‘PATIENT SAFETY IN SCOTLAND’
PUBLIC INQUIRY
UPDATE 2

25 August 2015

Roger M Livermore

Preface

The reason given by the Solicitor General of Scotland for not prosecuting the driver in the Glasgow bin lorry incident as statement of policy by the Scottish Government’s most senior legal advisers and prosecutors was ultra vires. It would overthrow 200 years of law affecting safety and make protecting the public impossible. The officers said that they could not prosecute the driver as they could not prove criminal intent, ‘mens rea’. Ever since safety law was introduced in 1800 the requirement to prove criminal intent was removed from application to such legislation. The requirement was to be able to prove criminal negligence, not criminal intent. This led to the creation of the concept of ‘strict liability law’ which has much application across society. The Scottish officers have introduced an additional barrier to justice and if allowed to stand would end prosecutions and other enforcement action on safety and in many other areas.

The bin lorry case is very high profile case but it does explain the underlying factors in the failures to deliver patient safety in Scotland as required by law. There is evidence that where investigations have been made into possible safety offences by both Police Scotland and the Crown Office and Procurator Fiscal Service (COPFS), they have incorrectly sought evidence for criminal intent and not the required criminal negligence. The implications of the error of a basic principal of law are great. It applies to the many number of deaths in which criminal negligence is factor, a number far exceeding those involving criminal intent. At this stage it is not known how often and for how long this error of Scottish law practice has been made over the 200 years.

In legal terms the error affects much of the law. In terms of consequences it is a factor in thousands of avoidable deaths and extends beyond the largest category which is related to patient safety. It currently appears that it could well be the biggest error in law, as well as public safety.

The failure of Scotland’s senior law officers to understand safety law completes the picture. It is one where the intent of law to ensure public safety is absent, the law is not present as a driver to deliver acceptable standards of safety, and Scotland fails to comply with the legal requirements and a very large number of avoidable deaths and other harm are allowed to take place. Patient safety in Scotland is not achieved. The position cannot be allowed to continue.

Scotland’s senior aw officers have failed to uphold the law that would ensure public safety.

Introduction

This is the second update to the case for a public inquiry 'Patient Safety in Scotland' of 29 January 2015. The previous update was of 18 May 2015 and it included what should have been an objective, comprehensive and systematic assessment of whether there should be a public inquiry. The situation continues of a very large number of avoidable deaths associated with failures in Scottish health and social care, resulting from non-compliance with GB and UK-wide legislation. The issues have not been recognised by the Scottish Government and there has not been effective action by other dutyholders to ensure that the law is complied with and harm avoided so far as is reasonably practicable. The overwhelming evidence is in favour of an inquiry, with little that could be said against it - beyond political embarrassment, a matter of insignificance in relation to the thousands of preventable deaths.

Whilst an inquiry is essential to fully explore the issues, the consequences of the failures mean that each day's delay in actioning them will result in about 5 avoidable deaths, 2,000 a year. For this reason it needs urgent action as was noted in the initial case for an inquiry. The Scottish Government has been aware of the main issue since April 2012. Because the problem is underpinned by a series of fundamental errors of law and practice, the evidence builds continually, with the harm continuing at what is an alarming rate. The issue of avoidable harm in healthcare has been recognised internationally but in Scotland there is a refusal to admit to the problem, let alone address it as the law requires.

Contents

1. Fundamental Position

The hierarchy on delivering patient safety, or any aspect of safety, is the legislation, approved codes of practice (ACOP), and guidance. In the Scottish approach to patient safety it omits the legislation and the ACOPs, and it only has guidance which does not meet the legal requirements. Guidance has the feature of being optional and this is wholly inadequate in safety, particularly in the sector with the highest hazards and risks in the UK. This is compounded by there being no regulator to make sure that the law is complied with.

To deliver patient safety and legal compliance in what is a high hazard and high risk sector requires a systematic approach. This law has eight main requirements:

1. **Law – Recognition (Health and Safety at Work etc Act 1974 (HSWA)**
2. **Responsibility -Recognition**
3. **Competent Person(s)**
4. **Regulator**
5. **Culture**
6. **Management Systems**
7. **Risk Assessment**
8. **Precautions- Effective**

These are all statutory requirements under HSWA and related legislation for the protection of the public and this includes patients. They also provide a practical means to ensure compliance with the Human Rights Act 1998 (Article 2 'Right to Life') and discharge responsibilities under the Scotland Act 1998. They provide a means to avoid action under the Corporate Manslaughter and Corporate Homicide Act 2007. **We in Scotland do not have the legal requirements in place, and large-scale avoidable harm occurs as a result. The Scottish Government is doing nothing about this.**

These legal requirements are to achieve effective risk management, to make sure that precautions are effective to prevent harm. Offences are for failures to have effective measures in place, and not for any actual harm that may result from the failures. This point is often not understood. As risk can be both 'good' as well as 'bad' the sector should be able to create a single risk management system that optimises patient care as well as ensures patient safety. This is not a legal requirement under HSWA but the benefits of a comprehensive systematic risk management system should be effective and efficient, the best that can be achieved and also serves the needs of the NHS Scotland Act 1978.

1.1 Law – Recognition (HSWA)

The Scottish Government (SG) has shown an almost total absence of reference to the Act, compliance and regulation. It only seems to have secured recognition after repeated reminding. The current CS Health finally recognised this at the Patients First meeting of 31 March 2015. Despite being the principal

legislation on patient safety, it is notably absent from healthcare organisations, their plans and other documents in Scotland. Repeatedly senior ministers have refused to acknowledge the Act applies to patient safety. It may be that as healthcare was devolved, they incorrectly assumed everything related to it including the requirement on patient safety was too. It is not. Whatever the cause, the mistake has been costly for the people of Scotland.

1.2 Responsibility - Recognition (HSWA reg 1, 2, 3, 7, 36, 37, and 48)

The Scottish Government, its organisations, other bodies, and senior officers have not been aware of their responsibilities, let alone take them on or fully comply – e.g. Health and Social Care Directorate, NHS Scotland, Healthcare Improvement Scotland (HIS), Health Environment Inspectorate (HEI), NHS Boards, Care Commission, Mental Welfare Commission Scotland, other providers, Scottish Public Sector Ombudsman. SG sought to distance itself from responsibilities for devolved matters including healthcare delivery and patient safety. The CS Health has responsibilities under the NHS Scotland Act 1978. HSWA is a responsibility on the Scottish Government, its ministers and other individuals – HSWA s 2, 3, 7, 36, 37 and s 48.

1.3 Competent Person(s) (**MHSWR Reg 7**)

All organisations are required to have appointed one or more competent persons to advise them on how to comply with HSWA and related legislation. SG has been unable to supply the name of such persons (Ministers, PQ, Paul Gray CEO NHS Scotland/ HSCD). What spokespersons there are demonstrate their lack of understanding of the law and what it means in terms of protecting patients. Ignorance of the law is never an excuse for non-compliance and certainly not when the consequences are thousands of avoidable deaths. However the Scottish Government abolished the independent regulator of healthcare in 2010. This removed any potential pressure on SG and healthcare to comply with the law. The regulator could and should have acted as an independent competent person to tell the SG what it needed to do to ensure compliance with HSWA and so secure patient safety, and start to prevent the large-scale unnecessary harm. The absence of an active regulator in Scotland over the last 5 years creates a vacuum. This permits many avoidable deaths and is illegal.

1.4 Regulator (HSWA s18)

Scotland is unique in the UK in not having the legally required regulator. It recently changed its position from stating that NHS Scotland's own Healthcare Improvement Scotland (HIS) is the regulator (e.g. Alex Neil at Holyrood 17 December 2013 and Shona Robison 31 March 2015) to it being the Health and Safety Executive, HSE (PQ 26 June 2015). HSE is in no position to take on the role of being the regulator of healthcare, to be Scotland's Care Quality Commission (CQC). CQC is the independent regulator for England; the other parts of the UK also have their independent regulator. So it remains that we have no regulator ensuring precautions are in place to ensure patient safety. The Glasgow bin lorry Fatal Accident Inquiry has shown that HSE is no longer

able to carry out its established role and so not able to start to undertake such a large and important role in Scotland of regulating on patient safety. It does not have this role in the rest of GB. HSE has neither the funding nor competences to be Scotland's independent regulator of healthcare. The Scottish Government's position on the regulation of healthcare in Scotland has been chaotic and still nothing happens to make sure that patients are safe.

1.5 Culture (HSWA s 1, 2, 3, 7)

With the lack of recognition of HSWA and what it means, there is not an understanding or appropriate attitude to the legal requirements on safety. The legal requirements are not being embedded in Scottish healthcare, they are excluded by the Scottish Government. Consequently there is not the corporate or organisational culture to deliver compliance with the law. NHS Scotland's HIS is in consultation on its scrutiny work and is asking what to do about culture. This matter has already been addressed by regulators of HSWA (e.g. ORR and its 'Five Requirements of Organisational Culture' which is grounded on the legal requirements that also apply in Scotland).

1.6 Management Systems (MHSWR Reg 5)

In Scotland there are not the effective planning, organisation, controls, monitoring, and review of precautions to ensure that they are effective in controlling the risks to patients according to HSWA. These are required by law and to be written down.

1.7 Risk Assessment (MHSWR Reg 3)

There is no recognition of the scale of the problem of avoidable deaths in health and social care ('reasonable preventable premature deaths'). The Scottish Government does not know the scale of the problem or the risk profile of where the main problems lie. There is not an effective system of risk assessment and certainty not in proportion to the sector being that with the highest hazard and risks in the UK.

1.8 Precautions- Effective (HSWA s1,3, MHSWR Reg 5)

There are not effective precautions in place to prevent avoidable harm and deaths of patients. Whilst SG and the NHS Scotland do not assess the risks and consequences of failures of precautions, some of the consequences are shown in Critical Incident Reports and SPSO reports. NHS Scotland's HIS and HEI show some of the failures, e.g. Hospital Acquired/ Associated Infections (HAI) but the failures of precautions go unregulated and they continue to have a significant prevalence in Scottish hospitals. Such infections are life-threatening. The Lanarkshire Rapid Review, the Ayrshire and Arran '40 suspicious deaths', the Vale of Leven Hospital infection deaths, NHS Lothian end of life care are examples. The lack of regulation (and independent scrutiny) of the NHS in Scotland is a barrier to ensuring that effective precautions are in place to ensure patient safety.

2. Parliamentary Questions

The answers to PQs in June 2015 by the CS Health Shona Robison on behalf of the Scottish Government once again demonstrated one of the causes of the problems in Scottish healthcare. The answers were confused but in essence in the answers there was:

2.1 Failure to recognise the scale of avoidable deaths associated with Scottish healthcare (and associated social care). They hadn't got any figures, or estimates and no suggestion that they had any idea or would try and find out. The answer is that there will be about 2,000 reasonably preventable premature deaths a year in Scotland.

2.2 The CS Health finally recognised on 31 March 2015 that HSWA did apply to patient safety. But then refused to implement it, or to make it SG policy, or make sure that health and social care providers were fully aware of it, or the need to comply with it to a high standard. In response to the PQ on this, SG said that 'it expected dutyholders to comply with the law'. That is SG was doing nothing to promote and ensure that the law that would start preventing these 2,000 deaths a year and other avoidable harm was complied with. SG has a 'do nothing' approach to HSWA compliance, so the avoidable deaths continue.

2.3 The PQ asked about the regulation of the NHS on patient safety. Over recent years SG has been saying that it is NHS Scotland's Healthcare Improvement Scotland, despite HIS saying that they are not the regulator and cannot be as they are part of the NHS. The previous CS Health Alex Neil on the review of the apparent excess death rates at NHS Lanarkshire called HIS 'the independent regulator' in Holyrood (17 December 2013) so giving false reassurance. The current CS Health was still insisting that HIS was the independent regulator on 31 March 2015. Finally in the PQ the CS now says that it is HSE. SG has finally recognised that HIS is not an independent regulator. It seems that HSE has not been consulted on this change of position by SG, as HSE was also not consulted when SG abolished what independent regulator of healthcare there was in 2011 (Public Services (Scotland) Reform Act 2010). HSE is in no position to take on the role of being Scotland's CQC (Care Quality Commission). So still Scotland has no regulator making sure that the precautions are in place to prevent harm to patients and that the law is complied with to the standard. There can be no other conclusion than that on the regulation of Scottish healthcare, SG says one thing then the other. So there is confusion chaos and nothing happens. Healthcare in Scotland has the highest hazards and risks of any sector in the UK, and rather than having the appropriate high standard of regulation, we have nothing. This is safety stood on its head, it's illegal, and it's dangerous.

With this change in position, according to Scottish Ministers the HSE is now the body for complaints on patient safety and non-compliance with HSWA, since they longer regard HIS as a regulator of the NHS. The SPSO (the Ombudsman) does not use health and safety law, such as HSWA, in his work

and has no powers to compel NHS compliance. So SPSO also fails to protect the public.

2.4 By law all organisations are required to have competent person(s) to advise them on how to comply with HSWA according to their activities. There has never been anyone in SG with the remotest understanding of HSWA and what it means, particularly on healthcare. Even when SG has consulted HSE, it has managed to misinterpret their advice and get it completely wrong. The COPFS still does not understand HSWA and its enforcement as has been shown in the Glasgow bin lorry FAI, and the ongoing matter of the 40 plus 'suspicious deaths' at Ayrshire and Arran NHS Board. In the PQ SG were unable to name their competent person(s) let alone give their experience.

3. Scottish Healthcare Performance: NHS Scotland Act 1978

The CS Health (s1) and its Health Boards (s2) are not providing an effective healthcare service. There is not a system to ensure that it is effective. SG has no body independently checking NHS quality performance, it has no 'Care Quality Commission'. In effect there is not the accountability or acceptance of responsibility for performance as well as safety. The 1978 Act requires:

1 General duty of Secretary of State.

(1)It shall continue to be the duty of the Secretary of State to promote in Scotland a comprehensive and integrated health service designed to secure—

(a)improvement in the physical and mental health of the people of Scotland, and,

(b)the prevention, diagnosis and treatment of illness,

and for that purpose **to provide or secure the effective provision of services** in accordance with the provisions of this Act.

Section 2 applies to Health Boards.

The Scottish Government and its CS Health are responsible for policy, the organisation of healthcare, and its resourcing. The current arrangements are failing to deliver an acceptable or legal standard of patient care or safety (e.g. NHS Lothian and IPCC). It appears from the independent review (see below) that the quality of care compares unfavourably with the rest of the UK, or even with NE England that spends the same per head of population.

4. Scottish Healthcare Performance: Independent Review

There is a rare independent comparative assessment of healthcare across the UK. This is the Nuffield Trust and Health Foundation's review of healthcare in 'The Four Countries of the UK; how do they compare?' April 2014. The research is the only longitudinal analysis of its kind, which built on a previous report published by the Nuffield Trust in 2010 and revised in 2011. That report

presented three snapshots before and after devolution, with the most recent data being for 2006/07. The latest report gives trends over time for a wider range of performance indicators from the late 1990s to 2011/12, or 2012/13 where data was available. It found that in terms of ***health outcomes*** Scotland was the worst of the four countries and by a substantial margin, and it is getting worse. These are on the indicators of the quality of healthcare in the respective countries, both in terms of positive outcomes and ensuring patient safety. It needs urgent work to identify why Scotland is underperforming and what needs to improve. There are obvious factors which could be the cause of Scotland's problems on healthcare.

The independent review shows Scotland to be increasingly falling behind in health outcomes. Life expectancy is the lowest in the UK and the gap is widening. On deaths that could be prevented by timely quality healthcare interventions we are the worst, substantially worse than England and again the gap is widening. On other mortality rates we are the worst for both men and women, and falling further behind.

The report presents the most authoritative and systematic assessment. Whilst it looks at inputs into healthcare it also looks at the prime requirement of healthcare - the actual outcomes. The main indicator of healthcare performance is 'amenable deaths'. This has been used internationally since 1976 and is used by the Department of Health in its outcomes framework. 'Amenable deaths' are outcomes that ought not to occur, or that occur rarely in healthcare systems that deliver high quality care. These are the premature - unnecessary deaths that should not occur in the presence of timely and effective care management. Amenable deaths have been generally at about 30% of all deaths.

These avoidable deaths are 20% worse in Scotland than in England. The report also compares Scotland with the similar socio-economic North-East of England which as a region also spends the same per head on healthcare. Again the gap is substantial at 10%. This is statistically very significant and shows a real difference in healthcare. This particular indicator is internationally recognised as an indication of the quality of healthcare.

Life expectancy is an indication of the health of a population, part of the indicator of quality of healthcare is by how much it increases over time. Twenty years ago Scotland and NE England had similar life expectancy, but now we are a year below in Scotland, which is considered to be a substantial gap. England overall has a life expectancy of three years more than Scotland, and this despite there being a substantially greater spend on healthcare per head here in Scotland.

On other mortality rates for under-75s we have the worst for both sexes. For men we have 477/ 100,000 year compared with 249 for England, and for women it is 396 to 198. These are very big differences. Whilst the mortality rates have been decreasing across the UK, they have been decreasing at a slower rate in Scotland, and so the gap increases and we remain the worst. We

were 20-25% worse in Scotland but are now 30%, this is another very big difference. The same also applies if considering under-65s.

There needs to be work to determine why Scottish healthcare performance in terms of outcome is so far below where it should be. For the present there are three obvious differences between Scotland and the rest of the UK. One is that there is no independent body inspecting healthcare providers to make sure that they meet performance standards. Secondly there is no independent regulator of healthcare such as the Care Quality Commission (CQC) working towards ensuring patient safety as required under the Health and Safety at Work etc Act 1974 or the equivalent. The data shows that it would be possible to save thousands of preventable premature deaths by addressing these two areas. The Scottish Government abolished the independent regulator of healthcare in 2010. A third difference is that there is not the independent scrutiny that there is elsewhere in the UK. There is no Monitor, Kings Fund, Health Foundation, Nuffield Trust, Doctor Foster, no high profile patient pressure groups, no Keogh Review and there has been no equivalent of the Francis Report. The lessons of these bodies and reviews have *not* been applied in Scotland. Indeed the recent Vale of Leven and Penrose public inquiries make no reference to the law. Allied to these points, in England the NHS is answerable to HM Treasury for its performance and use of public funds. The money spent by devolved governments is provided by UK taxes, but there is not the accountability for whether this money is spent effectively and efficiently. In Scotland the head of the NHS is also the head of the Health and Social Care Directorate of the Scottish Government, there is no distance between the two bodies. The absence of any independent viewpoint on Scottish healthcare means that there is a monoculture that is a barrier to achieving acceptable standards of health outcomes.

The CS for Health is legally accountable for the performance of healthcare under section 1 of the NHS Scotland Act 1978. However with the Scottish Government abolishing the regulator, it is not clear whether there is any mechanism to ensure that it is complied with. As well as the very real differences in health outcomes in Scotland, there are also substantial legal, financial and constitutional anomalies.

The independent Nuffield review of healthcare states there is not a proper or effective system of accountability for healthcare in respect of service and finance. In addition in Scotland there is no accountability on patient safety either. Elsewhere there are independent bodies verifying and seeking to ensure healthcare quality and safety, and in the case of England there is a strict system on financial accountability (e.g. Monitor and the Treasury). Scotland has Audit Scotland which has a limited role.

5. Scottish Royal Academy of Medical Colleges and Faculties

In the reports of March and July 2015 the Scottish Royal Academy called for urgent action by the Scottish Government, the NHS Boards and the professional bodies to address serious failings in Scottish healthcare. This was based on such reports as those on NHS Lanarkshire, Vale of Leven Hospital

(see also main case for the public inquiry), NHS Grampian, and NHS Tayside. It also referred to learning the lessons from the Francis Reports on Mid-Staffordshire, and Morecambe Bay (also referred to in the case for a public inquiry in Scotland, and its first update). The Royal Academy identified - 'key issues which contributed to these serious failings', including:

- poor leadership at all levels (including senior clinical staff and management) resulting in a defective culture, a disconnect between clinical staff and management, inappropriate targets and poor accountability mechanisms;
- staff shortages, an inappropriate skills mix on the team, inappropriate use of inexperienced staff or failure to supervise;
- poor staff morale and motivation;
- poor dealings with patients (inadequate care and poor communication);
- inadequate complaints handling (poor feedback and complaints mechanisms and inhibition to whistleblowing); and
- limitations of external assessments (remit and nature of the reports, composition of the review teams, inappropriate methodologies, omissions, unclear follow-up and questions of confidentiality and disclosure)'.

The Academy made recommendations to address these failings.

6. Crerar Review 2007

The Scottish Government's 'Report of the Independent Review of Regulation, Audit, Inspection and Complaints Handling of Public Services in Scotland' appeared in September 2007. It influenced the policy on regulation and unintentionally generated widespread confusion which is now endemic in SG policy and failings in patient safety. The confusion arises in the first sentence of the Executive Summary:

'This report considers Scotland's systems of regulation, audit, and inspection (referred to as 'external scrutiny' throughout)'.

Subsequently scrutiny is taken to be the same as regulation. 'Regulation' has almost vanished from the vocabulary of the Scottish Government and it is now all about 'scrutiny' of services even when regulation is required. Regulation is not the same as scrutiny. Scrutiny is part of regulation, but scrutiny does not contain regulation. Hence NHS Scotland's Healthcare Improvement Scotland (HIS) is a scrutiny body and makes no pretence to be a regulator of the NHS, only the Scottish Government pretended that it was – a view that the CS Health has only just abandoned in the PQ answer of June 2015. SG considered in-house scrutiny was an adequate replacement for a fully independent effective regulator (as required by law, and emphasised by the Mid Staffs NHS inquiries and the Piper Alpha disaster inquiry). Scrutiny is 'critical gaze, a close investigation or examination of details'. Regulation is 'the act of regulating, a prescribed rule, an authoritative direction, in accordance with regulations.

Regulate is control by rule, subject to restrictions. There is a great deal of difference. There is nothing in scrutiny that ensures that any standard is achieved.

A second problem is that whilst the review excludes UK regulation, by confusing regulation with being the same as scrutiny it has substituted the regulation of healthcare with internal scrutiny. It did not realise that the regulation of healthcare and patient safety is itself a statutory requirement and not optional. The Health and Safety at Work etc Act 1974 contains its own requirement that it is effectively regulated to make sure safety – including that of patients, is achieved. The result is that SG abolished what regulator there was and there still is not effective regulation to ensure patient safety. This is an illegal position created by the Scottish Government.

Despite the confusion generated, what the Crerar review does contain is the following:

'Most scrutiny bodies have a degree of independence from government and from providers, with the exception of health'. Also

***Recommendation**: 'We propose one significant change to scrutiny in the health sector, where we believe that, in order to ensure independence, the functions and resources currently controlled by NHS Quality Improvement Scotland (QIS), along with resources controlled by the Care Commission in relation to private hospitals and related treatment, and some of those controlled by the Scottish Government's health directorates should be redistributed to **one external scrutiny organisation'**.* And

'Accountability:
*Independence is a fundamental principle of effective scrutiny and most scrutiny bodies have a degree of independence from government and from providers. One exception is health, where scrutiny by NHS QIS is internal to the health service, because NHS QIS is itself a special health board, which makes its independence less clear. Government will rely on the outcomes of, and often direct the use of scrutiny. **If there is to be public and Parliamentary confidence in scrutiny, scrutiny must carry out its duties without inappropriate influence from government** because central and local government is often itself part of the service delivery system, either as a funder or policy maker or the negotiator of outcome agreements'.*

Crerar makes it totally clear that having an in-house 'scrutiny' body is wholly unacceptable (irrespective of HSWA and regulation). However whilst SG uses Crerar as the basis for its current consultation on the changing work of HIS it then disregards the main Crerar point of the need for independence from the NHS and from the Scottish Government. This is the **c**onsultation which was launched on the future model of healthcare reviews in Scotland - 'Building a comprehensive approach to reviewing the quality of care: Supporting the delivery of high quality services'. Crerar points out that without the independent body his other recommendations and five principles of independence, public focus, proportionality, transparency and accountability are unachievable on

healthcare. Of course what is missing from Crerar is the first requirement that legal compliance is achieved and with regulation. The consultation immediately fails by its own standard without creating an independent body which is not HIS. It also means that the consultation has not referred to page 1 of the second Francis Report on Mid Staffordshire on regulation and its subsequent handling of the subject of poor regulation (*passim* Scottish healthcare's 'no regulation').

6. NHS Scotland's Healthcare Improvement Scotland (HIS)

Since the case for an inquiry and the first update, the status of HIS has changed. Previously the Scottish Government regarded HIS as its regulator of NHS Scotland but now it no longer does. They say it is HSE, but it does not seem to have discussed this with HSE.

HSE is unable to fulfil the role of 'Scotland's CQC' of regulating safety and quality of healthcare. SG has not said what it is going to do about the regulatory vacuum in Scotland; it doesn't seem to know what it is doing. The position is very confused but the net result is that there is no regulator in Scotland carrying out regulatory work to ensure that patients are safe with effective precautions in place to prevent harm, and the law complied with. The current situation is highly dangerous, it is the biggest gap between the standard of safety that is required and what is currently being achieved of anywhere in any sector in the UK ('compliance gap'). By UK enforcement code and policy this would result in prosecutions of those responsible.

Once again I sought to get HIS to take the initiative to try and get the Scottish Government to address this major problem - in what is in terms of policy and consequence about as bad as it can get. It is also one that is echoed on page one of the second Francis Report. There is a never-ending stream of errors associated to healthcare and failures in patient safety that are not being addressed as they should be. HIS's HEI Chief Inspector Susan Brimelow writes that regulation of infection control is not required (such as complying with the HSWA and the COSHH regulations that also apply). I wrote to the CEO of HIS Angiolina Foster CBE who kindly replied. The CEO regarded the current situation as satisfactory; regulation of healthcare is not required. I understand that this unfortunate complacency has been repeated by the chair Dr Denise Coia. The senior officers of HIS have all treated regulation of healthcare as if it is optional, it is not. I now understand that Dr Coia has invited Mr Rab Wilson and Dr Peter Gordon of the pressure group Action for People's NHS Scotland to meet and discuss Scotland's lack of a regulator. It will need HIS to recognise the problem and make a representation to the Scottish First Minister Nicola Sturgeon, and the CS Health Shona Robison to create an effective fully independent regulator of healthcare.

This matter has been addressed in the main case for the public inquiry, but what is definitely required is such a body, and we do not have one. There is no chance of achieving acceptable standards of patient safety or legal compliance without one; the law itself requires it. Not having a regulator of patient safety is not a legal option; there is no choice in it. In addition to its requirements in HSWA and as interpreted and restated in public inquiries (Mid Staffs, and

Morecambe Bay) it appears in judgements and interpretation of the Human Rights Act (HRA) 1998 on Article 2.

Given the status of HRA and the importance it attaches to the 'Right to Life' I give specific judgements. It appears in the House of Lords case of Regina (Middleton) v HM Coroner West Somerset (2004), Lord Bingham and others. Article 2 is as follows, and the judgement follows:

Article 2 *imposes three distinct duties on the state:*
(a) A negative duty, namely a duty not to take a person's life intentionally, save in the circumstances specified in the article.
(b) A positive duty, namely to ***take all reasonable steps to protect a person's right to life*** *under the article. This entails "above all a primary duty on the State to put in place a legislative and administrative framework designed to provide effective deterrence against threats to the right to life." There must be "effective criminal-law provisions to deter the commission of offences against the person* ***backed up by law-enforcement machinery for the prevention, suppression and sanctioning of breaches of such provisions****." (see the summary of the position in R (Middleton) v West Somerset Coroner [2004] UKHL 10 by Lord Bingham). In some situations this duty (the "protective duty") requires the state to do more than to operate an effective criminal justice system designed to deter the taking of life. One example is that the state is required to take all reasonable care to protect the life of a person involuntarily in its custody (Lord Bingham in R (Amin) SS Home Dept [2004] 1 AC 653 at para 30).*
(c) A second positive duty, collateral to the first, namely the investigative duty. Article 2 requires the State to "initiate an effective public investigation by an ***independent official*** *body into any death occurring in circumstances in which it appears that one or other of the foregoing substantive obligations has been, or may be, violated, and it appears that agents of the state are, or may be, in some way implicated" (Middleton at paragraph 3).*

Judgement *2. The European Court of Human Rights has repeatedly interpreted article 2 of the European Convention as imposing on member states substantive obligations not to take life without justification and also to establish a framework of laws, precautions, procedures and* ***means of enforcement*** *which will, to the greatest extent reasonably practicable, protect life. See, for example, LCB v United Kingdom (1998) 27 EHRR 212, para 36; Osman v United Kingdom (1998) 29 EHRR 245; Powell v United Kingdom (App No 45305/99, unreported 4 May 2000), 16-17; Keenan v United Kingdom (2001) 33 EHRR 913, paras 88-90; Edwards v United Kingdom (2002) 35 EHRR 487, para 54; Calvelli and Ciglio v Italy (App No 32967/96, unreported, 17 January 2002); Öneryildiz v Turkey (App No 48939/99, unreported, 18 June 2002).*

3. The European Court has also interpreted article 2 as imposing on member states a ***procedural obligation to initiate an effective public investigation by an independent official body*** *into any death occurring in circumstances in which it appears that one or other of the foregoing substantive obligations has been, or may have been, violated and it appears that agents of the state are, or may be, in some way implicated. See, for example, Taylor v United Kingdom (1994) 79-A DR 127, 137; McCann v United Kingdom (1995) 21 EHRR 97, para*

161; Powell v United Kingdom, supra p 17; Salman v Turkey (2000) 34 EHRR 425, para 104; Sieminska v Poland (App No 37602/97, unreported, 29 March 2001); Jordan v United Kingdom (2001) 37 EHRR 52, para 105; Edwards v United Kingdom, supra, para 69; Öneryildiz v Turkey, supra, paras 90-91; Mastromatteo v Italy (App No 37703/97, unreported, 24 October 2002).

The ruling applies to healthcare and the NHS. The current system in Scotland fails to meet HRA 1998 as well as HSWA.

The SG and HIS ' Consultation on Regulation of Independent Healthcare in Scotland' of 2010/2012 once again omitted reference to the law that applied such as HSWA and COSHH, that compliance was essential and that it must be regulated. The consultation treated the law, compliance and regulation as optional! That encourages entirely the wrong perspective on the need for very high standards in healthcare. The questions in the consultation cannot have been drawn up by a body or person that understands the law or regulation.

The current consultation on the future of HIS inspection work has its basis in the Crerar Review referred to in section 6 (above). However the exercise falls at the first fence by disregarding the Crerar Report point on healthcare that the body that 'scrutinises' the NHS needs to be independent of the NHS and the Scottish Government. Crerar here is being consistent with UK and European Law whilst HIS and the Scottish Government are in defiance of it. The HIS consultation makes no reference to the statutory requirements on standards of patient safety or for the need for regulation.

8. Police Scotland

Police Scotland was involved in the initial request to investigate critical incident reports at Ayrshire and Arran NHS Board (A &A). There was a great deal of difficulty obtaining these under Freedom of Information (FOISA). The Board initially refused to provide them to Mr Rab Wilson. They were finally obtained following the judgement of the Scottish Information Commissioner. The Board had said reports did not exist but eventually were 'found' after the sustained pressure of the Commissioner, quote-

"This case has involved a catalogue of failings by NHS Ayrshire and Arran to search for and find information falling within the scope of Mr Wilson's request ? perhaps the most serious such case by an authority in my time as Commissioner. Claims made to Mr Wilson turned out to be wrong and prior assurances given to me and my staff turned out to be unjustified. At the very least, this constitutes a significant failure of records management, but, given the nature of the information which was the subject of the request, the failings may point to wider governance issues which have to be addressed.

Subsequently the police and COPFS were asked to consider the critical incident reports for offences particularly HSWA. The police reported that there were no cases to answer. The only exception was the case of Nicola Black where after four years of pressure from her parents, it resulted in A & A being prosecuted for HSWA offence in relation to the death. This response from the police was highly suspicious and raised questions as to how the police and the COPFS

had investigated the matters to come to their unbelievable conclusion. There was even one subsequent death that was very similar to that of Nicola Black and yet no enforcement action of any kind had taken place. Critical Incident Reports from across all NHS Boards show serious failings and breaches of HSWA that require addressing by enforcement notices (improvement usually) and could result in selective prosecution of the Boards to address systematic failings that exist in Scottish healthcare (e.g. poor management of patient's vital signs).

As a former HM Inspector and Prosecutor on behalf of the Crown, in March 2015 I reviewed a larger batch of A & A reports. The associated action plans demonstrated reasonable means that could have been taken to prevent the incidents and harm. These 85 reports had 46 that related to fatalities where the failures on HSWA could have been a factor. The GB-wide enforcement code for HSWA offences (reserved legislation) is the Enforcement Management Model (EMM). I was involved in developing EMM; I initiated its application to health topics, I advised sectors on how to apply it, and continually applied it as an operational inspector working across most UK sectors. I also inspected the police and introduced the application of HSWA to the police (The Police (Health & Safety) Act 1997) carrying out the first inspection of a police force under HSWA. So I am familiar with their workings. In 49 of the 85 reports the HSE's EMM determination is to consider prosecution for breaches of HSWA. In 64 of the cases there is determination of issuing legal enforcement notices. The Lord Advocate said that there were none that required action against the NHS Board. That is as wrong as anyone can be. The reason for this wrong decision is now evident with his defective justification of not prosecuting the Glasgow bin lorry driver. As noted earlier he, the Solicitor General and COPFS do not understand safety law. **HSWA does not require criminal intent**. If he and COPFS were looking for criminal intent it is no wonder he said no prosecutions. If he had looked for criminal negligence, knew the law and the GB-wide enforcement code he would have come to a similar answer to me.

Mr Rab Wilson referred the matter back to the police and asked how they had come to their opinion that no action was required when the EMM showed numerous cases could have been prosecutions, and there were no legal notices issued to ensure the lessons were learned and precautions improved.

The police claimed FOISA exemption. This decision was appealed against but the police continued to refuse to give any information on how they had arrived at their decision. The request under FOISA was revised to ask if the police policy is to use EMM or equivalent enforcement criteria when assessing what enforcement action to take on HSWA, and was it used in these cases? The police still claimed exemption. The question is whether the police have a policy on enforcement and was it followed at A & A, or do you have a procedure as to how you do the job and was it followed? This is not FOI exempt; EMM is a GB-wide policy and is available on the HSE website together with an explanation of how it should be used. If the police cannot answer this then it raises questions on their ability to be involved in HSWA cases, and perhaps wider questions of how they determine other enforcement actions.

The matter has now been referred to Scottish Information Commissioner.

There is now recorded evidence that in assessing the 85 reports and '40 suspicious deaths' Police Scotland did indeed look for criminal intent. The police did not look at them as HSWA, they did not look for criminal negligence. They are not qualified to act as HSWA specialist, they would not know what constituted criminal negligence in healthcare. They did not use the EMM enforcement code.

The situation is of about 40 'suspicious deaths' at Ayrshire and Arran NHS Board where the police are unwilling to say how they assessed them and came to the decision to do nothing, not even arrange for HSE to issue statutory improvement notices. Accordingly the problems persisted and major avoidable harm continues. If HSE did actually look at the cases then their actions too are suspect. HSE inspectors no longer have the experience or understanding of healthcare and clinical practice as they ceased inspecting on patient safety many years ago because the independent regulator of healthcare was supposed to do the job. HSE would lack the competence in what is quite specialist work of healthcare. So we have '40 suspicious deaths' and no action to ensure that precautions to prevent similar are in place.

This and the Glasgow bin lorry FAI have shown that neither COPFS nor Police Scotland have sufficient understanding and competence to deal with the situation at A & A. They could have, and still can prosecute on both cases.

9. Crown Office and Procurator Fiscal Service (COPFS)

It became apparent from 2012 and particularly during 2013 that the Scottish Government had failed to recognise the application of HSWA to patient safety (even after the Mid Staffs prosecution). They refused to require health and social care providers to comply with it, and they had even abolished the regulator of NHS Scotland on patient safety. The matter was extremely serious as it related not to a few deaths but to a very large number and continues so. It was referred to the Lord Advocate as chief legal adviser to the Scottish Government but he declined to advise them on it and said it was matter for the SG's Health and Social Care Directorate. Another reply also demonstrated the lack of understanding by suggesting that you needed to have deaths before action under HSWA could be taken. The Lord Advocate was totally incorrect, the offences are for failures to have effective precautions in place, not for any harm that may or may not occur. I am afraid that this is such a basic lack of understanding of HSWA, and this relates to the body that takes HSWA prosecutions. The bewildering lack of understanding of HSWA is currently being shown at the FAI on the Glasgow bin lorry deaths (see section 9). It also seems to be apparent in the inaction on the Edinburgh legionlella outbreak.

The failings of COPFS on the '40 suspicious deaths' at Ayrshire and Arran were addressed in the first update to the case for the public inquiry. Briefly COPFS did a paper exercise on the reports, they excluded ones that they thought that they had looked at before (see Police above), obtained no evidence on the deaths (this is a novel approach to investigating deaths), demonstrated a lack of

understanding of the application of HSWA (again even after Mid Staffs) and did not apply the EMM or an equivalent means of determining actions. Some of the critical incident reports were comparable with the inquiry into the Morecambe Bay maternity unit and the Mid Staffordshire prosecution. 'No action' was most certainly the wrong answer. The Nicola Black case showed that COPFS were very slow to see that HSWA applied, they had to be forced to recognise it, and that the death needed a prosecution. The Solicitor General and COPFS also thought that because there had been a HSE/HSWA prosecution related to Nicola Black's death there was no need for a FAI because all the issues would be covered. This is not the case. While HSE/HSWA prosecutions give some background to the case, it then only covers sufficient matters to prove the case. They do not deal with the wider issues such as management systems and higher responsibilities such as with the Nicola Black case the Scottish Government's failure to implement and ensure compliance with HSWA on patient safety. A similar death occurred subsequently at A & A and across other similar units in Scotland because there was no FAI and the lessons were not learnt and applied. The deaths continue.

On A & A the Lord Advocate was given the file of 85 critical incident reports which included over 40 suspicious deaths. So there was no attempt by COPFS to obtain primary evidence on the cases. It relied on the evidence of the body that would be the suspect in the case. Irrespective, the Board's own evidence showed that by the applicable UK standards that applied there was sufficient reason to prosecute in 49 cases, many of them associated with avoidable deaths, and the need to issue enforcement notices in 65 cases. This was not a call for prosecution in all cases but as further evidence of the consequences of the law of HSWA as it applied to patient safety not being implemented and complied with in Scotland. This is not a matter of opinion, it is what the law requires. The Act should be preventing the very large number of avoidable deaths. The Lord Advocate said that there was no need for legal action. From UK data and Department of Health estimates this disregard for the law by the Scottish Government and its law officers permits about 2,000 avoidable deaths /year in Scotland, or 4% of all deaths. Refusing to recognise the problem that other countries recognise and not doing anything about it is like to continue to deny that the earth is round, except this error is vastly more dangerous.

The decision-making process on HSWA and particularly patient safety appears to be wrong and exposes the public to avoidable risk to life. The position is very confused and does not meet UK law and standards. Whilst this is on HSWA cases, it suggests that the failings could apply to other areas of COPFS work**. In addition to the public inquiry there needs to be an independent review of the decision-making process on safety-related prosecutions to protect the public to the standards that the law requires.**

The approach to HSWA cases need reviewing. There are these 2,000 potential deaths that could be covered by HSWA each year in comparison to about 50 'conventional' homicides. It would be unusual if the problems of the police and COPFS on legal process were only confined to HSWA cases. The current position does not give public confidence when the basic legal process is not followed, even when it knows it is on public display. The bin lorry shows basic

misunderstanding of safety law and strict liability law by Scotland's most senior law officers.

The review of A & A cases raised further doubts about COPFS having the competence to deal with HSWA cases in its present state. The lack of competence was given a very high profile with the Glasgow bin lorry incident where it did not know a basic principle in law, the law itself or how it was required to be enforced. On safety, it is case of not understanding the law, not applying the law, and not complying with the law.

Health and safety legislation is widely misunderstood, that it is not by Scotland's senior law officers should be a major concern and require immediate action.

10. Glasgow Bin Lorry FAI: COPFS and Legal Process

On the 25 February 2015 the Crown Office said there was no evidence that either the driver or Glasgow City Council was to blame for the incident (of 22 December 2014). It concluded that there would be no criminal prosecution over the crash**,** with senior lawyers deeming it a "tragic accident". At the preliminary to the Fatal Accident Inquiry the Crown Office stated that the driver had never given a Police Scotland statement since the crash. At the end of the FAI he still hasn't (21 August 2015). It is unusual.

In a statement on 31 July 2015, the COPFS said that the driver was unconscious when the bin lorry veered out of control in Glasgow city centre "and therefore not in control of his actions". The Crown Office statement said the driver did not "have the necessary criminal state of mind required for a criminal prosecution". "In addition the Crown could not prove that it was foreseeable to the driver that driving on that day would result in a loss of consciousness". '*That day'* is irrelevant to HSWA, it applies to '*any day',* incident or not*.* The Crown statement paid no regard to HSWA responsibilities of the driver and this is consistent with its lack of understanding on patient safety.

However whilst it had already become very obvious that the Lord Advocate, the Solicitor General and COPFS had a very poor understanding of HSWA on patient safety, the next revelation of the FAI was remarkable. As has been referred to in the preface, it came out that they did not understand that safety law was strict liability law. That is, it is not required to have criminal intent to have a criminal offence, criminal negligence is sufficient. In safety law it is about negligence that gives rise to an offence, and does not need intent. This is such a basic point. However it is now seen to be consistent with the stream of odd (i.e. wrong) decisions being made by the current COPFS. The bin lorry is the highest profile; the position on healthcare is the one with the greatest consequences.

The systematic error of COPFS is on a matter which goes back 200 years. In 1800 safety law commenced and it was immediately realised that 'mens rea'- criminal intent was inappropriate. This gave rise to criminal negligence being the issue to be proved, and this law was 'strict liability law' which exists across

most parts of society. The misunderstanding of COPFS is fundamental and basic. Safety law and offences are about:

- Not having effective precautions in place is the offence (not any accident which may/may not occur)
- Negligence in failing to take the precautions is the offence (not needing any element of intent).

The COPFS have been getting both wrong. To press the point on them, when safety law was introduced it was to protect children working in factories. The prosecutions were on failing to take precautions to prevent serious harm to the children and on the negligent behaviour of the factory owner. It was not to wait until a child had been killed and to prosecute if they could prove that the factory owner was awake and intended to harm children. The latter is the position that the senior law officers have taken in their decision not to prosecute the driver.

The case shows the senior lawyers of COPFS including the Solicitor General failing to apply HSWA to the case or understand it. The Lord Advocate, the Solicitor General, and the COPFS have previously displayed a lack of understanding of HSWA in relation to healthcare. This is a high profile example of the failures and shows them to be unsuitable in their current state for assessing safety-related situations for prosecution or undertaking them. It is such a serious error that they cannot justify confidence in their decisions.

I have investigated a fatality associated with the movement of a refuse collection vehicle under HSWA. I assessed the situation relative to the law and the policy on HSWA offences and prosecutions. I had to make the decision as to whether to initiate legal proceedings against the driver, the council, or others. I had to carry out the correct procedures, to do them properly, and to do them in the correct order. For example I would not say 'no prosecution' until I had sufficient evidence to make the decision. Even then it would be done with cautionary clauses. The evidence is that when COPFS said that there would be 'no prosecution' there had not been a competent investigation, it had not got the relevant evidence to decide, and it got the law wholly wrong in looking for criminal intent when none was required for a prosecution.

The opinion of the legal profession in Scotland seems to be of serious concern at the Solicitor General's and COPFS decision not to prosecute as stated on 25 February 2015. The decision on such a high profile matter would not be left at the level of Solicitor General. The COPFS statement on the driver being unconscious at the time of the incident is not relevant to HSWA offences. The decision is regarded in the Scottish legal profession as 'very hasty', 'remarkable', 'rather odd' and 'perplexing'. A former top prosecutor with COPFS said it was wrong and that 'whoever made the decision would, find themselves in a "very difficult position" if the sheriff overseeing the FAI found that the driver failed to disclose his previous blackouts to the DVLA'. The early decision also made it more difficult to properly investigate the matters under HSWA and ensure that the wider lessons were learned and applied.

Despite this – what so far has not been recognised is that the driver could still be prosecuted under HSWA s7(a) and 7(b). It does not need the accident.

This case is an all too real example of the failures of COPFS understanding safety law. It is consistent with what I have found in looking at the approach to safety – such as the failures of the Vale of Leven Hospital Inquiry and the Penrose Inquiry and many many more. Both COPFS and Police Scotland are involved in matters where they are looking for criminal intent when they should be looking for criminal negligence. The consequences of this error seem never-ending, they cast into doubt all decisions on safety such as those related to sudden and suspicious deaths. Current deaths that could come under criminal negligence outnumber those where there is criminal intent by about 40 to 1.

The bin lorry FAI and the very early decision not to prosecute showed that senior law officers and COPFS had disregarded half the law that applies to the incident by not obtaining a competent HSE investigation, not securing the evidence (e.g. still no police interview or statement from the driver, and the FAI showed that they did not have 'all the relevant evidence') and did not follow due legal process by giving the verdict of no prosecution before having the considered the law, understanding the law, or evidence in the right order. They do not understand that HSWA is about precautions and prevention or not require criminal intent. It was very clear they did no have or apply a systematic approach to arriving at their decisions. It gave every appearance of being made up on the hoof, is this usual approach to decision-making? COPFS showed that they have nothing which gives a legal, systematic, proportionate, consistent, transparent approach to decision-making that justifiably commands public confidence. They showed that did not understand strict liability law, they inadvertently threw out 200 years of law, acted ultra vires by putting in place an additional barrier to the law and justice, and all with major implications for the rest of their work and the delivery and reputation of the Scottish legal system, and on-going major consequences for public safety. I am afraid that they reduced the process to one of farce, the Red Queen's 'sentence first, verdict afterwards' would not have been out of place

The COPFS and senior law officer's lack of understanding of strict liability law, safety law, and the enforcement code (EMM) makes them unsuitable for assessing HSWA cases for prosecution. It also makes the senior law officers who are the main legal advisers to the Scottish Government unsuitable for the role. It renders their advice as being untrustworthy at the minimum.

Scotland's senior law officers have failed to uphold the law that would ensure public safety.

11. Continuing/Complex Care (IPCC) and End of Life Care

The first update to the case for a public inquiry showed serious problems at NHS Lothian on In-Patient Complex/Continuing Care (IPCC). This related to long-standing inadequate care being given to patients with complex medical needs, general nursing being given rather than specialist, very low nursing levels, inadequate numbers of trained nurses including no trained staff. Medical

input was very limited – Monday to Friday 9-5, and then often not Monday or Friday either, with none at weekends. On-call services were weak and not used, with lack of personal care and woeful pain control. Staff were very concerned at the conditions. There was gross under-funding of the IPCC (and NHS Lothian generally in relation to needs) and this translated to unsafe levels of nursing and medical input. The evidence shows breaches of HSWA on patient safety, and of inadequate quality of care. Given the scale of the problem and detail of the information this will be the subject of a separate report by others.

There are concerns elsewhere in the UK about end of life care and it has been addressed by the UK's Health Committee 'End of Life Care' report March 2015. Related to this the Secretary of State for Health, Jeremy Hunt has called for much improved weekend care. He identifies the deficiencies in weekend care responsible for about 6,000 avoidable deaths; this would be about 500 in Scotland. To seek to address the problems of end of life care NICE has produce draft guidelines on care for the dying. It is not apparent what action the Scottish government is taking to address these issues.

The issue of IPCC arises following the death of Mr William Oliver at Ellen's Glen, NHS Lothian. There is a detailed and currently confidential report on his death but it also links to the wider issues. The family of Mr Oliver are clear that the issues found at Ellens Glen are not unique and that the issue of continuing care and end of life care are addressed across all of Scotland. It affects a very large number of people and often those who are not able to speak up for themselves or others. It is also a great concern to staff that they are unable to provide the care that is required.

12. NHS LOTHIAN CRITICIAL INCIDIENT REPORTS

Despite the Scottish Information Commissioner's damning report on Ayrshire and Arran NHS Board over FOI and Critical Incident Reports the problems continue. The commissioner was also concerned that serious incidents were not visible, that there were issues of governance and not learning from them. With the ongoing COPFS failures on the '40 suspicious deaths' at Ayrshire and Arran, it requires no imagination to read the whole mishandling of the cases as an almighty cover up.

The Scottish Government has issued guidance to boards, and their health spokesperson has said on a BBC special program that they should be making the reports (redacted sufficiently for patient confidentiality) public available – in part to learn the lessons. Boards are still being obstructive. I have gone through hundreds of FOI requests for NHS Lothian and seen the ethos as one of being as awkward and as uncooperative as possible. I asked for a selection of the reports, the action plans to deal with the problems found, and the policy on them. They provided the policy but did not provide any reports or action plans. I asked for the reports and they continued their obstruction. They defied both the Scottish Government's guidance and the Information Commissioner's judgement. They ignored the ability to redact sufficiently and reduce the number of reports if the costs exceeded the FOI standards.

NHS Lothian state:

'It is not possible to provide copies of the reports and action plans from these reviews, as the reports contain individual patient details. Since we do not have their consent to release this data from their records, the information is exempt under section 38 of the Freedom of Information (Scotland) Act, as to provide it would breach the 7th Principle of the Data Protection Act 1998. The time and resources which would be required to summarise or redact these 301 reports to make them publishable would be significant.

They know very well the ability to provide redacted reports. They have been given options, and the Commissioner has been informed. The issue of Lothians and their failure on FOI immediately was notified to the Scottish Information Commissioner given its similarities with Ayrshire and Arran. This is relevant to the new guidance from NHS Scotland guidance to NHS Boards on FOI and critical incident reports. There is a history of Lothian reports either not being completed or going missing. This has been pursued by Neil Findlay MSP.

The response from NHS Lothian is similar to public service (civil servant) responses on patient safety. The responses do not answer the points. It is not usually clear if their failures are ones of competence (basic reading and comprehension, technical knowledge) or obstruction. Regrettably this runs through all the patient safety issues to the very top. Elsewhere this matter is being referred to the new head of the Scottish Civil Service, Leslie Evans as it has involved systematic failings to comply with the Civil Service Code. The breaches are often at the instruction of ministers and this on the matter of a very large number of avoidable deaths. When officers cannot answer the points (the norm), they give the usual approach of saying that they have answered the points when they have definitely not and ban any future correspondence with the individual. An example is the Lord Advocate and Solicitor General refusing to deal with one letter challenging its inaction on the ’40 suspicious deaths’ at Ayrshire and Arran. This is no way to run a democracy.

13. Scottish First Minister Response

A summary of failures on Scottish patient safety was provided to the Scottish First Minister in April 2015. The SFM said that she would respond via Professor Jason Leitch. Despite reminders (26 June and 05 August 2015) the promised response has not been received and large-scale deaths, other avoidable harm, and major breaches of legislation continue. The SFM was asked in April if she would support the case for the public inquiry into patient safety in Scotland. The SFM would neither confirm nor deny. Professor Craig White apologised and is chasing the response.

Scottish Ministers should have been aware of their primary responsibility to deliver a healthcare service that is safe for patients as a devolved matter. With the Public Services (Scotland) Reform Act 2010 they abolished the independent regulator of healthcare. The ministers who abolished it were John Swinney (bill sponsor), Nicola Sturgeon (Health Minister), and Alex Salmond (Scottish First Minister). Since April 2011 Scottish Ministers have been reminded that HSWA

applies to patient safety. This was following their poor response to a letter on the failures of power supplies to operating theatres at an Edinburgh hospital during operations. Since then Scottish Ministers refused to acknowledge the Act (till 31 March 2015). They have shown no understanding of what it meant, have refused to implement it, or to require healthcare providers to comply with it, or to regulate it. This has been from three CS Health (Nicola Sturgeon, Alex Neil, Shona Robison), two Justice Secretaries (Kenny MacAskill, Michael Matheson) and two First Ministers (Alex Salmond, Nicola Sturgeon). Another minister, the Lord Advocate, Frank Mulholland has refused to act on his job of being the chief law officer and principal legal adviser to the Scottish Government and to address this fundamental breakdown in law and one with severe consequences. The Glasgow bin lorry incident and failure to understand safety law has emphasised the error of the senior law officers. The consequences of such a failure in law will gradually become evident across other areas. For the moment patient safety is the priority.

The Scottish Government had three years to recognise, understand and address the issue affecting the lives of most people in Scotland. Regrettably they refused to do so and as the over-arching legislation is all reserved it is only by the legitimate and essential use of a UK inquiry that the matters can be properly investigated and act as the prompt for immediate action. Irrespective of the current position of the inquiry, immediate action is still required to deal with the avoidable and daily loss of lives in Scotland that should be prevented.

In the approach to public safety and what the law requires, every error that can be made in it and patient safety has been made and continues to be.

14. Conclusion

There has been a refusal by the Scottish Government to recognise the problem of avoidable deaths in Scottish healthcare. They do occur on a very large scale and these could be prevented by complying with long-standing legal requirements. The error of understanding of what the law requires is present across all Scottish health and social care. Together with there being no regulator this major error of public policy and harm has continued. Reference to other parts of the UK should have revealed the problem, e.g. Francis Report and inadequate regulation. Besides not having the required regulation we do not have the independent scrutiny bodies present elsewhere that reveal the problems. They are very much present as revealed in critical incident reports across all NHS Scotland Boards, and in the particular issues at Ayrshire and Arran, Lanarkshire, Lothians, and Vale of Leven, and infection control failures at most hospitals.

The responsibility for delivering a safe, effective healthcare service lies with the Scottish Government. They have been advised for well-over three years of the problems on patient safety and the law but have chosen to disregard them. A factor may be that their senior law officers whose role is to advise them on law have both refused to do so and have shown with the Glasgow bin lorry and many other cases that they do not understand the law on public safety.

The Scottish First Ministers have had every opportunity to act to protect the safety of the people of Scotland. They have refused to do so. The situation cannot continue. The requirement that the ministers and the Scottish Government ensure public safety is ultimately governed by GB and UK-wide legislation. In the failure of Scottish Ministers to fulfil their responsibilities it falls to this legislation and process. It needs prompt action to address the immediate and on-going risks to the people in Scotland. To drive this forward it needs a full investigation of the issues by means of a pubic inquiry. Whilst inquiries are often long and expensive this one can be made to be effective and efficient, but also its benefits could be quickly achieved. In significance it would exceed that of Mid Staffordshire. Inquiries can work, as the Piper Alpha did for off-shore safety. What is needed is one for patient safety in Scotland.

15. References

1. Patient Safety in Scotland (PSIS) 29 January 2015
2. PSIS Update 1 and Analysis of Case for the Public Inquiry 18 May 2015
3. Ayrshire and Arran NHS Board Critical Incident Reports 14 March 2015
4. NHS Lothians IPCC Report (confidential) 07July 2015
5. Nuffield Trust and Health Foundation review of healthcare in 'The Four Countries of the UK; how do they compare?' April 2014 https://www.google.co.uk/#q=Nuffield+Trust+and+Health+Foundation+review+of+healthcare+in+%E2%80%98The+Four+Countries+of+the+UK%3B+how+do+they+compare
6. The Crerar Review: Report of the Independent Review of Regulation, Audit, Inspection and Complaints Handling of Public Services in Scotland. http://www.gov.scot/Publications/2007/09/25120506/0
7. NHS Scotland's Healthcare Improvement Scotland (HIS) Consultation http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_reviews/qoc_reviews_consultation.aspx
8. Health Select Committee End of Life Care https://www.google.co.uk/#q=health+committee+end+of+life+care
9. NICE End of Life Care https://www.nice.org.uk/guidance/indevelopment/GID-CGWAVE0694/consultation/care-of-the-dying-adult-draft-guideline-consultation
10. Royal Academy of Medical Royal Colleges and Faculties in Scotland 'Learning from Serious Failings in Medical Care' 10 July 2015
11. Royal Academy of Medical Royal Colleges and Faculties in Scotland and Royal College of Nursing 'Future and Sustainability of NHS Scotland' 04 June 2015