Transform Milton Keynes

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Summary of findings

Letter from the Chief Inspector of Hospitals

Transform Milton Keynes is operated by TFHC Limited. The service provides cosmetic surgery outpatients and diagnostic services. The service has no beds or wards. Facilities include two clinical consulting rooms and administrative areas.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 2 May 2017 along with an unannounced visit to the clinic on 12 May 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

We regulate cosmetic surgery services but we do not currently have a legal duty to rate them. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following issues that the service provider needs to improve:

- Patient information was not always kept confidentially or securely.
- There were no arrangements in place to allow patients who did not speak English to consent for procedures and family members were permitted to consent on patients' behalf.
- A significant amount of equipment was found to be past its expiry date and there were no stock management systems in place to prevent this occurring.
- We could not be assured safeguarding training was in line with national guidance. Staff did not have an understanding of the level of safeguarding training they required to carry out their roles or an understanding of the level of safeguarding training they had received. Staff were unaware of a safeguarding policy in place to assist them.
- There were a number of governance concerns identified during the inspection in relation to identifying risks within the service, such as monitoring of did not attend rates and access to up to date policies.
- There were no clear risk registers or strategies at corporate or local level.
- There were not clear mechanisms in place for learning from incidents or complaints.
- Cleaning equipment was not stored in a secure way, leaving it accessible to patients using both services located in the building.
- Patient feedback was not routinely collected or monitored within the service.
- There were not clearly defined responsibilities for the shared premises.

However, we found the following areas of good practice:

- Patients were provided with choices with regard to location and which surgeon would carry out their procedures. Evening and weekend clinics were available.
- There was a wide range of written information for patients to take away and use to inform their decisions.
- There was a good culture among staff, who enjoyed their roles within the organisation.

Summary of findings

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with four requirement notices that affected cosmetic surgery outpatient services. Details are at the end of the report.

Heidi Smoult
Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Outpatients and diagnostic imaging		We do not currently have a legal duty to rate cosmetic surgery services. We found that: • Patient information was not always kept confidentially or securely. • There were no arrangements in place to allow patients who did not speak English to consent for procedures and family members were permitted to consent on patients' behalf. • A significant amount of equipment was found to be past its expiry date and there were no stock management systems in place to prevent this occurring. • There were a number of governance concerns identified during the inspection in relation to identifying risks within the service, such as monitoring of did not attend rates and access to up to date policies. • We could not be assured safeguarding training was in line with national guidance. Staff had received computer-based safeguarding training however they did not have an understanding of the level of safeguarding training they required to carry out their roles or an understanding of the level of safeguarding training they had received. • There was not a corporate or local level strategy in place. • There were not clear mechanisms in place for learning from incidents or complaints. • Cleaning equipment was not stored in a secure way, leaving it accessible to patients using both services located in the building. • Patient feedback was not routinely collected or monitored within the service. • There were not clearly defined responsibilities for the shared premises. • Staff were not aware of what level of safeguarding training they had completed and the provider could not clarify this for us. However:

Summary of findings

- Patients were provided with choices with regard to location and which surgeon would carry out their procedures. Evening and weekend clinics were available.
- There was a wide range of written information for patients to take away and use to inform their decisions.
- There was a good culture among staff, who enjoyed their roles within the organisation.

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Background to Transform Milton Keynes

Transform Milton Keynes is operated by TFHC Limited. The service was previously located within an independent hospital but had relocated to its current location in 2016. The service primarily serves people in Milton Keynes and surrounding areas.

The service has had a registered manager in post since the location registered in 2016.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector,one other CQC inspector, and a specialist advisor with expertise in cosmetic surgery. The inspection team was overseen by Julie Fraser, Inspection Manager.

Information about Transform Milton Keynes

The service has two clinical consulting rooms and was registered to provide the following regulated activity:

- Surgical procedures

During the inspection, we reviewed all areas of the service. We spoke with three staff including the registered manager who was also a registered nurse, a surgical co-ordinator and a member of the administrative team. We spoke with two patients who were using the service. We also received 20 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed six sets of patient records.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The service had not previous been inspected by the CQC since its registration in 2016.

Activity

- In the reporting period January 2016 to December 2016 there were 630 outpatient total attendances.

Five consultant surgeons worked in the service under practising privileges. The service employed one registered nurse, one surgical co-ordinator and two administrative staff.

Track record on safety

- No Never events
- No clinical incidents
- 10 complaints
- No serious injuries

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Maintenance of medical equipment
- Pathology and histology

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following issues that the service needs to improve:

- Equipment was not managed in a way to ensure its suitability for use. A significant amount of equipment was found to be past it expiry date.
- The service did not have a service level agreement with the co-located salon that shared some clinical areas; this meant there were not clear boundaries of responsibility.
- We could not be assured safeguarding training was in line with national guidance. All staff had received computer-based training however staff did not have an understanding of the level of safeguarding training they required to carry out their roles or an understanding of the level of safeguarding training they had received.
- Staff were unaware of a safeguarding policy in place to support them.
- The service shared patient information with the co-located salon without consent of the patient or any confidentiality agreement in place.
- Patient records were not always stored securely.
- We did not see clear mechanisms in place to share learning across the organisation.
- We were not assured that safeguarding training was in line with national guidance.

However we also found the following areas of good practice:

- There was a system and supporting policy for reporting untoward incidents within the service.
- The service was visibly clean and tidy. An infection control policy was in place that outlined staff responsibilities.
- All staff were up to date with mandatory training.

Are services effective?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following issues that the service needs to improve:

- Consent to treatment was given by a patient's friend or relative if they did not speak English which was not in line with best practice.

Summary of this inspection

- Patient outcomes were not routinely collected or monitored and we saw no evidence of outcomes being discussed at clinic meetings.
- Some policies and guidelines within the service were out of date.

However we also found the following areas of good practice:

- There was an annual audit programme.
- All staff had received their annual appraisal. Learning needs of staff had been identified during their appraisal, but were not always met.
- Current evidence based guidance was used to provide patients' care and treatment.

Are services caring?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following areas of good practice:

- Staff within the service demonstrated kind and non-judgemental attitudes towards patients.
- Patient feedback was positive about the service provided.
- Patients were given time to make decisions about their care and told us they felt well supported to make decisions.

Are services responsive?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following issues that the service needs to improve:

- The service did not always take into account patients' individual needs. Translation services were not available and there was no disabled access to the clinic.
- There was a policy in place for managing complaints and patients knew how to make a complaint should they wish. However, we saw no evidence of discussions relating to complaints and learning from complaints was not identified.

However we also found the following areas of good practice:

- Evening and weekend consultations and post-operative appointments were available.

Are services well-led?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following issues that the service needs to improve:

Summary of this inspection

- The service did not have a risk register in place at corporate or local level. Staff could not describe the key risks to the service at a local or corporate level.
- Whilst several key governance and clinical meetings were carried out at a corporate level, the service was not involved in these. Clinic meetings were carried out but these were not held on a regular basis.
- There was not a corporate or local level strategy in place.
- There was not clear oversight of quality indicators within the service.
- The service did not routinely collect or monitor patient feedback.

However we also found the following areas of good practice:

- There was a good culture among staff in the service; staff told us they enjoyed their roles.
- Patients gave positive feedback about the service provided.
- There was a corporate level governance framework in place to support the service.

Outpatients and diagnostic imaging

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are outpatients and diagnostic imaging services safe?

Incidents

- The service had a system in place for reporting incidents. There was a corporate level policy that detailed the system and the procedures for reporting and investigating incidents.
- There had been no incidents reported between January 2016 and January 2017. Staff understood their responsibility to report concerns, safety incidents and near misses.
- We asked staff if any learning from incidents was shared across the service if they occurred, or if themes were provided from a corporate level for learning. Staff told us that incidents were sometimes discussed at clinic meetings but they could not recall any recent learning.
- From March 2015, all independent healthcare providers were required to comply with the Duty of Candour Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person.Staff were aware of the duty of candour regulation (to be open and honest) ensuring patients received a timely apology when there had been a defined notifiable safety incident.

Cleanliness, infection control and hygiene

- All areas of the service were visibly clean and tidy. Domestic staff were contracted from an external provider. We observed cleaning schedules that domestic staff adhered to and documented when they had cleaned an area.
- Cleaning equipment was stored within the patient and staff toilet. This meant that patients and visitors could access cleaning materials.
- Staff completed Control of Substances Hazardous to Health training if necessary for their role.
- Cleaning of medical equipment including blood pressure cuffs and scales was the responsibility of nursing staff and consultants after each patient use. There was a daily decontamination check sheet that staff were required to complete daily. We reviewed check sheets from March 2017 to April 2017 and found all days were completed. There was no process in place to demonstrate which items of equipment had been cleaned after each patient use. We observed that disinfectant wipes were available within the service to clean equipment and trolleys in line with national standards.
- Personal protective equipment (PPE), including gloves and aprons, was available in clinical consulting rooms. Staff knew when to utilise PPE during patient care.
- The most recent infection control audit was carried out in September 2016, which showed 99% compliance. These audits were carried out twice yearly; therefore regular ongoing compliance was not monitored closely to provide day to day assurance.
- The service had an infection control policy in place and staff knew how to access this. Alcohol hand gel and handwashing facilities were available in both clinical consulting rooms.

Environment and equipment

Outpatients and diagnostic imaging

- The facilities and premises was shared with a beauty salon which did not require CQC registration. This meant that one clinic room, some staff areas, waiting areas and toilet facilities were shared with staff and clients from the beauty salon.
- There was not a service level agreement (SLA) in place to clearly document boundaries, roles and responsibilities in relation to shared areas. This meant that it was not clear who was accountable for equipment and suitability of the environment in shared areas.
- When patients arrived in the building they attended the beauty salon reception where they were required to provide their full name. The beauty salon staff would then telephone or go up to Transform staff and inform them of the patient's arrival. During this time, patients were required to remain in the beauty salon waiting area along with their clients. Beauty salon staff were provided with a list of patient names each day, there was no documented agreement in place to ensure beauty staff would keep this information secure and confidential. Therefore we were not ensured that patient privacy was maintained at all times.
- Once Transform staff were aware of the patient's arrival they would then be taken upstairs to another waiting area. This area was shared with the beauty salon and was located with their manicure and pedicure areas. The clinic manager felt this was inappropriate for patients and was looking to work with the beauty salon to find a resolution but due to space constraints, this was difficult to resolve quickly.
- There were systems in place to ensure the safety and maintenance of portable items of equipment. The service had an SLA with a medical devices maintenance provider to support this.
- During our inspection, we found over 400 individual items of disposable equipment to be past their expiry date within the two clinical consulting rooms. These items included; syringes, dressing, blood sample tubes, nasal speculums, swab taking equipment and needles. The dates on these items ranged from October 2010 to April 2017.
- Effective systems and arrangements were not in place for managing equipment. Within daily clinic room check sheets there was a section relating to ensure some items of equipment were in date. This section was marked as complete on check sheets from March 2017 to April 2017. This was not accurate as we found items of equipment listed to be past their expiry date. We escalated concerns relating to equipment immediately to the registered manager who took action to remove these items and dispose of them appropriately.
- Arrangements were in place for managing clinical waste and the service had a policy, which outlined key staff responsibilities relating to this. Each clinic room had sharps and clinical waste bins for safe disposal of clinical and potentially infectious waste. Once this was full, waste was transferred into an outside secure large clinical waste bin. There was an SLA in place for an external company to collect clinical waste at required intervals.

Medicines

- Due to the nature of the service, only two medicines were stocked. We observed that these were both within their expiration date and stored securely with only qualified staff having access.
- The service did not store or use any controlled drugs or medicines that required refrigeration.
- An oxygen cylinder was stored within a resuscitation bag for use in emergencies only. We observed this was ready for use and within its expiry date.

Records

- Records were not always stored securely or in a way that maintained patients' confidentiality.
- There were processes in place for storage of records. There was secure storage within the administrative office for all patient records and associated documents. These were clearly labelled and accessible only to authorised staff.
- During our inspection, we found 10 items of patient confidential information within one of the clinical consulting rooms in an unlocked drawer next to where patients would sit. This meant unauthorised persons could access them. We escalated this immediately to the registered manager who removed the information from the clinic room.

Outpatients and diagnostic imaging

- We reviewed six sets of patient records. We found these to be complete, legible and contemporaneous. All consultant and anaesthetic notes remained at the hospital where the patient received their surgery.

Safeguarding

- We were not assured that there were appropriate safeguarding arrangements in place within the service. Two staff had completed safeguarding adults training, but were unsure what level of training this was. We requested this data but the provider was unable to advise us on the safeguarding level staff had completed. The service did not see patients under the age of 18 years; however children did accompany adults to their appointments within the service.
- There was not a safeguarding policy on site at the time of inspection. The provider informed us there were working practices available to staff titled Adult Protection Procedure and Protection of Children however they were not provided to us despite our request for a safeguarding policy and staff were not aware of them. There was information about safeguarding vulnerable adults within the consent policy. We saw brief local guidance on how to contact the local authority if they had a safeguarding concern however this guidance did not contain the full details of what to report or steps that must be taken.
- Staff within the service were not aware whether there was a safeguarding lead at a corporate level or whom they would approach for further safeguarding support and information.
- There were posters to advise staff on how to make a safeguarding referral if they identified a patient at risk of abuse. This involved informing the relevant local authority for the area.
- Staff told us that patients were discouraged from bringing children with them to consultations but this could not always be prevented. Staff stated that if they had a concern about a child they would report this to the local authority as with an adult referral.
- Staff showed an awareness of female genital mutilation, human trafficking and child exploitation, but were not sure if this was covered in their training or they just learnt from other colleagues.

Mandatory training

- Staff completed mandatory training in areas such as; fire safety, equality and diversity, infection control and basic life support.
- All staff were up to date with all relevant mandatory training subjects for their role.
- Staff training was all e-learning and staff knew how to access this. Staff would receive a flag on their account if they were due/over date for a training module.

Assessing and responding to patient risk

- Patients were risk assessed prior to confirming their suitability for cosmetic surgery.
- Patients were initially seen by the surgical co-ordinator for their initial consultation. The co-ordinator worked from a patient selection criteria to determine whether a patient was suitable for the requested service. This criteria detailed areas such as; a patient's body mass index, cardiac history, allergies and previous surgeries. The co-ordinator was not responsible for advising a patient if they were unsuitable for surgery but would refer to the nurse or consultant for further guidance. Some medical conditions meant that the service would require a GP letter to proceed with any treatment, patients were informed and consent requested if this was the case.
- If any concerns were found during the patient's pre-operative appointment with the nurse, they would be escalated to the consultant surgeon to assess whether the patient was still suitable for surgery.
- Staff showed awareness of providing services to patients with psychological conditions. If a patient had a history of psychological disorders, the service would require a GP letter to explain whether they were having ongoing treatment or whether the condition was no longer a concern. Staff would refer patients back their GP if they felt the patient was unsuitable or required counselling.
- There was a deteriorating patient guideline for staff to use in the event of a medical emergency; however, the copy in the clinic was due for review in 2015. The guideline stated staff should remain with the patient and call 999. There was emergency equipment for anaphylaxis available, along with basic resuscitation equipment.

Outpatients and diagnostic imaging

Nursing staffing

- There was one qualified nurse for the service, who was also the clinic and registered manager. We observed that their revalidation was complete and up to date.
- If the nurse was off sick or on annual leave then patients would be seen at another Transform location.

Medical staffing

- Five consultant surgeons worked under practising privileges within the service. One consultant surgeon had been on long term sick and was not working at the service at the time of our inspection.
- Staff and patients could access the resident medical officer at the hospital where their surgery was carried out if they had any immediate concerns about the operation or any ill effects they were feeling post operatively.

Emergency awareness and training

- The service had a fire safety policy in place. Staff received fire safety training, fire marshal training and also took part in fire drills. We observed that fire extinguishers were available and had been serviced at the necessary intervals.
- The service did not have a business continuity plan in place. The registered manager advised us that they were looking at doing a joint piece of work with the beauty salon to set out responsibilities in relation to flooding, loss of electricity/water, but this had not yet been started.

Are outpatients and diagnostic imaging services effective?

Evidence-based care and treatment

- Policies and guidelines for staff were developed in line with relevant and current evidence based guidance and standards, such as the National Institute for Health and Care Excellence (NICE) best practice guidance. However, some policies displayed were out of date. For example, the medical emergency policy and procedure was dated 2015 and the daily decontamination procedure which was dated February 2016. We raised this with the registered manager who told us that they only print out new policies once sent from headquarters.
- Preoperative assessments and discussions between patients and the nurse were in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016) guidance and included asking the patient why they wanted the intervention and the outcome they hoped for.
- Care was managed and the patient selection criteria that had been developed was in line with NICE guidelines NG45: Routine preoperative tests for elective surgery (April 2016).
- The recording and management of medical device implants was in line with the RCS Professional Standards for Cosmetic Surgery (April 2016). Patients who received implants had details included on the Breast and Cosmetic Implant Registry.
- Preoperative tests were managed in accordance with NICE guidance CG3. Past medical histories were taken to identify any ongoing or previous medication history. Women were asked whether they could be pregnant, and pregnancy tests were available.
- Staff we spoke with said the needs of patients were assessed and their care was planned and delivered in line with best practice guidance. We were told this was monitored by carrying out an annual audit of clinic nurse records and the surgical patient coordinator records however; the audits had not yet been completed.
- People were supported to be as fit as possible for surgery. For example, patients were informed of the risks associated with smoking and drinking alcohol and how this could impact their outcomes.
- Initial consultations with the patient coordinator and pre-operative assessments with the nurse and surgeons included documenting relevant psychiatric history and discussions about body image in line with best practice guidance. The clinic required a letter from the patients GP or appropriate specialist if they had, or historically had, a psychiatric or psychological medical condition.
- Patients were given a two week cooling-off period to allow time to reflect on the information provided prior

to making a final decision. This was in line with the RCS Professional Standards for Cosmetic Surgery, which sets out the requirement for a two-week cooling off period, between deciding to have cosmetic surgery and the procedure taking place.

- We requested information in relation to how patients with suspected sepsis were screened and managed appropriately however we did not receive this.

Pain relief

- Patient feedback was not captured specifically on pain relief.
- Transform Milton Keynes did not provide pain relief to patients. If a patient presented with pain, the nurse would contact the patient's surgeon or the resident medical officer (RMO) at the hospital where the operation took place who was then able to discuss pain relief options with the patient.

Nutrition and hydration

- Patient feedback was not captured specifically on nutrition and hydration.
- The nurse told us nausea and vomiting following surgery was managed at the location of surgery.

Patient outcomes

- Transform Milton Keynes did not participate in any national audits.
- Information about the outcomes of people's care and treatment was not routinely collected. Outcomes were not monitored or discussed at a local level therefore staff could not be assured that intended outcomes were being achieved.
- There were no cases of Milton Keynes clinic patient's unplanned returns to the operating theatre or unplanned readmission within 28 days of discharge. The clinic did not collect data on planned returns to the operating theatre if a patient was dissatisfied with their outcome of their procedure.
- Staff were unaware of how outcomes of Transform patients compared to other similar services and Transform Milton Keynes did not participate in any local benchmarking.
- The service did not routinely collect quality patient reported outcome measures (Q-PROMs) however, we were told that a system was being developed to collect and collate this information. Q-PROMs are a patient's own measurement of their health and health-related quality of life, and how this has been changed by a cosmetic surgery intervention.
- The service had an annual audit programme however most audits were only completed once annually. This included infection control, consent, records and pregnancy screening audits. Audits were completed by the clinic nurse however they were not verified and involved the clinic nurse reviewing their individual compliance.
- The provider submitted data to the Private Healthcare Information Network (PHIN). For example, the percentage of patients who had their procedure performed as a day case and critical care arrangements. Patients were required to sign a consent form to confirm their agreement for Transform to submit their data to PHIN. PHIN became a legal requirement in September 2016.
- Clinical and quality audits were not discussed locally however they were discussed at corporate clinical governance meetings.
- Surgical site infection rates for Transform patients nationally were below 1% in February 2016. There were no reported surgical site infections for Transform Milton Keynes patients from January 216 to December 2016.

Competent staff

- There was an induction programme for newly appointed clinical and non-clinical staff.
- All staff had received an appraisal within the last 12 months. Staff we spoke with said their learning needs were identified during their appraisal meetings.
- We saw evidence that learning and development needs were not always met. For example, management training was not provided despite being identified and documented as a learning need during a staff member's appraisal.
- Staff did not always have appropriate training to meet their learning needs, for example management training. Transform's training and development policy stated that

different staff roles were offered role-specific training when new products and services were introduced to enable staff to confidently undertake their roles. However records showed that role specific training topics were not always updated. For example, a member of staff had not received finance or sales training for over 12 years.

- As part of an annual appraisal, the clinic nurse received clinical supervision annually from a lead clinic nurse who was located in a different Transform clinic. Clinical supervision included wound care, aseptic technique, infection prevention and control and patient care.
- A senior member of Transform staff managed poor performance. Meetings with staff members were recorded and actions taken were documented clearly.
- We saw no evidence of arrangements in place to ensure local healthcare providers were informed of cases where a staff member was suspended from duty. However, staff informed us that they had never encountered a staff member being suspended.
- All surgeons provided care under a practising privileges agreement and were reviewed every two years. All surgeons working at Transform Milton Keynes had received an appraisal within the last 12 months.
- All surgeons at Transform Milton Keynes had operative exposure in their individual areas of certification as recommended by the RCS. Operative exposure is determined by the experience of surgeons to carry out specific procedures and the number of procedures they have performed.
- Each surgeon had a profile outlining their professional qualifications, professional bodies, General Medical Council (GMC) number and the number of procedures they have performed. All surgeons were registered with the GMC, which meant patients could be assured that registered practitioners treated them.

Multidisciplinary working

- A range of different staff were involved in assessing, planning and delivering care and treatment. This included surgeons, nurses, GPs, specialists, coordinators and administrative staff.
- The clinic staff worked with patients GPs and specialists, where the patient gave consent, to ensure information was shared about their relative medical history pre and post-surgery.
- There were joint working practices and agreements in place with other Transform clinics. For example, a clinic nearby often helped cover annual leave and sickness to ensure patients were seen.
- The nurse worked with the RMO at the hospital and a lead clinic nurse in a different Transform clinic when advice and support was required.
- Staff at Transform Milton Keynes were informed when their patients were discharged from hospital following a procedure.
- Some information was shared with Transform Milton Keynes about other Transform clinics via the cascading of clinical governance minutes. For example, incidents and surgical site infection data.
- Staff we spoke with understood that the surgeon carrying out the patient's procedure had overall responsibility of care.

Access to information

- Hard copies of patient records were stored in the administrative office and were accessible to relevant staff such as the nurse and surgeons.
- Patient records were scanned and sent securely and electronically to the hospital prior to the date of their surgery. Surgical notes were sent electronically to the clinic following their procedure and were filed in the patient's record.
- Patients who had consented to the sharing of information with their GPs had their pre-operative and post-operative discharge letters sent by post to their GP practice. We were unable to identify how soon after discharge the letters were sent to a patient's GP.
- Blood samples and MRSA swabs were sent to a laboratory at an independent hospital and results were accessed electronically.
- Transform policies and working practices were accessible to all staff. They were stored on the intranet and staff were able to tell us how they could be located.

Outpatients and diagnostic imaging

- Patients were able to view their own records and could make a written request for a copy of their records should they wish in line with the Transform patient access to medical records policy. However, the policy was out of date, at the time of our inspection and had not been reviewed since March 2015.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Patients received verbal and written information relating to their procedure. Patients were required to sign a disclaimer to confirm they had provided an accurate and complete health history. They were also required to confirm they understood the impact of withholding any medical information and the risks this posed during their procedure.
- There were no translation services available for patients who did not speak English. Staff we spoke with said patients who required an interpreter usually attended with a friend or relative. This meant there was a risk that patients were not consenting to their own treatment and a friend or relative was verbally consenting on their behalf however the patient was required to sign the consent form. This was not in line with the Transform consent policy, which stated patients were able to access translators when required.
- We saw evidence that surgeons had explained the associated risks to patients prior to agreeing to go ahead with surgery. This was documented in the patient's notes and patients were required to sign to confirm they understood.
- Patients were given a two week cooling-off period between the consultation and committing to the procedure, to allow them time to reflect on the information prior to making a final decision. This was in line with The RCS Professional Standards for Cosmetic Surgery.
- The coordinator explained to each patient the benefits of sharing information with patients' GPs. Patients were encouraged to sign a consent form detailing their agreement for information to be shared with their GP.
- Pre, intra-operative and post-operative photographic consent was requested from patients however this was not a requirement.
- The nurse had an understanding of the Mental Capacity Act 2005. However, staff we spoke with said they had never been required to assess a patient's capacity to make decisions or consent to treatment.
- The clinic manager reviewed ten sets of patient notes in relation to informed patient consent. In March 2017, the results showed 99% compliance.

Are outpatients and diagnostic imaging services caring?

Compassionate care

- We observed staff providing friendly and considerate care to patients within consultations.
- Staff were non-judgemental when discussing cosmetic surgery options with patients.
- We observed consultation and treatment room doors were closed during consultations and that conversations taking place in these rooms could not be overheard.
- Staff took steps to maintain patients' privacy and dignity during examinations, investigations and treatments.
- We received 20 comment cards from patients who had used the service. These were all positive and comments were very complimentary of staff within the service.

Understanding and involvement of patients and those close to them

- Staff allowed patients relatives or friends to attend appointments for support if required.
- Patients were provided with time to ask any questions about their intended procedure and realistic expectations were explained to patients during consultations.

Emotional support

- Comments from patients told us that they felt well informed about the treatment they were receiving. Patient also stated they felt staff listened to and addressed their concerns or worries prior to and post procedures.

Outpatients and diagnostic imaging

- Patients we spoke with told us that they felt staff spent as much time as necessary with them and they were not rushed into making decisions.

Are outpatients and diagnostic imaging services responsive?

Service planning and delivery to meet the needs of local people

- The clinic was open in the evenings and at weekends to provide flexibility and choice for patients that were unable to attend during the day. The nurse told us this reflected the needs of the population served.

Access and flow

- Patients self-referred to the clinic by contacting the Transform contact centre who would pass their details to the coordinator in the clinic.
- Waiting times were not monitored or audited. Staff told us patients had access to an initial assessment and could usually be seen within a week of enquiring.
- Staff were flexible in relation to the shifts they worked, as far as possible, to ensure patients were seen at a time that suited them.
- Actions were taken to minimise the time patients waited for treatment. For example, staff accessed different surgeons' diaries if patients wanted to be seen sooner.
- Staff we spoke with said services generally ran on time. Patients were contacted by telephone to be informed of any delays or disruption. Transform Milton Keynes did not collect or monitor cancellations, delays or disruption to the service. We requested information regarding the number of procedures that had been cancelled for a non-clinical reason however this information was not provided.
- Post-operative patients were booked to see the nurse within seven days of surgery. Patients were also booked for a post-operative consultation and review with the surgeon. Both appointments were booked during the patient's pre-operative assessment appointment.
- Appointments were only cancelled when absolutely necessary. Pre-operative patients were offered an alternative appointment date and time and were given an explanation. Post-operative patients were offered an appointment with the nurse at the nearest Transform clinic. We were told this only happened during episodes of staff sickness and annual leave.
- The number of patients that did not attend their appointment was not monitored locally for quality purposes. The nurse contacted post-operative patients by telephone who did not attend their appointment. A letter would be sent to the patients address following two failed telephone attempts. However, the nurse informed us that post-operative patients always attended their first appointment following surgery.
- There were no cases of unplanned readmission within 28 days of discharge or unexpected return to the operating theatre from January 2016 to December 2016.

Meeting people's individual needs

- Services were not planned, delivered and coordinated to take account of people with complex needs, for example those living with a learning or physical disability. Staff we spoke with said they had not encountered patients with a learning disability.
- There was no disabled access to the clinic. Patients living with a physical disability, which prevented them from using the stairs, were advised to attend the nearest Transform clinic with disabled access. This was usually established during the initial call to the contact centre.
- There were no translation services available for patients who did not speak English. Staff we spoke with said patients who required an interpreter usually attended with a friend or relative. This was not in line with Transform's consent policy, which stated that patients were able to access translators.
- There were no arrangements in place for patients with hearing or visual impairments. This was not in line with Transform policies, which stated that interpreters were available for patients who required them.
- Arrangements were in place to ensure the suitability of patients with a psychological or psychiatric condition. A letter was required from the patients GP or an appropriate specialist and was then reviewed by a surgeon. Patients assessed as unsuitable could be reviewed again after six months in line with the Transform patient selection criteria.

Outpatients and diagnostic imaging

- Pregnant women were informed they did not meet the patient selection criteria and were asked to rebook, should they wish, after their pregnancy.
- Chaperones were available for patients undergoing examination. A consultation with a clinician of the same sex was accommodated with prior notice.

Learning from complaints and concerns

- Patients were provided with information on how to make a complaint during their initial assessment. The complaints process was also documented in the patient guide information booklet.
- Patients were encouraged to raise concerns with clinic staff who tried to resolve their complaints locally. Informal complaints were not recorded therefore we were unsure how many informal complaints had been made and if they had been resolved.
- Formal complaints were recorded on a complaints log. Actions, resolutions and outcomes were documented on the log. There were ten complaints from Transform Milton Keynes patients from January 2016 to December 2016. Eight of the ten complaints related to patients being unhappy with the aesthetic outcome of their cosmetic surgery procedure. One complaint was related to pain following a procedure and another was a complaint related to a consultation with a surgeon.
- All formal complaints received from January 2016 to December 2016 were acknowledged within two working days. All formal complaints were responded to within 20 working days.
- Staff we spoke with said complaints were discussed at corporate quarterly clinical governance meetings. We saw evidence of the number of complaints across all Transform clinics highlighted in meeting minutes however; we saw no evidence of discussions around complaint themes and investigations.
- Complaints were also discussed at clinic quality meetings however we were told clinic meetings were irregular and we saw no evidence of complaints being discussed from June 2016 to March 2017. We were told staff reflected on complaints individually.
- We saw no evidence of learning from complaints.

Are outpatients and diagnostic imaging services well-led?

Leadership and culture of service

- The service was managed by the clinic manager (who was also the registered manager). They had been in this position since 2014, at both the previous and new location. The clinic manager felt they had not been provided with sufficient managerial training for the role of registered manager and this had been raised during their appraisal. We observed that they had relevant clinical qualifications but no managerial qualifications.
- The service was overseen at a national level along with all other Transform locations. There was a clear structure of senior managers within the organisation and who was accountable at a corporate level. All service plans and improvement were led at a corporate level. Staff could describe who their immediate managers were but did not feel that senior managerial staff were visible within the service.
- All staff said they enjoyed their jobs within the service and that the clinic manager was approachable. Staff felt there was good teamwork and support.
- Staff said that the service felt quite different following the change of location from a hospital setting to a small clinic in the community. Some staff felt the working environment was not as suitable as the previous location.
- Staff knew who to speak to if they had concerns or wished to raise an area for improvement. The clinic manager told us that if staff had ideas of how to improve an area of the service they would take this up to a corporate level for review/approval.

Vision and strategy for this core service

- There was a corporate level vision in place, which was "to provide leading cosmetic surgeons, with unbeatable hygiene standards and excellent aftercare, giving patients all the reassurance they need to choose Transform for cosmetic surgery." Staff we spoke with knew that Transform had a vision but could not describe this vision.

Outpatients and diagnostic imaging

- There was not a corporate level or local strategy in place. This meant that staff were not aware of what the service was working towards or its plans for the future.

Governance, risk management and quality measurement

- The service had a governance framework, which supported the delivery of patient care. This framework detailed the structures and procedures in place including incidents, claims, complaints and audit schedules.
- There was a clinical governance committee that oversaw areas including medicines management, complaints, clinical incidents and clinical policies. These meetings were held quarterly at a corporate level and included Transform staff, and independent experts and specialists. Staff from the Milton Keynes clinic were not invited to these meetings and had never attended however the clinic manager did receive a copy of the meeting minutes.
- There was a risk management strategy at a corporate level. This document did not detail individual locations but each location was expected to work towards this strategy. The main aims of this strategy were to:
  - Provide a high quality service to patients
  - Strive to achieve improvements in the Risk Management within the business
  - Demonstrable improvements across relevant Regulatory Standards as part of wider measurement of the Companies performance by the CQC
  - Achievement of national targets in relation to the management of risk
  - Monitoring of trends/demonstrable 'learning of lessons' from incidents, complaints and claims through audit of risk management practices and procedures.
- The service did not have a risk register in place. Staff and managers we spoke with could not describe key risks present within the service. They were also unsure if there was a risk register at a corporate level. At corporate level there was not a working risk register; the service instead used their risk management strategy. This document did not detail up to date risks, show accountability for each risk or make it clear how long each area of risk had been present.
- The service did not monitor quality data in relation to "did not attend" (DNA) rates, cancelled or delayed clinics. This meant there was no oversight of patient risk or quality of the service in relation to clinic appointments and patient care. If patients missed post-operative appointments this also meant outcomes of their surgery would not be recorded.
- Practising privileges were granted through the clinical governance committee. The committee reviewed newly appointed surgeons activity and outcomes for the first six months. This included a review of audits, note keeping, complications, readmissions, extended patient stays, complaints and infections.

Public and staff engagement

- The service previously utilised an online feedback service which allowed patients to share positive and negative comments. This feedback would be shared with the appropriate clinics/staff. However, this had stopped being used within the past 12 months and a system had not been put in place to replace this feedback mechanism.
- Staff told us that hospital sites sometimes utilised paper feedback forms following a patient's surgery but this did not provide data at a location level.
- Staff felt there were minimal opportunities for engagement at a corporate level. Staff did not feel that they had input in shaping the service and this was fed from a corporate level. Local clinic meetings were held to allow staff feedback about the service.
- Staff surveys were not conducted within the service.

Innovation, improvement and sustainability

- We did not observe any areas of improvement or innovation.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take action to ensure that patient information is kept confidentially and their privacy is protected.
- The provider must ensure that appropriate translation arrangements are in place to allow patients to consent for procedures and family members are not used for this purpose.
- The provider must take prompt action to address concerns identified in relation to equipment within the service, including managing expiry dates and identification of which service is responsible for items of equipment.
- The provider must ensure a policy is in place in relation to safeguarding, and also review safeguarding training levels to ensure staff are trained to the correct level.
- The provider must take prompt action to address a number of governance concerns identified during the inspection in relation to having an accurate and up to date risk register, monitoring of did not attend rates, storage of confidential records and access and availability of up to date policies.

Action the provider SHOULD take to improve

- The provider should review mechanisms in place for learning from incidents and complaints.
- The provider should stores cleaning equipment in a secure way so it is not accessible to unauthorised persons.
- The provider should consider implemented written clarification regarding roles and responsibilities in relation to the building and facilities with the co-located beauty salon.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Surgical procedures	Regulation 10 HSCA (RA) Regulations 2014 Dignity and respect **Dignity and respect** **10.**—(1) Service users must be treated with dignity and respect. (2) Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular— (a) ensuring the privacy of the service user; • Patients were required to attend reception of a beauty salon and provide their name to reception staff of the beauty salon. A list of patient names was provided to the beauty salon each day of who had appointments with Transform which did not protect patient confidentiality.

Regulated activity	Regulation
Surgical procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent **Consent** **11.**—(1) Care and treatment of service users must only be provided with the consent of the relevant person. • Support was not provided for patients who do not speak English. Family members were routinely used to consent on behalf of patients.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Surgical procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment **Safeguarding service users from abuse and improper treatment** **13.**—(1) Service users must be protected from abuse and improper treatment in accordance with this regulation. (2) Systems and processes must be established and operated effectively to prevent abuse of service users. • The service could not advise us what level of safeguarding training staff had received. • Staff were not aware of a clear policy in place to describe safeguarding procedures at the Milton Keynes clinic.

Regulated activity	Regulation
Surgical procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment **Premises and equipment** **15.**—(1) All premises and equipment used by the service provider must be— (a) clean, (b) secure, (c) suitable for the purpose for which they are being used, (d) properly used (e) properly maintained, • A significant amount of disposable equipment was past its expiry date within the service. • There was no stock check or monitoring system in place which would allow staff to identify equipment that had expired or was due to expire shortly.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Surgical procedures

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Good governance

17.—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.

(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—

(a) assess, monitor and improve the quality and safety of the services provided in the

carrying on of the regulated activity (including the quality of the experience of service

users in receiving those services);

(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;

(c) maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided;

- Information relating to “did not attend” rates, cancellations and delays in clinics was not monitored by the service.
- There was no local risk register in place and staff could not describe risks at a corporate or local level.
- Confidential patient information was not always stored securely.
- Policies and procedures were not always in date within the service.