Memorandum of Understanding between the Care Quality Commission and the Human Fertilisation and Embryology Authority

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Introduction

1. This Memorandum of Understanding (MoU) sets out the framework to support the working relationship between the Care Quality Commission (CQC) and the Human Fertilisation and Embryology Authority (HFEA), in order to safeguard the wellbeing of the public receiving health and social care services in England.

2. The working relationship between CQC and the HFEA is part of the maintenance of a regulatory system for health and adult social care in England that promotes patient safety and high-quality care.

3. CQC is the independent regulator of health and social care in England. The HFEA regulates the use of gametes and embryos in fertility treatment and research across the UK. The responsibilities and functions of CQC and the HFEA are set out in Annex 1. Both organisations share a concern for the quality and safety of health and care services and recognise that the development of models of health and care service delivery requires closer cooperation between the two organisations.

4. This MoU relates only to the regulation of healthcare in England. It does not override the statutory responsibilities and functions of CQC and the HFEA and is not enforceable in law. However, CQC and the HFEA are committed to working in ways that are consistent with the principles of this MoU.

Principles of Co-operation

This MoU is a statement of principle which supports our focus on promoting patient and public safety and wellbeing. More detailed operational protocols and guidance can be developed as required.

5. CQC and the HFEA intend that their working relationship be characterised by the following principles:

    a. The need to make decisions which promote people's safety and high-quality health care.
    b. Respect for each organisation's independent status.

c. The need to maintain public and professional confidence in the two organisations and the regulatory process.
d. Openness and transparency between the two organisations as to when co-operation is and is not considered necessary and/or appropriate.
e. The need to use resources effectively and efficiently.
f. Addressing overlaps and gaps in the regulatory framework.
g. The aim of learning from each other about good practice in regulation and working together to collectively influence policy where relevant.

Areas of Co-operation

6. The working relationship between CQC and the HFEA involves co-operation in the following areas:
    a. Exchange of information will be expected where either the CQC or the HFEA identifies concerns about a provider organisation and those concerns are considered to be relevant to the other party's regulatory functions or patient safety and it is fair and lawful to do so to achieve the objectives of this MOU.

    b. Exchanging information about each other's functions and making sure that wherever possible regulatory overlap is identified, and action taken to minimise this as much as possible.

    c. Sharing information when it is appropriate, necessary and fair and lawful to do so about media interest in a provider organisation, for which both CQC and HFEA have regulatory responsibilities which may give rise to concerns which need further consideration by either CQC or HFEA

    d. Acknowledging the responsibilities and functions of each other and taking account of these when working together.

7. The Joint Working Protocol (JWP) in Annex 3 sets out the detailed arrangements for sharing information between the parties.

8. Both organisations recognise that all processing of personal data (including the sharing of personal data) must be carried out in accordance with the General Data Protection Regulation, The Data Protection Act 2018, section 76 to 79 of the Health and Social Care Act 2008, the Human Fertilisation and Embryology Act 1990 (as amended) , The Human Rights Act 1998, and all relevant CQC and HFEA legislation relating to these matters and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues. Both organisations agree that the sharing of personal data will be considered on a case by case basis and carried out in a manner

consistent with the Data Sharing Code of Practice published by the Information Commissioner's Office.

9. Both organisations recognise their responsibilities under the Freedom of Information Act 2000. Where either organisation receives a request under the Act for information received from the other, both organisations agree to take reasonable steps to consult on the proposed disclosure and the application of exemptions but recognise that the responsibility for disclosure lies with the organisation that received the request.

Resolution of Disagreement

10. Where there is disagreement between CQC and the HFEA, this should be resolved in the first instance at working level. If this is not possible, it may be referred through those responsible for the management of this MoU, up to and including the Chief Executive of the CQC and the Chief Executive of the HFEA, who will then be jointly responsible for ensuring a mutually satisfactory resolution.

Duration and Review

11. This MoU commences on the date of the signatures below. It is not time limited and will continue to have effect unless the principles described above need to be altered and/or cease to be relevant.

12. This MoU will be reviewed every 2-3 years but may be reviewed at any time at the request of either party. Any alterations to the MoU will, however, require both parties to agree.

13. Both organisations have identified a person responsible for the management of this MoU (known as 'Relationship Leads') and their contact details are set out in Annex 2. Relationship Leads will liaise as required to ensure that:

    a. This MoU is kept up to date.
    b. They identify any emerging issues in the working relationship between the organisations.
    c. They resolve any questions that arise in regard to the interpretation of this MoU.

Signatures

Ian Trenholm
Chief Executive
Care Quality Commission
Date: 16 May 2019

Peter Thompson
Chief Executive
Human Fertilisation and
Embryology Authority
Date:16 May 2019

Annex 1:

Responsibilities and functions of CQC and the HFEA

Care Quality Commission

- CQC is the independent regulator of health and adult social care in England. Its purpose is to make sure health and care services provide people with safe, effective, compassionate, high-quality care and to encourage them to improve.

- CQC does this by registering, monitoring, inspecting and regulating health and social care services in England, to make sure they meet fundamental standards of quality and safety. We set out what good and outstanding care looks like and we make sure services meet these standards which care must never fall below.

- CQC reports publicly on what it finds locally, including performance ratings for care providers, to help people choose care and encourage providers to improve. It also reports annually to Parliament on the overall state of health and adult social care in England.

The Human Fertilisation and Embryology Authority

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. 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 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);

- ensure compliance with the Human Fertilisation and Embryology Act 1990 (as amended) and promote compliance with the Code of Practice;

- maintain information about embryos, 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;

- 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.

Annex 2: Contact details for all parties

Care Quality Commission 151 Buckingham Palace Road London SW1W 9SZ 03000 616161	**Human Fertilisation and Embryology Authority** 10 Spring Gardens London SW1A 2BU 0207 291 8200

Named contacts between CQC and HFEA are as follows:

Relationship Leads: (First points of contact for any specific matters relating to this MoU)		
	Care Quality Commission	**HFEA**
Name:	**Matthew Tait**	Sharon Fensome-Rimmer
Position:	**Head of Acute Policy**	Chief Inspector
Email:	**Matthew.tait@cqc.org.uk**	sharon.fensome-rimmer@hfea.gov.uk
Tel:	**020 7448 4568**	020 7291 8263 or 07776 477078

Chief Executives (Internal escalating policies should be followed before referral to Chief Executives)	
Ian Trenholm Chief Executive, CQC Ian.Trenholm@cqc.org.uk	**Peter Thompson** **Chief Executive, HFEA** **Peter.Thompson@hfea.gov.uk**

Other Useful Contacts: (e.g. Media Team, Legal Team etc.)		
	Care Quality Commission	**HFEA**
Name:		Niamh Marren
Position:	**CQC Media Team**	Regulatory Policy Manager
Email:	media.team@cqc.org.uk	Niamh.marren@hfea.gov.uk
Tel:	**020 7**489 401	0207 2918219
		Press Office
		Press.Office@HFEA.GOV.UK
		Policy team
		policy@hfea.gov.uk

Annex 3: Joint working protocol

Introduction

Providers must be registered with the Care Quality Commission (CQC) if they carry out one or more Regulated activities, which are set out in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Some providers registered with CQC also carry out activities that require them to be licensed by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended). Therefore, some providers are subject to regulation by both the CQC and HFEA, albeit for different activities.

CQC inspections will not include, report or rate any activity that is not within CQC scope of regulation.

The CQC 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 also means registered or licensed providers.

Operational protocols

1. Sharing information

1.1 Who will share information?

Information will generally be shared at an operational level, between HFEA inspectors and CQC inspectors and registration inspectors via the CQC national contact centre. The information shared will relate to an organisation which is licensed by HFEA and registered with CQC.

1.2 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 an organisation in their portfolio which is causing them concern. CQC inspectors will in the first instance contact the single point of contact for the HFEA. These contact details are:

- HFEA: compliance@hfea.gov.uk (tele: 0207 2918954 or 0207 2918276

The CQC contact details for HFEA inspectors are:

- enquiries@cqc.org.uk
  or telephone: 03000 616161

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 and licensed by both regulators and where it is fair and lawful to do so. CQC has Information Sharing Guidance which will allow employees to determine when it is fair and lawful to share with HEFA.

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

CQC	HFEA
• Whistle-blowing event as defined by CQC	• Whistle-blowing event as defined by HFEA
• The following type of statutory notification is submitted: Death of a person who uses the service (Regulation 16) Notifications about 'other incidents' Regulation 18) Other incidents includes: Serious injuries, abuse and allegations of abuse, incidents reported to, or investigated by, the police and events that stop, or may stop, the registered person from running the service safely and properly.	• Grade A incident reported • An increase or a noticeable trend of increase in grade B or C incidents.
• A responsive (focused) inspection is being undertaken	• A responsive inspection is being undertaken
• Registration is suspended or cancelled or conditions of registration are imposed by CQC to restrict the activities permitted	• License is suspended or revoked or varied to restrict the activities permitted
• Enforcement powers are used, including issuing a warning notice, simple caution or fixed penalty notice	• Significant regulatory sanctions are imposed
• Referral is made to another agency or professional body, for example the HSE, HTA,GMC, MHRA, HSIB or the HCPC	• Referral is made to another agency, for example the HSE, HTA, GMC, or the MHRA, HSIB or the HCPC
• Media interest in an organisation, which may give rise to concerns which need further consideration.	• Media interest in an organisation, which may give rise to concerns which need further consideration

In the circumstances listed above, the inspector or media officer will be expected to contact their counterpart in the other organisation, 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. Contact may occur in other circumstances where it is considered to be appropriate and proportionate, and if necessary agreed with a relevant manager.

Each regulator should record the information shared in line with their operational protocols.

2. What information will be shared?

The information to be shared in the situations listed above will include:

- background information about the organisation concerned and its Compliance history;
- information about regulatory action taken to date and the effect it has had;
- the steps in place for on-going monitoring of compliance or follow up of required improvement or enforcement actions.

Only non-patient identifying information will be shared between the regulators under this protocol. Sharing patient identifiable information is a criminal offence under the Human Fertilisation and Embryology Act 1990 (as amended) 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.

3. 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, which may include information about individuals. For example, if a CQC inspector informs an HFEA inspector about allegations made by a whistle-blower, following which an FOI request is received by the HFEA for information held about the organisation concerned, no information relating to the incident would be released without discussion with the CQC 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.

4. 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 CQC, and vice versa, shall be communicated to the relevant person specified in Annex 2 of this MOU.

For the purposes of the DPA and, where applicable, the GDPR, the CQC is the data controller for all personal data it holds in order to fulfil its own functions. The CQC will become the data controller for the personal data it receives from the HFEA as part of any information disclosure.

The CQC is responsible for meeting individuals' requests regarding the exercising of their rights under the DPA and, where applicable, the GDPR for the personal data it holds.

For the purposes of the DPA and, where applicable, the GDPR, the HFEA is the data controller for all personal data it holds in order to fulfil its own functions. The HFEA will become the data controller for the personal data it receives from the CQC as part of any information disclosures.

The HFEA is responsible for meeting individuals' requests regarding the exercising of their rights under the DPA and, where applicable, the GDPR for the personal data it holds.

The CQC 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 DPA or the GDPR (whichever is in force at the time).

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 CQC 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.

5. Media enquires where an organization is both registered with CQC and licensed with HFEA

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

Joint management arrangements

This JWP will have effect for the same period as the MOU The JWP may be reviewed at any time at the request of either party.

Policy leads in CQC and policy and compliance leads in the HFEA will meet annually; the meeting will include consideration of joint working arrangements. Additional meetings may be called at any time if required.