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JUSTICE SELECT COMMITTEE

Inquiry into the role and purpose of COPFS (September 2016)

1. Introduction

1.1 ASAP-NHS is concerned at the Scottish government's refusal and failure to implement binding UK-wide legislation that would secure patient safety. The consequences of the failure to comply with the law will, by Department of Health estimates, result in about 2,000 reasonably preventable premature deaths a year in Scottish healthcare and associated social care.

1.2 The justice system and COPFS are not addressing these failures. The law has not been upheld, and it is not being complied with. Healthcare and patient safety is not regulated in Scotland to ensure compliance with the law, and to prevent avoidable deaths and other harm. Serious offences are not being prosecuted, the offences continue, and so do the deaths. The required lessons are not learnt, offenders are not being brought to justice, and there is no deterrent.

1.3 The points made in this report would need verifying but they will be found to be correct. For the main points there is prosecution-grade evidence available.

2. Core Role

2.1 **COPFS Status**: The briefing for the inquiry states that 'COPFS is Scotland's independent prosecution service'. This is not correct. It is ' the Scottish government's prosecution service'. Prosecutions are taken in the name of the Lord Advocate a government minister, and so too is the Solicitor General. The COPFS website does not say that it is independent, it is 'Scotland's prosecution service'. COPFS is headed by two government ministers.

In the particular case of the acts and omissions of Scottish ministers in respect of their legal responsibilities this lack of independence of COPFS is crucial. Ministers and the government are responsible for policy, organisation, and resourcing on devolved matters. Inter alia, section 48 of the Health and Safety at Work etc Act 1974 (HSWA) makes it clear

that the law applies to ministers and senior officers as well as all employees. This is emphasised with the Corporate Manslaughter and Corporate Homicide Act 2007 in schedule 1 applying the Act expressly to the Scottish government ('executive').

The refusals to implement UK law on patient safety are acts of intent not just negligence. Most offences under HSWA and related legislation are for criminal negligence, that is as strict liability law. This has been the case for over 200 years of safety law. It is highly unusual for breaches of HSWA to be deliberate, to deliberately not fulfil responsibilities on acts and omissions, to be of criminal intent.

The committee may be familiar with the '40 suspicious deaths' at Ayrshire and Arran NHS Board (A&A). This has been covered by the BBC, the Sunday Times, and aspects by local and other national media. The local MP has expressed the wish that there is a public inquiry into patient safety at the NHS Board. The situation is on-going. The Scottish Information Commissioner made the board produce their critical incident reports. These involved many patient deaths. The board itself demonstrated in its reports and action plans that many of the deaths could have been avoided. These incidents were covered by HSWA and met the criteria for consideration of prosecution under the UK-wide statutory enforcement code. Whilst there are the HSWA responsibilities on the NHS Board and its officers they could legitimately state that they were following the policy of Scottish ministers to disregard HSWA law. On 13 March 2015 the critical incident reports were handed in to the then Lord Advocate. The covering letter asked him to investigate the incidents and the role of the ministers. He refused to investigate his ministerial colleagues. He said that the reports required 'no action'. What he apparently did not know was that one of the deaths was in the process of coming to court, and later in the year resulted in a conviction of the board. Another had resulted in a conviction the previous year. The reports were anonymised and so it was a blind test of the effectiveness of COPFS and the Lord Advocate. They failed. What he also did not know was that separately and independently Strathclyde Police had been asked to investigate the reports. This is serious criminal law, the police said that they had carried out an investigation. We subsequently obtained the evidence that their investigation failed every test of a criminal law investigation.

Police Scotland reopened the investigation in August 2016. However, Police Scotland have now refused to investigate the deaths, consequently there has still not been an investigation into these many avoidable deaths as covered by criminal law. The inability of the police to investigate according to standard procedures should be unbelievable. It appears to be a very serious case of misconduct in public office (see section 3.1.7). Remarkably the Chief Constable had not been told of the decision to not investigate these many deaths. The failures at A&A have now been referred to the Police Investigations and Review Commissioner (PIRC) and we will see if they can get the police to do their duty. The avoidable deaths at Ayrshire & Arran NHS and many other failures on patient safety are covered in the current case for the public inquiry 'Patient Safety in Scotland' (see https://asapnhs.org.uk/).

The failures of government on patient safety relate to the most serious offences in the 42-year history of modern health and safety legislation. It should not be in the gift of a government minister to block the investigation and potential prosecution of other ministers, and their own government. This is one of the starkest examples of conflict of interest. It

shows the major problem of the absence of the constitutional separation of powers. There has not been anything between the executive, the judiciary, and the legislature in Scotland. This is a gross constitutional error. This type of error was defined by the Greeks 2500 years ago and we are still getting it wrong. Here its importance is really brought home where it relates to many deaths past, current and future. Decisions on prosecutions must be separated from ministers and the executive (government).

2.2 **Public Interest**: 'Conventional ' homicides, are at about 40-50 a year in Scotland. The public safety deaths associated with work activities run at over 40 times that number and these can also be homicides attributable to criminal negligence. These deaths include the Glasgow bin lorry disaster, the M9 crash involving the death of Lamara Bell and the police control room, Sheku Bayoh in police custody, prison and other custody deaths, the Tayside mental health suicides, social care incidents, as well as the many avoidable deaths in healthcare. The latter usually occur in ones, often unseen, and unreported, COPFS will probably not be told of them in the great majority of cases. Procurator Fiscals have been aware of this problem of them not being informed of the deaths that should be notified. The problem of avoidable harm in healthcare is so widespread that all of us will be affected in some way - we will all know someone, friends, or family who have been affected. These many deaths are reasonably preventable and they are covered by the law. It should be at the highest level of public interest to get the law on public safety complied with in Scotland, it could affect any of us. It should be a high priority for the justice system. Currently we are not being protected to the mandatory UK-wide legal standards.

2.3 **Offenders and Justice**: Most of the avoidable deaths go unreported, un-investigated, and without justice. The Scottish government has given carte blanche to disregard the law on patient safety. We at ASAP-NHS have repeatedly reminded ministers of the law; of the twenty essential statutory requirements that must be in place to secure patient safety we have none of them.

3. Five Questions

3.1 COPFS Effectiveness

3.1.1 **Approach:** If we were to do a systematic analysis of COPFS we would use the structure of Objectives-delivered by Strategy, Structure, Systems with the Resources and Competences. This overarching approach (3S Model) was used by the UK regulator of rail safety, performance and economy when working with the UK rail sector to 'solve safety'. The sector showed it was capable of solving safety. The sector joined nuclear, major hazards (e.g. gas supply), petrochemicals, and off-shore in applying the legal and systematic requirements of HSWA to control the risks protecting both workers and the public. The Act has not yet been applied to patient safety in Scotland, nor have the serious failures to comply with the law been prosecuted.

3.1.2 **Scottish Work-Related Deaths Protocol (WRDP):** The work of COPFS deals with deaths related to work activities, be they workers or the public in relation to work activities. The protocol requires the multi-agency working of COPFS, the police and HSE (other regulatory bodies can be involved). The process is governed by the 'Scottish work-related deaths protocol'- e.g. http://www.hse.gov.uk/scotland/workreldeaths.pdf

This protocol is not being followed. The police and COPFS have routinely failed both in the many deaths in healthcare but most visibly in the high-profile cases of the Glasgow bin lorry disaster, the M9 crash and death of Lamara Bell involving the failure of the police control room, and the death of Sheku Bayoh in police custody. The police seem not to know about the protocol, perhaps thinking that 'work-related' only means workers. COPFS also fail to follow WRDP. A glaring example was the Lord Advocate stating in February 2015 that he would not be prosecuting Glasgow City Council over the bin lorry crash for health and safety offences. This statement was made when there had been no HSWA investigation. HSE had not investigated the disaster, they had neither investigated the council or the driver and their respective responsibilities under the Act. HSE said at the Fatal Accident Inquiry (FAI) that they only knew about the COPFS and Lord Advocate decision not to prosecute the council in May 2015. As the regulatory body responsible for investigating HSWA offences they had to be involved. COPFS had not followed the WDRP and this was in a high-profile case. COPFS are not warranted officers and do not have the legal status or practical competence to have made such a decision as 'no prosecution'. They made the decision on the basis of no competent investigation. The bin lorry driver had not been interviewed under HSWA (the BBC research said that he had also not been interviewed by the police), there was no HSWA statement. The position is odd all round as the Lord Advocate's decision was on the main news and all over the Scottish and UK media. HSE should have challenged the Lord Advocate and COPFS for their disregard of agreed protocol and due legal process. It is probable that the senior law officers and COPFS have obstructed justice on the bin lorry deaths. The statements and commentary of the Lord Advocate during the process also seems to have breached his own 'Prosecutors Code'.

There is a lack of knowledge of HSWA within COPFS. It was also shown with the former Lord Advocate and the Solicitor General. For example, they completely omitted the HSWA responsibilities of the driver of the bin lorry. At the time of the FAI there had been no HSWA investigation of his s7 responsibilities, we were informed that he had not even been interviewed. At the FAI the Solicitor General said that if the driver had taken reasonable precautions then the incident and deaths would not have occurred. Inadvertently she had said that the driver was guilty of the HSWA offence. But she made no reference to HSWA. The Lord Advocate and COPFS said that the driver would not be prosecuted for the incident of the crash. They did not realise that HSWA offences do not relate to the need for an incident or any harm. The offences are for not taking effective precautions to prevent any incident, at any time. Particular incidents and harm can be, and often are, used to demonstrate the failures and the consequences of failures of precautions. The bin lorry driver can still be prosecuted; no amnesty has been given to him on HSWA offences.

It should be of concern that COPFS and its most senior offices can make such basic errors and in a high profile case. What happens in cases without such media coverage? The Glasgow bin lorry and the '40 suspicious deaths at Ayrshire & Arran can be used as case studies to show most of the potential failures of a justice system. We informed the senior law officers and COPFS (and informed the Sheriff at the FAI) of the major failings in the legal process. The failings of COPFS were not addressed, and they had no answer. It does not need the families to take a private prosecution on the Glasgow bin lorry as they are currently, it needs the COPFS and its senior law officers to do their job. They still can.

There were the discussions amongst ministers over the legal proceedings. The decision to not prosecute was taken very quickly and this enabled the FAI to proceed. This action also resulted in the obstruction of due legal process and justice. Ministers should not be involved in prosecutions; it constitutes political interference with justice. That is how 'banana republics' carry on. We lost count of the major failings and myriad other issues over the bin lorry case which sadly has heaped gross failings of the legal process as an added stress and insult to the bereaved families. They should not have to go through all of this because COPFS did not do its job. Professionally it was very embarrassing to see the supposed cream of the Scottish justice system at work.

3.1.3 **WRDP Agreement:** The 'Scottish work-related deaths protocol' is rarely followed by the police and COPFS. It was not followed in the M9 crash involving Lamara Bell and the police control room, and the death of Sheku Bayoh in police custody. These two have the added complication and conflict of interests of Police Scotland being the main suspect in HSWA prosecution cases. WRDP was not followed in the Tayside mental health suicides, or in the death covered in the Mental Welfare Commission Scotland report 'Death of Ms MN' (31 January 2016). It is not followed in practically any of the large number of healthcare deaths covered by the protocol. In two cases that eventually resulted in convictions it took 2 years to implement the protocol and bring in HSE, and then another 2-3 years to get to court (Nicola Black, Gary Niven), two avoidable deaths from two incidents on the same day at the same hospital. COPFS prosecuted on the front-line failures but failed to investigate or prosecute on the systems failure offences behind them and many other deaths covered by HSWA. The systems failures were not addressed and consequently the deaths continued at this NHS Board. On the many other deaths at this board it took many years before there was any consideration of them by the police and COPFS, and that was just as a paper exercise without any investigation of the actual incidents and deaths. That is not a way to treat people's lives, a paper exercise. The protocol clearly applied to the deaths at Ayrshire and Arran NHS but it was not followed. This is a massive and critical failure of COPFS.

Without the police, COPFS and HSE all following the agreed protocol there is no risk of their being a competent investigation into the many other avoidable deaths covered by HSWA s3(1), the lessons are not learnt to prevent recurrence of the like or systematic failures, or there being justice. Offenders are not being brought to account.

3.1.4 **Legal Competence**: COPFS has serious failures with its lack of awareness of the principles of HSWA, the lack of ability to handle the more complex details of what constitutes non-compliance with HSWA, and the offences. They all require a high degree of experience and competence to make decisions on prosecutions. COPFS does not have this, and neither does its health and safety unit. The unit only takes the most straightforward cases. The former Lord Advocate and the COPFS showed an unfortunate lack of understanding, such as basing their decisions on them requiring the higher standard of proving *criminal intent* when since the year 1800 safety offences have required the lower standard of *criminal negligence*. When we asked the previous Lord Advocate to advise the Scottish government over its failure to implement the law on patient safety he said that it was not his job. It was, it is in the job description as the principal legal advisor to the government. When asked to act on patient safety he said he needed to see the deaths rather than what the law required - the failure to have effective systems and precautions in place. That is such a basic failure

of understanding of the law, which he then showed again in the Glasgow bin lorry disaster.

Scotland and its COPFS has traditionally taken a disproportionately low number of HSWA cases despite Scotland having a poorer safety record than the rest of the UK. It often has a fatal accident rate about twice that of England. Such that as worker in Scotland you are twice as likely to die than a worker down south. This cannot now be explained away in the statistics of Scotland and England having a different sector mix. The poor safety standards seen here could be partly explained by failures of regulation and prosecution in Scotland. Notably it seems that the Lord Advocate and the COPFS took no cases under the Corporate Manslaughter and Corporate Homicide Act 2007 (CMCHA). Again pro rate there should have been some. The Act has an important role to play in addressing corporate failings on safety, and that does include the responsibilities of the Scottish government. But once again Scotland has not applied the law. It seems to be a serial problem of law existing and being applicable but of it not being complied with, enforced, or prosecuted here.

With that lack of understanding at the top it follows that COPFS will get it wrong too. It needs legal competence in the current law of HSWA. In the UK, HSWA offences increasingly result in custodial sentences, there is now a significant proportion of all cases that attract such a penalty. The offences and cases must be taken seriously. It should be a concern that Scottish ministers have chosen to disregard this law as it applies to patient safety. In the rest of the UK the decisions on prosecutions and the preparation of cases is by HM Inspectors. These important cases must have a professional approach, and that is absent here at present. The COPFS Health and Safety Unit/ Division does not have the expertise or resources for such a high number of serious and complex technical cases. The best use of resources must be made. That would mean that HSE acting competently and using its range of legislation correctly makes the decisions on evidence and prosecutions. HSE to prepare the cases and COPFS does the actual court work. Any approach should also address the major problem of there being widely different standards of HSWA prosecutions in Scotland relative to the rest of the UK. Public and worker safety covered by HSWA, and CMCHA is reserved legislation and there must be the consistent application of UK-wide law and enforcement. The enforcement standards are UK-wide and statutory; they are not being followed by COPFS in Scotland.

3.1.5 **COPFS Decisions:** The lack of understanding by COPFS on HSWA and public safety, on investigations enforcement and prosecution standards is shown in a large number of cases. These are behind a lot of the puzzling and incorrect decisions of COPFS. The legal profession is often at a loss to understand what COPFS are doing. These include the Glasgow bin lorry disaster, the Edinburgh school buildings failure and death of a pupil, the 40 suspicious deaths at Ayrshire and Arran, the current lack of action on the mental health suicides such as in Tayside and the death of 'Ms MN'.

3.1.6 **FAI:** Whether to have an FAI seems to be partly determined by cost and politics. That does not fit with justice. It may be worthwhile to look to applying the system of Coroner's Inquests which are automatic and not governed by politics. The COPFS Fiscal review of sudden deaths is no substitute for a Coroner. It seems that the rush to get to the FAI in the Glasgow bin lorry deaths obstructed justice and the pursuit of any offenders. Whatever the merits or otherwise of FAIs the current system seems to cut across prosecutions and obstruct due legal process.

3.1.7 **'40 Suspicious Deaths' at Ayrshire & Arran NHS Board:** This like the bin lorry is another case study in how not to investigate public safety deaths. The whole process is a catalogue of errors. Given the number of deaths involved it would warrant an inquiry in its own right. The initial Strathclyde Police investigation failed to meet any of the requirements and tests of a criminal law investigation, as well as rules of evidence. Failing all the tests should be a matter of great concern. The details are covered elsewhere and in a Police Scotland statement. As an example, when does a potential homicide investigation and decision whether to prosecute be made solely on the basis of the written word of the main suspect? It is a novel approach which hopefully will not catch on. It is absurd. So when a dead body is found and someone is standing next to it, the policeman asks 'Did you do it?' The main suspect who is holding a weapon says 'Here is a report saying that I did it'. The policeman says 'It's OK then. Keep doing what you're doing'. This is serious, the 'investigation' into the 40 or more suspicious deaths is at that level of competence.

Strathclyde Police could not have done any appropriate check on the competence of the 'investigation'. The gross error was then repeated by the Lord Advocate and COPFS. They could have made no checks on the competence of the police inquiries. There cannot be an effective system within COPFS of verifying the quality of investigations and the evidence for the decision-making process. This is on a number of deaths the equivalent to their annual number of other homicides. The significance of the reports could not have registered with the police or COPFS or the Lord Advocate. There were failures both on the specific handling of the reports and on the lack of a COPFS system for handling them.

If none of the police, the Lord Advocate and COPFS can get it right on 40 deaths what confidence can there be for other deaths? Or prosecutions generally? How good is the COPFS system for securing quality evidence and the decision-making on prosecutions? Is the COPFS decision-making process codified or is it down to individual choice? These deaths at Ayrshire and Arran got extensive TV, radio and press coverage. But like the bin lorry's catalogue of errors, it seems that even with the 40 deaths being such high- profile, the senior law officers and the COPFS could not get it right if they wanted to. Otherwise they would have.

Police Scotland reopened enquiries into the deaths (August 2016). They were given a statement on the complete failings of the Strathclyde Police investigation. We now have the response by a Detective Chief Inspector dated 3 October on behalf of the Chief Constable of Police Scotland. The situation has now got very much worse. Police Scotland have now also shown that they are incapable of investigating patient safety deaths and criminal law. They still have no independent evidence or investigation into the 40 deaths. The deaths have still not been investigated. The DCI's response showed an astonishing lack of understanding of how to carry out a criminal law investigation. This has worrying implication for their ability to carry out the most basic of their tasks. The complete failure of Police Scotland to investigate 40 plus suspicious/ avoidable deaths is then compounded by COPFS not having a system to check the quality of the evidence presented to them. Without an effective system to ensure the quality of evidence the decisions by COPFS cannot be assured to be correct. Everything that follows from a non-existent investigation inevitably is of no value in a system of justice. The justice system falls apart.

The notifiable deaths in the reports were rarely reported to the COPFS Procurator Fiscal despite the reporting being mandatory. We have recently found out that the COPFS instruction on notifiable deaths is still not being followed at Ayrshire and Arran NHS Board. We have found that this situation is being repeated across NHS Scotland Boards. This needs further investigation. **The failure of NHS boards to report mandatory notifiable deaths to COPFS appears to be a major scandal in its own right.**

Police Scotland have based their decision not to reopen the investigation into the many incidents at A&A on the basis of no independent evidence. The NHS Scotland internal critical incident reports at A&A show a great number of failures affecting patient safety and avoidable deaths. They show the cause for major concern. The reports should be the starting point for an investigation. They are not the end. It should be a surprise that Police Scotland have just repeated the errors of Strathclyde Police. If the police cannot get it right when given a second chance and under the spotlight of a high-profile case, then it gives no confidence that Police Scotland can get it right on other investigations.

The DCI in his response unusually made reliance on the NHS Board's auditors PricewaterhouseCoopers (PwC). PwC do not do criminal law investigations into patient safety, they are not experts in patient safety and the law. They have not investigated the incidents in the reports. PwC only do a small amount on patient safety and even then it is based on a US system that fails to meet UK standards or UK law. They are neither competent nor independent. The DCI's reference to PwC is immaterial.

The DCI also makes reference to the Health and Safety Executive (HSE). But they did not visit the hospital and investigate the many deaths and breaches of the Health and Safety at Work etc Act 1974 (HSWA). All HSE did was on the initial Strathclyde inquiries and they looked at a report provided to them much later by COPFS which had no independent evidence, only some of the reports made by the main suspect on the incidents and potential offences. Neither Police Scotland or HSE have investigated the incidents or obtained any independent evidence, no-one has. To have 40 plus deaths and no investigation is about as big an indictment of Police Scotland and COPFS as it is possible to get. Not quite because failures to competently investigate happens across all Scottish healthcare.

Police Scotland then refer to NHS Scotland's Healthcare Improvement Scotland (HIS). HIS senior management are on the record as stating that as they and the NHS Boards are both NHS Scotland, HIS cannot be considered independent. Self-regulation is definitely not allowed in patient safety, and particularly not on criminal law. HIS are not a regulator of NHS Scotland and its Boards. The Chair of HIS is even on a recording saying that she finds the legal approach to patient safety as being 'interesting'. When asked if HIS would apply the legally required approach to ensuring patient's safety, she replied 'No'. HIS also would not back the call for the legally-required regulator of healthcare. HIS has not investigated the incidents at A&A, it is not independent, it does not believe in the rule of law or of regulation. When the HIS policy is to disregard the binding legal requirements, it should not be considered a fit and proper body to be involved in standards of patient safety in Scotland. The HSE have not investigated the many deaths at A&A, the other incidents reported, and the myriad breaches of HSWA. The Police Scotland reference to PwC and HIS is irrelevant. **There has still not been an independent criminal law investigation into the many deaths at Ayrshire and Arran NHS Board.**

The failure to investigate these deaths is a concern both in itself but also in what it says about Police Scotland procedures and COPFS lack of checks on the evidence that the police present to them. The justice system here provides its own evidence of its fundamental failings. At an individual level the failures to investigate the deaths could meet the criteria for prosecution under 'Misconduct in Public Office'. This is used a large number of times in the UK each year, it has been applied to the police failing to carry out their duty.

At A&A of the 20 essential statutory requirements that must be in place to ensure patient safety they have shown that it has none. By UK standards this requires the issue of statutory enforcement notices and prosecutions. It would also require the likely application of Corporate Manslaughter and Corporate Homicide Act 2007. The response of Police Scotland and COPFS of 'no action' could not be more wrong. **This is a prime example of COPFS not being effective.** Both COPFS and Police Scotland are allowing massive breaches of criminal law to continue, and with more avoidable deaths coming to light as a result of the failure to implement UK law on patient safety in Scotland. The situation has similarities with Hillsborough, but this is much worse, and the deaths continue. The police and COPFS are in effect giving the green-light to law-breaking on a very large scale and for the law on patient safety in Scotland to be disregarded. As well as A&A, the problems occur at all other Scottish hospitals, the law is being systematically broken. It seems to show a failure of a justice system on an unprecedented scale. ASAP-NHS support the local MP's stated wish for a public inquiry into Ayrshire and Arran NHS Board.

3.1.8 **Cases:** COPFS takes a minute number of cases in healthcare. The ones it takes are the very simple ones. These are the ones that do not require any medical knowledge or detailed understanding of HSWA law, or decided cases. This includes scaldings, falls, and suicides. COPFS does not seem to touch cases that would require competent medical opinion on what reasonable precautions should have been taken to prevent harm. That is determining what are the correct procedures and reasonable precautions. Even in the cases that do come to court they usually seem to happen where families have been extraordinarily persistent over a number of years. COPFS shows a decided reluctance to get involved let alone actually take cases, the involvement seems to be very variable depending on which Fiscal is involved. Enforcement on reserved legislation such as HSWA in the UK is required to be consistent and not down to individual preference. This should not be required, COPFS should be doing its job and not have families do much of the investigation of the issues for them. We now have another case, where a Procurator Fiscal is asking relatives to advise them on the required precautions in healthcare and the application of the law to protect patients. There is a very serious absence of competence on the law on patient safety.

Apart from competence, there is another major problem affecting the effectiveness of COPFS. This is the failure of the healthcare sector to ensure that the deaths that fall under the COPFS criteria are actually notified to them. Procurator Fiscals have long known that many identifiable deaths are not notified to them. From the instruction to the healthcare sector it is clear that the number of deaths which are not notified could be extremely large. There is not the legally required regulator of NHS Scotland that could be checking compliance with this mandatory requirement. COPFS often only gets to know about such deaths when families tell them of their concerns. The process is hit and miss. In terms of reporting it is quite foreseeable that there may be more misses that notifications. Whatever

the numbers, there are clearly a very large number that do not get to COPFS. Of these many will involve serious failures to meet HSWA. As COPFS points out in its instructions it needs to know about patient safety failures, but this does not happen. The failings on notifications could be one of the biggest, if not the biggest issue affecting the effectiveness of COPFS. This is in terms of deaths, enforcement, and the chance to prevent similar deaths. See for example the 35-50 deaths infection control deaths at the Vale of Leven Hospital which should quite possibly have been prevented if HSWA and COSHH had been complied with. But the law was and continues to be disregarded by NHS Scotland and the Scottish government's Health and Social Care Directorate (HSCD) and its ministers.

Up to the year 2000 HSE had the sole responsibility for patient safety across GB. The law and offences are about prevention, that is having effective precautions in place to prevent harm. That main principle of the law was unfortunately lost on the previous Lord Advocate and his Health and Safety Unit. The professional bodies are not regulators under the Act nor to do they deliver prevention. Similarly, other bodies such as the Mental Welfare Commission Scotland and the Care Inspectorate do not apply the Act. In 2000 with the growing concern about patient safety (e.g. 5,000 deaths a year due to hospital acquired infections in UK hospitals) each part of the UK created its own healthcare regulator. This still left HSE with the overarching responsibility. None of these health regulators were particularly good and so we got the scandals such as Mid Staffordshire NHS and NHS Lanarkshire. The latter had worse problems than those involved in the Mid Staffordshire prosecutions. But no prosecutions took place at Lanarkshire. There was not even an independent investigation into the patient safety problems, only the aforementioned NHS Scotland's HIS which does not mention the law and its requirements. Scottish patients do not get the protection that the law requires, COPFS does not act, it stands by.

In 2010 the Scottish government abolished the body that was supposed to be the Scottish healthcare regulator (with the Public Sector Reform (Scotland) Act 2010). That left us with the highest hazards and risks of any sector in the UK but with the lowest form of regulation - none. COPFS could even have prosecuted the Scottish government and ministers on that. It left Scotland in an illegal position. With the new parliament (September 2016), the Scottish government should have tabled a bill to create the missing regulator, but it did not. So we continue to not get the protection that the law requires (HSWA s18). The former Lord Advocate knew all this but he would still not advise the government. HSE cannot be Scotland's healthcare regulator, it cannot be our CQC. We are in the worst position in the UK on patient safety (see Nuffield and Kings Fund 2014).

With the creation of these health regulators HSE backed off on its involvement. HSE used to have expertise and its own medical advisers. HSE has greatly contracted over recent years (it even lost inspectorates such as railways and nuclear safety). Then its resources were further reduced by 35%. It has largely withdrawn from its original main role of prevention of harm and instead it does accidents and jobs that can bring in money. Consequently, it seeks to avoid a lot of work, and particular complex work. This might be acceptable if there are other competent regulators working to HSWA, but of course we do not have these in Scotland. So all patient safety in Scotland is the responsibility of HSE. It cannot do this, and it does not. So HSE is not there to assist COPFS on healthcare. It will only act 'when compelled to'. There are no exemptions to HSWA, healthcare and clinical

practice are included. The law also covers the need to have effective management systems to deliver safety. HSE would justifiably not get involved in the normal range of clinical practice, but it must for matters of negligence. That is those that are clearly outside the accepted standards of care such as in prosecutions at Mid Staffs (e.g. Gillian Astbury 2014, and Lillian Tucker October 2015). The system of protecting patients as the law requires, and of securing justice has fallen apart in Scotland. It does not happen.

3.1.9 **COPFS and Healthcare:** Of all the areas of work of COPFS, apart from the need to investigate and prosecute 'conventional' homicides, healthcare is the area where the problems are the greatest. In terms of the vast scale of non-compliance with the law and the consequences of thousands of avoidable deaths, and other major harm, this dwarfs any other subject. Until the law on patient safety is implemented and complied with in Scotland this must be a top priority for COPFS enforcement. Currently the situation is severely aggravated by the 'Reporting of Deaths to the Procurator Fiscal: Information and Guidance for Medical Practitioners' not being followed. The extent of the non-reporting is not known but it must be investigated. Without the above instruction being followed there is not reliable information and the incidents which should be investigated are not. Delays in reporting inevitably result in poorer information or evidence being available. We also become aware of many such incidents. The almost complete lack of knowledge and understanding of the legislation relating to patient safety is also a significant factor.

Quite often it is families who notify COPFS and apply pressure to get them involved in failures in healthcare and related social care. It is also characterised by COPFS and HSE being very reluctant to act despite there being major breaches of the law and avoidable deaths. Despite the ready availability of prosecution evidence, they are reluctant to take action against the NHS Boards. The law puts the main weight of responsibility on the NHS to have systems in place in which medical and nursing staff can then work safely. COPFS seems to prefer to not act. Similarly, HSE rarely issues the enforcement notices that would improve management systems and frontline precautions. What COPFS and HSE may not have thought through is the consequences of them not acting. These will greatly out-weigh those of acting. They both sometimes identify 'systems failures' but they seem to be reluctant to do anything about them. These systems failures are major breaches of the Management of Health and Safety at Work Regulations 1999 (MHSWR). We see cases of COPFS being slow and reluctant to act; this is most visible on avoidable suicides in mental health services, and in the most serious and distressing incidents that occur in Scottish maternity units. Here are some of the consequences of COPFS/HSE inaction on serious failings:

If COPFS and HSE do not Prosecute or issue Enforcement Notices

1. COPFS and HSE permit the continuation of the most serious breaches of HSWA and MHSWR. These offences relate to the failure to ensure that effective measures are in place to ensure the safety of patients so far as is reasonably practicable. Such that in a maternity unit compliance with the law would protect both the mother and the baby.
2. The failure to ensure compliance with the law in a very high hazard environment will result in a substantial risk to both babies and mothers. Avoidable harm including deaths are likely, and do take place.

3. The failures of COPFS and HSE to act will sanction the NHS breaking the law and harming even more patients. We have seen this happen. Already of the twenty essential statutory requirements that must be in place to ensure patient safety we in Scotland currently have none. In NHS Scotland any compliance with the law on patient safety is accidental, whereas for such a high hazard sector it must be properly organised to ensure that law is complied with and that patients are safe.
4. With their minimal involvement in healthcare and patient safety, COPFS and HSE are giving the 'green-light' to law-breaking on an unprecedented scale in Scotland. And with it the vast number of deaths which should be prevented.
5. COPFS (and HSE) will be failing to uphold the law.
6. COPFS and HSE as organisations will be failing in their own wider organisational responsibilities both as public bodies and as civil servants. There are particular breaches of HSWA that apply to these organisations and to individuals.
7. For individuals there are the matters of misconduct in public office. Each year in the UK there are about 130 cases taken, so it is a real risk. It should be pointed out that the potential penalties for this offence are very great, but then in the current circumstances it does relate to neglect of duty permitting many avoidable deaths.
8. The failure of COPFS to act effectively in an area of very serious widespread offences, and great consequences to the public, could critically damage its credibility and ability to act.
9. Similarly, Police Scotland and HSE are also at major risk.
10. The current lack of enforcement on patient safety by COPFS, HSE and Police Scotland, and the preference for inaction over action to protect the public, means that the Scottish justice system is not giving the public the protection that the law requires them to be given. The Scottish justice system it is not functioning as a justice system should.

3.1.10 **Challenge:** COPFS has been very poor in handling concerns about its activities. On our issues the Lord Advocate, Solicitor General and COPFS have never been able to address the points. They have been a brick wall. This has allowed the major problems in COPFS to continue and develop. Rather than being 'a learning organisation' it has been 'a let's ignore it and hope it goes away organisation', much to the detriment of public service. Its isolationism has meant that it has failed to handle current UK and EU legislation, and UK -wide standards. It has resulted in a justice system that fails to either protect the public as the law requires, or to secure justice when failures take place.

3.1.11 **Problems:**

A) Previous Lord Advocate refused to advise the Scottish government on the law and patient safety
B) Lack of knowledge on HSWA, CMCHA, HRA and associated legislation and principles. This is particularly noticeable for healthcare, the consequences are severe.
C) Failure to recognise and apply strict liability law
D) Fails to follow agreed procedure work-related deaths (WRDP) related to the public
E) Notifiable deaths not necessarily notified to COPFS
F) Poor quality of investigations, they do not meet tests of criminal law investigations
G) Failure to apply UK statutory enforcement code on HSWA offences

H) Failure to follow UK principles and standards of regulation and prosecution. Inconsistent with the rest of the UK on reserved matters (public safety) and legislation
I) Apparent absence of organisational and management systems, quality and performance management
J) Inadequate resources and competences
K) Open to political interference

3.2 COPFS and Stakeholders

3.2.1 Relationships with stakeholders is critically weakened by the widespread COPFS lack of understanding of health and safety legislation. The legislation is almost a model of good legislation, and it is highly effective when it is applied, it 'solves safety'. Our main concern is patient safety but it is also evident in other sectors. The Glasgow bin lorry FAI transcripts showed major problems in the participant's understanding of the law, its application and what it meant. These are stakeholders with COPFS. Accordingly, the FAI failed to properly investigate correctly the issues and causes of the deaths. There was not the investigation and coverage of the application of HSWA s7(1) to the driver. The FAI showed regulatory gaps opening up with parties avoiding taking responsibility for investigating the factors and the law that applied. Elsewhere, the police control room failure to act to respond to the M9 crash suggests a serious design problem. The control room is safety critical and should fail to safety, and not rely on human performance, the technological solution should have been available. It suggests a lack of understanding of the management of high consequence risks. Without changes to the control room system it sounds like an even more serious incident is possible. On the M9 incident it took a substantial period before HSE was called in under the work-related deaths protocol. Both the police and COPFS should have immediately notified HSE, and HSE should have seen the main news and gone in anyway. In this case Police Scotland would be the main suspect under HSWA. There is the conflict of interests. The response to such work-related deaths of the public incidents is painfully slow and/or lacking in competence, and that is if it happens at all.

3.2.2 The lack of understanding of the application to patient safety means that stakeholders do not know what to look for. With the lack of the Scottish government committing to, and upholding the law on patient safety it means that the NHS is unaware of breaches of the law. Hospitals are legally not required under RIDDOR (accident and incident notification regulations) to notify HSE of the deaths; but there does need to be an improved mechanism for informing COPFS on notifiable deaths.

3.2.3 The police are not experts in HSWA and are not of aware of what is in its scope. They are in no position to assess the main requirement of HSWA which is determining what are reasonably practicable precautions. There needs to be advice to the police on HSWA, particularly on its application to public safety. There needs to refresher training on the work-related deaths protocol and checked that it is applied. It also needs to apply it to incidents involving their own activities. COPFS and HSE must be involved.

3.2.4 The communication between the police and COPFS and HSE needs improvement. The 40 deaths at Ayrshire and Arran showed a complete failure of all parties to properly investigate them. COPFS, HSE and the Lord Advocate did not realise that their response of 'no action' was each based on 'no investigation'. A main factor in the Bradford City

Football Club fire disaster involved allied failures in communications of similar authorities.

3.2.5 Because of COPFS failings there are delays in notifying HSE under the protocol. In some cases it has taken years. Obviously this severely damages the quality of evidence that can be obtained, and the chance of justice. The vast delays (e.g. 5 years on a recent HSWA case) in securing justice can have devastating effects on the families. There needs to be a review of the process for notifying HSE, checks that it is happening, and for there to be refresher training for COPFS on the role of HSE and on the WRDP protocol.

3.3 COPFS Resources and Competences

3.3.1 Section 3.1.1 deals with the issues of resources and competences. We note the FDA concern and that of the Inspectorate of Prosecution in Scotland.

3.3.2 The issues that we have identified are such that it needs a systematic review of how COPFS handles work-related public safety deaths. Working through the COPFS objectives, the strategy, structure and systems should lead to the resources and competences required.

3.3.3 On healthcare there is the need for a range of competences required which are currently not held by COPFS or HSE. In particularly those who can creditably assess what is 'reasonably practicable' in the healthcare sector. That would either need expert witnesses or a competent healthcare regulator that could provide them. The healthcare regulator must be created as a matter of urgency.

3.3.4 The situation is made very difficult by HSE not having the competences and resources particularly for deaths in healthcare. HSE in Scotland could easily devote all its resources to dealing with the extremely serious breaches of HSWA in healthcare and social care. HSE is the overarching regulator of HSWA, and the regulator of last resort (see Mid Staffordshire public inquiries). As we have said elsewhere HSE cannot be Scotland's healthcare regulator. An effective fully-independent healthcare regulator working to HSWA compliance is essential to achieve the legal safety standards in this high hazard and high risk sector. This is both in practice and to achieve compliance with s18 HSWA on effective regulation. Having this essential regulator should reduce the resources and competences required both of COPFS and HSE.

This matter can fall within the remit of the Lord Advocate as principal legal advisor to the Scottish government. Also it comes in with their role of needing to ensure that the Scottish government operates according to the law. It requires a bill to create this fully-independent regulator of healthcare. This is required to ensure compliance with s18 HSWA. The imperative of 'fully independent' (such as of government and of the sector being regulated-NHS/healthcare) is repeatedly dealt with in major public inquiries such as Piper Alpha and Mid Staffordshire NHS.

Note: Occasionally the Scottish government has referred to NHS Scotland's Healthcare Improvement Scotland (HIS) as its independent regulator. It is no such thing and the HIS senior management even say that they cannot be the regulator as they are the NHS. Self-regulation is absolutely not allowed. Even the OECD (February 2016) has commented on the Scottish government 'marking its own homework' on healthcare safety and performance.

HIS demonstrate their inability to be a regulator by being on the record (a recording) as saying that they regard the law on patient safety as being optional, and that they are not going to do it. A senior manager (in HEI/HIS) has repeatedly said that they do not think that healthcare should be regulated. That in a part of healthcare that has involved thousands of avoidable deaths – from poor infection control. HIS do not work to HSWA standards, they do not even qualify as a quality assurance body. HIS cannot become the independent regulator without massive reconstruction. It needs a completely new start to create the healthcare regulator with assistance from other UK healthcare regulators.

3.4 COPFS and Victims of Crime

3.4.1 Delays: IPS noted the excessive delays on COPFS cases. In HSWA public safety cases this is much worse as there is the failure to comply with the work-related deaths protocol. There is a reluctance to get involved in these cases, they are regarded by COPFS as complex.

3.4.2 In these cases families often have to do the work of COPFS to explain why the incidents should be properly investigated and how the law covers them. A current case under consideration is aggravated where HSE has not got the medical competence to understand an incident. Compliance with current practice should have prevented the death. HSE acknowledged the failure of patient safety systems at the hospital but is still trying to do nothing. This in itself could involve HSE in breaching its own statutory responsibilities and potentially consideration of misconduct in public office. COPFS has no control over HSE. The local MP has said that they are calling for a public inquiry into the NHS Board and its poor safety record.

3.4.3 The Glasgow bin lorry disaster is the high profile case of COPFS failing victims. The families should not have needed to go to a private prosecution had the Lord Advocate, the Solicitor General and COPFS done their job. As noted previously, the Solicitor General in the FAI said that if the driver had complied with HSWA s7 then the deaths would not have occurred. Yet this was said without there being a HSWA s7 investigation. The transcripts to the FAI do show that there should be strong evidence for a prosecution and this can still take place. There is no time bar and no amnesty on HSWA offences for the driver being given. We are not sure on the next point as the statements of the chief legal officers are so unusual, they disregarded UK law, and are out of line with UK legal practice. However, we do not think that an amnesty could have been given for HSWA offences anyway.

3.4.4 From those families who have contacted us their view on the COPFS seems to be twofold. One is that there is dependency on the Fiscal, the second is that COPFS fails them. The latter point is to be expected as they have contacted ASAP-NHS. What does remain a constant is that COPFS does not have an effective system for pursuing public concerns on patient safety incidents, and that it does not have an effective system for managing the concerns. Again this was seen with the Lord Advocate appearing in the media trying to explain why there was to be no prosecutions on the bin lorry. This ‘on the hoof’ response seems to have been in breach of the Prosecutor's Code. The statements of the then Lord Advocate confirmed that due legal process had not been followed and that the incident had not been competently investigated or the prosecution process followed.

3.5 Inspectorate of Prosecution in Scotland (IPS)

3.5.1 We have not yet considered all the IPS reports. What we have not so far seen is IPS picking up on the type of issues that we are concerned about. There is COPFS not following the Work-Related Deaths Protocol. That is an issue which substantially affects the delivery of justice. It is also a factor in high profile cases that impact on the COPFS reputation and the degree of public confidence. If it had been followed through at the Glasgow bin lorry by involving HSE in decisions on prosecutions, then there would by the UK enforcement code (EMM) be a strong argument for prosecution of the driver under section 7 HSWA. As someone who has investigated a bin lorry-pedestrian fatality, we would expect the driver to be prosecuted under HSWA. With HSE taking the prosecution decisions in England and Wales this would have been the likely outcome. It would have very much been in the public interest, in part to deter others who fail to comply with the employee's organisation policy on the disclosure of the required medical information which could affect the safety of themselves, other workers and the public. Here the law was either not known about (the most probable scenario) or disregarded and not mentioned. Its absence from the FAI and in correspondence that we have had with the senior law officers reinforces that likelihood. The Glasgow bin lorry is a case study in fundamental errors, and errors in detail that would warrant an investigation by IPS. It would bring out the lack of awareness of the application of HSWA and what it meant. There are substantial lessons to be learnt.

3.5.2 The problems that we have found are characteristic of a COPFS cultural isolation both in time and space. There is the lack of awareness of current UK legislation and its principles, of two hundred years of strict liability law and safety law, of the UK-wide statutory enforcement code on HSWA offences, of prosecutor's and regulator's codes, the requirement that ministers (including senior law officers) uphold the law rather than disregard it, and that the prosecutor/ judiciary should not also be part of the executive. In our work on patient safety in Scotland and the underpinning of law, we have been continually surprised at the major basic errors of the ministers and COPFS. It is very unusual. An explanation would be that their errors in the approach to the law that currently applies in Scotland are made as if their calendar is set to 1799 and not 2016. That is the scale of the gap between what is happening on justice on public safety and what it should be.

The IPS would need to be aware of the culture of COPFS but not bound by it. It needs to have the awareness of Scottish Law, UK law, EU law, and ECHR. The latter is the backstop on patient safety where governments fail to protect their citizens. IPS needs to have the wider cultural and legal perspective. It needs to avoid the 'regulatory or cultural capture', i.e. it must not have the same way of thinking and acting as the body being overseen but be properly independent. This has very real consequences. In the field of healthcare that we are looking at a monoculture prevails; the law to protect patients in Scotland has not been implemented. Every essential statutory requirement of the twenty, is absent in Scotland. It had not been noticed (even by the Lord Advocate and COPFS). And that great error permits the many avoidable deaths.

4. Issues

4.1 **Context:** The points made in this submission are set in a wider context. We have pointed out that the UK-wide legislation that would ensure patient safety has not been

implemented in Scotland. There is no healthcare regulator to make sure that the law is complied with. The Scottish government's senior law officers have been inactive in advising ministers and in prosecuting the offences.

4.2 **Public Inquiry**: The legal issues are given coverage in the cases for the public inquiry 'Patient Safety in Scotland'. The documents are available via the website http://asapnhs.org.uk/

4.3 **Due Diligence Test:** The work on patient safety has shown major pieces of legislation that have not been implemented here. This is the HSWA, the Management of Health and Safety at Work Regulations 1992/1999 (MHSWR), the Control of Substances Hazardous to Health Regulations (COSHH which relates to many avoidable deaths from poor infection control). There is also the Human Rights Act 1998 (HRA) in respect of Article 2 'Right to Life'. The previous Lord Advocate seemingly did not use Corporate Manslaughter and Corporate Homicide Act 2007 (CMCHA). Ministers and senior civil servants have variously said that they regard the law as being optional and that they are not going to implement the law. Other ministers have repeatedly refused to implement the law, and they have been true to their word, compliance with the law is absent. With that position on the rule of law it needs a due diligence test to find out what other legislation is being disregarded by the Scottish government.

4.4 **Analysis**: We have not carried out a detailed analysis of COPFS but have collated problems that we have found and tried to make sense of them. The problems relate to justice and the many avoidable deaths covered by criminal law. It justifies a more fundamental, systematic analysis, and review of the justice system and how it deals with the law that now applies.

4.5 **Inquiry**: The range, the scale, and the consequences of the failure of the justice system on public safety in Scotland would justify a public inquiry in its own right. The issues of public concern meet the criteria for any Scottish minister to call an inquiry. That would include the senior law officers. The matters are of greater public concern than those of the Edinburgh trams inquiry which incurred no deaths. The failures of the justice system also leads to much greater financial losses than those associated with the poor management of infrastructure projects. The lack of the separation of powers in Scotland of the judiciary and the executive, places the Scottish government and its ministers in effect beyond the law, and the rule of law. Major consequences stem from this position including to potentially affect the status of Scotland and the UK, and to place them in breach of international agreements and treaties.