‘**PATIENT SAFETY IN SCOTLAND’ PUBLIC INQUIRY**

UPDATE AND SYSTEMATIC ANALYSIS

Roger Livermore 05 May 2015

1. Summary

The cases for a public inquiry ‘Patient Safety in Scotland’ was submitted to the Secretary of State 0n 31 January 2015. It was also submitted to the Scottish Affaires Select Committee on the 2 February 2015. The General election

Since the submission that has been substantial further evidence justifying the inquiry and this is addressed here. The evidence will continue to mount by virtue of the fundamental underlying failures on legal compliance. None of the issues have been addressed by the main bodies involved since the submission.

This report takes the criteria for a public inquiry and systematically accounts for the factors. The overwhelming evidence is in favour of an inquiry. To not have an inquiry sanctions thousands of avoidable deaths, the large scale breaking of four major pieces of GB and UK law by the Scottish Government. That government persistently disregards binding legislation and the breaking of the UK constitution.

2. Introduction

It is now the UK consensus that there are large-scale avoidable deaths, other harm, and costs caused by failures in healthcare. The current figure is put at 12,000 avoidable deaths in acute physical healthcare alone e in England each year. ‘Avoidable’ broadly equates to failures to do what is reasonably practicable to ensure the health and safety of patients - this is the requirement of the Health and Safety at Work etc Act1974 (HSWA) as it applies to patient safety in England and Scotland. .Until 31 March 2015 there had been no statement from the Scottish Government recognising that the Act applied in Scotland, despite it having done so for the last forty years; the problem being it had not been properly implemented. However the Scottish Government continues to refuse to implement the Act in Scotland and certainly not to the standard required. It refuses to comply with its own responsibilities under the

Act. itself. It refuses to set the policy and requirement for health and social care providers to comply with the Act./ It refuses to create the essential and legally required regulator.

There are four main bodies involved in ensuing patient safety in Scotland. These are the Scottish Government, health and social care providers – such as NHS Scotland, the default regulator of HSWA – Health and Safety Executive (HSE), and the Crown Office and Procurator Fiscal Service (COPFS). Individually and collective these have all failed to ensure that patients are as safe as can be reasonably be expected.

There are systematic failings by all these bodies that cannot be left to continue. The costs in Scotland amounts to each day's delay in meeting HSWA standards to be about 5 avoidable deaths.

This document update on developments since the initial submission. It takes the criteria for a public inquiry and considers the factors constituting public interest and presents the arguments for and against an inquiry. It considers the legal, social, economic, ethical, political and technical factors. It also does a comparison with other matters which have resulted in public inquiries.

3. Update

3.1 SG Refusal on HSWA and Regulation

The Scottish Government have for the last three years refused to recognise the application of HSWA to patient safety in Scotland. They certainly have not committed to implementing it to the required standards to secure patient safety. They abolished the health regulator and have persistently refused used to create one. The position has been confirmed by Ms Shona Robison, Cabinet Secretary for Health in a meeting with the pressure group Patients First on 31 March 2015. This was in response to written questions on the above. The only concession was that the CS did recognise that HSWA did apply. However she refused to do anything about the government complying with the Act or to requiring health and social care providers in Scotland to comply with the law.

The position of the CS and the Scottish Government as expressed at this meeting would provide strong evidence in any legal case. It presents an extreme position of disregard of UK law and the consequences that come with it.

3.2 NHS Ayrshire & Arran Critical Incidents Reports and Prosecutions

Critical Incident reports from across NHS Scotland boards show major failings of healthcare. Following a highly critical investigation and report by the Scottish Information Commissioner in February 2012 on NHS Ayrshire and Arran, some critical incident reports were made publically available. A file of 85 of these reports were submitted to the Lord Advocate on 14 March 2015 as evidence of potential statutory breaches. Forty-five of the reports dealt with

deaths, and there were 49 reports where the GB-wide HSE enforcement code (EMM) says consider prosecution. The majority of the reports justified the formality of statutory enforcement notices to ensure improvements made.

The reports were indicating a large number of avoidable deaths that took place because of failures to comply with the law. The failures were systematic and evidence of a Scottish –wide policy to comply with the law. Accordingly the Lord Advocate was asked to investigate the responsibilities not only of the NHS board and officers, but also those of NHS Scotland, and of the Scottish Government and senior ministers. The prosecution file represented a failure of the Scottish Government to recognise HSWA, to have it as an intent in Scotland or for NHS Scotland and its boards to comply with the law. The cases and some of the deaths are the consequences of the failure of the government's policy to disregard HSWA or to require dutyholders to comply with it. This file of critical incident reports would, by the example of the Vale of Leven Hospital public inquiry, justify a public inquiry in its own right.

In his reply the Lord Advocate refused to independently investigate the critical incident reports. He failed to understand the fundamental principal in HSWA that criminal offences were for failure to provide effective precautions rather than on any harm which might occur. He totally disregarded the request to consider Corporate Manslaughter and Corporate Homicide Act 2007, the Human Rights Act 1998, the Scotland Act 1998, and ECHR. He refused to investigate the role and legal responsibilities of NHS boards (either A&A or generally) and their senior officers, NHS Scotland and the Health and Social Care Directorate, and Scottish Ministers. This is of particular concern when one of his ministerial colleagues, Ms Robison had refused to comply with or implement the law. This policy costs lives. The Lord Advocate was aware of the policy of the minister and the Scottish Government but persistently refuses to act (see section 3.8). There are also major constitutional issues (see section 3.9)

3.3 Penrose Inquiry and Contaminated Blood Supplies

On 25 March 2015 the Penrose Inquiry reported on historic events in 1970s and 1980s related to contaminated blood being supplied to Scottish patients. The inquiry failed its first terms of reference, it was meant to look at the law that applied and the regulation. It totally failed to see that all the matters were covered by HSWA and that HSE was the regulator for all the period covered. This is such a fundamental failing, one it shared with November's Vale of Leven Hospital Public Inquiry. That's is two inquiries in four months failing to do the job after great expense and time. They did not investigate according to HSWA criteria and standards, they did not assess the evidence according to its requirements and the recommendations did not accord with HSWA.

The report was not well-constructed, but the evidence in its 1861 pages it suggests that were avoidable delays in screening and testing blood supplies, and that these would have resulted in avoidable deaths. The report identified serious problems with the Scottish National Blood Transfusion Service

(SNBTS) at the time in it decision-making Scotland was late to adapt screening and testing. The evidence needs to verified in the light of this and HSWA being disregarded yet again in Scotland.

The Prime Minister had to make a UK apology to the House of Commons on the day of the report's release. The UK were waiting on Penrose to decide their own actions. They now have a filed inquiry. I informed the PM's office, the Cabinet Office and the Department of health of the errors of Penrose and evidence of failures of SNBTS. They are looking into the matters.

3.4 Complex Care (IPCC Service)

The case for a public inquiry used evidence from acute physical and mental health care. In its recognition of the scale of the problem of avoidable harm it did however account for there being many areas of health and social care where no-one is looking to assess the problems or to ensure that safety is delivered. One area that has come to light since PSIS was submitted is that of what was called 'Continuing Care' and now renamed 'Complex Care', the IPCC service. There was concern about a 30 bed unit in NHS Lothian where in one week five patients died, the unit was severely understaffed with nurses and medical staff and standards of care, dignity and pain control. The mortality rate at these units is almost 100% but they do not have the provisions of a hospice. The service has failed to meet the needs of patients, it had not been reviewed, funding and staffing had not been provided to meet the needs.

This service has not only been subject to no regulation, it has not been subject to any preventive in-house quality assurance and scrutiny checks by NHS Scotland's Healthcare Improvement Scotland or Healthcare Environment Inspectorate. This is just one of many other areas of Scottish healthcare where not only is there no regulation, there is also no scrutiny, and none of it is to HSWA standards. No body be it the Scottish Government, providers, the COPFS or HSE are taking action to address this regulatory vacuum, and also absence of even scrutiny (either internal or independent scrutiny). .

In social care, the Care Inspectorate does not work to HSWA standards. So that area is also in effect unregulated to the standards required by law. These are areas where there appears to be little research and little data,. From the hazards, risks and levels of precautions it was, and should still be an area of concern.

3.5 Public Administration Select Committee (PASC)

On the 27 March 2015 the PASC published its report into 'Investigating Clinical Incidents'. This again emphasised the scale of avoidable hospital deaths quoting the Secretary of State for Health estimates of 12,000 every year. As part of addressing this major problem it required strengthened investigative capacity locally in most of the NHS, supported by a new, single, independent and accountable investigative body to provide national leadership, to serve as a resource of skills and expertise for the conduct of

patient safety incident investigations. This is going beyond the existing UK system of having an independent regulator (except in Scotland). The report was critical of the Ombudsman. They proposed changes and new legislation to make the ombudsman's much more effective than at present. On the detail in the report, the Scottish Public Sector Ombudsman has the same and worse problems. PASC wanted this new fully independent body in place to investigate clinical incident early ion the next parliament. We in Scotland are a long way behind, the problems are not recognised, and we do not even have a regulator (poor or otherwise).

3.6 NHS Scotland and Healthcare Performance

There is no systematic assessment of the performance of healthcare in Scotland except on finance (Audit Scotland 2013/14). There is no independent body assessing how the sector performs, there is not independent scrutiny, and there is very little by way of pressure groups. There does not seem to be an internal NHS system to systematically assess performance such as on compliance with patient safety, or the main purpose of healthcare aspects such as the effectiveness and efficiency of delivering healthcare. This for its impact on the length and quality of life by its contribution to the stages of 'a patients journey' (prevention, diagnosis, treatment, monitoring outcome, and feedback).

There is not the independent body such as the care Quality Commission, no Monitor, the Kings Fund, Dr Fosters, the Health Foundation (minimal), Healthwatch, or strong patient groups such as the Patients Association. Healthcare in Scotland has little scrutiny, no independent regulator

3.7 Health and Safety Advice

All organisations are required to have competent advice on how to comply with HSWA (Management of Health and Safety at Work Regulations s 1999, regulation 7). This covers both risks to employees and the public including patients. In the matters covered by the inquiry the organisations have not got anyone fulfilling this role. This is a reason for the specific and systematic failings of healthcare in Scotland.

The overall responsibility for patient safety is under ministers and senior officers, however the law requires them to be adequately advised both on law and specific precautions to ensure safety. On the 17 March 2015 in response to the BBC coverage of major failings at Ayrshire and Arran, a SG spokesperson gave the impression that compliance with HSWA was optional and said that the law was about prosecuting frontline healthcare staff. Its focus is on organisations and senior officers who set policy, management systems and resourcing, and only exceptionally the prosecution of frontline staff. He sought to undermine the law. That is not appropriate for a government officer or HSWA competent person.

For three years there has been no-one in the Scottish government who has been able to recognise the scale of the problem of avoidable harm, that the

law applies, and what it means in terms of policy and compliance. This has allowed many avoidable deaths. The two public inquiries dealt with matters within HSWA and yet no HSWA competent input and they missed the legal requirements and outcomes.

If there had been a competent independent regulator then it would have made sure that dutyholders in Scotland were aware of the requirements, and then ensured that they complied with legislation. This body has been absent in Scotland. HSE has withdrawn from preventative inspection to make sure that dutyholders in health and social care comply with HSWA, so no-one does. NHS Scotland has a limited body called HIS that does some scrutiny in some areas but has no powers, no independence and does do HSWA standards for the hazards and risks involved. This is where English scandals have been characterised by 'poor regulation', whilst the emerging greater Scottish scandals are characterised by 'no regulation'.

3.8 Lord Advocate Obstruction of the Law

In his reply of 01 May 2015 the Lord Advocate failed to address the issues of the covering letter to the file. He refused to investigate the absence of a commitment of Scottish healthcare to comply with the law. He did not investigate the systematic failures across all NHS Boards and their senior officers to have a policy on HSWA compliance on patient safety. Nor did he investigate NHS Scotland and Health and Social Care Directorate and their senior officers. He refused to investigate the role of Scottish Government ministers in respect of their policy of non-compliance with GB and UK law with HSWA, the Corporate Manslaughter and Corporate Homicide Act 2007 – such as in relation to the death of Nicola Black. There was no consideration of the Human Rights Act 1998 or the role of ministers and the Scotland Act 1998. He did not have any of the incidents investigated independently relying on the internal NHS reports, this is potential criminals investigating themselves on criminal acts. In my letter of 04 May 2015 the failings of his reply to address the issues were pointed out.

3.9 Constitutional Crisis

The Lord Advocate refuses to investigate Scottish Ministers when there is a vast amount of evidence of GB and UK law being disregarded in Scotland and with such severe consequences. The judiciary refuses to investigate the executive and the Lord Advocate both judiciary and as a minister is the executive. Even when a minister, Ms Shona Robison refuses to comply with and implement the law in Scotland he still refuses to act.

The Lord Advocate's refusal to investigate Scottish ministers under major GB and UK legislation creates another **constitutional crisis** – beyond that of Scottish ministers refusing to comply with GB and UK law. The Lord Advocate is also a Scottish minister; he is not in the cabinet but does attend cabinet meetings. There is not the separation of powers (executive, legislature, and judiciary) in Scotland, they are all one. The usual formal and informal checks and balances of an un-codified constitution to prevent abuse

of power are almost gone in Scotland. There is no longer the protection of the UK constitution that should be afforded citizens of all parts of the UK. Lord McCluskey the former Solicitor General for Scotland has recently expressed a similar concern in relation to evidence of corroboration

4 Criteria for Public Inquiry

The criteria for a public inquiry are issues and incidents which have high importance in the public interest. Public interest can cover a range of issues. These can be classified as Social, Technical, Ethical, Economic, Political, Legal, Environmental ('STEEPLE'). This provides the structure for assessing the case for an inquiry. The approach rearranges the order according to some priority, and 'environment' is not significant in this issue.

5 Analysis

5.1 Legal

For: The legal case is that major UK legislation has not been recognised, implemented, complied with, or regulated in Scotland. The consequences of these failings is that there will have been and continue to be large numbers of avoidable deaths, other harm and costs.

The failings are associated with those of primary dutyholders – the Scottish Government and the health and social care providers, particularly NHS Scotland. There are failings attributable to secondary bodies such as COPFS and HSE. These are in the failings to prosecute or to act as the over-arching regulator.

The legal considerations apply to organisations, and public officials including the most senior ministers. The number of avoidable deaths are at about 2,000 every year and this equates to about 4% of the total number deaths in Scotland. As these are avoidable deaths they are most certainly in the public interest.

It is by public standards and published UK policy on tolerability of risk wholly unacceptable for such level of harm to continue by virtue of the statutory failings of organisations and senior officers.

The case for the inquiry deals with matters of failing to uphold GB and UK law, obstructing it, and potentially indictable offences. These are extremely serious and important matters.

The Scottish Government and its ministers have set themselves above the law, this they are not entitles to do. They make compliance with the law optional for government and individuals. If allowed to stand it would bring great dangers and the principal sanctions other organisations and individuals disregarding laws that they didn't want to comply. That is a breakdown that

cannot be allowed to continue. The rule of law in principal would be undermined.

Against: None

5.2 Social

For: There is increasing concern at avoidable harm occurring in healthcare. In the UK and particularly following the Mid Staffordshire and other scandals it has been one of the scandals of the last five years. It is gradually being recognised that there are scandals in Scotland as well. The difference here is that the Scottish Government is part of the problem in that it has not recognised the scale of the problem, the failure to apply the law to prevent harm, and in how it organises health and social care. The inquiry is both about preventing large-scale preventable harm and dealing with the accountability of failures to act.

Against; None

5.3 Ethical

For: Preventing premature deaths and other harm, and the chance to optimise health outcomes considered highly ethical

Against None

5.4 Economic

For: Avoidable deaths and other harm involve unnecessary human and cash costs. In short-term calculations these will be high and ones which society would not want to pay. There are costs in terms of wasted activities, loss to patients, family and friends. There are costs of investigating errors and litigation costs. In Scotland NHS litigation costs run at about £35 million. Add in the public inquiries of Vale of Leven and Penrose and it runs at about £40 million a year that could be saved by 'solving' patient safety.

The objective measure of costs over time is neither straightforward nor without questioning value of extra years saved and the need for more complex care.

Against: Complex care required at later stages of elderly deaths. But ethically currently considered preferable to premature deaths.

5.5 Technical

There are the legal and technical means to solve patient safety, with the avoidable deaths, harm and wasted costs that currently occur. The Act and supporting legislation provide a comprehensive, systematic, proportionate,

reasonable and legally enforceable means. They address the overall structure for delivering safety and its regulation. They cover the management systems required, the corporate and organisational culture, and specific risks. The Act has been highly successful where it has been applied. In other high hazard sectors it has 'solved' the matters. These are nuclear, railways, chemicals, off-shore and gas distribution. .

Health and social care are the only land-based sectors (other than road transport) where the Act is not applied. These have substantial inadequately controlled risks. There is no need to consider safety from aviation as is sometimes suggested as the methods and law are already applicable to theses sectors. The other high hazard sectors have had between 20 and 30 plus years of systematic development and application of controls to reduce the risk so far as is reasonable practicable.

Because risk is about both 'good' outcomes and 'bad' outcomes, the methods of systematic risk management in these factors can be used to both prevent harm but also optimise health outcomes. This would result in a total risk management approach to health and social care that would make the best possible use of resources. That means not only would there be a stepwise reduction in avoidable harm but that there should be a similar stepwise improvement in the positive outcomes. It is the opportunity to establish a complete scientific approach to healthcare.

Against None. It will take time to adapt existing risk management methods to health care.

5.6 Political

For; The over-riding requirement is that the British Constitution is complied with. In a country with an un-codified constitution this is the collected legislation, associated rules and the necessary checks and balances to ensure a reasonable degree of the separation of powers (Executive, legislature and judiciary) to prevent what is termed and an elected or elective dictatorship.

It is an extremely important test of the constitution where GB, UK and EU legislation is disregarded and so far the judiciary has no action is against has been taken against the Scottish Government. Particular where the disregard results in thousands of avoidable deaths. There is the absence of the separation of powers, the Lord Advocate as a minister and no appropriate check on the COPFS, or other checks and balances that function elsewhere in the UK. The politics are of the situation are the absence of law and the move towards the elective dictatorship if action is not taken.

The ministers have not upheld the law, they have obstructed it such as by abolishing regulation, and there are potential indictable offences. These are relevant to the question of impeachment. Impeachment is still available. It had been considered to be redundant in the 1990s whereby government

ministers were answerable to Westminster. However with devolution, Scottish ministers appear not to be answerable to the UK except if there are prosecutions and/or impeachment.

Against: The above issues require addressing. It would create difficulties for the SNP government. Beyond that the calculations of the political impact are difficult to assess. However clearly the matter of thousands of avoidable deaths and the compliance with the rule of law are far and away more important than narrow short-term political interests. .

5.7 Comparisons

In measuring the case for an inquiry it is also worthwhile looking at matters which have resulted in public inquiries. There are the inquiries for Scotland and for other UK inquiries:

Scottish inquiries: Clackmannanshire Bridge, Dunblane school massacre, Edinburgh Tram Inquiry, Fingerprint Inquiry, Harris Super Quarry, Patrick Meehan, Napier Commission, Piper Alpha, Proposals for new tram lines in Edinburgh, Scottish Parliament Building, Stockline Plastics factory explosion, Castle Tioram, Penrose contaminated blood, Vale of Leven Hospital infections.

Other UK: Lynskey Tribunal, Aberfan, Ladbroke Grove, May Inquiry, Saville Inquiry, Widgery Tribunal, Lane Inquiry, Bristol Hospital Inquiry, Laming Inquiry, South Wales Ecoli outbreak, Hutton Inquiry, Dr Shipman Inquiry, Robert Hamill Inquiry, Ladbroke Grove and Southall Inquiry, Iraq Inquiry, Leveson Inquiry, Al- Sweady Inquiry, Mid Staffordshire Hospital Inquiries.

The inquires into parts of healthcare whilst very important in their own right, are very small aspects of the issues of the current case. The Piper Alpha inquiry was also on safety in another sector but even here it's large number of avoidable deaths are repeated every month in Scottish health and social care.

With its scale of historic and current harm, the future prevention of large-scale and continuing harm and costs, the opportunity to both prevent harm and optimise health outcomes, the failures of government and of regulation, and the failure of the law and constitution to protect its citizens, an inquiry into 'Patient Safety in Scotland' ranks very high, perhaps the highest of importance for public concern.

6. Conclusions

1. The case for an inquiry into patient safety is Scotland is overwhelming. The only argument against one could be on the political implications for the SNP and its government. Relative to the large number of avoidable deaths both in the recent past and the continuance, other harm, costs, the principal of disregard of the law and the constitution, such considerations are small and

cannot result in an inquiry being blocked by the UK government on a reserved matter.

2. The consequences of failing to address the issues in the case for an inquiry are extremely severe.
2.1 Sanctions large-scale avoidable deaths, harm and costs in Scotland
2.2 Removes the protection of patients in Scotland that they are entitled to by law
2.3 Sanctions law-breaking by the Scottish Government and its ministers.
2.4 Sanctions health and social care providers and other dutyholders breaking the law
2.4 Sets the precedent for organisations and individuals in Scotland disregarding the law.
2.5 Sanctions the breakdown of the constitution. This is in respect of the disregard of law, allied principles, the separation of powers (executive, legislature, and judiciary), and the further removal of formal and informal checks and balances on the abuses of elected power.
2.6 Usurps and acts counter to the law and principles on public safety in Scotland, UK, EU and Europe.

These consequences are ones which cannot be tolerated.

7. Actions

The actions required to address the avoidable deaths occurring on a daily basis in Scotland cannot wait for an inquiry. Accordingly an adjunct to the inquiry would be for the Scottish Government to take immediate action to comply with the law. Such matters are non-contentious, and these will include:

1. Explicit statement recognition that HSWA applies to all health and social care in Scotland
2. Adopt it as SG policy and integrate into its functions
3. Explicit statement requiring all health and social care providers and allied dutyholders to comply with HSWA.
4. Initiate plans for SG to comply to the required standard, its Health and Social Care Directorate and NHS Scotland
5. Create the fully independent regulator of healthcare.

SG, as all organisations, are required to have competent person advice to advise them on how to comply with HSWA and related legislation. As an interim measure such a body could be formed to advise it on how statutory responsibilities can be ensured, and this body could form the fully independent regulator.