

FACT SHEET 6: HOW WE INSPECT CLINICS

HFEA conducts inspections in the public interest to uphold standards and ensure centres are complying with the HFEA Act, HFEA policies and are providing safe and effective services to patients. Clinics are subject to different inspections – full (detailed below), interim and unannounced.

Setting up the inspection

- Inspections are set up six months before a visit

Preparing for the inspection

- One of the HFEA's senior regulatory managers will normally chair the inspection. The team is selected to include inspectors with relevant scientific, clinical, counselling and nursing experience. The Chair ensures that none of the inspectors has a potential – or actual – conflict of interest with the centre under inspection. If so, alternative inspectors are appointed to the team.
- Clinics are required to provide the HFEA with details of all donors, patients and all licensed treatments carried out at their clinic, and all the outcomes from the treatments. They must also conduct an annual audit of all stored eggs, sperm and embryos and match the samples against patient records, including consent. This information is also included in the material used to brief inspection teams prior to an inspection, and to assist them in identifying any emerging issues.
- The Chair briefs the inspection team about emerging issues relevant to the centre being inspected and sets an appropriate timetable for the inspection. They work with the team to agree on what key questions to ask during meetings and interview and by whom. The Senior Regulatory Manager leads the team during the inspection visit and co-ordinates their activities throughout.

What happens on the day?

A typical inspection day would be:

Morning

- Meeting the Person Responsible and other members of the centre to explain the inspection process for the day and also discuss any concerns from the centre
- Reviewing a sample of patient records to check on compliance with policies
- Interviewing relevant staff members – the embryologist, senior nurse, counsellor, Person Responsible and Nominal Licensee. In addition, the team will split up and inspect the various areas
- Meetings to share evidence and discuss emerging findings
- Planning further interviews with the Person Responsible (PR) and other staff

Afternoon

- The team identifies questions and issues to raise with the Person Responsible (PR) and centre staff
- Team interviews the PR and nominated staff

- Team starts to draft reports and feedback
- Feedback given to the PR and a summary of the team's key points that will be presented to a licence committee

The Inspection Report

- The team reaches a consensus on the content of the report. Each section of the report uses evidence based on interviews, documents, data, observations or audits.

Report to the licence committee

The results of the inspection are presented to a licence committee

How are patients involved

We have piloted different ways of seeking the views of patients in each inspection and now use patient feedback questionnaires on all inspections

Unannounced Inspections

We carry put a programme of unannounced inspections. In 2004, there will be four randomly chosen and four based on risk assessment. These inspections follow a specially designed protocol.