

ELM Alliance Limited Extended Hours and Out of Hours Service (known as the STAR service)

Quality Report

ELM Alliance Limited
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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 service	Inadequate	
Are services safe?	Inadequate	
Are services effective?	Inadequate	
Are services caring?	Good	
Are services responsive to people's needs?	Requires improvement	
Are services well-led?	Inadequate	

Summary of findings

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Overall summary

Letter from the Chief Inspector of General Practice

We carried out an unannounced comprehensive inspection of ELM Alliance Limited Extended Hours and Out of Hours service (known as the STAR service) on 11 and 12 July 2017 as we had received some information of concern about the out of hours service being provided. Overall the service is rated as inadequate. We visited two locations that the service is delivered from; Park Surgery in Middlesbrough and Bentley Medical Practice at Redcar.

Our key findings across all the areas we inspected were as follows:

- There was no open and transparent approach to safety and no effective system in place for recording, reporting and learning from significant events.
- Risks to patients were not adequately assessed or acted upon.
- We found concerns about the management of medicines.
- There was a system in place that enabled staff access to patient records, and information was shared with the patients GP following contact with patients using the out of hours service

- The service managed patients' care and treatment in a timely way with the exception of home visits which were below the national quality requirements.
- Patients said they were treated with compassion, dignity and respect and they were involved in their care and decisions about their treatment.
- Safeguarding procedures were not always followed.
- There was a lack of overarching governance.
- There was an ineffective system for handling complaints and complaints handling was not used to improve services within the organisation.
- The vehicle used for home visits was not well equipped and some emergency equipment was not readily available at the sites visited.
- There was a leadership structure but communication between staff and management was limited and some staff felt unsupported by managers.

The areas where the provider must make improvement are:

- Implement appropriate processes for assessing and checking that the candidate holds the required qualifications and has the competence, skills and experience required and is of good character.

Summary of findings

- The provider must deploy sufficient numbers of suitably qualified, competent, skilled and experienced staff to make sure that they can meet people's care and treatment needs.
- Providers should use incidents and complaints to identify potential abuse and should take preventative actions, including escalation, where appropriate.
- The Provider must maintain a record of all complaints, outcomes and actions taken in response to complaints. Complainants must be kept informed of the status of their complaint and its investigation and be advised of any changes made as a result. The provider should monitor complaints over time, looking for trends and areas of risk that may be addressed.
- The provider must establish systems and processes and operate effectively to ensure they assess, monitor and mitigate the risks relating to health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. Fire drills should be carried out and outcomes documented. Fire training for all staff must be kept up to date. There must be an appropriate documented fire risk assessment in place that is bespoke to the out of hours service provided from each location.
- The provider must ensure the safety of their premises and the equipment within it. Process and systems must be in place that assure compliance with statutory requirements, national guidance and safety alerts. There must be documented processes in place for monitoring clinical equipment, to ensure that it is fit for purpose and that disposable items are in date.
- Medicines must be available in the necessary quantities at all times.
- Incidents that affect the health, safety and welfare of people using services must be reported internally and to relevant external authorities. They must be reviewed and thoroughly investigated by competent staff, and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result.

- Systems and processes must support the confidentiality of people using the service and not contravene the Data Protection Act 1998. Smart cards (a unique user system for accessing electronic patient records) must only be used by the person whom the smart card has been issued to and the practice of sharing or using another person's card must cease.

The areas where the service should make improvements are:

- Clinical supervision should be facilitated for all clinicians and this should be recorded. One to one support should be made available to all staff.
- An effective induction programme which includes areas of mandatory training should be implemented.
- Infection control audits, specific to each location must be undertaken and these should include action plans and review dates.
- The provider should implement an effective process to make sure that all staff are kept up to date and informed of key issues taking place at the service.
- Have systems in place to ensure that National Quality Requirement (NQR) key performance indicators are met each month in respect of face to face consultations in patients' homes.
- Implement an effective system to record staff training and be satisfied that this is accurate and up to date.
- Implement an effective system for the management of controlled drugs, in line with the provider's Home Office licence.

I am placing this service in special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate for any population group, key question or overall, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve.

The service will be kept under review and if needed could be escalated to urgent enforcement action. Where

Summary of findings

necessary, another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to remove this location or cancel the provider's registration.

Special measures will give people who use the service the reassurance that the care they get should improve.

Professor Steve Field (CBE FRCP FFPH FRCGP)
Chief Inspector of General Practice

Summary of findings

The five questions we ask and what we found

We always ask the following five questions of services.

Are services safe?

The service is rated as inadequate for providing safe services and improvements must be made.

- Staff were not clear about reporting incidents, near misses and concerns. Investigations were not thoroughly carried out by the provider when there were unintended or unexpected safety incidents.
- Lessons learned were not demonstrated or communicated and so safety was not improved.
- Patients did not always receive an explanation or an apology when one was appropriate.
- Patients were at risk of harm because systems and processes were not in place or were not implemented in a way to keep them safe. Some areas of concern included the safe recruitment of staff, medicines management, and the availability of emergency equipment.
- There was insufficient attention to safeguarding children and vulnerable adults. Staff did not always recognise or respond appropriately if they suspected abuse had occurred.

At the time of the inspection there were enough staff available and on duty to keep patients safe.

Inadequate



Are services effective?

The service is rated as requires improvement for providing effective services, as there are areas where improvements should be made.

- Data showed the service was not meeting the National Quality Requirements (performance standards) for GP out of hours services. For example, it was non-compliant in the key performance target of visiting patients at home within 90 minutes of arrangement. Target minimum is 90%; compliance was 69% for the month of June, 2017.
- Clinicians had an awareness of national guidelines.
- There was limited recognition of the benefit of an appraisal or developmental support process for staff and little support for any additional training that may be required.

Training opportunities were limited and there was no effective system for recording staff training so that staff could update their skills when required.

Inadequate



Are services caring?

The service is rated as good for providing caring services.

Good



Summary of findings

- Feedback from patients through our inspection was positive.
- Patients said they were treated with compassion, dignity and respect and they were involved in decisions about their care and treatment.
- Information for patients about the services available was easy to understand and accessible.
- We saw staff treated patients with kindness and respect.
- Patients were kept informed with regard to their care and treatment throughout their visit to the out-of-hours service, but were not always kept informed about waiting time delays.

Are services responsive to people's needs?

The service is rated as requires improvement for providing responsive services.

- The service had reviewed the needs of its local population but as a new organisation it was still working towards securing improvements for all of the areas identified. The locations were predetermined by the commissioners in the service contracts and there were no planned changes.
- The urgency of patients' conditions and their order of being telephone consulted are based on the urgency predetermined by 111 dispositions. Patients pre-booked by their own GPs would be treated routinely. Patients with priority conditions did not always receive treatment in a timely manner, especially with regard to home visits.
- The service was not fully well equipped to treat patients. For example, it was not sufficiently stocked with medicines and oxygen.
- Patients could get information about how to complain but this was not widely accessible. Complaints were not always recorded and there was no evidence that learning from complaints had been shared with staff.

Requires improvement



Are services well-led?

The service is rated as inadequate for being well-led.

- The service had have a vision and strategy but staff were not clear about their responsibilities in relation to this.
- There was no clear leadership structure and staff did not feel supported by management.
- The service had a number of policies and procedures to govern activity, but these were not tailored to the locations and were often inaccessible to staff.

Inadequate



Summary of findings

- The service did not hold regular governance meetings. Issues were discussed at ad hoc meetings but these were not effectively cascaded to staff.
- The service had not proactively sought feedback from staff or patients.
- Staff told us they had not received regular performance reviews and did not have clear objectives.
- There was no system held by managers to verify that staff had attended training sessions.
- There was some ad hoc assessment of the telephone triage capabilities for some clinicians.
- Smart cards (unique user cards which allow access to patients' electronic records were not being protected.

Summary of findings

What people who use the service say

Feedback received from patients about the out-of hours service they received was limited. Patient feedback was obtained by the provider on an ongoing basis and included in their contract monitoring reports, but as the service was in its infancy, this data was not available at the time of inspection.

There was no nationally reported GP patient survey data available for this service (which asks patients about their satisfaction with an out-of-hours service).

We spoke with three patients during the inspection. All three patients said their dignity and respect was maintained by nursing and medical staff and receptionists.

Areas for improvement

Action the service MUST take to improve

- Implement appropriate processes for assessing and checking that the candidate holds the required qualifications and has the competence, skills and experience required and is of good character.
- The provider must deploy sufficient numbers of suitably qualified, competent, skilled and experienced staff to make sure that they can meet people's care and treatment needs.
- Providers should use incidents and complaints to identify potential abuse and should take preventative actions, including escalation, where appropriate.
- The Provider must maintain a record of all complaints, outcomes and actions taken in response to complaints. Complainants must be kept informed of the status of their complaint and its investigation and be advised of any changes made as a result. The provider should monitor complaints over time, looking for trends and areas of risk that may be addressed.
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- The provider must ensure the safety of their premises and the equipment within it. Process and systems must be in place that assure compliance with statutory requirements, national guidance and safety alerts. There must be documented processes in place for monitoring clinical equipment, to ensure that it is fit for purpose and that disposable items are in date.
- Medicines must be available in the necessary quantities at all times.
- Incidents that affect the health, safety and welfare of people using services must be reported internally and to relevant external authorities. They must be reviewed and thoroughly investigated by competent staff, and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result.
- Systems and processes must support the confidentiality of people using the service and not contravene the Data Protection Act 1998. Smart cards (a unique user system for accessing electronic patient records) must only be used by the person whom the smart card has been issued to and the practice of sharing or using another persons cards must cease.

Summary of findings

Action the service **SHOULD** take to improve

- Clinical supervision should be facilitated for all clinicians and this should be recorded. One to one support should be made available to all staff.
- An effective induction programme which includes areas of mandatory training should be implemented.
- Infection control audits, specific to each location must be undertaken and these should include action plans and review dates.
- The provider should implement an effective process to make sure that all staff are kept up to date and informed of key issues taking place at the service.
- Have systems in place to ensure that National Quality Requirement (NQR) key performance indicators are met each month in respect of face to face consultations in patients' homes.
- Implement an effective system to record staff training and be satisfied that this is accurate and up to date.
- Implement an effective system for the management of controlled drugs, in line with the provider's Home Office licence.

ELM Alliance Limited Extended Hours and Out of Hours Service (known as the STAR service)

Detailed findings

Our inspection team

Our inspection team was led by:

Our inspection team was led by two CQC Inspectors. The team included a CQC Inspection Manager, CQC GP specialist adviser, a member of the CQC medicines team, and two second CQC inspectors.

Background to ELM Alliance Limited Extended Hours and Out of Hours Service (known as the STAR service)

As a response to some safety concerns raised with the Care Quality Commission, we undertook an unannounced inspection of ELM Alliance Limited on the evening of 11 July 2017 and 12 July 2017. ELM Alliance Limited is an independent health care provider commissioned by South Tees Clinical Commissioning Group (CCG) to operate the enhanced urgent care service (extended and out of hours service with appointments during the night) across South Tees. ELM Alliance, a not for profit federation of all independent GP practices, took over the operation on 1

April 2017, offering care to around 330,000 patients. The service operates from 6pm until 8am every day. From 6pm until 9.30pm extended hours appointments are available at all four of the locations. At 9.30pm every evening the locations at North Ormesby and Brotton close. The Middlesbrough and Redcar locations continue to deliver services from 9.30pm until 8am every day, as the organisation operates as an out of hours service during these times. It offers urgent care appointments, as well as routine face-to-face and home visit appointments to patients who have been referred to it via their own GPs; or urgent care appointments by the NHS 111 service.

Park Surgery, Linthorpe Road, Middlesbrough TS1 is one of four locations used by ELM Alliance Limited to deliver the enhanced urgent care service across the South Tees area. The additional locations are at Redcar Primary Care Hospital, Hirsell medical Practice in North Ormesby and Brotton Hospital in Saltburn. On the evening of our inspection we visited the hub at Redcar in addition to Park Surgery. The service also has a vehicle which is used to transport clinicians to home visits during the night.

There are 113 staff members working for the provider, many of whom have a zero hours contract arrangement in place. These include 45 GPs, 25 advanced nurse practitioners, one emergency care practitioner, six treatment room nurses, ten health care assistants and 26 administrative staff.

Detailed findings

Locums are used on a regular basis, in addition to the contracted staff. Many staff carry out their duties from more than one of the registered locations.

As a result of our inspection the Care Quality Commission requested an immediate action plan from the provider to address the serious shortfalls that were identified in terms of the health, safety and well being of patients who were accessing the out of hours service. We were supplied with an action plan detailing specific changes made to systems and processes that were failing to keep people safe on the evening of our inspection.

Why we carried out this inspection

We carried out a comprehensive inspection of this service under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions as a response to some safety concerns raised with the Care Quality Commission. The inspection was planned to check whether the provider is meeting the legal requirements and regulations associated with the Health and Social Care Act 2008, to look at the overall quality of the service, and to provide a rating for the service under the Care Act 2014.

How we carried out this inspection

Before visiting, we reviewed a range of information we hold about the service and asked other organisations to share what they knew. We carried out an unannounced visit on 11 July 2017 and returned by appointment on 12 July 2017 to complete our checks.

During our visit we:

- Spoke with a range of staff (GPs, nurses, administrative staff, car drivers) and spoke to patients who used the service.
- Observed how patients were cared for in the waiting areas.
- Inspected the out of hours premises, looked at cleanliness and the arrangements in place to manage the risks associated with healthcare related infections.
- Looked at the vehicle used to take clinicians to consultations in patients' homes, and we reviewed the arrangements for the safe storage and management of medicines and emergency medical equipment.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

Please note that when referring to information throughout this report, for example any reference to the National Quality Requirements data relates to the most recent information available to the CQC at that time.

Are services safe?

Our findings

Safe track record and learning

There was no effective system in place for reporting and recording significant events.

There was an incident recording form available on the service's computer system but many staff had difficulties in accessing this. Staff could demonstrate they understood Duty of Candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment). However, we saw evidence that when things went wrong with care and treatment, appropriate procedures were not always followed. Analysis of incidents was not carried out and there was little investigation. Communication with staff was ineffective and there was limited action taken to improve processes to prevent the same thing happening again. Learning points were not disseminated with staff in an appropriate or timely manner.

We reviewed safety records, incident reports, patient safety alerts and minutes of meetings where these were discussed. We saw evidence that lessons were not analysed or shared and action was not being taken to improve safety in the service. For example, We were told that a weekly meeting took place with the three clinical directors and the head of operational management. The minutes recorded at these meetings lacked content and detail and we saw that these were not taking place weekly. A brief sentence which summarised significant incidents was put into a newsletter and distributed by email to staff, but key learning points were not shared. There had been one newsletter produced since April 2017.

A number of significant incidents involving medicines had been recorded in the preceding three months, for example medicines for use in an emergency, antibiotics and pain relief being unavailable. The service had not acted to adequately investigate these incidents or review practices to prevent reoccurrence.

Overview of safety systems and processes

The service had systems, processes and services in place to keep patients safe and safeguarded from abuse, but these were not being adequately followed:

- Arrangements were in place to safeguard children and vulnerable adults from abuse. These arrangements

reflected relevant legislation and local requirements. Policies were not accessible to all staff due to difficulty in accessing the computer systems shared drive where policy documents were stored. There were no hard copies available for reference. The policies outlined who to contact for further guidance if staff had concerns about a patient's welfare.

- There was a lead member of staff for safeguarding but staff were unclear about who the safeguarding lead person was. Staff demonstrated they understood their responsibilities and we were told by managers that staff had received training on safeguarding children and vulnerable adults relevant to their role. However, this had been undertaken within other employments, and ELM Alliance Limited had no oversight or evidence of this training. We were told that GPs were trained to child safeguarding level three and nurses were trained to level two, but there was no evidence to support this and a significant incident we sampled indicated that procedures were not always followed and there had been a delay in the process of making a safeguarding referral for a child.
- A notice in the waiting room advised patients that chaperones were available if required. Staff who acted as chaperones were not always trained for the role and they had not received a Disclosure and Barring Service (DBS) check. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). Due to the lone working nature of the out of hours service, chaperones could not always be offered, for example, during home visits.
- The service maintained appropriate standards of cleanliness and hygiene. We observed the premises to be clean and tidy. There was an infection control lead that covered all four locations. There was an infection control protocol in place but no evidence that staff had received infection control training. We did not see infection control audits or action plans that were relevant to ELM Alliance Limited
- A review of eight staff files demonstrated that staff were not always recruited in accordance with the policy and some information was either incomplete or missing. For example, we reviewed eight staff files during the inspection. Five of these files contained no

Are services safe?

references and Disclosure and Barring Service records were not present in all eight of the files.

- There was no evidence confirmation that a robust induction programme had been completed.
- There were no records that any General Medical Council or Nursing and Midwifery Council checks had been undertaken prior to or during the recruitment process of clinicians. The service also employed locums provided by an agency. The service relied on the agency to inform them of recruitment procedures and evidence of recruitment checks for the staff they provided. However the provider had not assured themselves that the locum agency had robust processes in place to ensure that checks were complete. Without effective systems in place to evidence the recruitment procedures of staff, the provider was putting patients at potential risk of being treated by inappropriately qualified staff.

Medicines Management

Arrangements for managing medicines were checked at the service. Medicines were issued at both the Redcar and Middlesbrough sites for people who required them out of hours.

The service held stocks of controlled drugs (medicines that require extra checks and special storage arrangements because of their potential for misuse), and had policies in place governing their management. Controlled drugs were stored in a controlled drugs cupboard and the keys held securely. We checked entries in the controlled drugs register and found they had not been made in accordance with the relevant legislation. For example, the name and address of the supplier, the person the drugs had been supplied to, and details of the person authorising the supply had not always been recorded. In addition, staff did not routinely check stock balances of controlled drugs in accordance with the service's policy to ensure the amounts held reflected what was recorded in the register.

The service had a stock list that set out which medicines they should stock. We checked medicines stocks at the Park Surgery site and found some medicines including antibiotics and medicines used for people who are at the end of their life, were not available. We raised this concern with staff who told us stock was replenished twice weekly

on a Monday and Friday, and that the box had not been swapped this week but would be changed at the start of the shift. When we returned at 10:55pm, we found these medicines were still not available.

There were adequate stocks of emergency equipment and medicines, oxygen, and a defibrillator with pads held at both sites. These were shared with other GP practices; however there was no system in place for the out of hours service to assure themselves all necessary items were available and within their expiry date. This meant there was a risk items may not be replaced when they were used, especially over the weekend. We found some medicines had expired in the emergency trolley held at the Redcar site. In addition, some of the staff we spoke to did not know how to access emergency medicines and equipment.

We checked medicines and equipment in one of the transport vehicles and found expired medicines in one of the doctor's bags. The supply of oxygen in the vehicle was less than half full and there was no adult sized oxygen mask available. Staff were unable to tell us who was responsible for checking these were in place and fit for use, and could not provide us with any records of checks being undertaken. Medicines were removed from the vehicle to safe storage when not in use and a record was kept of medicines transferred in and out.

The service kept blank computer prescription forms and pads securely, however there was no system in place to track their use in accordance with national guidance.

Monitoring risks to patients

Risks to patients were not assessed and managed effectively.

- The service had no up to date fire risk assessments and had not undertaken any fire drills.
- Electrical equipment was checked to ensure the equipment was safe to use and clinical equipment was checked to ensure it was working properly. Clinical equipment that required calibration had not yet been calibrated according to the manufacturer's guidance, but a date to carry this out had been set. ELM Alliance Limited operated from, but did not own their premises.
- They had not satisfied themselves that there were no risks posed by the premises. For example, the service had no oversight of other risk assessments in place to monitor safety of the premises such as control of substances hazardous to health and infection control

Are services safe?

and legionella (Legionella is a rare bacteria which can contaminate water systems in buildings). A risk assessment of the building at the Park surgery location had not been undertaken even though this had been highlighted as a significant risk by staff.

- There were systems in place to ensure the safety of the out of hours vehicles. Checks were undertaken at the beginning of each shift by the drivers. These checks included vehicle maintenance and equipment. Records were kept of MOT and servicing requirements. We checked the vehicle and found it to be clean.
- Arrangements were in place for planning and monitoring the number of staff and mix of staff needed to meet patients' needs. There was a rota system in place for all the different staffing groups to ensure enough staff were on duty. However, the rota was confusing and it was difficult to analyse whether shifts were adequately covered. The rota was not completed within an adequate timeframe. For example, the rota we looked at on 11 and 12 July 2017, had still not been fully covered for August 2017. Some staff were confused who they were expecting on duty, and from which locations they were working.
- With patients' consent, clinicians have access to a patient's full medical record via a computerised system and a summary of their record (where the computer system is non-compatible with a patient's own GP practice). This allows clinicians to view relevant background conditions, recent consultations, allergies, hospital letters, blood results, current and repeat medication and any special notes, for example, palliative care patients.

Arrangements to deal with emergencies and major incidents

The service did not have adequate arrangements in place to respond to emergencies and major incidents.

- There was a system to alert staff to any emergency via the computer system.
- There was no evidence that staff had received basic life support training, including use of an automated external defibrillator.
- The service had defibrillators available on both premises we inspected, and oxygen with adult and children's masks (with the exception of the out of hours vehicle). This was kept behind a door which had a coded keypad to keep it locked. On the evening of our inspection, several staff members did not know the code for this door and would therefore have been unable to, or slow to, respond in an emergency. This posed a significant risk to patients attending with urgent care needs.
- The service had a business continuity plan in place for major incidents such as power failure or building damage. The plan included emergency contact numbers for staff. The plan was activated during a recent national cyber-attack on NHS computer systems, but some staff felt that the plan had not been effective enough and lacked robust contingency.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment

We were told that the service assessed needs and delivered care in line with relevant and current evidence based guidance and standards, including National Institute for Health and Care Excellence (NICE) evidenced based guidelines, however:

- Staff had limited access to guidelines from NICE. Hard copies for reference contained only four NICE guidelines and we saw no evidence that relevant updates on medication safety had been circulated to clinical staff.
- The health care assistants who undertook baseline observations when patients arrived at the service had information relating to normal values and vital signs, which enabled them to easily escalate concerns to clinicians.

Management, monitoring and improving outcomes for people

From 1 January 2005, all providers of out-of-hours services have been required to comply with the National Quality Requirements (NQR) for out-of-hours providers. The NQR are used to show the service is safe, clinically effective and responsive. Providers are required to report monthly to the clinical commissioning group on their performance against standards which includes audits, whether face to face assessments happened within the required timescales, seeking patient feedback and actions taken to improve quality.

NQR 4: Providers must regularly audit a random sample of patient contacts and appropriate action will be taken on the results of those audits.

ELM Alliance had undertaken some sampling of telephone triage calls due to concerns highlighted to the provider. Evidence indicated that this sampling had uncovered further concerns about the same clinician's triage competency. A triage summary was recorded but this did not include any analysis or actions. There was no evidence that these triage concerns were investigated, which potentially could have put patients at risk of harm. There was no evidence that this had been shared with the multidisciplinary team, therefore not meeting the national quality requirement standards.

NQR 12: Face-to-face consultations (whether in a centre or in the patient's place of residence) must be started within the following timescales, after the definitive clinical assessment has been completed:

- Emergency: Within 1 hour.
- Urgent: Within 2 hours.
- Less urgent: Within 6 hours.

Data from June 2017 showed that the provider achieved 100% compliance with this NQR when patients were seen in the registered locations. The exception to this was where patients were visited in their own home. Here the provider's results were below the 90% minimum target, at 78% which did not meet the national quality requirement standards.

In addition to these national quality requirements, the provider had a contract agreement with the local CCG that it would visit not less than 90% of its patients needing a home visit within 90 minutes of that disposition being made. Data for this indicated that the provider had only achieved a compliance of 69% for this key performance area.

Quality improvement including clinical audit had not yet been completed due to the infancy of the organisation. We saw no evidence of any audit plans for the following months.

There was no evidence that information about patients' outcomes was used to make improvements to services.

Effective staffing

Staff had the skills, knowledge and experience to deliver effective care and treatment, however:

- The induction programme for newly appointed staff was poor. It did not cover topics such as safeguarding, infection prevention and control, fire safety, health and safety and confidentiality.
- There was no supervision, one-to-one or appraisal system in place for staff.
- The service could not demonstrate how they ensured role-specific training and updating for relevant staff.
- The learning needs of staff were not being identified as there was no system of appraisals, meetings and reviews of service development needs. There was no

Are services effective?

(for example, treatment is effective)

system of ongoing support, one-to-one meetings, coaching and mentoring, or clinical supervision. Staff had not yet received an appraisal, since the organisation was in its infancy.

- There was no evidence that staff had received training that included: safeguarding, fire safety awareness, basic life support and information governance. Managers had access to the online system which tracks individual staff online training, but there was not a central record of all training. Staff reported difficulties in accessing this online training.

Coordinating patient care and information sharing

The service worked with other service providers to meet patients' needs and manage patients with complex needs. It sent out-of-hours notes to the registered GP services electronically by 8am the next morning.

The information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way through the service's patient record system and their intranet system.

- This included access to a summary care record which detailed information provided by the person's GP. This helped the out of hours staff in understanding a person's need.
- The service shared relevant information with other services in a timely way, for example when referring patients to other services.

- If patients needed specialist care, the out-of-hours service, could refer to specialties within the hospital. Staff also liaised with the mental health and district nursing team if they needed support during the out-of-hours period.
- Providers must have a robust system for identifying all immediate life threatening conditions and, once identified, those calls must be passed to the ambulance service within three minutes. The provider's key performance data from June 2017 showed that they had achieved 100% on this target.

Consent to care and treatment

Staff sought patients' consent to care and treatment in line with legislation and guidance.

- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. When providing care and treatment for children and young people, staff carried out assessments of capacity to consent in line with relevant guidance.
- Where a patient's mental capacity to consent to care or treatment was unclear clinical staff assessed the patient's capacity and, recorded the outcome of the assessment.

Are services caring?

Our findings

Contract management arrangements with the clinical commissioning group (CCG) included the regular audit of samples of patient experiences of the service. As the organisation was still in its infancy, these findings had not yet been obtained and could not be included in our inspection findings.

Kindness, dignity, respect and compassion

We observed members of staff were courteous and very helpful to patients and treated them with dignity and respect.

- Curtains were provided in consulting rooms to maintain patients' privacy and dignity during examinations, investigations and treatments.
- We noted that consultation and treatment room doors were closed during consultations; conversations taking place in these rooms could not be overheard.
- Reception staff knew when patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.

Patients said their dignity and respect was maintained by nursing and medical staff and they were treated with dignity, compassion and respect by the receptionists.

There was no available national GP patient survey data (which asks patients about their satisfaction with the out-of-hours service) as the service only came into operation on 1 April 2017.

Care planning and involvement in decisions about care and treatment

Patients told us they had enough time during their consultation, felt involved in their care and treatment and were listened to.

The service provided facilities to help patients be involved in decisions about their care:

- Staff told us that translation services were available for patients who did not have English as a first language.
- Information leaflets were available in easy read format.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The service reviewed the needs of its local population and engaged with its commissioners to secure improvements to services where these were identified. For example, a second visiting car was obtained when it was felt that providing the service with one vehicle was insufficient. However, we found on the evening of our inspection that the second vehicle had been acquired but not used since its acquisition, some weeks earlier.

- Home visits were available for patients whose clinical needs resulted in difficulty attending the service, but this did not include children. There were delays in providing home visits to patients that needed them.
- There were accessible facilities, a hearing loop and translation services available.

National Quality Requirement data for June 2017 showed that: 100% of patients who were unable to communicate effectively in English were provided with an interpretation service within 15 minutes of initial contact, during that month.

Access to the service

The service operated from 6pm until 8am every day. From 6pm until 9.30pm extended hours appointments were available at all four of the locations. At 9.30pm every evening the locations at North Ormesby and Brotton closed. The Middlesbrough and Redcar locations continued to deliver services from 9.30pm until 8am every day, as the organisation operated as an out of hours service during these times. It offered urgent care appointments to patients who had been referred to it via their own GP or by the NHS 111 service. The service did not see 'walk in' patients and those that came in were told to ring NHS 111 unless they needed urgent care in which case they would be stabilised before being referred on. There were arrangements in place for people at the end of their life so they could contact the service directly.

Feedback received from the National Quality Requirements scores indicated that in most cases patients were seen in a timely way.

The service had a system in place to assess:

- whether a home visit was clinically necessary; and
- The urgency of the need for medical attention.

This was done through a telephone triage system, where clinicians gathered information and made decisions according to clinical need.

Listening and learning from concerns and complaints

The service had an ineffective system in place for handling complaints and concerns.

- Complaints were not being consistently recorded.
- Recorded complaints lacked analysis, action and feedback.
- The complaints policy and procedures were not in line with the NHS England guidance and their contractual obligations.
- Complaints from staff were not awarded the same significance as those made by people using the service.
- There was a designated responsible person who co-ordinated the handling of all complaints in the service.
- We saw that information was available to help patients understand the complaints system on the ELM Alliance Limited website.

We looked at five complaints received since 1 April 2017 and found that these were not all satisfactorily handled. There was limited investigation in some examples, and root cause analysis was not demonstrated. Complainants were not advised how to proceed if their complaint was not satisfactorily resolved. Lessons learnt were not demonstrated from individual concerns and complaints. Action was therefore not taken to improve the quality of care. For example, when a parent of a patient made a written complaint about a GP's attitude during a telephone consultation regarding their unwell baby, there was no evidence of any investigation or learning points identified and shared with staff.

Are services well-led?

Inadequate 

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action)

Our findings

Vision and strategy

The service had a vision to deliver high quality care and promote good outcomes for patients, but it did not instil this vision in its staff. The service had no mission statement nor business development plan, however, the organisation was still in its infancy and was moving towards the development of this.

Governance arrangements

The service had an overarching governance framework but did not effectively implement the governance of the organisation.

- There was a staffing structure and staff were aware of their own roles and responsibilities. However staff were not all aware of the responsibilities the senior leadership team held, for example they didn't know who the safeguarding lead was.
- Policies were not always service specific and were not always available to all staff.
- The provider had an understanding of their performance against National Quality Requirements. These were discussed at senior management level but information was not regularly cascaded to all staff. Performance was shared the local clinical commissioning group as part of contract monitoring arrangements.
- There were ineffective arrangements for identifying, recording and managing risks, issues and implementing mitigating actions.
- Smart cards (a unique user system for accessing electronic patient records) were not always protected. On occasions, staff were allowing others to use their card which contravenes the smart card usage policy. During our inspection we saw a smart card left unattended in a computer.
- There was a considerable lack of evidence that training was effectively taking place.

Leadership and culture

On the day of inspection the provider of the service could not fully demonstrate they had the experience, capacity and capability to run the service and ensure high quality care.

The provider was aware of the requirements of the duty of candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment). There was limited support training for all staff on communicating with patients about notifiable safety incidents. There was a culture which lacked openness and honesty, and when some staff raised concerns they received no response from managers. When things went wrong with care and treatment:

- The service gave affected people only a limited explanation and an apology where appropriate. This was not in compliance with the NHS England guidance on handling complaints.
- The service kept some, but not all, written records of verbal interactions as well as written correspondence.

There was a leadership structure in place but some staff felt unsupported by management.

- There were limited arrangements in place to ensure the staff were kept informed and up-to-date. This included a lack of clinical and non-clinical meetings or clinical supervision. Staff were communicated with by a quarterly emailed newsletter.
- Staff told us there was a culture which lacked openness within the service and they had limited opportunity to raise any issues. When raising issues, they did not feel supported by managers. Issues raised were sometimes not responded to at all, despite repeated requests for action, from staff.
- Some staff described the leadership of the service as chaotic.

Seeking and acting on feedback from patients, the public and staff

The service did not value the importance of feedback from patients, the public and staff:

- The service had not gathered feedback from patients through surveys prior to our inspection, partly due to the fact that it was a new organisation.

Are services well-led?

Inadequate 

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action)

- Complaints received from patients were insufficiently analysed which resulted in learning not being disseminated and services not being improved as a direct result
- The service had not gathered feedback from staff despite the awareness it had around some staff raising concerns about the safety of patients and staff.
- Staff felt hesitant to give feedback and discuss any concerns or issues with colleagues and management as these were not acted upon and there was a culture which discouraged staff from highlighting concerns.
- Staff felt they had little involvement as to how the service was run.

Continuous improvement

On the evening of our inspection we saw no evidence or indicators of continuous improvement.

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
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints</p> <p>How the regulation was not being met:</p> <p>The registered person had not done all that was reasonably practicable to establish and operate effectively an accessible system for identifying, receiving, recording, handling and responding to complaints by service users in relation to carrying out the regulated activity</p> <p>Specifically:</p> <ul style="list-style-type: none">• Verbal complaints were not recorded• Appropriate action was not taken without delay to respond to any failures identified by a complaint or the investigation of a complaint.• Information was not provided to a complainant about how to take action if they were not satisfied with a response to their complaint.• The provider did not look for trends within complaints, or areas of risk that may have needed to be addressed. <p>This was a breach of Regulation 16(1) and 16(2) of the Health and Social Care Act (Regulated Activities) Regulations 2014.</p>

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed</p> <p>How the regulation was not being met:</p>

Requirement notices

The registered person had not done all that was reasonably practicable to protect service users against the risks associated with ineffectively operated recruitment procedures to ensure that the persons employed meet the conditions set out in Regulation 19.

Specifically:

- The provider had not followed its own recruitment procedures outlined in its policy.
- Disclosure and barring checks had not been received prior to commencement of employment. No risk assessments had been undertaken to mitigate this risk.
- The provider had not sought employment references, to confirm good character.
- The provider had not taken steps to satisfy themselves that employees had the required competence, skills and experience to carry out the role.

This was a breach of Regulation 19 of the Health and Social Care Act (Regulated Activities) Regulations 2014.

Regulated activity

Diagnostic and screening procedures
Family planning services
Maternity and midwifery services
Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing

How the regulation was not being met:

The service provider had failed to ensure that persons employed in the provision of a regulated activity received such support, training, professional development and supervision as was necessary to enable them to carry out the duties they were employed to perform. In particular:

- There were gaps in training including, infection control, information governance, safeguarding vulnerable adults and fire safety.
- There was no formal documented induction programme in place.

This was a breach of Regulation 18 of the Health and Social Care Act (Regulated Activities) Regulations 2014.

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 Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment How the regulation was not being met: <ul style="list-style-type: none">• Medication and emergency equipment was not readily available in case of emergencies.• Records were not being made in accordance with relevant legislation or the terms of the provider's Controlled Drugs license.• The provider did not have effective systems in place for recording and managing risks in all areas.
Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment How the regulation was not being met: <p>There was a lack of effective safeguarding procedures in place. Urgent safeguarding referrals were not followed up to ensure that correct processes had been adhered in order to keep vulnerable patients kept safe.</p>
Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: <ul style="list-style-type: none">• There were a lack of effective mechanisms to ensure that the learning outcomes from significant events such as serious incidents and complaints were shared with staff.

This section is primarily information for the provider

Enforcement actions

- There were no mechanisms in place to ensure that clinical staff were aware of and take appropriate action on safety alerts.