

Amvale Limited

Amvale Medical Transport -Ambulance Station

Quality Report

Unit 1D Southpark Industrial Estate, Birkdale Road, Scunthorpe, DN17 2AU Tel: 01724 874999

Website: www.amvalemedical.co.uk

Date of inspection visit: 31 July 2015 Date of publication: 12/02/2016

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Amvale Medical Transport - Ambulance Station (Amvale) is an independent medical transport provider based in Scunthorpe. The company transports patients, national organ retrieval service teams, organs, bloods and tissue. They are the accredited service provider for NHS blood and transplant services. Amvale has a number of remote locations including a hub location based at a hotel in Leicester. The services provided from that location include 999 emergency services. Services are staffed by trained paramedics and ambulance technicians and commissioned by regional NHS ambulance services.

The Care Quality Commission (CQC) carried out an unannounced focussed inspection on 31 July 2015. The reason for undertaking this inspection was because the CQC had received concerning information about the operation of some aspects of the service. The inspection was therefore focused on limited aspects of the safe, effective and well-led key questions. We have not rated this inspection because independent ambulance services are not currently rated by CQC. During our inspection we spoke with the provider, and eight members of staff of various grades. We reviewed records, and inspected five vehicles. We did not meet patients during this inspection.

The on-site inspection was conducted by the Head of Hospital Inspections, an inspection manager, two CQC inspectors, and the CQC National Professional Advisor for Ambulance and Urgent Care.

Our key findings at inspection were that storage arrangements for medicines including medical gases and controlled drugs were inappropriate and unsecure. Whilst there was a procedure and audit trail to account for the transfer of controlled drugs between locations we found that this was not always followed. The procedures to store keys meant that there was unrestricted access to ambulance vehicles. The procedures for handling documents which included patient identifiable information were not robust.

Staff told us they accessed policies and guidance to support working with NHS providers. The provider worked effectively with the NHS to coordinate services with other providers. However, staff were not following best practice and legislative requirements for the management of controlled drugs and medical gases to prevent unauthorised access and use. The appraisal system for paramedic staff supported the service in working effectively with the NHS. The provider used a clinical skills record booklet for paramedic staff and staff were required to maintain registration with the Health and Care Professions Council (HCPC).

Immediately following the inspection we asked the provider to take action and sought further assurances from the provider that changes had been made in November 2015.

The provider told us in August 2015 that they had taken action following the July 2015 inspection to strengthen governance arrangements. They stated that risk assessments had been undertaken for the storage of medical gases and storage procedures had changed. We were told that standard operating procedures for medicines had been reviewed. The provider also said they had changed procedures for the handling of documents and reviewed its policy for contracting ambulance staff.

The provider must:

- Ensure risk assessments are routinely completed for all medical gas and controlled drug storage facilities, that these meet national guidance for safety and security and, restrict access to only authorised individuals.
- Maintain a standard operating procedure for the distribution of controlled drug storage keys which includes an audit trail that showing how keys are managed and used. This must include the requirement that the controlled drugs key is kept on a separate key ring to vehicle keys to ensure that access is restricted to registered paramedics.
- Ensure there is a robust audit trail for the issue, transport, receipt and recording of stock levels of medicines, controlled drugs and medical gases.

Summary of findings

- Ensure there is regular audit of the safe and secure management of medicines and medical gases. The registered manager must act promptly on actions arising from outcomes of audit.
- Ensure medicines management training needs are routinely assessed where required provide regular training in the safe and secure management of medicines, controlled drugs and medical gases for all contracted staff.
- Ensure that there is effective on-site co-ordination and management of the remote locations to include ensuring procedures are implemented monitored and audited for key holding; access and storage of controlled drugs and medical gases.

Professor Sir Mike Richards Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Emergency and urgent care services

Rating Why have we given this rating?

We have not rated this focussed inspection because independent ambulance services are not currently rated by CQC.



Amvale Medical Transport - Ambulance Station

Detailed findings

Services we looked at

Emergency and urgent care

Detailed findings

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Background to Amvale Medical Transport - Ambulance Station

Amvale Medical Transport - Ambulance Station (Amvale) is an independent medical transport provider based in Scunthorpe. The company transports patients, national organ retrieval service teams, organs, bloods and tissue and they are the accredited service provider for NHS blood and transplant services. Services provided include 999 emergency services which are commissioned by regional NHS ambulance services. Services are staffed by trained paramedics and ambulance technicians

Amvale Medical Transport - Ambulance Station was registered on 3 June 2011 and the location was inspected on 8 January 2013 following relocation in Scunthorpe. Previously known as Amvale Medical Transport, the service was last inspected in December 2013 and was meeting all essential standards.

The provider is Amvale Limited, which operates a range of transport related services including special educational needs transport, home to school and coach transport, private hire, car and van rental and driver training.

Our inspection team

Our inspection team was led by:

Head of Hospital Inspections: Amanda Stanford, Care Quality Commission

The on-site inspection team also included an inspection manager, two CQC inspectors, and the CQC National Professional Advisor for Ambulance and Urgent Care.

How we carried out this inspection

This was an unannounced focussed inspection based on concerns received by CQC as to the operation of some aspects of the service. Concerning information received by CQC indicated that Amvale was operating a service based at a hotel in the Leicester area with ambulance vehicles using the hotel car park and that medication including controlled drugs was not being stored safely and correctly. The services provided from this site included 999 emergency services contracted by the local NHS ambulance service for the general public.

We responded to these concerns by conducting an unannounced inspection on 31 July 2015. During our inspection we spoke with eight members of staff of various grades including paramedics, and ambulance technicians. We reviewed records and inspected seven vehicles. We did not meet patients during this inspection.

Safe	
Effective	
Caring	
Responsive	
Well-led	
Overall	

Information about the service

Amvale Medical Transport - Ambulance Station (Amvale) is an independent medical transport provider based in Scunthorpe. The company transports patients, national organ retrieval service teams, organs, bloods and tissue and they are an accredited service provider for NHS blood and transplant services. Amvale operates from a number of remote locations. The services provided include 999 emergency services which were mainly operated during the day. Services are staffed by trained paramedics and ambulance technicians and commissioned by regional NHS ambulance services. The remote location we visited provided base facilities for emergency ambulance services.

Summary of findings

The provider worked effectively with the NHS to coordinate services with other providers. However, staff were not following best practice and legislative requirements for the management of controlled drugs and medical gases to prevent unauthorised access and use. The appraisal system for paramedic staff supported the service in working effectively with the NHS. The provider used a clinical skills record booklet for paramedic staff and staff were required to maintain registration with the Health and Care Professions Council (HCPC). Staff accessed policies and guidance to support working with NHS providers.

Storage arrangements for medicines including medical gases and controlled drugs were inappropriate and unsecure. Whilst there was a procedure and audit trail to account for the transfer of controlled drugs between locations we found that this was not always followed. Management of key storage meant that there was unrestricted access to ambulance vehicles. The procedures for handling documents which included patient identifiable information were not robust.

The provider told us they took prompt action following the July 2015 inspection to strengthen its governance arrangements. They stated that risk assessments had been undertaken for the storage of medical gases and storage procedures changed. We were told that standard operating procedures for medicines had been reviewed. The provider also said they had changed procedures for the handling of documents and reviewed its policy for contracting ambulance staff.

Are emergency and urgent care services safe?

We found inappropriate and unsecure storage arrangements for medicines including medical gases and controlled drugs at this location. While there was a procedure and audit trail to account for the transfer of controlled drugs between locations, we found this was not always followed. Keys for ambulances, controlled drugs and storage areas were stored insecurely and where the public may have access to them. This meant that there was unrestricted access to ambulance vehicles and controlled drug storage boxes when not in use. The procedures for handling documents which included patient identifiable information were not robust.

Cleanliness, infection control and hygiene

- We saw personal protective equipment (PPE) was provided on ambulance vehicles. We did not inspect actual patient care so could not observe how effectively the PPE was used by staff to prevent infections.
- We spoke with staff about their cleaning processes whilst on duty. Staff told us they used facilities at local hospitals to clean ambulance vehicles as required between patients.
- Staff told us they had access to yellow clinical waste bags and they disposed of used bags at the local hospital towards the end of their shift.
- The ambulances we looked at were clean.

Environment and equipment

- At the time of our visit, seven ambulance vehicles were located in the hotel car park. Staff confirmed they had access to a spare ambulance vehicle.
- We spoke with staff about how they prepared the ambulance prior to their shift. Most ambulances were parked overnight at the hotel site and this was where the vehicles were checked and prepared prior to shift starting. A vehicle came from the provider's location in Scunthorpe to top up supplies as required.
- One member of staff told us they had a documentation checklist which involved them checking over the vehicle. Staff told us they were responsible for ensuring the ambulance vehicle was ready for the start of their shift. We observed staff checking their vehicles and saw

- that they used a vehicle checklist when they carried out this activity. Staff told us that if a vehicle was not ready for the start of their shift they notified the Amvale headquarters.
- Prior to our visit, inspectors received information which alleged that keys for the ambulances and the controlled drug safe held within each vehicle were given to hotel staff in the evening. At our inspection we observed and staff confirmed that keys for ambulance vehicles and the controlled drugs safe were kept in the hotel reception office. We talked with Amvale staff who confirmed they left their keys at the hotel reception. This meant that unauthorised people had access to both the vehicle and the controlled drugs supply.
- We spoke with staff about replenishing stock. Staff told us and we observed that staff used a general store room in the hotel for ambulance crew kit and appliances for ambulances. For example we saw first aid items and controlled drugs destruction kits in the storeroom. We asked staff about access to the store room and they told us they accessed the key at the hotel reception.
- Following the inspection visit the provider confirmed details of the vehicle maintenance policy and provided the service records for vehicles and equipment which were found to be in order.

Medicines

- We found the procedures for the storage of medical gases and handling medicines were not robust.
- Medical gases should be stored in a secure locked area with clear signage to indicate the risk of flammable gases. We observed that an external storage area of the hotel was being used by the ambulance service to store medical gases and other equipment. This was adjacent to the main hotel building. There were four small oxygen cylinders, two large oxygen cylinders and one small analgesic gas cylinder. Attached to the internal wall of the storage area was a poster which stated "Full Cylinders". The cylinders were not secured and there were no warning signs attached to the external doors of the storage area to indicate that oxygen or flammable gas cylinders were stored within this area. We saw keys to the external building being stored at the hotel reception office and Amvale staff confirmed this arrangement.
- Prior to our visit inspectors received information which alleged that the ambulances returned to the hotel and parked in the public car park at the end of the shift.

When the crew were ready to leave the vehicle, medicines including controlled drugs were either stored in the paramedic's own vehicle overnight or left in the safe in the unattended ambulance vehicle overnight. Alternatively, when paramedics stayed overnight in the hotel, it was reported to us that the paramedic stored the medicines unsecured in their hotel room as no safe was available in the room.

- Staff explained the ordering procedure for obtaining medicines from Amvale's headquarters: a completed order form was sent to head office, a driver delivered the medicines from the Amvale base location and order documentation was signed to confirm receipt. One member of staff told us they had received medicines including controlled drugs the previous evening from the delivery driver from the Amvale base location. They had stored these in the vehicle safe and the keys for the vehicle and safe were kept overnight at the hotel reception office. Staff confirmed that the controlled drugs safe keys were kept on the same key ring as the vehicle key. We checked the safe on the vehicle and saw two sealed envelopes which contained a box of injectable controlled drugs and medications. These were not stored securely; controlled drugs should be stored in a locked container/safe within a further locked storage area. Due to the way the keys were stored people other than those working for Amvale could have had access to the medicines.
- We asked to see the documentation supporting a recent delivery of controlled drugs, as part of the audit trail supporting the safe and secure management of controlled drugs. The staff member told us they had not signed any document and had received the paramedic bag and a tin containing controlled drugs. We checked the controlled drugs record book within the tin. The last dated entry was correct but there was no evidence of receipt. We asked the member of staff if they had checked that the controlled drugs record book and the amount of controlled drugs stock given to them was correct before receiving them. They confirmed that they had not done this. We spoke with the member of staff who had handed over the controlled drugs who confirmed there was a medicines transport sheet. They told us they had forgotten to get it signed as it had been a busy shift.

- Staff also explained the procedure for the destruction of controlled drugs. Paramedic staff told us that they discarded items using the small containers in the storeroom and recorded this in their personal controlled drugs register.
- Paramedics, as independent practitioners are by law, and within strict specifications, allowed to keep and store controlled drugs for their work. The drugs must be stored in line with national controlled drugs regulations. One member of staff told us they kept their own controlled drugs and took them home after shifts and locked them in a safe. We observed a member of staff's personal issue bag of controlled drugs stored in a small lockable cash tin. Contents included a sedative and controlled drug. We checked their personal controlled drugs record book and the last entry accounted for the controlled drugs held in the tin.
- We spoke with another member of staff who also told us they held personal issue controlled drugs in a cash tin which they kept in a safe at home and also that they used a safe in their own car. This was in accordance with national regulations. We reviewed the control drugs stock held and their personal controlled drugs record book and found the record to be correct and up-to-date.
- Following the inspection, the provider wrote in August 2015 and told us of changes to the procedures for handling medical gases. The provider informed us that oxygen cylinders had been removed from the remote storeroom and when not in use were returned to the Scunthorpe base. We were told that all controlled drugs in their safes were also returned at the end of the working day to the Scunthorpe base which had a Home Office certificate for the storage of controlled drugs.
- A courier vehicle was adapted for the transport of medical gas cylinders and had relevant signage at the front and rear of the vehicle. A lockable metal storage box was secured to the floor of the vehicle used for the transport of controlled drug safes to and from the remote Leicester base. The courier made two journeys daily; the early morning journey coincided with the crew start time and the late evening journey coincided with crews' shift finish times. We were told a medicines in transport form was completed daily.
- The provider also informed us that following the inspection visit the medicines management standard operating procedure for prescription only medicines was reviewed and that each bag now carried a card

visible through a transparent window that showed the bag number, the date the bag was checked, who it was checked by and the number of the tamper evident seal that locked the zip fastener.

Records

- The procedures for handling documents which included patient identifiable information were not robust. We saw that patient records were not always kept securely within the vehicle or away from public view. Ambulance staff kept records in their hotel room.
- Immediately following the inspection the provider informed us of changes to the procedures for handling documents. Document pouches were issued to each ambulance and a standard operating procedure set out instructions that all patient identifiable information must be placed in the document pouches whilst in the ambulance therefore ensuring this information was out of public view. These document pouches were returned to the provider's Scunthorpe location in the vehicle used to transport supplies at the end of each shift and locked in a secure mailbox.
- We were told these records were subsequently collected for data input and secure archiving.

Are emergency and urgent care services effective?

(for example, treatment is effective)

Staff accessed policies and guidance to support working with NHS providers. The provider worked effectively with the NHS to coordinate services with other providers. However, staff were not following best practice and legislative requirements for the management of controlled drugs and medical gases to prevent unauthorised access and use. The provider used a clinical skills record booklet for paramedic staff and paramedics were required to complete quarterly declarations of clinical skills. The appraisal system for paramedic staff supported the service in working effectively with NHS ambulance services. Paramedic staff were required to maintain registration with the Health and Care Professions Council (HCPC).

Evidence-based care and treatment

 Ambulance staff were able to access policies and procedures for the service to support working with NHS ambulance providers.

- Guidance documents with pathway advice and contact details were available to paramedic, technician and emergency care assistant staff working with NHS ambulance services
- We did not review any audits of compliance with these procedures during this inspection.

Competent staff

- Ambulance service staff were required to complete an on-line induction course prior to working with NHS ambulance services. Some staff had not completed this at the time of our inspection. We subsequently received an assurance from the provider that staff completed their induction in August 2015.
- We found staff were not following best practice and legislative requirements for the management of controlled drugs and medical gases to prevent unauthorised access and use.
- The provider's induction and familiarisation policy and procedures for ambulance service staff included clinical pathways; for example, which hospitals received stroke patients following an emergency call.
- In August 2015, the provider sent us evidence that the provider maintained a clinical skills record booklet for staff to complete.
- Paramedics were contracted by Amvale from all parts of the UK for specific shifts and usually worked three to four shifts in a row at this location. All contracted paramedics were required to complete quarterly declarations which covered clinical skills, any criminal records, driving offences and continuing professional development. We saw evidence of this during the inspection and the provider gave us examples following the inspection for August and November 2015.
- Following the inspection visit the provider sent us details of the policy and procedures for contracting paramedic staff which were available but not checked at the time of the inspection visit.
- The service provided evidence of its annual appraisal system for paramedic staff. We saw evidence of how the appraisal system for paramedic staff was developed to support the service in working effectively with NHS ambulance services.
- We were told that the provider undertook checks on the Health and Care Professions Council (HCPC) register for paramedics. Paramedics were also required to provide copies of their HCPC certificates with their declarations in August 2015. We saw an example of this.

Coordination with other providers

- The local NHS ambulance service contracted with Amvale to provide a varying number of crews, most days, to support the NHS 999 service. Amvale crews were allocated to specific geographical areas on a daily basis based on the needs of the NHS ambulance service.
- We were told that paramedics were usually paired up in the ambulances with a technician or emergency care assistant who was permanently employed by Amvale. This helped ensure that each crew had local knowledge of hospitals in the area and any local pathways and procedures, for example, which hospitals received stroke patients following an emergency call.
- Clinical bulletins issued by NHS ambulance providers were shared with ambulance staff by email, at hub locations and by being placed in ambulance vehicle folders, to support effective working with NHS providers.
- Ambulance service staff communicated with NHS ambulance emergency operations centres and other NHS providers by mobile phone to support urgent and emergency services.

Are emergency and urgent care services caring?

This was a focussed inspection and therefore we did not inspect this domain.

Are emergency and urgent care services responsive to people's needs? (for example, to feedback?)

This was a focussed inspection and therefore we did not inspect this domain.

Are emergency and urgent care services well-led?

We did not inspect all aspects of well led. We focussed on the governance and management of risk at the hotel location where the service was operating from. We found a lack of effective on-site co-ordination and management of the location. There was no evidence at this site of a system which ensured procedures were implemented, monitored and audited for the security of sets of ambulance keys; access and storage of both controlled drugs and medical gases and; the security of the ambulances.

The provider told us they had taken action following the July 2015 inspection to strengthen its governance arrangements for the remote location. This included informing us of risk assessments they had undertaken for the storage of medical gases and reviewing the medicines management standard operating procedure.

Governance, risk management and quality measurement

- Amvale operated a number of remote locations including a hub location based at a hotel in Leicester. Information received by CQC expressed concerns about Amvale operating a service based at a hotel in the Leicester area with ambulance vehicles using the hotel car park. The remote location we visited provided base facilities for emergency ambulance services. We found a lack of effective on-site co-ordination and management of the location.
- There was no evidence at this site of a system that ensured procedures were implemented, monitored and audited for the security of sets of ambulance keys; access and storage of both controlled drugs and medical gases and; the security of the ambulances.
- At the time of the inspection, there was a lack of local co-ordination and leadership. Following our inspection, we sought assurances from the provider as to the governance arrangements that were operated and managed from this site.
- In August 2015 the provider told us that they would be interviewing and restoring the local team leader role. We were told that part of this role would be to ensure that there were safe systems in place and that these were implemented effectively.
- The provider also informed us of risk assessments they had undertaken for the storage of medical gases and that they were reviewing the medicines management standard operating procedure.
- In November 2015 we requested a further update from the provider. We received a response setting out the action taken to date by the provider following the July 2015 inspection visit. The provider confirmed the risk assessments had been undertaken for the storage of medical gases in the ambulance station and in

ambulance vehicles. The provider also provided details of changes to the procedures for handling medical gases. The medicines management standard operating procedure for prescription only medicines had been reviewed.

Outstanding practice and areas for improvement

Areas for improvement

Action the hospital MUST take to improve

The provider must:

- Ensure risk assessments are routinely completed for all medical gas and controlled drug storage facilities, that these meet national guidance for safety and security and, restrict access to only authorised individuals.
- Maintain a standard operating procedure for the distribution of controlled drug storage keys. This must include the requirement that any controlled drugs key is kept on a separate key ring to vehicle keys to ensure that access is restricted to registered paramedics.
- Ensure there is a robust audit trail for the issue. transport, receipt and recording of stock levels of medicines, controlled drugs and medical gases.

- Ensure there is regular audit of the safe and secure management of medicines and medical gases. The registered manager must act promptly on actions arising from outcomes of audit.
- Ensure medicines management training needs are routinely assessed where required provide regular training in the safe and secure management of medicines, controlled drugs and medical gases for all contracted staff.
- Ensure that there is effective on-site co-ordination and management of remote locations to include ensuring procedures are implemented, monitored and audited for key holding; access and storage of controlled drugs and medical gases.

Requirement notices

Action we have told the provider to take

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

Regulated activity Regulation Transport services, triage and medical advice provided Regulation 12 HSCA (RA) Regulations 2014 Safe care and remotely treatment Storage arrangements for medicines including medical gases and controlled drugs were not secure; the procedure for the transfer of controlled drugs between locations were not always followed; management of key storage provided unrestricted access to ambulance vehicles; procedures for handling documents which included patient identifiable information were not robust. The provider must ensure: • Controlled drugs are stored safely. Regulation 12 (2) (g). • Keys for ambulances, controlled drugs and storage areas are not stored insecurely or where the public may have access to them. Regulation 12 (2) (g). • Oxygen and other medical gases are stored securely with any warning signs displayed. Regulation 12 (2) (g). • An effective and appropriate audit process and audit trail is maintained of the transfer of controlled drugs from the provider. Regulation 12 (2) (g).

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	The procedures for handling documents which included patient identifiable information were not robust.
	The provider must ensure:
	 Robust procedures are followed for handling documents which include patient identifiable information. Regulation 17(2) (c).

This section is primarily information for the provider

Requirement notices

• Effective on-site co-ordination and management of remote locations to include ensuring procedures are implemented, monitored and audited for key holding; access and storage of controlled drugs and medical gases.

Regulated activity

Transport services, triage and medical advice provided remotely

Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing

Staff were unaware of best practise and legislative requirements for the management of controlled drugs and medical gases to prevent unauthorised access and use.

The provider must ensure:

• Staff training includes legislative requirements for the management of controlled drugs and medical gases to prevent unauthorised access and use. Regulation 18(2) (a).