

Pall Mall Medical (Manchester) Limited

Pall Mall Medical Diagnostic Treatment Centre

Inspection report

1 Belvedere Road Newton Le Willows WA12 0JJ Tel:

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inspected but not rated	
Are services safe?	Inspected but not rated	
Are services effective?	Inspected but not rated	
Are services well-led?	Inspected but not rated	

Overall summary

We inspected this service as a follow up to the issue of a warning notice for a breach in Regulation 17 'Good Governance' which was issued on 15 July 2020 following an inspection conducted on 05 June 2020. During our inspection we found there had been some improvements since the last inspection. We saw that;

- There had been improvements in the audit processes used by the service to assess, monitor and improve the quality and safety of the services provided. The service had introduced an improved system of audit, however there remained further areas where audit would support assurance.
- We saw that there were systems in place to monitor progress against plans to improve the quality and safety of services. Although, we found that the pace of change was not as per the notice due to the challenges of the pandemic, there remains room for further improvement.
- Whilst there were positive improvements in the governance processes, there was limited evidence of improvement in the medical advisory committee processes and its ability to oversee the safe and appropriate clinical performance of the service.
- There had been improvements in the consent process, we saw that cooling off periods were observed. However, we found omissions in the documentation of consent in two of the 16 records we checked.
- The management of incidents had improved, but the process of sharing learning still needed to be embedded.
- There had been improvements in record keeping and documentation, although we identified some gaps in one record we reviewed.

However, we also found some additional areas that required improvement:

- The service had a system to maintain staff records but we found gaps within the records we reviewed for example, continuing professional medical and nursing registration.
- The service did not have evidence that they had carried out checks and continued to meet the criteria to ensure that people who hold director level responsibility for the quality and safety of care, and for meeting the fundamental standards of care, were fit and proper to carry out this important role.
- Audits did not always review quality as part of the process, for example, records and consent audits reviewed the presence of key documentation but not the quality of the recording.
- Although the provider had a system to monitor registration with a professional body, there was no audit, review or reporting to provide assurance to leaders.
- Although the provider had a system for the granting and maintaining of practising privileges, there was no effective system to regularly provide scrutiny to these decisions.

Our judgements about each of the main services

Service Rating Summary of each main service

Surgery Inspected but not rated



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- There had been improvements in the audit processes used by the service to assess, monitor and improve the quality and safety of the services provided. The service had introduced an improved system of audit, however there remained further areas where audit would support assurance.
- We saw that there were systems in place to monitor progress against plans to improve the quality and safety of services. Although, we found that the pace of change was not as per the notice due to the challenges of the pandemic, there remains room for further improvement.
- Whilst there were positive improvements in the governance processes, there was limited evidence of improvement in the medical advisory committee processes and its ability to oversee the safe and appropriate clinical performance of the service.
- There had been improvements in the consent process, we saw that cooling off periods were observed. However, we found omissions in the documentation of consent in two of the 16 records we checked.
- The management of incidents had improved, but the process of sharing learning still needed to be embedded.
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- Audits did not always review quality as part of the process, for example, records and consent audits reviewed the presence of key documentation but not the quality of the recording.
- Although the provider had a system to monitor registration with a professional body, there was no audit, review or reporting to provide assurance to leaders.
- Although the provider had a system for the granting and maintaining of practising privileges, there was no effective system to regularly provide scrutiny to these decisions.

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Summary of this inspection

Background to Pall Mall Medical Diagnostic Treatment Centre

Pall Mall Medical Diagnostic Treatment Centre is an independent health care facility under the management of Pall Mall Medical (Manchester) Limited. The service provides elective day case cosmetic surgery and the option of overnight stays with nursing care for those who chose this. They also provide diagnostic procedures such as endoscopy and magnetic resonance imaging.

The centre has had a registered manager in post since 2013. The service is registered for the following regulated activities;

- Treatment of disease, disorder or injury
- Diagnostic and screening procedures
- Surgical procedures
- Family planning

We inspected this service as a follow up to the issue of a warning notice for a breach in Regulation 17 'Good Governance' which was issued on 15 July 2020 following an inspection conducted on 05 June 2020.

We raised concern regarding poor systems to ensure the quality of the care and service provided was regularly monitored, assessed and steps taken to improve the quality and safety of the services provided in the carrying on of regulated activity. In that;

- There was no annual audit programme in place and the audits completed did not have a meaningful outcome or
 action plan to identify how issues uncovered would be improved, nor how these would be followed up and repeated
 to assess improvement.
- Clinical governance meetings were not regular enough nor did they effectively enable the understanding of performance or record on safety.

The Medical Advisory Committee did not adequately assess, monitor and mitigate the risks to patients. They were not frequent enough and did not demonstrate an effective approach to risk management and it did not discuss and examine the issues necessary in order to understand risk, safety and competency of staff. The Medical Advisory Committee process did not employ a stringent procedure to provide assurance around the skills and competency of those holding practising privileges at the hospital and they did not engage in the revalidation and appraisal process for doctors.

- The 'Serious Incidents and Never Events' policy was not consistent with expected practice around serious incident reporting and provided inconsistent and unclear advice on the recognition, recording and notifying of serious incidents. It lacked clarification on what constituted a serious incident and may result in the failure to identify an incident and therefore fail to reduce the chances of reoccurrence. It was unclear on the definition and recognition of never events. It may lead the service to fail to report serious incidents to the Care Quality Commission appropriately.
- The risk register included clinical and other risks. Four clinical risks were on the risk register from November 2019 and were graded as high, however two of them had no actions attached to mitigate the risks and there were no review dates in place.

Summary of this inspection

- Other policies such as the 'Practising Privileges', 'Medical Advisory Committee', complaints, and consent, were not in keeping with national guidance standards and did not support staff to follow effective and safe systems of work.
- There was no policy in place around theatre staffing requirements and perioperative practice to ensure safe systems of working and following national guidance.

We continued to engage regularly with the provider to assess their progress against the requirements from both the inspection and notice.

We inspected the service to further assess compliance against the requirements of the warning notice.

We carried out an unannounced focussed inspection on 07 January 2021, which was during a national lockdown due to the COVID-19 pandemic. We looked at specific areas including records, incidents, consent, leadership, governance, Fit and Proper Persons Regulation, managing risks, issues and performance, engagement and learning and continuous improvement and innovation.

How we carried out this inspection

During the inspection, we visited clinic treatment areas. We spoke with 14 members of staff including registered nurses, medical staff and senior managers. We did not speak to any patients. During our inspection, we reviewed 16 sets of patient records. We also reviewed policies, audits, meeting notes and other documentation.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

We told the service that it must take action to bring services into line with five legal requirements.

- The provider must ensure that records for directors contain current assurance to meet the requirements of Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and is available for supply to the Commission. Regulation 5
- The provider must ensure that there is scrutiny to the granting and maintaining of practising privileges. Regulation 17
- The provider must ensure records relating to all staff employed include information relevant to their employment in the role and their ability to practice appropriately in line with the Health and Social Care Act 2008 (Regulated Activities) 2014, Schedule 3. Regulation 19(4)
- The provider must ensure that arrangements for governance and performance management operate effectively and that the systems in place support the delivery of high-quality person-centred care. Regulation 17
- The provider must ensure that they have effective systems to regularly monitor and ensure that staff meet the requirements of registration with their relevant professional body. Regulation 18(2)(c)

Summary of this inspection

Action the service SHOULD take to improve:

We told the service that it should take action because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall.

- The provider should consider implementation of a regular periodic review of disclosure and barring service checks for staff.
- The provider should continue to improve record keeping and documentation. Ensure that documentation audits capture quality of records and clinical entries in addition to ensuring key documents are present.
- The provider should continue improvement work around incident reporting and sharing learning from incidents, so that there is a robust system for feeding information back to staff and to ensure this reaches all staff.
- The provider should extend the provision of discharge information to all patients including those who had a procedure completed in the treatment room.

Our findings

Overview of ratings

Our ratings for this location are:

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	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated

	Inspected but not rated	
Surgery		
Safe	Inspected but not rated	
Effective	Inspected but not rated	
Well-led	Inspected but not rated	
Are Surgery safe?		
	Inspected but not rated	

Records

Staff kept records of patients' care and treatment. Records were appropriate, up-to-date, stored securely and easily available to all staff providing care.

At our previous inspection, we found that documentation around consent was not always complete. We looked at sixteen patient records as part of this inspection. Six of these were for inpatient procedures and 10 were for outpatient procedures such as minor surgery, which was performed in the treatment room, or endoscopy. In all but one record we saw that consent to treatment was completed in full.

At our previous inspection we found patients did not always receive discharge letters or information which enabled the safe transfer or continuity of care. The provider had informed us prior to the inspection that all patients were now receiving a copy of discharge information. At this inspection, we saw evidence that discharge summaries were completed for cases in the operating theatre, however we did not see any discharge summaries in the records of any of the patients who had a procedure completed in the treatment room.

Most of the patient records were fully completed in line with staffs registered body, for example the Nursing and Midwifery Council (NMC) for nursing staff and the General Medical Council (GMC) for medical staff. However, we saw one record with some gaps. This was for an endoscopy procedure, the record had two signatures missing, no patient identification sticker or written details on one sheet and no patient signature on the consent form. In addition, the form was not completed to indicate if there were any contraindications to the throat spray used during the planned procedure.

Incidents

The service improved the way patient safety incidents were managed. Staff recognised and reported incidents and near misses. Managers investigated incidents and kept records, however there was limited evidence these were shared with the wider team. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers had introduced a system where actions from patient safety incidents were monitored.

At the previous inspection we found that the incident reporting systems and processes did not always enable the identification, monitoring and escalation of risk nor was learning from incidents sufficiently robust. We found during this inspection, that the policies and processes around incident reporting had been revised and improvements were seen, though this needed to be embedded.

Inspected but not rated



Surgery

Managers told us incidents were shared at daily huddles and that department leads would escalate incidents as part of compliance and governance meetings, these would be escalated to the director of clinical services. A draft policy was in place which included a list of the type of incidents staff were required to report. An event reporting form had been developed and had been in use for the two months prior to the inspection. We were told that staff in wards and theatres had been trained in and encouraged to report incidents and discuss these with their department leads (such as theatre manager) for escalation and to determine if these required escalation or reporting externally.

The Managing Director confirmed there had been no serious incidents reported by the service during the period January 2020 to January 2021.

The hospital manager had responsibility for reporting incidents externally (such as to CQC). A clinical member of staff was allocated with responsibility for submitting Private Healthcare Information Network (PHIN) data submissions.

The service used a paper-based incident reporting system. During this inspection we looked at 15 incident reports. Of these 11 related to theatre cancellations on the day of surgery and three were other incidents. Thirteen of the report forms provided an appropriate level of detail about the incident, the reason the incident had occurred, the actions taken at the time and those taken to prevent reoccurrence. Two forms had minimal information documented which did not enable further evaluation of the incident. We saw that reasons for cancellations on the day of surgery appeared reasonable.

We saw that incidents were included on clinical governance and medical advisory committee meetings as a standard agenda item. We saw that incidents were discussed at management meetings. How this was shared with staff not in attendance at such meetings was less clear. The staff we spoke with did not identify a system by which information was shared. Some indicated that there had been no incidents and others stated this was done by word of mouth. Another told us they were not aware of any incidents, that they were aware there was a system but had never used it. They said they thought information would be shared by email if necessary. Another staff member stated they were not aware of any formal shared learning mechanisms but they do hear things informally. There was also some contradiction over the method of reporting and whether this was electronic or paper based. Therefore, there was limited assurance of an effective system for sharing learning from incidents.

Are Surgery effective?

Inspected but not rated



Consent

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

We reviewed the consent process in six patients records, all who had undergone cosmetic surgical procedures at the hospital since our last inspection. We saw that a two stage process was in place. The consent documentation was fully completed at the preoperative stage in all of the records we reviewed. A 14 day cooling off period was evident from initial consent to the procedure being undertaken.



We also reviewed the consent process for 10 patients who underwent minor procedures in the outpatient area. This included two examples from patients having endoscopy procedures. We saw that patient consent was documented in eight of the 10 records. In one record the patient had not signed the consent form in the records. In another record there was no consent form present in the records.

We spoke with a surgeon who told us they now included additional information for patient consent. This included, for example, implant size for breast augmentation surgery, being discussed with the patient and documented on the consent form at the preoperative stage.

Are Surgery well-led?

Inspected but not rated



Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.

Since our last inspection the service has recruited a hospital manager to support the improvements required in governance. We found that the new manager had a good understanding of what good governance should look like and had a plan to move the service further forward in this respect.

An anaesthetist and cosmetic surgeon were members of the medical advisory committee and an external NHS consultant has recently been appointed to provide independent scrutiny and advice on clinical governance.

During the inspection it was not possible to speak with the registered manager as she was not available due to other commitments. We were advised the registered manager attended on site once or twice a month and did not have day to day involvement in the running of the service. This was done by the managing director and the hospital manager. It was these managers who were visible and approachable for staff and patients.

Governance

Leaders did not yet operate a fully effective governance process. No all staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Prior to the inspection the provider had shared changes to the governance processes including restructuring of relevant meetings, formalising of agendas and escalation processes. We were informed that the medical advisory committee and the clinical governance committee would be held monthly for the next six months before review of their frequency.

At our last inspection we saw the medical advisory committee was held once a year and it was unclear where the practicing privileges were approved although they were listed to be monitored at a number of the meetings. At this inspection, we were still not assured that the service had a robust and effective medical advisory committee in place. However, one of the management team told us an 'exceptional' medical advisory committee had been held on the 5 January 2021. The senior team and medical staff we spoke with did not provide a consistent view of the medical advisory committee's functions and purpose.



We were told one of the company directors, whose speciality was general practice, was the medical advisory committee chair and approved practising privileges for doctors wishing to practice in the service. The senior team said these were then also reviewed at the medical advisory committee. We were told there were two medical advisory committee meetings held during 2020 but there was a plan for these to move to a quarterly basis. We asked if new surgeons and anaesthetists waited for the approval through the medical advisory committee prior to practising at the service. The senior team were not clear if this happened. Therefore, we were not assured that the medical advisory committee was functioning effectively.

The service had a revised practising privileges policy in place. This did give some information about the criteria for applying for practising privileges and stated that the medical director would review the application and confirm to the human resources officer if practising privileges had been granted or refused or if this was restricted or subject to any reviews. It did not specify the role of the medical advisory committee if any, within this process. It did however state that practicing privileges could be reviewed by the medical director at any time as appropriate and that they may seek advice from members of the medical advisory committee if required in reaching their decision. A checklist was in place to record the checks in place to support an application.

There had been two medical advisory committee meetings since our last inspection these were undertaken on 20 August 2020 and 5 January 2021. The minutes of this meeting indicated medical advisory committee membership included the registered manager, medical director, managing director, director of clinical services, consultant anaesthetist and consultant surgeon. Also in attendance, but not medical advisory committee members were the hospital manager, theatre manager and hospital co-ordinator. We were told the consultant was a member of the British Association of Aesthetic Plastic Surgeons and checks confirmed this to be the case. The anaesthetist and surgeon were invited to the August 2020 meeting but were not in attendance and provided their apologies for the January 2021 meeting, it is noted however they were involved in some discussion outside of the meeting. The meeting in January 2021 was an extraordinary meeting in response to the national lockdown and did not contain standard agenda items. The meeting in August indicated the standard agenda items included the risk register, human resources and practising privileges, health and safety, policies and procedures, clinical governance and incidents.

We were told that there were plans to introduce a new independent member to the medical advisory committee to establish some impartiality within the committee. The service had made an offer of employment to an individual they deemed suitable and the roles and responsibilities were being agreed with a view to the person taking post in January 2021.

The most recent clinical governance meeting had been held in December 2020. We reviewed the minutes of this meeting and saw that this was the first of the new style meetings, we saw that standing agenda items such as incidents, complaints, safety, patient experience and audit were included. Attendees included the registered manager, business consultant, managing director, outpatients manager, hospital manager, project coordinator, director of clinical services and theatre manager. The clinical governance meeting was to take place monthly until the systems and processes had been embedded and while improvements were being monitored.

We were told incidents were shared through daily huddles and were reviewed through the clinical governance meeting.

A member of medical staff told us they had not seen any clinical governance meeting minutes.

A theatre staffing policy was in place to ensure that theatre staffing complied with Association for Perioperative Practice guidance on staffing levels. The service had also introduced training for surgical first assistants and whilst this was being done, the service ensured these were supplemented by agency staff in order to meet the standards.



We were not able to gain assurance of the efficacy of the governance processes that had been instigated as they were not yet mature enough.

Fit and Proper Persons Regulation

The service did not have evidence that they carried out checks to ensure staff continued to meet the FPPR criteria. This was particularly for people who held director level responsibility for the quality and safety of care, and for meeting the fundamental standards of care.

During the inspection we asked to see the personnel files relating to the directors of the organisation. We were unable to establish if there was a personnel file for the two company directors or if they had undergone 'Fit and Proper Persons Regulation' checks in line with requirements. Further information was requested, and we saw that a self-declaration had been completed in 2016, there was also a curriculum vitae for each on file. There was no evidence that other elements of the 'fit and proper persons regulation' had been checked and other necessary checks had been completed. We requested the service's policy covering this and we received a policy dated 12 January 2021, together with other staff declarations as fit and proper persons dated 12 January 2021.

The managing director confirmed he was not a fully appointed company director and the service had two directors who were the owners of the service, they occupied the roles of registered manager and medical director. The managing director and hospital manager confirmed there was a recruitment policy in place, however they were unclear if there was a formal process for 'Fit and Proper Persons Regulation' for appointed directors.

The service had a recruitment policy which stated what evidence is required when a member of staff was recruited. We also saw a checklist used when a member of staff started at the organisation. We reviewed three files for staff employed by the service and saw that most checks had been conducted upon commencement of their employment, however there was no system in place which reviewed the criteria and that the staff members remained registered and their disclosure and barring service check repeated. For one staff member, there was no evidence their nursing registration had been checked upon commencement of employment. For another it had been checked upon commencement but had not been checked since 2018 which did not meet best practice. For two their disclosure and barring service checks had not been checked since 2016 and 2017. However, we received an updated Recruitment and Selection policy after the inspection which identified that DBS checks would be checked every three years for employed staff.

We reviewed three files of those holding practising privileges. They showed one had not had their disclosure and barring service check since 2013 and last appraisal on file was 2018. Another had no evidence of a disclosure and barring service check in the file, their last appraisal was completed in 2019 and only had one reference checked. A further file had a disclosure and barring service check and appraisal check in 2013 and only one reference checked.

We also reviewed two files for those holding abbreviated practicing privileges, these are for staff who are observing practices or trainees under supervision and not undertaking clinical procedures. These appropriately contained a curriculum vitae, an application form and identification checks.

Managing risks, issues and performance

Leaders and teams did not always use systems to manage performance effectively. Systems in place did not always enable the identification and escalation of relevant risks and issues nor identify actions to reduce their impact. The service did have plans to cope with unexpected events and staff contributed to decision-making to help avoid financial pressures compromising the quality of care.



At our previous inspection we found, there was a lack of auditable documentation as to the management of the risks and actions taken to mitigate those risks and their process did not demonstrate regular review and update of the risks. At this inspection, we were told a plan was in place to review each of the risks on the risk register. We were told no new risks had been added recently.

We were told that when necessary, items could be escalated from the clinical governance meeting to the medical advisory committee (MAC). As the medical advisory committee and clinical governance committee had not commenced the revised meeting schedule, we could not assess this at the inspection.

Managers planned to implement a consultant dashboard. This was being designed to enable the leadership team to have oversight of practising privileges, surgical site infection rates, audits and mandatory training. A draft policy had been drawn up, but this had not yet been implemented.

We spoke with a surgeon who told us they had a responsible officer in the NHS who completed their yearly appraisal for both their NHS and private practice. They completed their mandatory training as part of their full time NHS contract and this was shared with Pall Mall Medical Diagnostic Treatment Centre. This member of staff told us there was a medical advisory committee and whilst they were not involved with it, they had attended a recent online meeting.

Engagement

Leaders and staff actively and openly engaged with staff to plan and manage services. There were limited systems in place to engage with patients and the public.

A member of staff told us patient reviews of the service left on the website were shared by email. This member of staff also said patient complaints were not routinely shared, but staff did get to know about them informally.

The organisation conducted patient satisfaction surveys quarterly. We reviewed the results from July to September 2020 and October to December 2020, they had completion rates of 21% and 22% respectively. Generally, the results were good and they had a number of positive comments by patients.

They had produced an action plan however; learning was limited by the questions asked in the survey as they did not always support the responder to provide sufficient details to drive improvement.

Learning, continuous improvement and innovation

Staff were committed to learning and improving services, however there was limited understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation where possible and had introduced some new systems.

Following the previous inspection, the service had embarked on a compliance improvement programme and created a compliance action plan. This included a weekly compliance meeting with managers to assess progress and devise new processes and a spreadsheet to chart progress again their action plan and determine who holds responsibility for follow up actions.

Opportunities to continuously improve and learn were not always captured and acted upon within the service. Whilst improvements have been seen across governance processes, further work would enable the service to develop at a greater pace. There was a willingness from managers to achieve this.

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 18 HSCA (RA) Regulations 2014 Staffing We reviewed three files for staff employed by the service and saw that most checks had been conducted upon commencement of their employment, however there was no system in place which reviewed the criteria and that the staff members remained registered and their disclosure and barring service check repeated. For one staff member, there was no evidence their nursing registration had been checked upon commencement of employment. For another it had been checked upon commencement but had not been checked since 2018 which did not meet best practice. For two their disclosure and barring service checks had not been checked since 2016 and 2017. However, we received an updated Recruitment and Selection policy after the inspection which identified that DBS checks would be checked every three years for employed staff.

Regulated activity	Regulation
Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	Although the provider had a system for the granting and maintaining of practising privileges, there was no effective system to regularly provide scrutiny to these decisions. The Medical Advisory Committee process did not employ a stringent procedure to provide assurance around the skills and competency of those holding practising privileges at the hospital.

This section is primarily information for the provider

Requirement notices

The provider had improved arrangements for governance and performance management however it was too early to be able to evidence that they operated effectively and that the systems supported the delivery of high-quality person-centred care.

Regulated activity

Regulation

Surgical procedures

Regulation 5 HSCA (RA) Regulations 2014 Fit and proper persons: directors

The service did not have evidence that they carried out checks to ensure staff continued to meet the FPPR criteria. This was particularly for people who held director level responsibility for the quality and safety of care, and for meeting the fundamental standards of care.

During the inspection we asked to see the personnel files relating to the directors of the organisation. We were unable to establish if there was a personnel file for the two company directors or if they had undergone 'Fit and Proper Persons Regulation' checks in line with requirements. Further information was requested, and we saw that a self-declaration had been completed in 2016, there was also a curriculum vitae for each on file. There was no evidence that other elements of the 'fit and proper persons regulation' had been checked and other necessary checks had been completed. We requested the service's policy covering this and we received a policy dated 12 January 2021, together with other staff declarations as fit and proper persons dated 12 January 2021.