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

South East Fertility Clinic Ltd (Amberley House)

Amberley House, 9 Queen's Road, Tunbridge Wells, Kent, TN4 9LL

Tel: 01892614110

Date of Inspection: 26 March 2013

Date of Publication: May 2013

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

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<td>Respecting and involving people who use services</td>
<td>✓</td>
</tr>
<tr>
<td>Care and welfare of people who use services</td>
<td>✓</td>
</tr>
<tr>
<td>Management of medicines</td>
<td>✓</td>
</tr>
<tr>
<td>Requirements relating to workers</td>
<td>✓</td>
</tr>
<tr>
<td>Assessing and monitoring the quality of service provision</td>
<td>✓</td>
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### Details about this location

<table>
<thead>
<tr>
<th>Registered Provider</th>
<th>South East Fertility Clinic Limited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Manager</td>
<td>Mrs. Ruth Hardy</td>
</tr>
<tr>
<td>Overview of the service</td>
<td>South East Fertility Clinic Ltd (Amberley House) provides in vitro fertilisation and other fertility treatments. It is licensed by the Human Fertilisation and Embryology Authority (HFEA), who regulate treatment using eggs and sperm, and of treatment and research involving human embryos. Most of the care provided by the clinic is inspected by HFEA, and we use this to inform our assessment of the service.</td>
</tr>
<tr>
<td>Type of service</td>
<td>Acute services without overnight beds / listed acute services with or without overnight beds</td>
</tr>
<tr>
<td>Regulated activities</td>
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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 26 March 2013, talked with people who use the service and talked with staff. We reviewed information we asked the provider to send to us, reviewed information sent to us by other regulators or the Department of Health and talked with other regulators or the Department of Health.

What people told us and what we found

The service was last inspected by the Human Fertilisation and Embryology Authority (HFEA) on 28 November 2012. The service is licensed to provide in vitro fertilisation (IVF) and other fertility treatments until 30 April 2014.

We were only able to speak with a limited number of people using the service. They were positive about the service they had received. They told us they had received a "100-page booklet" about the service and their own individual pack. They said that "all the information is in there, but you focus on the bits you need" and that it was "very comprehensive". They were clear about what happened during treatment, and how and when to take medication. People said the service was good at communicating, and regularly contacted them at each stage of the process.

The care records we saw showed that the service recorded their consultation with people, which included an explanation of treatment and its outcomes, the likely success rate of pregnancy, and possible risks. We saw that there were standard procedures for carrying out all treatments.

There were effective recruitment and selection processes in place, and appropriate checks were undertaken before staff began work.

The provider monitored the quality of the service. This included reporting clinical information to HFEA, responding to incidents and complaints, and monitoring training needs. People were invited to complete an online survey. We saw that most feedback from this was positive.

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

Respecting and involving people who use services  ✔  Met this standard

People should be treated with respect, involved in discussions about their care and treatment and able to influence how the service is run

Our judgement

The provider was meeting this standard.

People's privacy, dignity and independence were respected. Their views and experiences were taken into account in the way the service was provided and delivered in relation to their care.

Reasons for our judgement

People who use the service were given appropriate information and support regarding their care and treatment. We saw that extensive information was available for people who used the service and their partners. The clinic had its own website which included information about treatment and a guide to fees. There was a detailed downloadable book about the assisted conception procedures and the services that it provided.

Staff told us that at a person's consultation they went through the procedures, and gave them a booklet that focused on the particular treatment they received. We saw an example of the booklet given to people who received in vitro fertilisation (IVF). This contained detailed information about treatment and aftercare, which included what to do if they were concerned and possible complications. The booklet included a personalised treatment plan and a checklist of the information they had been given, which they and their partner were asked to sign. The person kept the book and brought it with them when they had treatment.

People who used the service understood the care and treatment choices available to them. We were only able to speak with a limited number of people using the service. They told us they had received a 100-page booklet about the service, and then when they started treatment they had been given their own individual information pack. They said that "all the information is in there, but you focus on the bits you need" and that it was "very comprehensive". They were clear about what happened during treatment, and how and when to take medication. They said the service was good at communicating, and regularly contacted them at each stage of the process. They told us there was information in the booklet about how to complain, and that they felt able to speak with staff if necessary.

The manager told us that information wasn't routinely available in other languages. However, on their appointment letter people were asked if they had any special needs, which included language, so they could make this available on an individual basis.
People's dignity was promoted. We saw that blankets were available for women to cover themselves during procedures, and the scanning room had ensuite toilets. Staff told us that when the men's donation room was in use, a light went on outside so that staff did not inadvertently enter.

Staff told us that many of their treatments were provided to couples, but each person had an individual care record. Staff told us this was to maintain confidentiality in the event of a relationship ending, particularly if one of the people attended for further treatment with another partner.

People's diversity, values and human rights were respected. The manager told us that they provided treatment to both heterosexual and homosexual couples, and single women. The service provided both privately funded and NHS treatment. There were some limitations as to whom and what treatment was provided that were out of their control for NHS funded treatment.
Care and welfare of people who use services  ✔ Met this standard

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

Our judgement

The provider was meeting this standard.

People experienced care, treatment and support that met their needs and protected their rights.

Reasons for our judgement

The service was last inspected by the Human Fertilisation and Embryology Authority (HFEA) on 28 November 2012. The service was currently licensed to provide in vitro fertilisation (IVF) and other fertility treatments until 30 April 2014.

Care and treatment was planned and delivered in a way that was intended to ensure people's safety and welfare. We were only able to speak with a limited number of people using the service. They were positive about the service they had received. Staff walked us through the pathway of care for a person having IVF treatment. This began with a consultation, scan and provision of information from a nurse and doctor. The woman was then sedated (though still conscious) whilst her eggs were removed. The embryologists analysed the eggs and semen samples, and provided the person/couple with information and advice about their findings, and the next stages of treatment.

People's needs were assessed and care and treatment was planned and delivered in line with their individual care plan. The nurse told us that they discussed and completed the HFEA consent forms with the woman/couple. They explained the full cycle of treatment to them which included scans, medication, injections, possible side effects, egg collection and transfer. They also provided any pertinent life style advice, for example about how diet or smoking may affect fertility.

The doctor told us that after a consultation with the nurse, person/couple would meet with the doctor. The doctor took details of the woman and man's medical history which included any previous pregnancies and medical tests. They discussed the chances of the person having a successful pregnancy. We saw an example in the case records where the person had been advised that their chances of a successful pregnancy were very low.

The sample of care records we looked at showed that the service recorded the outcomes of their consultation with people, which included an explanation of treatment and its outcomes, and if there were any complex issues. We saw that in the electronic record system there was a checklist where it recorded that relevant information had been discussed. This included the likely success rate of pregnancy, and possible risks such as multiple pregnancies and ovarian hyperstimulation syndrome (OHSS).
Care and treatment was planned and delivered in a way that was intended to ensure people’s safety and welfare. Staff told us that the service used local anaesthetic and sedation for some treatments, such as egg collection, but did not use general anaesthetics. We saw that there were standard procedures for all treatments, which included surgical procedures, which staff told us ensured they provided correct and consistent care. Staff told us that there was an allocated theatre nurse for each session. Every theatre nurse completed a checklist to confirm that the theatre was adequately prepared before the person was treated. The sample of checklists we looked at had all been fully completed.

After the egg collection the woman sat in a private room and recovered, where she was monitored by nursing staff. The laboratory staff analysed the eggs and semen, and carried out the process of fertilising the eggs. They then contacted the woman/couple and discussed what they had found, what the woman needed to do, and when they needed to come back to the clinic to have the egg transferred back. The procedure for transferring fertilised eggs back into the woman did not require the use of anaesthetic.

People's care and treatment reflected relevant research and guidance. Staff told us that new ideas and information were discussed within the teams. We saw evidence of discussion of practice in minutes of meetings. We were told that they had introduced a standard template for presenting proposals to the board, which included a business case, costs, and an impact statement. The clinical director gave an example of how they had introduced the technique of ‘scratching’ the endometrium, or womb lining, as research had found that this may increase the chance of a successful pregnancy in some women.

There were arrangements in place to deal with foreseeable emergencies. Staff told us that the service provided was relatively low risk, but there was an emergency procedure if a person was unwell. For example if a person had a reaction to the medication used, there was always a doctor available when the procedure took place. Staff told us that if there was a medical emergency, all staff had completed basic life support training, some of the nurses had completed immediate life support training, and the doctors had completed advanced life support training. This was confirmed in the training records.

We saw that there was an emergency kit with oxygen, suction and emergency drugs. The emergency kit included emergency drugs to take in the event of a reaction to the medication used in treatment. They were provided in pre-filled syringes so that they could be given quickly. We saw that these were routinely checked, and were all in date. Staff told us that the emergency equipment was checked by the theatre nurse before each session, which was confirmed by the sample of checklists we looked at.
Management of medicines

| Met this standard |

**People should be given the medicines they need when they need them, and in a safe way**

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**Our judgement**

The provider was meeting this standard.

People were protected against the risks associated with medicines because the provider had appropriate arrangements in place to manage medicines.

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**Reasons for our judgement**

Medicines were safely administered, and people received support to administer their own medication. People were trained to give themselves injections at home, during their consultation with the nurse. We were only able to speak with a limited number of people using the service. They told us it had been clearly explained to them about how to give themselves injections. We saw an example of a patient information booklet for people receiving IVF treatment. This included detailed information, including diagrams, about how to self administer a subcutaneous injection, which was given just under the skin. There was a form for people to record when they’d had medication.

Appropriate arrangements were in place in relation to obtaining medicine. The manager told us they had a contract with a pharmacy service for the supply of medication. People told us they used the pharmacy service, but could source their own medication if they wished. We saw a demonstration bag of medication in the consultation room, which nurses used to show people what to expect when they had their medication delivered. Staff demonstrated how they safely recorded and labelled medication when people were provided with it directly from the service. We saw an example of printed labels that included information about what the medication was, when it should be taken, and who it was for.

Appropriate arrangements were in place in relation to the recording of medicine. Staff told us there were standard procedures in place for handling medication. The doctor prescribed medication for people during their consultation. Staff demonstrated how this was processed and recorded on both paper and electronic record systems. From this it was clear who had prescribed, supplied and administered each medication.

Medicines were kept safely. We saw that there were adequate and secure storage facilities for medication, which included controlled drugs and medication that needed to be refrigerated. The provider may find it useful to note that the medication fridge was unlocked, although it was kept in a locked cupboard. We saw that fridge temperatures were regularly monitored, and were within the correct range. We saw that there were processes for the secure handling of controlled drugs. Staff explained the process for ensuring stock levels remained adequate, and showed us how routine stock checks of medication were carried out.
Medicines were disposed of appropriately. There were processes for the disposal of medication, which included controlled drugs. Medication was disposed of through the use of a 'denaturing kit' which prevented the drug from being usable. The service had a contract for the disposal of waste, which included the kits.

The incident records showed that an issue had arisen with out of date medication, and how this had been resolved. Out of date medication had not been given to people using the service, but the processes for checking and rotating medication had been reviewed to reduce wastage.
Requirements relating to workers

People should be cared for by staff who are properly qualified and able to do their job

Met this standard

Our judgement

The provider was meeting this standard.

People were cared for, or supported by, suitably qualified, skilled and experienced staff.

Reasons for our judgement

There were effective recruitment and selection processes in place, and appropriate checks were undertaken before staff began work. The service had computer software packages for monitoring staff information. The manager described the procedures for recruiting staff, and we saw how this was documented on the electronic system. The manager showed us that all staff had had the necessary recruitment checks before they started working in the service. This included proof of identification, confirmation of professional registration and qualifications where necessary, and police checks.

We saw that the service had a contract with an NHS trust for the provision of an occupational health service, which included medical screening. The manager said the service screens for and, if necessary, provided vaccinations and top ups for staff. The manager showed us the questionnaire that staff completed when they were screened by the occupational health service. This included reviewing the person's general health and checking their vaccination status.

The manager showed us that the computer system flagged up when staff's professional registrations were due for renewal. For example, nurses must renew their registration to practice every three years, and pay an annual registration fee. When a renewal was due, the service checked that this had been completed.

New staff received an induction to the service to prepare them for their role. Staff told us that all new staff had a general induction, with specific training and support provided depending on their profession and experience. Staff told us there was a competency framework that they must work through and complete. We were shown an example of this for a new member of staff, and saw that competencies and training were recorded on the electronic system.
Assessing and monitoring the quality of service provision

The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care

Our judgement

The provider was meeting this standard.

The provider had an effective system to regularly assess and monitor the quality of service that people receive. This included identifying, assessing and managing the risks to the health, safety and welfare of people who use the service and others.

Reasons for our judgement

There were processes in place for monitoring the quality of the service which identified and resolved problems, and made improvements. The service used a computer system to monitor and track the quality of the service provided. This included clinical information that must be reported to the Human Fertilisation and Embryology Authority (HFEA), incidents, complaints, staff competencies and training.

The service held a programme of meetings which, obtained feedback from staff and reviewed the quality of the service. These consisted of monthly departmental and management meetings with quarterly quality meetings. We saw examples of minutes from these meetings which showed that all aspects of the service were discussed, and information from audits, incidents and complaints were shared. There was a quality manager who produced a quality report covering all aspects of the service which included clinical outcomes, staffing, incidents, complaints and finance. In addition an all staff meeting took place twice a year, which focused on the strategy of the service.

Decisions about care and treatment were made by the appropriate staff at the appropriate level. The clinical director told us there was a weekly clinical review meeting held with medical, nursing and embryology staff where they looked at records and embryology findings to see if there were any concerns or particular issues that needed to be addressed.

People who used the service, their representatives and staff were asked for their views about their care and treatment and these were acted upon. There was a comments box in the waiting area, however the manager said they received very few comments through this. The service had set up an online satisfaction survey that people could log into. The manager told us that the feedback was presented at the quarterly quality meetings, and the twice-yearly staff meetings. The survey was ongoing, so the results were collated when required. We looked at a summary of feedback since June 2012. There had been 36 responses from people who used the service, most of whom were satisfied with the information they had received and were positive about the staff. There were some negative comments, though these were relatively minor and included breakdowns in
The provider took account of complaints and comments to improve the service. There was information about how to complain and how to contact HFEA in the waiting room. The manager told us that the number of complaints they received had reduced. She said many of the complaints had been about their financial information and waiting times, so they now provided people with an Estimated Treatment Cost plan, and had reduced waiting times for scans. The manager said that people see staff at least ten times during a cycle of treatment, so they tried to identify and resolve issues as they arose. One of the nursing staff said they sometimes received complaints but also lots of compliments. Staff told us that people often wanted to see the same nurse each time they came to the service, but this wasn't always possible.

There was evidence that learning from incidents / investigations took place and appropriate changes were implemented. The manager showed us how incidents were recorded in the computer system and where they could be tracked and monitored. This identified the concern, the action taken to address it, a route cause analysis of why it happened, and who was responsible for ensuring action was taken and followed up. A date was set for review, so that the staff responsible could check the problem had been resolved. The manager and staff described examples of how they had learnt from incidents and made changes to the service. On the computer system we saw examples of minor incidents or complaints, and the action the service had taken to resolve them and prevent their reoccurrence. We saw that these were discussed and followed up in the quality and managers' meetings.
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 dentists and other services at least once every two years. 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 but we always inspect at least one standard from each of the five key areas every year. We may check fewer key areas in the case of dentists and some other services.

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. We make a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation) from the breach. 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:

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**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.