Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Gwirio bod pobl yng Nghymru yn derbyn gofal da

Checking people in Wales are receiving good care

Human Fertilisation & Embryology Authority

Memorandum of Understanding (MoU) between Healthcare Inspectorate Wales (HIW) and Human Fertilisation and Embryology Authority (HFEA)

Revision history and approval

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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 Human Fertilisation and Embryology Authority (HFEA).

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 HFEA 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 purpose of the MoU is to define the joint agreement between the two organisations and to describe how HIW and HFEA will work in partnership to support improvement in the quality of care. It covers in fertility treatment and research across Wales.

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

6. HIW is the independent inspectorate and regulator of 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 we find 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. 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.

Human Fertilisation and Embryology Authority

10. The responsibilities and functions of the HFEA are set out in the Human Fertilisation and Embryology Act 1990 (as amended). The HFEA is a non-departmental public body established under the 1990 Act.

11. In summary, the HFEA must:
    - issue licences under the Human Fertilisation and Embryology Act 1990 (as amended);
    - inspect establishments licensed under the Human Fertilisation and Embryology Act 1990 (as amended);
    - issue a Code of Practice setting out maintain a statement of the general principles which it considers should be followed in the carrying-on of activities governed by the Human Fertilisation and Embryology Act 1990 (as amended);
    - promote compliance with the Human Fertilisation and Embryology Act 1990 (as amended) and with the Code of Practice;
    - keep under review information about embryos and about the provision of treatment services and activities governed by the Human Fertilisation and Embryology Act 1990 (as amended), and advise the Secretary of State about those matters; and
    - provide advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by the Human Fertilisation and Embryology Act 1990 (as amended), or may wish to do so.

Principles of co-operation

12. HIW and HFEA acknowledge their respective statutory and non-statutory responsibilities and functions, and will take account of these when working together.

13. In implementing this agreement, HIW and HFEA intend that their working relationship will be characterised by the following principles:
    - the need to make decisions that promote high quality healthcare and which protect and promote patient 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;
- the need to use resources and intelligence effectively and efficiently through appropriate coordination and information sharing;
- the need to maintain public confidence in the two organisations; and
- a commitment to address any identified overlaps or gaps in the regulatory framework and responsibilities.

14. HIW and HFEA 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

15. Co-operation between HIW and HFEA will often require the exchange of information. Exchange of information will be expected, but not limited, to cases where:
    - either HIW or HFEA identifies concerns about the health and wellbeing of the public, particularly in relation to fertility treatment and research across Wales.
    - a resolution to a concern would benefit from a coordinated multi-agency response.

16. 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.

17. 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 HFEA legislation relating to these matters, and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

18. Both HIW and HFEA are subject to the Freedom of Information Act 2000. If one organisation receives a request for information that originated from the other the receiving organisation will discuss the request with the other before responding.

Media and Publications

19. HIW and HFEA 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.

20. HIW and HFEA commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations.

21. HIW and HFEA 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

22. The effectiveness of the working relationship between HIW and HFEA will be supported by regular contact, either formally or informally. This contact and any partnership working is described in Annex A.

23. 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, if necessary. Contact details of relevant operational level contacts in each organisation are shown at Annex B.

24. Any disagreement between HIW and HFEA 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

25. 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.

26. 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 every two years by the MoU managers identified at Annex B, but may also be reviewed more urgently at any time at the request of either organisation.

Signed

Alun Jones

Interim Chief Executive

Healthcare Inspectorate Wales

Date: 19/10/2020

Peter Thompson

Chief Executive

Human Fertilisation and Embryology Authority

Date: 13/10/2020

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 HFEA:

Routine Information Sharing

In order to facilitate the joint working arrangements between HIW and HFEA it is necessary to have routine sharing of information. The information to be shared will include:

- Planned inspection activity which falls under the regulatory remit of both organisations
- Any concerns or themes emerging from recent inspection or review activity
- Organisational plans and expected reviews

More information on how HIW and HFEA will work together can be found in the Joint Working Protocol in Annex C.

Annex B – Contact Details

Healthcare Inspectorate Wales	**Human Fertilisation and Embryology Authority**
Welsh Government Rhydycar Business Park Merthyr Tydfil CF48 1UZ Tel: 0300 062 8163	2 Redman Place London E20 1JQ Tel: 020 7291 8200

There will be named contacts between HIW and HFEA as follows:

Chief Executives	
Alun Jones *Interim Chief Executive* Alun.Jones39@gov.wales	***Peter Thompson*** *Chief Executive* peter.thompson@hfea.gov.uk
MoU managers	
Joseph Wilton	**Emily Tiemann** *Regulatory Policy Manager*

Head of Partnerships, Intelligence and Methodology joseph.wilton@gov.wales Tel: 0300 025 2663	Emily.Tiemann@HFEA.GOV.UK Tel: 020 7291 7870
	Sharon Fensome-Rimmer *Chief Inspector* Sharon.Fensome-Rimmer@HFEA.GOV.UK Tel: 020 7291 8263
Concerns Mailbox	
hiw.concerns@gov.wales Tel: 0300 062 8163	compliance@hfea.gov.uk

Annex C: Joint working protocol

This joint working protocol sets out the detail of the working arrangements between HIW and the HFEA.

HIW and the HFEA endeavour to identify possible ways in which both regulators could work together to reduce and improve regulatory overlaps for the benefit of registered or licensed organisations where possible, and to develop mechanisms for sharing information about organisations where they are registered or licensed by more than one regulator.

HIW and the HFEA necessarily use different terminology to describe some aspects of their work according to its governing legislation. Where this document refers to organisations, it means registered or licensed providers.

Joint inspections

HIW and HFEA will, whenever appropriate and feasible, attempt to do joint inspections of fertility clinics licenced with the HFEA and registered with HIW. HIW and the HFEA will liaise and make an effort to agree on a joint inspection date of these organisations, where possible.

Joint inspections will require HIW and the HFEA to meet prior to and following an inspection, via teleconference or in person, to discuss the following:

Before a joint inspection takes place:

- background information about the organisation concerned and its compliance history;
- information about any regulatory action taken to date and the effect it has had;
- any areas of concern;
- the scope of the inspection;
- the overall inspection lead; and
- which inspectors from HIW and the HFEA will lead on certain areas of the inspection, to avoid duplication.

After a joint inspection takes place:

- general observations and any areas of concern;
- the need to monitor compliance, or follow up areas that require improvement or enforcement actions;
- where there are areas of regulatory overlap, which inspection report will note the outcomes of inspection findings (including any non-conformities); and
- where there are areas of regulatory overlap, whether HIW or the HFEA will lead on following up areas that require improvement or enforcement actions (including liaising with the organisation and receiving assurance that actions have been, or are being, taken).

Finalised inspection reports will be shared by the HFEA with HIW once the minutes have been released from the relevant committees.

Sharing information

Who will share information?

Information will generally be shared at an operational level, between HIW and HFEA inspectors. The information shared will relate to an organisation which is licensed or registered by both regulators.

Situations in which information will be shared

We will aim to foster a culture of information-sharing, in which inspectors are empowered to pick up the phone to their counterpart to discuss any organisation in their portfolio. HIW and HFEA inspectors will contact the single point of contact for each organisation to speak to the relevant inspector. These contact details are:

HIW	HFEA
Zoe Weaver	Sharon Fensome-Rimmer
Head of NHS Inspections	Chief Inspector
	sharon.fensome-rimmer@hfea.gov.uk

Tel:	Tel: 020 7291 8200

There will be a two-way sharing of information, which may be volunteered by one regulator to the other, or provided in response to a particular request. Information will only be shared where the organisation is regulated by, or carrying out activities which should be regulated or licensed by, both regulators.

Under certain circumstances, there will be an expectation that information held by one regulator will be shared in confidence with the other. These circumstances are as follows:

HIW	**HFEA**
Whistle-blowing event as defined by HIW	Whistle-blowing event as defined by HFEA
Planned and routine inspection activity schedules of private organisations that are licensed or registered by both regulators	Planned and routine inspection activity schedules of organisations that are licensed or registered by both regulators
Serious untoward incident reported that has the potential to cause potential harm to patients or reputational risk to the establishment	Grade A incidents reported, or trends in grade B and C incidents
A non-routine inspection is arranged	A responsive inspection is being undertaken
Licence is suspended or revoked, or steps are taken to restrict licensable activities	Licence is suspended, revoked or varied to restrict licensable activities
Significant regulatory sanctions are imposed	Significant regulatory sanctions are imposed
Referral is made to another regulator or agency (e.g. the Health and Safety Executive (HSE) or the Medicines and Healthcare products Regulatory Agency (MHRA))	Referral is made to another regulator or agency (e.g. the HSE or MHRA)
Media interest in an organisation, which may give rise to concerns that need further consideration	Media interest in an organisation, which may give rise to concerns that need further consideration

In the circumstances listed above, the inspector will be expected to contact their counterpart in the other organisation using the details above, both to pass on the information and to ascertain whether there is any additional information held by the other regulator which should be taken into account. The counterpart should ensure relevant colleagues within their organisation are aware that the information sharing has taken place. Contact between HIW and the HFEA may occur in other circumstances where it is considered to be appropriate and proportionate, and is necessary agreed with a relevant manager.

Each regulator should record the information shared, who it was shared with and when, and any outcomes. The manner in which this is done is up to individual regulators to determine.

What information will be shared?

Only non-patient identifying information will be shared between the regulators under this protocol. Anyone disclosing register data in circumstances other than those which are prescribed in the HFE Act 1990 may be committing a criminal offence. Before any register data and other personal or patient identifying information is disclosed, consideration must be given to the basis for disclosure including under the HFE Act 1990, data protection and any other applicable legal frameworks. Account must also be taken of the General Data Protection Regulation (GDPR) when information is shared about registered or licensed individuals and people who work for the provider.

Any proposed sharing of patient identifiable data should follow the policies and guidance of the disclosing organisation, and must be lawful and proportionate.

Where needed, case management meetings will be arranged between the regulators. This would be in exceptional circumstances only and subject to the agreement of the relevant senior managers.

Freedom of Information (FOI) requests for information shared between the regulators

Any request under the FOI Act relating to information which was all or in part provided by the other regulator will not be released without first seeking advice from the organisation that provided the information. This includes information or data relating to serious incidents that may include information about individuals. For example, if a HFEA inspector informs an Health Inspectorate Wales (HIW) inspector about allegations made by a whistle-blower, following which an FOI request is received by the HIW for information held about the organisation concerned, no information relating to the incident would be released without discussion with the HFEA about whether the information which had been shared is subject to any exemptions under the FOI Act or Data Protection Act.

Legal responsibility for responding to an FOI Act request – including final responsibility for making any decision to withhold information under exemption – remains with the organisation receiving that request.

General Data Protection Regulation (GDPR) for information shared between the regulators

From 25 May 2018 the EU General Data Protection Regulation (GDPR) supersedes the UK Data Protection Act 1998 (DPA). It was designed to harmonize data privacy laws across Europe, to protect and empower all EU citizens' data privacy and to reshape the way organizations across the region approach data privacy. It applies to all organisations processing and holding personal data of data subjects residing in the EU, regardless of the company's location.

Personal data includes any information related to a natural person or 'Data Subject' that can be used to directly or indirectly identify the person. It can be anything from a name, a photo, an email address, bank details, posts on social networking websites, medical information, or a computer IP address.

Compliance to the GPDR regulations is essential to ensure data shared is kept in a manner compliant with GDPR regulations. Any organisation who is not compliant with GDPR regulations by 25 May 2018 will face heavy fines. Information that is requested from the HFEA about the HIW, and vice versa, shall be communicated to the relevant person specified in Annex C of this MOU.

The HIW and the HFEA will ensure that the personal data held by them and shared with each other will only be processed (including internally) in accordance with the GDPR.

It is important that any information received by the other is not disseminated to any other third party without the prior written permission of the originating party. Information passed between the parties is to be used only for the purposes that it was shared. If the originating party gives written permission for the information to be disclosed to a third party, the origin of the information should be made clear to the third party, in order that they can take appropriate action on flagging the origin of the information on their own internal systems.

It is recognised that personal data provided to the HIW or the HFEA may be lawfully shared by the other with law enforcement agencies and the Information Commissioner's Office (ICO) without the need for prior consent from the originating party.

Press enquiries

Where inspectors share information about regulatory non-compliance within an organisation, and that organisation becomes the subject of press interest, the regulators will co-ordinate their press responses, while ensuring that the judgement or position of each is adequately reflected.