

Memorandum of Understanding (MoU)

Healthcare Inspectorate Wales (HIW)
and Health and Safety Executive (HSE)

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Introduction

1. The purpose of this Memorandum of Understanding (MoU) is to set out a framework to support the working relationship between Healthcare Inspectorate Wales (HIW) and the Health and Safety Executive (HSE).
2. This working relationship is part of the maintenance of an effective regulatory system for health and adult social care in England and Wales which promotes patient safety and high quality care.
3. This MoU relates only to the regulation of healthcare in Wales. It does not override the statutory responsibilities and functions of HIW and HSE and does not create legally binding rights or obligations; its purpose is to define the joint agreement between the two organisations and to indicate a common line of action.
4. The MoU describes how HIW and HSE will work in partnership to support improvement in the quality of care. It covers risks to care and the health and safety of patients, service users, workers and members of the public visiting relevant healthcare premises.
5. As part of the activities undertaken as part of this MoU, other agreements (for example, information sharing agreements, or joint working protocols) may be established. Such agreements will exist separately to this MoU.

Roles and responsibilities

Healthcare Inspectorate Wales (HIW)

6. HIW is the independent inspectorate of healthcare in Wales and a regulator for Independent Healthcare in Wales. HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational autonomy. HIW's main functions and responsibilities are drawn from the following legislation:
 - Health and Social Care (Community Health and Standards) Act 2003;
 - Care Standards Act 2000 (and associated regulations);
 - Mental Health Act 1983 and 2007, Mental Health (Wales) Measure 2010;
 - Independent Health Care (Wales) Regulations 2011;
 - Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008; and
 - Ionising Radiation (Medical Exposure) Regulations 2017 and Amendment Regulations 2018.
7. HIW aims to:
 - Provide assurance: Provide an independent view on the quality of care.

- Promote improvement: Encourage improvement through reporting and sharing of good practice
 - Influence policy and standards: Use what it finds to influence policy, standards and practice
8. HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to check that patients, the public, and others are receiving safe and effective care which meets recognised standards. Health services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services to ensure that rapid improvement and learning takes place.
 9. As part of its inspections and review activity, HIW will regularly review the healthcare providers' policies, procedures and audit logs. This will include any relevant mandatory health and safety training and incidents. In addition to this, HIW will inspect the environment, making sure it is suitable for providing safe care to patients and a safe working environment to staff.
 10. HIW also has a role in respect of [deaths in custody](#). The Prisons and Probation Ombudsman (PPO) is required to undertake an investigation of every death that occurs in a prison setting. HIW contributes to these investigations by undertaking a clinical review for all deaths within a Welsh Prison or Approved Premises. This arrangement is defined within a Memorandum of Understanding between the PPO and HIW.
 11. HIW also acts as a [Review Service for Mental Health](#). This involves reviewing the use of the Mental Health Act 1983 and check that it is being used properly on behalf of Welsh Ministers.
 12. HIW is also responsible for the registration and regulation of [independent healthcare providers](#) under the [Care Standards Act 2000](#). The regulation of such establishments is governed by the [Independent Health Care \(Wales\) Regulations 2011](#). This gives HIW powers to regulate in respect of patient health and safety matters. HIW inspects a range of independent healthcare providers, such as hospitals, dentists and clinics¹.

Health and Safety Executive (HSE)

13. The Health and Safety Executive (HSE) is an enforcing authority responsible for the regulation of health and safety at work in Great Britain and was established by the Health and Safety at Work Act 1974 (HSWA). HSE is a non-departmental

¹ See [HIW website](#) for more information

public body with Crown status, sponsored by the Department for Work and Pensions (DWP) and accountable to its ministers.

14. HSE also investigates incidents and concerns about health and safety practices and develops new or revised health and safety legislation and codes of practice.
15. HSE regulates health and safety across a range of sectors and industries including major hazard sites such as offshore gas, oil installations and onshore chemical plants through to more conventional sites, quarries, farms, factories, waste management sites and hospitals. HSE and LA are co-regulators of health and safety in the workplace. This includes private or publicly owned health and social care settings in Great Britain. HSE inspects, investigates and where necessary takes enforcement action. HSE regulates residential nursing care and local authority (LA) provision.
16. To enable HSE to conduct its functions in an open and transparent manner all of the operational procedures that it works to, plus the associated internal guidance and instructions, are publicly available on its [website](#).
17. As part of Operational Procedures for Investigation, HSE uses a published [incident selection criteria](#) for selecting which incidents should be selected for investigation by an inspector.
18. HSE has a [HSWA section 3 enforcement policy](#) about whether or not specific accidents to non-employees (e.g. patients) should be investigated and associated guidance on [priorities for enforcement of section 3](#), which includes situational examples covering various industry sectors, including health and social care, to assist in decision making.
19. The guidance states:
 - HSE does not, **in general**, investigate matters of clinical judgement or matters related to the level of provision of care. Other legislation and regulatory bodies deal with these issues. Examples of 'provision of care' include situations where poor hydration, poor nutrition or the development of pressure ulcers was the primary cause of death.
20. In Wales, HSE deals with the major non-clinical risks to patients such as trips and falls, scalding, electrical safety etc.; and with some aspects of risks that apply to both staff and patients alike, such as manual handling. Such incidents are normally reported to HSE under the [Reporting of Incidents, Diseases, Dangerous Occurrences Regulations 2013 \(RIDDOR\)](#), and HSE follows its published [incident selection criteria](#) when deciding whether to investigate. Examples of safety and health topics can be found [here](#). Further information on HSE's role in patient and service user incident investigation can be found [here](#).
21. HSE has prepared and published an [Enforcement Policy Statement](#) (EPS) which sets out the general principles and approach which HSE staff, mostly inspectors, are expected to follow when taking enforcement decisions. The EPS covers areas

such as the purpose and method of enforcement, the principles of enforcement, investigation, prosecution and death at work.

22. The [duties of employers](#) and powers of HSE are laid out in [HSWA](#) and its relevant statutory provisions. [Section 20 of HSWA](#) sets out powers of inspectors.
23. Where there is evidence of poor compliance or serious harm (which meets its selection criteria) HSE has recourse to regulatory powers including serving enforcement notices and undertaking prosecutions against individuals or corporate bodies. Further information is available on HSE's website at: <http://www.hse.gov.uk/enforce/enforcement.htm>.

Principles of co-operation

24. HIW and HSE acknowledge their respective statutory and non-statutory responsibilities and functions and will take account of these when working together.
25. In implementing this agreement, HIW and HSE intend that their working relationship will be characterised by the following principles:
 - making decisions that promote high quality healthcare and which protect and promote patient and worker health, safety and welfare;
 - full openness and transparency between the two organisations as to when cooperation is, and is not, considered necessary or appropriate;
 - respect of each other's independent status;
 - using resources and intelligence effectively and efficiently through appropriate coordination and information sharing;
 - maintaining public confidence in the two organisations.
26. HIW and HSE are also committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of better regulation).

Joint Priorities and Areas of Work

Exchange of Information

27. Co-operation between HIW and HSE will often require the exchange of information. Exchange of information will be expected, but not limited, to cases where:
 - either HIW or HSE identifies concerns about the health and wellbeing of the public, particularly in relation to risks to care and the health and safety of patients, service users, workers and members of the public visiting relevant healthcare premises.
 - an incident occurs in a healthcare setting in which patient safety is identified to be at risk

- an outbreak of a communicable disease has been identified in a healthcare provider setting
- a resolution to a concern would benefit from a coordinated multi-agency response.

28. In such cases, all exchanges of information will be lawful and proportionate and shared in confidence with the named contact in the other organisation at the earliest possible opportunity. The contact details in **Annex B** will be used for the raising and sharing of concerns.

29. All arrangements for co-operation and exchange of information set out in this MoU and any joint working protocol that may be developed will take account of and comply with the General Data Protection Regulation (GDPR), Data Protection Act 2018, Freedom of Information Act 2000, Health and Social Care (Community Health and Standards) Act 2003, section 76 of the Health and Social Care Act 2008, Care Standards Act 2000 and all relevant HIW and HSE legislation relating to these matters, and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues. Please refer to **Annex E**.

Incident investigation

30. Where a work-related death occurs, the police take primacy initially in the investigation in accordance with the [Work Related Deaths Protocol \(WRDP\)](#) and the associated [Practical Guide](#). The police / Crown Prosecution Service (CPS) are responsible for the investigation and prosecution of certain offences. This includes individual or corporate manslaughter, ill treatment or wilful neglect and extends to cases of theft in an abuse case. HIW or HSE will notify them of such incidents and work with them in accordance with the WRDP and this MoU.

31. Where primacy for investigation into work-related death or serious harm needs to be passed from the police, a decision will be made as to whether HIW or HSE assumes primacy for the investigation. The flowchart in **Annex D** is provided to assist in making such decisions.

32. **Annex A** sets out the partnership working arrangements between HIW and HSE to facilitate effective information sharing and collaboration.

Communicable Disease Outbreaks (National Impact)

33. In the NHS, both HIW and HSE may have a role in improving standards for workers and patients. HIW can secure improvements through inspection and producing reports for Health Boards. HSE can secure improvement through inspection / investigation and enforcement.

34. In Independent Healthcare, HIW also has [regulatory powers](#) to secure compliance and may be the best placed regulator for patient related health &

safety. Where the actions of employees may impact on the safety and wellbeing of patients (eg infection control / social distancing / PPE), these regulations may give sufficient powers to require improvements in working practice and competence of workers. Both organisations should liaise in accordance with this MoU to help identify who may be best placed to lead.

Strategic collaboration and supporting improvement

35. HIW and HSE will have regard to the circumstances in which their objectives may be best served by collaboration. Each organisation will seek to give consideration to the other when planning their work programmes and identify any possibilities for joint working.
36. They may, by agreement, undertake joint inspection, investigation or other work. Throughout such work HIW and HSE will retain and act in accordance with their own statutory powers. This work may include joint reviews, site visits, and coordination of any follow up action planning to address any recommendations.

Liaison for individual incidents

37. Where there is uncertainty about jurisdiction the relevant organisations will:
- determine who should have primacy for any action and whether joint or parallel action will be conducted;
 - keep a record of this decision and agree criteria for review, if appropriate;
 - designate appropriate contacts within each organisation to establish and maintain any necessary dialogue throughout the course of the action; and,
 - keep duty holders / providers, injured parties and appropriate relatives informed accordingly.

Referral of concerns to professional bodies

38. HSE and HIW have Memoranda of Understanding (MoU) with some professional bodies. Where HSE does not have a MoU in place, HSE will liaise, where appropriate, with HIW to get advice on a relevant contact within the relevant professional body.

Cross border issues (e.g. commissioning)

39. HSE is a GB regulator and is not confined to border constraints between Wales and the rest of GB. HIW's remit relates to Wales. Where care is commissioned from England or Scotland into services in Wales, HSE/HIW will need to liaise with then appropriate regulator to address any commissioning issues. Likewise, where care is commissioned from Wales into England or Scotland and HSE or HIW have intelligence of poor compliance or standards, each organisation will need to liaise with the relevant regulator to share intelligence where appropriate.

Media and Publications

40. HIW and HSE will seek to give each other adequate warning of, and sufficient information about, any planned announcements to the public on issues relevant to both organisations, including the sharing of draft proposals and publications.
41. HIW and HSE commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations.
42. HIW and HSE respect confidentiality of any documents shared in advance of publication and will not act in any way that would cause the content of those documents to be made public ahead of the planned publication date.

Governance

43. The effectiveness of the working relationship between HIW and HSE will be supported by regular contact, either formally or informally. This contact and any partnership working is described in Annex A.
44. Meetings to discuss intelligence, policy and operational issues of interest to both organisations should take place between relevant colleagues at both organisations when appropriate; at least twice a year. Contact details of relevant operational level contacts in each organisation are shown at **Annex B**.
45. Any disagreement between HIW and HSE will normally be resolved at working level. If this is not possible, it must be brought to the attention of the MoU managers identified at **Annex B**, who may then escalate it as appropriate within the two organisations to reach a mutually satisfactory resolution. Both organisations should aim to resolve disagreements in a reasonable time.

Duration and review of this MoU

46. Both organisations have identified a person responsible for the management of this MoU in **Annex B**. They will liaise as required to ensure this MoU is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.
47. This MoU is not time-limited and will continue to have effect unless the principles described need to be altered or cease to be relevant. This MoU will be reviewed annually by the MoU managers but may also be reviewed more urgently at any time at the request of either organisation.

Memorandum of Understanding: HIW and HSE

Signed



Alun Jones

Interim Chief Executive
Healthcare Inspectorate Wales

Date: 7th April 2021



Samantha Peace

Director of Field Operations
Health and Safety Executive

Date: 29th March 2021

Annex A – Partnership Working

While this MoU sets out the guiding principle of information and incident sharing, there are also some specific activities which will facilitate the partnership between HIW and HSE:

Healthcare Summits:

HIW host a Healthcare Summit every 6 months, which focuses on the sharing of intelligence about each Health Board. Attendees include professional regulators, performance bodies and the Community Health Councils. HSE are active members of this Summit and can present their findings to HIW and the other attendees.

While individual concerns and incidences are to be shared as they occur, themes and general concerns about health boards or Wales-wide provision of care are to be raised and discussed with the attendees of the Summit.

Regular engagement activities

In between each Healthcare Summit, representatives from HIW and HSE will meet, as appropriate, to discuss any specific issues or concerns they may have about specific settings or incidences. The focus of this engagement will be to:

- Share information about specific concerns or incidences that are relevant to the other organisation
- Facilitate joint planning of inspection, investigation and review activity
- Discuss any incidents that have been raised by either organisation

Incident reporting

Both organisations may identify failings which falls outside of their regulatory remit. These incidences will be raised as a concern with the respective organisation through the arrangements described in Annex B.

HSE will refer individual incidences and cases of relevance to HIW and this information will be used as part of HIW's intelligence gathering and informing the risk profile of individual settings and health boards.

Annex B – Contact Details

Healthcare Inspectorate Wales Welsh Government Rhydycar Business Park Merthyr Tydfil CF48 1UZ Tel: 0300 062 8163	Health and Safety Executive Wales Engagement Partnership Team Ty William House, 6 Central Square, Central Square, Cardiff, CF10 1FS Tel: 020 3028 2260
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Concerns

For specific incidents where **imminent risk** has been identified and where HIW have regulatory powers, contact should be made directly with the Concerns team, who will pass the incident to the appropriate 'Relationship Manager' or Head of Independent Healthcare.

HIW.Concerns@gov.wales

Tel: 0300 062 8163

For specific incidents where **imminent risk** has been identified in the following LA areas and where HSE is the enforcing authority for health and safety, contact may need to be made directly with HM Principal Inspectors for the relevant geographical areas:

North Wales (Wrexham, Flintshire, Denbighshire, Conwy, Gwynedd, Anglesey, Powys)

Contact HSE Wrexham: Tel: 0203 028 5080

South West Wales (Pembrokeshire, Carmarthenshire, Ceredigion, Swansea, Bridgend, Neath Port Talbot, Merthyr, Rhondda Cynon Taf)

Contact HSE Cardiff: Tel: 0203 028 2260

South East Wales (Cardiff, Caerphilly, Newport, Torfaen, Vale of Glamorgan, Blaenau Gwent, Monmouthshire)

Contact HSE Cardiff: Tel: 0203 028 2260

Alternatively, complete an [online request form](#)

Intelligence

For routine concerns identified by HSE where there is **no imminent risk** to patient safety, and the concerns are being shared to inform HIW's ongoing monitoring of health services, contact:

Intelligence Team
HIW.PIM@gov.wales

For routine concerns identified by HIW where there is **no imminent risk** and where HSE is the enforcing authority for health and safety contact:

Concerns Team
Tel: 0300 0031647
or complete an [online request form](#)

Alternatively, more general queries can be directed to:

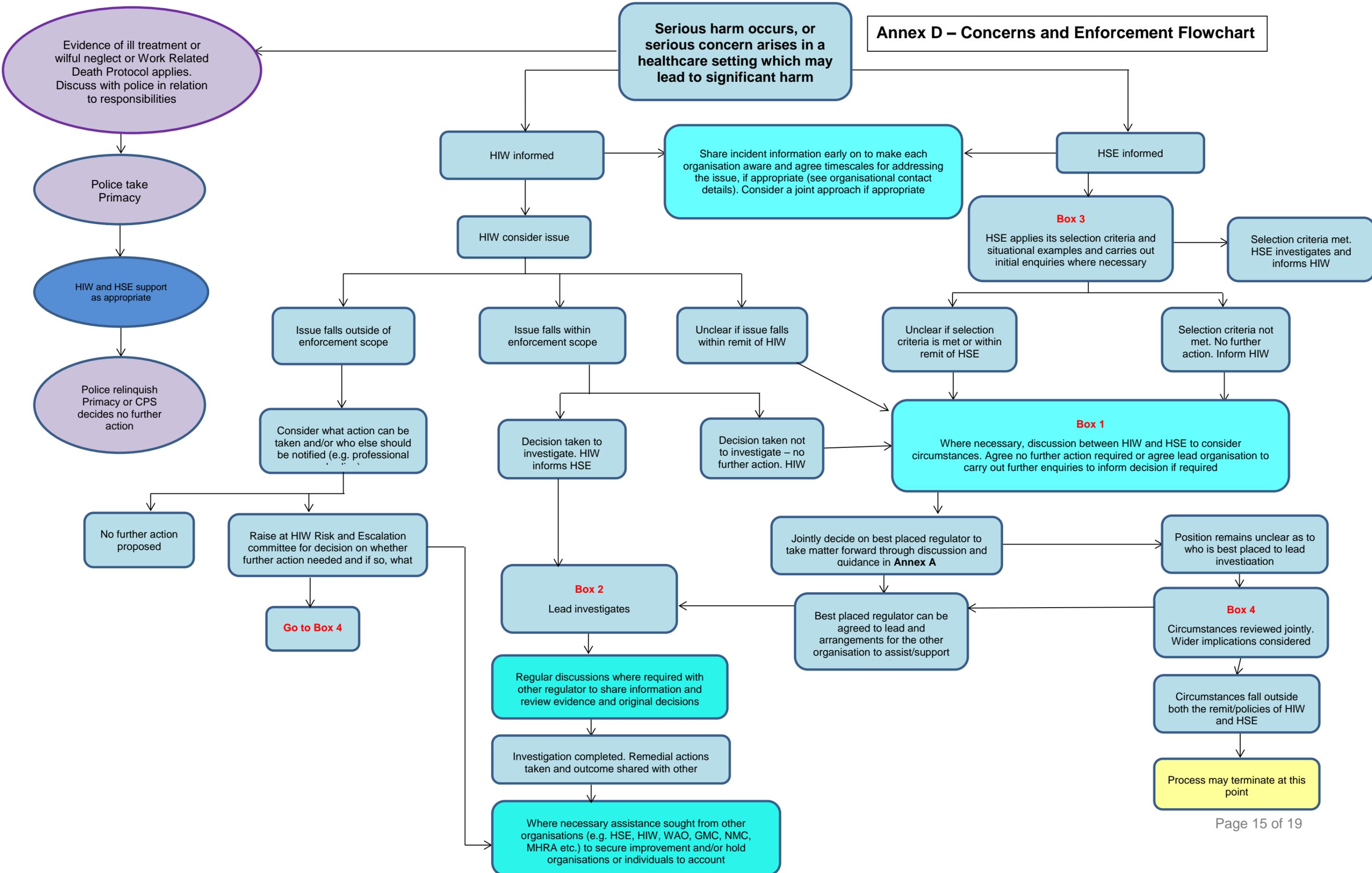
Annex C – IR(ME)R / IRR reporting

Dataset	Lead Organisation	Description	Frequency / Timing
IR(ME)R Incident Reports	HIW	IR(ME)R incident reports reported to the Welsh Government	Contact HSE only if relating to health and safety and/or IRR17 issues
IRR17 Incident Reports	HSE	IRR17 incident reports reported to HSE. In relation to employees and/or other persons not subject to medical examination	Contact HIW only if relating to medical equipment failure or patient exposure
IR(ME)R / IRR Self-Assessment Returns	HIW	If areas of concern from completed self-assessments relate to health and safety and/or IRR17 incidents	Contact HSE following return of completed self-assessment
IR(ME)R Inspection Feedback	HIW	If areas of concern following site visits relate to health and safety and/or IRR17 incidents	Contact HSE following site visit
IRR17 Inspection Feedback	HSE	If areas of concern following site visits relate to IR(ME)R, medical equipment failure and/or the quality and safety of Welsh healthcare	Contact HIW following site visit

HSE Contact: irnot@hse.gov.uk

HIW Contact: IRMERIncidents@gov.wales

Annex D – Concerns and Enforcement Flowchart



Annex E – GDPR Article 26 Joint Data Controller Declaration

Purpose

1. The purpose of this annex is to explain the respective roles HIW and HSE will play in managing the processing of personal data associated with serious incidents. HIW and HSE are considered joint-controllers of the data collected, as both parties (independently) determine the means and purpose of processing personal data as part of the functions defined in this broader MoU.

Data Protection

2. HIW and HSE will comply with all relevant provisions of the Data Protection Act 2018 (and the General Data Protection Regulation). HIW and HSE will act as joint data controllers, in respect of any personal data pursuant to this MoU; they will only process such personal data to the extent defined in the relevant regulatory framework.
3. Neither HIW nor HSE will transfer any personal data it is processing outside of the European Economic Area, unless appropriate legal safeguards are in place, such as Privacy Shield or Model Contract Clauses.
4. HIW and HSE will ensure that they have appropriate technical and organisational procedures in place to protect any personal data they are processing. This includes any unauthorised or unlawful processing, and against any accidental disclosure, loss, destruction or damage. HIW will promptly inform HSE, and vice versa, of any unauthorised or unlawful processing, accidental disclosure, loss, destruction or damage to any such personal data. Both parties will also take reasonable steps to ensure the suitability of their staff having access to such personal data.

Specific HIW Responsibilities

5. HIW has the following specific responsibilities:
 - i. Carrying out any required Data Protection Impact Assessment for any element of business or process change
 - ii. Following HIW Data Security Guidance to ensure that the necessary measures are taken to protect personal data.
 - iii. Ensuring HIW staff are appropriately trained in how to use and look after personal data and follow approved processes for data handling.
 - iv. Ensuring HIW staff have appropriate security clearance to handle personal information collected as part of this process.
 - v. Secure transfer of personal data to HSE as necessary for fulfilment of HSE's regulatory functions.
 - vi. Responding to Data Subject Access Requests when and where required.
 - vii. Reporting any data breaches within HIW to their Data Protection Officer and the ICO (where appropriate).
 - viii. Maintaining any Article 30 processing records for data held on HIW systems

Specific HSE Responsibilities

6. HSE has the following specific responsibilities:
 - i. Carrying out any required Data Protection Impact Assessment for any element of business or process change
 - ii. Following HSE Data Security Guidance to ensure that the necessary measures are taken to protect personal data.
 - iii. Ensuring HSE staff are appropriately trained in how to use and look after personal data and follow approved processes for data handling.
 - iv. Ensuring HSE staff have appropriate security clearance to handle personal information collected as part of this process.
 - v. Responding to Data Subject Access Requests when and where required in relation to personal data being processed as part of the regulatory function
 - vi. Reporting any data breaches to their Data Protection Officer and the ICO (where appropriate)
 - vii. Maintaining any Article 30 processing records for data held on HSE systems

Individual Rights

7. GDPR specifies new rights for individuals over the processing of their data. These rights, and the process an individual should follow when making a request, are listed in both HIW and HSE's privacy notice. Both parties should ensure they consult and comply fully with their respective privacy policies in the event of a Data Subject exercising any of their rights under data protection legislation.
8. In response to any subject access request, HIW or HSE will undertake a proportionate and reasonable search and respond within one month of the original request.

Data breach

9. HIW is responsible for reporting any breach occurring within their authority to their Data Protection Officer and the ICO (where appropriate). HIW will also inform HSE of the breach if there is any direct impact on their staff or wider interest.
10. HSE are responsible for reporting any data breaches within their Authority to their Data Protection Officer and ICO (where appropriate), as well as to HIW if there is any direct impact on their staff or wider interests.
11. Any personal data breach as defined by GDPR Article 4(12) that meets the relevant threshold criteria will be reported to the Information Commissioners' Office (ICO) within 72 hours of notification. This will include informing the affected data subject should the circumstances warrant it. The appropriate Data Protection Officer (see below) will be responsible for making the report, following consultation their Chief Executive Officer (CEO).

12. If financial penalties are imposed by the Information Commissioner on a party in relation to any data processed under this agreement and if in the view of the Information Commissioner, one party is responsible for the imposition of those penalties, that party shall be responsible for the payment of the penalties imposed.
13. If the Information Commissioner expresses no view as to responsibility, then each party shall bear responsibility for half of the penalty imposed.
14. If either HSE or HIW are the defendant in a legal claim before a court of competent jurisdiction by a third party in respect of data processed under this agreement, then the party determined by the final decision of the court to be responsible for the damage shall be liable for the losses arising from such damage. Where both parties are liable, the liability will be apportioned between the parties in accordance with the decision of the court. If the court does not apportion liability between the parties then each party shall bear responsibility for half of the penalty imposed, unless it can prove that it is not in any way responsible for the event giving rise to the damage.
15. The provisions of this clause do not prevent the parties coming to a mutual agreement as to the apportionment of financial responsibility for any losses, cost claims or expenses arising from the processing of data under this agreement.

Data retention

16. HIW and HSE will retain personal data associated with serious incidents in accordance with their respective organisational disposal policies. Each party is responsible for ensuring appropriate technical and procedural functions are in place to ensure the secure and timely destruction of personal data.

Information Disclosure

17. Either party to this MoU may receive a request for information from a member of the public or any other person under the various pieces of information disclosure legislation (EU General Data Protection Regulation 2016/679 (GDPR) and the Data Protection Act 2018 (DPA)), Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) etc.).
18. The recipient party to any request for information is ultimately responsible for making the final decision on disclosure. All requests for information will be considered on case-by-case basis, and all resulting disclosures must be lawful. The default position for both parties is to disclose unless one or more absolute exemptions (as defined by the appropriate legislation) apply to a specific request. Where the recipient party wishes to apply a qualified exemption (as defined by the appropriate legislation) to all or part of a request, they must ensure this is validated by a documented public interest test.

19. If a party receives a request for information that has been supplied by the other party (“the information supplier”), the party that has received the request for information will consult the information supplier as early as possible and before any information is disclosed in response to the request to enable sufficient time for the views of the information supplier, including any objections to disclosure, to be taken into account when determining whether the information is to be disclosed or withheld.
20. If a party receives a request for information that it holds and knows or believes the information is held by the other party, the party that received the request will consult the other party as early as possible and before any information is disclosed in response to the request. The purpose of this consultation is to ensure that the party that received the request is able to share any concerns about information that might be disclosed to the requester, that the party holding the information is able to take those concerns fully into account in its decision-making, and that the parties can co-ordinate their handling of requests.

Data Protection Officers

The contact details of the Joint Controller Data Protection Officers are:

Healthcare Inspectorate Wales	Health and Safety Executive
Data Protection Officer Welsh Government Rhydycar Business Park Merthyr Tydfil CF48 1UZ Email: DataProtectionOfficer@gov.wales	Data Protection Officer Health and Safety Executive 1.3 Redgrave Court Merton Road, Bootle Liverpool L20 7HS Email: Data.Protection@hse.gov.uk