

Policy: Complaints about licensed clinics policy

Introduction

When to apply procedure

More than 80,000 cycles of IVF treatment are carried out each year in the UK. Most of those cycles are carried out without any problem occurring. Our inspection process considers how well clinics deal with complaints and ensures each clinic has a complaint process in place. Overall, we see good practice in how clinics handle complaints.

However, on occasion, patients or donors will be unhappy with the care they receive. When a complaint is made, we expect clinics to carry out an investigation into the issues raised, if appropriate, explain to the complainant what went wrong and what has been done to ensure lessons have been learnt (and where necessary practice has been changed). Where things have gone wrong, we expect the clinic to offer a sincere apology.

Summary of procedure

This document sets out the procedure we will use, and the principles we will consider, when considering complaints from patients or donors about the treatment they received at a clinic that is licensed by us.

In establishing our complaints policy, we have had regard to the Statutory Code of Practice for Regulators issued on 17 December 2007.

1. What is a complaint?

A complaint is an expression of dissatisfaction with the treatment or service you received from a licensed clinic, which actively seeks a remedy.

2. What is our role in dealing with complaints against licensed clinics?

We are the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

When dealing with complaints we expect clinics to follow the guidance set out on our Code of Practice – the fundamental requirements placed on licensed clinics:

It may be appropriate to deal with a complaint as soon as it arises, without using a formal complaints procedure. In such cases, staff should deal promptly and thoroughly with issues as they

are raised. Staff should treat all complaints seriously and show the complainant due respect, however minor the complaint may appear. Staff should not deter people from making formal complaints if they wish to do so.

The clinic should nominate a member of staff to act as complaints officer. The complaints officer should be the first point of contact when a person makes a formal complaint and be responsible for investigating complaints and ensuring the complaints procedure operates effectively. Complaints should be investigated by staff who were not involved in the circumstances that gave rise to the complaint.

3. What complaints about a licensed clinic can we consider?

We can only consider a complaint made by a patient or donor, where the complaint indicates a potential breach of the Act, licence conditions, or the guidance set out in our Code of Practice.

4. How to make a complaint about a licensed clinic

In the Code of Practice that we issue, we require all clinics to maintain a quality assurance system, and to have in place a system for dealing and responding to complaints.

If you are dissatisfied with the treatment or service that you have received at a clinic licensed by us, we would normally expect you to complain to that clinic directly in the first instance, and to have exhausted their complaints procedure first.

If having complained to the clinic, you remain dissatisfied with the response you received from them and then wish to bring the matter to our attention, please do so in writing via email and send it to us at:

By email: enquiriesteam@hfea.gov.uk

When making a complaint, please provide your full name. To investigate a complaint, we will need to obtain your consent to contact the clinic to discuss your complaint with them and obtain copies of your medical records. We are therefore not able to consider anonymous complaints.

5. Time limit for making a complaint

If you wish to make a complaint about the treatment or service that you have received at a licensed clinic, please do so as soon as possible after the matter that you wish to complain about has occurred.

Please note that we will not normally consider complaints if they are made more than 6 months after you became aware of the matters that gave rise to the complaint, or after the conclusion of the clinic's complaint process. The reason we set this limit is that it can sometimes be difficult to investigate, for example if staff have left, and the opportunity for learning is lessened.

6. What principles will we apply when dealing with a complaint about a licensed clinic?

We will:

- Acknowledge all complaints that we receive within five working days
- Keep you informed of the progress of your complaint
- Endeavor to ensure that complaints are handled fairly and as promptly as possible
- Provide people who are the subject of a complaint with a reasonable opportunity to respond
- Inform you, the licensed clinic and people who are the subject of a complaint of the outcome of any investigation that we undertake

- We aim to provide you with a full and thorough response within 25 working days
- Where appropriate, identify actions to secure any necessary improvements
- Where appropriate, share any learning points.

7. Acknowledgement of complaints about licensed clinics

We aim to acknowledge all complaints within five working days of receipt. The acknowledgment will give you the name and contact details of the person who will be responsible for responding to you.

All complaints about licensed clinics that we receive are logged and the Chief Inspector will be notified of the existence of the complaint.

8. How do we deal with a complaint about a licensed clinic?

When we receive a complaint about a licensed clinic, we will first check whether the issues raised in the complaint are those we are able to deal with, and if so, whether you have first tried to resolve the matter with the licensed clinic directly.

If you have not tried to resolve the matter directly with the licensed clinic, we will usually ask you to use the clinic's own complaints procedure before we take the matter further. If we feel the clinic can do more to resolve your complaint e.g. a meeting or a further response, we will suggest this.

However, if the complaint indicates that a serious adverse event or serious adverse reaction may have taken place, we will consider the matter in accordance with our policy for investigating serious incidents and adverse reactions.

If you have exhausted the clinic's complaint procedure and remain dissatisfied with the outcome, we will convene a panel consisting of senior members of staff within our Compliance and Information department to review the complaint and the clinic's response.

Where we can consider the complaint, we may contact you to obtain further details and may ask for your written consent to obtain records relating to your treatment at the licensed clinic.

A copy of the complaint, and any additional information or material that you provide, will be shown to the person responsible at the licensed clinic and any other person who is the subject of your complaint, for comment.

We will ask your permission before we share your complaint and the information you have provided with the licensed clinic. Depending on the issues raised in your complaint, and the timing of the next scheduled inspection of the licensed clinic, we may decide to discuss your complaint with the person responsible as part of the inspection process.

9. What might happen as a result of my complaint?

Any learning points may be shared with the licensed clinic and other stakeholders in the fertility and healthcare sectors to enable them to improve their quality assurance systems.

Where the complaint reveals evidence of non-compliance by a licensed clinic with its statutory requirements, licence conditions, directions issued by us or the Code of Practice, the matter may be brought to the attention of our Licence Committee in accordance with our Compliance and Enforcement Policy.

Where your complaint reveals general learning points which we consider should be shared more widely, we may issue an alert to all licensed clinics, or modify the guidance set out in our Code of Practice. If we do so, we will endeavor to ensure that the details set out in our alert or guidance do

not identify you.

10. Who will investigate my complaint?

Complaints reported to us will be considered by the complaints' investigator. The inspector assigned to the licensed centre may also be asked to assist in the consideration of your complaint.

11. What complaints about licensed clinics are we not able to consider?

Unlike some other healthcare bodies, we do not have a specific statutory duty to investigate patient complaints. However, we do consider complaints made by a patient or donor, where that complaint indicates a potential breach of the law, licence conditions, directions (rules) issued by us or the guidance set out in our Code of Practice for clinics. We also have a duty to consider complaints which indicate that a serious adverse event or serious adverse reaction has taken place.

As we have no specific statutory duty to investigate complaints, our power to intervene in complaints against licensed clinics is limited. We cannot force clinics to apologise or to pay compensation or refunds. Neither are we able to act as a mediator between the patient and the clinic.

We are not able to consider general complaints about the statutory framework governing fertility treatment and research (e.g. complaints about the HFE Act) or matters which are the responsibility of other regulatory bodies.

If we think your complaint reveals concerns about a healthcare professional's fitness to practise, we may refer your complaint to a professional body such as the General Medical Council, the Nursing and Midwifery Council or the Health Professions Council. If we do so, we will seek your consent before making the referral and provide you with the contact details of the relevant professional body.

We are not able to consider complaints which relate to contractual issues between a patient and a licensed clinic or matters such as the cost of fertility treatment generally. Nor are we able to investigate complaints that are subject to a legal claim.

12. What if I am not satisfied with the response?

If you are not satisfied with the outcome of the initial consideration of your complaint, you can ask for a review to be conducted by the Chief Inspector. If you wish a review to be conducted, you must write to, or email, the Chief Inspector:

By email: enquiryteam@hfea.gov.uk

You will need to request the review within 10 working days of receipt of our letter informing you of the outcome of our consideration of your complaint. If you do not follow this time limit, we may decide not to conduct the review.

You should set out in your letter or email the specific reason(s) for your dissatisfaction with the outcome of the original consideration, what aspects of the original complaint and response you believe require further investigation and the reasons for this.

A review will only take place if you produce new or additional information which was not, for a valid reason, available at the time of the original consideration and which might have influenced the outcome.

We will write to you within five working days of receipt of your request, to inform you whether or not a review is to be held. If a review is to be held, the person conducting that review will inform you of the likely timescales for completion of the review. If a review is not to be held, you will be informed of the reason for this decision.

We aim to complete any review within 28 working days. When the review is complete, the person conducting the review will confirm the outcome in writing to you. The decision of the person conducting the review will be final.

13. Vexatious and persistent complaints

Whilst we recognise that most complainants will exercise their rights to complain sensibly and responsibly, some individuals or organisations may attempt to abuse their rights with requests which are vexatious, persistent or are an abuse of process.

A complaint will be considered to be vexatious and/or persistent and/or an abuse of process if:

- It makes demands for action or information that would impact substantially and unreasonably on our work
- It is persistently pursued when our complaints procedure has been fully and properly exhausted
- The substance of the complaint is continually changed with new issues and concerns being raised whilst the complaint is being addressed or following conclusion of the review/investigation under our complaints procedure
- The complainant refuses to identify precisely the issues that they wish to be investigated despite reasonable efforts by staff to help them identify their concerns
- It is designed to cause disruption, annoyance or expense or has the effect of harassing us, including where the complaint is identical or substantially similar to a previous complaint made by you or on your behalf
- It can be fairly characterised as obsessive or manifestly unreasonable, and
- The subject matter of the complaint is, or has been, the subject of legal proceedings.

We reserve the right to deal with vexatious or persistent complaints or complaints that are considered to be an abuse of process by:

- Limiting communication to just one form and to one point of contact
- Confirming in writing that the investigation/review is complete, and that continued correspondence will serve no purpose
- Confirming in writing that if you continue to complain unnecessarily, we reserve the right to take no further action in response to your complaints, or
- Suspending any investigation/review pending the conclusion of any legal proceedings in an appropriate case.

14. Monitoring and recording

All complaints will be recorded on a central complaints database and monitored regularly by us. This knowledge will be used to improve the way in which we continue to operate.

15. General data protection regulation and freedom of information

Email us: enquiriesteam@hfea.gov.uk
Our ICO registration number is [Z7597763](#).

A data protection officer (DPO) is a role required by current data protection laws for public bodies. Data protection officers are responsible for overseeing data protection strategy and implementation

to ensure compliance by using our complaints procedures, you consent to us processing your personal data for purposes related to your complaint.

We would like to use the personal details you have provided to us to investigate your complaint. This includes your contact details and the details of your complaint. You have contacted us with a complaint and for our complaints team to investigate it, we may need to communicate with third parties, such as your clinic.

We are choosing to request your consent in this instance because although it is reasonable that we should use your contact details and details you provided relating to your complaint to investigate it, you may not be aware that in some instances we must liaise with third parties (clinics or legal advisors) to investigate it.

We will use, store, and process your personal data in line with our privacy policy, which is available on our website: <https://www.hfea.gov.uk/>.

We will only share or seek to access the minimum amount of information that we need to investigate your complaint. You can withdraw your consent at any time by emailing enquiryteam@hfea.gov.uk. Subject Access Requests can be made by e-mailing dataprotection@hfea.gov.uk.