Pall Mall Medical Diagnostic Treatment Centre

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

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 surgery and the option of overnight stays with nursing care for those who chose this.

We inspected this service as a response to concerns raised about the provision of surgery at this location. We carried out an unannounced inspection on 05 June 2020, we interviewed managers on 12 June 2020.

In order to respond specifically to the concerns raised to us we only looked at some aspects of the safe, effective, responsive and well led domains. Specifically, we looked at the following key lines of enquiry;

In 'Safe' we looked at;

- Mandatory training
- Incident reporting
- Cleanliness and Infection prevention and control
- Environment and equipment
- Records
- Assessing and responding to risk
- Theatres staffing
- Incidents

In 'Effective' we looked at;

- Competent staff
- Consent

In 'Responsive' we looked at;

- Learning from complaints and concerns

In 'Well-led' we looked at;

- Governance
- Managing risk and performance

During the inspection, we visited the operating theatres, the recovery areas, the ward and treatment areas. We spoke with eleven members of staff including registered nurses, health care assistants, medical staff and senior managers. We spoke with one patient. During our inspection, we reviewed six sets of patient records. We reviewed 11 sets of records following the site visit and reviewed policies and other documentation.

We did not rate this service.

During our inspection we found some good practice, we saw that;

- Infection prevention and control practices enhanced as a result of the coronavirus situation appeared comprehensive and commensurate with public health guidance.
- The environment appeared pleasant, well equipped, clean and hygienic.
- Staff believed that there have been positive changes around safety and improvements in operational systems and practices, since the arrival of a new director of clinical services.

Managers appeared engaged and willing to make improvements. However, we found areas of practice that could be improved;

Summary of findings

- Governance systems did not support the identification, capture and management of risks and measures to improve safety and quality.
- The consent processes did not enable informed consent to be sought and recorded in line with recommended guidance.
- The complaints policy and procedures around complaints did not support people to complain, it also may have led to opportunities for learning to be missed.
- Policies and procedures did not support safe systems of practice.
- Record keeping did not always meet recommended minimum standards.

Following this inspection, we told the provider that it must take some actions to comply with the regulations. We issued the provider with a warning notice and requirement notices. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery		During our inspection we found that; • Governance systems did not support the identification, capture and management of risks and measures to improve safety and quality. • The consent processes did not enable informed consent to be sought and recorded in line with recommended guidance. • The complaints policy and procedures around complaints did not support people to complain, it also may have led to opportunities for learning to be missed. • Policies and procedures did not support safe systems of practice. • Record keeping did not always meet recommended minimum standards. However, • Infection prevention and control practices enhanced as a result of the coronavirus situation appeared comprehensive and commensurate with public health guidance. • The environment appeared pleasant, well equipped, clean and hygienic. • Staff believed that there have been positive changes around safety and improvements in operational systems and practices, since the arrival of a new director of clinical services.

Summary of findings

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Services we looked at:
Surgery.

Summary of this inspection

Background to Pall Mall Medical Diagnostic Treatment Centre

We inspected this service as a response to concerns raised about the provision of surgical procedures at this location. We carried out an unannounced inspection on 05 June 2020 and conducted interviews with managers on 12 June 2020.

Pall Mall Medical Diagnostic Treatment Centre is an independent private hospital in Newton Le Willows, Merseyside. They are a registered location under Pall Mall Medical (Manchester) Limited and provide diagnostic and treatment services to private patients. The diagnostic and treatment centre opened in 2013. The centre has two operating theatres, a treatment room, a recovery bay, five en-suite rooms and clinical consultation rooms.

The centre has had a registered manager in post since 2013, they are registered to provide:

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

Our inspection team

Our inspection team comprised of two CQC inspectors, and a specialist advisor. The inspection team was overseen by Judith Connor, Head of Hospital Inspection for the North West.

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 found;

- Infection prevention and control practices enhanced as a result of the coronavirus situation appeared comprehensive and commensurate with public health guidance.
- The environment appeared pleasant, well equipped, clean and hygienic.
- Staff believed that there have been positive changes around safety and improvements in operational systems and practices, since the arrival of a new director of clinical services.

However, we also found;

- Policies and procedures did not support safe systems of practice.
- Record keeping did not always meet recommended minimum standards.

Are services effective?

We found;

- The consent processes did not enable informed consent to be sought and recorded in line with recommended guidance.

Are services caring?

Not inspected.

Are services responsive?

We found;

- The complaints policy and procedures around complaints did not support people to complain, it also may have led to opportunities for learning to be missed.

Are services well-led?

We found;

- Governance systems did not support the identification, capture and management of risks and measures to improve safety and quality.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

We did not rate this service.

Mandatory training

Managers defined the mandatory training required for each job role for all non-medical staff. They monitored the completion of mandatory training by staff and most staff had completed the required learning within the specified time frame.

Safeguarding

Not inspected

Cleanliness, infection control and hygiene

We found that the environment was visibly clean and hygienic. We saw that cleaning regimes were in place and these were recorded appropriately.

We saw the service had appropriate measures to control the spread of infection in line with guidelines for responding to the coronavirus pandemic. Staff used appropriate personal protective equipment and precautions in line with current Public Health England guidelines.

Before entering the hospital, all patients were temperature checked and issued with a face mask.

During our inspection we found there was not a robust process for monitoring and reviewing surgical site infections. However, the service acted quickly when we raised this issue. Following our inspection, the service conducted a review of all surgeons' procedures for the last six months, focussing on surgical site infections. They told us they intended to do a deep dive into minor incidents found and conduct an ongoing review of surgical site infections.

The service told us that their review found that there had been 11 surgical site infections from 594 procedures. These infections were treated with antibiotics.

There was personal protective equipment (PPE) in various sizes in the clinic room.

The ward areas had sinks and hand gel dispensers and we saw that staff were wearing appropriate PPE for the task they were undertaking. There were signs on the walls informing staff about the current Public Health England Guidelines.

Environment and equipment

We saw that the environment was clean and tidy. All areas were air conditioned.

Staff completed daily checks of the environment in the anaesthetic and recovery areas. We reviewed a sample of completed records which showed these checks were consistently and fully completed.

The environment in theatre was suitable for the procedures being carried out, sharps bins were labelled appropriately.

Staff carried out manual handling of patients in line with health and safety requirements.

The clinic room was tidy and had an adjustable couch for patient and staff comfort. There were shades at the window for privacy and dignity. There were appropriate bins for clinical waste. There was a ward for female patients with five bays. All had access to oxygen and suction. This was where patients waited to be taken to theatre and they were returned to this area post -operatively.

The hospital had en-suite rooms for overnight patients but at the time of the inspection there were no procedures being carried out that would require an overnight stay.

Assessing and responding to patient risk

Surgery

Pre-operative risk assessments were completed during consultation with patients. There was evidence that the patient's medical background, risk factors and suitability for surgery was assessed and recorded.

However, if patients were returning for further follow up treatment, pre-operative risk assessments were not routinely reviewed or revisited. We looked at eleven cases where a second procedure was conducted. In all cases there was no new preoperative assessment documented. We saw that in one case there was a 5 month gap, in two cases there was a 4 month gap and in one case there was a 15 month gap between procedures. Best practice suggests a pre-operative assessment remains valid for three months before requiring an update.

For patients admitted for procedures in the main operating theatres we saw that patient risk assessments were reviewed again prior to their surgery commencing. We saw evidence that a surgery was cancelled when there were concerns regarding a patient's health at the time they attended for a procedure.

We saw that allergies were discussed with patients on admission and were noted in their records and prescription charts and also documented in theatre team briefing forms.

Patient risk was discussed at theatre briefings, each patient's individual needs and risk factors such as allergies and health backgrounds were discussed at the start of each theatre session. During our inspection we observed this practice and found this to be of an acceptable standard.

We were told that if a patient was staying overnight, there would be a resident medical officer who would remain on duty. The resident medical officer was available to assess and respond to potential clinical concerns during this time.

There was a service level agreement in place for patients to be transferred to the local NHS acute hospital services should this be necessary. We saw evidence that this had been done in the past where staff had identified the patient needed immediate attention. The service did not carry out any procedures that required blood transfusion and staff told us that in an emergency situation, caused by blood loss, they would call 999.

There was a nurse on call service so that patients who had been discharged from the hospital could call the nurse for advice and support. We spoke with one of the nurses who said that the system worked well and sometimes patients needed reassurance.

During our inspection observation in theatres, we saw that safer surgery practices such as the World Health Organization's safer surgery checklist and the five steps to safer surgery guidance was completed but some aspects were not always to the standard expected. We saw that during the 'sign out' phase the surgeon did not observe silent focus and continued to engage in the task they were carrying out. Furthermore, during the debrief stage not all staff were engaged, nor was the process fully interactive. This was because the debrief was conducted when the procedure was still in progress, therefore not all staff could engage.

However, where procedures were carried out in the treatment room, the service had not adapted the World Health Organization's safer surgery checklists to support safe practice such as the counting of accountable items. Therefore, there was a risk of never events such as retained objects such as swabs and sutures and wrong site surgery.

Furthermore, part of the World Health Organization safer surgery checklist is the 'sign in' phase, this includes checking with the patient the procedure and the consent form. As surgery in the treatment room did not always have a consent form, or where they did, there were omissions on the form, compliance with this aspect of the checklist would be difficult.

Staff told us that the theatres team were in the process of implementing a review of the intra-operative processes and had implemented initiatives to improve practice and the safety culture in theatres. Staff told us that the processes had improved in the months leading up to the inspection and they saw positive improvements. However, the absence of robust intra-operative standard operating procedures and policy meant there was little tangible guidance to direct staff on a consistent approach in line with national guidance and best practice. There had been no audits of these processes to demonstrate improvement.

Following a recent incident, managers told us they had recently introduced clear guidelines for surgeons on

procedures which were suitable to carry out in the treatment rooms. This no longer allowed for surgeon discretion. We saw a draft copy of this policy which was awaiting ratification.

Staff recorded a count of items used during surgery such as swabs and sharps in the register of operations logbook. However, no such record was kept for surgery carried out in the treatment room, this meant there was a risk of retained objects being left inside following open surgical procedures.

Patients did not always receive discharge letters or information which enabled the safe transfer or continuity of care. Similarly, GP letters were not always sent to patient's GP. This was confirmed by the managing director who stated discharge letters are only given to patients who are admitted to the ward. This meant that if a patient experienced deterioration or required the services of other healthcare providers such as a GP visit, or accident and emergency treatment, it may not always be clear what procedure had been undertaken to enable ongoing care to be delivered, particularly in an emergency. We were advised that discharge summaries and continuing care documentation was only given in certain circumstances, that is those admitted for an overnight stay and if the patient or surgeon requested it. In the 11 sets of notes we checked for those who had had cosmetic surgical procedure completed in the treatment room; none had discharge summaries, GP letters, nor continuing care documentation. This is not in keeping with guidance contained in Professional Standards for Cosmetic Surgery (2016), which stated patients should receive written information that explains the intervention they have received in enough detail to enable another doctor to take over the patient's care. The exception being if the patient objected, in which case the objection should have been recorded in the patients notes.

Nurse and support staffing

Not inspected

Medical staffing

Not inspected

Theatre staffing

During our inspection we found that staffing numbers and skill mix did not always meet minimum staffing requirements as per guidance by the Association for Perioperative Practice. In particular, we found that for some procedures such as an abdominoplasty there was no surgical first assistant or surgical care practitioner in the theatres team as required for procedures classed as 'more than minor'. We were advised that the scrub practitioner often performed this role as a 'dual role', which is not in keeping with guidance around roles and responsibilities by the Royal College of Surgeons. We found that there was no policy in place around theatre staffing requirements and perioperative practice, which would guide staff to follow recommended best practice and guidance.

Records

Records were mainly electronic but there were some paper records also. We observed that records of surgery and procedures undertaken in the main operating theatres were of a satisfactory standard.

Expected standards of record keeping are described in guidance such as GMC 'Guidance for Doctors Who Offer Cosmetic Interventions' and 'Good Medical Practice' and the Royal College of Surgeons 'Good Surgical Practice' and 'Professional Standards for Cosmetic Surgery'. Additionally, the provider's own policy entitled 'Practising Privileges' states, "Practitioners are responsible for maintaining accurate patient's Pall Mall Medical notes and to update, time and sign them after each entry. Furthermore, they are responsible for ensuring that records are fully completed at the end of any consultation.

However, records we reviewed for procedures carried out in the treatment room did not meet such standards. Such cases did not contain the level of detail expected and it was not always clear what exact procedure had been completed and the nature of the communication with the patient around consent documented.

We found that documentation around consent was not always complete. In the 11 records we checked, all had errors in the consent documentation, for example seven had not been signed by the surgeon, six did not state intended benefits, risks or side effects, five had illegible side effects or risks stated, five were completed on the same day as the procedure, and one the patient signed the wrong section of the form.

Handwritten documentation we received for surgery in the treatment room, particularly records of intra-operative care and treatment did not include safety information such as swab counts or safer surgery checks. Also, documentation

did not always contain sufficient patient identifiable information, such as hospital number and date of birth. Nor were they always dated, timed and the details of the staff members designation stated.

Medicines

Not inspected

Incidents

The service had a 'Serious Incidents and Never Events' policy in place. This had been implemented in May 2018 and was due for review in May 2021. The 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.

The policy lacked clarification on what constituted a serious incident and as such may result in the failure to identity and therefore investigate such an incident effectively. This could have meant that lessons were not learned, and the chances of reoccurrence may not be mitigated.

The policy provided incorrect advice about how serious incidents are reported and may have led the service to fail to report serious incidents to the Care Quality Commission appropriately.

Furthermore, the policy was unclear on the definition and recognition of never events.

The policy did not direct, instruct, or support staff to report incidents in a way that met CQC guidance or in a way that ensured safety and other incidents were recognised, acted upon and which enabled improvements to be made.

The service had a separate 'Significant Events' policy in place. This had been implemented in June 2016, had been reviewed in December 2017 and was due for review in June 2022. The policy was intended to capture incidents from which the service could learn and improve and gave some examples of what may constitute a significant event such as an emergency situation, medicine errors and near-miss incidents.

Documentation around incidents was shared during the inspection period, including incident reports and a spreadsheet of incidents. We saw evidence that some incidents were reported and there was some evidence that lessons were considered. However, the reports lacked appropriate detail and analysis.

Managers we spoke with told us there was a culture that encouraged clinicians to have open discussions and raise incidents and there was a report form for consultants and surgeons to fill in at the end of every shift to report incidents. However, we were also told that medics rarely filled this in as they told managers there were no issues. Senior managers told us they relied on a 'voluntary, hands up' approach to incident reporting. Managers did demonstrate how they gained assurance that all incidents and opportunities for learning were identified and acted upon.

We found that systems, processes and standard operating procedures were not always reliable and appropriate to keep people safe nor was the monitoring of systems in place robust. We found that information and guidance around safety was not always comprehensive and that safety concerns are not identified autonomously through the organisation's governance structures, therefore they were not addressed or mitigated. There is limited use of systems to record and report safety concerns as issues are not being identified. When things do go wrong, reviews and investigations are not always sufficiently thorough or do not include the relevant people and so necessary improvements are not always achieved.

Safety Thermometer (or equivalent)

Not inspected

Are surgery services effective?

We did not rate this service.

Evidence-based care and treatment

Not inspected

Nutrition and hydration

Not inspected

Pain relief

Not inspected

Patient outcomes

Surgery

Not inspected

Competent staff

We learned that all medical staff worked under practising privileges. Practising privileges is a well-established process in independent healthcare where a medical practitioner is granted permission to work in an independent hospital or clinic.

Managers told us they would only grant practising privileges to doctors who held an NHS contract, they stated this provided reassurance that the individual was competent in the specialist area and that revalidation and performance was being monitored. A review of the practising privileges checklist/ tracker provided, noted that not all medical staff had an extant NHS contract and nor was this part of the practising privileges policy.

The managers stated that they did not check the NHS employment status periodically following the clinician's initial appointment and they relied upon individuals advising them of any changes. This arrangement did not offer assurance that those holding practising privileges were competent in the specialism of the work carried out for this organisation, or that they were undertaking specialist work sufficiently and regularly to maintain competence and compliance with latest practice.

Checks on those with practising privileges included checking that the individual had General Medical Council registration to provide reassurance that they were still registered. They also checked that they held medical indemnity insurance. However, the practising privileges spreadsheet that was supplied on 5 June 2020 entitled 'clinician's documentation' identified that 57 of the 205 medical staff on the list had expired GMC registration, there were also three blank spaces where no date was provided and no reference to checks of the Specialist Register. Furthermore, it showed that 99 of the medical staff had expired indemnity insurance.

Multidisciplinary working

Not inspected

Seven-day services

Not inspected

Health promotion

Not inspected

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

The service had a consent policy in place which had been in place since June 2008 and was last reviewed in June 2016. This was not consistent with expected standards as set out in key guidance such as 'Good Surgical Practice' (Section 3.5.1 -Consent) by The Royal College of Surgeons; 'Consent: patients and doctors making decisions together (2008)' by The General Medical Council and 'Professional Standards for Cosmetic Surgery (2016)' The Royal College of Surgeons.

The policy referred to 'implied consent' being applicable to procedures which were carried out unless they may result in 'significant risk' to the patient. Furthermore, it suggested that verbal or written consent is acceptable for procedures which carry significant risk.

We saw evidence that written consent had not been obtained for procedures that would be expected to have written consent as per guidance from the Department of Health, the Royal College of Surgeons and the General Medical Council. Managers stated they did not believe written consent was required for some procedures.

Managers stated that where a patient had a procedure and completed a consent form for that procedure, they considered this consent remained valid for subsequent and follow up procedures. Even where the procedure, although related was a different procedure and where the risks, complications and intended benefits were different. They also believed that consent continued unless a patient stated otherwise, despite there potentially being several months in between the various procedures taking place. This is not in keeping with expected standards and national guidance on consent.

We reviewed case notes for treatment room procedures, we found that four consent forms had been relied upon as evidence of consent for an original procedure, and again later for further procedures, yet none had been signed by the surgeon and none had intended benefits, risks or side effects stated. The forms relied upon as evidence of consent, where four procedures took place 13 months, five months and four months earlier and were for a different procedure that carried different risks. For example, the risk of perforation or piercing an implant was not a risk for the original procedure but was for the revision procedure. These forms were also not revisited and re-signed by the

patient or surgeon with the new risks highlighted. We found that there was no evidence that the patient understood the second procedure, nor the associated risks and so informed consent had not been appropriately gained and documented.

Of the other seven consent forms examined all had other omissions or errors on the forms, some with multiple omissions and errors. Specifically, we found that two were not signed by the surgeon and on a further form the patient had not signed the agreement but signed the interpreter's declaration. Three had no intended benefits, risks or side effects stated and for the other four these were illegible. One form had no procedure being undertaken stated. In summary, none of the eleven consent forms were completed accurately.

The consent policy we reviewed did not make any reference to mental capacity considerations and the requirements of the Mental Capacity Act 2005. The service stated there was a separate policy entitled "mental capacity policy", the consent policy did not direct staff to consider this policy in relation to consent or describe the interdependency between both policies.

The policy did not adequately direct practitioners to follow the correct procedure around consent.

Staff we spoke with stated all patients underwent a psychological assessment prior to consenting to treatment and that they were given a two week 'cooling off' period and second consultation was offered. They stated any exceptions to this were recorded in patient notes by the consultant. However, in notes we reviewed regarding cosmetic surgery and procedures carried out in the treatment room, we saw no evidence that such cooling off period was offered and in cases where consent was attained, this was carried out on the same day as the surgery. For some minor treatments this would not always be necessary, but the practice adopted by the service and the policies in place did not support practitioners to follow guidance on cooling off periods.

The service undertook a consent audit in February 2019, they found that 100% of 81 patients had signed a consent form. The audit did not appear to have considered whether the forms were completed fully and if details of the procedure, the risks, complications and intended benefits were fully recorded.

Guidance on implementation of safer surgery checklists from the World Health organisation and the National Patient Safety Agency instruct that the procedure being undertaken, and the completion of the consent form be checked with the patient prior to surgery. From the documentation we saw, this aspect of the guidance could not have been achieved.

Are surgery services caring?

We did not rate this service.

Compassionate care

Not inspected

Emotional support

Not inspected

Understanding and involvement of patients and those close to them

Not inspected

Are surgery services responsive?

We did not rate this service.

Service delivery to meet the needs of local people

Not inspected

Meeting people's individual needs

Not inspected

Access and flow

Not inspected

Learning from complaints and concerns

Information received prior to our inspection indicated concerns with the service's complaints processes. This was supported by evidence found on inspection.

The service had a complaints policy in place, this had been implemented in April 2013 and was last reviewed in March 2020. This was available to the general public on the organisation's website along with information on how to complain.

The policy was unclear and offered inconsistent advice and instructions about the complaints procedures. The policy

indicated that formal complaints were accepted in a particular format and on Pall Mall Medical forms. The policy did not indicate what would happen if the complaint was received in the wrong format. Managers told us they would accept a complaint in any format, however the wording of the policy and the instructions on the organisation's website may have deterred feedback. Feedback from patients and users is beneficial in assisting a service to monitor their performance and continually improve as it can highlight areas of focus and where improvement may be required.

The policy did not indicate what happens when verbal complaints and concerns are raised and how they might feed into service improvement.

The complaints policy stated that a third party could only complain with the written consent of the patient involved. However, a potential complaint may not necessarily be about treatment and would not therefore impact on patient confidentiality or privacy, so consent would not be necessary, such as a visitor observing an incident, witnessing poor practice etc. Not allowing such a complaint, therefore would deny the opportunity to learn and improve some aspects of the service.

Furthermore, documentation supplied by the service made reference to the Parliamentary Health Service Ombudsman (PHSO), but this is associated with NHS care and not private health provision. The service did not subscribe to Independent Sector Complaints Adjudication Service (ISCAS) which is a voluntary subscriber service for independent healthcare providers.

Documentation provided by the service recorded 22 complaints in the period 1 April 2019 to 1 April 2020. It showed that all complaints had been acknowledged within three days although their policy stated that all formal complaints would be acknowledged within two days, 50% (11) had been responded to within the 20 day timescale, 18% (4) were not responded to within the timescale and 32% (7) were deemed not to be applicable to timescales.

With regard to learning outcomes and actions, from the 22 complaints received, for four there was meaningful actions as a result, for four the actions were limited to staff training, four had no outcome recorded and for 11 no actions were identified. The monitoring of complaints seemed to focus on whether the complaint was well-founded or unfounded. This implied the service did not embrace the feedback and complaints process as an opportunity to learn.

The complaints process did not fully enable the service to assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service.

Are surgery services well-led?

We did not rate this service.

Leadership

Not inspected

Vision and strategy

Not inspected

Culture

Not inspected

Governance

There were regular meetings seen from a tracker document shared by the provider. The Medical Advisory committee was held annually, a clinical governance meeting was held annually. There was a six-monthly Health, safety and facilities meeting and imaging meeting.

There were monthly meetings including guacamole meetings (focussed on surgical services) and managers meetings which were minuted. There were also weekly scheduling discussions; quarterly compliance and team meetings and daily huddles.

We reviewed minutes of the managers meeting from January 2020, which was the last meeting held due to Covid-19 pandemic and found that this was a business focussed meeting.

We found that it was unclear where the practicing privileges were approved although they were listed to be monitored at a number of the meetings.

We reviewed 19 policies provided and found that they were all in date.

The service had a 'Practising Privileges' policy in place, the service advised this had been in place since 2013, the

document indicated it had been approved in October 2018 and was due for review in October 2022. This policy did not dictate how practising privileges were granted, nor how the organisation gained assurance that staff were suitable, competent and the checks and measures the organisation took to assure itself of this. The policy did not dictate that the practitioner should be suitable skilled, qualified or experienced, nor who had responsibility for granting and monitoring those with practising privileges. It did not it indicate how ongoing monitoring, performance management and review of practising privileges was continued, or how the organisation shared information with the individual's designated body. During a telephone interview with the medical director, he described an informal, ad-hoc approach to the granting of practising privileges and a review of meeting minutes also supported this approach.

The practising privileges policy did not indicate the role of the medical advisory committee in assuring the organisation of the appropriate review of practising privileges and the assurance of safe clinical practice.

The practising privileges policy did not indicate how and when the provider would check the NHS employment status following the granting of practising privileges. This check mechanism would be required to assure that those holding practising privileges were competent in the specialism of the work carried out for the organisation.

The practising privileges policy did not include how the service would inform NHS trusts where the medical staff worked about poor practice or issues about capability that had occurred whilst working in this service.

Therefore, the process around the governance of medical staff holding practising privileges was not robust.

The service has a 'Medical Advisory Committee' document, which they described as their policy, but which was actually a 'terms of reference' document. This had been implemented in October 2017, was last reviewed in September 2018 and was due for further review October 2020. This was very limited and did not set clear expectations or describe what the organisation expected from members of the committee. It did not clearly specify the functions and purpose of the group and what members should do in terms of their behaviour, actions, and processes. It did not specify frequency of the meetings nor how decisions would be made, nor the election of members.

Senior managers we spoke with were unable to clarify how often the medical advisory committee met and the constituent membership. They could not clarify how the medical advisory committee was elected or their terms of office. The organisation's meeting schedule indicated this was an annual meeting, therefore occurred once a year. Managers indicated there was a more ad-hoc and informal approach to these and other governance meetings, due to the same individuals being involved in decision making in other groups.

The last medical advisory committee meeting was on 26 May 2020, the one prior to this was on 7 January 2019, a gap of 16 months without a meeting. Furthermore, minutes from the meeting in May 2020 indicated the meeting was an extraordinary meeting to discuss the re-opening of the hospital following the coronavirus pandemic rather than discussing routine committee business. The minutes of the meeting in January 2019 did not demonstrate an effective approach to quality assurance and clinical effectiveness as the expected topics were not discussed.

The composition of the committee was described as the director of clinical services, medical director, managing director, surgeon, anaesthetist and a representative from management. The nursing perspective on the medical advisory committee was said to be provided by the director of clinical services, who was an operating department practitioner, not a registered nurse

The complaints policy stated that complaints would be acknowledged within two days of receipt and would be responded to within 20 days. Documentation supplied by the service showed they kept a record of complaints received and if they were acknowledged within three days and if they were responded to within 'the timescale agreed with the complainant'. This was inconsistent with the policy. There was also no reference to where complaints would be discussed and reviewed within the governance process although the meeting tracker indicated that they would be discussed at medical advisory, clinical governance, intersite compliance and managers meetings. During the inspection period we reviewed a sample of minutes from such meetings and did not see evidence that complaints and learning outcomes were discussed.

Surgery

The Minor Surgery Policy was approved in May 2010 and was last reviewed in January 2018. It contained relevant information however the section on Staff Competence referred to General Practitioners but not surgeons or anaesthetists.

The clinical governance and quality policy (November 2019) did not clearly articulate the governance process by which safe, high quality care would be assured. It only referenced the clinical governance committee and the appended terms of reference for the committee had no reference to where the committee reported or escalated concerns.

We reviewed the Governance and Quality report 1 April 2018 to 31 March 2019. It reported on activity, complaints and significant events and post-operative quality indicators. This did not lead to any actions or action plan.

Managing risks, issues and performance

The service had a schedule of meetings including the 'guacamole' meeting, the clinical governance meeting, the medical advisory committee meeting, management meetings and team meetings.

The clinical governance meeting was scheduled to be an annual meeting. There was no set agenda for the meeting and the terms of reference of the meeting was that agenda items would include serious untoward incidents, risk management, complaints and significant events. In the minutes of the meeting dated 16 January 2020, we saw that none of these items were on the meeting's agenda and that there had been a number of significant events and complaints in the preceding year.

We saw that there had been clinical governance meetings on 17 October 2018, 5 June 2019 and 16 January 2020. Indicating they are undertaken every six months. The minutes of the meeting do not evidence a focus on and analysis of clinical risks, performance, safety and patient experience, the content indicated it to be an operational meeting.

We saw evidence that some audits had taken place but there was no structured audit plan or annual audit calendar. We saw evidence that a documentation audit had been carried out, however this did not lead to an action or improvement plan. It was not clear how audits were used to improve standards within the service.

Staff we spoke with on inspection told us they had not conducted any audits or were aware of an audit programme, but managers were in the process of reviewing this. We noted that within some policies there was reference to audit. In the Minor Surgery Policy under section Clinical Audit and Effectiveness, it stated that the service would develop an audit plan and staff would undertake regular audit. In the Significant Events Policy under the section annual analysis the policy states that Pall Mall Medical will establish an annual significant events analysis, an audit of significant events. Managers told us there was no audit plan but would look at how this may be introduced.

Following a request for information during inspection concerning surgical site infections, managers undertook a surgical site infection audit and went on to look at trends and recommendations for improvements. This enabled managers to better understand their performance and enable them to seek improvements in practices.

We reviewed the service risk register dated February 2020. This included clinical risks and other risks including health and safety and facilities. Four clinical risks had been added to the register in November 2019. These risks were graded as high and two of them had no actions attached to them. There were no review dates against any of the risks. From the evidence supplied and reviewed during the inspection period, we did not see a discussion or reference to the risks from the risk register within any of the minutes of the various meetings shared with us where risk and risk management were items on the agenda. It was unclear who in the organisation had responsibility for the management of risk.

One of the risks on the risk register dated February 2020 was the out of hours needs of patients. This was rated as high and had no actions attached to it. It had been open since November 2019. We could find no evidence that this had been reviewed since it was added to the risk register.

Another was emergency complications. This was rated as high and although there were actions attached to the risk, the risk was still open. This had been on the risk register since November 2019. We could find no evidence that this had been reviewed since it was added to the risk register.

Therefore, 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. Managers explained the process for managing risk and performance issues was through the weekly scheduling meeting and daily ward and theatre 'huddles'. They also had regular 'guacamole' meetings which were clinical meetings and looked at revision rates, the patient journey and reviewed performance. Managers told us these meetings were documented, action focussed and identified accountable staff for actions. We reviewed the minutes of the guacamole meetings from the 23 January 2020 and 12 March 2020. There was no set agenda for the meeting, and it was not clear if actions had been completed. There were no agenda items for clinical risk or a review of the risk register. Clinical risk was included in the description of the meeting in the Medical Meeting Tracker. This inconsistency may lead to clinical risk not being identified or addressed.

We found there was not a robust and effective process or system to ensure staff followed up to date best practice guidance and policy. There was also no robust system to ensure all policies and processes were in line with current national guidelines and best practice.

We were not assured that patient safety and clinical quality was a priority for the service. We were not assured that there was an effective system for identifying, capturing, and managing issues and risks at team and organisational level. Significant issues which may threaten the delivery of safe and effective care were not identified, therefore action was not implemented to manage them.

Managing information

NOT INSPECTED

Engagement

NOT INSPECTED

Learning, continuous improvement and innovation

NOT INSPECTED

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The service must ensure there are effective systems in place to ensure that care and treatment was provided with consent. They must ensure that the policies and procedures for obtaining consent reflect current legislation and guidance. The service must ensure the person from whom consent was required, is provided with sufficient information about their proposed care and treatment, which includes full information about risks and complications, to enable informed consent to be achieved. **This was a breach of Regulation 11(1).**
- The service must ensure that they do all that is reasonably practicable to mitigate the risk to ensure the safe care and treatment of patients. They must follow good practice guidance and adopt control measures to reduce risk, they must ensure staff follow acceptable pathways and established safe systems of working. They must consult nationally recognised guidance about delivering safe care and treatment and ensure these are followed by staff. **This was a breach of Regulation 12(2)(b).**
- The provider must ensure that person's providing care and treatment to service users have the qualifications, competence, skills and experience to do so safely. **This was a breach of Regulation 12(2)(c).**
- The provider must ensure that the policy and procedures in place support people to make a complaint easily. They must ensure that when people do complain they receive a timely and satisfactory response. They must identify and use lessons learned from complaints as an opportunity to learn. **This was a breach of Regulation 16(2).**
- The provider must ensure they have an effective system or audit process in place to identify, capture and manage issues and risks at team and organisation level. **This was a breach of Regulation 17(2)(a).**
- 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. They must ensure there are systems in place which enable them to identify and assess risks to people who use the service. They must ensure that policies and operating procedures reflect best practice and national guidance and direct staff to follow safe systems of practice. **This was a breach of Regulation 17(2)(b).**
- The provider must ensure that a secure, accurate, complete and contemporaneous record is maintained in respect of each service user. They must ensure that the record is legible and complete and contains an accurate record of all decisions taken in relation to the care and treatment, this includes consent records. The provider must ensure sufficient documentation is provided to a patient who has received treatment to enable safe ongoing care to be provider by another medical practitioner. **This was a breach of Regulation 17(2)(c).**

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
	Regulation 11 HSCA (RA) Regulations 2014 Need for consent Diagnostic and screening proceduresFamily planning servicesSurgical proceduresTreatment of disease, disorder or injury

Regulated activity	Regulation
	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Diagnostic and screening proceduresFamily planning servicesSurgical proceduresTreatment of disease, disorder or injury

Regulated activity	Regulation
	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints Diagnostic and screening proceduresFamily planning servicesSurgical proceduresTreatment of disease, disorder or injury

This section is primarily information for the provider

Enforcement actions

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
Diagnostic and screening procedures Family planning services Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance