Quintiles Health Management Services

Quality Report

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

Ratings

Overall rating for this location	**Good**
Are services safe?	**Good**
Are services effective?	**Not sufficient evidence to rate**
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Good**

Overall summary

We have rated the home infusion service as 'good'.

Care and treatment took account of current legislation and nationally recognised evidence-based guidance.

There was a small patient base with sufficient staffing levels to carry out the service.

Staff were competent to carry out their role and the organisation maintained a register of training required and undertaken by staff. Staff told us management support and the annual appraisal system worked well and was worthwhile.

Appropriate governance structures were in place for clinical governance, health and safety and infection control.

Summary of findings

Patient feedback regarding their treatment and care was overwhelmingly positive. Patients told us they felt included and informed about the treatment they received.

Summary of findings

Contents

Good

Quintiles Health Management Services

Services we looked at
Community health services for adults

Summary of this inspection

Background to Quintiles Health Management Services

Information about the service

Quintiles Health Management Services is a large multinational organisation with a business unit that specialises in health management, including the provision of highly specialist service giving infusion therapy to patients in their own homes.

Our regulation of the organisation covers only the provision of the infusion of Tysabri home treatments. This is a specific treatment for patients with multiple sclerosis (MS), which the organisation provides in partnership with NHS trusts. The treatment involves patients receiving a medicine by infusion in their own homes; the treatment lasts an hour.

Patients had the infusion medicine delivered directly to their homes by a separate delivery company one day prior to the day of the infusion. The delivery service is not covered under this registration and therefore was not inspected.

Patients who wish to receive home infusions are referred to the service by their local NHS trust. They must satisfy eligibility criteria to ensure they are suitable to receive their infusion at home.

At the time of our inspection the service was used by six patients. All patients remained under the care of clinicians at their local NHS trust, two were with one trust and four were with another.

Quintiles employ specially trained nurses to infuse the home treatment to these selected patients. Managers within the service are also nurses who have been trained to give the home infusion treatment.

At the time of our inspection, there were three registered nurses who attended patients' homes. They visited patients in their own homes every 28 days to carry out the treatment. These treatment visits were carried out on a pre-arranged and appointment-only basis.

Our inspection team

Our inspection team was led by:

Keith Morris, Inspector, Care Quality Commission.

Why we carried out this inspection

We inspected this core service as part of our comprehensive (independent) community health services inspection programme.

How we carried out this inspection

To get to the heart of people who use services' experience of care, we always ask the following five questions of every service and provider:

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

Before visiting, we reviewed a range of information we hold about the core service and asked other organisations to share what they knew. We carried out an announced inspection on 1 November 2016.

Summary of this inspection

We talked with three people who use services and with two member's staff who delivered the treatment. We did not observe clinical care but reviewed three treatment records of people who use services.

What people who use the service say

People who used the service told us that the nurse advisors were "fantastic", they treated them with dignity, compassion and respect. They said they were very kind, caring and thoughtful.

They also told us the overall service was "absolutely brilliant" and that it was much better receiving treatment at home instead of having to travel to a hospital. They said that they "just hope the service doesn't stop".

Good

Community health services for adults

Safe	Good
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Good
Well-led	Good

Are community health services for adults safe?

Good

Summary

By safe, we mean people are protected from abuse* and avoidable harm.

We rated safe as 'good' because:

- The home infusion service had a detailed and comprehensive set of standard operating procedures for staff to follow.
- Staff were trained effectively to provide the home infusion service.
- Staff had the appropriate equipment and training to enable them to treat patients.
- Staff utilised technology to keep patient records up to date and available to those who needed them.
- Hygiene, cleanliness and infection prevention processes were robust and adhered to by all staff.
- Staff had access to training courses to ensure competencies were maintained.
- Risks were assessed and checks were in place to ensure identified risks were mitigated.

However, we also found:

- The service did not have a documented duty of candour policy, although staff understood the principles of the duty.

Detailed findings

Safety performance

- Performance parameters for the service were monitored to provide a level of assurance to the company who provided the medicine and lead clinician with up to date safety performance. Harm free care was checked by ensuring that, for example, the infusion pumps were accurately maintained and up to date medical information for patients was available and reviewed prior to each treatment.

Incident reporting, learning and improvement

- There was a corporate policy for the reporting of incidents, near misses and adverse events. Staff were encouraged to report incidents using an electronic reporting system. The staff we spoke with were able to describe the process of incident reporting and understood their responsibilities to report safety incidents.
- Nurses followed a detailed standard operating procedure (SOP) during home visits. The SOP provided nurses with detailed instructions to follow for all elements of the home infusion treatment. This SOP directed nurses to report incidents to the company that provided the medicine. This was done via an online tool, which was reviewed by the third party contractor.
- Managers were able to describe the process nurses would use to report an incident. We saw an example where a nurse had reported medicine delivered to a patient was frozen due to the way it had been packaged. On this occasion, the infusion was cancelled and rearranged at the patient's local hospital. Managers described that information from this incident reporting regarding packaging was relayed to the delivery company.

Duty of Candour

- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person.
- The organisation did not have a formal policy specifically regarding the duty of candour as this information was incorporated into other quality and safety documents. However, managers were able to describe that the organisation had a no blame culture.
- Nurses we spoke with understood the principles duty of candour requirements for a written apology. Although they were not able to recount any specific examples, all nurses told us they worked with the principles of the duty in mind, being open, offering verbal apologies and documenting errors in patient notes.

Safeguarding

- The organisation had a safeguarding policy, and safeguarding training formed part of the mandatory training for the nurses providing the home infusion service. Training records we saw confirmed all nurses had received safeguarding vulnerable adults level 2 training, which was appropriate for their role.
- One of the managers was the designated safeguarding lead and had received additional training, to level 3, for this role. Staff told us they knew who the safeguarding lead was for their service.
- Managers were able to describe how awareness of safeguarding was important for their service. They had not made any safeguarding referrals but were able to describe when they might do so and the process they would follow if required.

Medicines

- The service had a SOP which provided nurses with instructions to follow for all elements of the home infusion treatment and detailed patient eligibility and criteria for patients in the home infusion service. This SOP showed that medicines were prescribed by the NHS trust under which the patient was being cared. Another company delivered these direct to the patients' home.
- The home infusion medicine is required to be reconstituted by the nurse prior to the infusion. To avoid drug wastage this was not done until the nurse had carried out pre-infusion checks and patient has been clinically prepared, and consented to receive the infusion.
- Nurses completed and signed a treatment record form during each appointment. This included a patient consent form, which was signed by both the patient and the nurse, and contained details regarding the infusion medicine such as the batch number of the medicine, the expiry date of the medicine and the time the infusion started and finished.
- All the treatment record forms we reviewed were completed fully and were legible.

Environment and equipment

- Prior to the first appointment the nurse conducted an environmental audit to ensure that it was suitable and safe. The audit included checks on access to the patients home, heating and water provision, type of flooring and parking.
- Nurses transported the infusion pumps and all other equipment necessary to carry out the home infusion. Equipment was removed and taken by the nurse at the end of the appointment, no equipment was left with the patient
- A third party company provided and delivered additional clinical supplies directly to the patient at their home. Patients received training and guidance from the registered nurse regarding the safe storage of these supplies.
- The same third party company collected clinical waste from the patient's home for disposal.
- Nurses were trained to use and carry personal protective equipment. Training records confirmed this had been received. Patients told us that nurses wore gloves and aprons when providing treatment and care.

Quality of records

- Nurses completed a paper patient record form for each patient visit and treatment. Once completed the forms were stored in the patient's notes, which were kept with the patient at home. The forms were also electronically scanned and sent, using a secure fax or email, to the multiple sclerosis (MS) specialist nurse based at the patients NHS trust, and to Quintiles Health Management Services to be uploaded onto the patients' record.

- We were not made aware of any audits carried out regarding the completion of the paper patient record forms. All the patient record forms we reviewed were completed fully and were legible.
- Risk assessments of patients homes were documented and stored with the patient notes at home.

Cleanliness, infection control and hygiene

- The organisation had an up to date infection control policy, available on the intranet, which staff were able to access.
- Nurses followed a SOP during all patient visits. The SOP provided nurses with detailed instructions to follow for all elements of the home infusion treatment including standard principles of infection prevention and control. The SOP set out the process the nurse should follow throughout the visit.
- Nurses carried appropriate materials for hand washing and for the disposal of sharps and waste. Nurses we spoke with were able to describe the process, and patients confirmed they saw nurses washing their hands and using personal protective equipment when in attendance and delivering the infusion.

Mandatory training

- The organisation had a range of training courses available for nurses. These included basic life support and anaphylaxis training, cannulation, manual handling, adverse event reporting form training, safeguarding vulnerable adults level 2.
- Nurses had additional, specific training regarding the home infusion medicine. This included training on how to prepare and administer the infusion.
- Training records we reviewed showed all nurses had received appropriate training and updates at regular appropriate intervals.

Assessing and responding to patient risk

- Risk assessments of the patients home was carried out prior to the patient starting with the service. These included suitability checks on the room in which the infusion would be given for example are there enough electricity points, are there suitable facilities for hand –washing. Further assessments were carried out if the patient moved house. This was to ensure all potential risks had been noted and events planned around this. These risks were documented and kept with the patients notes.
- Nurses used a pre-infusion checklist prior to each treatment. This required the nurse to check the patient for any significant changes to their physical and psychological condition before proceeding with any infusion process. If so, the nurse would not start the infusion and would contact the patient's consultant and specialist nurse for advice. We saw treatment records which showed these checks had been carried out. On one record we saw that a treatment did not commence due to the infusion medicine being frozen. The patients consultant was informed and an alternative appointment was made for the patient to receive their infusion at their local NHS trust.
- Nurses performed pre-infusion clinical measurements of the patient's temperature, pulse, respiration, blood pressure and, at pre-defined periods, blood test results. If any of the results fell outside the defined ranges, the nurse sought advice from the patient's consultant.
- All Quintiles home infusion nurses were trained and validated annually in the management of anaphylaxis and patient resuscitation. All Quintiles home infusion nurses carried a pre filled syringe and needle combination containing adrenaline, for intramuscular injection for use in anaphylaxis, in the event of any level of hypersensitivity patient reaction observed by the nurse.

Staffing levels and caseload

- At the time of our inspection, there were three registered nurses who were all trained to deliver the infusion medicine. They attended patient's homes and provided the home infusions. Nurses attended appointments on their own unless there was a specific need for two nurses.
- Although there were three registered nurses who routinely delivered the infusion medicine they were part of a larger team of registered nurses who were also trained to deliver the same medicine. Patients kept their notes in their homes and all other treatment documentation was scanned onto an electronic system that all the nurses could access remotely. This ensured that cover could be provided should one of the nurses be unable to attend an appointment and that they would have access to all relevant patient information.
- There was no reported use of agency or bank staff.
- All new staff complete a six month induction programme which included a corporate and local team induction.

Good

Community health services for adults

Managing anticipated risks

- The organisation defined anticipated risks as planned (known) or crisis (unknown). Managers were able to describe both known and unknown risks and explained contingencies in place for both. For example, if adverse weather conditions meant a nurse could not attend an appointment as arranged then an alternative appointment would be made at the patients local NHS trust. If a member of staff was unwell then cover would be provided by another nurse from the team trained to give the infusion.
- Nurses carried lone working devices, which had GPS tracking facilities; they were able to record conversations via the 'man down' button, which could be pressed in case of an emergency. These devices were managed by a third party provider. Nurses logged their status or location at the beginning and end of the day and when entering or leaving a property; this ensured their lone worker location was always known.
- Nursing teams used a buddy system if the GPS tracking was not working or if they were in an area where it could not work effectively, such as a rural area or high rise building. Nurses would liaise with each other before and after appointments to ensure safety.
- The service did not provide evening appointments unless required, for which specific arrangements were put in place.
- Risk assessments for each patient location were carried out and, if required, two nurses would attend an appointment.

Are community health services for adults effective?

(for example, treatment is effective)

Not sufficient evidence to rate

Summary

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

We inspected but did not rate 'effective', as we do not currently collate sufficient evidence to rate this. However, we found the following area's of good practice:

- There was an eligibility criteria prior to patients being accepted for the home infusion service.
- During the treatment, the patients remained under the care of their prescribing clinician.
- Staff employed were all registered nurses who received on-going training to enable them to carry out their duties.
- Nurses all had honorary contracts with NHS trusts which enabled them to maintain up to date skills.
- Nurses received regular clinical supervision.
- The service worked with NHS trusts and multiple sclerosis (MS) nurses who were responsible for their patients.
- The service had a pre-infusion checklist, which ensured patients had provided informed and documented consent for the treatment to be given.

Detailed findings

Evidence based care and treatment

- NICE guidelines, quality standards, national service frameworks and other good-practice guidance were followed by the staff under guidance of the patients lead clinicians.
- Prior to being accepted for the home infusion service, a patient eligibility checklist was completed by the patients' referring clinician. The checklist included questions regarding their clinical condition, for example, had the patient received a minimum of six infusions within a hospital setting, was their MS currently stable? If the answer to either of these questions was NO, then the patient was deemed not suitable for home infusion. The patient was informed of this decision and reasons for this were discussed. Other questions included; is the patient prone to repeated infections, is the patient highly anxious, is there any known reason why the patients' home environment would not be suitable for the home infusion service. If any of these questions were answered Yes then the patient was informed they were not suitable for the service in line with good practice guidelines.
- Patients eligible for the home infusion service remain under the care of their prescribing clinician. This enables clinical oversight of the effectiveness of the care and treatment being supplied.

Patient outcomes

- Patients were inducted onto this continuous course of treatment with no sepcifc end date, as this was deemed to be of continual benefit. In this very small cohort of patients all stayed on this protocol unless removed by their lead NHS clinician.
- The service did not hold outcome data for patients regarding their condition, as this was held by the NHS trust responsible for the patient.

Competent staff

- All nurses employed by Quintiles Health Management Services were Nursing and Midwifery Council registered. They held honorary contracts with the NHS trusts that looked after the home infusion patients. These contracts enabled the nurses to work within the NHS trusts and in the community with these pre-selected patients.
- These nurses supported infusion clinics held at the trusts and undertook local hospital inductions. This meant that they had access to training and up to date NHS procedures.
- Nurses providing the home infusion treatment received clinical supervision every six to eight weeks. Nurses we spoke with told us that this supervision took place and that it was useful.
- New staff were subject to comprehensive pre-employment checks, which included Nursing and Midwifery Council registration checks, two forms of photo identification, Disclosure and Barring Service checks (DBS).
- All new staff were required to complete a six-month probation period within the service. During this period, the new member of staff would not treat any patients unless supervised. If there were any delays receiving all the required documentation, for example DBS checks not being received due to backlogs with the issuing organisation, the staff member would not treat any patients until all documentation had been received and checked.
- Staff had annual face-to-face appraisals and records indicated that all three nurses had received their appraisal.
- Staff also had quarterly formal conversations with their managers. Where possible these were carried out face-to-face. If this was not possible then teleconferencing would be utilised.

Multi-disciplinary working and coordinated care pathways

- Managers and staff were able to describe how they liaised with MS nurses and hospital consultants regarding the care of the patients should they need to discuss any concerns. We were told that staff would telephone the consultants and MS nurses for advice when necessary. They told us the MS nurses and consultants were always responsive when contacted. In addition, the home infusion nurses also worked with the consultants and MS nurses when working under their honorary NHS contracts in local trusts.
- Patients, who were unable to have their infusion at home, because they were unwell or the medication was faulty, would attend the next available clinic at their NHS trust. Patients and nurses told us there was never a problem arranging an appointment in these circumstances.

Referral, transfer, discharge and transition

- Patients were referred to the service by their MS nurse at the NHS trust under which they were receiving their care.
- Given the nature of the condition, and the service provided, patients were not discharged from the service, as they required on-going and long-term treatment.

Access to information

- Patients' records were stored in paper format in their own homes.
- Patient records were also held in electronic format by the NHS trust under whose care the patient is given.
- Treatment records created by the home infusion nurses were scanned using hand-held devices and uploaded to records held by the service.
- Nurses had access to organisational procedures and policies via an online system. This allowed them to access policies relating to and including health and safety, clinical governance and corporate governance.
- Nurses also worked for local NHS trusts within their role with Quintiles Health Management Services, which ensured that they had access and training for up to date clinical practices.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The service used a corporate-wide consent policy which we saw addressed situations where patients lacked the ability to give consent. Staff we spoke with understood the principles of consent and the Mental Capacity Act.

Good

Community health services for adults

- Consent was obtained prior to each home infusion treatment and was documented on the treatment record form. We reviewed four forms, which confirmed this had always been done, and appropriately recorded.
- All patients we spoke with told us that they were always asked to provide consent prior to each treatment.
- Mental capacity was also considered as part of the pre-infusion checklist and staff were instructed not to proceed with the infusion if there had been a change in the capacity of the patient. This could, for example, be temporary, due to clinical reasons, such as an infection. In these circumstances, the hospital consultant was contacted for advice.

Are community health services for adults caring?

Good

By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect.

We rated caring as 'good' because:

- Patients told us that nurses were kind and caring.
- Patients told us that nurses took an interest in their general well-being and were not there to just provide treatment.
- Nurses had visited patients monthly for a number of years and became a valued means of support for patients.

Detailed findings

Compassionate care

- We spoke with three patients receiving home infusion treatments. All of the patients told us how caring and kind the nurses were.
- Patients told us nurses would discuss their general well-being and welfare at each home visit. Staff said they used the time while the infusion pump was running to chat with the patient
- Alternatively, staff told us that sometimes patients preferred to sit quietly while the infusion pump was running and they would respect that.
- Patients told us that some nurses would bring cakes to the appointments and would make drinks for the patients while they were connected to the infusion pumps. They made active attempts to make the occasion as social and non-clinical as they could, recognising that patients had specific and personal preferences.

Understanding and involvement of patients and those close to them

- Patients told us that although nurses attended their homes regularly the nurses always explained the treatment each time and ensured that the patient was involved in their treatment. For example, allowing the patient to decide in which room they preferred to receive their treatment.
- Patients told us that the nurses asked after family members when they visited.
- Relatives were able to ask questions about the treatments and support their relative in a practical way during the infusion.

Emotional support

- Patients reported good emotional support from the nurses. The majority of the patients had been using the service for many years and the nurses had visited their homes on a monthly basis for the whole period. Because of this, good relationships had been built and maintained.
- Patients also told us they received good support from their multiple sclerosis (MS) specialist nurses and their consultants. They told us they were able to contact them if they had any concerns or questions.

Are community health services for adults responsive to people's needs?

(for example, to feedback?)

Good

Summary

By responsive, we mean that services are organised so that they meet people's needs.

We rated responsive as 'good' because:

- The service was designed specifically to provide a convenient clinical infusion service at home for patients, and this kept them out of the hospital environment.

Good

Community health services for adults

- Home infusion appointments were arranged directly with the patient.
- Appointments were flexible and could be altered if a patient wishes to change the date.
- The service had received no complaints and patients told us they had not felt the need to complain.

Detailed findings

Planning and delivering services which meet people's needs

- The home infusion service was designed to provide patients with a more flexible and convenient way to receive their monthly infusion. This meant less travel for patients to attend hospital appointments, which were sometimes located significant distances from their home.

Equality and diversity / Meeting the needs of people in vulnerable circumstances

- Patients were risk assessed prior to commencing the home infusion service and were re-assessed if circumstances changed. The assessment included confirming the language spoken at the patients' home address, were there any cultural or religious considerations to consider, would the patient have any preference to be treated by a male or female nurse. At the time of the inspection there were no patients requiring these adjustments, however staff told us that they would access interpretation services if necessary. Also a male nurse worked for the service and could attend appointments if required. Any issues identified were given an action, with a responsible person for that action and a date for completion. The risk assessment was kept in the patients notes.
- All patients we spoke with did not report any issues.

Access to the right care at the right time

- There were no waits for appointments and no waiting list. Patients were referred to the service by their NHS consultant and allocated a nurse who then arranged appointments with the patient.
- Nurses pre-arranged appointments directly with the patient. They would do this in person at the end of the current appointment. The appointments were at regular times that suited the patient. There was only one appointment per day for the nurses meaning they were not rushed.
- The delivery company would call the patient one week before the infusion date to confirm the delivery of the medicine.
- Nurses would contact each patient by phone one week prior to the appointment to remind them of the appointment time and date. During this conversation, they would check that the delivery company had phoned the patient to confirm delivery of the medicine. If not the nurse would contact the delivery company to check the situation.
- Patients told us that the nurses were flexible and had rearranged appointments if the patient had another engagement, such as a holiday or wedding, to attend. Patients also told us that the nurses contacted them if they were running late on the day of the appointment, for example due to traffic congestion.

Learning from complaints and concerns

- Managers reported they had received no formal complaints since the service had started. This meant they were unable gain any learning. However, they told us they used team meetings to share and learn from their experiences.
- Patients we spoke with said they had never had any reason to raise a complaint or concern regarding the service. However they said that if they did, they would contact their multiple sclerosis (MS) nurse in the first instance.

Are community health services for adults well-led?

Good

Summary

By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

We rated well-led as 'good' because:

- Managers had developed the service since its inception.
- Managers and staff supported each other with advice and when in lone working situations.

Good

Community health services for adults

- Staff told us the organisation had a no blame, supportive, learning and open culture.

Detailed findings

Leadership of this service

- Managers had developed with the service, and had the skills and expertise to provide appropriate management and leadership of the home infusion service. This was achieved and monitored by regular training and clinical supervision.
- Staff told us managers and colleagues were approachable, accessible and available should they require advice or support.
- Lone working was key to how the service ran. Staff told us they were supported by their managers and colleagues to ensure that they were kept well trained, safe, knowledgeable and accessible to their patients.

Service vision and strategy

- The local strategy for the home infusion service was to provide an innovative, safe and patient centred regular infusion service for patients with long-term conditions. This was documented and in the standard operating process for the service, which served as it's overarching strategy document.
- The vision for the home infusion service was that patients would receive a standard of care comparable to that which they would receive in hospital. The home infusion service had been specifically designed to provide patients with a more convenient and flexible way to receive their monthly infusion.
- Managers and staff were able to describe the service strategy and vision. In most cases the managers and staff had been involved in the original set up of the service.

Governance, risk management and quality measurement

- The service had comprehensive systems to ensure the safety of patients and staff. These included eligibility criteria for patients to join the home infusion service, risk assessments prior to commencing the service and detailed standard operating procedures (SOPs) for nurses to follow during each visit. For example, clinical assessments of patients were carried out prior to each treatment and these were recorded in the patient notes
- Managers checked adherence to the SOP during field visit reviews. These reviews were carried out every six to eight weeks. Staff confirmed to us that these took place and were useful.
- The service had a risk register that was discussed at governance meetings held quarterly. Actions arising were allocated to team members and followed up at the following meeting.

Culture within this service

- All staff told us that they put patients at the centre of their care.
- Staff told us the organisation had an open and no blame culture.

Public engagement

- The home infusion service was very small, with only six patients, and the service told us they knew all of their patients. However, surveys had not been carried out and formal feedback had not yet been obtained from patients in the year leading up to the inspection. Patients told us that when the service originally commenced they were asked to complete a questionnaire, which provided feedback on the service.

Staff engagement

- Staff were field based workers. Managers told us they were aware that interaction with staff was important for morale.
- Quarterly office based team meetings were used as opportunities for team based training.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- **To provide clarity, the duty of candour policy should be made a stand-alone policy and document.**