

We are the regulator: Our job is to check whether hospitals, care homes and care services are meeting essential standards.

Herts & Essex Fertility Centre

Bishops' College, Churchgate, Cheshunt, EN8 9XP

Tel: 01992785060

Date of Inspection: 27 January 2014

Date of Publication: February 2014

We inspected the following standards as part of a routine inspection. This is what we found:

Consent to care and treatment	✓	Met this standard
Care and welfare of people who use services	✓	Met this standard
Cleanliness and infection control	✓	Met this standard
Supporting workers	✓	Met this standard
Records	✓	Met this standard

Details about this location

Registered Provider	Herts & Essex Fertility Centre Limited
Registered Manager	Mrs. Deborah Evans
Overview of the service	Herts and Essex Fertility Centre provides fertility advice and treatment to both NHS and private patients. Laboratory facilities are available on site and include storage facilities for sperm, eggs and embryos. The service is registered with the Human Embryo and Fertility Authority.
Type of service	Acute services without overnight beds / listed acute services with or without overnight beds
Regulated activities	Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury

Contents

When you read this report, you may find it useful to read the sections towards the back called 'About CQC inspections' and 'How we define our judgements'.

	Page
Summary of this inspection:	
Why we carried out this inspection	4
How we carried out this inspection	4
What people told us and what we found	4
More information about the provider	4
Our judgements for each standard inspected:	
Consent to care and treatment	6
Care and welfare of people who use services	8
Cleanliness and infection control	9
Supporting workers	11
Records	12
About CQC Inspections	14
How we define our judgements	15
Glossary of terms we use in this report	17
Contact us	19

Summary of this inspection

Why we carried out this inspection

This was a routine inspection to check that essential standards of quality and safety referred to on the front page were being met. We sometimes describe this as a scheduled inspection.

This was an unannounced inspection.

How we carried out this inspection

We looked at the personal care or treatment records of people who use the service, carried out a visit on 27 January 2014, observed how people were being cared for and talked with people who use the service. We talked with staff.

What people told us and what we found

We spoke with one person who used the service. They told us that the service always asked for their consent before any treatment was given. They said, "I have always signed paperwork to give my consent." They also said, "The service is amazing. There is always a friendly face and someone you know. It is lovely, I absolutely love it."

We looked at the treatment records of eight people who used the service. We saw that these contained detailed information on their medical and social history. This ensured that the service could properly assess the risk of any treatment to people's health and well-being.

On the day of our inspection the premises appeared to be bright, airy and spotlessly clean. We spoke with one person who told us, "Even if my boys play on the floor they still leave here clean." We saw that the service's infection control policy had been updated in January 2014.

The manager told us that they had put forward two members of the administration team, who had shown an interest in nursing, for an apprenticeship in health and social care. The staff had successfully completed the course and had become qualified health care assistants in December 2013.

We saw, that people's records were kept in locked cabinets within an area accessible only to people with the relevant security access. This meant that people's records were protected from access by unauthorised people.

You can see our judgements on the front page of this report.

More information about the provider

Please see our website www.cqc.org.uk for more information, including our most recent

judgements against the essential standards. You can contact us using the telephone number on the back of the report if you have additional questions.

There is a glossary at the back of this report which has definitions for words and phrases we use in the report.

Our judgements for each standard inspected

Consent to care and treatment

✓ Met this standard

Before people are given any examination, care, treatment or support, they should be asked if they agree to it

Our judgement

The provider was meeting this standard.

Before people received any treatment they were asked for their consent and the provider acted in accordance with their wishes.

Reasons for our judgement

We spoke with one person who used the service. They told us that the service always asked for their consent before any treatment was given. They said, "I have always signed paperwork to give my consent." They went on to tell us, "They say things like, "We're just going to give you the injection. Is that alright?"

The manager showed us that the Human Fertilisation and Embryology Authority (HFEA) had 19 different consent forms that the service was required to use dependent on the type of treatment people received. These covered; treatment and the storage of embryos, eggs and sperm, donation, surrogacy and parenthood. In addition the service had 24 locally produced consent to treatment forms, including consent for intracytoplasmic sperm injection (ICSI), that is, for sperm to be injected directly into an egg, and consent to embryo freezing.

We looked at the treatment records of eight people who used the service. We saw that each person had a treatment information appointment (TIA) with a nurse at which the appropriate consent forms for the planned course of treatment were completed. We saw that there were checklists in place to ensure that the consents needed for each type of treatment were completed. There were also other checklists for the appointment to ensure that other areas, such as counselling, blood screening and the cost of treatment were addressed. We saw that the appropriate consent forms had been completed in each treatment record that we looked at.

We saw that before a procedure was carried out the medical practitioner reminded people of what the procedure involved and the possible outcomes. People confirmed their consent to the procedure and the medical practitioner recorded this on the consent forms that people had signed at their interview.

The manager told us that people could withdraw their consent at any time. Where people had presented as a couple, whether heterosexual or of the same sex, both of them were required to consent at the start of treatment. If, at a later date, one of the couple withdrew

their consent the decision was binding on the service. The service could not then proceed with the proposed treatment for the other member of the couple.

We saw that the HFEA consent forms were available in languages other than English if these were required.

People should get safe and appropriate care that meets their needs and supports their rights

Our judgement

The provider was meeting this standard.

Treatment was planned and delivered in a way that was intended to ensure people's safety and welfare.

Reasons for our judgement

We spoke with one person who used the service. They said, "The service is amazing. There is always a friendly face and someone you know. It is lovely, I absolutely love it." They went on to say, "If I need a question answered there is always someone to answer it. My Mum had questions and they answered them for her."

People's needs were assessed and treatment was planned and delivered in line with their individual treatment plan. We looked at the treatment records of eight people who used the service. We saw that these contained detailed information in respect of their medical and social history. This ensured that the service could properly assess the risk of any treatment to people's health and well-being. People were required to complete a 'Welfare of the Child' history form produced by the Human Fertilisation and Embryology Authority (HFEA). This form asked questions to determine whether any child they may have would be likely to be at risk of serious harm. The consultant determined whether treatment was appropriate at the time or whether further information was needed concerning factors which could affect the welfare of any child produced as a result of the treatment.

We saw that there was a consultation checklist completed by the consultant and, if they were being treated as a couple, signed by both partners and the consultant. This showed that the consultant discussed the treatment options, screening for both partners, including those in same sex relationships, the length of time for each programme and the number of visits required. Also discussed during the consultation were the drug regime and side effects of the drugs, complications of the procedure and risks, such as miscarriage and ectopic pregnancy. The records also showed that the consultant explained HFEA regulations and other issues such as parenthood and counselling with people during the consultation.

We saw that where people had known allergies to medicines these were highlighted by coloured stickers on the front of their records and with highlighter pen within the history documentation. Each treatment record included a history form in which every contact with people was recorded.

People should be cared for in a clean environment and protected from the risk of infection

Our judgement

The provider was meeting this standard.

People were protected from the risk of infection because appropriate guidance had been followed.

Reasons for our judgement

On the day of our inspection the premises appeared to be bright, airy and spotlessly clean. We spoke with one person who used the service. They told us, "Even if my boys play on the floor they still leave here clean. Even the children's facilities are great."

The manager told us that the theatre manager was the nominated individual with responsibility for infection control. We saw that the service's infection control policy had been updated in January 2014. This policy included the basic principles of infection control, roles and responsibilities, standard procedures, hand hygiene, personal protective equipment and uniforms. It also included cleaning processes. The provider may find it useful to note that, although the policy included information on acceptable items of jewellery that could be worn by staff, it gave no guidance with regard to the wearing of watches by health care assistants and medical professionals.

We saw that all but three of the staff had received refresher training on infection control in September 2013. The manager told us that this was delivered under contract with University College London (UCL) by Infection Control Services (ICS). ICS also managed the service's infection control policy and completed independent audits of the service to ensure that it complied with their standards. We saw that an audit had been completed in December 2013 and the service had achieved 100% compliance with UCL's standards of infection control. We spoke with one member of staff who confirmed that they had received regular refresher training on infection control and hand washing techniques.

We saw that there was a comprehensive daily cleaning and equipment checklist and staff members signed every day to confirm that the cleaning of the different areas had been completed in accordance with the checklist. We looked in all the areas of the service. We saw that staff members were required to wear uniform scrubs when performing any clinical tasks. Staff who went into the laboratory area were required to change into special shoes and to cover their hair. The manager told us that the air within the laboratory was changed every 30 seconds. Staff who worked in the laboratory were not allowed to wear perfume or deodorant as this could contaminate the air.

We saw that the infection control lead had a cleaning policy in place which clearly detailed the responsibilities of staff members and the cleaning contractors in respect of cleaning

different parts of the service, such as the theatres. It also specified the frequency with which different elements, such as the floor space, doors, chairs and ceilings were to be cleaned. We saw that the infection control lead carried out a monthly inspection of cleaning and had monthly meetings with the contractor's representative.

We saw that all the consultation and treatment rooms had hand washing facilities with liquid soap and paper hand towels. There was also alcohol hand rub available within each consultation and treatment room and on the reception desk. We saw that the receptionist encouraged people to use this to disinfect their hands which would reduce the risk of infection being spread.

Staff should be properly trained and supervised, and have the chance to develop and improve their skills

Our judgement

The provider was meeting this standard.

People were cared for by staff who were supported to deliver treatment safely and to an appropriate standard.

Reasons for our judgement

Staff received appropriate professional development. The manager told us that the doctors and nurses were responsible for ensuring that they undertook the required amount of continuous professional development (CPD) for their own professional registration. We saw that the manager, a qualified nurse, regularly exceeded the number of hours required to maintain their registration with their professional body.

Staff were able, from time to time, to obtain further relevant qualifications. We saw that both the manager and the theatre sister had successfully completed an advanced life support qualification in May 2013.

The manager told us that they had also put forward two members of the administration team, who had shown an interest in nursing, for an apprenticeship in health and social care. The service was required to have two internal assessors for this course which had lasted 20 months and covered 12 core standards and eight peri-operative standards. Two members of the management team had trained as assessors to enable the administration staff to undertake the apprenticeships. The staff had successfully completed the course and had become qualified health care assistants in December 2013.

We saw that the service had an effective appraisal system in place in which staff members were able to reflect on their performance against their objectives. At the appraisal interview staff members were able to discuss their performance with their manager and set objectives for the year. There were objectives set for each staff member. One of these was quality based, one business based and one identified by the staff member as a personal objective.

We spoke with one staff member who told us that they felt very supported by the management at the service. They told us that their appraisal had been a two way conversation and they had been able to identify areas for development for themselves. Following their most recent appraisal they had been able to become more involved in a particular area of the work of the service. This had stimulated their interest in it.

Records

✓ Met this standard

People's personal records, including medical records, should be accurate and kept safe and confidential

Our judgement

The provider was meeting this standard.

People were protected from the risks of unsafe or inappropriate treatment because accurate and appropriate records were maintained.

Reasons for our judgement

Records were kept securely and could be located promptly when needed. The manager told us, and we saw, that people's records were kept in locked cabinets within an area accessible only to people with the relevant security access. This meant that people's records were protected from access by unauthorised people.

People's personal records including medical records were accurate and fit for purpose. We looked at the records of eight people who used the service. We saw that these were comprehensive and contained all the relevant paperwork in respect of the treatment that they received.

Records were kept for the appropriate period of time and then destroyed securely. People's records were archived 18 months after their last contact with the service. The Human Fertility and Embryology Authority (HFEA) required that all records were kept for a period of 50 years. The service had contracted out the archiving of their records to an external contractor. The contractor scanned the records and, after receiving confirmation from the service that the images were of an acceptable quality, securely shredded the paper records. The archived files were then returned to the service via a disk. The information was loaded on to computer software which only four people within the service were able to access.

Because of the terms of the HFEA licence only named individuals within the contracting organisation could archive the service's records. The manager told us that they had completed an audit of the contractor in 2013 to ensure that the protocol had been followed.

Staff records and other records relevant to the management of the services were accurate and fit for purpose. The manager showed us the master list of management documentation which was stored on the computer system. The management of the service's information technology had been contracted to the local council and access to the system was password controlled. Staff members had access to view documentation within the system but only the manager was able to edit the documents within it.

We saw that staff member's personal files were kept in locked cabinets within the

manager's office. Entry to the office was by key fob. Only certain staff members of a managerial level were able to access the office with their key fob. This meant that staff members records were kept securely but could be accessed easily when required.

About CQC inspections

We are the regulator of health and social care in England.

All providers of regulated health and social care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The essential standards are described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. We regulate against these standards, which we sometimes describe as "government standards".

We carry out unannounced inspections of all care homes, acute hospitals and domiciliary care services in England at least once a year to judge whether or not the essential standards are being met. We carry out inspections of other services less often. All of our inspections are unannounced unless there is a good reason to let the provider know we are coming.

There are 16 essential standards that relate most directly to the quality and safety of care and these are grouped into five key areas. When we inspect we could check all or part of any of the 16 standards at any time depending on the individual circumstances of the service. Because of this we often check different standards at different times.

When we inspect, we always visit and we do things like observe how people are cared for, and we talk to people who use the service, to their carers and to staff. We also review information we have gathered about the provider, check the service's records and check whether the right systems and processes are in place.

We focus on whether or not the provider is meeting the standards and we are guided by whether people are experiencing the outcomes they should be able to expect when the standards are being met. By outcomes we mean the impact care has on the health, safety and welfare of people who use the service, and the experience they have whilst receiving it.

Our inspectors judge if any action is required by the provider of the service to improve the standard of care being provided. Where providers are non-compliant with the regulations, we take enforcement action against them. If we require a service to take action, or if we take enforcement action, we re-inspect it before its next routine inspection was due. This could mean we re-inspect a service several times in one year. We also might decide to re-inspect a service if new concerns emerge about it before the next routine inspection.

In between inspections we continually monitor information we have about providers. The information comes from the public, the provider, other organisations, and from care workers.


You can tell us about your experience of this provider on our website.


How we define our judgements

The following pages show our findings and regulatory judgement for each essential standard or part of the standard that we inspected. Our judgements are based on the ongoing review and analysis of the information gathered by CQC about this provider and the evidence collected during this inspection.

We reach one of the following judgements for each essential standard inspected.

 **Met this standard** This means that the standard was being met in that the provider was compliant with the regulation. If we find that standards were met, we take no regulatory action but we may make comments that may be useful to the provider and to the public about minor improvements that could be made.

 **Action needed** This means that the standard was not being met in that the provider was non-compliant with the regulation. We may have set a compliance action requiring the provider to produce a report setting out how and by when changes will be made to make sure they comply with the standard. We monitor the implementation of action plans in these reports and, if necessary, take further action. We may have identified a breach of a regulation which is more serious, and we will make sure action is taken. We will report on this when it is complete.

 **Enforcement action taken** If the breach of the regulation was more serious, or there have been several or continual breaches, we have a range of actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers include issuing a warning notice; restricting or suspending the services a provider can offer, or the number of people it can care for; issuing fines and formal cautions; in extreme cases, cancelling a provider or managers registration or prosecuting a manager or provider. These enforcement powers are set out in law and mean that we can take swift, targeted action where services are failing people.

How we define our judgements (continued)

Where we find non-compliance with a regulation (or part of a regulation), we state which part of the regulation has been breached. Only where there is non compliance with one or more of Regulations 9-24 of the Regulated Activity Regulations, will our report include a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation). This could be a minor, moderate or major impact.

Minor impact - people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.

Moderate impact - people who use the service experienced poor care that had a significant effect on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.

Major impact - people who use the service experienced poor care that had a serious current or long term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly

We decide the most appropriate action to take to ensure that the necessary changes are made. We always follow up to check whether action has been taken to meet the standards.

Glossary of terms we use in this report

Essential standard

The essential standards of quality and safety are described in our *Guidance about compliance: Essential standards of quality and safety*. They consist of a significant number of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect. A full list of the standards can be found within the *Guidance about compliance*. The 16 essential standards are:

Respecting and involving people who use services - Outcome 1 (Regulation 17)

Consent to care and treatment - Outcome 2 (Regulation 18)

Care and welfare of people who use services - Outcome 4 (Regulation 9)

Meeting Nutritional Needs - Outcome 5 (Regulation 14)

Cooperating with other providers - Outcome 6 (Regulation 24)

Safeguarding people who use services from abuse - Outcome 7 (Regulation 11)

Cleanliness and infection control - Outcome 8 (Regulation 12)

Management of medicines - Outcome 9 (Regulation 13)

Safety and suitability of premises - Outcome 10 (Regulation 15)

Safety, availability and suitability of equipment - Outcome 11 (Regulation 16)

Requirements relating to workers - Outcome 12 (Regulation 21)

Staffing - Outcome 13 (Regulation 22)

Supporting Staff - Outcome 14 (Regulation 23)

Assessing and monitoring the quality of service provision - Outcome 16 (Regulation 10)

Complaints - Outcome 17 (Regulation 19)

Records - Outcome 21 (Regulation 20)

Regulated activity

These are prescribed activities related to care and treatment that require registration with CQC. These are set out in legislation, and reflect the services provided.

Glossary of terms we use in this report (continued)

(Registered) Provider

There are several legal terms relating to the providers of services. These include registered person, service provider and registered manager. The term 'provider' means anyone with a legal responsibility for ensuring that the requirements of the law are carried out. On our website we often refer to providers as a 'service'.

Regulations

We regulate against the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Responsive inspection

This is carried out at any time in relation to identified concerns.

Routine inspection

This is planned and could occur at any time. We sometimes describe this as a scheduled inspection.

Themed inspection

This is targeted to look at specific standards, sectors or types of care.

Contact us

Phone: 03000 616161

Email: enquiries@ccq.org.uk

Write to us at: Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Website: www.cqc.org.uk

Copyright Copyright © (2011) Care Quality Commission (CQC). This publication may be reproduced in whole or in part, free of charge, in any format or medium provided that it is not used for commercial gain. This consent is subject to the material being reproduced accurately and on proviso that it is not used in a derogatory manner or misleading context. The material should be acknowledged as CQC copyright, with the title and date of publication of the document specified.
