Care Quality Commission

The state of care in independent ambulance services

Findings from CQC's programme of comprehensive inspections in England

March 2019

Care Quality Commission

Our purpose

The Care Quality Commission is the independent regulator of health and adult social care in England. We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

Our values

Excellence – being a high-performing organisation

Caring – treating everyone with dignity and respect

Integrity – doing the right thing

Teamwork – learning from each other to be the best we can

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Foreword

The independent ambulance sector is a significant and growing area of health care and it is important that patients who use services in this sector receive safe, high-quality care.

In March 2017, we wrote to all registered independent ambulance providers setting out the emerging findings from our first 70 inspections. In this, we highlighted our concerns about poor medicines management, cleanliness and infection control practices, a lack of appropriate recruitment checks and poor safeguarding practices. Following the completion of our comprehensive inspection programme, we have looked at the findings from our inspections in more detail and are concerned that we are still finding the same issues.

While we found examples of good practice in individual services, and infection control practices more generally have improved, we continue to have significant concerns about how safely and effectively independent ambulance services care for their patients. We have found ongoing issues with poor recruitment, training and safeguarding processes, with evidence of incidents of serious harm to people from staff that had not been properly recruited and vetted. Patients continue to be put at risk from inadequate or poorly maintained vehicles and equipment, and the inappropriate use of restraining equipment. We continue to have concerns about medicines management, including how providers manage controlled drugs, with some providers not holding the required Home Office licence.

Providers have a duty to protect people who use their services and they need to be aware of their professional responsibilities. However, findings from our inspections show that many providers do not understand what it means to be a regulated organisation, and the requirements they must meet. We will continue to work collaboratively with providers to ensure that the risks in the sector are understood and they take steps to improve.

We recognise that there is a complex range of commissioners for the sector, including NHS England, clinical commissioning groups, NHS trusts, care homes, local authorities, event organisers, and individual members of the public. We also acknowledge that there is a tendency for commissioning decisions to focus on financial rather than quality indicators, often with poor contract monitoring arrangements in place.

As a result, we will be strengthening our assessment of how NHS trusts that have a subcontracting arrangement in place make sure that they have systems for monitoring performance and quality. We urge NHS England and clinical commissioning groups to fully consider the safety and quality of the services they commission. As of July 2018, independent ambulance services are rated and this will help commissioners to more easily identify the strengths and weaknesses of each registered provider, and use this to inform their decisions.

As well as concerns from our first programme of inspections of registered providers, this report also draws attention to issues with unregulated areas of the sector, where there is no requirement for providers to register. We have serious concerns about the safety of

independent ambulance services on event sites. We are working with NHS England, local authorities and other bodies involved in the organisation of events to share our concerns. Those organising and licensing events need to understand the duties upon them to make sure that event medical services are of good quality. Longer term, we recommend a review of the regulations, and the associated exemptions, to close the regulatory gap highlighted in this report.

Professor Ted Baker
Chief Inspector of Hospitals

Introduction

Independent ambulance providers offer a range of services including specialist patient transfer, non-emergency patient journeys, overseas repatriation services and, increasingly, additional emergency response capacity to NHS ambulance trusts.

The introduction of NHS reforms and competitive tendering for non-emergency patient transport services in the 1980s saw a spike in the growth of the independent ambulance sector. Today, non-emergency patient transport services account for most of the services it provides. The Independent Ambulance Association estimates that the sector spends some £500 million on patient transport services annually, but without a financial overview of the sector it is difficult to verify this figure.

Over the last decade, an increasing number of independent ambulance providers have entered the emergency sector, working in partnership with NHS ambulance trusts to provide additional emergency response services.

Providers vary in terms of their size and scale, including the number of employees, the number of vehicles and the geographical area they cover. Ownership models also vary from large public limited companies, to small family owned companies, and voluntary sector owned providers. As at 31 January 2019, there were 246 independent ambulance service providers registered with CQC, covering 286 locations.

CQC's role and regulatory approach

CQC only regulates those providers registered in England that provide regulated activities. Independent ambulance services must be registered with CQC if they provide a regulated activity.

The two regulated activities that providers of independent ambulance services are most commonly registered to provide are:

- Treatment of disease, disorder or injury: this includes treatment that is provided by a healthcare professional, or team that includes a healthcare professional.
- Transport services, triage and medical advice provided remotely: this includes services that involve a vehicle that was designed for the primary purpose of transporting people who need treatment.[a]

There are some services offered by independent ambulance providers that are out of CQC's scope of regulation and, as a result, mean that the providers cannot be registered with us. For example, an independent ambulance provider that only provides services on site at an event

[a] The scope of registration states that the term 'designed for' will also apply where a vehicle has been made suitable for this purpose.

does not fall within the scope of regulation. This and other exemptions are discussed further in the section on the unregulated independent ambulance sector.

When we inspect independent ambulance services, we look at the following core services, where appropriate, and ask if these are safe, effective, caring, responsive and well-led:

- **Patient transport services:** non-urgent and non-specialist services that transport patients between hospitals, home and other places such as care homes.
- **Emergency and urgent care:** assessment, treatment and care of patients at the scene by ambulance crews with transport to hospital, as well as assessment, treatment and discharge from the care of the service. High dependency and intensive care transport between hospitals or other care settings is included.

This report explores what we found about the quality of care delivered by regulated independent ambulance services in England in our first round of inspections. Our findings are based on an analysis of inspection reports and interviews with inspection staff. We also explore the issues and areas of concern with providers who are outside our scope of regulation.

We do not provide information on ratings as we did not have the powers to rate independent ambulance services during this period. However, following a change in legislation, the Department of Health and Social Care has since given CQC the power to rate providers in the independent health care sector, including independent ambulances. Since July 2018, all services inspected are now rated.

What we did

This report is based on the findings from our programme of comprehensive inspections of the independent ambulance sector, which was completed in March 2018. We analysed a sample of 26 published inspection reports for key themes, and carried out focus groups and interviews with 19 inspection staff involved in inspecting and registering independent ambulance services to explore the themes further. We also analysed regulatory breaches found on our independent ambulance inspection visits.

This analysis focused on:

- the scope of registration – this document provides guidance for people and organisations that provide, or intend to provide, health care or adult social care in England. It helps them decide whether they need to register with the CQC under the Health and Social Care Act 2008[1]
- issues identified on inspection
- the characteristics of good quality care and notable practice
- outcomes from re-inspecting where we had previously found poor quality care.

Findings from inspections

CQC's programme of comprehensive inspections of independent ambulance services began following pilot inspections in 2015. Initial findings from the first 70 inspections identified some serious common concerns around poor medicines management, cleanliness and infection control practices and a lack of appropriate recruitment checks. In March 2017, we wrote to all registered providers to outline our concerns based on these provisional findings.[2]

This section looks at the findings of the comprehensive inspection programme, completed in March 2018. Analysis of our findings showed that we have found pockets of good practice in the sector, with independent ambulance services generally found to be caring. We have also found examples of services improving in response to CQC inspections. However, we continue to have serious concerns about many of the issues flagged in our letter.

Where we find concerns, we take appropriate action, including enforcement, to make sure that those responsible for poor care are held to account. Our enforcement policy sets out what action we take to require providers to improve and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it.

This section of the report looks in more detail at the findings by each of the five key questions.

Safe

Under this key question we looked at areas including training, safeguarding, infection control procedures, vehicles and equipment, staffing and recruitment, records management, medicines management, and managing and learning from safety incidents.

Staffing and training

Many of the services we inspected had a poor understanding of governance requirements. This often led to weak recruitment practices, with 14% of all breaches relating to Regulation 18 – 'Staffing'. Many providers did not realise the importance of ensuring they have appropriate recruitment processes in place, and in some cases human resources policies were non-existent. Inspection reports flagged that staffing checks were being enforced inconsistently, including Disclosure and Barring Services (DBS), driving licence, photo identification, references and health checks.

> *"We found a number of examples where providers were not doing DBS checks so they were not clear [whether] their staff [were] appropriate to work. That's a huge issue in this sector because people working on ambulances have privileged access to people who, by virtue of the fact that they need to use an ambulance, are often quite vulnerable."*

Levels of completed mandatory training also varied hugely, as did the quality, consistency and monitoring of the training. This was particularly relevant to the emergency and urgent care service where patients may be transported using audible and/or visual warnings ("blue lights"). Many providers had no, or very limited, training for their staff. We were told of one example where a driver believed he could drive the wrong way down a one-way street if he had a blue light on. Inspectors reported that this was a difficult area to assess as there is no nationally agreed standard of training for driving.

Safeguarding

Staff knowledge and training on safeguarding was mixed and there were concerns about the quality, consistency and audit of safeguarding training, with Regulation 13 – 'Safeguarding services users from abuse and improper treatment' accounting for 17% of total breaches.

Echoing the attitude towards recruitment checks, some providers thought training received by staff while employed elsewhere could be transferred. However, this lack of training sometimes meant that staff were unable to recognise safeguarding concerns. In one example, an extremely confused dialysis patient was found wandering in the street by neighbours, as the crew had not made sure that he got into his home safely.

There were also delays in notifying other bodies of safeguarding concerns, as some services providing transport on behalf of an NHS ambulance trust did not understand that they needed to have processes in place to alert local authorities. The competitive nature of the sector also resulted in a lack of willingness to share knowledge with, and learn from, other providers, and there were insufficient links made with local safeguarding teams.

Medicines management

Medicines management, which was reviewed in those locations providing an emergency and urgent care core service, was inconsistent across the sector. While some services had robust policies to support the safe administration of medicines, others showed a lack of understanding, especially around controlled drugs. How providers obtained, stored and recorded the administration of medicines and controlled drugs caused concern for inspectors. Some did not have the required Home Office licence for procuring and storing controlled drugs.[3,4]

Inspectors gave many examples of poor practice including:

- one provider who was based in a hotel room and did not store controlled drugs appropriately
- a paramedic who had their drug bag under their bed in a B&B
- morphine books with pages missing, illegible entries and incorrect information.

Some providers did not understand the complexities of medicines management, or that they might need Patient Group Directions (PGDs) in terms of supplying and administering medicines

to patients.[b] Staff were also administering medicine without the proper governance frameworks in place to support the process.

However, we did find some examples of good practice, including a provider who used a barcode system that could track individual tablets and link them to individual patient report forms.

Vehicles and equipment

For most services, inspectors found evidence of vehicles and stations having regular deep cleans, up-to-date MoTs, insurance and equipment processes:

> *"I've seen an independent ambulance…with a really good equipment database, so they knew exactly when each piece of equipment needed safety testing and which ambulance it was on. It was better than a lot of NHS trusts I've seen in terms of keeping track of their equipment."*

However, our inspections did find some issues with both the availability and maintenance of vehicles and equipment, including:

- concerns about the poor maintenance of vehicles
- vehicles that have not been regularly serviced, and a lack of written guidance or systems for monitoring vehicles
- missing or faulty equipment (including paediatric apparatus for transporting children in emergencies) and an absence of equipment audits and servicing
- poorly maintained vehicle storage, including one provider who was using a garage without running water in the sluice
- inappropriate storage and maintenance of medical gases.

Effective

To consider how effective providers were in caring for patients, we looked at the assessment, care and treatment of patients, quality improvement activity (including audit), training and supervision for staff, consent to care and treatment and how providers comply with the Mental Capacity Act 2005 (MCA). We found particular concerns around the latter.

[b] A PGD, signed by a doctor and agreed by a pharmacist, can act as a direction to paramedics to supply and/or administer prescription-only medicines (POMs), that they would not otherwise be able to legally administer, to patients using their own assessment of patient need without necessarily referring back to a doctor for an individual prescription.

The Mental Capacity Act 2005

Staff understanding and application of the MCA was mixed and this may link to providers' tendency to accept that training carried out by their employees elsewhere is legitimate and appropriate for the needs of their client group. With some staff being former members of the police, prison service or armed forces, they have been used to engaging with people in a different way to what is required in this sector. For example, our inspectors observed inappropriate use of restraining equipment.

Staff competency and supervision

As well as the concerns highlighted around mandatory training, our inspections found a lack of ongoing support offered to independent ambulance staff. Appraisals did not always take place, and where they did, they were not always recorded. As remote workers, staff were lacking the opportunity to have regular supervision with their managers and to discuss training needs or performance management concerns.

Caring

Of the five key questions that we looked at, quality of care was the highest for the caring question. As part of our inspections, we looked to see how patients are treated with compassion, dignity and respect, and their involvement in decisions about care and treatment. Inspection reports were largely positive and inspectors found plenty of evidence of good one-to-one care being delivered to patients. These included crew taking the time to make sure that patients being taken home were made comfortable and had something to eat and drink. However, finding evidence for the caring key question on inspection can be challenging. This is because of limited opportunities to speak to people using services or witness direct care, as many services only carry a few patients as part of their regulated activity.

Responsive

For this key question, we looked at how services were responding to and meeting people's needs, access to services, and listening and learning from concerns and complaints.

Meeting individual needs

How services responded to and met patient needs, particularly those with more complex needs, varied. The provision of training for supporting patients with dementia, learning disabilities and mental health conditions was inconsistent, and access to language aids and translation services was variable. While some staff were unable to explain how they would support vulnerable patients, others could clearly demonstrate their approach. One service carried out their own

analysis and reviewed the types of incidents they attended to help plan future capacity and support patient outcomes.

Listening to and learning from complaints

Complaints in the sector tend to be low. This may indicate high satisfaction with the service received, but in some services there were unclear processes and procedures to support patients who wished to make a complaint, which is likely to affect complaint numbers. Not all services had a complaint procedure, nor did they log complaints received. While there were some examples of complaints being investigated and learnt from, this was not the norm.

Well-led

This key question considers strategy and governance arrangements, leadership values and culture, and whether services are seeking and acting on feedback and continuous improvement.

The most highly performing independent ambulance services were those that understood the responsibilities of regulation and had strong governance and financial management arrangements. Having a formal vision or business strategy supported services to deliver good quality care. They had robust HR procedures and work culture, evidenced by high job satisfaction and staff feeling empowered to raise concerns. They strived to continually improve, and this has been demonstrated in some of our re-inspections:

> *"When I had my first meeting with them I remember saying they didn't seem to be focusing on the patients. I've recently been to a meeting with them and the turnaround was incredible…. everything they spoke about was patient-focused."*

Another provider embedded a new approach to safeguarding in response to enforcement action:

> *"They've really looked into their spot-checks and they actually go to staff and they give them scenarios to make sure their knowledge of safeguarding is good. So they're not just giving them training, they're trying to continue it and that's something they've recently introduced from our inspection. They want to try and improve their quality and they do take it seriously, they're striving to make the improvements that come out of the report."*

However, many providers do not understand what it means to be a regulated organisation and the requirements placed on them. Better commissioning and contract monitoring is required to make sure that the right provider is selected to transport patients. This has often been driven by financial reasons, without due regard given to the ability of the provider to operate a safe, high-quality service.[5,6,7]

Our inspection teams have found that providers are not always able to fulfil their contractual obligations and have then subcontracted to another organisation. Each time there is a subcontracted element it adds risks and there have been instances where registered providers,

in order to meet their contractual obligations, have subcontracted to an unregistered provider, without understanding or recognising that it is unsafe and it is a risk.

Subcontracting, without due diligence, can have an even bigger impact when transporting vulnerable patients:

> *"There was one provider I remember, a particularly large independent mental health provider who was commissioning an ambulance provider that wasn't registered, so you know there's a real lack of understanding about regulation and about what's appropriate for that particular group of patients."*

Leadership in an independent ambulance service had a significant impact on our findings at inspection. In some cases, providers have established their own business having volunteered in the sector, or as an ex-NHS paramedic, and they often did so without realising the processes they need to follow or what it means to be a regulated service.

Governance and risk management

Our inspections found a lack of governance arrangements. This is particularly the case with very small providers because they are often the sole owner and provider and it can be hard to implement a robust governance system. However, larger providers can also struggle to adopt robust procedures.

> *"When I asked [the committee] what processes they used to check…to assure themselves [that the director was fit and proper in line with regulation 5] they all laughed and said: 'he's the director, he only needs to assure himself so we don't need a process'."*

Regulation 17 - 'Good governance' is the most commonly breached regulation, accounting for 29% of total breaches. Issues raised during focus groups with inspection staff included:

- a provider having policies and procedures in place that had been photocopied from another company, without even changing the name
- a provider transporting dialysis patients with no policies in place, no monitoring of transport time and no monitoring of fluid, nutrition or toilet breaks
- non-existent or very limited documentation, such as the statement of purpose, audits and complaints
- a provider that held governance meetings over dinner with their colleagues without keeping records
- inspection teams having to rely on witness statements for enforcement evidence due to a complete lack of documented evidence.

Risk management was also an area of weakness across the sector, and many services did not have a risk register.

A similar approach to information management is evident, with routine reporting often not in place. Some patient transport services were operating in a manner more like a taxi than an ambulance service, which may reflect the limited monitoring requirements set out in contracts:

> *"We found a few where they've just got an excel spreadsheet of who they picked up, where they dropped them off."*

Some providers have a tendency to rely on the commissioner for oversight and learning, which means that they struggled to share information with CQC either in advance of, or during, their inspection.

The unregulated independent ambulance sector

As noted in the introduction, there are some services offered by independent ambulance providers that are out of CQC's scope of regulation. For example:

- Treatment of disease, disorder or injury (TDDI) excludes:
    - providing treatment in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of persons taking part in, or attending, sporting activities and events
    - providing treatment under temporary arrangements to deliver health care to those taking part in, or attending, sporting or cultural events.

  A provider only needs to be registered for this regulated activity if the service includes treatment carried out by, or under the supervision, of a healthcare professional.[c]

- Transport services, triage and medical advice provided remotely excludes:
    - transport services that are provided in the confines of the site or venue being used for an activity or event.

Without the ability to regulate these aspects of the independent ambulance sector, we are limited in our knowledge as to how safe and high-quality these services are. However, from the evidence we have seen, we believe there is significant risk in the sector. We have three main areas of concern, which we look at in more detail in this section. Where the quality of these providers has the potential to cause harm, we are working closely with partners, such as local authorities, to ensure the safety of patients. If we believe that a provider should be registered with CQC, we will investigate and take the appropriate action.

Temporary events

The exemption for temporary sporting and cultural events means that any care and treatment provided on site at an event or associated premises is not a regulated activity. This means that the direct care of patients, which in other settings would be regulated, is unregulated. Given the issues we have found in our inspections of regulated services, such as poor medicines management processes, there are likely to be similar or greater risks in the unregulated environment.

[c] Individuals regulated and/or licensed to provide some type of health or social care. For more detail see page 60 of the scope of registration.

Services that can expect to transport a patient off an event site to a hospital do need to be registered with CQC. This provides the following challenges:

- Some providers may intend to transport off an event site, but on inspection may not have done so for a significant amount of time, or may do so very rarely. Our inspection teams can spend significant amounts of time trying to determine whether the provider continues to require registration. If so, the regulated activity may be as limited as a single patient transfer from an event site. Such a low volume of activity makes it difficult to assess a provider against our assessment framework, and collect the necessary evidence to take enforcement action in the event of poor practice.
- Conversely, other providers may choose not to convey a patient from an event site in order to remain out of scope of registration. This can have a number of consequences:
    - Members of the public visiting an event may have to wait for an emergency response from the NHS ambulance trust. This may not only cause unnecessary and potentially harmful delay for the patient, but also puts extra pressure on the NHS ambulance resource.
    - Whistleblowers may contact CQC to report unsafe practice about an unregistered provider, who on investigation does not fall under regulation. There have been several reported incidents where patients have received poor quality care at events, which in some cases have resulted in death. Commissioners of such events are often unaware that the medical cover they appoint to oversee the event is not regulated.

Vehicle design

Patient transport services that are provided in vehicles not designed for the primary purpose of carrying a person who requires treatment are not regulated. This means that providers using taxis, volunteers in private cars, or mortuary vehicles do not need to be registered with CQC, unless the vehicles have been modified to be made suitable for transporting patients. It is up to providers to establish whether any of their vehicles would meet this definition, which has led to the following inconsistencies:

1. Some providers have tried to gain CQC registration to give themselves a greater advantage when tendering for contracts. For example, some contracts and tenders require CQC registration, even when they are not actually commissioning for a regulated activity, but rather a pure transport service.
2. Other providers have used the wording of the regulated activity to ensure that they are out of scope by using vehicles that do not meet the scope of registration. As a result, there are potentially vulnerable people accessing unsafe services, without fully understanding who is caring for them, and with no regulatory oversight of these providers.

Provision of treatment by non-healthcare professionals

We are concerned that some providers are operating services that are not being delivered by, or under the direction of, a registered healthcare professional, and therefore do not fall under the regulated activity of TDDI. If these are also being delivered in a vehicle that does not meet the requirements of the transport regulation it is possible that vulnerable patients are using high risk, complex services that are unregulated.

We heard an example of one such service that was commissioned to transport children with severe physical and psychological disabilities and complex health needs from home to school. Some of the children required suction or rectal medication to be administered during the journey. Although the ambulance care workers were trained to administer these interventions, they were not under the supervision of a registered healthcare professional and, as a result, we could not register the provider.

Conclusion and next steps

The independent ambulance sector is a growing and evolving area. Our first round of comprehensive inspections has highlighted that the quality and safety of services varies greatly. While we have found pockets of good practice, we have also found significant risks around the safety of care and treatment and how well-led services are, including:

- recruiting and training staff
- safeguarding practices
- medicines management
- vehicles and equipment
- leadership and governance.

We will continue to take appropriate and proportionate actions, including enforcement actions, where we find that providers are not meeting the requirements or regulation and need to improve.

Our re-inspections have shown that even though some providers have been hampered by a lack of financial backing to make the necessary improvements, there is a willingness to adapt and improve. As the regulator, we believe we have an important part to play in driving improvement through positive engagement with providers. This has been demonstrated through our reports on driving improvement in other sectors.

It is not just providers that have learned from the first round of inspections. Our inspection reports have also drawn attention to commissioners about the issues in the sector. The new power to rate independent ambulances will further shine a light on poor performance in a sector where commissioning has largely been driven by financial decisions. Ratings will help commissioners make more robust decisions around the quality of providers.

We have set out some significant concerns with aspects of the independent ambulance sector that fall outside our scope of regulation. We are exploring ways in which that lack of oversight and regulatory gap can be addressed. These include:

- Continuing to liaise with local authorities, whose licensing boards have responsibility for ensuring the health and safety of temporary events, to highlight our concerns. We have recently written to local authorities, asking them to consider these concerns when licensing events.[8] As a local authority licence is not required for all events, we are also working to identify other organisations and groups involved in events management.
- Continuing to liaise with the Department of Health and Social Care (DHSC) to highlight our concerns around the events exemptions and recommend that the regulations are reviewed to address this area of significant concern.

- Considering whether there are changes that we can make to our scope of registration to make sure that the interpretation of a vehicle “designed for the primary purpose of carrying a person who requires treatment” enables the appropriate regulation of independent ambulance services. We are also highlighting our concerns to the DHSC about the wording of this regulated activity, with the recommendation that the wording be reviewed to address this concern.

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8. Care Quality Commission, Letter to Local Authority Chief Executive Officers, November 2018

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