CASE FOR A PUBLIC INQUIRY

‘PATIENT SAFETY IN SCOTLAND’ 2015

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The case for a public inquiry under the Public Inquiries Act 2005 into patient safety in Scotland and the failures to comply with the reserved legislation of the Health and Safety at Work etc Act 1974, the Human Rights Act 1998 and the Scotland Act 1998. The terms of reference to cover NHS Scotland and other healthcare providers in Scotland, the role of the Scottish Government, and the Scottish Justice and Legal System.

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1. Summary

1.1 Objective: The Health and Safety at Work etc Act 1974 (HSWA) applies to patient safety. If the Act is implemented it can deliver safety across healthcare and social care as far as could reasonable be expected. By definition its methods have the ability to 'solve' patient safety.

1.2 Implementation, Compliance and Consequences: The Act applies across all Great Britain (NI has analogous legislation, making the requirements UK-wide) but it has never been implemented to a standard to discharge responsibilities under the Act. In Scotland the Act has not been in the stated intent of the Scottish Government, NHS Scotland, or the independent sector. There is not the legally required organisational and management systems to deliver the safety of patients as the Act requires. The consequences of this non-compliance are that there are a very large number of reasonably preventable premature deaths occurring each year, maybe about five deaths a day. These severe consequences are only partially and gradually being recognised in Scotland.

1.3 Regulation: The situation in Scotland is aggravated by the absence of effective regulation as required by the Act to prevent avoidable deaths and other harm. In Scotland there is no independent healthcare regulator to ensure that the appropriate protective measures are in place. Other parts of the UK have the required independent healthcare regulator. In Scotland there is no healthcare regulator. HSE has an over-arching responsibility for the Act. It does not carry out preventative inspections or other actions to ensure that patient safety is delivered to the standard that the Act requires. Healthcare and social care are sectors of high hazard and high risk and the Act requires a proportionate approach that means that precautions must be to a high standard 'so far as is reasonably practicable'.

1.4 Optimising Healthcare and Social Care: The Act has well-established legal and supporting methods of managing risk to prevent harm proportionate to the risks. It has been highly successful. As risk is both 'good' and 'bad', methods of risk management can be used to both optimise outcomes and prevent harm. This is an area to develop means to optimise health outcomes. The risk management methods also have the ability to optimise the deployment of healthcare resources as well as minimising wastage on compensation and legal costs from reasonably preventable errors.

1.5 Public Inquiry Requirement: The consequences of the failure to implement the UK-wide Health and Safety at Work etc Act 1974 commensurate with the high hazards and high risks in healthcare and social care are extremely serious. The numbers of avoidable deaths run into thousands. The issues are substantially more serious than those of other public inquiries held either in Scotland or the UK. The potential

benefits are the prevention of this large-scale harm and secure legal compliance.

2. Introduction

The background section 3 below shows the scale of the problem and the Scottish Government's failure to recognise it or implement UK law that would prevent the harm. The matter justifies a public inquiry on patient safety in Scotland on the basis of the criteria of the Public Inquiries Act 2005. The background gives an outline of the legal requirements and how they are addressed in other areas of high hazards to public safety and the current issue of healthcare and social care. There then follows three major recent examples in Scottish healthcare illustrating the problems and the role of the Scottish Government, its legal officers and ministers. The report then moves on to cover organisations and individual ministers involved in the failure in Scotland to secure patient safety to the legal standard. The legal position and failings are summarised and broad conclusions made. There is then a section on solutions; these are mostly directly related to legal requirements but move on to Scottish Parliamentary and Civil Service requirements. The final point is to establish a comprehensive system of risk management in healthcare and social care that both prevents harm but also optimises health outcomes. Appendix 3 gives a sample of the evidence showing the scale of the preventable harm. Appendix 4 summarises what the law requires to prevent such harm.

This document is the situation as it appears. It would require formal investigation to confirm the picture that has been presented of healthcare and social care in Scotland.

3. Background

3.1 Issue It has been generally recognised that there are a large number of reasonably preventable premature deaths and cases of major harm occurring in healthcare and social care across the UK. These are cases that can and should be prevented by the full implementation of existing legislation, legislation which has mostly been in place for the last forty years. The role of legislation and regulation has been generally recognised particularly following the public inquiries into the Mid Staffordshire NHS Foundation Trust. In most of the UK, steps are being taken to bring compliance and regulation up to standard. The statutory requirements come with the Health and Safety at Work etc Act 1974. The intent of the legislation is given in:

1: Preliminary.

(1)The provisions of this Part shall have effect with a view to—

(a)securing the health, safety and welfare of persons at work;

(**b)protecting persons other than persons at work against risks to health or safety arising out of or in connection with the activities of persons at work**

The actual requirement on compliance is given in:

3. General duties of employers and self-employed to persons other than their employees.

(1)It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety.

This has not been recognised in Scotland. There is not the policy, plan or regulation to comply with the law. From this exceedingly low position of legal compliance and organisational arrangements there is in effect no chance of achieving acceptable standards of patient safety. The issue of patient safety in Scotland gets very little coverage even when it has a direct bearing on cases such as the 30-50 deaths from an infection outbreak at the Vale of Leven Hospital. That outbreak should have been prevented by compliance with this comprehensive legislation. The legislation was explicitly disregarded at the hospital and in the public inquiry into the outbreak. The problem is not recognised by the Scottish Government. It does not reference the binding UK law. It has no plan to comply with it, or see that it is fully implemented, and does not perceive that it applies across healthcare and social care. In addition the Scottish Government abolished the independent healthcare regulator and refuses to recreate it.

There is a large amount of evidence from across the UK and in Scotland to demonstrate that patient safety is a major problem. Here in Scotland it is not being addressed. See Appendix 3 for a sample of evidence contained in a letter to the Lord Advocate on 13 December 2013. The actual size of the problem is not known. This is partly because of the lack of awareness of (1) what constitutes a reasonably preventable death and (2) how HSWA applies to healthcare and social care. Using the prosecution of Mid Staffordshire NHS Foundation Trust following the public inquiries as a guide to the definition, then the number of such reasonably preventable deaths would be in excess of 12,000 in acute physical healthcare alone across all the UK. Additionally there are deaths associated with non-acute healthcare and mental health, primary care and the very poorly researched area of social care. It is not unreasonable to estimate 20,000 reasonably preventable premature deaths (RPPD) a year for the UK. Even if this errs by a factor of ten, the number would still be very high. The Department of Health was using a figure of about 4,000 for deaths in acute physical health in the NHS England. For Scotland the issue is about 2,000 RPPD a year that could be reasonably prevented. This is about five a day, or about 4% of the total number of deaths occurring in Scotland.

The issues for an inquiry include the failure of the Scottish Government and its ministers to recognise the issue and the applicable legislation, the failure to have an effective plan throughout healthcare and social care to comply with the law, and the Scottish Government's insistence on not having healthcare or social care regulated in compliance with the law (HSWA and Human Rights Act 1998).

3.2 Public Inquiries Act 2005

An inquiry into patient safety in Scotland can be covered under three pieces of legislation. These are the Public Inquires Act 2005, the Health and Safety at Work etc Act 1974 section 14, and the Fatal Accident Investigations and Sudden Deaths Inquiry (Scotland) Act 1976. Whilst the last two can be broad in their scope the issues here are of the widest nature. They affect the safety of almost all of the Scottish population, they involve the largest sector and employer in Scotland, and they deal with a fundamental role and behaviour of a government and its ministers, the Human Rights Act 1998, the Scotland Act 1998, and the role of the legal system to protect the public by preventing crime. It seems most appropriate to hold an inquiry under the 2005 Act.

According to the Public Inquiries Act 2005:-

'1 Power to establish inquiry
(1) A Minister may cause an inquiry to be held under this Act in relation to a case where it appears to him that—
(a) particular events have caused, or are capable of causing, public concern, or
(b) there is public concern that particular events may have occurred.
(2) In this Act "Minister" means—
(a) a United Kingdom Minister;
(b) the Scottish Ministers; a Northern Ireland Minister; and references to a Minister also include references to the National Assembly for Wales'.

In this matter it is recognised, and polls confirm, that the quality of healthcare and the safety of patients is at or about the top of matters of public concern. In the case of the Mid Staffordshire NHS Foundation Trust Public Inquiry the issue was of poor conditions and inadequate regulation related to possible excess mortality of 100-300 patients a year. In this current case the matters are much wider and deeper. They relate to the failures across Scottish healthcare and social care to comply with long-standing legislation that would 'solve' the problem of patient safety by securing it so far as was reasonably practicable. There is a large amount of information from across Scottish healthcare of the consequences of this failure. Whilst Mid Staffordshire was about poor conditions and poor regulation, in Scotland the information is both of (1) frequently poor conditions, and (2) absence of regulation. The Scottish Government is complicit with its policy of disregard for the law, and the Crown Office and Procurator Fiscal Service (COPFS) and Justice Secretaries have failed to act to get the Scottish Government to adhere to binding legal requirements.

The avoidable harm has been going on for many years. There will be avoidable deaths on a daily basis, as failings are regularly reported that show breaches of HSWA and the consequent harm. None of the bodies with responsibilities for healthcare in Scotland are acknowledging HSWA as the essential standard to comply with. The consequences of this disregard for compliance with the law, to the required standard proportionate to the risks, are so widespread that they almost certainly will affect all of those living in Scotland in some way.

The position of the Scottish Government is one of refusing to recognise that HSWA applies. They do not set it as a prime requirement in Scottish healthcare and social care, they have no plan to achieve compliance, and the current administration abolished the independent healthcare regulator, and have been refusing to create a replacement. It appears to be unprecedented in the UK for a devolved Government to stand in such defiance of UK law, particularly when compliance with it would secure the safety of its people. Ministers and senior officers leave themselves liable to legal sanctions for their failings.

In the case of patient safety in Scotland, the principal Act is the Health and Safety at Work Act 1974 which is reserved legislation and applies across the entire GB. The other main pieces of legislation are the Human Rights Act 1998, the Scotland Act 1998, and the related responsibilities under the European Convention on Human Rights. There is also the potential for cases under the Corporate Manslaughter and Corporate Homicide Act 2007. All these are reserved matters. Consequently it is for the UK Government to determine if there should be an inquiry under the 2005 Act. The Scottish Ministerial Code (4.19) requires that public inquiries into devolved matters consult with the (Scottish) First Minister. In this case it is the duty of the Scottish First Minister and the Scottish Government to comply with GB/UK-wide law and policy. It requires that the Scottish Government ensures that its policies are aligned with UK law to deliver patient safety. For this reason the case for a public inquiry is submitted to the Secretary of State for Scotland, the Attorney General, and the Cabinet Office in the first instance. Any decision on the holding of a public inquiry under the 2005 Act does not appear to require any input from the Scottish Government, though it would probable be advisable to inform it. Whilst healthcare is devolved the requirement on patient safety is a reserved matter and by the 2005 Act the subject of the inquiry is not a 'Scottish matter'.

The consequences of the failings in Scotland on patient safety run into thousands of deaths and these deaths are continuing on a daily basis. The numbers affected far exceeds that related to any public inquiry held in the UK so far. In Scotland there is currently a 2005 Act public inquiry into the Edinburgh trams which was set up by the previous Scottish First Minister Mr Alex Salmond, which involved no deaths or injuries, it was about cost overrun. This current matter is vastly more important than that in its significance. This is about the safety and well-being of the people in Scotland. It deals with many avoidable deaths, and role the

Scottish Government and its ministers in perpetuating and aggravating the problem.

3.3 Health and Safety Legislation Development

Safety legislation really began with the Factories Act 1833 and over the following century the law was extended to include construction, mines, quarries, agriculture, offices and shops, by Acts and Regulations. This legislation made major improvements to worker safety but then advances plateaued. Accidents and ill-health continued at a high rate.

By the start of the 1970s the legislation and its regulation had not addressed large areas of work-related harm. It still left many sectors outside the scope of safety legislation: it did not deal with (1) occupationally related health matters, nor (2) risks to the public from other's work activities, nor (3) the responsibilities of senior management and individual workers, nor (4) underlying causes. The approach to safety was limited in scope, unsystematic and prescriptive rather than an apparent need to be comprehensive, preventive, systematic, proportionate, reasonable, legally enforceable and proportionately regulated in compliance.

The Health and Safety at Work etc Act 1974 (HSWA) addressed the above deficiencies. It has been supported inter alia by the Management of Health and Safety at Work Regulations (1992) which set down the required management arrangements to deliver the intent of the Act. There are regulations to deal with specific risks, such as the Control of Substances Hazardous to Health Regulations (COSHH) which includes microbiological risks. COSHH applies to infection control for patients and for those in social care. These also meet, and are required by, European safety directives and common standards.

The conventional **high hazard** sectors such as nuclear, railways, and major hazards (gas supply and storage, chemicals, petro-chemicals and off-shore), have even stricter regulations to license the activities. These sectors have been subject to a stricter regulatory regime to ensure that a high standard of precautions are in place and maintained to make sure that the risks to employees and the public are prevented from harm (See section 3.4 below). HSWA also gives provision for more enforcement powers and greater powers for the prosecution of dutyholders for failures to ensure that the protective measures in any sector are effective. The Act and the regulatory regime have been highly effective. It covers specific risks, the management system to control them, and both the corporate and organisational culture required. The Act has continued with only minor changes for forty years. However there are two sectors where this approach was not applied as required, namely **healthcare** and **social care**. The consequence of this failure have been severe. NHS Mid Staffordshire was one example of an historic and on-going problem. The independent healthcare regulator (IHR) in England, the Care Quality Commission (CQC), is seeking to bridge the regulatory gap

identified by the Francis Report into Mid Staffordshire. There is no exemption for healthcare and social care from the requirements of HSWA and section 3 in particular.

HSWA, inter-alia, contains statutory responsibilities on organisations and individuals, and these are matters relevant to the healthcare and social care sectors in Scotland:

- Intention to secure health and safety of employees and the public (s1)
- Prevent risk to employees (s2)
- Protect non-employees affected by work activities (s3)
- Responsibilities of senior officers (s37, s36, s7)
- Responsibilities of all employees (s7)
- Safe place of work (s2)
- Safe equipment and systems of work (s2)
- Duties of suppliers (s6)
- Training and information (s2)
- Consultation with employees (s2)
- Enforcement (s21, s22)
- Regulator (s18)
- Public Inquiries (s14)
- Power of court to order remedy of offence (s42)
- Application to Crown public servants (s48)

3.4 Requirements of the Legislation and Application to Health and Social Care

The Act's purpose is given is section 1 and is:

a) securing the health, safety and welfare of persons at work; and
b) protecting persons other than persons at work against risks to health or safety arising out of or in connection with the activities of persons at work.

These two main requirements are expanded in sections 2 and 3 of the Act. **There is no exemption for healthcare or social care**. The Act has the effect of providing legal protection to both employees and patients in the sectors of healthcare and social care so far as is reasonably practicable. The Act applies to organisations both private and public, to individuals, to senior officers in organisations, and to ministers involved in all sectors in the UK.

Whilst the Act gave the comprehensive requirements on what was required it was the Management of Health and Safety at Work Regs (MHSWR) in 1992 that made explicit the requirement to have effective management systems in place according to type and size of the risks. The regulations came from an EU Directive. From that date there was a requirement for all sectors to have such systems of risk management in

place proportionate to the risks. There was a slight change to MHSWR in 1999 which introduced a hierarchy of controls of risks.

A main principal of HSWA is that the precautions to control the risk are proportionate to the risk itself. There can be activities which should not be engaged in if the risks are so high. Other risks which are very high need to be controlled to a very high standard. Given the requirement of proportionality sectors which have high hazards and the capability to cause major harm, receive special treatment in terms of the precautions, the legislation and their regulation. These major hazards sectors require very tight control to ensure that the chance of them causing major harm is very low. The resultant risk level is therefore low and should remain so, although the intrinsic hazards can be high. For example railways have the capability to cause major accidents but there has not been one caused by its failure since Potters Bar and Grayrigg (nine deaths in 2002 and one death in 2007). 2013 was the first year where there had been no passenger deaths and no rail worker deaths, a testament to the sector and the success of the regulatory regime.

The high hazard sectors were given recognition with special legislation and regulatory regimes. This began with nuclear safety (1965), major chemical plant, gas, petrochemicals (1984), off-shore oil and gas production (1992), and railways (1994). All operate under safety licensing regimes. The sectors and regulators have improved safety such that currently risk levels are low, whilst hopefully avoiding complacency. The number of deaths associated with these major hazards is currently very low, and the main risk now being the risk to employees and transport to the work locations. The history of progress on health and safety risk management is marked by disasters. Windscale 1957 resulted in the establishment of nuclear safety regulation, the Flixborough disaster of 1974 showed the failure to control the risk on major chemical plant and the safety risk to the public with deaths on site and off-site. The Piper Alpha disaster 1988 and its public inquiry led to the safety case legislation and HSE regulatory regime for offshore oil and gas production.

Whilst the deaths in healthcare are high they tend to be single deaths. They are most obvious when there are infection outbreaks, or total numbers may be alluded to in excess hospitality standardised mortality rates. There was the recent report (24 November 2014) of the public inquiry into the C-difficile outbreak at the Vale of Leven Hospital in 2008 which resulted in the infection being identified as the major factor in 30-50 deaths. This would generally be considered of disaster proportions. Remarkably the public inquiry did not notice that HSWA applied to the control of infections, and that compliance with the Act should have prevented the outbreak. If it had been noticed, it could have led to the required changes in Scottish healthcare. But it was not, and the harm continues. The appropriate lessons were **not** identified, and **not** learnt.

In terms of the number of reasonably preventable premature deaths (RPPD) the numbers in health and social care are extremely large. The numbers are not recorded. There is no assessment of whether particular deaths could have been prevented by the application of existing legislation and the risk management methods that it requires. This is a definition of what the law requires and the concept of RPPD. Despite the law having applied to these deaths for forty years the assessment of legal compliance on deaths in healthcare and social care is not routinely and systematically carried out. The matter has not been subject to rigorous research. What research there is agrees that the RPPD is in the thousands across the UK. For acute healthcare in England the lower limit estimate is about 4,000 pa, reputable research suggests 12,000 pa for all the UK, some research puts it even higher. This is for acute physical health in hospitals; there are RPPD associated with mental health, primary care and social care. The last two areas particularly have very poor data, but the hazards are very high and, since the precautions are not commensurate, the resultant risks are also very high. The total number of RPPD for all healthcare and social care is likely to be in the region of 20,000 pa for all the UK.

There will be variations in healthcare and social care across the UK but the actual practice in the sectors is sufficiently similar that the RPPD **hazard** rates will be high in all parts of the UK. As suggested above, poor regulation and little coverage suggest that the RPPD **risk** rates will be higher in Scotland than in better-regulated parts of the UK. Even in countries with claims to being the best in the world they recognise that it is a major problem for them too, with thousands of avoidable deaths still occurring. Arguments are advanced as to why healthcare in Scotland would be better than the rest of the UK, but there are other arguments to predict it would be worse. The independent data on patient safety performance in Scotland and of those in social care in Scotland do not exist on which to assess the position. Scotland mostly relies on self-reporting which is notoriously unreliable (such as at NHS Lanarkshire on precursors of patient mortality, see section 5). The usual access to data on incidents and major harm that is recorded in other sectors is not available in healthcare. Such incidents are not required to be reported to HSE under the general reporting requirement of RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2012), as it does not apply to those under the care of a medical practioner. Reports of deaths in healthcare and social care to the COPFS and to the police do not give the data, particularly as those doing the reporting are not aware of the application of HSWA and what it means. There is no body independently determining the performance of the healthcare and social care sectors on health and safety.

The health and social care sectors have operated outside the main stream of health and safety and its risk management methods ever since the enactment of the 1974 Act. HSE took some major steps in the mid to late 1990s to address what was and still is the biggest gap in HSWA compliance. A decade later, Mid Staffordshire showed some of the

extent of the gap but there is much more that could and should be done by law. The legislation requires that, that which is reasonably practicable must be done to prevent harm to patients, in the case of deaths this translates to the prevention of RPPD. The law is the demonstration of that which could reasonable be done to prevent avoidable deaths is being done; HSWA compliance by definition and practice 'solves' patient safety. Occasionally reference (e.g. UK Health Select Committee) is made to healthcare learning from safety in aviation but there is already the legal requirements and risk management methods which cover all risks and which are consistent with other major hazards sectors. The general UK policy on risk (and covers regulation) is given in 'Tolerability of Risk' and 'Reducing Risk Protecting People' (HSE's decision-making process). From both the situation in Scotland should clearly be seen to be untenable.

3.5 Legislation and Risk Management Model

Whilst the HSWA has stood the test of time it has been complemented by other legislation and developments. Health and safety now has a comprehensive, proportionate, systematic and enforceable approach to managing risk to employees and the public potentially affected in all sectors including healthcare. Expanding the points:

- Health and Safety at Work etc Act 1974 gives the overall requirements and aspects.
- Management of Health and Safety at Work Regulations 1992/1999 gives the systematic approach to managing the risks.
- Risk-Specific legislation. There are risk specific regulations requiring compliance within HSWA and MHSWR frameworks. Examples are ionising radiation, manual handling, and toxic substances. The Control of Substances Hazardous to Health (COSHH) Regulations is extremely important in healthcare as they are the ones that apply to infections in hospitals and other aspects of healthcare (e.g. dentists and care homes). The proper application of these alone would prevent a very large number of avoidable deaths.
- High Hazard Regimes. These apply to areas of high hazards where controls must be tighter. These are nuclear, major chemical and fire and explosion hazards, off-shore gas and oil, and railways. The stand-out omissions from being considered high hazards or being subject to the proportionate standards are healthcare and social care.
- Culture both corporate (what an organisation wants) and organisational (what it actually has) is recognised as being the main determinant of health and safety performance. For a long time safety culture was seen as a vague requirement with approaches to it being descriptive of what culture there was ,only covering some of the aspects of safety culture, and only guidance not law. In 2006 the Office of Rail Regulation devised

and implemented the comprehensive and legally–based model of how to get the right culture to deliver health and safety ('5R'-Five Requirements of Organisational Culture). This was applied successfully to a high hazard sector.

The approach to risk management in health and safety is such that it is applicable to other risks and particularly to ones that rate as high. It is a generic approach that can be adapted and applied to specific hazards.

Further, risk can be 'good' as well as 'bad'. It is possible to use the techniques of risk management used to prevent harm, to optimise the chance of positive outcomes. This opens up the possibility of using a single approach in healthcare to deliver the optimum healthcare in a reasonable, systematic and proportionate manner. This is a potentially substantial advance in both risk management generally and healthcare in particular, but one of currently undeveloped opportunity. Such an approach would be consistent with the need to make best use of resources to minimise direct costs and those of dealing with errors and litigation.

3.6 Healthcare Regulation and the Health and Safety Executive (HSE)

The HSE is appointed under the HSWA to enforce the Act or to delegate responsibilities to other independent regulators such as Environment Health Officers. The legal requirement under HSWA is that such delegation and responsibilities are discharged such that regulation is effective. Regulation is required to be appropriate to the hazards and risks and so is proportionate to them and according to what is 'reasonably practicable'. This is further demonstrated in HSE's Enforcement Management Model (EMM) which is the codified decision-making process to determine what enforcement action is required for a particular situation. EMM applies to both safety and health risks.

The Act requires that effective precautions are in place to prevent harm. The main offences under the Act are generally on the failure to ensure that the right protective measures are in place to prevent the risk of harm, rather than on any harm that may or may not occur (R v Board of Trustees British Museum). Where HSWA prosecutions do refer to cases of harm, such as deaths, then they have to be shown to relate to the failure of protective measures required by the Act.

Since 1974 both healthcare and social care have been covered by the Act in respect of employees and patients or those in its care. For patients part of section 3 can be regarded as a practical form of the requirement of the Hippocratic Oath of 'first do no harm'. The HSE prosecution of the Mid Staffordshire NHS Foundation Trust after the public inquiries gave a high profile example of what section 3 responsibilities could mean in healthcare.

After the introduction of HSWA and the creation of HSE formed out of HM Factory Inspectorate, HSE was slow to address the risks in healthcare. It took several years to create a central policy group and then to create what was called 'Services' groups in each of its twenty or so Area offices. These groups only contained about three inspectors and healthcare was just one of a large number of sectors that they were responsible for. Only gradually was the scale of health and safety issues in healthcare and social care recognised. The numbers of people exposed to the risks was very large. Initially the involvement was reactive looking at traditional physical risks such as fatal or severe scaldings, falls from height, trapping in cot sides, and some suicides associated with mental health. With the high risk of back injuries and new regulations on 'manual handling' more interest was taken in risks to healthcare and social care staff. HSE specialist microbiological inspectors started to inspect pathology laboratories with concern to protect laboratory staff.

Resources increased slightly in the Services sector and proactive inspection commenced. This took in hospitals, mental health units, GPs, dentists, care homes and also social services care. The introduction of the Management of Health and Safety at Work Regulations 1992 gave a legal basis and framework for inspecting both management systems as well as frontline controls. The regulations required organisations to have effective management systems to ensure that precautions on risks controlled them so far as was reasonably practicable. They required effective planning, organisation, controls, monitoring, and review of precautions. The legislation now provided a comprehensive management system requirement to control health and safety risks to both employees and to the public affected by work activities.

In the mid-1990s HSE started to carry out a programme of wide-ranging 'hospital audits'. These were team inspections of a significant proportion of each NHS Trust, inspecting on both management systems and how effective they were at controlling frontline risks to employees and patients. It was once these audits started that inspectors looked at the 'risk profile' (an objective determination of the priorities on what gives the most risk) of hospitals that it was realised that major areas of risk covered by HSWA were not being addressed either by HSE or by the healthcare sector. The first risk addressed by HSWA was from infections out in patient areas rather than constrained to the pathology laboratories. HSE started to work on this with its specialist microbiological inspectors and Employment Medical Advisers (doctors and nurses). It became apparent just how big the issue of Hospital Acquired Infections (HAI, later renamed Hospital Associated Infections) was. NHS research in the mid-1990s suggested that in acute healthcare, infections may have been responsible for about 5,000 deaths each year. It appeared to HSE that of these about 3,000 RPPD may be preventable by applying the existing legislation of the Control of Substances Hazardous to Health Regulations 1989 (COSHH) and HSWA. Infection control became an essential part of hospital audits and

seemingly progress was made on frontline controls and infection control management.

A development of this was that HSWA also applied to healthcare practice. HSE made it clear from the start that it did not get involved in matters within the normal range of clinical judgement but HSWA did apply to gross errors, and failures of process and equipment. Some issues were more easily dealt with than others but again some incidents were investigated. Alongside traditional risks, initial discussions took place during hospital audits with medical and clinical staff and directors as to how the risk management techniques from HSWA particularly from the high hazard sectors could be applied to clinical practice. This opened up the opportunity of using new methods to improve healthcare performance and the suggestions were understood and positively responded to. It was an approach that was consistent with legal requirements and HSE policy at the time. However within a year or two in around 2000 the Independent Healthcare Regulators (IHR) were created and HSE withdrew from this developing line of patient safety.

3.7 Healthcare Regulation and Independent Healthcare Regulators (IHR)

There was growing concern over patient safety in the late 1990s. The UK Government decided in 1997 to create independent healthcare regulators (IHR). These were set up in each of England, Scotland, Wales, and Northern Ireland. These bodies made no commitment to inspect and regulate to the standards of HSWA proportionate to the high hazards and risks present. HSE made agreements with these IHRs, in effect working protocols, where each side would co-ordinate activities, and there would be an exchange of information on 'matters of evident concern' within each body's remit.

What did not happen was a due-diligence check to see that the requirements of HSWA as it applied to patients in healthcare were being delivered. This meant there was not a check to make sure that section 18 of HSWA (which deals with the responsibility for the enforcement of the relevant statutory provision) was being achieved, there was not a check for effective regulation. With HSE's withdrawal from being the lead in patient safety it lost the intent, drive and expertise to apply its legislation to patient safety even though it still retained an overarching responsibility. Over the succeeding fifteen years there has been a stream of high profile cases showing that the regulation of the health and safety on patient safety was not working. In no part of the UK was there a body applying HSWA standards, particularly not to the high standards required for the very high hazards and high risks encountered. These IHR bodies had expertise in healthcare but not in health and safety risk management, the law, or the control of high hazards. The strong driver provided by HSWA standards being a legal requirement was lost. Standards were lost and a strong motivation to achieve them vanished. The situation continued with the IHRs going through bouts of severe

criticism and changes without the issue of HSWA or equivalent standards being addressed. Each year the IHRs and HSE renewed their Memoranda or Letters of Understanding. There was still no due diligence check on HSWA compliance on section 3 and patient safety.

The issue got some airing with the second public inquiry into Mid Staffordshire NHS Foundation Trust and the Francis Report. Sir Robert Francis found what he called a 'regulatory gap'. That is neither the IHR - the Care Quality Commission (CQC) nor HSE alone or in combination ensured the safety of patients either at the hospital or for healthcare in England generally. The Francis Report spent about 300 pages on regulation and made a large number of recommendations (numbers 19-63, 87-89) on the need to improve the regulation of healthcare. It called for a strengthened, improved organisation and fully independent healthcare regulator. These IHRs were certainly not as effective as they needed to be, but they were regulating, and they were driving up standards. The bodies themselves were something to work with; they could be made to work. The UK Government accepted the Francis recommendations and they are being put to effect by the CQC and other bodies.

The situation in Scotland has similarities and differences. There was the same error of not having effective compliance or regulation on HSWA. However in 2010 the Scottish Government took the unusual, and illegal, step of abolishing the IHR. This was a contravention of HSWA. Francis recommendation 87 (and others) clarifies that the situation in Scotland is wholly unacceptable, and unsafe.

3.8 Healthcare in Scotland and No Regulation

HSE had transferred the lead responsibility for regulating healthcare and social care in Scotland to 'The Scottish Commission for the Regulation of Care' (known as the Care Commission). In 2010 the Scottish Government (SG) under Mr Alex Salmond, with the Cabinet Secretary for Health and Well-Being, Nicola Sturgeon, and Mr John Swinney as sponsor of the Bill abolished what was the independent healthcare regulator for Scotland, and so with it ended the proactive regulation of patient safety in Scotland. With its Public Sector Reform (Scotland) Act 2010 the SG created the NHS Scotland body – 'Healthcare Improvement Scotland' (HIS). The in-house HIS was given a limited range of quality assurance and scrutiny roles, but the Act itself had created the regulatory vacuum for the NHS in Scotland. In failing to implement HSWA and abolishing regulation, in two respects the Scottish Government has set back patient safety in Scotland by forty years to the time before the creation of HSWA in 1974. Since April 2011 Scotland has had no independent healthcare regulator for HSWA. No regulation in a high hazard and high risk sector is not the 'effective regulation' that the law requires (s18 HSWA). This is major breach of HSWA in itself and one created by the Scottish Government and its then Cabinet Secretary for Health and Well-Being. The SG had created the extreme

situation of the area of highest risk covered by the lowest form of regulation – none. This is the exact opposite of what the law and UK policy requires. Additionally there could be a Judicial Review of the SG's decisions.

The anomaly has continued unabated with HSE in Scotland making annual agreements with a body which was not a regulator. It is not clear if HSE realised that Scotland had no regulator for healthcare. In the absence of an IHR the Act required that HSE should have assumed the full responsibilities of regulating healthcare. It did not. HSE does not have the resources to fulfil this role.

Scotland thereby moved from a position of having inadequate regulation to that of having no regulation to prevent harm to patients in NHS Scotland. The rest of the UK had a 'regulatory gap' (Francis Report) but Scotland has a 'regulatory vacuum'. The law requires regulation to ensure that there are effective protective measures in place to secure patient safety under the Act before any harm occurs, not just to be there to take action on a few limited cases after deaths have occurred which is the situation in Scotland. This means that patients in Scotland have a much lower standard of protection than those in the rest of the UK and the effects can be demonstrated. An obvious example is on infection control. There is the repeated poor infection control at NHS Lanarkshire's Hairmyres Hospital (November 2014) and Edinburgh Western General (January 2015), at NHS Greater Glasgow and Clyde (October 2014), and another C. difficile outbreak this time at Edinburgh Royal Infirmary (December 2014) and the three or more associated deaths (see NHS Scotland's Healthcare Environment Inspectorate (HEI) reports on all four from the last four months). HEI says it does not investigate causes of outbreaks, there is no body investigating causes of outbreaks, or root causes, or carrying out regulatory action, no application of the law; the situation on infection control in Scotland is literally lawless. In all other UK sectors health and safety regulation is required and this is proportionate to the hazards and risks. In healthcare and social care both hazards and risks are extremely high and the controls and regulation are required to be of a high order. Scottish healthcare with its no regulation is absolutely not allowed by UK law or policy. However, Scottish Ministers, HIS and its Healthcare Environment Inspectorate think that it is allowed. If regulation is not required for healthcare where the hazards and risks are the highest of any sector then by that logic safety regulation is not required anywhere. The Scottish Government reduces its position on patient safety to one of absurdity.

The acts and omissions of the Scottish Government and its ministers constitute major breaches of UK and EU law with consequences for both of them. These stem from the two points:

1. The Scottish Government has devolved responsibility for healthcare and social care. It has not implemented the UK-wide HSWA in

respect of how it applies to patients and those in its care. The SG and its ministers have been reminded of this responsibility since April 2012. But they have refused to act and ignore the law.

2. The Scottish Government and its ministers abolished the regulation of healthcare and have refused to create the required independent healthcare regulator. They have been reminded of their responsibilities on this since December 2013, they refuse to act.

These and related matters create breaches of UK-wide law. The breaches relate to the SG duty of care under section 3 of HSWA to those affected by its acts and omissions. Also on social care to those in care as the SG's regulator, the Care Inspectorate does not operate to the required HSWA standards. Ministers and senior officers have organisational and personal legal responsibilities under HSWA, the Human Rights Act 1998 (HRA) in the duties to protect life and the Scotland Act 1998. In addition to the Government, its Health and Social Care Directorate (HSCD) and NHS Scotland are in breach of s3, whilst individuals will be in breach of the general responsibility of s7 but also s37 and s36 as they apply to the failure to implement an effective plan and other management arrangements to deliver HSWA compliance on patient safety. Ministers and senior officers do not have Crown protection as HSWA s48 makes clear. The failure to implement the Act and then to block its regulation has severe consequences and relates to loss of life and other harm on a very large scale. There are serious penalties for organisations and individuals under section 33 of the Act.

The HSWA is a practical means of the government complying with HRA 1998 in respect of preventing deaths of those in its care. Irrespective of HSWA, HRA places responsibilities on the Scottish Government. The failure to have in place effective precautions and regulation to prevent death is an omission that constitutes a breach of regulation 6(1) under article 2 of the European Convention on Human Rights (ECHR) duty to protect life. The abolishing of the independent healthcare regulator and other acts by ministers counter to patient safety are also covered by the Scotland Act 1998. This is under s57(2) 'A member of the Scottish Executive has no power to make any subordinate legislation, or to do any other act, so far as the legislation or act is incompatible with any of the Convention rights'. With HRA and the ECHR, to act counter to ECHR constitutes a breach by the Scottish Government as a result of its ministers.

The situation is of major breaches of HSWA, HRA and the Scotland Act 1998 by the Scottish Government and its ministers with the consequences of large-scale avoidable deaths.

The Scottish Government, two Scottish First Ministers, three Cabinet Secretaries for Health and Wellbeing and the Lord Advocate have not shown an understanding of the issues and have not indicated any sign of action to address the breaches of law and severe consequences that it creates. There was no sign that the previous Justice Secretary was acting on what is a very large gap in Scottish statutory compliance

related to large-scale avoidable harm. The new Justice Secretary is continuing the policy. Since the November 2014 reshuffle following Mr Salmond's resignation the policy of defiance of HSWA, HRA and the Scotland Act 1998 has continued under Ms Sturgeon in relation to healthcare and social care.

The situation of a constituent government in the UK disregarding and defying major UK, EU and International Law and related to such loss of life appears to be without precedent. It could also be convicted for numerous cases under the Corporate Manslaughter and Corporate Homicide Act 2007. It does not appear to be a situation that can be allowed to continue. Three pillars of what might be called a civilised society, that of public safety, a just and legal government, and a sound legal system are in serious jeopardy in Scotland.

4. Vale of Leven Hospital Public Inquiry 2009-2014

The Vale of Leven Hospital (VOLH) public inquiry was set up by Ms Nicola Sturgeon as Scottish Cabinet Secretary for Health and Wellbeing and Scottish Ministers to investigate the occurrence of a Clostridium difficile infection at the Vale of Leven Hospital 2007/2008. The Inquiry in particular investigated the deaths associated with C. difficile which occurred between 1 December 2007 and 1 June 2008. HSE and the police made an initial investigation within their remit but then withdrew. Subsequently the chair, Lord MacLean, of the inquiry met the then Cabinet Secretary for Health and Wellbeing, Ms Nicola Sturgeon, in Glasgow on 29 July 2009 and discussed the terms of the remit (foreword to VOLH report). The CS for Health should have known the main legislation that applied to the issues of the inquiry. For whatever reason Ms Sturgeon did not inform the chair that it was HSWA, the Control of Substances Hazardous to Health Regulations (COSHH 1989 onwards) as applied to microbiological agents, and the Management of Health and Safety at Work Regulations 1992/1999 (MHSWR). The inquiry was about infection control and HSWA had at that date applied to this matter for 35 years. For whatever reason Ms Sturgeon did not correctly brief Lord MacLean.

The error of Ms Sturgeon and the Scottish Ministers is confirmed in the supporting documentation to the inquiry. There is the Scottish Ministers Closing Submission of 30 August 2012. This is in the information they say they provided to the inquiry to assist it in meeting its terms of reference on investigating the C. difficile outbreak affecting 143 patients and a major factor in at least 34 deaths. There is a section headed *Legislative Arrangements* paragraphs 258-266 'The Scottish Ministers consider that the inquiry might find it helpful to have a short outline of the legislative framework in Scotland regarding healthcare'. They did not mention the main legislation that applied to the prevention of the outbreak and the consequent deaths. They then state para 264 'In conclusion Scottish Ministers submit that…. (iii) the legislative

arrangements in place in Scotland relating to healthcare are appropriate'. This statement is incorrect. The Scottish Ministers completely disregarded the main legislation that does apply and if complied with should have prevented the outbreak. It should also prevent the infection control failings at other NHS boards. This legislation should be embedded with all healthcare bodies, and complied with to the standards commensurate with the high hazards and very high risks. It must also be effectively regulated by a fully independent healthcare regulator.

HSE was not a Core Participant of the inquiry nor did it give evidence. HSE was involved about the 24 November 2008 when it carried out some enquiries with Strathclyde Police. In May 2009 Crown Counsel (COPFS) instructed that no criminal proceedings were to be taken. There is no evidence of any other HSE involvement in the inquiry. In view of the massive failings to comply with HSWA, COSHH, and MHSWR reported in the VOLH report of 24 November 2014 then it would have seemed essential for COPFS to have reviewed its decision.

None of the Core Participants in the public inquiry- NHS Scotland, Healthcare Protection Scotland, expert witnesses, VOLH and NHS Greater Glasgow and Clyde and staff, made any reference to the main legislation that applied and would have prevented the outbreak as far as one could reasonably expect. This is a gross omission demonstrating and indicative of systematic failings of a monumental scale. These failings of healthcare in Scotland are not restricted to infection control or to VOLH.

Whilst the report disregards the law and regulation it does refer to inspection. There is the NHS Scotland in-house body Healthcare Environment Inspectorate (HEI) that carries out inspections. It is not a regulator, does not apply the legally binding standards of HSWA, COSHH and MHSWR. It says that it does not investigate the causes of infection outbreaks. It does not have the enforcement powers required e.g. that regulators such as HSE, ORR, ONR have. There have to be strong enforcement powers in high hazard sectors including stopping very dangerous activities, securing improvements within a specified time, and to initiate if not carry out prosecutions. These powers are essential particularly given the very high hazards and risks of healthcare and social care.

HEI states both in the VOLH report (section 6.6) and in personal correspondence that it does not need enforcement powers and that the current situation is satisfactory. This is the situation of one of the highest hazards in Scotland being dealt with by the lowest standard of regulation, i.e. none. If regulation is not required for infection control and healthcare generally then the logic would be that it is not required anywhere, in any sector. Whereas by law, the reverse is the case. A basic familiarity with the public inquiry reports for Mid Staffordshire and for the Piper Alpha disaster will remind that there must be the effective

independent regulator. In Piper Alpha, Lord Cullen made the point, as is similarly the case here, that part of Government, the Department of Energy, had blocked safety improvements that could have prevented the disaster (the introduction of the now well-established safety case regime used in other conventional high hazard sectors). The position of the VOLH report is to stand in the face of the legal requirement to have effective regulation and this has implications for compliance with both UK and EU legislation. The position is not tenable. There must be effective fully independent healthcare and social care regulators working to the standards of HSWA (or equivalent statutory standards which achieves the same standard as HSWA).

The Scottish Government commissioned the Crerar Review on "Regulation, Audit, Inspection and Complaints Handling of Public Services in Scotland" of September 2007. The review displayed no understanding of the level of risks in healthcare, of HSWA or of regulation. Crerar relied on 'scrutiny' rather than regulation. Scrutiny is not regulation. The SG confuses regulation (IHR, HSE) and scrutiny (HIS, HEI). The two are very different functions. Scrutiny is 'critical gaze', 'a close examination of details or investigation'. Regulate is 'control by rule, subject to restrictions, so that an activity may work accurately'. Scrutiny does not ensure that something does happen, it is much more passive; regulation in healthcare has to be active to prevent harm. Piper Alpha was seminal in the history of Scotland and its lessons including that on regulation should not be forgotten. In terms of avoidable deaths in healthcare and social care the numbers are likely to be comparable with one Piper Alpha disaster occurring every month.

In the Francis Report recommendations 19-63, 87-90 and others deal with the independent healthcare regulator. This topic was totally missing from VOLH. In Francis there are about 300 pages devoted to regulation, here there is no regulation. There is only the limited range of subjects scrutinised by NHS's HIS and HEI inspection without the underpinning law and no regulation. The independent healthcare regulator needed to be created as a matter of urgency. VOLH did not address this, and was probably totally derailed by being misled by the SG on the applicable law. Even so, a public inquiry should make its own checks particularly when the information was provided by a vested-interest body such as SG.

Ms Sturgeon and the Scottish Ministers misled the inquiry, and so obstructed its purpose. The report could not thereby meet it terms of reference. VOLH should have had major lessons for healthcare across Scotland in respect of frontline controls, management systems, corporate and organisational culture and effective regulation. These are all required by HSWA and to a very high standard commensurate with the high hazards and current high risks. The report did not address these and certainly not to the standard required.

In the 1990s HSE was carrying out proactive inspections on infection control dealing with issues that formed the terms of reference for the inquiry on the risk of harm. An HM inspector finding the conditions reported on by the inquiry report would recognise major breaches of HSWA, COSHH and MHSWR. Given the scale of the breaches and the risk of deaths, it would very strongly point to a prosecution and immediate enforcement action on all three pieces of legislation. HSE's enforcement code (EMM Enforcement Management Model) would confirm that professional opinion. I developed the code's application and initiated the development on how it applied to health risks.

The report should have investigated the issues with the legal requirements as the basis, but it did not. There is a great deal of difference between the report's 'guidance' and 'inspection' and the essential legal requirements and regulation by a fully independent healthcare regulator. The report did not identify the underlying causes or the legally required remedies. For several reasons the inquiry took six years and cost over £10 million. From personal experience, a small team from an effective regulator should have been able to come up with the main findings within a week and issued enforcement notices to solve both frontline failures, management systems and other underlying causes of the outbreak.

Any reading of the second report of the Mid Staffordshire NHS Foundation Trust public inquiry would make it clear that the law, HSWA, applies and its compliance requires effective regulation. The first page of the text would be sufficient to show that. Similarly reading the Piper Alpha public inquiry report on the disaster showed the consequences of the error that the Scottish Government is repeating on its refusal to have a fully independent healthcare regulator.

The covering letter to the VOLH report stated that 'The terms of reference were very wide-ranging and I have addressed these, I hope, comprehensively, as can be seen from the Report which I now present to you'. The report made not one reference to the legislation that should have been the primary standard by which to judge the situation at VOLH and the requirements to prevent a recurrence or address the management and cultural issues both here and across healthcare in Scotland. There is a Scotland-wide absence of knowledge that the law applies to healthcare to prevent harm, what it means, and the essential high standard of fully independent healthcare regulation.

In comparison the Mid Staffordshire NHS Foundation Trust report found poor conditions, poor management and poor regulation. VOLH found poor conditions, poor management but then made no reference to the need for effective regulation. No regulation exists for NHS Scotland to prevent avoidable harm, and SG had not noticed. It seems to be a permanent blind spot.

Healthcare in Scotland gets very little scrutiny in comparison with other parts of the UK. The VOLH public inquiry dealt with the avoidable deaths of 30-50 patients but in terms of its coverage and impact it was very little. Mid Staffordshire made a big impact in the rest of the UK but not here. The Vale of Leven has not had the impact required of a public inquiry into what was a disaster. The report needed to address the unsatisfactory conditions in Scottish hospitals not just VOLH. HEI reports show continuing allied failures in other Scottish hospitals including VOLH's parent NHS Board – Greater Glasgow and Clyde (October 2014), in NHS Lanarkshire (November 2014) , with the Edinburgh Royal Infirmary C. difficile outbreak of November/December 2014, and Edinburgh Western General January 2015. These basic hygiene problems should have been solved twenty years ago. **The position on infection control in Scottish hospitals is indefensible and highly illegal**. VOLH needed to address failures of management and culture, of competent HSWA input, absence of law or compliance, and the absence of effective regulation. VOLH failed to make the recommendations required.

By contrast Mid Staffordshire has made a major impact. VOLH doesn't look able to do so. It omitted the fundamental law. Mr Salmond regarded Mid Staffs as 'an English problem' (Scottish First Minister questions after the second report came out). The recommendations from the Francis Report were said by him to be considered by SG. As above, SG could not implement a large number of the recommendations as it had no regulation, the 'regulatory vacuum'. Mr Salmond relies on Scottish healthcare being organised differently to that in England whereas any assessment should be based on what the law requires and what is effective, adapted to the considerations of what is possible and willing to be paid. Mr Salmond paid no regard to the defects in Scotland.

The VOLH report dealt with a high hazard and risk issue being a major cause implicated in the deaths of a large number of patients. Poor infection control has been responsible for the deaths of thousands in the UK. It is covered by UK-wide legislation that requires high standards of physical controls, management, and both corporate and organisational culture. The report did not require healthcare in Scotland to comply with the law: it did not appreciate the very high standards required commensurate with the hazards and the risks, and it omitted the statutory need for effective regulation. Previous public inquiries have stressed that regulation must be fully independent of those who have the responsibilities for controlling the risks and other stakeholders. The VOLH report in effect sanctions the failures of the SG in disregarding the main legislation that should have prevented the outbreak and their insistence on there being no need for regulation. The report has implications for SGs breaches of HSWA, HRA and the Scotland Act 1998. The inquiry and its report should not be considered acceptable for a Scottish, UK, or international standard for a public inquiry.

VOLH displays that the SG has a lack of understanding of risk management particularly for a high risk environment, the most basic principle of regulation needing to be proportionate to the hazard and risk, and a lack of understanding of the role and responsibilities of government. These deficiencies are the personal responsibilities of Ms Sturgeon and Mr Salmond. The lessons are not being identified or learnt, and lives are being lost unnecessarily.

There is another public inquiry due to report shortly that points to the underlying cause of all the problems. This is the Penrose Inquiry into contaminated blood products associated with transmission of Hepatitis C / HIV and subsequent deaths. This is another issue covered by HSWA and formerly HSE inspected and regulated blood transfusion services. I inspected the Manchester regional centre of the National Blood Transfusion Service and dealt with matters relevant to the inquiry. The inquiry term of reference 1, deals with the role of government in regulation, with 8 and 11 also applying. Whilst the report will not be issued until the 25 March 2015, the briefing to the inquiry, evidence and the 'Scottish Government Closing Submission' all disregard HSWA that encompasses the matters. The documents refer to the Medicines Acts but that is only part of the legislation and is not the legislative framework that covers the range of matters in preventing harm. It is difficult to see how the inquiry can fulfil the terms of reference if it does not consider the main legislation that should apply and prevent harm, and the Scottish Government has no regulation of the main matters being considered.

The Scottish Government's submission deals with 'The Standard of Scrutiny' whereas Lord Penrose term of reference required 'regulation', presumably because SG had not got a regulator to regulate. The SG deals with its decision-making in paragraphs 23 -27. It talks of 'public law':

'26. Nonetheless the Scottish Government's view is that the public-law test is helpful in showing the approach that is most appropriate.'

Public law (*ius publicum)* includes criminal law but SG then disregards HSWA. This leads to the position whereby the decision-making process is in error if it does not include the criminal law that applies to a particularly situation. SG does not include HSWA in healthcare and social care. The general situation may be summarised as **the Scottish Government's decision-making on patient safety is criminally negligent**. It does not know where the law applies, it does not know what it means, it does not comply with the law, and as a consequence a great deal of avoidable harm occurs and with it many avoidable deaths

5. NHS Lanarkshire Hospitals

In 2013 NHS Scotland's in-house quality assurance and scrutiny body, Healthcare Improvement Scotland (HIS) carried out a 'A Rapid Review

of the Safety and Quality of Care for Acute Adult Patients in NHS Lanarkshire'. This was as a result of concern over apparent excess standardised mortality rates at three NHS Lanarkshire hospitals. This was the first time that HIS had carried out such an exercise. The exercise was limited and did not investigate the range of factors that could affect patient mortality. The HIS lack of experience showed. It did not seem to have anyone with the appropriate experience of such exercises. The review also did not reference the main legal requirement, HSWA. It was predominantly carried out by NHS personnel without apparently anyone with healthcare - HSWA risk management expertise. The Management of Health and Safety at Work Regulations 1999 (MHSWR) Regulation 7 requires HSWA competence input to advise on dutyholder's legal responsibilities.

The Review did find serious concerns over patient care (report section 6). The tone of the report is calm and reassuring whereas its findings should have been a cause of great concern. HIS found evidence of very poor monitoring, and management of patient's vital signs. HSE as the default regulator should have been called in immediately to carry out a further investigation to HSWA standards. HIS found the standard of compliance on MEWS (Modified Early Warning System) warning of patients deteriorating by another audit team was between 17- 40% at the three hospitals and this is on something which is patient safety critical (6.21). The NHS board had self-reported much higher performances, with in ward self-reporting at over 95%. This is on data reviewed by the board's SPSP (Scottish Patient Safety Programme). That is a staggering error of misrepresenting safety performance and suggesting performance was acceptable when it certainly was not. This is one example of the dangers of being reliant on NHS board performance data (this is also a breach of HSWA and MHSWR 1999 Regulation 5 with respect to the monitoring of performance). The SPSP was of little relevance to staff and it had not made significant improvement at the hospitals reviewed.

Responses to patients deteriorating conditions was highly variable and depended on the time of day it occurred (probably day of the week as well). HIS found initial evidence of the same problem that gave rise to the prosecution of NHS Mid Staffordshire, i.e. poor communications at shift handovers related to the death of Gillian Astbury (poor communications at shift handover was also a major cause of the Piper Alpha disaster, and for that matter the UK/Scotland's biggest rail disaster at Quintinshill 1915). These two findings alone would warrant a thorough investigation by those with healthcare expertise and with legal HSWA- risk management expertise in high hazard and risk. This did not take place. HIS did not inform HSE of these matters that would have justified prosecution by HSE's enforcement code (EMM). When eventually HSE was informed (this report's author in March 2014) HSE refused to get involved and said it was a matter for the Scottish Government. The effect of this is that Scotland gets a lower standard of protection than the rest of the UK due to SG and HSE. At Lanarkshire,

there were very serious problems that put patients at risk, and would certainly have been expected to result in avoidable deaths. Here in Lanarkshire as in the rest of Scotland there was no regulation. This is another case of Scotland's areas of highest risk getting the lowest form of regulation, none.

The HIS report on Lanarkshire should be read in comparison with the Mid Staffs NHS Foundation Trust public inquiry report for the types of issues that could be investigated in relation to avoidable deaths. Both involved consideration of excess standardised mortality rates but their investigations were very different. The Lanarkshire inquiry should have been expanded to deal with the range of factors that could affect excess standardised mortality rates, and should have explicitly dealt with statutory compliance. It should have recognised the absence of legal compliance, and the absence of regulation. It should have identified what was needed to bring Lanarkshire and NHS Scotland up to statutory compliance.

At NHS Lanarkshire's Hairmyres hospital (2013-2014) there has been a further demonstration of the failure of NHS – HIS and HEI scrutiny to achieve acceptable standards. HEI has made repeated visits inspecting on infection control and finds major concerns. It is not a regulator and does not have enforcement powers to make sure that recommendations are effectively acted on. HEI found major breaches of COSHH, MHSWR, and HSWA, just as in Vale of Leven, it did not notify the default regulator HSE and refused to do so when I pointed out their failure to involve the regulator on very serious breaches of law was putting lives at risk.

The NHS Scotland HIS 'Rapid Review' was presented to the Scottish Parliament by the then Cabinet Secretary for Health and Well-Being, Alex Neil on 17 December 2013. At the end of Mr Neil's statement, he referred to the HIS as 'the independent regulator'. http://www.bbc.co.uk/news/uk-scotland-glasgow-west-25414691 HIS is not a regulator of the NHS. The HIS senior management say that it is not nor can it be as it is part of the NHS. The NHS in Scotland has no independent healthcare regulator; Scotland is the only part of the UK without the essential regulator. Here patient safety is not regulated.

At Lanarkshire the NHS was inspecting and reporting on itself. HIS does not have the independence (either in its governance or in culture) or regulatory powers or competences for HSWA inspections. Its findings should have been characterised as matters of evident concern and as a responsible body reported them as soon as they were discovered to HSE as the default regulator. It could have notified HSE and carried out a thorough joint investigation but it did not. In a situation such as this HSE should have investigated properly and used its enforcement powers proportionate to the high risks found. Mr Neil was factually incorrect and his statement gave false assurance to the Scottish parliament and the public on the report, and actions to follow to bring NHS Lanarkshire up to

standard. The HIS Rapid Review was inadequate to assess patient safety and possible excess mortality rates. If NHS had had an effective independent healthcare regulator then the failings at NHS Lanarkshire should not have happened.

I challenged Mr Neil on the absence of the IHR and his misleading statement to Holyrood. He would not answer the points. Mr Neil was also challenged in a written PQ on 13 February 2014 by Neil Findlay Shadow Health and Well-Being over his false statement. By this time it looks as if it had registered with Mr Neil that HIS was not a regulator of the NHS, and he did not repeat his error, instead he made another serious error. Mr Findlay asked Mr Neil and his Government to recreate the IHR. Mr Neil on behalf of the Scottish Government refused to do so. This placed Mr Neil in breach of HSWA s7, 36, and 37 as provided for by s48 as it applies to servants of the Crown (i.e. ministers and senior civil servants). The misleading of Holyrood and the failing to uphold HSWA led to the breach of the commensurate Human Rights Act 1998 as it applied to prevention of deaths of those in its care. In addition, this meant that the Cabinet Secretary for Health was in breach of The Scotland Act 1998 s57 (2).

The position of Mr Neil misleading parliament was a prima facie breach of the Ministerial Code. By not implementing HSWA or ensuring that the NHS in Scotland had a plan to comply with the standards required, or to create the regulator he was obstructing the law and justice. This position was quite conscious. He had also received the reminders on HSWA. The consequences of this wilful neglect were a large number of reasonably preventable premature deaths (RPPD). I referred the matter to the Scottish Presiding Officer, Ms Tricia Marwick and to the Scottish First Minister, Mr Alex Salmond. It is not within the remit of the Presiding Officer to enforce the Ministerial Code and so the responsibility was with Mr Salmond. This went to Mr Salmond in March 2014. Mr Neil continued as CS Health and also continued his policy of failing to have as his primary intent on patient safety, that health and social care providers comply with HSWA, and that they comply with the high standard required. He continued to refuse to create the IHR.

SG has its Scottish Patient Safety Programme (SPSP), which is a collection of initiatives but it is not strategic, coherent, nor based on an adequate risk-profile of the factors affecting patient mortality or other harm. It definitely does not meet the requirements of HSWA. SPSP was supposed to address creating a culture of safety. You do not do this by wholly disregarding the law and standards that apply. SPSP is part of a system of guidance. There is a distinction to be drawn between ‘nice to have, optional’ guidance and standards backed by regulation and the law (see CQC terminology). The law requires a systematic plan to control the risks in a proportionate and legally robust manner. Mr Neil was moved from his post 22 November 2014. However, his successor Ms Shona Robison has said that she is continuing Mr Neil’s and the

Government's policies, which are of disregard of the law and its regulation.

Mr Salmond was fully aware of the situation and his Government's failings to comply with UK-wide legislation. Despite numerous chasing messages, he refused to answer despite his repeated promises to do so. His Deputy First Minister for Scotland, the CS Health, CS Justice, and the Lord Advocate were all aware of the situation and major breaches of the law. It is one of those cases where each day's delay, by Mr Salmond and his ministers, in acting to prevent the harm would subsequently result in avoidable deaths. It is incontrovertible that this is the case, the exact numbers of deaths each day is unknowable, but it is high and unacceptable. Not one of the ministers seems to have taken any effective action within their roles and responsibilities to address the issues. Since they relate directly to what the law requires it constitutes failures to uphold justice and so too breaches of the Ministerial Code.

Mr Salmond failed to require the resignation of Mr Neil in what was a straightforward misleading of parliament. This was not on a trivial matter but one relating to a very large number of avoidable deaths. Mr Salmond did not uphold the Ministerial Code so setting himself against parliamentary procedures. When challenged on this he did not refer himself to the independent advisors on the Ministerial Code. He was condoning Mr Neil's misleading of Holyrood in giving false assurance, and pretending that the SG had effective regulation of healthcare when it had none.

Mr Salmond also presided over the government that misled the Vale of Leven public inquiry, the abolition of the legally required and essential independent healthcare regulator, and the further disregarding of HSWA even after being reminded of the major gap in April 2012 onwards. Since then there are likely to have been around 5,000-6,000 reasonably preventable premature deaths in Scotland associated with his government's failure to implement HSWA to the standards required. Summarising Mr Salmond's position, he:

1. presided over the removal of the Scottish independent healthcare regulator.
2. presided over the SG's disregarding of UK-wide law that should have saved thousand of avoidable premature deaths.
3. misled the VOLH public inquiry as a 'Scottish Minister' making submissions to the inquiry.
4. did not uphold his responsibilities under the Ministerial Code by not dismissing Mr Neil after he misled parliament on a major issue affecting the lives of many.
5. breached the Ministerial Code by not upholding justice by obstructing HSWA
6. committed breaches of HSWA s7, 36, and 37 as allowed by s48. Custodial sentences can apply.
7. caused the Scottish Government to be in breach of HRA 1998

8. is personally responsible for breach of s57(2) of the Scotland Act 1998

When it became apparent that the Cabinet Secretary for Health (Alex Neil) and the Director General Health & Social Care and Chief Executive NHS Scotland (Derek Feeley) were unwilling to address the issues, the matters were referred to the Lord Advocate Frank Mulholland on 12 December 2013. Even before HIS found the major problems at NHS Lanarkshire the underlying problems for SG and healthcare in Scotland were very apparent. These showed in the large number of NHS adverse incident reports, most of Scottish Public Service Ombudsman reports, and in particularly cases brought into the media attention. None of these numerous reports made any reference to HSWA as the legislation that would, if complied with, have prevented them as far as was reasonable. Apparently, in Scotland there was no knowledge or application of the law, this is quite possibly the biggest error in terms of law, and with major consequences, that a government could make.

On 12 December 2012 I hand-delivered a letter to the Lord Advocate Mr Frank Mulholland on the 'Absence of Legal Process' to secure patient safety and of those in social care. I provided background information, a selection of the large amount of evidence to show the scale of the harm caused by not complying with the law (Appendix 3), and what the main legal requirements were (Appendix 4). I chased up over the following ten months but Mr Mulholland refused to intervene on the major case of legal and procedural maladministration, such as by advising the SG on the matters or by applying pressure to Scottish Ministers to comply with the law. He regarded it as a matter for the CS Health (who had already shown his disregard for the law and its regulation) and HSCD (Health and Social Care Directorate) who had already spent 18 months showing their lack of understanding of the law and the consequences of the failures to comply with it. The SG policy was of to do nothing on patient safety and HSWA compliance.

The Lord Advocate has responsibilities. According to the SG, his role and functions include being head of the systems of prosecution and investigation of deaths and being principal legal adviser to the Scottish Government.

Further, like the other UK Law Officers, the Lord Advocate is given a particular role in relation to ensuring that legislation passed by the Scottish Parliament is within the legislative competence of the Parliament. He has particular powers under the Scotland Act in relation to the resolution of legal questions about the devolved powers of Ministers and the Parliament. In view of this responsibility, the Lord Advocate should not have allowed the Scottish Public Services Reform (Scotland) Act 2010 to proceed as presented by Mr Swinney. The Act contained a matter of substance that was not within the legislative competence of the Parliament because it related to reserved legislation – the effective regulation of HSWA. This was the legislation that

removed a regulator (s52) namely the Scottish Commission for the Regulation of Care. The role of the Commission involved the safety of patients and of those in social care as is covered by HSWA. The 2010 Act also concreted in place Scotland's lack of the IHR and so ensured that there could not be the effective regulation of HSWA as required by s18 of HSWA. It left Scotland without regulation in what is one of the highest if not the highest area of risk covered by the legislation in the UK. This also contributed to Scotland's First Minister Mr Salmond, Ms Sturgeon as CS for Health, and Mr Swinney being in breach of s57 (2) of the Scotland Act 1998 and the Scottish Government being in breach of HRA 1998. Scotland now has a lower standard of protection for patients and those in social care than there is in the rest of the UK. The omission creates further breaches of HSWA s7 and s37, and quite probably s36 as provided for by s48. The Ministerial Code applies to the post of Lord Advocate and this includes upholding justice, where sanctioning the disregard for GB-law on patient safety would not seem to be in accord with the position.

Further in the case of the Scottish Public Services Reform (Scotland) Act 2010, before the Bill could be introduced in the Parliament by the Government, the minister responsible had to state that it was in his or her view within the legislative competence of the Parliament. This view is supposed to be reached on the advice of the Law Officers. The minister who introduced this Bill this was Mr John Swinney the Cabinet Secretary for Finance & Sustainable Growth. This is another error of procedure. Mr Swinney's action creates breaches of HSWA, HRA and the Scotland Act 1998, for which he holds personal responsibility. It is worth noting that the Scottish Parliament website states that the Bill was not subject to consultation. This suggests that HSE were not asked if they would take on a 'CQC' role. HSE was never going to be in a position to do this, even if it wanted to. If there had been the usual consultation and due diligence test this error of removing the IHR could have been prevented. That would have averted a very serious case of Scottish Government maladministration, and the on-going inadequate protection for the Scottish public.

As head of the Crown Office and Procurator Fiscal Service (COPFS) a main role and responsibility of the Lord Advocate is to 'investigate, prosecute and prevent crime'. It may not have been initially appreciated but the probable main breach of legislation in Scotland results in a large number of deaths. It is of course criminal law and falls within the role of the Lord Advocate and COPFS to prevent. There also seemed to be a fundamental misunderstanding at the office of the Lord Advocate. In correspondence directly on behalf of the Lord Advocate the suggestion made was that breaches in HSWA occur when deaths or other harm occur. Whereas unlike most COPFS homicide cases, HSWA offences are for failures to have in place effective precautions period, and not any harm that may result from these failures. Any deaths that do occur may be a prompt for enforcement action but they still have to be shown to be as a result of the failures. Offences occur *before* any harm occurs. This

is fundamental and shifts the emphasis to prevention rather than action after any death or harm occurs. Action is required to prevent harm and that is how the independent healthcare regulator should function, not wait until deaths occur. It was disconcerting to see this apparent lack of understanding by the Lord Advocate. It was subsequently corrected by one of his officers. The Lord Advocate has not regarded it as his job to advise SG on this very important legal matter, he regarded it as being for the 'Health Directorate' alone to sort out when they are one of the major problems in ignoring the main law applying to patient safety. It is the Lord Advocate's role and job description to uphold the UK law, and to advise SG of their errors and regulatory vacuum in Scotland.

Mr Salmond was frequently reminded of the SG failures, and of his failure to remedy the defects. These were the responsibilities of his ministers at that time. These were former CS Health and Scottish Deputy First Minister Nicola Surgeon, CS Health Alex Neil, CS Justice Kenny MacAskill, CS Finance John Swinney and the Lord Advocate Frank Mulholland. The reminders continued right up to the Scottish First Minister's resignation on 19 September 2014. These failures related to on-going preventable deaths occurring on a daily basis and the matter should definitely not have been ignored; but it was, by Mr Salmond and his colleagues.

The Francis Report majors on patient safety which is a UK-wide issue covered by GB/UK law. The Scottish Government disregards the law, and has done very little to implement the Francis Report, and the people of Scotland pay the price.

The new cabinet continues the policy with HSWA not recognised in Scotland, not implemented, not regulated, and massive harm is permitted as a result.

6. NHS Ayrshire and Arran (A & A)

The Ayrshire and Arran (A & A) NHS Board were convicted under section 3 HSWA (18 August 2014) relating to the death of Nicola Black. As was noted by the Sherriff Brian Murphy this should have been a 'never event'. There were gross failures of physical precautions, management systems, corporate and organisational culture to prevent the death. Prior to the creation of independent healthcare regulators across the UK (c2000), HSE was carrying out preventative inspections of mental health units to try to ensure that such incidents were indeed 'never events'.

In the sentencing of A & A the COPFS did not make reference to other relevant cases at the hospitals. There were four similar such hanging suicide/para-suicide type incidents prior to Nicola Black's death (among the 56 CIR/SAER events in the period 2007 – 2011). These could have also been part of a Fatal Accident Inquiry (FAI). No lessons appeared to

have been learnt from these events. Had lessons indeed been learnt and applied, as they should have been, then it should have been certain that Nicola Black's condition would have been managed very differently – and her death would not have occurred. The errors were the most basic and serious ones that could be made on a mental health unit.

The other similar incidents are on the NHS A & A website. These are reports DB06; DB43; DB44 and DB40. Nicola Black's report was DB66 – so therefore lessons should have been learned from the previous incidents and applied in Ms Black's case. They were not. This seems to be blatant criminal negligence above and beyond the specifics used in the information of the case taken in the prosecution. If there was compliance with HSWA backed by HSWA regulator then there should a very good chance that these deaths would not have occurred. There should have been prevention of the first instance, and then if not the following incidents should hopefully have been prevented.

The COPFS had indicated from the outset to the family of Nicola Black that a FAI would take place but later said that there would not be. There are strong grounds for a FAI. It was ruled out by COPFS particularly because there had been a successful prosecution and conviction of A & A. The Crown later said that it covered all the main issues. This was not the case. However by the criteria of FAI it is justified on the grounds that the prosecution did not cover the relevant matters of Nicola Black's death. The prosecution evidence was sufficient to prove the case, there were many other issues relating to the actual death that were not covered such as the roles of line management and senior NHS officers. Secondly, the prosecution did not address the prevention of other deaths, which is particularly relevant in view of other suicides and para-suicides within the NHS board's domain. When HSE was the regulator it carried out preventative regulatory inspections to mental health units and specifically sought to ensure that such events did not happen. There is now no regulator in Scotland doing this. The Mental Welfare Commission Scotland (MWCS) do not do this nor does any organisation. There should not be these 'never events' at any unit in Scotland but precautions at other boards are still lacking. Thirdly, given the role of the Scottish Government, its ministers, and senior officers in setting the policy of healthcare's disregard for HSWA and abolishing the regulator that should have prevented the death, then it is very much in the public interest that there is a FAI if that is what her parents continue to wish for. In view of continuing suicides in Scottish mental health units, it needs to be ensured that all that reasonably can be done, which is the law, is being done.

From information from the parents of Nicola Black, it took two years between her death and HSE starting to investigate the circumstances. If that is the case then that is not the way to investigate a fatality. The evidence needs to be collected promptly and justice delivered in a reasonable time. It needed another two years before the case was heard, the 'legal process' took four years. Any kind of investigation by

the NHS board and COPFS into the death should have immediately shown very blatant breaches of HSWA and the need to contact the regulator urgently. The NHS board is also required to have competent person advice to advise the board on how to comply with the law and on such cases as this (MHSWR Regulation 7). Were they involved? They cannot have been. It would be scandalous if it really did take two years to notify the default regulator, HSE. It seems that it took COPFS two years (firstly with COPFS Kilmarnock, then Glasgow) to involve HSE. If that was the case then the bodies involved could be considered to have obstructed justice, as well as any other offences related to the failures to prevent the death. That would apply to A & A, and may apply to COPFS.

The conviction of Ayrshire and Arran under HSWA enables the specific proven defects to be linked to underlying causes and wider failings to implement HSWA in relation to patient safety as is required. There is a continual stream of avoidable deaths in NHS Scotland that demonstrate similar failings of compliance but this is a prima facie case that requires no further proof of frontline failings and so saves much time and effort in proving other cases.

There was not the effective regulation to HSWA standards at A & A that is specifically required by s18 of HSWA. There is still no IHR as SG refuses to create one (Mr Neil, Mr Salmond, Ms Sturgeon, and Ms Robison). In effect, the SG is refusing to recognise HSWA and understand what it means for the hazards and risks in the sector. This means that it does not require healthcare and social care providers to comply with the legal standards. It has also failed to require the Care Inspectorate that inspects social care facilities, to work to HSWA. This is yet another breach of the Act.

There is no HSWA regulator in either healthcare or social care to make sure dutyholders do understand the law and comply. It is therefore understandable that healthcare providers do not comply with HSWA and substantial harm results. For this misdirection ministers, SG and HSCD, NHS Scotland, and HIS all have responsibilities and liabilities. Ministers are specifically in jeopardy under s7, and 37 but also in the above with respect to section 36 of the Act: Section 36 is relevant to the conviction of Ayrshire and Arran:

HSWA Section 36 Offences due to fault of other person.

(1) Where the commission by any person of an offence under any of the relevant statutory provisions is due to the act or default of some other person, that other person shall be guilty of the offence, and a person may be charged with and convicted of the offence by virtue of this subsection whether or not proceedings are taken against the first-mentioned person.'

Note 'person' includes a Body Corporate

The Scottish Ministers have systematically disregarded HSWA as shown by VOLH, PSR 2010 abolishing the regulator, their refusal to refer to the Act in any of its documentation or consultations, and the failure to direct HSCD, NHS Scotland, the Care Inspectorate HIS, HEI, HPS to set the standards of HSWA for healthcare and social care providers. The ministers' refusal to have the required IHR also sends the message to all to disregard the Act. The IHR is a main vehicle to secure compliance with the law, take away the regulator ('regulatory vacuum') and breaches of the law are usually to be expected particularly when duty holders are in general ignorant of the law, which in Scotland the healthcare and social care sectors are. Whenever a provider breaks the law such as Ayrshire and Arran, whether or not they were prosecuted then this other person such as ministers, who are at fault can be prosecuted under s36.

The ministers would, or certainly should know, the law that applied and under which legislation NHS boards are prosecuted from time to time by HSE. As a former regulator of healthcare and social care using HSWA, I have also been reminding ministers of this since April 2012. Therefore, if it was ignorance initially, it promptly became wilful neglect. However ministers have failed to act, and refuse to press the intent of complying with the law in these two sectors. They have continued to refuse to do so despite being aware of their personal risk of prosecution, conviction, fines, and / or imprisonment. The Scottish ministers stand in defiance of the law. In addition to personal jeopardy to ministers and senior officers under HSWA they have also created the circumstances for multiple cases under 'The Corporate Manslaughter and Corporate Homicide Act 2007' Section 1:

1 The offence
(1) An organisation to which this section applies is guilty of an offence if the way in which its activities are managed or organised—
(a) causes a person's death, and
(b) amounts to a gross breach of a relevant duty of care owed by the organisation to the deceased

(2) The organisations to which this section applies are—
(b) a department or other body listed in Schedule 1

(3) An organisation is guilty of an offence under this section only if the way in which its activities are managed or organised by its senior management is a substantial element in the breach referred to in subsection (1).

The death of Nicola Black can be covered by the 2007 Act. The death occurred on 31 August 2010 after the date of its commencement, she was a detained patient (section 2(2) (e)), the Scottish Executive is specifically included and any succeeding organisation such as the Scottish Government. The Scottish Government does not have a prime intent of HSWA compliance, it, HSCD and NHS Scotland do not have an effective plan for compliance with HSWA, the SG abolished the

independent healthcare regulator. These are directly applicable to the failures at A & A and in effect permitted the death of Nicola Black.

The Scottish Government organised its activities, the HSCD, NHS Scotland and NHS Boards without regard to the primary legal requirements of HSWA to protect patient safety and as corroborated by HRA. This is not a decision of public policy (so it is not exempt by s3 or under any other exemption), it is a reserved matter. The SG responsibility is to comply with UK/GB law on reserved matters. SG specifically disregarded the law in its activities in healthcare (and social care). It set the agenda and policy for health and social care. This was done by senior ministers, the CS for Health and as backed by the First Minister. It was also done under the senior management of HSCD and NHS Scotland. The errors found in the prosecution and conviction of A & A were very obvious and a gross failure under HSWA s3 (1). SG also abolished the independent healthcare regulator.

If there had been the legally required effective IHR carrying out inspections to ensure compliance with HSWA then this death should not have taken place, it should have been a 'never event'. In the 1990s HSE was seeking to achieve this. In Scotland there is no body undertaking this function and certainly not to the standards required. The SG organised and managed the NHS so as to invite non-compliance with the law. Consequential deaths duly occurred. In this case Nicola Black was known by A & A to be in a very vulnerable condition and she was put in a place where she was not safe. The standards were a gross breach of duty of care and of HSWA.

Consequently there are further considerations under the Corporate Manslaughter and Corporate Homicide Act 2007:

8 Factors for jury
(1) This section applies where—
(a) it is established that an organisation owed a relevant duty of care to a person, and
(b) it falls to the jury to decide whether there was a gross breach of that duty.
(2) The jury must consider whether the evidence shows that the organisation failed to comply with any health and safety legislation that relates to the alleged breach, and if so—
(a) how serious that failure was;
(b) how much of a risk of death it posed.
(3) The jury may also—
(a) consider the extent to which the evidence shows that there were attitudes, policies, systems or accepted practices within the organisation that were likely to have encouraged any such failure as is mentioned in subsection (2), or to have produced tolerance of it;

(b) have regard to any health and safety guidance that relates to the alleged breach

Usefully section 9 of the 2007 Act allows the court to make an order requiring that the offences which gave rise to the death be remedied. This means in this case that the remedies could be far reaching and bring Scotland into line with HSWA, HRA and the Scotland Act 1998 in respect of patient safety provided that such an order were drafted correctly.

In the case against the SG, they had the attitude of disregarding the legislation, had no policy on HSWA binding compliance in the NHS, inadequate systems, and counter to accepted UK policy that has been in place for over 18 years. The ministers accepted a policy of tolerance and even de facto encouragement of such breaches. They abolished the regulation of healthcare that should have been the prompt and driver for healthcare in Scotland to comply with the law. The attitude of ministers and the Scottish Government would conventionally be regarded as wilful criminal neglect.

As stated previously, the prosecution of A & A by COPFS only addressed sufficient matters to prove the case. There were much wider issues across A & A and through line management that were not dealt with. The prosecution did not deal with the failings within the context of A & A being part of NHS Scotland, and the Health and Social Care Directorate. Under HSWA these bodies cannot absolve themselves of responsibilities. Any secondary legislation seeking to distance these parties doe not remove HSWA and HRA responsibility. There has been pressure for a Fatal Accident Inquiry (FAI), and the parents of Nicola Black were given to understand from COPFS that it would take place. COPFS has now refused and so too has Mr Salmond from a request to him, via his legal advisers. Further on 9 December 2014, COPFS was asked to investigate the role of senior officers and Scottish Ministers with respect to s7, s36, and s37 as applies by virtue of s48 as it applied to healthcare in respect of the offence by A & A. The issue of the application of 'The Corporate Manslaughter and Corporate Homicide Act 2007' in respect of the Scottish Government needs to be addressed.

In summary the Scottish Government and particular its ministers have failed, and continue to fail to:

1. Recognise that HSWA applies to the safety of patients and to those in social care, and that it requires it to be embedded in these sectors as a primary intent.

2. Implement an immediate and effective plan to bring healthcare and social care up to compliance with HSWA to the high standards required in these areas of very high hazard and current high risk.

3. Create the legally required independent healthcare regulator, and to bring regulation of social care into compliance with HSWA standards.

The COPFS and Lord Advocate, and the Justice Ministers have failed to apply the requirements on HSWA to prevent harm. The COPFS have so far refused to investigate the role of senior officers in the death of Nicola Black or any other deaths that could be said to have occurred because of the policy failure to implement HSWA to the standards required. It has refused to give reasons for not investigating. (Reference COPFS letter to Mr R Wilson 13 January 2015). The Solicitor General has been asked on the 19 January 2015 to reconsider the decision.

Even after the death of Nicola Black there seems to have been another suicide with similarities, this is DB89 (Nicola Black's is DB66). http://www.nhsaaa.net/media/288224/db89report.pdf The NHS report is quite critical. There is no reference to HSWA or the involvement of the default regulator, HSE. Why not? With the Scottish Government's failure to set a policy of legal compliance and regulation, combined with the NHS failures in compliance, then COPFS delays in notifying HSE, investigating and addressing the defects on previous incidents, this may have been yet another reasonably preventable suicide. This matter needs investigating. Underlying causes have not been dealt with. A & A seems to provide examples of collective failures of the NHS, the Scottish Government and the COPFS. Whilst not atypical of NHS boards, these examples appear to show an 'archetype of failure' to ensure the safety of those in their care.

The statutory HSWA system to prevent avoidable deaths and other harm in mental health units is not in place in Scotland. Further, the existing reactive legal system is not functioning to prevent further harm to patients or to secure the legitimate interests of families. Justice is obstructed and denied.

7. Scottish Healthcare Organisations

7.1 Scottish Ministers and Scottish Government

Scottish Ministers have failed to implement UK-wide legislation that would secure the safety of patients and of those in social care so far as is reasonable. The consequences of this failure are of thousands of reasonably preventable premature deaths. They should have known of the requirement and have been repeatedly reminded of this failure since April 2012. If this was an initial oversight, the refusal to implement the law and to the standard required has now become wilful neglect on the part of the Scottish Nationalist Party (SNP) Government. It is not clear whether the failing to comply with the law is an absence of competence or politically motivated, or a combination of the two. In any case, the consequences for people in Scotland are severe. The Scottish Government does not have the competent person advice to assist it in

complying with the Health and Safety at Work etc Act 1974 and related relevant statutory provisions as required by the Management of Health and Safety at Work Regulations 1999, Regulation 7.

The Scottish Ministers abolished the Scottish Commission for the Regulation of Care. This body was set up in April 2002 under the Regulation of Care (Scotland) Act 2001 to regulate all adult, child, and independent healthcare services in Scotland. It did not work to HSWA standards. The Scottish Government abolished the regulator.

Ministers are in breach of HSWA, HRA, the Scotland Act 1998, ECHR, and the Ministerial Code for multiple failures. These offences are considered to be very serious both on an individual basis and in their role as a corporate body. The criminal law penalties for individuals are substantial. Section 7 of HSWA applies to all employees of whatever rank, section 37 applies to senior officers including ministers:

Section 37 Offences by bodies corporate.

(1)Where an offence under any of the relevant statutory provisions committed by a body corporate is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or a person who was purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Ministers and senior officers may also be convicted under section 36 as noted in respect of Ayrshire and Arran, above and indeed in connection with many other offences committed which may be attributed to ministerial misconduct.

The failures of Ministers results in the Scottish Government being in breach of its duty of care to the people of Scotland and to occur many avoidable deaths. If the Ministers had discharged their legal, parliamentary, and moral responsibilities then these many deaths would have been prevented. Their omissions result in the current Scottish Government being at risk of prosecution under the Corporate Manslaughter and Corporate Homicide Act 2007. The specified penalty is an unlimited fine. The Act specifically applies to the Scottish Executive (now Scottish Government) and the Crown Office and Procurator Fiscal Service (COPFS).

The problems may be summarised in the three points repeatedly put to Scottish First Ministers, Cabinet Secretaries for Health and Well-being, Cabinet Secretaries for Justice, and involving the Lord Advocate:

1 Recognition of Health and Safety at Work etc Act 1974: Scottish Ministers and Government to recognise that HSWA applies to patient safety and to those in social care (HSWA s1, s3).

2 Plan on Compliance in Healthcare Scottish Ministers and Government and bodies working in healthcare create and implement an effective plan to secure HSWA compliance proportionate to the high hazards and high risks in healthcare (MHSWR Regulation 5, HSWA s3).

3 Creation of Independent Health Regulator (IHR) Scottish Ministers and Government create a fully independent healthcare regulator working to the high standards of effectiveness securing compliance with HSWA (HSWA s18, HSWA s3). This requires urgent primary legislation to restore the IHR.

It is not apparent why the above creates such difficulties for Scottish Ministers, and it is what the law requires. The first two can be commenced immediately, the third requires primary legislation but actions can be taken to develop part of HIS ready to become fully independent as soon as the legislation can be implemented. As it stands it is hardly credible that there is somewhere in the UK where such defiance of the law takes place. The current situation deserves neither the confidence of the public nor of healthcare professionals.

The then First Minister, Mr Alex Salmond at the time of the release of the Francis Report into Mid Staffordshire NHS Foundation Report, in Holyrood regarded the failings as 'an English problem', and that his Government would look at the recommendations. He made play of the different way that the NHS was organised in Scotland but gave no evidence that it would not have similar problems to Mid Staffordshire. His own NHS Scotland's Healthcare Improvement Scotland found the same and worse failings at NHS Lanarkshire as those that gave rise to the prosecution of Mid Staffordshire. The lessons of Francis have since not been addressed in Scotland, and the consequences show.

If Mr Salmond or Mr Neil and their policy advisers had looked at even page one of the Francis Report then they would have seen the glaring error of the way healthcare in Scotland is organised. Effective fully independent regulation is essential. Acceptable performance in healthcare is not possible without the IHR, and the law requires it. Page one of the Francis Report refers to regulation, Scotland has, owing to the actions of Mr Salmond's administration, no regulation. Recommendations 19-63, 87-89, and others of Francis refer to regulation; here the situation should be one of despair, there is nothing. There is also not an independent assessment of performance of NHS Scotland. There is only in-house reporting and this is inappropriate, unreliable and does not command the confidence of healthcare professionals or the public. A major frontline example of this was at NHS Lanarkshire hospitals which showed the quality of ward self-reporting on monitoring patient's vital signs. Analysis showed a figure which was still not acceptable for something which is critical to patient's safety. An audit showed the figures analysed to have been a vast exaggeration and real performance was very poor. The actual levels

monitoring of patient's vital signs suggested that lives were at risk. In any other situation such performance would have resulted in enforcement and/or prosecution.

Healthcare and social care in Scotland do not comply with the legally required standards and great harm results. The sectors have failed to recognise and address the issue. The Scottish legal system has failed to recognise the very large gap in compliance with UK and EU law, or address it. The Scottish Ministers and its Health and Social Care Directorate have explicitly misled the public and refused to implement the law. These are major omissions of what constitutes a civilised society, where the proportionate laws are in place, they are complied with and the government supports justice.

Eight current or recent Scottish Ministers including two First Ministers have refused to comply with either the legislation that applies to patient safety or with the Ministerial Code on upholding the law. The First Ministers have refused to apply the Ministerial Code. Mr Swinney failed to comply with the code on upholding justice by introducing legislation that undermined patient safety and also breached major legislation. Mr Salmond refused to apply the code, for example when Mr Neil intentionally misled Holyrood by saying that Scotland had got an independent regulator, when the body he referred to makes it clear that is not a regulator nor is it independent of NHS Scotland. Subsequently when Mr Salmond breached the code on an allied matter he did not refer himself to the independent advisers on the code. The Ministerial Code in Scotland was not observed.

There is a competence gap in the ability of the Scottish Ministers and the Scottish Government to recognise the role of the law to deliver safety and their failure to embed legal compliance with health and social care, to implement it to the high standards required for the very high hazards and risks and the absence of regulation constitutes a competence gap. For the health and safety of the public in Scotland this must be closed out and promptly.

The Health and Safety Executive uses its Enforcement Management Model (EMM) to make objective decisions about what sanctions are appropriate for identified shortcomings. Under the EMM, such a large gap between what is required and what is achieved, and the consequent harm, such as we have here, would trigger legal proceedings.

Nicola Sturgeon in a letter of 22 December 2014 confirmed that she would be continuing Mr Salmond's policy on patient safety and the law. This meant that she was not going to implement the binding HSWA, comply with its standards or create the independent healthcare regulator. So Ms Sturgeon continues the policy that permits the large number of avoidable deaths, the equivalent of about five occurring every day. Nor is Ms Sturgeon going to do anything about her own misleading of the Vale of Leven Hospital Public Inquiry and the multiple breaches of

the Ministerial Code and breaches of HSWA by her predecessor as Scottish First Minister and by five other ministers, and one former minister.

7.2 Health and Social Care Directorate (HSCD)

The Directorate allocates resources and sets the strategic direction for NHS Scotland and is responsible for the development and implementation of health and social care policy.

In setting the strategic direction HSCD should be the executive branch of the Government that sets the standard that the NHS needs to comply with. Patient safety is a highly important aspect of health and social care and yet its health policy disregards the legislation and need for the sectors to comply. In particular HSWA is missing from its intent and strategy, as well as being a practical means of discharging the SG responsibilities to comply with the Human Rights Act, on the right to life. If the body that sets the strategic direction for the NHS omits the legal requirement then it is reasonable to expect that healthcare and social care will not comply with the high standards necessary to avoid preventable deaths. HSCD should be making the intent clear and should do whatever it can to make it as easy as possible to achieve the standards required. HSCD should not ignore the law. Failures in healthcare and social care appear to be leading to about 4% of all deaths each year in Scotland.

HSCD has been reminded of the application of HSWA (since 2012), but the previous director Mr Feeley chose to disregard it. The HSCD policy defect is in keeping with Scottish Minister's misconduct. There is a major cultural problem here. If HSCD cannot get it right it is a major case of maladministration. HSCD had the opportunity with the Vale of Leven Hospital Public Inquiry to ensure that the Act, which should have prevented 30-50 deaths at the Vale of Leven Hospital, was implemented across all health and social care. It did not. This left Scotland with 'optional' guidance when it must have legal enforceable standards. There is a great deal of difference between guidance and the law. When the risks are high the standard of legal compliance must be high too. It is not optional.

This is a directorate that presides over no regulation in the sector of highest risk of any in the UK. It cannot apply or implement the relevant parts of the Francis Report, recommendations 19-63, 87-90 on regulation, as well as the application of the law to healthcare. To the team reviewing the application of Francis to Scotland the point of not applying or regulating to HSWA would have been very apparent. However there is still no HSCD policy on HSWA compliance and the creation of the fully independent healthcare regulator.

The SG and HSCD have made great reliance on the SPSP. But SPSP is non-compliant with HSWA, it is not strategic, it is not a coherent set of

actions based on a valid risk profile, it is just a collection of initiatives which would occur anyway. NHS Lanarkshire demonstrated its lack of frontline impact. A repeat point for bodies involved in healthcare in Scotland is that HSCD does not have the competent person advice to assist it in complying with the Health and Safety at Work etc Act 1974 and related relevant statutory provisions as required by the Management of Health and Safety at Work Regulations 1999, Regulation 7. It does not have the legally required expertise in patient safety policy.

A particular feature of healthcare in Scotland is that policy, delivery and scrutiny (what should have been regulation) are all found together. This is a major conflict of interest. The head of HSDC Paul Grey is the Director General of the Health and Social Care Directorate, he is also the Chief Executive of NHS Scotland, and this includes Healthcare Improvement Scotland (the quality assurance and scrutiny body) and Health Environment Inspectorate (that scrutinises on infection control). With Scotland only having a population of just over five million, the costs of overheads of Government are proportionately high and the available personnel are proportionately very much lower. In some disciplines they are not available. It is understandable why there is much pressure to try to reduce overheads by reducing the numbers of bodies involved. In healthcare this comes at an unacceptable cost.

This can be illustrated by the comparison of the NHS Vale of Leven outbreak and the problems at Mid Staffordshire and their respective inquiries. At Mid Staffs there was a distance between government and policy, the NHS hospital and delivery, and CQC and HSE as the independent regulators. The issues at Mid Staffordshire of poor hospital and poor regulation were able to be dealt with in an objective way. By consensus Francis got the analysis and the solution right, the UK Government accepted almost all of the recommendations and they are being implemented. Unfortunately here the VOLH inquiry was misled right from the start by the Scottish Government, the law whose compliance should have prevented the outbreak was wholly disregarded. At the inquiry no-one mentioned the law. It is as if a spell has been cast to forget HSWA. Small groups tend to produce a monoculture of group-think and that seems to have happened here with no independence of thought, and so the solution to the VOLH and required recommendations were missed. The required checks and balances are absent in Scotland. The VOLH inquiry was a costly waste and major missed opportunity. Mid Staffordshire's inquiry should mark a paradigm shift in patient safety and will change healthcare in the rest of the UK (Francis has not had an impact here in Scotland and cannot properly as we do not have a regulator). So far it doesn't look as if VOLH will make a difference; it certainly did not deal with the main legal determinants. The outbreak did prompt the creation of HEI inspecting on infection control (fifteen years after it was happening under HSE). However the monthly occurrence of HEI reports finding major infection control defects in Scottish hospitals shows that HEI has not solved what was an urgent problem and major risk to life. With government, delivery and scrutiny being together in

Scotland any concern almost immediately becomes political rather than being dealt with objectively. The issue of the absence of HSWA and the absence of the independent healthcare regulator on patient safety quickly passed from being a legal issue to being a legal and political one. Rather than the issue being dealt with on its legal and operational merits, the SG became defensive and set up further obstacles and refusals to act, so digging a continuing deepening hole for the government and ministers. Meanwhile patients die because of this apparent vanity. Policy, delivery and regulation need a distance to be effective. This is another expression of the lessons of the Piper Alpha disaster.

The Francis Report addresses patient safety (a reserved matter), how it is ensured and how it is regulated. After two years there is minimal evidence of Scotland and HSCD acting on it. Whilst there are differences in how healthcare is organised the actual practice is similar, and there are always issues of governance and regulation. Scotland cannot deliver patient safety without the legally required effective regulator. There is much else in Francis that applies here in Scotland but there is no sign of its recognition or action. Reading the Scottish Government's press release on the report it is hard not to see it filled with complacency and as a total misreading of Francis.

7.3 NHS Scotland and NHS Boards

NHS Scotland and the NHS Boards follow the policy line set by Scottish Ministers, the Scottish Government and HSCD. There is no evidence that NHS Scotland and its NHS Boards set HSWA as a prime requirement and certainly not in comparison to the standard required by the high hazards and high risks present. There is not the evidence of HSWA, MHSWR or COSHH compliance. Standards, such as they are, are as guidance but do not have legal backing and motivation for compliance and safety. The need for standards backed by law and regulation is covered by the Francis Report and the role of the IHR. In it he refers to the IHR, CQC either using HSWA or having similar powers.

BBC Scotland ran a programme on 26 November 2012 'How Safe is Your Hospital?' Supporting this was a large number of Adverse Incident Reports obtained via Freedom of Information (FOI) requests. As a former regulator of the NHS, I analysed a sample of 200 of the Adverse Incident Reports from across all NHS Scotland boards. Using the criteria of the prosecution of Mid Staffordshire NHS Foundation Trust under HSWA after the public inquiry (relating to the death of Gillian Astbury), I found that they revealed serious breaches of HSWA in 80% of the cases, usually resulting in serious harm and often fatalities. In none of these adverse incident reports was there any reference to the statutory requirements of the Act.

There was no sign that HSWA was a consideration in incident reporting or that information was passed to HSE as the default regulator in the absence of the IHR that exist elsewhere across the UK. There is the

standard requirement that NHS Scotland and NHS boards have the competent person advice to assist them in complying with the Health and Safety at Work etc Act 1974 and related relevant statutory provisions as required by the Management of Health and Safety at Work Regulations 1999, Regulation 7. There was no reference to such a competent person being involved in the reports or investigations relative to HSWA.

Among the Scottish NHS boards there does not appear to be any stated intent to comply with HSWA to the high standards required of them. It does not seem to get mentioned at all; neither does COSHH on infection control nor MHSWR on the risk management control. Offences are routinely occurring in the NHS but there is not the regulation or enforcement to ensure that improvements are made to bring the whole sector up to standard in Scotland. Healthcare Improvement Scotland recently revised its guidance to hospitals on adverse incidents. However HIS still did not refer to HSWA requirements despite seeking my advice as a former regulator of healthcare in a specific meeting to discuss the matter (11 March 2013). In putting out information to the NHS boards on matters that would involve the very serious issue of compliance with HSWA, HIS wilfully neglected the main legal standard that would apply to adverse incidents. That is a conscious breach of HSWA by HIS setting a defective and misleading policy. Partly encouraged by HIS, failings in the NHS still go largely unrecorded.

Even as the VOLH public inquiry was reporting on the 30 plus deaths there was another C-difficile outbreak at Edinburgh Royal Infirmary and at least three more deaths, and the reports of poor infection control at NHS Greater Glasgow and Clyde, NHS Lanarkshire (see HIS/HEI reports), and Edinburgh Western General. All involved very basic errors and breaches of HSWA and with no regulator involved there was no enforcement action taken. NHS Scotland was still not getting it right on what should have been the lessons of VOLH six years after the original outbreak. The system of HIS/HEI guidance to boards is inadequate as well as not meeting statutory requirements.

In other sectors serious failings on HSWA compliance are seen when deaths and other harm are reported to HSE under the HSWA accident reporting regulations (RIDDOR – Reporting on Incidents, Diseases and Dangerous Occurrences Regulations, now 2013). However incidents under medical treatment are exempted (by Regulation 14). In Scotland sudden and unexplained deaths are required to be notified to COPFS, but this reporting is incomplete and the relevance and criteria of HSWA are not necessarily considered or appreciated. The VOLH report was a further demonstration that there should not have been reliance on the accuracy of death certificates. Procurator Fiscals recognise that they are not necessarily informed of all the deaths that they should be. As has been apparent throughout this document, HSWA is not understood how it applies to patient safety by the NHS or other healthcare and social care bodies in Scotland.

Scotland has very little independent scrutiny (e.g. no Kings Fund) and of course no healthcare regulator. Failings in the NHS are often brought to light by 'whistleblowers'. Those who report failings are often penalised, with bullying, blockage of careers and long term suspension, with pay offs and gagging clauses. The current Francis Review 'Freedom to Speak Up' shows a disproportionately large number of cases in Scotland and as represented by Patients First. In Scotland there is no independent body such as the CQC to which whistleblowers can go. A newly created IHR instead of an internal NHS body could be the means to independently handle complaints and whistleblowing concerns.

7.4 NHS Scotland's Healthcare Improvement Scotland (HIS)

Amongst its roles, HIS is the NHS in-house quality assurance and scrutiny body. It also acts as a regulator of independent healthcare in Scotland. It makes no pretence to be a regulator of the NHS. Its senior management make it clear that it cannot be as it is part of the NHS. The Cabinet Secretary for Health and Well-Being did though call HIS 'the independent regulator' of the NHS. This was a very serious misleading of Parliament and of the public and still requires his resignation.

Once again Mid Staffordshire and Piper Alpha make it extremely clear that the regulator must be fully independent of those it is regulating. This is the policy across the UK and was the case in Scotland until the Scottish Government abolished the IHR for Scotland in 2011. Scotland now has no such body for healthcare. HIS is certainly not it. This is a fundamental failing. Here we have the highest risks and no regulation once again.

The stated HIS focus is 'to reduce the healthcare associated infection (HAI) risk to patients, to improve the care of elderly patients and to regulate Independent Healthcare Services'. Thus it only covers a very limited range of the risks in healthcare. It is not independent, it is not working to HSWA standards, it does not automatically inform HSE when serious patient issues are found (outside a narrow range of 'matters of evident concern') so as to exclude the Mid Staffordshire-type issues on patient safety. It has no enforcement powers for the NHS. It does not have the power to initiate or take prosecutions; it has not got the expertise in the law, the risk management methods for a high hazard and high risk sector, nor expertise in management systems and both corporate and organisational culture requirements. The HIS is not the body to regulate healthcare. It is not suitable for the independent healthcare sector either as it does not use HSWA and its standards (e.g. COSHH as the legal standard on infection control) or have the appropriate range of expertise. Consequently without the effective fully independent healthcare regulator there is a much lower standard of protection in Scotland than the rest of the UK. It is also an illegal position under HSWA s18, and is a major case of Scottish Government maladministration.

In respect of the Vale of Leven Hospital Public Inquiry and on-going C-diff outbreak, according to the Letter of Understanding HIS and its HEI do not investigate the cause(s) of outbreaks of infection. There is therefore no organisation with any degree of separation from the hospital's governance and culture that is investigating what causes the outbreaks to objectively enable their future elimination or proper prevention. It is barely credible that such an approach to safety exists in the UK; it is like going back in time by over 40 years. It is highly negligent.

A risk-based approach (this is the statutory approach) by HIS would require it to have a risk profile of factors affecting patient safety particularly those causing major harm and RPPD. From its reports it does not seem to have the information on which to work or use this approach. It should have identified the factors to concentrate on. At NHS Lanarkshire it found evidence of very serious failings which if correct would have been probable causes of excess mortality. It should have pursued and investigated the evidence further and notified HSE, but it did not. What should have been major concerns were left as unanswered questions. HAI is very important but there are many other factors. Monitoring and management of patient's vital signs, communications and shift handovers, hydration levels, nutrition, competence management, staff workloads, fatigue and motivation are just a sample of the factors affecting RPPD.

Healthcare Improvement Scotland does **not**:

- Check for general compliance with HSWA on patient safety.
- Regulate the NHS.
- Act independently of the shared governance of NHS Scotland, NHS boards and HIS/HEI/HPS.
- Carry out comprehensive risk-based preventative inspections (to HSWA or equivalent).
- Inspect on the range of risk-profile topics affecting patient safety.
- Routinely inspect on the monitoring and management of patient's vital signs.
- Routinely inspect on communications and shift-handovers on patient's conditions.
- Inspect on training and competence management systems.
- Inspect on hydration and risk of kidney failure of patients.
- Inspect on clinical practice and processes.
- Investigate medication errors.
- Investigate complaints.
- Inspect HAI to COSHH, MHSWR, HSWA.
- Regulate the independent healthcare sector as required to the standards of HSWA, MHSWR, COSHH.
- Enforce to make certain requirements are achieved by dutyholders.
- Apply the lessons of Francis and Mid Staffordshire.

7.5 NHS Scotland's Healthcare Environment Inspectorate (HEI)

'The Healthcare Environment Inspectorate (HEI) carries out safety and cleanliness inspections across NHS Scotland hospitals and services'. It was created in the aftermath of VOLH C-difficile outbreak of 2008 as part of NHS Scotland's Healthcare Improvement Scotland (HIS). It is not a regulator; it is part of the NHS, with the same governance as the NHS. Hospital Acquired/ Associated Infections (HAI) present one of the most serious risks associated with work activities and as covered by HSWA. HAI is on or around the top priority of all the areas requiring a high standard of compliance and regulation.

Such an organisation as HEI should have been created as a specialist part of a Scottish IHR. It should have the necessary competences on microbiology, healthcare practice, standards, HSWA statutory requirements including COSHH, major hazards risk management, management systems (MHSWR), competence management, investigation and evidence collecting skills, organisation and corporate culture understanding and practice. It should have similar enforcement powers to HSE, including enforcement notices both improvement and prohibition, and the ability to initiate prosecutions. HEI wasn't; and it does not have the competences to be a regulator of HAI.

At the VOLH, HEI confirmed that it does not have enforcement powers such as the improvement notices of Scotland's Care Inspectorate or HSE. The HEI Chief Inspector did not consider that it needed such powers. Though they did recognise that there were times when a prohibition capability would be of use to stop admission to a ward when the risks were high. This statement is advocating no regulation for very high risks, repeating a most basic error of risk management. Legally HEI does not have a choice in how defective infection control risks are dealt with. They are so high that they require very strict legally-backed standards, compliance, and a high standard of regulation.

It is worth noting that 'HEI will not assess the fitness to practise or performance of staff (i.e. it does not do competence management which is an essential requirement in high hazard activities), investigate complaints, nor investigate the cause of outbreaks of infection'. The lessons of Francis have not been applied here.

In practice HEI inspections frequently identify very serious breaches of COSHH, MHSWR and HSWA. HEI do not have the power to ensure that their requirements are met. Their reports show repeated failure to stop such breaches. A regulator would have the necessary powers to ensure that breaches were stopped and not permitted to be perpetuated as currently happens. HEI requirements need to meet the standards of law, and have its backing to make sure that they are achieved. Despite HEI listing HSE as a key stakeholder they did not routinely contact HSE when they found these serious breaches of COSHH etc. HEI may not have previously realised that the law applied and how it applied. After

HEI found serious repeat infection control failings, with COSHH, and HSWA breaches at Hairmyres Hospital I politely asked if HEI had notified HSE. They had not and did not want to. Whether or not formal agreements exists between parts of Government it is standard practice to inform another Government agency when a serious failing is seen. This was major issue and factor that allowed the Bradford City stadium fire disaster of 1985 to occur and 56 deaths resulted. Communications between regulators and a public body were not commensurate with the risk, and action was not taken to remove the fire risk. A similar scale of disaster is quite foreseeable in the case of HAI, the VOLH outbreak probably accounted for a similar number of deaths. HEI should formally notify HSE of problems as the default regulator until the required IHR is created. The HIS – HSE Letter of Understanding is inadequate and requires improving. The Bradford City Fire was also subject to a public inquiry and that involved challenging the regulators and public bodies and created major problems for them. In this report, that makes three public inquiries that are highly relevant to the issue of patient safety, as well as its regulation in Scotland, the lessons of these disasters and their inquiries really need to be remembered and embedded.

7.6 Healthcare Protection Scotland (HPS)

HPS is part of the NHS; it provides assistance on improving services to protect people in Scotland from infectious and environmental hazards. It provides advice to health professionals, national and local government, and to the general public.

It was a Core Participant at the VOLH public inquiry and provided evidence to it. It made a Closing Submission to the VOLH in section 4 National Structures and Systems. In this, it sought to assess independent monitoring of HAI in hospitals before the creation of HEI, whether the SG and other agencies performed an adequate role, and 'what were the roles of SG and other agencies such as HPS in the prevention and control of infections such as C. difficile?'

Their submission addresses guidance but wholly ignores regulation. There is absolutely no mention of COSHH, MHSWR and HSWA. This is the legislation that applies, it is the legal standard and compliance should have prevented the outbreak. The issues have been covered by HSWA for the last 40 years and yet it gets no mention in Scotland. This means that HPS is not doing its job. It is essential in working with such high risks that there is an awareness of the law and what it means. HPS is involved in the training of healthcare professionals on infection control and so this has implications on its quality.

The written submission of HPS to VOLH was prepared by an experienced QC and a similar Advocate. Their collective omission of binding British legislation concerned with preventing a large number of avoidable deaths is another basic legal error. In any subject such as this, the first question is what legislation applies and how does it apply?

The hospital is a work environment and there is comprehensive long-established legislation dealing with the safety of staff and patients with suitable penalties for those involved in non-compliance. The law was totally ignored again, legal advice should have been well aware of the law that applied and accounted for it in any submission.

If it had been understood that the law applied then it would have readily been realised that there are major deficiencies in Scotland. The HSWA, COSHH and MHSWR are not recognised to apply. There is no plan to secure compliance with the law, it is not complied with and major harm results. The SG has abolished the regulator which would have 'reminded' dutyholders of the need to comply. For some reason there is a total blind spot in Scotland on HSWA and patient safety which also affects the legal profession. Once again if the legal profession had even a glance at the Sir Robert Francis QC report on Mid Staffordshire then they would know that HSWA applied, how important it is and the essential requirement for an effective fully independent healthcare regulator. That would have informed the HPS report and the VOLH public inquiry outcome.

The HPS failure to deal with HSWA meant that it omitted the type of regulatory control that used to take place back in the 1990s. At that time HSE inspectors with specialist microbiological inspectors undertook preventative hospital inspections applying COSHH, MHSWR and HSWA. It started in pathology laboratories but soon moved out into all relevant areas of hospitals, other healthcare and into social care. A full range of enforcement powers were available proportionate to the offence and risk of harm. This protection for patients has vanished from Scotland.

HPS in its advisory role to NHS boards needed to have known that the law exists, it applies and how it applies, HPS should have reminded the boards. The HPS programme on HAI (Hospital Associated Infections) is overseen by the HAI Task Force. Is this task force aware of what law applies? It does not look like it did. It is still reliant on guidance. That must affect its ability to perform the task. The HPS VOLH report makes reference to learning and as an example quotes the C-difficile outbreak at Maidstone and Tunbridge Wells NHS Trust. If that was the case it would have been known that HSE and Kent Police investigated after the English independent healthcare regulator (Healthcare Commission, now CQC) had carried out their regulatory role. HSE investigated under COSHH, HSWA and MHSWR. As there is no independent healthcare regulator in Scotland, HPS needs to establish the impact of the legislation on its role.

7.7 Scottish Public Sector Ombudsman SPSO

Of SPSO's full investigations 80% relate to healthcare and of these 80% show serious HSWA breaches that could or do affect patient safety (from two years analysis 2011-2013). In these two years of investigations

there was absolutely no reference to HSWA. Neither did the SPSO notify the many serious safety defects and incidents to a regulator who would be able to effectively deal both with investigating the breaches and applying the legally required remedies. This would include dealing with underlying causes and getting the lessons learnt across all of healthcare in Scotland. The SPSO has not got the powers to make sure serious issues are addressed. It does not address the right issues, and even if it did, it does not have the powers required to ensure that its findings are put into effect.

Non-health SPSO investigations also often showed HSWA offences, but there is no reference to the application of the law, no action to ensure compliance achieved and no notification of HSE. The SPSO is carrying out serious investigations without seemingly knowing what law applies or what it meant. The errors keep on repeating. In any situation that is being investigated the first question is - does the law apply? If so, what legislation, and what does it mean in this situation? The SPSO is not using a main criterion that should apply to its work. To carry out professional investigation into health matters it needs the medical technical knowledge combined with the HSWA related skills of knowledge and experience of HSWA and law, investigation, managements systems and culture change skills. It does not have these.

The SPSO owes a duty to the public to perform a professional job. To disregard the law, particularly such major legislation that would have prevented the failures being investigated is a breach of duty. The failure of SPSO means that there is yet another body disregarding the law and perpetuating problems rather than solving them.

I politely informed the SPSO in May 2013 but he chose to disregard the main legislation involved in his complaints. The SPSO is failing to use the appropriate criteria in dealing with his investigations. His investigations for 2014 show that the lessons have still not been learnt.

SPSO find serious HSWA defects but they did not inform the default HSWA regulator for healthcare, HSE. SPSO has a Civil Service responsibility and legal and professional duty to act in accordance with HSWA to inform the regulator. There is no evidence of an agreement or process to inform HSE of significant HSWA defects liable to affect patient safety. Again the Bradford City fire disaster lesson is relevant.

On the SPSO role on maladministration it only deals with limited types of complaint. It does not do major cases of maladministration – such as those of underlying causes that would deal with complaints at source. In this case the Scottish Government not implementing HSWA to standard is a rather large case of maladministration. In terms of breaching the law and consequences in loss of life it looks like the biggest. The Scottish Public Services Ombudsman Act 2002 is too restrictive to address major cases of maladministration or underlying causes (e.g. regulation 5

'Matters which may be investigated'). This current issue is one of the biggest cases of maladministration possible – of disregarding the law that would prevent thousands of avoidable deaths of those in the Government's care. There is no organisation preventing the Government on its highly damaging course of action against the people in Scotland. The law is being disregarded, it is a case of lawlessness. The SPSO does nothing to try and prevent the maladministration. It could press HSE to be involved.

The SPSO needs the legislation, the expertise and the powers to fulfil its task. Currently it has none of these. When the independent healthcare regulator is created, the IHR could take on the function of the SPSO in respect of healthcare and social care complaints and cases of maladministration. The current system for handling complaints about the NHS in Scotland pays no regard to the law and is not addressing underlying issues. In the rest of the UK there is increasing recognition of the problems and there are moves to create a separate health and social care ombudsmen.

7.8 Social Care and Social Work Improvement Scotland - Care Inspectorate (CI)

The Care Inspectorate does not make reference to the main legislation governing the safety of those in care, HSWA. There is also much other related legislation in particularly COSHH on infection risk and MHSWR on effective management arrangement to control risks. The Care Inspectorate does not work to HSWA; it is dealing with vulnerable people at often very high risk and the standard of HSWA compliance should be high.

HSE has a protocol with Care Inspectorate a body which does not enforce HSWA. The protocol has the overall aim of generally improve standards within the care sector. The aim needs to be much stronger given the level of hazards and risks. It should be to ensure that standards are achieved commensurate with HSWA for the hazards and risks to those in care. CI has a duty on the safety of service users. The situation on social care is far less understood than in healthcare. The sector has far less scrutiny, less of a profile, and the application of HSWA is even less used since routine inspection was transferred from HSE in the late 1990s. Prior to this HSE carried out preventative inspections to care homes and other facilities to the standards of HSWA and to prevent harm to staff, residents and service users. In healthcare RPPD generally go unreported and a similar situation will happen in social care facilities. HSWA is not embedded in the sector in Scotland. The regulations used by CI and National Care Standards would need to be assessed for comparison with HSWA. It is unlikely that they meet the requirements on the comprehensive requirements (physical controls, structure, management and culture) and high standards of HSWA for the hazards and risks. For example it does not have the equivalent of

COSHH on infection control or MHSWR on effective risk management on the high hazards present.

This is a sector that need further investigating to determine the scale of any problems and the role of the existing HSWA legislation in controlling them. From my experience of inspecting and regulating social care they will be significant.

7.9 Scottish Human Rights Commission (SHRC)

In a meeting with a senior officer of SHRC (27 January 2014), it was recognised that HSWA compliance provides a reasonable and practicable way of the Scottish Government delivering the requirements of the UK-wide Human Rights Act 1998. SHRC were looking to use this in their work in the healthcare and social care sectors. The general approach to HRA is to act after harm has occurred whereas HSWA is to act in advance to prevent harm and to ensure that effective precautions are in place, and in the case of death they need to be to a very high standard. The HRA often has a poor reputation, in the profile of issues covered by HRA; the prevention of 2,000 deaths a year in Scotland would realign the law, policy, public concern and justifiably restore the law's reputation.

As a related issue, HSWA also applies to HRA in respect of the prevention of deaths of those in custody and prisons. With the general withdrawal of HSE from high standard preventative inspection on such safety issues, it probably justifies a review of the application of HSWA to these areas compatible with HRA compliance. In prisons there are about 5-10 RPPD, frequently of those untried. This is another area of significant risk but out-with mainstream health and social care.

7.10 Mental Welfare Commission for Scotland (MWCS)

The Mental Welfare Commission for Scotland aims to ensure that care, treatment and support are lawful and respect the rights and promote the welfare of individuals with mental illness, learning disability and related conditions. MWCS references 'The Mental Health (Care and Treatment) (Scotland) Act 2003'. This contains at section 7:

'(7) Duty to bring matters generally to attention of Scottish Ministers and others The Commission shall bring to the attention of—

….

(f)the Scottish Commission for the Regulation of Care; or

(g)such other person, or group of persons, as it considers appropriate,

any matter of general interest or concern as respects the welfare of any persons who have a mental disorder which is a matter that the Commission considers ought to be brought to their attention.'

The Scottish Commission for the Regulation of Care is the body that Mr Salmond and Ms Sturgeon as Scottish First Minister and the then Cabinet Secretary for Health and Well-Being abolished as the independent healthcare regulator with the Public Sector Reform (Scotland) Act 2010 (PSR). This created breaches with regard to mental health as well as to physical health, of HSWA, HRA and the Scotland Act 1998 by reducing the standard of protection for those in its care. The Scottish ministers brought in legislation that reduced protection.

Mental health was now without the legally required independent healthcare regulator (IHR). This section 7 of the 2003 Act should now explicitly include HSE as being the default and sole regulator of the health and safety (equivalent to HSWA) of those with 'a mental disorder'. Regulations 8(3), and 9(2) of the 2003 Act are similarly in error. The term used in the above 2003 Act is 'welfare' but in the context of mental health this is taken to include their health and safety. Precautions in Scottish mental health units are not to the high standards required by HSWA to prevent suicides and para-suicides. The 2003 Act does not seem to have been appropriately amended to reflect the removal of the IHR.

When the Scottish Ministers in PSR 2010 abolished the independent healthcare regulator, in section 8A, they replaced it with NHS Scotland's in-house quality assurance and scrutiny body Healthcare Improvement Scotland. Again this is not a regulator of the NHS and it cannot be, is not independent, it does not have the competences and powers of a regulator such as HSE. Section 8A of PSR 2010 made no reference to HSE. The Scottish Government explicitly removed regulation of the health and safety of those in mental health units and those under their care for mental disorders. Section 8A should not have referred to HIS but instead put in HSE as the default regulator provided it got HSE's agreement to take on this role where Scotland had no regulator. HSE does not have the resources to undertake this role. The Scottish Ministers acted totally counter to GB and EU law, and also UK-wide policy as emphasised by public inquiries involving safety regulation.

In the MWCS aims it is not stated if this 'lawful' includes HSWA. It needs to as MWCS says it is concerned with patient welfare. The 2003 Act covers MWCS but they do not give it a regulatory role for patient safety merely to 'monitor' the Act. These functions are very different. Relevant to the role of MWCS is the situation at A & A where the board was found severely at fault with the recent conviction in relation to the death of Nicola Black. MWCS should be conversant with the requirements of HSWA as it applies to the range of hazards and risks, and the required precautions, be they physical, management systems, or organisational safety culture. The standards of protection required by HSWA in relation to high hazards and risks are required to be proportionately high. The hierarchy of controls required (MHSWR Regulation 4) sets elimination of risk in such situations as the priority within the continuing bounds of what is reasonably practicable. The

precautions and law apply to physical controls and work practices, but also to management system and having the right corporate and organisational culture. Their aims do not indicate if MWCS is an advisory body undertaking scrutiny, or if it was a regulator. The MWCS indicates that the staff are health and social care professionals but not whether they have expertise in the law, risk management in high hazards sectors, management systems or in safety culture.

There have been and continue to be suicides occurring that should just 'never be'. Many of the causes should have been designed out. Some of the issues are very basic and simple to address. The safety of those in mental healthcare in Scotland is not what it should be and not up to HSWA standards. It is not clear what MWCS are doing to assist in getting HSWA compliance that would 'solve' the safety of mental heath patients as far as was reasonably to do so. There is apparently no Memorandum of Understanding with HSE. There is nothing to indicate that MWCS know what is required by HSWA.

HSWA is not referenced under the 'Law' section of the MWCS website, yet HSWA was the legislation used in the prosecution of A & A following an avoidable death on a mental health unit. HSWA applies to prevent other harm to mental health patients. There is the MWCS document 'Monitoring Deaths in Detention'. In 2012-13 there were 78 deaths in a detained population of 6721. Of these that MWCS were aware that 11 of the deaths were suicides. From the sample of three deaths quoted, two of them would come under HSWA/HSE remit for investigation. HIS gets informed on the suicides but does not automatically notify HSE. In 2009, Lord Cullen recommended a mandatory fatal accident inquiry be held into the death of any person who is subject at the time of death to compulsory detention by a public authority (Review of FAI Legislation). The Scottish Government's response in 2011 noted this recommendation, considered that it would result in unnecessary inquiries and looked at a range of options to produce a more proportionate response. It still has not got a viable alternative nor does the Scottish Government comply with UK and EU legislation on the prevention and independent investigation of deaths. A competent independent regulator working with HSWA and using the legally required hierarchy of risk controls should be able to address the control the risk of suicides of detained patients. They can deal with problems comprehensively and at source so as to reduce them as far as could reasonably, and legally, be expected. In respect of deaths of patients in MWCS documents on the NHS there is not a reference to a regulator, HSWA investigation or a notification procedure to HSE for it to consider whether it was in their remit. A regulator must be involved in both the prevention of deaths and in investigating them when they do take place. It took two years and a lot of pressure before HSE was involved in the Nicola Black suicide at Ayrshire and Arran that led to a conviction. HSE needs to be involved from the start particularly with the need for quality evidence. With the best intent the police are not experts in HSWA cases. HIS is not a suitable body for investigating deaths in the independent healthcare

sector or NHS as it does not have the competences or powers. This absence of HSWA in mental health is consistent with defects in other healthcare bodies in Scotland.

In 2012 there were 106 deaths caused by probable suicide for which the relevant NHS board carried out a suicide review because the individual had had contact with NHS mental health services in the year prior to their death (14% of all Scottish suicides in that year). However not one of the 106 deaths was referred to the Mental Welfare Commission for Scotland.

Who is now carrying out routine preventative regulatory inspections in Scotland to ensure the health and safety of both staff and patients in mental health services to the standards of HSWA proportionate to the hazards and risks? Formerly these inspections were carried out by HSE. The answer now seems to be, no-one.

7.11 Scottish Government Legal Directorate

The Scottish Government's Legal Directorate is there 'to assist the SG in achieving its purpose, being a proactive legal service, promoting robust decision-making. It is involved in instructing bills and drafting subordinate legislation, and being competent in legislative and devolution matters including the European Convention on Human Rights and EU law'.

In terms of its net result, it failed to recognise that the SG was not implementing UK law, HSWA and related legislation that should save a large number of lives, and prevent other harm. It failed to notice that the subordinate legislation of the Public Service Reform (Scotland) Act 2010 acted contrary to UK law and counter to the European Convention on Human Rights and EU law. It did not recognise that the NHS in Scotland became unregulated unlike the rest of the UK. This is a very basic error of legal understanding. Who checked PSR 2010 for legal compliance and implications? The minister(s) carry the overall responsibility but the Legal Directorate says that it has a role in such matters. It also seemed to have missed the implications for 'The Mental Health (Care and Treatment) (Scotland) Act 2003'.

The Legal Directorate in support of Scottish Ministers signed off the Closing Submission to the Vale of Leven Public Inquiry. In the section on legislation the Scottish Ministers and the Legal Directorate omit any reference to HSWA which is the determinant of the acceptability or otherwise of health and safety conditions, particularly the infection risk under COSHH at the hospital. This as well as the implications for the Human Rights Act 1998 and the European Convention on Human Rights as it applies to healthcare. The Scottish Ministers submission misled and derailed the inquiry into the deaths of 30-50 patients. Again any competent legal advice would have known that HSWA, COSHH and MHSWR applied and that this legislation was likely to have prevented

the outbreak. The legal advice should have also indicated that it would be the basis of preventing further outbreaks. Consequently the right lessons have not been identified from VOLH or for healthcare across Scotland, and so the infection control defects, the outbreaks, and the deaths continue.

With such major legislation as HSWA being disregarded by the Scottish Government, ministers, directorates and legal directorate, what other UK law is being disregarded? Has there been a competent due-diligence test carried out on the implementation and compliance with the legislation on reserved matters? Where is the review of this? What did it show? Did it identify the 'vacuum' on HSWA?

The NHS's Healthcare Protection Scotland 'Closing Submission' on the VOLH was prepared by a QC and an Advocate who also omitted any reference to HSWA and regulation. This further misled the inquiry and demonstrated that HSWA is not addressed as well as not being complied with by healthcare in Scotland. There will soon be the Penrose inquiry report which from the preliminary report is likely to show a similar omission.

The SG's position on disregarding the law as it applies to healthcare and social care and the consequences of its error are part of one the biggest cases of maladministration it is possible to imagine. It has also put ministers in breach of the Scotland Act and at personal risk under HSWA. Competent legal advice should have identified this risk to public safety caused by this disregard, to the position of the SG, and direct risk to ministers.

Neither the Scottish Government nor the Legal Directorate have the competent person advice to assist it in complying with the Health and Safety at Work etc Act 1974 and related relevant statutory provisions as required by the Management of Health and Safety at Work Regulations 1999, Regulation 7.

7.12 Scottish Civil Service and Scottish Government Policy Units

Allied to the Legal Directorate are the governmental policy advisers such as those in the 'The Quality Unit'. The ministers consistently have failed to understand HSWA in fundamental ways that have severe consequences for the people in Scotland. Their policy advisers have been culpable in this major case of Governmental law-breaking and maladministration. This is a case where the failings of ministers, their directorates and their civil servants do permit a large number of avoidable deaths. A basic knowledge of the governmental roles and responsibilities should have addressed the requirements of the law, its need for compliance, and would lead to the prevention of such large numbers of reasonably preventable premature deaths.

The behaviour of civil servants on the issue of the Scottish Government's failures to discharge its responsibilities on patient safety, and of those in social care, has not met the requirements of the Civil Service Code and its core values of integrity, honesty, objectivity and impartiality, let alone technical competence. Civil servants in co-operation with competent legal advice should have recognised the problem of the Scottish Government being non-compliant with HSWA, and averted the SG errors and the loss of life. That the Civil Service in Scotland did not fulfil its responsibilities nor have the competences to help protect the public should be of great concern.

It should not have required me to identify, raise and relentlessly pursue the issue of the Scottish Government's failure to implement GB– wide legislation that would secure patient safety and so save a large number of lives as far as was reasonable to do so. The mechanism of the Scottish Government should have done this for itself. The matter is not one of detail; it is one of gross maladministration and extensive breaches of HSWA, HRA and the Scotland Act 1998 right at the top of the administration with implications through to the frontline delivery of healthcare. The consequences are likely to affect all of us in Scotland in some way with the scale of the avoidable harm and deaths that result.

Since I first raised the matter in April 2012 absolutely none of the many responses from civil servants have even made an attempt to answer the very serious points. None have answered any of the points in part because there will be no answers, the policy has been to do nothing, as if all is well when the contrary in the case. It is a catalogue of Scottish Government failures that required addressing. The SG need for defensive responses has been a major obstacle to getting the issues addressed and patient safety secured. They will have costs lives. Such responses as there have been have been trivial in the extreme and this in response to one of the most serious issues that they would have been called on to address. Almost every one of the replies has breached one or more of the core values of the Civil Service of integrity, honesty, objectivity, and impartiality. Correspondence in December 2014 on behalf of Ms Sturgeon, Ms Robison and Mr Matheson managed to breach all four of the values (e.g. 100% dishonest in saying that issues had been answered before the issue had occurred, so requiring time travel to have a chance of being 'tenable' responses). These three replies would have been written under the direction of these three ministers. This applies to replies from Glenn Hunter 19 December 2014 on behalf of Nicola Sturgeon, and David Leslie on behalf of Shona Robison December 2014 and Michael Matheson also December 2014.

In democracies there is the requirement of governments to have the separation of the three powers of the executive, the legislature and the judiciary to prevent centralisation and domination, and the abuse of power. Some countries do this with a clear separation of the powers, whilst others allow some overlap to give flexibility to aid effectiveness and efficiency, but with compensatory checks and balances. The British

Constitution takes the latter approach and the formal checks are having two parliamentary houses, an effective system of parliamentary opposition, an independent judiciary and an independent Civil Service. In Holyrood these are not present; the precautions to prevent abuse of power are not in place. This has allowed four major pieces of legislation that are required to ensure patient safety, which are the relevant constitution, having been and continue to be neglected. The Civil Service has failed in its responsibilities towards the constitution. It is partly culpable in the government's inaction that allows avoidable deaths. The Civil Service in Scotland is a part of the Home Civil Service and owes its duty to the whole of the British Constitution and not just that selectively chosen by the Scottish Government particularly when it ignores life-saving legislation. Civil servants should not be required to promulgate illegal policies of the SG such as ignoring HSWA.

On some of the actual policy positions there are other issues apart from the generality of the total disregard for HSWA, and the impact on HRA and the Scotland Act 1998. A few examples should give the flavour. The Quality Unit for Health and Social Care has a Route Map to the 2020 Vision for Health and Social Care. It refers to Francis and then totally missed the points. Recommendations 19-63 and others such as 87 deal with the healthcare regulation that delivers patient safety, and yet they cannot be applied here in Scotland as there is no regulator. Francis is about securing the end result of patient safety, again the objective is a reserved matter, and Scotland needs to apply itself to the issues and solutions put forward. Delivery of Francis and patient safety falls here at the first fence.

The Route Map has an aim of 'delivering enhanced patient safety with major reductions in levels of Healthcare Associated Infections (HAI)'. However it disregards HSWA, MHSWR and COSHH as it applies to HAI. Instead of getting dutyholders, including itself, to comply with the law, it relies on guidance. This is one of the highest areas of risks across all sectors, and yet the SG policy is a complete inversion of UK policy and law on protecting the public's safety. The Scottish Government's policy units stand policy on patient safety on its head. It is a fundamental gross error on public policy and law.

The Quality Unit issue Consultation Documents (CD) on healthcare, including two in October 2014. One was 'Offence of Wilful Neglect or Ill-Treatment in Health and Social Care Settings'. The unit did not realise that the offence is already covered by HSWA, the document made absolutely no reference to binding UK legislation. This is indicative of the systematic disregard for existing law on patient safety throughout the Scottish Government and Scotland generally. If the law had been implemented there would have been no need for the CD. The second was on a 'Statutory Duty of Candour for Health and Social Care Services'. This too missed both the law and the essential requirement of the independent healthcare regulator. This meant that there was no independent competent body to refer cases of adverse incidents in the

NHS to. This CD is based on the English CD where the IHR has an essential role. So here the Scottish CD without an IHR has to omit a vital part of the process.

For whatever reason the Civil Service in Scotland has failed in its purpose of supporting the Government in developing, implementing and communicating its policies in accordance with the Civil Service Code. For example, under 'Integrity' civil servants are required to 'comply with the law and uphold the administration of justice'. This has not happened on GB/UK law and patient safety. Firstly civil servants are servants of the Crown as members of the Home Civil Service and that requires compliance with binding legislation such as HSWA. That comes ahead of statements that Scottish civil servants 'owe their loyalty to the devolved administration rather than the UK government'. It certainly does not apply when the Scottish Government acts illegally. The Service has played a role in the Scottish Government's failure to implement GB and UK-wide legislation that should prevent a large number of avoidable deaths and other harm. It has not advised ministers correctly and it has failed to invoke established governmental 'whistleblowing' procedures. If that had been done and failed then it is required by Civil Service procedures to go to the Civil Service Commission.

The standard of responses from civil servants both in their own right and under the direction of Scottish Ministers has been exceptionally poor and certainly not up to UK standards for such officers. A review of the responses frequently shows an absence of basic abilities in comprehension. Here, it certainly does not deserve the required public respect. With their failures and continual breaching of the core values of the Civil Service Code, and the matter of the unacceptable standards of the Civil Service in Scotland, I asked that the matters involving ministers be referred to Sir Peter Housden Permanent Secretary to the Scottish Government. Ms Sturgeon refused. With his departing the request should go to his replacement. There is ample evidence readily available to justify such a review. As the matters of law are reserved (HSWA, HRA, the Scotland Act 1998, Corporate Manslaughter and Corporate Homicide Act 2007) it seems an independent review under Sir Jeremy Heywood, Head of the Civil Service and the Cabinet Office is needed. It should not be the role of the Civil Service in Scotland to obstruct major pieces of reserved GB/UK legislation. The standards of the Civil Service need to be restored to fulfil the requirements of the constitution.

8. Crown Office and Procurator Fiscal Service (COPFS)

As the independent public prosecution service in Scotland, the COPFS together with its departmental head, the Lord Advocate, should have a major role in the application of the law as it applies to patient safety. The responsibilities include the investigation and prosecution of criminal offences and the investigation of sudden or suspicious deaths. It

presides over and decides on what cases Fatal Accident Investigations (FAI) are to be carried out. The Lord Advocate is the ministerial head of COPFS, leading the system of criminal prosecutions and the investigation of deaths. He is the senior Law Officer. He is a minister of the Scottish Government and acts as its principal legal adviser but he is not subject to the rules on collective ministerial decisions.

As has been pointed out many times here, the Health and Safety at Work etc Act 1974 has not been implemented in Scotland by the Scottish Government, or by healthcare and social care providers to the legally required standards proportionate to the high hazards and risks that are present. The Government, HSCD, NHS Scotland and other bodies do not have the legally required effective plans to secure compliance with the relevant statutory provisions on HSWA. The Scottish Government abolished the independent healthcare regulator (IHR) so creating ensuring that there was not effective regulation of HSWA compliance. The consequences of these failures to meet legal responsibilities is that there has been and continues to be a large number of reasonably preventable premature deaths (RPPD). The law requires that these RPPD do not occur by virtue of there being effective precautions in place to prevent them and backed by effective regulation.

The Scottish legal system has failed to secure the protection of patients and of those in social care to the standards that GB/UK-wide legislation requires.

Unlike the rest of GB, in Scotland it is the COPFS that takes prosecutions under HSWA. Elsewhere in GB, in the lower courts, cases are taken by HM Inspectors of Health and Safety of the Health and Safety Executive. The COPFS despite it role in carrying out prosecutions under HSWA had not noticed that HSWA had not been implemented in healthcare and social care in Scotland. Across Scotland and from the Scottish Ministers through to frontline services, HSWA is disregarded. There is no reference to the intent to comply with HSWA which is the legislation that if implemented correctly would prevent harm so far as is it is reasonable to expect. There are not the actions here to either comply with the law or to prevent harm to the standards required. The COPFS and apparently the Lord Advocate had not noticed that the HSWA was absent as the prime legal standard to secure patient safety and that there was not the proactive regulator to ensure compliance in these sectors with very high hazards and risks. The scale of the consequences and the legal failings that permitted them had not been recognised by COPFS.

From April 2012 through to December 2013 the absence of HSWA and the lack of the IHR became more apparent together with the Scottish Ministers inability to see or understand the problems let alone address them. Since the failings stemmed directly from the failure to apply the law, I informed the Lord Advocate of the ‘absence of legal process for delivering patient safety‘ to the standard required by HSWA. Mr

Mulholland did not regard it as his job to do anything about the issue and said that it was a matter for the Health Directorate, and the CS for Health. Whereas the HSCD and the CS for Health are major obstacles to legal compliance. It was also very much in the Lord Advocate's stated role and job description as principal legal adviser to the Government and the role of 'the investigation and prevention of crime'. When a government disregards major UK and EU law and the Scotland Act 1998 and with such dire consequences in avoidable deaths, then the role requires a principal legal adviser to put the government right.

Secondly there is the issue of the prevention of crime. With RPPD associated with work activities the law is there as a driver to secure appropriate behaviour and standards of safety, and to use in prosecutions as a measured response to the crime. In Scotland the law is only used very rarely and then reactively. In the Nicola Black case compliance and regulation was missing that would have prevented her death. I was told that it took two years for COPFS to notify the default regulator, HSE, which was then brought in to investigate. Two years for a death that resulted in a prosecution on very obvious HSWA failings and no-one thought to refer the matter to a regulator. Where was the regulatory action to prevent further deaths? The failure to notify HSE was itself a failure to meet a key objective of COPFS to ensure that all deaths reported to the Procurator Fiscal are investigated appropriately and speedily. In December 2013 I provided a sample of evidence to the Lord Advocate to show the massive scale of the problem caused by the failure to comply with HSWA on patient safety (Appendix 3 Evidence of Harm). I also said as a former HM Inspector, Crown Prosecutor and regulator of health and social care what was required to comply with HSWA (Appendix 4 Legal). The breaches of the law are on a very large scale, perhaps technically they are now the biggest criminal subject and yet the Lord Advocate and COPFS by their inaction are sanctioning it. The use of the law in actual prosecutions should need to be infrequent and exceptional. The current situation with the Scottish Government and its ministers is exceptional. The omissions on HSWA apply to those involved in delivering healthcare services and senior officers in the organisations. As provided for by s48 of HSWA, government ministers are included in being liable for prosecution in relation to their acts and omissions. Here there is their setting the policy of disregarding HSWA, misleading the VOLH public inquiry, not requiring effective HSWA plans and obstructing its regulation. Scottish ministers are not upholding the law, and that regrettably includes the Lord Advocate. It is an exceptional position for a Lord Advocate to have put himself in, and not one without legal and professional jeopardy, as well as reputational risk for the role of the Lord Advocate. The role has become allied with Scottish Government's political interests; any competent legal advice would have recognised the illegality of the Scottish Government's position and the need to bring it into line. To fail to intervene on a straightforward failure to implement UK law is a policy and hence political decision not one of legality and justice. Consequently it is not in accordance with the Ministerial Code.

On a systems approach, a government department would be expected to carry out a due diligence test of the legislation within its domain and to verify that it was both being implemented and complied with to the required standard. In the case of COPFS and the judiciary this would mean knowing what legislation was in force and who had responsibilities to comply and those who ensured that it was complied with, being proportionate to the issues the law covered. It does not appear that this has been done. This would be necessary on international, UK and Scottish law. In this case there is a massive gap on UK and international law. The consequences of the failure to comply may be compared with homicides in Scotland running at about 50 a year, and HSWA Reasonably Preventable Premature Deaths (RPPD) at about 2,000. A risk profile of subjects within the COPFS remit should have readily identified this major omission.

It asks the question of what other international and UK law is not being implemented or complied with in Scotland? What is the due diligence review process? How often is it carried out? Where are the reports?

As well as the massive consequences for the people in Scotland in terms of avoidable harm there are the commensurate legal issues. The problem of disregarding HSWA is firmly set with the Scottish Ministers. They should have known the main legal requirement applicable to securing patient safety. For a Cabinet Secretary for Health it is a basic initial ministerial briefing matter. Ministers will or certainly should be aware of their HSWA responsibilities of under S7, 36, 37 and as permitted by s48. When COPFS investigate and draws up prosecution cases, HSWA requires that root causes are addressed. It is not only about frontline failures. In healthcare the issues are, or as here should be, traced back to the role and responsibilities of senior officers in the organisation. If this was done in any of the HSWA cases taken by COPFS it would have been apparent that there was a general absence of HSWA compliance and the required management arrangements to make sure that such incidents are prevented. HSWA and RPPD are about prevention, unlike most homicides where action is taken after the death occurs. It seems that this fundamental point was not understood by COPFS, and perhaps from correspondence, by the Lord Advocate's suggestion that HSWA is about actual deaths. That should be a worrying position if that has been the understanding of the law.

As well as HSWA tracing back frontline failures on fatalities to the responsibilities of line management, senior officers and ministers, there is the parallel responsibility of the organisations under section 3 HSWA and the Corporate Manslaughter and Corporate Homicide Act 2007. Since SG sets the policy of disregarding HSWA then both ministers and SG should be considered for prosecution in all healthcare and social care deaths covered by HSWA under HSWA and the 2007 Act respectively. Exemplary cases should be sufficient to rectify the systemic defects of the Scottish Government and its ministers. In a

letter to Mr R Wilson of 13 January 2015 COPFS refused to investigate the responsibilities of senior officers, the Scottish Government and ministers under HSWA in respect of the death of Nicola Black and others. The duties exist in law, and there can be no justification on legal grounds for them not investigating. It appears to be a political decision on the part of the COPFS. The net result of not investigating is one with political implications.

The COPFS well-know that all the fatal incidents that should be reported to them in healthcare and social care are not. In such cases as suicides in mental health units the number of FAIs is exceedingly low. The SG rejected Lord Cullen's view that they should be subject to FAIs by saying that it would come up with a suitable alternative but has not. Again a sample of cases or perhaps one done properly such as the Nicola Black (if her parents continue their view that there should be one) should be sufficient. The FAI should properly address underlying causes in terms of management, corporate and organisational culture and trace back to the policy set by NHS Scotland, HSCD, and Scottish Ministers. This FIA should address the issue of RPPD and suicides across all healthcare providers and make sure that this time the lessons are properly identified, learnt and applied across all of Scotland.

Even the incidents that are notified to COPFS, they are not being investigated to the standards required. HSWA is a comprehensive, systematic and proportionate package of legislation to prevent harm so far as is reasonably practicable. It deals with frontline controls but also the essential management systems, structure for safety and the organisational and corporate cultures related to the incident. Predominantly investigations concentrate on the first without the full consideration of the other legal requirements. The initial investigation into the Vale of Leven Hospital C-difficile outbreak and large number of deaths was an obvious case. The actual inquiry found major breaches on all the aspects noted above and yet the investigation was curtailed without enforcement action. The initial COPFS, Police and HSE inquiries failed to result in enforcement notices let alone a prosecution.

On the VOLH public inquiry the initial briefing and closing submission came from the then Cabinet Secretary for Health and the Scottish Ministers respectively. The Minister's submission was made with the assistance of Scottish Government's Legal Directorate. These and the whole inquiry missed the application of HSWA and that compliance with it should have prevented the outbreak and deaths. Given the scale of the 'disaster' it should be expected that the quality of the Government's legal advice would be of the top order. As it was it could not have been more wrong. Together with the Ministers, it derailed the inquiry and meant that it did not serve the purposes of a public inquiry. The inquiry actually perpetuates the major problems and law breaking found here. COPFS were initially involved in the investigation into the outbreak, and here there should have been an official interest in the proceedings of the inquiry. It would be standard procedures for the draft inquiry report to be

verified by the Government's top legal advisers prior to release. Any examination of the evidence presented to the inquiry and the closing submissions by competent legal advisers would have shown the stark omission of the law, - HSWA. The inquiry should not have been incorrectly briefed but even so there should have been other checks on its proceedings and the final report to ensure that such a major error was averted.

On patient safety the people of Scotland are being failed by healthcare providers who have been given a policy by the current Government of disregarding the GB/UK-wide legislation that would protect them. The responsibility lies with NHS Scotland, the Health and Social Care Directorate and the policy set by Scottish Government ministers. The COPFS and the Scottish legal system should have acted as a check to such serious disregard of the law, and to have secured the correction of Government policy. The COPFS and the Lord Advocate have not done this and refuse to accept the role that is explicit in their remit. The avoidable deaths continue as the law is not recognised, implemented or regulated.

9. Scottish Government Ministerial Responsibilities

A competent inquiry and regulator should be able to verify the following points:

9.1 Mr Alex Salmond: Scottish First Minister (16 May 2007–19 November 2014) There is no evidence that for his period as Scottish First Minister Mr Salmond considered HSWA as a prime requirement of healthcare and social care in Scotland. During that time healthcare providers were occasionally prosecuted under the Act, but there should have been an awareness of major UK legislation protecting both employees and the public. The overall responsibility for this failure lies with Mr Salmond. During that time the failure to set HSWA as a prime requirement for healthcare and social care providers would be associated with a very large number of reasonably preventable premature deaths (RPPD). His ministers were repeatedly reminded of this and the consequential avoidable deaths. Mr Salmond was again reminded of the application of HSWA on 17 February 2014 and periodically until his resignation on 19 September 2014. This was essential as RPPD would occur each day that he delayed initiating action on compliance with HSWA. He refused to change the Scottish Government's policy of disregard and refused to recreate the independent healthcare regulator that he had abolished.
Breaches: HSWA s7, 36, 37, as provided for by s48. Responsible for breach of Human Rights Act 1998 s6 'Acts of public authorities 'Life'', personally under the Scotland Act 1998 s57(2).
Ministerial code in obstructing the law, failure to uphold justice, and the code itself with respect to Mr Neil, and in misdirecting civil servants to break the Civil Service Code.

9.2 Ms Nicola Sturgeon: Cabinet Secretary for Health (17 May 2007–05 September 2012), DFM (17 May 2007–19 November 2014), **Scottish First Minister** (19 November 2014 -)

Misled Lord MacLean Chair of Vale of Leven Public Inquiry in the briefing meeting of 9 July 2009. Abolished Scotland's independent healthcare regulator in the Public Service Reform (Scotland) Act 2010. The Scottish Commission for the Regulation of Care as set up by the Care (Scotland) Act 2001 was abolished and a NHS in-house body set up which was: not a regulator; not independent; does not oversee HSWA; has no enforcement powers; only covers a limited range of healthcare topics (mostly HAI and care of the elderly) and, is not effective on HAI. This error was not subsequently identified by the CS or SG.

Contact with other parts of the UK would have also revealed this major anomaly of Scottish healthcare being unregulated (the 'regulation' of healthcare professional bodies is not HSWA compliant). Ms Sturgeon was reminded of the application of HSWA to patient safety and social care in April 2012 but still did not implement the legislation. She and Scottish ministers misled VOLH in the 30 August 2012 Closing Submission 'Scottish Ministers'. This was a fundamental misleading of the public inquiry. This came after I had reminded the Scottish Ministers of Scotland's failure to implement HSWA (April 2012). As the DFM, was aware of the failures of SG on recognition, implementation and absence of regulation but still did not act. Possible ignorance (inexcusable in itself) became wilful neglect.

Ms Sturgeon's letter of 19 December 2014 confirms her intention to continue to disregard the law protecting patients and to not address her own failures and that of her ministers, or the former Scottish First Minister Mr Salmond, in respect of HSWA and the Ministerial Code. This response breached both the Ministerial Code and the Civil Service Code.

Breaches: HSWA s7, 36, 37, as provided for by s48. Responsible for breach of Human Rights Act 1998 s6 Acts of public authorities 'Life'. Scotland Act 1998 s57 (2). Ministerial Code in obstructing the law and failure to uphold justice, and in misdirecting civil servants to break the Civil Service Code such as stating issues (e.g. VOLH report) had been addressed before they had occurred.

9.3 Mr John Swinney CS Finance & Sustainable Growth (17 May 2007 -). **Scottish Deputy First Minister** (21 November 2014-) introduced Public Services Reform (Scotland) Act 2010 that abolished the Scottish independent healthcare regulator. The bill had no consultation. Sponsoring ministers have the responsibility to make sure that the bills are legal. This was not, it obstructed justice.

Breaches: HSWA s7, 36, 37, as provided for s48. Responsible for breach of Human Rights Act 1998 s6 Acts of public authorities 'Life'. Scotland Act 1998 s57(2).
Ministerial Code in obstructing the law and failure to uphold justice,

9.4 Mr Alex Neil: CS Health (5 September 2012– 21 November 2014**)**

Mr Neil was aware of Scottish healthcare failings on HSWA from taking office from Ms Sturgeon. He refused to do anything on the issues of the failure to implement HSWA in healthcare and social care. He misled Parliament during the statement on the HIS report on failings at NHS Lanarkshire (comparable with Mid Staffordshire prosecution and worse) on 17 December 2013 by calling NHS Scotland's HIS an independent healthcare regulator. After reminders to him in January 2013 he stopped calling HIS a regulator for NHS. In Holyrood PQ he however refused to create the IHR and continued to do so backed by Mr Salmond, and his refusal continues as SG policy with his successor Ms Shona Robison.
Breaches: HSWA s7, 36, 37, as provided for s48. Responsible for breach of Human Rights Act 1998 s6 Acts of public authorities 'Life'. Scotland Act 1998 s57(2).
Ministerial Code in misleading Parliament, obstructing the law and failure to uphold justice, and in misdirecting civil servants to break the Civil Service Code.

9.5 Mr Frank Mulholland: Lord Advocate (19 May 2011-) Mr Mulholland was aware of the issue of the absence of implementation and regulation of HSWA from 12 December 2013 and in four items of follow-up evidence in correspondence. He refused to intervene and persuade ministerial colleagues of the need to comply with binding GB/UK and EU legislation. He said that it was matter for the CS Health and the Health and Social Care Directorate and not his job. The Scottish Government's published information says that it does fall within his remit as chief legal adviser and head of COPFS whose role is to prevent crime (crime of course also includes crimes by ministers and senior officers).

A due diligence approach and test of Scotland's compliance with GB/UK and EU law would have discovered the vacuum of compliance and regulation. There may be other gaps in Scotland discharging its legal responsibilities. Whilst the role of Lord Advocate is exempt from some legislation it is not from HSWA, and the COPFS is listed in schedule 1 of the Corporate Manslaughter and Corporate Homicide Act 2007.
Breaches: HSWA s7, 36, 37 as provided for by s48.
Ministerial Code in not upholding justice regarding UK-wide legislation.

9.6 Mr Kenny MacAskill: CS Justice (17 May 2007–21 November 2014) Mr MacAskill was aware of the issues from before February 2014 but there is no evidence of action taken. His role has particular responsibilities to uphold justice and so involves ensuring that SG does implement and comply with the law itself. The justice vision and the

'justice dashboard' on avoidable deaths fails to include those related to healthcare and social care. It has a requirement that the risk of avoidable deaths in Scotland is reduced. RPPD in healthcare and social care is much larger than the ones that the dashboard does cover.
Breaches HSWA s7, s37 as provided for by s48
Ministerial Code in failure to uphold justice and UK and EU law and supporting procedures.

9.7 Ms Shona Robison: CS Health (21 November 2014 on) Ms Robison took over from Mr Neil on 21 November 2014. On 24 November Ms Robison was informed of the failings of the Vale of Leven Hospital Public Inquiry which was published on the same day. She was also informed of the SG failure to recognise that HSWA applied to patient safety of those in social care, its refusal to implement an effective plan for healthcare in Scotland to comply with the Act (MHSWR Reg 5), or to recreate the independent healthcare regulator required to deliver effective regulation (HSWA s18). Ms Robison in a letter of 17 December 2014 refused to address any of the above matters and continued with existing SG policy. This constituted evidence of her failures and that of her government.
Breaches: HSWA s7, 36, 37 as provided for by s48.
Human Rights Act 1998 and ECHR Scotland Act 1998
Ministerial Code in obstructing the law and failure to uphold justice, and in misdirecting civil servants to break the Civil Service Code.

9.8 Michael Matheson, CS Justice (21 November 2014 on) Mr Matheson took over from Mr MacAskill on 20 November 2014. He was informed of the above on 10 December 2014 of the failings of SG to recognise, promote and implement, or regulate HSWA. He was asked to address and get ministerial agreement to implement HSWA to the standards required and to recreate the IHR. Mr Matheson in a letter of 17 December 2014 refused to address any of the above matters, constituting evidence of his failures and that of his government.
Breaches: HSWA s7, 36, 37 as provided for by s48.
Ministerial Code in obstructing the law and failure to uphold justice, and in misdirecting civil servants to break the Civil Service Code.

None of the above ministers showed any sign of understanding let alone addressing the issues. The issues may have been newly brought to the attention in Scotland but they are widely recognised in the rest of the UK. Even the smallest amount of inquiry into the issues would have shown a justification for taking the matters seriously. Avoidable deaths are continuing as a result of ministerial inaction. These ministers show a systematic disregard for the law and on a matter that would affect most if not all of us in Scotland in some way, including themselves. My own experience as HM Inspector, Crown Prosecutor and regulator of healthcare and social care, and of forty years of the legislation seemed to not be worth a moment's regard. The Scottish Government does not have the expertise in HSWA. The absence of competent person advice on HSWA is a further breach MHSWR Regulation 7 'Health and Safety

Assistance'. The Ministerial Code is not functioning. Mr Neil was able to make a major statement on the safety of the people in Scotland that was as clear as can be a false assurance and totally wrong. Yet Mr Salmond took no action. There was no sanction such as the required resignation, Mr Salmond did not require it nor did Mr Salmond uphold the code or the law and justice. It gives the message that the Ministerial Code in Scotland does not deliver acceptable behaviour of Scottish Ministers. They may mislead Holyrood without concern. They do not justify public confidence in their statements. The Ministerial Codes needs to be reviewed and probably the role of the Presiding Officer strengthened.

The ministers are involved in what are cases of obstructing justice such as misleading a public inquiry such that it did not do its job, refusing to implement and comply with HSWA, refusing to comply with HRA and the Scotland Act 1998, multiple breaches of the Ministerial Code and Civil Service Code and upholding none of the aforementioned. There are also cases of what constitute abuse of power such as abolishing the independent healthcare regulator, and opting out of following and enforcing the Ministerial and Civil Service Codes. There are others. The situation of ministers of a constituent part of the UK disregarding major UK legislation and with such grave consequences is exceptional Obstructing justice and abuse of power are the usual attributes of cases warranting impeachment. Indictable offences such as those under HSWA and the role in the Scottish Government in corporate homicide make this sanction even more appropriate.

Impeachment has not been used in the UK for a long time. The last trial was a Lord Advocate, Henry Dundas, 1st Viscount Melville, First Lord of the Admiralty in 1806. Whilst the existence of impeachment is occasionally questioned it is still available in the UK. With the changes in the UK Parliament over the centuries such that officers and ministers being answerable to the UK Parliament it was thought that impeachment was an unnecessary and redundant aspect of UK law. However since that point was made there have been the creation of devolved governments. Neither Halsbury Laws of England nor Stair Memorial Laws of Scotland or other legal references seem to consider this situation. We now have a new situation but within existing legal provisions and procedures. As such it must be taken that impeachment is available and from the above very much appropriate for application to the current behaviour of Scottish Ministers. Impeachment needs to be available to protect UK citizens from harm carried out or permitted by a constituent government in the UK so as to ensure that the misuse of power and obstruction of justice is checked by the removal of errant officers.

Over recent years in Scotland there has been an amalgamation of governmental organisations. There has been the reorganisations of the Scottish Executive as the Scottish Government, the Health and Social Care Directorate is joined with NHS Scotland, and the staff of what was the independent healthcare regulator joined the NHS and its function

lost. The Civil Service in Scotland whilst still being part of the Home Civil Service role has become the stated Scottish Government's position of it serving the devolved government rather than the UK government; this at the expense of UK-wide legal and policy requirements. The COPFS and the Lord Advocate have been drawn further into government in their practice and policy. Despite Scotland neglecting such major legislation as HSWA, the Human Rights Act 1998 as it applies to healthcare, and the Scotland Act 1998 as it applies to ministers acting contrary to ECHR, the Lord Advocate has refused to intervene. Consequentially major breaches continue and permitting large-scale loss of life. The COPFS has also refused to act in the role of preventing and prosecuting crime. Further it has refused to investigate the role and legal responsibilities of the Scottish Government, ministers and senior officers for their policy of disregard of the legislation that relates to avoidable deaths, and as an example the conviction relating to the death of Nicola Black (15 January 2015). Despite a pre-emptive request for COPFS to provide justification for its decision it failed to do so. This is further confirmation of the position of the Scottish judiciary acting partially.

MPs have been told by government officers that they have no right to get involved in their constituent's concerns on patient safety. This is wholly incorrect. The legislation that applies is reserved. The responsibility of the Scottish Government is to deliver healthcare and social care, and the safety of patients. When there is a failure to have in place effective measures to prevent harm then it is a UK-wide matter of public safety and legislation. This is with or without actual harm occurring. The Scottish Government if it denies the legitimate role of MPs in patient safety it is acting counter to the legislature, it is acting as if was the legislature when it is not. It is a further obstruction of justice and abuse of power. The matter needs further investigation, if it is the case it looks like a very serious usurping of democracy.

With the proper role of legislature removed the overall effect has been to bring the Executive, the Legislature, and the Judiciary into one - the Scottish Government. This is contrary to a basic principle of modern government and democracies – that of 'The Separation of Powers'. This principle has been in place for 250 years and is there to minimise the risk of the abuse of power and the obstruction of justice. Hence the parlous situation we have on healthcare in Scotland.

- **10. Health and Safety Executive (HSE)**

HSE is the lead body for the UK on setting policy and regulating the health and safety of employees and of those affected by work activities. HSE was created as the body to put into effect the Health and Safety at Work etc Act 1974 (HSWA). The Act is a comprehensive, systematic, proportionate, reasonable and legally enforceable means to control the risk to employees and the public affected by work activities. It applies to patient safety and to those in social care. It has been highly successful

where it has been applied, in particularly to areas of high hazards such as nuclear, chemicals and petro-chemicals, off-shore, gas supply and railways. The one area of failure has been healthcare and social care where the Act has never been applied properly.

The problem of patient safety is a long way off being solved and the costs of this are severe. There is the allied problem of there not being effective regulation to make sure that the law is complied with to achieve tolerable levels of risk. HSWA has the ability to 'solve' patient safety. If done properly it operates on three levels covering: specific risks and controls; effective management arrangements to ensure that the controls are working, and; having the right corporate and organisational culture. The latter is in the overall context of organisations having the right intent, and that frontline staff have the right competence and attitude to deliver safety. The levels can be seen as concentric spheres, with specific risk at the centre, then management systems, and then culture surrounding all. 'Culture' is how an organisation or individual thinks, feels, and so acts.

An illustrative example of the three levels is in the widespread problem of Hospital Acquired / Associated Infections (HAI). Infections are caused by microbiological agents and their control is covered by the Control of Substances Hazardous to Health Regulations 1989 revised regularly (COSHH). These operate within the requirements of the Management of Health and Safety at Work Regulations 1992/1999. In turn they function within the overall intent, general requirements, structure and attitude (culture) of HSWA. The Vale of Leven Hospital public inquiry report failed to address any of these issues, the Scottish Government also fails to.

Prior to the 1974 Act neither hospitals nor patient safety were covered by health and safety legislation. HSE then made slow progress in addressing these issues. Patient safety only gradually became recognised in the late 1980s and that was on basic physical safety issues such as falls, bath scaldings and asphyxiation risks from trapping in beds ('cot sides'). In 1989 to support HSWA, HSE produced guidance 'Successful Management of Health and Safety' (HSG 65). Guidance was then overtaken by the simpler and effective legal requirements of MHSWR 1992. By the mid-1990s HSE was carrying out team audit inspections of hospitals. These combined frontline inspection of the effectiveness of the control of risks and the related performance of the management. Initially these were based on HSG 65 but HSE (Manchester) used the statutory requirements of MHSWR and made what was optional guidance on 'good' management into a legally enforceable requirement to have effective management.

Once these HSE audits of hospitals started there was an increased understanding of the profile of risk in health and then social care. HSE used to concentrate its work on microbiological risk on pathology laboratories. However it quickly became apparent that the main risk of

infections was overwhelmingly out in the rest of the hospitals. At the time (1997) the NHS was suggesting that there were about 5,000 deaths occurring each year due to HAI. Of those it appeared that a substantial proportion (perhaps 60% plus {equivalent to 3,000 deaths}) could have been prevented by applying COSHH, MHSWR and HSWA. HSE then made HAI and infection control a priority in its inspections of hospitals. HSE gradually extended the work on HAI into other parts of healthcare and into social care such as nursing homes. It was shortly after that the prime role on patient safety and social care transferred out of HSE's responsibility and over to independent healthcare regulators (IHR). HSE mostly withdrew from healthcare to only acting on a very limited type of issue noted above on simple physical hazards, as its policy says 'when compelled to do so'.

The final part of the three levels is culture. This is recognised to be very important but often poorly expressed, or understood as to what it is and how to get the right culture. Models on culture were passive, describing what there is rather than what is required and how to get it. They were also incomplete only dealing with some aspects of culture. They did not relate to legal requirements. This was addressed by HM Inspectors of Health and Safety within the Office of Rail Regulation in Manchester. A legally enforceable model was devised and implemented based on HSWA and MHSWR; this was the 'Five Requirements of Organisational Culture' ('5R'). Its first field test was on the culture and performance of those working on their own or in small groups where their performance was highly safety critical. This has a commonality with healthcare and social care workers. HSWA now had the complete package to deliver health and safety performance.

There is the need for a proportionately high standard of risk management in high hazard and high risk sectors. Again this started to be addressed for healthcare in the mid-1990s. Legal requirements already applicable to healthcare and techniques from conventional major hazard sectors could, and should, be applied. Major hazards sectors are traditionally geared to the prevention of high consequence–low probability events. They are addressed in a very systematic way and have been successful. There was consideration by inspectors and clinical directors of applying them to clinical practice prior to the transfer of healthcare out of the HSE remit and the introduction of Datix (Healthcare Incident Systems software) type systems. Risk management in healthcare and social care needs to be reviewed relative to HSWA as applied to major hazards and for these sectors what is still very high risk environment. HSE makes the appropriate point that it does not seek to get involved in matters within a normal range of clinical judgement.

The momentum for progress on patient safety and effective regulation faltered in about 2000 with the transfer to the IHRs. These bodies employed health and social care professionals but they did not adopt the continuing legal requirements of HSWA, COSHH and MHSWR. They

did not have the expertise in risk management or the law. HSE made rolling agreements with the IHRs over what each body's role was and the need for transfer of information. The IHR were not given HSWA powers despite the fact that the matters of patient safety (and social care) that they inspected were covered by HSWA. HSE did not carry out due diligence tests to ensure that these bodies were verifying that healthcare and social care provision fully implemented health and safety to the standards required by HSWA and related legislation. This was essential to secure compliance with section 18 of HSWA on enforcement and the need for effective regulation of compliance. A continuous stream of cases since has demonstrated that the new arrangements were not securing effective regulation and the delivery of the safety of patients and those in social care. The Francis Report on Mid Staffordshire NHS Foundation Trust identified a 'regulatory gap' that should not have occurred and had to be filled. With Scotland not having a regulator this is a 'regulatory' vacuum that is still not being filled, SG is refusing to do so.

It is open to HSE (and by the HSE powers and their enforcement code (EMM) most probably a legal duty), to take enforcement action against the Scottish Government, its ministers and senior officers for their failings on such a serious matter the non-implementation of HSWA as required and to then obstruct its regulation.

In Scotland with the abolition of the IHR, HSE then made agreements with NHS Scotland's HIS for healthcare, and SG's Care Inspectorate for social care. Neither body uses the standards of HSWA. The agreement with NHS's HIS is made as if it is a regulator and performing the functions such as is the case in England with the Care Quality Commission (CQC). The Letter of Understanding does not even mention that HIS is part of the NHS. This would lead most readers to not know that they are the same organisation and encourages misunderstanding. It suggests unjustified confidence as if HIS was an independent and competent body, when it is not. HSE is now aware of the absence of independent regulators working to HSWA standards but Scotland still continues without an IHR. The HSE-HIS agreement in effect withdraws regulation from a large part of healthcare and social care. This has some similarity with an HSE experiment of the early 1980s to allow part of construction to 'self-regulate'. This experiment was very quickly abandoned after the first fatality. The agreement between HSE and HIS could be subject to a Judicial Review. The Scottish Government almost completely disregards the Francis Report on Mid Staffordshire and certainly all the recommendations on regulation.

The Letter of Understanding on patient safety refers to infection control (just as HIS) but omits all the other highly risky areas of healthcare. So it would not address the matters covered by the prosecution of Mid Staffordshire NHS Foundation Trust. This is a major gap in HSE policy. No-one in Scotland is regulating these matters. This is possibly the

worst error of health and safety and of regulation in the UK. HIS only scrutinise and even then their brief is very limited relative to the risk profile, as it says - it is mostly about care of the elderly and HAI. SG confuses the HIS scrutiny with regulation, not understanding the difference. There is a big difference between the two.

HSE still recognises that the prevention and control of risks arising from Healthcare Associated Infections (HAI) come under HSWA but it will not carry out inspections or implement its regulatory role. Generally it leaves a subject that is responsible for many hundreds of avoidable deaths to very limited non-independent, non-regulatory bodies, HIS and HEI, with no enforcement powers. This is a breach of s18 HSWA of the highest order in terms of the type of offence and the consequences of it (para 18 of the agreement). HSE will only get involved in this as one of the highest risks covered by HSWA when compelled to do so (para 19). HSE took no role in the actual VOLH inquiry, and dismissed its interest prior to it commencing.

There does not appear to be an appropriate intention by HSE in Scotland to secure compliance with HSWA on patient safety in most of the cases; it only deals with a few cases out of the hundreds of probable fatalities caused by non-compliance. HSE policy does not comply with section 18 on effective regulation. HSE in Scotland and national senior HSE management are aware of the issue but have not addressed it.

The law (HSWA) is about preventing harm, with any actual harm that does occur not being the offence. It is imperative that effective precautions are in place and that is tied in with the regulatory regime. Inspections are required particularly when risks are high to make sure that they are effective. In Scotland both healthcare and social care there is close to zero preventative inspections to HSWA, there is not the effective regulation. There is a complete absence of an acceptable policy or agreements for areas of such high hazards and risks in healthcare and social care.

When the HIS report on Lanarkshire found major problems on patient safety including issues similar to those involved in the HSE prosecution of Mid Staffordshire then HIS should have notified HSE of the likelihood of serious breaches of the law resulting in the major risk to lives. Irrespective of any agreement it is a public duty of HIS, and given their role as a public scrutiny body then there is an argument that it was a HSWA duty to inform the only regulator and body with the legal enforcement powers. HIS did not. Lanarkshire could have been a ‘Mid Staffordshire’, where the latter eventually brought major improvements to healthcare in England and lessons for Wales and Northern Ireland. When I informed HSE Scotland and the Director General of HSE of the public HIS document showing the failings they chose not to become involved regarding it as a ‘Scottish Government’ matter; whereas in England it was a matter for HSE and for prosecution. HSE policy required enforcement to be consistent, this was not. Also UK policy is

that self-regulation, or in this case no regulation, is not allowed either in law or in practice.

The problem repeated in NHS Lanarkshire Hairmyres hospital where HEI keeps finding poor infection control. This would involve breaches of COSHH, MHSWR and HSWA. I suggested to the Chief Inspector of HEI that they should inform HSE but they said that they had enough powers without enforcement, not realising that there is no choice by UK law and policy on the matter of effective regulation (i.e. no regulation is not allowed).

HSE's behaviour in Scotland is counter to HSE national policy on public safety, 'section 3' HSWA:

> *'Enforcing section 3 in areas key to our mission (e.g. in major and high hazards, including the nuclear industry and construction) remains a high priority. HSE will continue to address the most serious risks to the public's health and safety from work activities, using its expertise to best effect and taking into account the regulatory responsibilities of others.*

Healthcare and social care have much higher hazards and very much higher risks to the public associated with work activities than those sectors mentioned. In Scotland there is no regulator working to HSWA in either healthcare or social care. There is no body in Scotland to meet HSE's criteria of effectiveness, capability, health and safety expertise, economy or efficiency to deal with these sectors. It needs a specific independent regulator combining both healthcare and social care sectors as they progressively merge in terms of delivery and organisation. This current contravention of its own policy unfortunately is a very serious error on the part of HSE, and one which costs a lot of lives and other harm.

Shortly after the VOLH report into 30-50 C-difficile deaths came out, in November 2014, another C-difficile outbreak occurred this time at Edinburgh Royal Infirmary. It affected patients in four wards and was given as a major factor in the deaths of three or four patients. NHS Scotland's HIS and HEI were again involved but no regulator. After VOLH errors, SG, and HIS/HEI will have known the need for HSWA compliance and involvement of a regulator, with only HSE existing is Scotland. Still HIS would not and did not contact HSE. This is now a serial problem of HIS/HEI failing to contact the default regulator in an area of major risk to life, actual deaths, and breaches of COSHH, MHSWR and HSWA. Given the HIS/HEI failure I contacted HSE on 23 December 2014 to check that they had not been involved, they had not and apparently received no request from HIS/HEI. I further requested that HSE investigate at the Edinburgh Royal Infirmary as a formal complaint if necessary, that it be recorded as a major incident, and that the role of Scottish Ministers and the Government be investigated. HSE agreed to make initial enquiries to see if it had an interest. The existing

arrangements on patient safety are not working, not legal; and not tenable, and avoidable deaths are occurring.

Further with the highly anomalous situation of Scotland having no IHR, it falls to HSE to take on the full responsibilities for HSWA and patient safety. In effect it should have to perform the CQC patient safety role for Scottish healthcare. HSE is not equipped to take on this role in terms of resources or have the intent to deal with the range of patient safety hazards and risks. This means that the current number one hazard and risks covered by HSWA goes unregulated. I asked if HSE were to take on the 'CQC role' in the absence of the IHR, however in a letter of 29 January 2015 it refused to enforce on HAI or take on the role.

One area where HSE has a direct role on matters affecting patient safety is with the health of staff in NHS Scotland with its 160,000 employees and other providers. A major concern should be the fatigue risk to both healthcare staff and the consequent effect on their patients. There is misunderstanding on fatigue risk in the NHS and indeed with the previous Director for HSE in Scotland. This was shown with the approach of NHS Scotland and HSE, both thought that the Working Time Regulations (WTR) 1998 were health and safety regulations, and that complying with them was sufficient to meet HSWA. The regulations work on the basis of average hours worked and within those averages it is possible to work vastly excessive shifts and shift patterns that would certainly give an intolerable fatigue risk to staff. The emphasis on average hours had been the criteria used by HSE in the death of Dr Lauren Connelly of Inverclyde Royal Hospital in October 2011. She drove off the road after a 12 hour shift combined with a pattern of working excessive hours and consequent fatigue over the preceding weeks. HSE and NHS only looked at the recorded WTR average hours (even this is often not recorded properly in hospitals). What both have missed is the overriding requirement to control fatigue risk under HSWA. There is also the actual detail of WTR Reg 4(2) Maximum weekly working time

' An employer shall take all reasonable steps, in keeping with the need to protect the health and safety of workers to ensure that the limit specified in paragraph (1) is complied with in the case of each worker employed by him in relation to whom it applies'.
The limit is 'a worker's working time, including overtime, in any reference period which is applicable in his case shall not exceed an average of 48 hours for each seven days'. The average allows impossible working hours. HSE's enquiries into the death of Dr Connelly relied on data provided by the hospital; the investigation definitely did not meet HSE standards of investigation particularly of a fatal incident.

Fatigue risk management is much more advanced in others sectors, and where the complexity of tasks is much lower, such as on the railways. HSE is not using up-to-date HSWA standards to ensure the health and

safety of healthcare staff. The effect of tired staff on patient's safety is not well- documented but is becoming recognised.

Employee fatalities under HSWA in Scotland now run at about 10 per annum. In addition there will be about 10 members of public who also die from accidents associated with work activities. The predicted number of similar classified deaths in healthcare and social care will be about 2,000. With the highly anomalous position of there being no IHR, all of these deaths will fall to HSE's responsibility as the default regulator. HSE once had a comprehensive role on health and safety sectors but over the years there has been a spilt between major hazards and middle/low risks. In the last decade railway safety and nuclear safety left HSE and other major hazards had moved into specific divisions separated from the field operations of HSE's Field Operation Division (FOD). FOD's work is now middle and low risk sectors but it also has the over-arching responsibility for healthcare and social care, which are very high hazard and risk. Such sectors require a much higher standard of risk management, preventative inspection and enforcement. FOD do not have the resources or expertise for major hazards. This leaves Scotland in a very poor position, and with a lower standard of protection that the rest of the UK.

This is emphasised with the Francis Report Recommendation 87

'The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the Care Quality Commission should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the Care Quality Commission has power to launch a prosecution'.

In Scotland with no CQC there is currently no alternative but for HSE to undertake the role of regulating healthcare on patient safety to HSWA. As Francis deduces this is not effective regulation and so healthcare in Scotland is in breach of section 18 HSWA.

Before healthcare and social care transferred to independent healthcare and social care regulators, HSE during the audits of NHS Trusts commenced work with board members on the use of HSWA risk management. This began to bring in both the methods for the normal range of risks but also those from major hazards – which is in effect what healthcare is. This offered seemingly new techniques for clinical and medical directors. Given the level of hazards and risks these could be regarded as legally essential. I do not fully know the current status of risk management in these sectors but from adverse incident reports it certainly is not adequate and not HSWA complaint.

A development of HSWA methods of risk management is that because risk can be both 'good' as well as 'bad' it offers longer-term opportunities. It should be possible to create a single practical risk

management approach for healthcare that both prevents harm but also optimises health outcomes.

11. Legal Position in Scotland

11.1 The Health and Safety at Work etc Act 1974 The Scottish Government has not made as its intent, compliance with this Act as it applies to health and social care. It does not have an effective plan or organisation to deliver compliance. There is large-scale non-compliance for these high hazard and high risk sectors resulting in a large number of reasonably preventable premature deaths.

The Scottish Government abolished the independent healthcare regulator which should be the organisation ensuring legal compliance with acceptable standards. In social care the regulator does not apply the legally required standards of the Act.

The responsibilities of the Scottish Government, its agencies, its ministers, and other officers under the Act have not been discharged.

11.2 The Human Rights Act 1998 The main requirement of the Human Rights Act is for the Government to protect life. This applies to those under its care including those in healthcare, and relates to its role in social care. This is to implement Article 2 of the European Convention on Human Rights (ECHR). Compliance with HSWA is a practical means of complying with the HRA and ECHR (reference SHRC).

The Scottish Government does not have effective actions to deliver compliance with HRA. There is no regulator to make sure that HRA is complied with. There is the Scottish Human Rights Commission (SHRC) but it is not a regulator. The Scottish Government abolished the independent healthcare regulator that should have ensured compliance with both HRA and HSWA. The actions and inactions of the Government mean that it does not comply with HRA, and in introducing legislation that abolished the independent healthcare regulator it acted counter to HRA and ECHR.

11.3 The Scotland Act 1998 The acts and omissions of the Scottish Government and its ministers do not protect life as required by HSWA, HRA and the European Convention on Human Rights (ECHR). They do not meet the requirements on them. The abolishing of the independent healthcare regulator by enacting the Public Services (Scotland) Reform Act is in direct contravention of the ECHR and as such the Scotland Act 1998. This is an offence by ministers under Section 57 of the Scotland Act.

(2)A member of the Scottish Executive has no power to make any subordinate legislation, or to do any other act, so far as the legislation or act is incompatible with any of the Convention rights or with [F1EU] law.

11.4 The Corporate Manslaughter and Corporate Homicide Act 2007 There could be a large number of potential cases against the Scottish Government. This because of its policy of failures on management and organisation, and deaths associated with breaches of duty of care to those in healthcare.

12. Conclusions

12.1 Healthcare None of the bodies involved in patient safety in Scotland were aware of the GB-wide legislation, they did not know what it meant nor did they comply. There was no regulator to make sure that they did comply. The consequences are a large number of reasonably preventable premature deaths, other harm and avoidable costs.

12.2 Scottish Government The Scottish Government was similarly unaware of the applicable legislation that would secure patient safety and prevent avoidable deaths. The Government refuses to comply with the law and is allowing avoidable deaths and harm to continue. Ministers have refused to comply with the law or the Ministerial Code. The Scottish Government failed to act to secure the safety of patients and of those in social care to the standards legally required. Legal sanctions are applicable to a number of ministers, and possibly other senior officers. There are similar cases against the Scottish Government as provided for by Schedule 1 of the Corporate Manslaughter and Corporate Homicide Act 2007.

12.3 Legal System The legal system has similarly been unaware of the application of GB legislation and its implications for the public, the Human Rights Act 1998 and the Scotland Act 1998. This problem applies to the Justice Secretaries, the Lord Advocate, COPFS, Scottish Government's Legal Directorate, the Chair of the Vale of Leven Hospital Public Inquiry, and to QCs and Advocates. They have failed to recognise the application of HSWA, breaches of major legislation and have not addressed or investigated them.

12.4 Public Inquiry An inquiry under the Public Inquiry Act 2005 is required to address what are an unprecedented combination of major failings on public safety, failings of a Government and ministers, and failings of the legal and justice system.

A statement of the calling of an inquiry should trigger actions to address the issues raised. Prompt actions are required to save lives and cannot wait for the completion of a public inquiry. A failure to cause a public inquiry to be held would act counter to the public interest. It would sanction the continuation of intolerable standards of patient safety in Scotland. It would tolerate the statutory failings of Scottish Ministers, the Scottish Government and their officers. Healthcare in Scotland would remain in wholesale breach of the law and without effective regulation. Major

pieces of GB, UK and EU law would not be complied with and be devalued. This could attract external intervention. The legal and justice system that has failed to act to bring Scottish Government policy into legal compliance, or to investigate or to act to prevent offences, would continue to fail and public confidence would be further undermined.

13. Solutions There are practical solutions available to bring the safety of patients, and of those in social care, up to the appropriate standard and to bring Scotland into line with the binding legislation of HSWA, HRA and the Scotland Act 1998. The actions on these are required as a matter of urgency as they relate to a daily toll of avoidable deaths.

13.1 Recognition of Health and Safety at Work etc Act 1974: Scottish Ministers and the Scottish Government need to acknowledge that HSWA applies to patient safety and to those in social care (HSWA s1, s3).

13.2 Plan on Compliance in Healthcare Scottish Ministers, the Scottish Government and bodies working in healthcare need to create and implement effective plans to secure HSWA compliance proportionate to the high hazards and high risks in healthcare (MHSWR Regulation 5, HSWA s3).

13.3 Creation of Independent Health Regulator (IHR) Scottish Ministers and the Scottish Government forthwith, to create a fully independent healthcare regulator working to high standards of effectiveness in order to secure compliance with HSWA (HSWA s18, HSWA s3). This requires urgent primary legislation to restore the IHR.

13.4 Care Inspectorate The Scottish Ministers and Government need to get the Care Inspectorate to act as an effective regulator of HSWA compliance in all aspects of social care. In view of the bringing together of healthcare and social care it would be appropriate to make it a single IHR covering healthcare and social care (HSWA s 3, 18).

13.5 Human Rights Act 1998 The Scottish Government to review how it secures compliance with HRA in respect of healthcare and social care and to implement actions. HSWA compliance should be a suitable and sufficient means (Human Rights Act 1998 section 6).

13.6 The Scotland Act 1998 The Scottish Government needs to review how it, and particularly its ministers, complies with their responsibilities under the Scotland Act in respect of healthcare, and to implement actions (The Scotland Act 1998 section 57). Comply with HSWA and HRA.

13.8 Scottish Ministers and HSWA Scottish Ministers have failed to discharge their legal responsibilities under HSWA. It requires an

independent investigation into the acts and omissions of the Scottish Ministers. This should be by HSE as the default regulator for HSWA matters.

13.9 Scottish Ministers, HRA, ECHR and The Scotland Act 1998 Scottish Ministers have acted counter to the Human Rights Act 1998, the European Convention on Human Rights and the Scotland Act 1998. These matters should be referred to the Secretary of State for Scotland and to the Attorney General for consideration.

13.10 Scottish Government and Corporate Manslaughter and Corporate Homicide Act 2007 The Scottish Ministers and Government and its Health and Social Care Directorate have set a policy of disregarding HSWA on healthcare and social care. This permits, and in its wilful neglect, leads to reasonably preventable premature deaths contrary to section 1 of the Act. COPFS to carry out a thorough investigation for appropriate action on specific deaths. Also refer matter to the Secretary of State for Scotland and to the Attorney General for consideration.

13.11 Impeachment There are the cases of Scottish Ministers not upholding justice such as by not implementing HSWA particularly not to the standards that it requires; and the misleading of a public inquiry. Similarly they have abused their powers such as by abolishing the independent healthcare regulator and interfering with the delivery of patient safety, a reserved matter. Either of these are causes for impeachment. In this case they are backed by indictable offences and relate to the Scottish Government being in breach of the law and permitting a very large number of avoidable deaths. Impeachment is an appropriate check on ministers obstructing justice and abusing powers out-with other parliamentary sanctions.

13.12 Scottish Ministerial Code The Ministerial Code has not been complied with and its self-regulation system is not functioning. The operation of the code requires reviewing so that it can be made effective in securing acceptable behaviour by Scottish ministers. The role of the Presiding Officer needs to be strengthened.

13.13 Civil Service The Civil Service in Scotland has not been adhering to the Civil Service Code on a very serious matter which has promulgated an illegal policy by the Scottish Government. The service routinely breaks all the core values of the code. It requires an independent review of the behaviour Civil Service in Scotland and the operation of the code to be carried out under the Cabinet Secretary and Head of the Home Civil Service.

13.14 Scottish Legal System With the widespread absence of awareness of HSWA and its application by legal practioners, it needs to be brought to the attention of all.

13.15 Performance There is no accurate information on the performance of compliance with HSWA, in either healthcare or social care, nor in the level of harm caused in terms of reasonably preventable premature deaths, or major harm. This should be a function of the IHR. It can also be the source of independent data on the performance of healthcare and social care sector performance to give justifiable public and professional confidence in the data.

13.16 Francis Report Many of the Francis Report recommendations cannot be implemented in Scotland as there is no independent healthcare regulator. However there are many other recommendations that can apply albeit adjusted for governance and organisational differences. A review of Francis in delivering the reserved matter of patient safety Scotland should be carried out and assessed independently of SG.

13.17 Risk Management The approach to risk management should be a prime factor in delivering both patient safety and positive health outcomes. In healthcare and social care it needs to be of a very high standard similar to that in other major hazard sectors. The approach to risk management should be reviewed and brought up to HSWA standard both in terms of its requirement and in its delivery. If a complete approach is to be taken it should have a framework in which risk management fits, covering all aspects of healthcare ('the patient's journey').

This should cover prevention, diagnosis, treatment, monitoring, and feedback into prevention, stabilisation or control of condition. Within this framework the risk management should be proportionate to the hazards and risks. The recent advances in healthcare risk management have existed in other major hazards sectors for a long time. To make best use of risk management there should be a single system developed within the framework that prevents the negative outcomes, delivers best positive outcomes and contains contingencies for when things go wrong. This approach presents the systematic means to profile healthcare and social care and to apportion resources.

13.18 Public Inquiries Act 2005 Carry out a public inquiry into patient safety in Scotland in view of the Scottish Government's failure to implement the UK-wide Health and Safety at Work etc Act 1974. Failures to comply with the Act to the required standards will result in a large number of reasonably preventable deaths. The inquiry remit to cover healthcare providers in Scotland, the role of the Scottish Government, the administration, and the Scottish Justice and Legal System. Also include the Human Rights Act 1998, the Scotland Act 1998 and Corporate Manslaughter and Corporate Homicide Act 2007. The statement of intent to hold an inquiry would prompt action and would save lives.

Appendices

14. Appendix 1 References

- Health and Safety at Work etc Act 1974
- Management of Health and Safety at Work Regulations (1992) 1999
- Control of Substances Hazardous to Health Regulations COSHH (1989) 2014
- Fatal Accident Investigations and Sudden Deaths Inquiry (Scotland) Act 1976
- Corporate Manslaughter and Corporate Homicide Act in 2007
- Vale of Leven Hospital Public Inquiry Report 24 November 2014
- Mid Staffordshire NHS Foundation Trust Public Inquiry Reports (Francis Report) 2010 and 2013
- Piper Alpha (Cullen Report) Inquiry Report 1991
- NHS Scotland's HIS 'A Rapid Review of the Safety and Quality of Care for Acute Adult Patients in NHS Lanarkshire' December 2013
- NHS Ayrshire and Arran conviction August 2014
- HSE Policy on HSWA section3
- HSE Enforcement Policy
- HSE Enforcement Management Model (EMM) operational version 3.2
- HSE-NHS Scotland's Healthcare Improvement Scotland agreement Letter of Understanding (renewed annually) to be reviewed after VOLH
- Reducing Risk Protecting People–HSE's decision-making process 2001
- The Scottish Public Services Ombudsman Act 2002
- The Tolerability of Risk from Nuclear Power Stations (1989)1992
- Working Arrangements Protocol between the Health and Safety Executive, Local Authorities in Scotland and Social Care and Social Work Improvement Scotland ("Care Inspectorate")
- The Social Care and Social Work Improvement Scotland Requirements for Care Services) Regulations 2011 (SCSWIS (RCS)R)
- The Mental Health (Care and Treatment) (Scotland) Act 2003.
- Civil Service Code (Scotland) 2010
- Ministerial Code (Scotland) 2010

15. Appendix 2 Abbreviations

A & A	Ayrshire and Arran NHS Board
AKI	Acute Kidney Infection
CI	The Care Inspectorate
CIR/SAER	Critical Incident Report/ Significant Adverse Event Report
COPFS	Crown Office and Procurator Fiscal Service

COSHH	Control of Substances Hazardous to Health Regulations 2014
CQC	Care Quality Commission
ECHR	European Convention on Human Rights
EHO	Environmental Health Officer
EMM	HSE Enforcement Management Model
FAI	Fatal Accident Inquiry
FOD	HSE's Field Operations Division
HAI	Hospital Associated (Acquired) Infection
HIS	Healthcare Improvement Scotland (NHS Scotland)
HEI	Healthcare Environment Inspectorate (HIS/ NHS Scotland)
HPS	Healthcare Protection Scotland (NHS Scotland)
HRA	Human Rights Act 1998
HSCD	Health and Social Care Directorate
HSE	Health and Safety Executive
HSWA	Health and Safety at Work etc Act 1974
IHR	Independent Healthcare Regulator
MWCS	Mental Welfare Commission Scotland
MHSWR	Management of Health and Safety at Work Regulations (1999)
ONR	Office of Nuclear Regulation
ONS	Office of National Statistics
ORR	Office of Rail Regulation
PSR	Public Services Reform (Scotland) Act 2010
5R	ORR model of 'Five Requirements of Organisational Culture'
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2012
RPPD	Reasonably Preventable Premature Deaths
SCHR	Scottish Commission on Human Rights
SCSWIS	Social Care and Social Work Improvement Scotland
SG	Scottish Government
SPSO	Scottish Public Sector Ombudsman
VOLH	Vale of Leven Hospital
WRDPS	Work Related Deaths Protocol Scotland
WTR	Working Time Regulations 1998

16. Appendix 3 Evidence of Harm (Lord Advocate December 2013)

Below is a brief collation of types of evidence of the scale of harm that falls with the remit of the Health and Safety at Work etc Act 1974. They are taken mostly from acute NHS. There are many other cases of harm from the less well-documented parts of the sector of mental health, community health care, and from social care.

1. Imperial College and London School of Hygiene and Tropical Medicine: The report 'Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study'

published in the British Medical Journal (July 2012) suggests a high number of preventable deaths at 5.2% of all hospital deaths. Previous estimates of the scale of the deaths have been between 1,000 and 40,000 each year. The estimate in the paper would put the number of deaths at about 12,000 across the UK (approaches to clinical risk management are roughly similar across the UK, and certainly of the same order of magnitude). This does not include deaths in private healthcare, most of the mental health causes, community healthcare, or social care. The Health and Safety at Work etc Act 1974 (HSWA) applies to all of these sectors. Pro-rata, an estimate of 2000 reasonably preventable premature deaths each year or 5 a day in Scotland would seem appropriate, enough to give an indication of the scale of the harm.

2. Royal College of Physicians: The Royal College of Physicians identified about 6000 deaths each year across the UK that could be prevented by effectively monitoring (and managing) patient's vital signs. A response to the issue was given in 'National Early Warning Score (NEWS): Standardising the assessment of acute-illness severity in the NHS (July 2012). This is a step towards managing the risks. So far there has not been agreement on what constitute these vital signs, how they are monitored or recorded, or the actions required, and this results in the right actions not necessarily being taken. The management of safety critical functions and indicators is a top priority in working in areas of high hazard and risk. This report demonstrates a fundamental error in the sector.

3. The National Institute for Health and Care Excellence (NICE): NICE have identified serious dehydration problems in NHS hospitals leading to a large number of avoidable acute kidney injury and deaths (AKI). The National Clinical Director Professor Donal O'Donoghue said that around 12,000 preventable deaths were occurring each year and that these were simple to avoid. AKI is a risk to about one in four patients, it not prioritised, and hydration is not one of the usual patient vital signs. This is another fundamental error of risk management.

4. Scottish Public Sector Ombudsman (SPSO): The SPSO investigates complaints against NHS Scotland. Using the criteria of the prosecution of Mid Staffordshire NHS Foundation Trust (death of Gillian Astbury), from a sample of 100 full investigation reports (May 2011-May 2013) 85% showed serous HSWA breaches. The reports show a range of failures to ensure patient safety, often involving serious outcomes including preventable fatalities. Compliance with the Act would have prevented the harm, avoided other 'near hits', and dealt with the underlying issues.

There was no reference in the SPSO investigations to legal requirements. Despite the often serious consequences of the failures in the NHS the incidents were not referred to the Health and Safety Executive (HSE). HSE would be the default regulator in Scotland because there is no independent healthcare regulator. SPSO had been

unaware of the law covering patient care and treatment and how it applied. They say that they investigate using guidance rather than the legal requirements. The guidance is from the NHS which is not HSWA compliant, it does not deliver the standards that the law requires. The SPSO and all UK ombudsmen are signed up to a first principle of ombudsmen of verifying that '*All public bodies must comply with the law and have regard for the rights of those concerned*'. In the case of Scotland and its Ombudsman the use of the law both in preventative and reactive actions to deliver acceptable standards in the NHS is absent. Whilst the NHS is the dominant area of work for the SPSO they also investigate complaints where HSWA applies, and again the law is not used as the first or any test of acceptability.

5. NHS Scotland: A sample of 200 Adverse Incident Reports from across all NHS Scotland boards revealed serious breaches of the HSWA in 80% of the cases, usually resulting in serious harm and often fatalities (BBC Scotland and FOI request, and personal communications). In none of these was there any reference to the statutory requirements of the Act. Healthcare Improvement Scotland recently revised its guidance to hospitals on incidents. However it did not refer to HSWA despite being made aware of its application.

6. **Lanarkshire Hospitals**: In common with a significant number of NHS trusts, the excess on the standardised mortality rates at Lanarkshire hospitals were sufficient to cause concern. The action plan implemented dealt with areas of concern that would be typical of those across the NHS. The UK Government have instigated extensive investigation of the issues behind excess mortality rates and the remedial actions required.

7. Office of National Statistics (ONS): ONS collates statistics on cause of deaths including in hospitals and nursing homes. They do not give evidence of poor care or adverse incidents. However amongst the data are high numbers for causes that would arouse suspicion of poor patient/ resident safety sufficient to warrant further investigation by both dutyholders and the regulator. The data includes dehydration, malnutrition, and deaths caused by infections from healthcare acquired infections (HAI). HAI has been a HSWA concern for the last twenty years.

8. Media Reports: There are numerous reports of incidents in health and social care that receive media coverage. These can be analysed from a HSWA perspective. The vast majority of them suggest serious breaches of the Act. However the Act is hardly ever mentioned. The recent case of four deaths at an Edinburgh nursing home are an exception, perhaps in part prompted by the recent attention to the role of the Act in this sector.

9. Secretary of State Department of Health: The Minister of Health, Jeremy Hunt and the UK Government have recognised the scale

of the problem of avoidable deaths in acute healthcare. The department uses estimates in the thousands for deaths each year and perhaps a half a million in other harm and less than optimum outcomes. The UK Government has responded very fully to the Mid-Staffordshire NHS Foundation Trust Public Inquiry Report (the Francis Report) and accepted the majority of the recommendations. The detailed response is given in 'Hard Truths: The Journey to Putting Patients First' (November 2013). It includes using legislation to provide the structure for delivering acceptable levels of healthcare (including HSWA or equivalent legislation to achieve the same standards), and the role of a strong, effective and independent healthcare regulator taking on a prime role for the sector.

10. Professional Experience: I have experience of proactive/preventative inspection and reactive investigation work as a regulator for the health and social care sectors. I have also had a similar role in the high hazard sectors of the chemicals industry, nuclear safety and the national railway system. The standard of risk management in acute and community healthcare, both physical and mental, both NHS and private, and in social care, is of a standard well below that which is reasonably practicable. The number and nature of deaths and other harm occurring in these sectors match my expectation arising from the sector's failure to use the appropriate risk management required by law.

17. Appendix 4 Legal Requirements (Lord Advocate December 2013)

Patient Care and Treatment: Health and Safety at Work etc Act 1974 (HSWA) Main Statutory Requirements:

Application: The Act applies as under point 1 below; there is no exemption in relation to patients. Health and safety under HSWA is a reserved matter. As such compliance with the Act is a statutory requirement and the intent of ensuring compliance and its regulation to ensure that it is are as is stated by the Act itself (sections 1 and 18).

1. Duty to Patients: Section 3(1) of HSWA 1974 requires the undertaking of healthcare to be carried out in such a way, as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health and safety. This applies to patients. There is no exemption for the sector. The sector does not have the intent nor organisation to ensure compliance to the standard required. It does not achieve compliance.

2. Intent and Plan: Healthcare in Scotland does not have as a prime requirement that the sector complies with HSWA. There is an absence of a plan to comply with HSWA as required by the Management of Health and Safety at Work Regulation 1999 (MHSWR) Regulation 5

and HSWA S3. It is not stated as a requirement of the Scottish Patient Safety Programme to comply with the Act as it applies to patient's health and safety.

3. Organisation: There is not the effective organisation to deliver an effective plan and compliance with HSWA to secure effective control measures to control the risks to patients so far as is reasonably practicable (MHSWR R5, HSWA S3).

4. Control: The precautionary measures to control the risks to patients are not effective, and as a result there is a large amount of reasonably preventable harm and premature deaths (MHSWR R5, HSWA S3). There is a large range of evidence giving an indication of the size of the harm (Appendix 3 Evidence of Harm). This is demonstrated by most NHS Scotland boards' adverse incident reports and Scottish Public Sector Ombudsman full investigations showing serious non-compliance with HSWA. Patient treatment is not verified for compliance with HSWA and specific cases demonstrate the consequences. Risk management in the sector is not to HSWA standards for a high hazard sector. Examples are the management of competence and performance of staff, monitoring of, and action on, patient's vital signs, infection control, excess mortality rates, and individual cases. Research within the NHS and from professional bodies and Care Quality Commission suggest for the UK a figure of around 20,000 reasonably preventable premature deaths per annum in healthcare. The UK Government now recognise that these deaths do run into thousands each year. Healthcare practice and its risk management are sufficiently similar across the UK to deduce a pro-rata death rate of about 2,000 preventable deaths each year in Scotland caused by non-compliance with HSWA, five a day.

5. Monitoring: Similarly, there is not the monitoring of precautionary measures for compliance with MHSWR R5 and HSWA.

6. Review: Healthcare does not review its arrangements and compliance with HSWA (MHSWR R5, HSWA). The law requires an effective 'management control loop' to ensure that risks are controlled (MHSWR R5). The sector in Scotland needs to bring itself into line with the requirements of the Act. MHSWR and HSWA require a systematic approach to controlling risks, and this is missing in healthcare and patient safety.

7. Regulation: Scotland, unlike Wales, Northern Ireland and England, does not have an independent healthcare regulator. Healthcare Improvement Scotland (HIS) does not regulate the NHS, it is part of the NHS. HIS has a regulatory role for private healthcare but even here it does not verify compliance with, or regulate to, HSWA standards for what is a high-hazard and high-risk sector. The HSE has a limited role and does not have the resources to act as the independent healthcare regulator. It will act when compelled to do so. HSE cannot

be relied on to ensure that the sector complies with HSWA. The arrangements for the regulation of the safety of patients in Scotland do not achieve nor comply with sections 1 and 18 of HSWA. There is not an alternative, equivalent means of delivering standards of patient safety to that required by HSWA.

Of the above statutory requirements, HSE applied numbers 1 to 6 to healthcare in England and Wales and enforced on them. On the formation of independent healthcare regulators in the late 1990s there was a major transfer of HSE's responsibilities for patient care and treatment to them. These independent regulators did not however work to or achieve the standards required by the above to deliver patient safety, hence the preventable harm recorded by the sector and in external investigations. The Francis Report on Mid Staffordshire NHS Foundation Trust was just one example of the failings of the regulatory system that has applied in England over the last twelve or so years. Scotland does not even have an independent healthcare regulator, nor apparently yet have any plans to form one.

Human Rights Act 1998

I also understand that the Joint Parliamentary Committee on Human Rights have been concerned about the issue of the absence of independent investigation into the deaths of patients detained under the Mental Health Act. The UK's statutory body for the Human Rights Act 1998, the Equality and Human Rights Commission (EHRC) has also sought a judicial review on the matter. The Commission argued that 'a lack of an automatic referral for investigation to an independent body is discriminatory under the Equality Act 2010. Further, it constitutes a violation of the right to life under Article 2 of the European Convention on Human Rights - written into UK law through the Human Rights Act 1998'. The Human Rights Act 1998 is outside my expertise but as a layman, it seems to require independent investigation into certain deaths within health and social care covered by regulation 6(1). Currently any independent investigations only take place in an extremely small number of cases.

The European Court of Human Rights seems to have already expressed its view on the need for independent investigation into deaths where there may have been a breach of regulation 6(1). This case arose out of a death in police custody. From what I can see the distinction between custody and 'in the care' of a public body is not made in the regulations or judgements. From the EHRC's submission to the IPCC on deaths in custody and their investigations:

> 'In the case of *Khan v United Kingdom* (*at* 46, App. No. 35394/97) the European Court of Human Rights found that IPCC's predecessor lacked the required Article 2 independence because of its close nexus with Government.

Article 2 requires that those responsible for and who conduct investigations into a potential breach of the right to life must be *"independent and impartial, in law and in practice"* (see *Nachova v Bulgaria* 2005-V11; 42 EHRR 033 at 112) And in *Jordan v United Kingdom* (2003) 37 E.H.R.R. 2, it was emphasised by the European Court of Human Rights (at106) that people responsible for and carrying out investigations must be independent of those implicated in the event. The Court went on to say this means a lack of hierarchical or institutional connection and practical independence. Independence is not just about whether there is actual impartiality, it is also about perception. One of the essential functions of independence is to ensure public confidence and, in this context, perception is important. The Courts have noted that *"public perception of the possibility of unconscious*

[1] Lawal v Northern Spirit Ltd [2003] I.C.R. 856 at §14 and R. (on the application of L) v Secretary of State for Justice [2009] EWHC 2416 (Admin) at §37

Appendix 5 DIAGRAM OF PATIENT SAFETY AND THE HEALTH AND SAFETY AT WORK ETC ACT 1974