate and poor urine volumes
- Gap of 12 hours between observations
- Observations either not carried out, incomplete, or frequency not increased in response to the deteriorating clinical condition
- Lack of MEWS scores
- Medical decision-making at SHO, when it should have been escalated to a senior clinician (is SHO term still being used?)
- Absence of a senior clinician involvement in patient's care plan at early stages
- No evidence that surgical SHO had any communications with a clinician in assessing, planning and reviewing patient's condition
- Indications of infections, not recognised?

- Chest X-ray reviewed by anaesthetist showed problems but not picked up when subsequently reviewed
- Indication of stress ulceration but not treated
- Medical staff asked that patient be observed but nursing staff did not respond as required. This required close monitoring of patient's vital signs four-hourly
- Poor communications between medical and nursing staff
- Lack of MEWS meant no consideration given to medical intervention
- In 48 hours leading up to the patient's death they were not directly assessed by a consultant. This was done by a SHO during this critical period

Prosecution considered. Enforcement notices.

2. **DB04** Fatal

- Indications of pulmonary embolism but appropriate tests not performed
- Subsequently more indications but results not interpreted correctly
- No attempt recorded of obtaining senior clinician
- Confusion over who had lead responsibility for care
- Physician opinion sought over the phone, and later conflicted with preliminary diagnosis
- Prioritisation of patients incorrect
- Delay in treating pulmonary embolism
- Lack of assessment tool for assessment and management of DVT or pulmonary embolism
- Number of missed opportunities to assess and treat patient

Prosecution considered. Enforcement notices.

3. **DB12** Fatal

- Nursing care poor standard resulting in medical complications unidentified until too late
- Bed management policy inadequate. Here led to the 'loss' of the patient within the system, and so sub-optimal care
- Lack of consistent medical care and failure to pursue medical review
- There was not a system for ensuring consultant cover for periods the consultant was on leave
- Not a process on proper management of patient transferred to another speciality, to be recorded, received and actioned in a timely manner
- Care plans need to reviewing wounds medically
- Nursing care plan was missing and not implemented
- **Needs to be a systematic audit of nursing practice in relation to documentation and care planning**

- Needs improvement to bed planning and manager's role, including tracking of patients and notifying consultants
- Needs system-wide review of boarding process to ensure continuity of care
- Wounds not checked, not seen by medics
- Neither nursing, medical or AHP followed up on a no-show medical referral
- Consultant and associate registrar both on leave
- Nursing RA only partially completed
- Poor recording of pressure sore, and treatment of
- Record not indicate that the patient had other wounds
- Moving and handling RA contradicts activates and daily living assessment on patient's level of alertness. 'Manual Handling Operations' (MHO) assessment incomplete
- Wounds not redressed as required by tissue viability nurse`

Prosecution considered. Enforcement notices.

4. **DB18** Fatal

- Pressures on A&E
- SIGN 48 not followed 'Early Management of Patient with Head Injury'
- No half-hourly checks
- No staff member assigned to do ½ hourly checks
- Waiting time exceeded. Arrived 2050, second fall at 2300 (i.e. > 2 hours)
- GCS (Glasgow Coma Scale) readings suggested concern. Should have been a CT scan
- Patient not tracked. Documentation errors location, when records done, and when interventions carried out
- Documentation incomplete, e.g. head injury form incomplete
- Documentation unsigned, and lacking in location details
- Re-education needed on SIGN 46 procedure

Prosecution considered. Enforcement notices.

5. DB23 CT scans policy

- CT cancellation policy not followed
- Generally low risk from having unnecessary scan

6. DB26 **Fatal** Almost hopelessly redacted making analysis almost impossible

- More proactive approach to care may have prevented death

- Future response needs to account for the first 24-48 hours with increased risk of complications
- Need for consistency in reviewing patients
- Current guidelines need reviewing to make more easy to use in an emergency situation

Prosecution considered, but unlikely. Enforcement notices.

7. DB27 Fatal More excessive redaction

- Hydrogen Peroxide used to irrigate an abcess. This has benefits in dislodging materials but brings increased risk of producing emphysema
- Known cases and risk
- Recommendation that this process is discontinued

NFA ? Research into whether acceptable practice would be needed

8. DB31 **Fatal** Oxygen treatment fire

- Submitted to HSE. Smoker, severe burns
- Patient had obtained lighter
- HSE said they would not attend at this time but the inspector said wanted to be kept informed with regard to the trust's investigation. The inspector did not think that the incident was reportable (RIDDOR), would discuss with colleagues.
- Smoke alarm not sound
- Note: Reportability could be seen as ambiguous, investigation should have clarified. Could be classified as a dangerous occurrence. In any case RIDDOR reportability in healthcare is definitely not an indicator of HSWA importance and seriousness of breaches. As an example, the notable prosecution of Mid Staffordshire NHS Foundation Trust was on a death relating to a non-reportable incident, a lack of care.
- Previous warning to patient on smoking whilst getting this treatment
- Lack of clarity on smoking policy
- Inadequate training for staff on the dangers from smoking whilst on this therapy
- Trust not fully complaint with Hazards Notice HAZ(SC) 95/05 Scottish Healthcare Supplies
- No general RA and action plan by Trust on risk associated with oxygen therapy
- Patient provided with a lighter
- Ward and room layout restricted nursing staff observation of patient
- Inadequate staff knowledge on risk
- Lack of written information and signage for patients and visitors

Prosecution considered. Enforcement notices.

9. **DB34** Wrong organ removed Heavy redaction

- Incorrect surgical procedure
- A&A Health and Safety officer involved (not usually mentioned in CIR)
- Systems failure
- 'GPASS' system not allow GPs to see all reports and episodes in patient's care
- Differences between CT scan and ultrasound but not highlighted
- System required revision such that it identifies all investigations and episodes carried out
- Fault in radiology systems, required review
- Not a system in place for all radiologists within the radiology department to report real time on the findings of their investigations
- No operational policy and procedure on verification of results within the department
- Not a mechanism in place within radiology department for 'near hit' incident reporting
- Clinicians had problems accessing X-ray images. Alternative ways are available such as using 'Hospital Unit Number'
- Patient not admitted to speciality ward. This may also have meant images not available for surgery
- Patients for major planned surgery should be on appropriate speciality ward
- Patient consent form, reports and images needs refining
- Case notes lacked all reports and investigations at outpatient appointment
- On day of surgery X-rays not viewed in theatre as a final opportunity to ensure correct procedures
- Correct site protocol needs refining , needs all relevant information
- Loan equipment was used. This may have added pressure to surgery. Patient not informed of the use of this equipment
- At no point during the patient's care did any member of the surgical team see CT images on hard copy or electronically prior to surgery

Prosecution considered. Enforcement notices.

10. **DB37** Fatal

- Incorrect means of administering medication
- Should have been via use of Hickman line not the gastronomy tube
- Delay of 10 hours between death and identification of the link to means of medication
- Nurse had no experience of Hickman line or TPN (Total Parenteral Nutrition). Note form says 'Parental'
- At third or fourth medication patient collapsed

- Admission assessment and documentation incomplete
- Nurse with no experience of TPN 'allowed' to perform the procedure
- Another nurse missed medication, as patient was unable to swallow
- Nursing notes specified administration of medication via the Hickman line. This was entered after the patient's death
- This entry went unnoticed by senior nursing staff and medical staff during the day of the _____ (redacted)
- Recommendation that Scottish Healthcare Supplies label all IV lines
- **Recommend audit of all deaths within surgery to review quality of documentation**

Prosecution considered. Enforcement notices.

11. DB60 Complication

- Change in practice may reduce risk of complications occurring. Applies to 0.3% of patients. NFA

12. DB63 ? Report missing, plan update only

- Incomplete notes on day of discharge
- Unclear communications involving junior medical staff on the responsibility for ordering investigations

Not enough information

13. DB75 Fatal Heavy redaction

- 'Care appropriate', exception being incorrect administration of _____
- Inadequate nursing records
- Some clinical observations not recorded
- Need for better communications between team members
- Need for better communications between A&A and COPFS

Not enough information

14. DB81 **Fatal**

- Links between A&A, Cancer Support Services (CSS), and Workforce Solutions (WFS)
- Staff unregistered, untrained carer
- Equipment became dislodged _____(redacted)
- Delay at home of calling ambulance
- CSS unfamiliar with this type of patient care
- No formal referral pathway to CSS for this type of patient
- WFS requested and received training for 4 WST staff

- Particular care involved had not received the training
- Patient may not have been placed in the recovery position required but left sitting in chair
- Non-registered nurse delivering care task to unregistered member of staff
- Need for improved liaison protocols with Scottish Ambulance Service on investigations
- SAS successfully reinserted equipment but carer could not
- No guidance for staff of the Ambulance Service in use of uncuffed over cuffed tracheotomy tube in the event of a resuscitation
- Action 'contrary to adult _____Management guidelines for hospital and community care'
- Lack of clear line of responsibility

Prosecution considered. Enforcement notices.

15. **DB83** Almost wrong site surgery Heavy redaction

- Patient admitted for left nephroureterectomy
- Consultant surgeon obtained consent form from patient for incorrect site of surgery
- Did not review images (e.g. on PACS)
- Omission repeated, signed that they had checked the results but had not
- Charge nurse asked senior trainee doctor (ST6) to check PACS and error discovered, no harm
- No safety briefing
- Had been similar incident but full learning had not taken place
- Further improvements to systems required. And to facilities such as PACS and reviewing
- Systems not to WHO surgical safety checklist, and the five steps to safer surgery

Prosecution considered. Enforcement notices

16. **DB88** Fatal Heavy redaction

- Record keeping not good
- MEWS rating of 7 (extremely unwell), not properly acted on
- Later omission of urine output record, record unsigned
- Omission in treatment _____
- Missed GCS rating on level of consciousness
- Required review of record keeping , clinical information, filing
- Need to reduce time to first antibiotic dose
- Need to review process of escalation to consultant

- Need for medical staff to escalate acutely unwell patients to consultant for assessment.
- Needs a review of this system

Prosecution considered. Enforcement notices

17. **SAER 00002** Unspecified harm to patient Heavy redaction

- CVC (Central Venous Catheter) inserted into artery and not the vein
- A ST5 reviewed deteriorating patient.
- Patient had been reviewed by consultant surgeon
- Records incomplete
- Nursing staff identified problem
- 'It is the opinion of the review team that the multi-disciplinary care delivered to this patient was of a high standard'
- Further checks required in process
- Elsewhere in A&A a relevant checklist is used

Prosecution considered. Enforcement notices

18. SAER 00003 n/k Heavy redaction, report render almost unreadable and often meaningless

- Prompted by SPSO (Ombudsman)
- Long time, 4 hours, from A&E to medical review. 'Happens with having fewer junior doctors'
- Problem of transfer of patient transfer onto trolley at reception for A&E. Should have had specialist equipment
- ANP did not record patient assessment
- Poor X-ray image which complicate diagnosis
- Radiology analysis not correct
- Needs better communications between radiology and clinician

Enforcement notices

19. **SAER 00005** Fatal Excessive obstructive redaction

- Discharge documentation not completed – Immediate Discharge Documents (IDD)
- Actions contrary to local and national policy
- Resulted in patient not being given medication
- Also patient and family not have information on diagnosis and treatment
- Weakness in system of discharge
- Patient died that night

- Recognised issue in A&A that IDD routinely not completed for 1-2 days after discharge
- Inadequate '' system
- IDD must be done before discharge
- CT scan was planned by junior doctor but consultant recorded it as unnecessary (reasons redacted)
- Staff levels low on day of discharge
- Reason for the prescription not given on notes
- Intention of the consultant to further review patient prior to discharge, but this was not documented in the medical records
- Confusion over discharge, e.g. was there justification for a Criteria Based Discharge?
- Usual practice in other medical units is for a a doctor to review prior to discharge
- Doctor missed a significant indicator prior to discharge. This would have required patient to stay in hospital. SIGN says poor outcome and need for an intervention
- **Common practice for patient discharge without appropriate medical input, no IDD, information on diagnosis, medication, or planned follow up.** Due to workload pressures on junior doctors
- SIGN says that IDD should go to the GP on the day of discharge
- Significance of blood results was not recognised. These were not seen by an experienced doctor
- No protocol for use of 'Criteria Based Discharge' in A&A
- Culture tolerated failure on IDD and discharge procedures
- Failed assessments by a number of doctors

Prosecution considered. Enforcement notices

5.5 Appendix 5 Maternity

1. **DB10** Stillborn ('out come may not have been different') heavy redaction

- Delay in care and treatment
- Domicilary Fetal Monitoring (DFM)- cessation of procedure as it gave rise to delays in care and treatment
- Inadequate recording of assessment, and of reason for decision-making
- Midwife's first DFM
- Questionable whether DFM satisfactory
- DFM guidelines say 'If trace unsatisfactory community midwife stays with the woman till medical advice received. This did not happen
- Tracing of DFM could not be tracked by phone
- Use of DFM was out-with protocol 14 regarding gestation and patient risk. DFM should not have been used

- Use of DFM stopped
- Guidelines were out of date on DFM
- Incorrect handling of the woman's situation

Prosecution considered. Enforcement notices

2. **DB11** Fatal Heavy redaction making significant details unclear

- Failure to deliver appropriate care
- Failure on-call consultant attendance
- Failure of communications
- Lack of intervention on CTG trace (**cardiotocography**) and vital sign
- Possible equipment malfunction
- On-call consultant then gave advice
- CTG instructions not completed
- Dynamap (Dinamap?) machine suspect accuracy
- CTG trace was abnormal and required staff to call the consultant
- Instructions not questioned
- With suggested diagnosis of placental abruption it would require the attendance of the on-call consultant
- Inadequate information given to the next on-call consultant
- Problems on records, clinical records incomplete

Prosecution considered. Enforcement notices

3. **DB16** Outcome uncertain Heavy redaction

- Guidance of CTG not followed
- Should have been able to identify the difficulties
- Should have been paediatric assistance and quick resuscitation
- eClipse system contributed to case mismanagement
- Suggested that the baby sustained damage attributable to _____(redacted)
- CTG at upper limit – a concern
- Staff unaware of required observational needs
- No policy on taking fetal blood samples, none taken. Should have been
- Communications on the team a problem
- Lack of identification that the baby had difficulties and so there was no paediatric assistance prior to delivery
- CTG guidance displayed in labour rooms but not followed
- Confusion on handwritten notes and eClipse system, no cross-referencing, and lack of awareness of what records were. Linked to CTG interpretation errors
- Training issues

- Problems with early adoption of eClipse

Prosecution considered. Enforcement notices

4. **DB20** Harm to baby Heavy redaction, cavalier approach

- Overdose
- Midwife medicating errors
- Unfamiliarity with clinical procedures
- Need for junior doctors to comply with policy and procedures on checking administration of drugs
- Need system to allow junior doctors to identify staff allowed to administer IV drugs
- Improvement to medicine recording sheets
- Improved 'Alert' process needed
- Improved A&A code of practice on the management of medicines needed
- Review required of _____(redaction)
- Reminder to staff of Code of Practice regarding suspected defects in medical products
- Different strengths of medicines stored in close proximity, and wrong one selected
- Communications problems between Dr and _____ resulted in drug not being checked according to policy

Prosecution considered. Enforcement notices

5. **DB21** Heavy redaction

- Fetal blood not taken, if had been it would have led to immediate delivery (see also DB16)
- CTG trace identified as suspicious. Consultant not informed as should have been
- Relevant QIS standard requires that if woman has to wait more than one hour for epidural then consultant anaesthetist should be called, but was not
- QIS standard routinely not complied with
- Patient did not receive any analgesic control until just prior to delivery
- CTG misinterpreted
- Delay in getting medical review
- Consultant was available, but staff assumed that they were not
- CTG trace pathology overlooked (SIGN error)
- CTG deteriorated further. Not reported to registrar for 50 minutes, 'a significant error'
- Senior midwife disagreed with registrar over decision to deliver with forceps
- Doctor competent but the delay made action inappropriate

- Difficulties for baby underestimated_____ APGAR score of only one (critical)
- Baby harmed
- At no time during labour was a consultant obstetrician asked to assist, a significant error
- Significant adverse event was not raised with senior management until a compliant was received, 'a significant error'
- Adverse event policy and escalation policy not are or understood
- Policies had not been adopted by Obstetrics and Gynaecology Department
- Clinical Governance Department had an agreement that in view of the Women's , Children's and Obstetric Units monitoring of Datix reports, an unwritten policy was that a review was not required, 'a significant error'
- Appropriate decision-making process not used
- Obstetrics and gynaecology failed to document learning

Prosecution considered. Enforcement notices

6. DB57 ? Heavy redaction, very unclear

- Given high risk of uterine rupture early delivery should have taken place and led to an improved outcome
- Communications problems
- Multiple changes of care led to lack of clarity on planning
- Required urgent review of existing induction of labour protocol
- Required urgent review of how labour suite is covered by obstetric team
- Needs improved escalation of Significant Adverse Events Report (SAER)
- Concern over the management of intrapartum period
- Need for individualised management plan
- Infusion may have been a factor in uterine rupture
- Labour protocol not specific enough
- Rota fragmented because of consultant obstetric team availability. Too many handovers and effect on continuity of care and communications

Not enough information left unredacted on prosecution. Enforcement notices

7. DM62 ? Very heavy redaction

- Improved written and oral communication required
- Inadequate communications between doctors
- Doctors during the emergency did not communicate to other staff possible cause of medical problem
- This led to questioning of whether correct action taken, and to anxiety of staff during the emergency
- Lack of clarity on contacting on-call staff

Too heavy redaction to make much sense

8. DB79

- Improved pain control needed

9. **DB84** Fatal, stillborn

- Need accurate recording and timing of Caesarean section, and category of it
- Needed fetal heart monitoring carrying out immediately after insertion of spinal anaesthetic and documentation

Prosecution considered. Enforcement Notices

5.6 Appendix 6 Other

1. **DB19** Fatal Very heavy redaction

- Lift failure during transfer of patient to Intensive Care Unit
- Transfer of patient whilst stable from Medical High Care Unit
- Lift doors closed but controls not work
- Patient deteriorated, oxygen running low and flow rate reduced to 1/3 (15L down to 5L/ minute)
- Patient died 3 hours later; staff advised that delay did not contribute to death. Twenty minute delay (and reduced oxygen). A&A decided not to inform HSE. (It is still covered by HSWA 1974, in any case irrespective of reportability it relates to a serious problem; records show lift failures have been frequent over the years at A&A).
- Medical staff in lift regarded it as an urgent situation
- Took 15 minutes before lift release process commenced
- With redaction not clear on timings, whether lift entered at 1400, call stuck call at 1413, patient arrived at ICU at 1500, died 1720. Lift opened at 1435, stuck for 22 minutes or 35?
- Delay between lift calling switchboard and estates staff being contacted
- Oxygen supply carried insufficient for full supply to patient during incident (a full D cylinder lasts 23 minutes at patient's intended rate 15L/ minute, an E cylinder last 45 minutes).
- Portable suction unit battery completely flat, no power when patient and staff released
- 'If critically ill patient trapped for any longer with same equipment then risk to patient's safety' regarding oxygen and suction pump
- Needs thorough preparation for such patient transfers
- Portable medical devices need to be fully charged
- Should be two E cylinders available for higher oxygen demand patients
- Theatre lift should be used for transfers of critically ill patients
- Emergency box to be carried with potentially unstable patients , and as required

- Audit suction devices
- Lift release needs RA and safe system of work. This should include immediate contact of Estates and then the senior manager on call
- Revised guidelines on transfers of critically ill patients

Prosecution considered. Enforcement notices

2. DB38 Duplicating patient numbers Heavy redaction

- 'Near hit'
- Pharmacy discovered patients with same ID numbers
- Risk of incorrect care
- HISS issued one number but JAC electronic prescribing system showed it related to a different patient
- Potential for large number of duplicate numbers
- Problem of many different computer systems currently in use
- 'Presents potentially serious clinical risk'
- Difficulty in sharing information across hospital(s)
- Computer system change control procedures inadequate or non-existent
- Complex interfaces because of the numerous systems
- Lack of corporate knowledge
- Not a unified coherent system

(NHS Scotland –wide problem?)

Enforcement notices

3. DB47 Equipment problem Redaction problems

- Endoscopy diathermal systems
- Four clinical incidents
- Other hospitals not have the problems
- Differences in clinical practice
- Use on changed heat setting
- Training

NFA?

4. DB48 Locum consultant performance

- Question of competence with 19 discrepancies in 160 reports
- Checked and radiologist error rates were in range 10-15% (Was this the case? Why? Is it still so high?)
- Consultant was in the normal range
- Still problems with induction of locums

Enforcement notices

5. DB69 Infection control and equipment Redaction problems

- No audit process on risk management
- Problems with custom and practice and systems of work
- Small teams/ groups develop approaches unapproved ways of working
- Need to rotate staff to try to prevent group-think
- Was sharing of equipment between patients without cleaning
- Said, here no increase risk to the public
- Breach of guidance on decontamination of instruments
- Record keeping not good

NFA?

6. DB76 Wrong facility

- Unvalidated fridge used for vaccine storage and transfer
- No measurement of temperature
- Management of vaccines standard not followed
- Should not have affected these vaccines

NFA?

7. DB91 No report, action plan only. Redaction makes almost useless

- New equipment and staff not trained
- Competence assumed, was not checked and not there
- Need to use correct recording charts
- Faults with process

Enforcement notices