National Assembly for Wales
Health and Social Care Committee
The work of the Healthcare Inspectorate Wales
Evidence from the Health and Safety Executive – HIW 17

# National Assembly for Wales' Health and Social Care Committee Inquiry into the work of the Healthcare Inspectorate Wales (HIW)

# Written evidence provided by the Health and Safety Executive

### Background

1 HSE is the Great Britain wide independent regulator for work related health, safety and illness. Our remit is extremely broad, covering both policy and operational activity for most work related activities. This includes the healthcare sector, where it has a role in patient safety under Section 3 of the Health and Safety at Work Etc. Act 1974 (HSWA), as well as its more traditional role for employee safety.

2. This evidence includes links to guidance provided on our website, so that readers can explore particular topics in more detail, should they so wish.

### Summary

3 From our long experience of regulating in the healthcare sector, and drawing on the findings of, and Government response to, the Francis inquiry, HSE has three main issues it wishes to draw to the attention of the HIW inquiry. These are:

- that a regulatory gap exists between HIW and HSE, such that healthcare providers may escape prosecution even if their failures, and the consequences, have been very serious (see paras. 13-14);
- the need for absolute clarity for all parties, including the public, on the roles, responsibilities and remits of different regulators which are involved in the health care sector in Wales (see paras. 21-23 );
- the need for further agreement and clarity on sharing of information between regulators at the earliest stages of investigations to ensure that the right expertise is brought to bear at the right stage in the process ( see paras. 22-23).

4 We concentrate on two of the six Inquiry terms of reference: HIW's investigative/inspection function; and the effectiveness of its working

relationships. The former has the potential for the greatest overlap with our work, whilst the latter can help minimise potential gaps in regulation

**HSE'S role in healthcare regulation**

5 HSE's key purpose in this sector, as in the many others it regulates, is to secure effective management and control of health and safety risks. We seek to achieve this in a number of ways. As well as inspection of poor performers and investigation of selected incidents and complaints, we work extensively with healthcare stakeholders and publicise (either ourselves or with stakeholders) guidance on what effective management and control looks like and how it can be achieved. We work to develop stakeholder networks to secure high level buy-in and collective/corporate agreements. Where appropriate, we seek to include co-regulators in this process.

6 Section 3 HSWA is broadly framed and HSE has set clear policies and procedures for when it may, and when it is unlikely to, become involved in investigation of patient related (and other non-employee) incidents. These polices are set out in our 'who regulates' web pages. This section also lists others who have key roles in healthcare (including HIW) and, where these exist, there are links to relevant Memoranda of Understanding (MoUs) or Agreements.

7 In essence, HSE investigates incidents which are reportable under the Reporting of Incidents, Diseases and Dangerous Occurrences Regulations (RIDDOR), and meet our published incident selection criteria; or where other strict criteria apply, as described in our guidance. For non RIDDOR reportable incidents this generally means that we will only investigate deaths, (or where incidents may have led to deaths), which have arisen where clear standards have not been met because of serious systemic management failures. We do not, in general, investigate issues linked to the quality of care, such as hydration and nutrition, nor failures of clinical judgement. We provide guidance on the application of RIDDOR in health and social care**.**

8 Some important issues in healthcare can affect both employees and patients if they are not appropriately managed. Examples include tackling challenging behaviour and helping people with mobility. HSE provides extensive guidance on these and other issues, such as bedrail safety, on its health and social care web-pages.

9 We currently have both a liaison and information sharing agreement with the Care Quality Commission (CQC). Recent discussions with HIW support the development of a similar agreement in Wales – but both parties recognise that this will need to await the resolution of current uncertainties in the regulatory landscape in healthcare.

**The importance of investigating serious patient related incidents and complaints, enforcement, and the 'regulatory gap'.**

10 HSE has long held the view that investigation of certain selected serious incidents (for example where patient alerts have been ignored and patients have consequently died) is an effective way of uncovering serious systemic failure in organisations and securing improvement in standards. This view was supported by Francis in his Inquiry report and was also supported by Berwick in his report.

11 HSE's aims in investigating incidents and complaints are to determine the underlying causes and ensure that:

- action has been taken by the duty-holder to manage any ongoing risk and prevent similar incidents in the future;
- management failures with wider application across the organisation are identified and resolved;
- wider lessons are shared with other duty-holders; and,
- appropriate decisions can be made as to whether there is a significant failure to comply with health and safety law, for which enforcement action is appropriate.

12 HSE has taken enforcement action, including prosecuting, in a range of situations in health and social care where employers have significantly failed to manage risks that have led to serious harm. Recent prosecutions include those arising from failures to effectively manage risks from: challenging behaviour; manual handling; bedrail safety; scalding and falls. A number of cases have centred on other failures to effectively manage the safety of patients. If needed recent examples of prosecution in the healthcare sector can be provided.

13 The lack of a comprehensive set of powers by other specialist regulators (such as HIW), who may otherwise be better placed to act, often leads to HSE being called upon to act as a 'regulator of last resort'. However, HSE can only enforce where there has been a breach of relevant legislation, and the incident falls within its own selection criteria, so there is effectively a 'regulatory gap' in respect of failures outside these parameters. Healthcare providers may therefore escape prosecution, even if their failures and the consequences have been very serious. HSE has believed for a long time that this situation is unsatisfactory and made that view very clear, in giving evidence to the Francis Inquiry.

14 We therefore consider that it is important for specialist regulators (such as HIW) to investigate certain very serious patient related incidents within its own remit, and to have clear arrangements for referring incidents outside its remit to more appropriate bodies, including professional standards bodies such as the General Medical Council and the Nursing and Midwifery Council. Ideally we think that the specialist regulator should have adequate powers to secure both improvement and, in appropriate cases, justice. The Francis Inquiry supported this view. We recognise, however, that there are alternatives and touch upon this in discussing our response to the Francis Inquiry.

**HSE's reaction to relevant recommendations in the Francis report and the Government response**

15 The Francis report proposed that CQC be given HSWA, or equivalent, powers. HSE was content with this recommendation, as it had advocated a single regulator approach as one option in its evidence, and stood ready to assist those involved in its implementation.

16 In its interim response 'Patients First and Foremost' (PFF) the Government proposed an alternative approach. Instead a Chief Inspector of Hospitals has been created with the power to refer cases of 'criminally negligent practice' to HSE for consideration. PFF also referred to resourcing HSE to carry out this work.

17 HSE is equally content with this approach. This is consistent with an alternative option (to having a single regulator) put forward by HSE to the Francis Inquiry. Our main concerns are that, whatever arrangements are decided upon, they are:

- transparent and clear to all, particularly to the public
- practical and workable
- effective in addressing the regulatory gap
- effective in contributing to 'zero harm' in the healthcare sector.

18 Setting clear criteria in terms of what may - and what is unlikely to be - referred to us by the Chief Inspector will be critical in securing public confidence and achieving worthwhile objectives. We therefore remain in close contact with the Department of Health (DH) and CQC about practical implementation.

**Regulation of healthcare and collaborative working in Wales**

19 We think that the references in Francis to the importance of investigation and the 'regulatory gap', which mirrored our views, are equally applicable in Wales. It is for this reason that we have concentrated on these issues and the importance of clarity of roles and information sharing.

20 HSE is a signatory to the Concordat between bodies inspecting, auditing and regulating health and social care in Wales. We have also attended 'healthcare risk summits', led by HIW. Whilst these offer an opportunity to share information and experience between Concordat members, they do not provide the degree of clarity, about roles and responsibilities, that is necessary for effective regulation; and the objectives and expected outcomes from them, are not sufficiently clear.

21 HSE's view is that the roles, responsibilities and remits of different regulators should be made absolutely clear for the public and others. Individuals and organisations should be able to easily understand who will deal with their complaint; who will deal with major patient incidents; and what the potential outcomes might be. HSE thinks that the principles set out at

Paragraph 17 are critical – and that these principles are not currently met in Wales.

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22 It is essential that relevant organisations understand each others' roles and talk to each other at the earliest possible stage when this is in patients' interests. One of HSE's concerns is that its role is often not clearly understood and as a consequence it is not involved sufficiently early in incidents and investigations on those few occasions where it has a clear role. This has made investigation and effective evidence gathering very difficult. Involvement of the police, in accordance with the work-related deaths protocol may also be appropriate.

23 We believe that MoUs or Agreements can provide the necessary clarity and can help address regulatory gaps. Effective information sharing can both reduce burdens and help to support the safety of patients.

24 HSE would welcome working with the Welsh Government, HIW and others to help achieve these objectives and secure effective and appropriate investigation of complaints and incidents in Wales.

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