CASE FOR A PUBLIC INQUIRY
PATIENT SAFETY IN SCOTLAND
2015

Executive Summary

Roger M Livermore

1. Summary

Scotland has failed to apply GB-wide legislation that would secure the safety of patients and of those in social care. The consequences of this are a large number of avoidable deaths, other harm, and wastage of resources.

2. Introduction

The safety of patients in all the UK is covered by health and safety legislation, for GB this is the Health and Safety at Work etc Act 1974 (HSWA). If implemented as required it would secure the safety of patients and of those in social care so far as is reasonably practicable. The Scottish Government (SG) has failed to recognise the application of this Act, it has not set it as intent for these sectors, nor does it have the required effective plan on compliance. The sectors do not comply with the law and SG abolished the independent healthcare regulator and refuses to recreate it. The scale of harm as a result of Scotland's failings is likely to be about 5 deaths a day. The information in the reports and associated documentation are the picture presented. The situation requires confirming with an inquiry and any necessary criminal law investigations.

Whilst healthcare is devolved patient safety is not. The relevant legislation is all reserved. For the purposes of the Public Inquiries Act 2005 the issues are not "Scottish matters". It is a UK government decision.

Scottish ministers have disregarded binding legislation. This has placed themselves in jeopardy of action under HSWA and in breach of the Scotland Act 1998. They have placed the SG in breach of the Human Rights Act 1998 in respect of its duty to protect the life of those in its care. From the many avoidable deaths, cases could be made against the SG under the Corporate Manslaughter and Corporate Homicide Act 2007. The justice system in Scotland has failed to recognise the issues on patient safety; it has refused to correctly advise the Scottish Government and it has refused to investigate the statutory responsibilities of the government, its ministers and senior officers.

Implementation of statutory remedies is urgently required. However it requires a public inquiry under the Public Inquiries Act 2005 to cover the range of extremely serious defects and implications. This is on the Scottish Government, the justice system and healthcare providers. Such an inquiry would be more significant than any others held in Scotland in terms of deaths that it relates to, prospective benefits and justice. To not hold an inquiry

would have very serious consequences for public safety, the reputation of the Scottish justice system, and the lack of accountability of Scottish ministers.

3. Background

Patient safety has been covered by the Health and Safety at Work etc Act 1974 for the last forty years. It sets the overall intent, requirements, structure and culture for securing the health and safety of employees and of those affected by work activities. It gives both organisational and personal responsibilities which include senior officers within an organisation and this includes government ministers. It includes the requirement for effective regulation of compliance. The Management of Health and Safety at Work Regulations 1999 (MHSWR) give the statutory requirements on the management system including the 'management control loop' of effective planning, organising, control, monitoring, review'. There are regulations that deal with specific risks. Highly relevant to healthcare are the Control of Substances Hazardous to Health Regulations (1989) and now 2014 (COSHH). These cover microbiological agents, and apply to controlling the risks from Hospital Acquired/ Associated Infections (HAI). HAI are associated with a large number of avoidable deaths in healthcare. Scotland does not reference the legal requirements, it does not comply, and it does not regulate.

The UK has been slow to recognise how HSWA applies to healthcare and social care. The Act and associated legislation provide a systematic, comprehensive, proportionate, reasonable, and legally enforceable means to secure the safety of patients and of those in social care. The point was emphasised with the public inquiries into Mid Staffordshire NHS Foundation Trust and the resultant Francis Reports. The Trust was prosecuted under HSWA on patient care. Francis might be summarised as finding poor conditions, poor management and poor regulation.

In Scotland the situation is different. There are still poor conditions being found, but the NHS boards, the Health and Social Care Directorate, NHS Scotland and SG are all one governance, and there is no independent healthcare regulator. The Scottish Government abolished what regulator there was with the Public Services Reform Act 2010. There is not the intent or drivers to ensure that Scotland complies with the law on patient safety.

The **attached** core document 'Patient Safety in Scotland' assembles some of the evidence to support the call for a public inquiry into the matter. Evidence of the large scale of the harm that results from non-compliance with the law is given in its Appendix 3. There are also recent examples with the Vale of Leven Hospital Public Inquiry into 30-50 deaths associated with poor infection control. There is NHS Lanarkshire hospitals where the NHS Scotland's internal quality assurance and scrutiny body found similar failings to the Mid Staffordshire prosecution, and worse, but there was no involvement of a regulator. On the safety of mental health patients there is the 'never event' of the death of Nicola Black at Ayrshire and Arran NHS Board and the belated conviction of the board. But still the problems persist.

The report goes through the main bodies involved in healthcare. though It does exclude professional healthcare bodies for the present as it concentrates on principal duty holders and the regulation of HSWA. It looks at roles and how, with one exception, they all fundamentally fail to account for HSWA.

4. Vale of Leven Hospital Public Inquiry (VOLH) This inquiry reported in November 2014 on 30-50 deaths associated with infection control. The inquiry briefing by the Cabinet Secretary for Health and Well-Being and Deputy First Minister, and the Scottish Ministers written advice to it disregarded HSWA, MHSWR and COSHH, the binding legislation. The inquiry was misled. The inquiry failed in its terms of reference, it failed to identify the problems or the legally required solutions. Serious HAI problems occur every month in Scottish hospitals, and avoidable deaths. There has been no regulation. Compliance with the above should have addressed the outbreak and subsequent failings in infection control.

5. NHS Lanarkshire Hospitals NHS Scotland's in-house quality assurance and scrutiny body Healthcare Improvement Scotland (HIS) undertook a 'Rapid Review' into possible excess mortality rates at three hospitals. It did not inspect on the range of factors that could affect patient mortality. It did though find evidence of similar problems to those involved in the HSWA/HSE prosecution of Mid Staffordshire NHS Foundation Trust related to its public inquiries. HIS found even worse than the prosecution but it did not report the matters to the default regulator, HSE. The Scottish Government had abolished the independent healthcare regulator. There was no involvement of a regulator. Reporting on the Rapid Review, the CS for Health misled parliament by calling HIS an independent regulator. It is not.

6. NHS Ayrshire and Arran Board The board was prosecuted by HSE under HSWA in connection with the death of Nicola Black on a mental health ward. It took two years to notify HSE of the death. The failings found were a gross a breach of the duty of care and of HSWA. The SG and ministers , Health and Social Care Directorate NHS Scotland have not got an intent or effective plan on HSWA compliance. There is no regulator carrying out preventive inspections to HSWA as used to happen by HSE before the creation of independent healthcare bodies. Scottish ministers broke HSWA by abolishing the regulator. Ministers set the policy for health and this has been to disregard HSWA, they carry and breach HSWA responsibilities. The Crown Office and Procurator Fiscal Service has refused to investigate wider HSWA requirements on SG, ministers and other senior officers.

7. Scottish Healthcare Organisations

7.1 Scottish Ministers and Scottish Government Have failed to recognise the application of HSWA, to implement it, comply with it or regulate.
7.2 Health and Social Care Directorate (HSDC) Failed to set the policy for health and social care on HSWA, or work to its standards. Not implemented relevant parts of the Francis Report.
7.3 NHS Scotland and NHS Boards HSWA not embedded as a requirement, not complied with it, and large-scale avoidable harm results.

7.4 NHS Scotland's Healthcare Improvement Scotland (HIS) HIS not work to HSWA standards for the NHS or as regulator of the independent healthcare sector. Does not inform HSE of serious HSWA breaches.

7.5 NHS Scotland's Healthcare Environment Inspectorate (HEI) HEI not work to HSWA, MHSWR and COSHH standards for the NHS or as regulator of the independent healthcare sector. Does not inform HSE of serious breaches, or incidents even when involving multiple deaths.

7.6 Healthcare Protection Scotland (HPS) Does not work to HSWA and COSHH standards.

7.7 Scottish Public Services Ombudsman (SPSO) Most of work is on healthcare matters and most investigations show HSWA breaches. Does not use law as test, does not notify HSE of serious breaches.

7.8 Social Care and Social Work Improvement Scotland –Care Inspectorate (CI) Does not work to HSWA standards

7.9 Scottish Human Rights Commission (SHRC) Recognises HSWA as a practical means of delivering Human Rights Act 1998 responsibilities on government duty to protect life.

7.10 Mental Welfare Commission for Scotland (MWCS) Does not work to HSWA standards.

7.11 Scottish Government Legal Directorate Unaware of HSWA**,** where it applies and what it means. Disregard of law means that SG and inquiries incorrectly advised. Misled Vale of Leven Inquiry, perhaps Penrose Inquiry

7.12 Scottish Civil Service and Scottish Government Policy Units Systematic failings to address serious issues, promulgates illegal policies, consistently breaching Civil Service Code on core values, often as directed by ministers. Policy Units not addressing HSWA or Francis Report on patient safety and its governance.

8. Crown Office and Procurator Fiscal Service (COPFS) Failure to recognise how HSWA applies and that it not been implemented in Scottish health and social care. Senior law officer and adviser to SG regarded it as a matter for Scottish ministers and the 'Health Directorate' and that it was not their role to advise them. Refused to investigate role of Scottish Government, ministers and senior officers in having a policy which disregarded binding legislation. This policy permits large scale avoidable harm and reasonably preventable deaths. Incompatible with role of preventing crime.

9. Scottish Government Ministerial Responsibilities With the systematic failures to recognise and implement HSWA to the standards required for healthcare there have been major failures on HSWA compliance permitting a large number of reasonably preventable premature deaths (RPPD). The failures are associated with individual responsibilities under HSWA. They create breaches of the Human Rights Act 1998 for the SG. Individual ministers are involved in breaches of the Scotland Act 1998. Justice has been obstructed, ministers have exceeded their powers, and there are potential cases on indictable offences. They also involve multiple breaches of the Ministerial Code. The matters involve two Scottish First Ministers, five current ministers and a former minister.

10. Health and Safety Executive With SG abolishing the, albeit limited, Scottish Independent Healthcare Regulator this left HSE as the only body for HSWA. SG says it did not consult HSE on this. HSE is unable to take on this role. This leaves Scotland with no body regulating patient safety. Healthcare has the highest hazards and the highest risks of any sector in the UK but in Scotland it has the lowest form of regulation, - none. Scotland is in a highly illegal situation.

11. Legal Position in Scotland The acts and omissions of Scottish ministers and the Scottish Government has resulted in numerous failures to comply with the Health and Safety at Work etc Act 1974 as it applies to individuals and organisations. They have resulted in breaches of the Human Rights Act 1998, and the European Convention on Human Rights. Ministers have acted outside their powers and that has resulted in breaches of the Scotland Act 1998. The acts and omissions have opened up the potential of many cases against the Scottish Government under the Corporate Manslaughter and Corporate Homicide Act 2007.

12. Conclusions

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

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

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

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

13. Solutions

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

13.1 Recognition of Health and Safety at Work etc Act 1974 Policy.

13.2 Plan on Compliance in Healthcare Deliver HSWA to the high standards to match the high hazards and risks. Urgent

13.3 Creation of Independent Health Regulator (IHR) Urgent

13.4 Care Inspectorate Align with HSWA

13.5 Human Rights Act 1998 Review compliance on healthcare

13.6 The Scotland Act 1998 Comply

13.8 Scottish Ministers and HSWA HSE and COPFS investigate

13.9 Scottish Ministers, HRA, ECHR and The Scotland Act 1998. Independent investigation, public inquiry.

13.10 Scottish Government and Corporate Manslaughter and Corporate Homicide Act 2007. COPFS to investigate sample cases. Given politics independent input required.

13.11 Impeachment Consideration of the position of current and former Scottish ministers still in official office. Assert that impeachment has a role and importance with devolved governments. This includes when minsters act outside their powers, and obstruct UK/GB law.

13.12 Scottish Ministerial Code Apply to current ministers. Review operation of the Code and strengthen.

13.13 Civil Service Code Refresher training current staff. Carry out independent review on how the patient safety subject has been handled.

13.14 Scottish Legal System Align with requirements of HSWA, training issue on awareness and responsibilities.

13.15 Performance Give IHR role of independently assessing the performance of healthcare in Scotland**.**

13.16 Francis Report With the creation of the IHR, create a plan to implement Francis recommendations. Adapt to the Scottish situation and address governance issues.