Investigation into the out-of-hours services provided by Take Care Now

Part 2:
Take Care Now and its provision of out-of-hours services

July 2010

Introduction to the investigation

The Care Quality Commission has carried out an investigation into the out-of-hours services provided by the organisation Take Care Now (TCN). TCN was commissioned by several NHS primary care trusts (PCTs) to supply doctors providing out-of-hours care.

The investigation followed the death of Mr David Gray, who was treated in February 2008 by a locum doctor, Dr Ubani, and subsequently died following the administration of 100mg of diamorphine. The doctor practised in Germany and, through an agency, worked at TCN to cover some out-of-hours shifts.

At the inquest into Mr Gray's death, the coroner concluded that Mr Gray was unlawfully killed. Dr Ubani was found guilty in a German court of causing death by negligence and received a suspended prison sentence. He has since been struck off the General Medical Council register. TCN announced in February 2010 that it was to be taken over by Harmoni, an independent provider of primary care services.

The Care Quality Commission was asked in June 2009 to review the out-of-hours arrangements in relation to TCN and to be assured that all lessons have been identified and appropriate action taken.

We looked at TCN's management of calls (that is, initial call handling, prioritisation and subsequent decision-making about calls), staffing, medicines management, governance processes, and leadership and management.

We also examined the commissioning arrangements by the PCTs that used TCN to provide out-of-hours services for their patients, and also the performance management of these – particularly the governance and quality checks in place for monitoring contracts with TCN. Finally, we looked at the way that the PCTs administered the performers lists of GPs.

Progress statement in October 2009
We issued a progress report in October 2009. By then, TCN had completely withdrawn 100mg ampoules of diamorphine, significantly reducing the chance of the original mistake being repeated.

We noted that TCN had difficulty in filling shifts at times, particularly for doctors, which put pressure on other staff and could affect the quality of the service. We asked TCN to ensure that patients with symptoms of stroke were transferred without delay to the 999 service.

We also noted that the PCTs we had visited, needed to improve their monitoring of out-of-hours services and we recommended that all PCTs should scrutinise out-of-hours services more closely. This recommendation was endorsed by the Department of Health and the national director for primary care wrote to every PCT with this message.

Our final report

We have produced our final report following the conclusion of our investigation. We have split it into three parts:

- In Part 1, we set out the circumstances surrounding Mr Gray's death. We also describe previous incidents at TCN that involved overdoses of diamorphine.

- In this part, Part 2, we report in detail on TCN and its provision of out-of-hours services.

- In Part 3, we look at the commissioning arrangements for out-of-hours services and the monitoring of contracts by the five PCTs involved. We also examine the strategic role of the strategic health authorities and their performance management of the PCTs, and look at the way that the PCTs administered the performers lists of GPs.

We have also produced an overall Summary of the investigation, drawing together our main findings and conclusions from the three separate parts.

Finally, we have also produced an appendix document that includes our terms of reference, methodology and sources of information.

Part 2: Contents

Part 2: Main findings and conclusions

Findings

Call handling and reporting of activity

- Call handling was generally satisfactory, but patients with symptoms of a stroke were not transferred straight to 999 in line with national guidance. In some cases, calls were not given sufficiently high priority. Standards of triage were generally satisfactory, other than for advising callers what to do if symptoms got worse.

- TCN made fundamental changes to patient pathways, in contravention of the national quality requirements (NQRs), without clinical sign-off from the contracting PCTs and without appropriate auditing of the effects of these changes.

- TCN's reporting to PCTs of performance on the NQRs was not comprehensive or accurate, and did not reflect the actual performance of the organisation. Most TCN staff did not fully understand how activity was reported or what was included in the NQRs. TCN did not address concerns about how it reported activity.

Staffing

- TCN struggled to recruit doctors and relied on doctors coming from Europe to work shifts, particularly in 2007 and 2008. Some doctors worked excessive hours, including in 2009.

- TCN frequently failed to fill large numbers of clinical shifts. The resultant shortfall put pressure on other staff and potentially compromised the care of patients. In one PCT, the rate of unfilled shifts in autumn 2009 was 18%. Unfilled shifts were not reported to PCTs. Although TCN said they had a flexible system to ensure adequate coverage, we found several instances in September 2009 when the nurse on duty overnight at Wisbech was the only clinician for more than 70 miles.

- Communication with front line clinical staff, and their induction and training, were poor in 2007 and much of 2008. They then gradually improved. In 2007 and occasionally in 2008, some doctors worked shifts before they had been inducted. There was insufficient local clinical leadership.

- The out-of-hours bases were generally poorly signposted and often difficult to find.

Medicines management

- TCN had inadequate governance for medicines management, with limited pharmaceutical advice or support, no service level agreements or contracts, and policies that lacked clarity and detail. This resulted in an environment where controlled drugs were being stored and administered inappropriately. There was little knowledge of controlled drugs procedures, and limited opportunity to monitor and address concerns or staff awareness of controlled drugs.

- The NPSA issued a safer practice alert in 2006 about prescribing, labelling, supplying, storing, preparing and administering morphine and diamorphine. TCN did not take action in respect of this alert. The death of Mr Gray from an overdose of diamorphine happened in February 2008 and the 100mg vials of diamorphine were not removed until September 2008, and then at the insistence of NHS Cambridgeshire.

Governance and leadership

- TCN was poor at recording and handling both complaints and incidents, and trends were not consistently identified and acted on. TCN was poor at identifying clinical risk and failed to consistently identify serious incidents that required reporting and investigating. TCN did not investigate serious incidents thoroughly or learn lessons from them. In particular, although there were two overdoses of patients in 2007 involving diamorphine, operational changes were not introduced until after the death of Mr Gray.

- TCN had flawed governance systems – it was not able to provide the minutes of some important meetings, and the minutes of others were poor quality. Some of the information TCN provided to the CQC and PCTs about the events associated with the death of Mr Gray was incomplete or inaccurate. TCN appeared reluctant to accept its shortcomings, whether in respect of activity reporting, filling of shifts or governance systems.

- Between 2005 and 2009, TCN grew rapidly, winning three contracts and more than doubling the population it covered. This growth in business was not matched by an expansion in capacity in governance.

Surveys of TCN's performance

- In local surveys, TCN performed well on quantitative measures of satisfaction, with an 88% overall satisfaction rate. Using the relevant questions in the 2008/09 GP national survey, TCN achieved a score very close to the national average, and it was ranked 63rd out of 101 out-of-hours services.

Conclusions

1. TCN struggled to recruit local GPs and relied heavily on doctors flying in from Europe to work weekends. Some doctors worked long hours. TCN tolerated staffing levels that were potentially unsafe, with pressure on other staff.

2. TCN failed to recognise the importance of learning lessons from complaints and incidents. It was not sufficiently focused on clinical risk and did not adequately report or investigate serious incidents. In particular, it failed to act quickly enough on the concerns that emerged from the two overdoses of diamorphine in 2007, or on the National Patient Safety Agency alert in 2006.

3. TCN's systems for medicines management were inadequate, leading among other things to controlled drugs being stored and administered inappropriately. Recently medicines management had improved and the system for accessing controlled drugs was more robust and easily monitored.

4. TCN reported activity in a way that was confusing and potentially misleading, and did not act to resolve this. The performance that TCN reported to the PCTs on the national quality requirements did not accurately reflect the actual performance of the organisation, and could potentially have concealed poor performance.

5. TCN grew too rapidly and the focus on expansion and business priorities was at the expense of governance and clinical services. Although clinical governance was well articulated by TCN, there was insufficient capacity to deliver it. It was not rooted in frontline patient services, nor demonstrated by clear accountability or local clinical leadership.

6. TCN failed to recognise problems in its own systems that might have helped prevent the death of Mr Gray. It was reluctant to admit its shortcomings and provided information to the PCTs and to us that was often inaccurate or incomplete.

Introduction to out-of-hours services

GPs traditionally had individual responsibility for their patients 24 hours a day. However, over the last couple of decades the extent of this responsibility became increasingly onerous and, although responsible for care, most GPs did not provide their own out-of-hours services. Instead, responsibility was delegated to GP co-operatives (independent organisations run by GPs for the provision of out-of-hours services) or commercial providers. At the beginning of 2004, fewer than 5% of GPs provided out-of-hours services themselves, about 70 per cent of GPs had delegated the responsibility to a GP co-operative, and around 25 per cent to a commercial provider.

Under the general medical services (GMS) contract introduced in April 2004, GPs were able to opt out of direct responsibility for provision of out-of-hours care and transfer this responsibility to their local primary care trust (PCT). This led to 90% of practices opting-out and transferring responsibility to PCTs.

Since then, PCTs have had a legal responsibility to make sure patients are cared for when GP surgeries are closed, and that they continue to be offered safe, fast and convenient care. This is delivered through a number of different arrangements:

- Co-operatives set up by professionals, usually doctors, that tender for contracts to provide out-of-hours care for a set period for a PCT. Some of these are designated as 'social enterprises'. These organisations run as business models, but either invest all profits back in services or have expressed social aims.
- PCT-organised providers.
- Through other NHS providers, e.g. ambulance trusts.
- Private commercial companies that tender for contracts to provide out-of-hours care for a set period for a PCT.
- A mixture of the above.

Some GP practices or individuals have also continued to deliver out-of-hours services themselves.

What constitutes out-of-hours?

'Out-of-hours' refers to the periods when GP surgeries are generally closed. These are from 6.30pm to 8.00am on weekdays and all day at weekends and bank holidays. Around seven million patients contact GP out-of-hours services in England each year.

As noted in the Department of Health report in February 2010 on out-of hours, *Project to consider and assess current arrangements*, clinicians in out-of-hours services encounter a particular set of circumstances. These include unfamiliar patients, colleagues who may not be well-known to the clinician prior to the shift, unfamiliar surroundings/equipment and a higher proportion of vulnerable patients with care needs that are often more complex than those generally found in daytime general practice.

How out-of-hours services operate

In simple terms, most contacts with the out-of-hours service consist of a caller contacting the service by telephone and being given advice on the telephone, asked to come and see a clinician at a base or primary care centre, receiving a home visit or being transferred to another service.

We describe below a standard process for out-of-hours services for illustrative purposes; there are local variations.

Stage 1: Call handling

Initial contact with the service will usually involve the patient calling the service directly or being diverted after calling either their normal GP practice or NHS Direct. For most out-of-hours services this call will be answered

by a non-clinical member of staff (call handler), although some have clinical staff answering calls. The national minimum standards for the time to answer calls, and proportions of calls that are engaged or abandoned, are set out under national quality requirement 8.

The call handler's first step will be to ask for the patient's demographic details such as name, address, date of birth etc. The call handler will input these into the IT system to search for any previous records for this patient or to create a new record if this is the patient's first contact with the service. This search will also identify if the patient's GP has provided the service with any information (called special patient notes) relating to the patient's condition. At this stage the call hander will also try to identify whether the condition of the patient is of an immediately life threatening nature and if so, the call will be transferred to the emergency services along with the demographic information.

After taking demographic details and transferring any life threatening calls the call handler will ask a number of questions about the patient's condition/symptoms. The degree to which these questions are based on an algorithm or proscriptive process will vary depending on the organisation but all providers are likely to have some set questions to identify common urgent conditions.

The specific questions asked will depend on the caller's description of the patient's symptoms. The aim of this stage is to identify the urgency of the call rather than to take a full history or make a diagnosis. At the end of this stage the call handler will have entered notes on the system about the symptoms described by the caller/patient focussing on the most important details, and will have prioritised the call as either emergency, urgent or less urgent/routine.

The emergency calls are passed to 999, and the urgent and routine calls will be passed to stage 2 (triage) with appropriate advice such as telling the caller to re-contact the service should their condition deteriorate while waiting for a triage call back. This is often referred to as 'safety netting'. There will also be some calls, for example wrong numbers or callers asking questions like pharmacy opening times, that will end at stage 1 as they do not require clinical assessment.

For patients that walk into a primary care centre rather than telephoning the service, stage 1 will usually be undertaken by a receptionist asking similar questions to call handlers or giving the patient a form to fill in.

A minority of out-of-hours organisations have implemented a further process for some calls, usually referred to as 'call streaming'. For example as most children under the age of five will require a face-to-face assessment, some services bypass triage and the call handler arranges an appointment at the primary care centre for the patient. As this type of process is outside the national quality requirements, which assume that all calls should receive clinical assessment, it is important that services agree this variation with the commissioning primary care trust (PCT). They also need to be able report on the numbers and waiting times for these patients separately.

Stage 2: Triage/clinical assessment

Triage is a method of ranking sick or injured people according to the severity of their sickness or injury so that they receive the right service with the appropriate degree of urgency.

After the first stage, calls that have not been streamed, passed to the emergency services or ended, will pass to the triage stage. In national quality requirement '9' (see next section) there are set minimum standards for time to definitive clinical assessment by a clinician (i.e. the last triage assessment if there is more than one) for urgent (within 20 minutes) and less urgent/routine calls (within 60 minutes). This requirement also defines a three-minute time standard for emergency calls, from the time they were identified as an emergency, to be transferred to the emergency services.

The triage stage will always be conducted by clinical members of staff, doctors, nurses or emergency care practitioners, and will generally involve the clinician calling the patient to conduct the assessment over the phone. Some providers will have face-to-face triage available at their primary care centres for walk-in patients but many providers will move straight from stage 1 to stage 3 (face to

face assessment) for walk-in patients as they have already arrived at a centre (minimum standards for triage of walk-in patients are set out in national quality requirement 10).

At this stage the clinician will perform an initial evaluation of the patient's condition, checking that the call has been prioritised correctly and determining the necessary next step. For a number of calls the clinician may determine that based on the symptoms and medical history the patient does not need to be seen face-to-face by the out-of-hours service and the call can be completed with telephone advice. For example the doctor or nurse may recommend that a patient complaining of a headache should take some painkillers and then contact the service or their normal GP if the headache persists. If the clinician determines that a face-to-face consultation is necessary then the call will be passed to stage 3. As with stage 1, patients will be told to contact the service again should their symptoms worsen.

Stage 3: Face-to-face consultation

Patients will be seen either at the patient's place of residence or at a primary care centre (base). As well as the patient's clinical condition, the criteria for deciding whether to visit a patient's home or ask them to come to a base will vary, but will generally take into account location, available transport and other relevant factors. Some patients such as those receiving palliative care, will always receive home visits.

The national minimum standards for time from definitive clinical assessment to face-to-face consultation are set out in national quality requirement 12 and are broken down into three levels of priority emergency (within one hour), urgent (within two hours) and less urgent (within six hours). Base visits may be scheduled by appointment with patient's given a specific time to attend or patients may simply be told to come to base within an agreed time.

Face-to-face consultations in out-of-hours services are very similar to those conducted in surgeries in working hours. Usually the patient will be seen by a GP but, depending on the patient's condition, some services may use a nurse or emergency care practitioner to see the patient. At the end of the consultation the patient may receive advice, medication (or prescription), or be referred to another service, e.g. admitted to hospital. Face-to-face consultation will mark the end of that particular case (patient journey) but appropriate advice will be given about contacting the service should their condition worsen.

To ensure continuity of medical records the out-of-hours service will send the notes for any patient that has contacted the service to the patient's GP practice by 8 am the following day (national quality requirement 2).

GP practices are also encouraged to send any special notes on their patients, e.g. for palliative care patients, to the relevant out-of-hours service. These notes will then be kept on the system to assist clinicians and call handlers with prioritising calls (national quality requirement 3).

Frontline staff roles

Non-clinical roles

- Call handlers are generally responsible for the first stage of the process with their duties primarily consisting of answering calls, taking patient details, inputting these into the system and prioritising calls based on symptoms as described by the caller.
- Receptionists are responsible for receiving patients at primary care centres and will also conduct the first stage for walk-in patients who arrive without telephoning the service first.
- Duty managers are responsible for running the call centres or central hubs where calls are answered and where triage is often located. They manage call handlers, receptionists and dispatchers.
- Dispatchers are normally located at the call centre/hub and are responsible for assigning home visit calls to different mobile clinicians in cars. They may also be responsible for assigning triage calls to clinicians and booking base visit appointments. Some organisations manage all of their visits centrally using dispatchers to determine to which mobile clinician a home visit should be assigned and to call patients to book base visit

appointments. Others will manage calls by locality, e.g. sending all home visits for an area to a particular mobile clinician in a car, reducing the demands on central dispatching.

- Drivers are responsible for driving clinicians to and from home visits. They may also have responsibilities for stocking up on equipment and certain medications in the cars. Overnight drivers will often take the role of receptionist in between home visits.

Clinical roles

- General practitioner (GP): for most out-of-hours organisations the majority of clinical staff working in the service will be GPs. They may work for the service full-time but most do shifts on a part-time basis as freelance, locum or agency doctors. GPs will be responsible for clinical assessments (stage 2) and face to face consultations (stage 3).
- Nurses: as with GPs, nurses will be involved with stages 2 and 3 depending on their particular skills and qualifications. For example a nurse with experience of working in a minor injuries unit might see some patients, particularly if the provider has a base co-located with a minor injuries unit, but will probably not be used for telephone triage. A nurse practitioner may be employed in either role.
- Emergency care practitioners (ECPs): some organisations use ECPs to conduct home visits for particular categories of patients. Most ECPs are ambulance clinicians or paramedics with extended skills. There are usually restrictions in place on what kinds of patient an ECP can see. They can see patients in bases but they are not normally used for triage.
- Clinical lead: some services will also have a clinical lead covering a particular area who can be contacted if issues or problems arise, and can provide support and advice on clinical matters. The clinical lead is usually a GP or nurse with significant out-of-hours experience.

The specific skill mix of clinicians varies between organisations with some exclusively using GPs while others have a greater proportion of nurses and ECPs.

National Quality Requirements

In March 2000, the Department of Health commissioned a review for out-of-hours care in England and the 'Carson Review' was published in October that year.

The review proposed a flexible, national model of integrated out-of-hours provision. This was based on twin principles: patient access to services should be as simple and straightforward as possible, and professionals should work together co-operatively and collaboratively. The review made recommendations and proposed core quality standards for measuring quality of service. These included target times for actions to be completed, e.g. ensuring that urgent calls were passed to the ambulance service within three minutes.

In 2004, the standards were reviewed and formed the foundation for the national quality requirements (NQRs), which came into effect in January 2005. The current set of NQRs came out in July 2006 following the review by the National Audit Office. From that time all out-of-hours services had to be delivered to these requirements as a contractual obligation, regardless of where patients lived. As part of this, providers had to regularly report and exchange information, undertake regular audits, operate an appropriate complaints system, and demonstrate the availability of capacity to meet demand at all times. Providers also had to ensure an appropriately qualified member of staff was available when needed, that they met targets relating to the initial phone call, initial consultation and face-to-face consultation, and that provision was made for those who did not speak English. The requirements are set out in appendix H in the appendix document.

The National Quality Requirements were primarily designed to ensure a consistent baseline standard that the public could expect of their local out-of-hours service. However variations in the service model and the way data are recorded mean that reports of compliance by different organisations are not

always comparable. For example, as noted by the Primary Care Foundation, many providers measure NQR 9 as the time to first telephone assessment rather than definitive assessment as it should be measured. This makes it appear as if the patient waited a shorter time and means their reporting against this standard cannot be compared with those that report correctly. The NQRs are also largely limited to measuring access times and operational processes. Even with the need for auditing (NQR 4) and surveying pubic opinion (NQR 5) these requirements cannot give a full picture of the clinical quality of the service being provided, nor of outcomes for patients (although this would be difficult to assess given the patient mix seen in out-of-hours). It should also be noted that out-of-hours services have more information and measures being routinely reported than any other area of primary care. The Department of Health stated in February 2010 that it intended to make the NQRs more robust and has established an expert advisory group to review the standards.

National Audit Office report

In May 2006 the National Audit Office published a report examining the provision of out-of-hours care in England. It had four key findings. The report found some shortcomings in the initial commissioning process because PCTs lacked experience, time and reliable management data. Secondly, out-of-hours providers were beginning to deliver a satisfactory standard of service but most were not yet meeting all the national quality requirements, particularly on speed of response. Thirdly, the actual cost of running out-of-hours was higher than the money allocated by the Department of Health and finally, commissioners were entering into contracts with multiple providers and the market was maturing.

The report suggested that the Department of Health should encourage PCTs to improve the cost-effectiveness of the service through benchmarking of costs, improvements to local commissioning, and making available training and best practice. For PCTs, it was suggested that they should benchmark their costs against those of other geographically comparable PCTs. There was also a need to ensure that all groups within the community could access services effectively and that the PCTs, or their providers, met the access requirements set out within the national quality requirements. It noted that the manner in which patient feedback was collected, could be improved.

The case of Penny Campbell

At the end of the Easter bank holiday weekend in 2005, a journalist, Penny Campbell, who had a young son, died of septicaemia. This followed contact with eight doctors from Camidoc, a North London out-of-hours service commissioned by Islington, Camden, Haringey and City & Hackney PCTs.

An investigation by three independent clinical reviewers took place following this serious incident. It found failures in both ensuring notes from previous consultations were made available to doctors, and in following up complaints and investigation of concerns. It also found that there had been little overt clinical leadership or performance management at Camidoc and that its clinical governance was not fit for purpose.

The report suggested that all out-of-hours providers and commissioners should learn from what had happened and made a number of recommendations. These included a need to change the perception of the out-of-hours service as a ‘holding bay’ until the patient’s GP resumed care; raise the profile of the out-of-hours service and the professional reputation of those working in it; and address the policy confusion over whether an out-of-hours service is for urgent care or unscheduled care. *(*Unscheduled care is defined as services that are available for the public to access without prior arrangement where there is an urgent actual or perceived need for intervention by a health or social care professional. Urgent care should be used as the umbrella term to include unscheduled care, unplanned care, and emergency care. It refers to any care that needs to be delivered urgently, whether this is within or outside standard hours.)

In response to this report, in December 2006 the Department of Health issued new directions. NHS directions are instructions issued by the Secretary of State who has

powers under NHS primary legislation to give directions to health authorities, special health authorities and NHS trusts. These are legally binding and the recipient must comply. These directions required every PCT to review the systems in operation by out-of-hours providers, ensuring that arrangements were fit for purpose and that they achieved continuity of care.

Benchmarking

In 2007, the Department of Health commissioned the Primary Care Foundation to develop the audit tool used by the National Audit Office in their 2006 report *The Provision of Out-of-hours Care in England.* This was piloted across a number of PCTs and has now been adopted by two thirds of PCTs in England. The benchmark aims to assist PCTs to improve the quality of care and to allow services to identify where they might be able to operate more efficiently through comparison with other providers. The main indicators are cost, productivity, process, outcomes, performance and patient experience. 'Outcomes' in the context of this benchmarking does not relate to clinical outcomes but to whether patients received advice, a home visit or attended a centre and whether the patient was referred or made their own decision to go to hospital. Clinical coding is not generally complete enough to allow more detailed comparison of outcomes, though the Primary Care Foundation is looking to increase the factors included in the benchmark.

The latest Primary Care Foundation benchmark in November 2009 (covering 90 out-of-hours contracts) showed that compliance with these requirements was mixed. The majority of participants audited clinical contacts with patients and complaints monthly and reviewed patient experience quarterly. 70% of PCTs using the benchmark also met their providers at least quarterly to review their contract. Overall out-of-hours services were generally seen to be improving although wide variations were found in responsiveness and many providers were still falling short on the standard for definitive clinical assessment for urgent cases.

In January 2010, the Primary Care Foundation published '*Improving out of hours care: what lessons can be learnt from a national benchmark of services'.* This consisted of reflections and recommendations for out-of-hours services based on the first two rounds of the benchmark.

Software systems

Out-of-hours health care is delivered in a complex environment. It needs to co-ordinate the sharing of information flows not only across geographically dispersed bases/primary care centres and mobile clinicians, but also between different providers of health and social care. While there are significant variations in the details and layout of different software solutions, successful applications should to be able to meet the following basic requirements:

Input, transfer and secure storage of confidential patient information

The input of information will largely be conducted by simply typing the information into specified text fields (i.e. call handlers or clinicians entering patient notes) but more advanced applications will allow for daytime GPs to place special notes about their patients directly onto the out-of-hours database.

Transfer of patient information involves both transfer within the service, e.g. allowing clinicians to view previous consultation and triage notes, and transfer between services such as the national requirement to pass details of all consultations to the patient's registered GP by 8am the next day.

Prioritisation and 'time stamping'

At the initial contact stage and at the end of triage, calls need to be prioritised into three different categories – emergency, urgent and routine. In order to report whether the time standards in the National Quality Requirements are being met, the software application needs to record the time intervals between different stages, e.g. record the time taken between a call being answered and definitive triage being conducted.

These prioritisations and the associated time need to be immediately visible at subsequent

stages, so that for example a clinician at the triage stage can see which calls have been designated urgent, which are routine and how long each call has been waiting in order to determine which call they should triage next.

Search, retrieval and reporting of information held within the database

Each time a patient contacts the service, the system needs to be able to find any earlier information held about this person, e.g. any special notes provided by their GP or any past contact with the service.

In order to report on the National Quality Requirements the system has to produce the necessary data to show whether the relevant standards have been met.

The system will also record and report on the activities of staff, e.g. length of time spent on triage calls by each clinician.

National Quality Requirement 4 specifies auditing requirements; these audits will most commonly be conducted using the Royal College of GPs (RCGP) audit toolkit. It is possible to manually conduct these audits but the process can be made more efficient by using an in-built audit toolkit.

Compatibility with other telephone systems and mobile devices

Providers of software for out-of-hours services will often offer a telephone system as part of their software. If a different telephone system is used, the out-of-hours software has to be compatible with this. The telephone system must also fulfil basic requirements such as being able to record phone calls and details, and being able to record the information necessary to report against National Quality Requirement 8.

Given the need for clinical staff to conduct home visits the software has to be compatible with mobile devices (i.e. laptops) to allow clinicians to view and enter notes while travelling to and from home visits.

TCN used a software system called HMS (Hampshire Medical Services).

Department of Health's 2009 project to assess out-of-hours

In October 2009, the Minister of State for Health asked the National Director for Primary Care and the Chairman of Council, Royal College of General Practitioners to review the local commissioning and provision of out-of-hours services. This was published in February 2010, at the same time as the coroner's verdict on the death of Mr Gray.[*]

The reviewers visited five out-of-hours services and their commissioners across England. The sites visited demonstrated a range of service provision including PCT providers, ambulance services, social enterprises and commercial organisations.

The authors stated that they knew from their combined experience that the quality of out-of-hours services in many areas was good. During their visits they saw several examples of good practice but also examples of where improvement was needed from both the commissioners and providers of services.

The report noted that staff who work for out-of-hours services, face a number of challenges. They treat patients who are not known to them, often without access to their medical records. Furthermore, their initial contact and assessment of these patients is invariably on the telephone. They operate in settings that are not like their usual surgery or place of work, and they use unfamiliar equipment. They may work in an area unfamiliar to them, and with colleagues who they have never worked with before. In addition, they may deal with a higher proportion of patients who are in need of urgent care, and are therefore particularly vulnerable. These may be the young, the elderly, or those with chronic or terminal conditions.

The report made 24 recommendations. Eight of these referred to commissioning and performance management; ten to selection, induction and training of out-of-hours clinicians, and six to the management and operation of performers lists.

[*] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_111892

Overview of Take Care Now

TCN originated from a GP co-operative, Suffolk Doctors on Call. Suffolk Doctors on Call (SDOC) was established in 1994 as a not-for-profit organisation made up of local GPs. At the end of 2004, following the opt-out of GPs from responsibility for out-of-hours care, TCN was formed as a private company with a majority shareholder base of the GPs who were already members of SDOC. It was the commercial wing of the organisation, and began trading in 2005. SDOC also created a separate company called Suffolk GP Services (SGPS) in order to purchase the Riverside building in Ipswich, which had previously been rented by SDOC.

The original guild of local GPs chose to maintain SDOC to enable clinicians to retain their superannuation through the Guild of Suffolk Doctors. TCN also had shares in a Cambridgeshire based agency called MCD – Medical Consulting and Diagnostics Ltd.

Initially there was one chairman for TCN, SDOC and SGPS but this changed in 2009, following the recommendations about company directors in the Companies Act 2006, which came into effect in October 2008. TCN was overseen by GP shareholders and a board consisting of five GP members and two non-GP members.

Contracts with PCTs for out-of-hours services

The original contracts with Suffolk and Cambridgeshire PCTs were held by SDOC. Delivery of these services however was passed to TCN. The contract signed by Suffolk PCT in March 2008, dated 1 April 2007, was signed by TCN and states 'TCN working with SDOC'.

Cambridgeshire PCT was formed in October 2006 from a merger of three PCTs including East Cambridgeshire and Fenland. SDOC provided out-of hours cover in East Cambridgeshire and Fenland from October 2004 onwards. The SDOC/TCN contract with the PCT (which terminated in December 2009) was initially drawn up in October 2005, but the contract was not formally signed until March 2009. Some staff in the PCT were unclear which organisation was providing the service.

Between October 2007 and October 2008, TCN was awarded three new contracts for out-of-hours services; in Great Yarmouth & Waveney, South West Essex and Worcestershire. The contract with South West Essex was a subcontract of the main contract with the East of England Ambulance Service Trust (EEAST).

Summary

- **October 2004:** SDOC began providing services for Suffolk PCT and East Cambridgeshire & Fenland PCT.
- **October 2005:** SDOC agreed a contract East Cambridgeshire & Fenland PCT.
- **October 2007:** TCN was awarded the Great Yarmouth & Waveney contract.
- **January 2008:** TCN was subcontracted by EEAST to provide services for South West Essex PCT.
- **October 2008:** TCN was awarded the contract with Worcestershire PCT.
- **March 2009:** contract with NHS Cambridgeshire finally signed.
- **December 2009:** NHS Cambridgeshire terminated the contract, NHS Suffolk decided to award the contract from April 2010 to Harmoni.

Location of services

TCN operated from a number of bases or centres across the areas that it served, these bases were of varying size and some were co-located with other health care facilities such as a hospital, or minor injuries unit. Typically a base consisted of a reception area and one or

more consultation rooms. Bases generally had much of the equipment routinely found in GP surgeries and primary care centres. The bases also kept a small stock of common medications and a stock of medicines, including controlled drugs, for the immediate treatment of patients. The opening and closing times of bases in the description below came from TCN's website and information leaflets.

Suffolk: TCN had a total of nine out-of-hours bases in the county of Suffolk ranging from Felixstowe and Aldeburgh on the east coast to Newmarket in the west. While all of the bases were open for at least part of the day at weekends, the opening times for weekday evenings were more variable. Between the hours of 8pm to midnight seven bases were listed as being open. However, due to the need for clinicians to conduct home visits, only the Ipswich base was guaranteed to have a clinician present in the base during these hours. After midnight only the Newmarket and Ipswich bases were listed as open but again due to the need for clinicians to conduct home visits one or both of these bases might have no clinician for periods during this time.

East Cambridgeshire and Fenland: TCN operated a total of three bases in this area ranging from Ely in the south to Wisbech in the north with only the Wisbech base open during the evenings and overnight. As with Suffolk, due to the need to perform home visits the presence of a clinician at the Wisbech base throughout the night was not guaranteed.

Great Yarmouth & Waveney: TCN operated a total of four bases in this area ranging from Halesworth in the south to Great Yarmouth in the north. One base was only open on weekend mornings while two bases were open throughout the night. For the evening periods there was generally at least one clinician in the Great Yarmouth and Lowestoft bases. During the night the need to conduct home visits meant that the bases of Great Yarmouth and Beccles did not always have a clinician present.

South West Essex: TCN provided clinical services from two bases in this area located at Basildon and Thurrock hospitals. The Thurrock base was only open until 11pm both on weekdays and weekends while the Basildon base was open overnight.

Worcestershire: TCN operated a total of six bases in this county ranging from Malvern in the south to Kidderminster in the north. The three bases at Kidderminster, Worcester and Redditch were open all night both on weekdays and at weekends. As with all other bases, the need to conduct home visits meant that there was not necessarily a clinician in the base at all times, particularly after midnight.

Takeover by Harmoni

TCN announced in February 2010 that it was to be taken over by Harmoni, an independent provider of primary care services.

Harmoni purchased a controlling interest in TCN and subsequently began running TCN's former services. Where still applicable, PCT contracts switched to Harmoni on 1 April 2010 following approval by the individual PCT. EEAST has now entered into a new sub-contract with South Essex Emergency Doctors Service.

Call handling and reporting of activity

Summary of findings in this chapter

- Call handling was generally satisfactory, but patients with symptoms of a stroke were not transferred straight to 999 in line with national guidance. In some cases, calls were not given sufficiently high priority. Standards of triage were generally satisfactory, other than for advising callers what to do if symptoms got worse.
- TCN made fundamental changes to patient pathways, in contravention of the national quality requirements (NQRs), without clinical sign-off from the contracting PCTs and without appropriate auditing of the effects of these changes.
- TCN's reporting to PCTs of performance on the NQRs was not comprehensive or accurate, and did not reflect the actual performance of the organisation. Most TCN staff did not fully understand how activity was reported or what was included in the NQRs. TCN did not address concerns about how it reported activity.

Sources of evidence

- Observations during visits to TCN bases and call centres
- Interviews with TCN staff and doctors, CQC survey of TCN staff
- Interviews with PCT staff
- Manual and protocols for call handlers
- CQC Audit of call handling
- Performance reports and operational statistics
- TCN statements
- Contracts
- Minutes of meetings at TCN, and of contract monitoring meetings with PCTs
- Correspondence with TCN and PCTs
- Interviews with HMS

Initial receipt of calls, including emergency calls

The manual for call handlers contained an introductory sentence and a closing statement for handlers to use. The latter is referred to generally as 'safety netting' since it advises callers what to do if symptoms worsen. The call handlers did not use a specific algorithm but there were guidelines for particular conditions, e.g. stroke, chest pain and breathing problems.

The manual for call handlers listed 13 conditions which determined that a call should be designated as urgent.

Symptoms of stroke were not included in the manual but as a separate document. During a visit by CQC to Riverside in July 2009, we looked at the protocol for stroke in use at the call centre. It stated that for callers with a suspected stroke the call should be passed to a clinician for urgent call back (i.e. prioritised as urgent and placed into the triage queue) rather than being transferred to 999 as per national guidelines issued by the Royal College of Physicians in 2008.

As this presented a risk to the safety of patients, the issue was immediately raised with TCN. The next day an email was received from TCN with an updated stroke protocol which showed that patients with suspected stroke/TIA should be transferred directly to 999. TCN told us that the stroke protocol seen on our observation visit was out-of-date, despite it still being in use at the time. TCN said it would ensure that the updated policy was now in place everywhere.

During a visit to the Worcester call centre a month later we found that the out of date stroke protocol was still in use there. We raised this as a matter of urgency with TCN and further visits indicated that staff were using an up-to-date stroke protocol.

Checks were made on call handlers by TCN during their induction period and if a concern was raised. However TCN did not systematically audit call handlers to assess the quality of their interaction with patients. This meant that TCN could not be confident that call handlers were consistently following the correct protocols.

During visits to the Riverside call centre we observed that, beyond the introductory statements and questions, there was significant variation in the order and type of questions used by call handlers.

In the call handler manual call handlers were specifically instructed not to use the 'emergency' priority unless the patient was not breathing or was unconscious. TCN did not consider the majority of calls transferred to the ambulance service as representing calls where an 'immediate life threatening condition' had been identified and therefore only recorded a small number of calls against NQR 9a (those where the patient was not breathing and/or unconscious). All other calls that were transferred to 999 by call handlers were recorded as urgent, then coded as 'log call & finish'.

TCN staff were unsure what effect the recording of 999 calls as urgent would have on the performance statistics as presented to PCTs, i.e. whether these would count as quickly completed urgent calls for NQR 9b and portray performance in a favourable light. Our visit to HMS confirmed that these calls would only be counted against NQR 8 as they did not go into the queues for triage or visits. HMS also confirmed that it would require manual trawling to identify the calls passed to 999 by call handlers if they were being coded as 'log call & finish'.

TCN referred to this matter as being a national problem with the NQRs not clearly defining the criteria for emergency calls but we could not find evidence to support this. The report by the Primary Care Foundation on lessons learnt did not identify any national issues with defining 'immediate life-threatening conditions'. Other than for Worcestershire, there was no evidence that TCN's definition of 'emergency' calls had been discussed and agreed with the commissioning PCTs.

Minutes of the clinical management group at TCN showed that TCN had identified concerns about the recording of 999 calls but had only changed this for instances where clinicians referred the call to 999, i.e. the call summariser put in a 999 code after a clinician transferred the call to the ambulance service.

The figure for 999 calls transferred by clinicians formed part of the reports to Great Yarmouth & Waveney PCT after July 2008 but only began to appear in performance reports for other PCTs in August 2009. Some of the performance reports, such as those for Suffolk for August and September 2009, stated 'total calls transferred to 999' which was inaccurate as this figure did not include the majority of calls transferred to 999 by call handlers. The other reports stated 'calls referred to 999'- which again was ambiguous. TCN's client relationship managers confirmed that the figure for 999 calls in these performance reports was only for calls transferred by clinicians, and those transferred by call handlers where the patient was not breathing and/or unconscious.

At the Worcestershire call centre there were particular issues with transferring calls to 999 as calls from Worcester went through the switchboard in Ipswich, so calls appeared as if they had come from Ipswich. This meant they would be directed to the wrong ambulance service i.e. East of England instead of West Midlands. This should have been a fairly

straightforward issue to correct by stating that the operator should ignore the number showing, and giving the patient's number so the correct geographical area was assigned. TCN instead told callers to dial 999 themselves, which was a potential risk. The Primary Care Foundation found that this was also the practice in some other out-of-hours services, with some services arguing it was the quickest way to get an ambulance despatched (providing there was no immediate danger of the caller collapsing) . TCN subsequently stated in November 2009 that this issue had been resolved and calls were being transferred directly.

Key findings for initial receipt of calls

- TCN monitored call handlers at their induction but there was no routine audit of the quality of call handling.
- TCN 's protocol for stroke in use at the call centres meant call handlers did not prioritise symptoms of stroke and call 999. This changed after the intervention by the CQC.
- In Worcestershire, callers were instructed to call 999 themselves.
- Call handlers were instructed only to designate as emergencies, those patients who were unconscious or not breathing.
- Calls diverted to 999 by call handlers were not recorded unless the patient was unconscious or not breathing.
- In Great Yarmouth and Waveney in 2008, and in August 2009 in other areas, TCN had begun to report calls diverted to 999 by clinicians.

Auditing of clinicians by TCN – NQR 4

As part of the National Quality Requirements, providers of out-of-hours services are required to audit regularly the clinical quality of the service they provide. These audits should provide sufficient data to review the clinical performance of each individual working within the service (National Quality Requirement 4).

In response to the difficulties that some services encountered in meeting this requirement, the Department of Health commissioned the Royal College of General Practitioners to develop a toolkit to assist them in meeting this requirement.

The RCGP audit toolkit was first published in March 2007. It contains guidance on how to conduct an audit, how to feedback results and a framework for conducting the audit using 12 criteria. These are:

1. Elicits **REASON** for telephone call or visit
2. Identifies **EMERGENCY** or serious situations
3. Takes an appropriate **HISTORY** (or uses algorithm appropriately)
4. Carries out appropriate **ASSESSMENT**
5. Draws appropriate **CONCLUSIONS**
6. Displays **EMPOWERING** behaviour
7. Makes appropriate **MANAGEMENT** decisions following assessment
8. Demonstrates appropriate **PRESCRIBING**
9. Displays adequate **SAFETY-NETTING**
10. Develops **RAPPORT**
11. Makes appropriate use of **IT / Protocols / Algorithms**
12. Satisfies **ACCESS** criteria where appropriate [info available]

The scoring framework for the toolkit involves scoring each of the 12 criteria as either '0' for not met, '1' for partially met and acceptable but could be improved or '2' for largely or fully met.

The toolkit aims to cover the core criteria for all consultations in out-of-hours services, with the intended use of generic criteria to promote consistency in quality and standards. The scoring framework is designed to allow individuals to benchmark their performance against the organisation's mean score for each criterion and to help identify outliers with possible development needs. These audits are not intended to provide a complete picture of clinical quality and, as recommended by the RCGP, organisations should supplement audit results with other information sources such as incident reports and patient feedback.

TCN first received the RCGP audit toolkit in May 2007 and at the July 2007 contract monitoring meeting with Suffolk PCT, promised implementation of the toolkit by September. This did not happen until 2009.

The minutes of the contract meeting with Great Yarmouth & Waveney in April 2008 stated that TCN had just received the toolkit. At the request of the PCT, TCN then undertook a manual quarterly audit for clinicians in Great Yarmouth & Waveney.

The group of clinical leads for audit undertook considerable work in developing frameworks for scoring, training audit reviewers and developing a quality assurance process. TCN had a number of IT problems implementing the toolkit which were not resolved until February 2009 when TCN began to audit clinicians every three months. TCN could not easily match call sheets to call recordings and conducted the audits based on notes, without the use of voice recordings.

In terms of reporting on performance, TCN declared partial compliance against NQR 4 in Great Yarmouth & Waveney until September 2008, and in Suffolk and Cambridgeshire until February 2009, when full compliance was declared. This declaration of partial compliance was based on TCN's other methods for monitoring the quality of clinicians, including complaints and compliments, shift reports and HMS reports of time taken on triage and consultation.

There was little evidence of this monitoring being conducted via a formal system. However, minutes from clinical excellence meetings in January and March 2009 showed discussions about poorly performing clinicians with issues having been raised as a result of complaints, shift reports and information from the HMS system such as 'high rate of 999 transfer'. There was also evidence of discussions around information from the HMS system (such as slow consultation and triage times) at the operational metrics meetings and discussions of issues with individual clinicians at the meetings of the group set up to performance manage clinicians.

Up to September 2009 there were no audit results presented in the performance reports for Worcestershire, although TCN declared it was compliant with NQR 4. TCN provided us with audit results for individual clinicians in Worcestershire, but overall averages had not been calculated.

The audit results we received showed 'safe' scores for the majority of contacts assessed in most categories, with the average scoring overall being over 83% for met or partially met. The categories with the highest proportion of fully met scores in both the 2009 audits were for 'reason' (clinician elicits reason for the call/contact) and 'management' (clinician makes appropriate management decisions following assessment). Over 70% were deemed to have fully met these standards.

However there were high percentages of 'not met' for the categories of 'history' and in particular 'safety-netting'. For example, for the first three months of 2009, in the East of England 41% of staff did not record that they had given clear advice on when to call back (safety netting), and 39% did not record the medical history of the patient to a satisfactory standard. 76% achieved a satisfactory standard on 'emergency' i.e. identifying a serious or emergency situation but nearly a quarter did not. The second quarter showed some improvement with 36% not meeting the standard on safety netting, and 21% on emergency. It should be noted that as TCN only used clinical notes for conducting audits it was not possible for them to ascertain a full picture of the telephone consultations and therefore the actual quality of consultation may have been higher than shown in these results. For example safety-netting may have been performed appropriately but not recorded in the notes.

TCN used the audit to identify poorly performing doctors and a doctor was removed in 2009 whose poor performance had been identified solely through the toolkit.

TCN communicated matters such as the need for 'safety netting' with clinicians via the clinical bulletins and clinical appraisal. For example the Clinical Bulletin from 1 May 2009 gave tips on 'safety netting'. These included the need to be specific about when and why further help

should be sought and to document that this advice had been given.

Findings of fact on TCN's auditing of clinical staff

- TCN received the RCGP toolkit in May 2007. In February 2009 TCN began to audit clinicians every three months.
- The audits were based on notes, without the use of voice recordings.
- Before the audits TCN declared it partially met the standard for NQR4 based on complaints, compliments, shift reports and time taken on triage and consultation.
- The audits showed satisfactory responses for most categories. 83% met the desired standard.
- Between 36 and 41% did not give clear advice on when to call back, 39% did not take a good history and 20 -24% did not identify an urgent situation or emergency.
- TCN used the clinical bulletin to feedback from audits and to give advice.
- TCN had used the audit to identify poorly performing doctors.
- TCN did not have a formal plan to improve standards identified as weak in the audit.

CQC's audit of triage

The CQC undertook an independent audit of a selection of calls. This was to assess the quality of telephone triage and also to assess the quality of TCN's clinical auditing.

We initially used the HMS system to randomly select a subset of the triage calls for which TCN had already carried out clinical audit. Our external clinical adviser commented that the software facility to randomly select notes and call sheets from an electronic database was preferable to the paper based approach most commonly used by out-of-hours services.

Problems arose when CQC subsequently requested the audio recordings of call handlers and telephone triage for each patient episode. These were stored on a separate electronic database and therefore not easily matched to the list of call reference numbers generated by the HMS system. This was further complicated by the fact that some calls originated from NHS Direct, and therefore the initial audio recording was not held by TCN.

It was for these practical reasons that when auditing call handling and triage at the Worcester call centre, we requested a sample taken from a single Saturday in 2009, chosen at random. This allowed for each recording and call sheet to be identified sequentially and eliminated those calls for which no audio was available.

A total of 73 calls were assessed using both the notes and recording, with a further 82 calls audited using only the clinical notes.

The quality of triage of these calls was audited using the RCGP audit toolkit. The work was undertaken by one of CQC's external advisors, a GP with many years experience in out-of-hours and one of the contributors involved in formulating the RCGP audit toolkit.

As TCN conducted their clinical audits of triage using only the notes (i.e. did not listen to the call recordings) it was decided to conduct separate audits where both the notes and recordings were available. This allowed more direct comparisons to be made. Below is a summary of the results from this audit.

Comparison of CQC audit and TCN audits of triage

Due to the complexities involved with extracting audit scores for individual calls from the HMS system it was only possible to access these while on a PC connected to the TCN HMS database. This was done for a number of triaged calls on a visit to TCN headquarters in Ipswich where 101 calls were independently audited, using only the clinical notes. All of these calls were for the East of England region.

It should be noted that the TCN audit scores compared here were noticeably higher than those reported by TCN for the first two quarterly audits for 2009. The average percentage scores for 'not met' in TCN audits for these calls were between 2% and 6%. The same scores for 'not met' in those audits being

16.6% in the first quarter covering all East of England areas, and 13.7% in the second quarter covering all TCN areas.

CQC on average scored 11 of the 12 criteria lower than TCN's auditors, with one criterion receiving the same average score. This difference was largely due to the CQC scoring more calls as partially met rather than fully met. The average percentage of not met was the same for both audits. It should be noted that, due to the three point scale of the scoring framework, quite large variations in score could be caused by small variations in the auditor's assessment.

Examining the scores for individual criteria shows that triage of these calls scored consistently well for the criteria 'Elicits reason for call' (92% achieving a score of fully met in the CQC audit) and 'Satisfies access criteria where appropriate' (82% achieving a score of fully met in the CQC audit).

There were, however, some criteria where the scores were lower, this was particularly true for the criterion 'Displays adequate safety-netting' where only 21% of calls achieved a score of fully met, and 26% of calls scored not met, in the CQC audit. The other criteria with higher than average proportions of calls receiving a score of not met were 'Appropriate history taking' and 'Displays empowering behaviour'.

We subsequently received the call recordings of 19 of the triaged calls. This allowed us to compare three sets of audit scores for triage of these calls:
-TCN's
- independent audit using notes
- independent audit using the recording.

Comparison of TCN audit scores with independent audit using notes and recording

We compared our results for the quality of triage using only the notes, and the results when listening to a recording of the call. This showed noticeably higher scores for those audited using a recording. The average score for the 19 calls using notes only was 1.43 while the score with a recording available was 1.69, and average percentage for not met fell from 5% to 0%.

On this small sample of 19 calls no calls were given a score of not met for any criterion. For all 19 calls the initial priority assigned to the call by the call handler was determined by CQC to be correct. For three of the 12 criteria the average score for the CQC audit using the telephone recording was lower than the average score from the TCN audit. This was due to us scoring a lower proportion of calls as fully met and a greater proportion as partially met. This occurred for the criteria 'Identifies emergency or serious situations', 'Displays adequate safety-netting', and 'Satisfies access criteria where appropriate'.

Calls where a TCN audit score was not available

A further 54 triaged calls, with both notes and recordings, were audited without an available TCN score. 26 of these calls were from the East of England area and 28 were from the Worcestershire area.

In the East of England there was only one criterion for which the CQC score was on average higher using only the notes than using the recording. The average overall scores for the audit using a recording were higher for these 26 calls than they were for the 19 East of England calls discussed previously. There were 16 occasions (out of 312 scores, i.e. 5%) where a score of not met was received. Again it was the criterion of 'Displays adequate safety-netting' that received the lowest scores with 12% of calls receiving a score of not met for this criterion in both audits.

In Worcestershire for all 12 criteria the average CQC audit score was equal to or higher with the recording available, compared to only using the notes. The average score for the CQC audit using a recording was higher for this set of 28 calls than it was for any of the other audits. There were 11 occasions where a score of not met was given (out of 336 scores, i.e. 3%). As with all of the other audits 'safety netting' received the worst scores with 17% of calls deemed not to have met the standard.

Findings of fact for CQC's audit of triage

- Scores from CQC's audit differed, and were generally higher, when the call recording was used compared to those using only clinical notes. TCN itself audited using just the clinical notes.
- Overall the standard of clinical triaging for the calls audited was considered to be good.
- Averaging across all criteria and all calls audited using a recording, 3% were deemed not to have met the required standard.
- Giving the caller advice about what to do if symptoms worsened (the criterion of safety-netting) received the lowest scores.
- The selection process in HMS which generated random calls was identified as an area of good practice.

TCN's audit of call handling

TCN told us they did not perform any routine or systematic audits of call handlers. CQC considered that TCN's introduction of call streaming should have been associated with the introduction of routine auditing of call handling. Call handlers were reviewed at the end of training as part of their induction process, after a three month probationary period, and in the event of any concerns having been raised. TCN stated in the autumn of 2009 that they were planning to introduce routine auditing as part of the annual appraisal process.

TCN told us that they did not audit changes made to the classification of calls i.e. how frequently clinicians changed the priority initially set by call handlers.

The Carson review in early 2009 of TCN's governance systems also noted the lack of feedback on call dispositions (prioritising) for call handlers and recommended that TCN implement a system to benchmark and feedback and the classification of calls by call handlers.

Findings of fact on TCN's audit of call handling

- TCN did not perform routine audits of the quality of call handling but they were planning to introduce it in autumn 2009.
- Although TCN had introduced call streaming, it did not audit whether call handlers had made the correct prioritisation into emergency, urgent or routine.

CQC's audit of call handling

In order to assess the quality of call handling at TCN CQC undertook an independent audit of a selection of calls. A total of 80 calls, both recording and call slip, were requested from TCN. Of these 67 calls with all of the necessary details were received. The calls were then audited by one of CQC's external advisors, who has many years of experience of call handling and auditing. TCN's tool for auditing call handling was used. Below is a summary of the results from this audit.

We initially audited calls that were received by the call centre in Ipswich. A total of 37 calls from Ipswich call centre were assessed. Calls were given an overall score and scores of not met, partially met or met against the five categories. The four main categories were greeting; demographics and location of patient; assessment of symptoms (including allocating the correct priority); call closure. We also considered the attitude of the call handler and how long the call took.

The table below displays the overall scores achieved showing the number of calls that were scored fully met, partially met or not met for each of the above categories.

Category	Fully met	Partially met	Not met
Greeting/ salutation	37	0	0

Demographics and location	20	7	10
Symptom assessment	20	13	4
Call closure	21	9	7
Overall score	13	10	14
Proportions for overall score	35%	27%	38%

As can be seen from the table above 62% of the calls had an overall score of fully or partially met, and 38% of the calls assessed received an overall score of not met (fail).

The TCN call handlers performed consistently well on greeting callers. For all 37 of the calls the correct greeting and salutation were given and the checks for life threatening conditions were performed in accordance with TCN guidelines.

Ten call handlers read demographic information, such as the patient's address, off the screen to the caller which was strictly against good practice and TCN's own guidelines. Other problems involved incorrect spelling or the call handler not checking spelling, or the contact number.

In terms of symptom assessment, the most common concern identified in this category was call handlers not making a full record of the relevant symptoms described by the caller. This ranged from the failure to record details such as a sore throat to not recording serious concerns such as a child being short of breath. There were other concerns such as the correct TCN protocol not being followed in three calls.

When handlers closed the call, the most common problem was that some did not give adequate instructions about what to do if symptoms worsened, others gave no 'safety netting' instructions at all and a few gave no call back time or an inappropriate time.

Generally the call handlers performed well in terms of having a good manner and attitude. A small number of calls took too long or the caller was treated in an inpatient manner. It was not possible to perform an assessment of the priority assigned to calls by the call handlers. This was because the call notes that were received only showed the final priority assigned to the call, so it was not possible to determine if a clinician had changed the priority at the triage stage. However, when undertaking the audit of triage in Ipswich, we found four calls out of 45 (9%) where the call handler had determined too low a priority. There were no calls where the priority was too high. There was one call, which was graded less urgent, where the call should have been transferred to the ambulance service by the call handler if national stroke guidelines had been followed.

A total of 30 calls from the Worcester call centre were assessed. It should be noted that all of these calls occurred on the same day and therefore involved just nine different call handlers.

The methodology was essentially the same as for the calls from Ipswich. For the Worcester calls we could identify the initial priority given to the calls. We made a separate assessment of the priority that we would have given to each call and this was then compared with the priority assigned by the TCN call handler.

Overall the quality of call handling for this sample of Worcester calls was better than the standard of call from Ipswich. No call slip was received for four calls or the call slip received was not fully legible. These calls could not be assessed against the symptom assessment category and the prioritisation could not be compared for three of these calls.

The table below displays the overall scores achieved showing the number of calls that were scored met, partially met or not met for each of the categories that were assessed:

Category	Fully met	Partially met	Not met
Greeting/ salutation	30	0	0

Demographics and location	9	21	0
Symptom assessment	22	4	0
Call closure	29	1	0
Overall score	7	22	1
Proportions for overall score	23%	73%	3%

In terms of call prioritisation there were seven calls (26%) where the call prioritisation assigned by the TCN call handler was considered to be too low (i.e. the urgency of the call should have been graded higher) and there was one call where the prioritisation was considered to be too high. We noted that all of these patients had been triaged and none had gone straight to a base.

From the above table it can be seen that the majority of calls (73%) received an overall score of partially met while only one call (3%) received an overall score of not met.

The call handlers in Worcester also performed consistently well in the area of greeting. The correct greeting and salutation were given in all the 30 calls assessed and the checks for life threatening conditions were performed in accordance with TCN guidelines.

As with Ipswich there was an issue with call handlers reading demographic information off the screen. The Worcester call handlers took the postcode from the caller and then read out the street address. This led to the high number of calls scoring partially met for this category. In Ipswich there was a greater tendency to read the full address off the screen. The Worcester call handlers did well for symptom assessment although there were six calls where the symptoms were not fully recorded.

All call handlers advised callers what to do if symptoms got worse, although in one call this was at the behest of the caller. They gave call back times although in six instances this time was not in accordance with the National Quality Requirements. No concerns were noted in terms of the control/attitude/length of calls in the Worcester sample.

Overall

Combining the overall scores from Ipswich and Worcester, 30% fully met the standards, 48% partially met the standards and 22% did not meet the standards. Across both the CQC call handling and triage audits for a total of 103 calls the priority assigned by the call handler was assessed. From this, it was found that the priority assigned by the call handler was considered too low in 12 instances (i.e. 12% of calls).

Findings of fact on CQC's audit of call handling

- 37 different call handlers were audited at Ipswich and nine at Worcester.
- Overall, we judged that 30% of calls fully met the standards, 48% partially met the standards and 22% did not meet the standards.
- 62% of the calls at Ipswich received an overall score of fully or partially met, and 38% of the calls assessed received an overall score of not met (fail). 96% of the calls at Worcester received an overall score of fully or partially met, and 3% of the calls assessed received an overall score of not met (fail).
- Call handlers at Ipswich and Worcester performed excellently on the greeting.
- In ten calls at Ipswich, handlers read demographic information, such as the patient's address, off the screen to the caller, in contravention of TCN's guidelines. In 21 calls at Worcester, handlers took the postcode from the caller and then read out the street address.
- In a small number of cases at Ipswich, important clinical information was missed.
- In terms of call prioritisation, there were a total of 12 calls out of 103 (12%) where the call prioritisation assigned by the TCN call handler was considered to be too low. This could have implications for patients going straight to bases**.**

Call streaming

The policy stated that for calls classified by call handlers as non-urgent the call handler could offer the patient the choice of either further advice, a home visit or a base visit (i.e. without triage). This process was called 'call streaming' or 'straight to base'. Instructions for the call handler to 'safety net' were also included.

This system meant that, if the caller chose to attend a base they did not receive telephone triage from a clinician but instead were given an appointment slot at a base. Call streaming could present increased clinical risk as the call handler offering the appointment was not a clinician and could mistake an urgent call for a less urgent one. A further contractual issue was that after NQR 8 (call answering requirements), these calls were not reported against any of the NQRs.

TCN began trialling this system for children under five in 2007. Originally it was only at the Riverside centre and then it was rolled out to all areas in January 2008. TCN stated that in 2009 they piloted this approach for all patients. We asked TCN for audit results but they only provided them for one weekend in February 2009. For Worcestershire, TCN stated that trials were conducted in April 2009.

There was some confusion around when exactly this policy was in place. TCN stated: "In approximately May 2009 the trial was extended to bases in East Suffolk (Stowmarket, Aldburgh and Felixstowe). In June 2009 the trial was extended further to all East of England PCTs" (Suffolk, Great Yarmouth & Waveney PCT and Cambridgeshire PCT). However, TCN also told us in a statement, and the minutes of the contract monitoring meeting with Suffolk PCT in July 2009 recorded similarly, that it had stopped the 'straight to base' pilot for the last three months.

During visits by CQC to Riverside in the summer of 2009 we noted that the policy was not in operation. This was confirmed by position statements from TCN noting it had suspended the policy due to swine flu.

While for children under five call streaming may have been in regular use, for other age groups its use was more limited and on a more ad-hoc basis. TCN informed us during our visit to Riverside in November 2009 that the policy had been suspended.

We were told by some staff at TCN that the rationale for the call streaming policy was to improve patient choice. However we noted it was only implemented at weekends and bank holidays, when services were generally busier. TCN's executive director of business strategy and performance said the policy was designed to remove non-urgent patients from the usual system at times of high demand, without turning their calls away, indicating that this policy was also implemented for operational reasons.

The policy in relation to call streaming for children under five was included in the call handler manual and was mentioned as part of their introductory training. TCN did not provide evidence of any additional training programme for call handlers for implementing call streaming, but in our staff survey we found that 57% (13 out of 23 responses) of call handlers who booked 'straight to base' appointments reported they had received additional training. The other 43% (10 responses) said they had not had additional training. TCN told us that only long serving staff would have needed the training and we noted nine of the ten had worked for TCN for over a year.

It was unclear to what degree this change was discussed and approved by the contracting PCTs. There was evidence that TCN discussed this policy for 'under fives' with Great Yarmouth & Waveney, Suffolk, Cambridgeshire and Worcestershire, generally at contract monitoring meetings. These meetings typically did not have clinicians in attendance, apart from in Worcestershire, nor usually was any subsequent PCT clinical opinion sought for this change of service. Although this was a change to the standard pathway for patients and could have an effect on the time to definitive clinical assessment, we did not see any evidence that clinical staff at the PCTs had approved the policy.

At a contract monitoring meeting with Great Yarmouth & Waveney in 2009 there was discussion about applying the policy to all patients in Suffolk. Apart from this there was no evidence that the change to include

patients of all ages had been discussed with PCTs. In addition most PCT staff we interviewed were unaware that these patients would not be reported against a number of NQRs (they were only reported in the overall total and NQR 8). Similarly most TCN staff were not clear about how the outcomes of this policy were being monitored. Some staff thought that the visits might be recorded against NQR 12. Others were clear that these calls would not fit into the NQRs but thought that they were being reported separately.

TCN was unable to report timescales for these patients to be seen. This, in combination with no routine auditing of call handlers, meant that any adverse effects of this system would only be noticed if there was an untoward incident report or complaint. Audit results for calls that were streamed were provided for some of the trial weekends but this required separate manual identification of these calls. The data could not be extracted from HMS via a standard report.

Findings of fact for call streaming

- Call streaming was initially introduced for children under five but then rolled out to all patients.
- Call streaming was only for non-urgent patients, and operated only at weekends and bank holidays.
- The rationale was said by some at TCN to be to increase choice for callers; by others it was noted to be an operational response to busy periods.
- 57% of call handlers reported that they received additional training on call streaming, 43% stated they did not.
- The policy for call streaming for under fives was discussed with PCTs but the only evidence of discussion about the expansion of call streaming to older patients was at a meeting with Great Yarmouth & Waveney and the discussion was about Suffolk.
- Where the policy was discussed with PCTs, it was generally at contract meetings often with no clinicians from the PCTs present.
- Beyond NQR 8 (call answering requirements) if the patient chose an appointment this was not reported against any of the usual NQRs involved in measuring access times during the patient
- The straight to base appointment system increased the time after the initial call until a clinician became involved but there was no system to record how long this would be.
- PCT staff were not aware that these calls were not reported against a number of the NQRs.
- There was little evidence of clinical audit of this change in the patient pathway.

Reporting of activity

Every out-of-hours provider has to produce a regular report of performance for its PCT(s). Many produce reports on a monthly basis which show the activity in the previous month (i.e. May data reported at start of June) and their performance against the NQRs.

Most providers report activity such that for each patient there is just one record. The number of cases or ‘patient journeys’ is the same as the number of contacts, whether or not the patients receive advice, visit the base or have a home visit.

However, in the HMS appointment booking system, as used by TCN, if an appointment for a visit to a base was made after triage, two patient contacts were created for this one case (one patient). These were, one for the call handling and triage stage, and one for the visit to a base. This was sometimes referred to as ‘double counting’. The system was inconsistent because patients who received home visits and those who attended the base without an appointment did not generate another contact.

The activity tables presented by TCN in the monthly performance reports gave the figures for total contacts which were significantly higher than the total number of actual cases/patients. In Worcestershire, the

performance reports for Worcestershire stated on the front page a figure for 'total calls' which was actually total contacts, *not* total calls. This changed in April 2009. In August 2009 when we initially requested numbers of calls handled at each call centre broken down by PCT, TCN sent a table showing total contacts.

This presentation of activity was potentially confusing in a number of ways. A PCT might be under the impression that total contacts meant total cases/patients and therefore have overestimated TCN's activity, which could have affected contract negotiations. This is considered in more detail in Part 3 of our report. Reporting total contacts rather than cases also changed the proportions of each activity performed by TCN. For example for TCN the number of visits to bases as a proportion of total contacts was roughly what would be expected of many services. Looking at patients/cases however, TCN saw a higher proportion of their patients at bases than was typical of some out-of-hours services, where more patients simply receive telephone advice. This could be argued to be beneficial to patients or conversely, an inefficient use of resources. The PCTs were generally unaware that the breakdown related to contacts, not individual patients.

Finally, as a large proportion of base visits was not recorded against NQR 12, (the time from definitive triage to being seen face to face), TCN's reporting against this standard was based on small numbers. This meant that TCN's reporting against this standard was inaccurate due to the majority of base visits not being included. As TCN was unable to produce waiting times for these calls it was not possible to tell how long patients had been waiting between definitive clinical assessment and being seen face-to face.

In the induction packs and the clinical log book that were used as part of familiarisation/ induction session for new staff, the only mention of target times for base visits referred to a four hour target. There was no mention of differentiation between urgent and routine base visits. While TCN stated that they operated an internal four hour target for routine visits, the induction documentation made no mention of the national targets for emergency (one hour) or urgent (two hour) base visits.

The TCN document entitled 'Disposal Target Times' referred to "Normal TCN working practice in accordance with National Quality Standards" but gave a target time for urgent patients visiting the base after telephone assessment, as needing to be seen within 20 minutes of arrival at a TCN base, and within one hour of arrival for routine patients. Although interesting statistics, neither of these times were national requirements. They were also not reported to the PCTs.

As with call streaming it was clear from interviews that the PCT staff did not understand the appointments system as used by TCN and were unaware that the majority of base visits were not reported against NQR 12. This was because any base visit for which an appointment was booked, created a new contact so 'stopping the clock'. This meant the time from the end of the definitive clinical assessment was not recorded against NQR 12.

In addition TCN staff who we interviewed (including the client relationship managers who liaised with the PCTs) did not fully understand the effect that the appointment system had on TCN's reporting of activity and performance. They were therefore unable to explain it to the PCTs. None of the TCN and PCT staff who regularly attended these contract monitoring meetings had a full grasp of the appointment system and its effects on TCN's performance reporting. Any discussion of the extra activity reported as contacts largely focused on the fact that two lots of paperwork were sent to GP surgeries.

Evidence from internal minutes at TCN showed that they had identified concerns about this, at least as early as May 2008. The concerns involved the appointments system and how the data regarding base visits was presented in the reports from HMS. It was minuted that these matters had been raised with HMS but no resolution of the problems was achieved. TCN placed a moratorium on developments in HMS during 2008 due to setting up the Worcestershire service. Subsequently developments were put on hold due to TCN's plans to develop a 'data cube' so they could access their raw data more directly. This meant that there was no change as to

how activity was presented in the performance reports. One member of staff who had left TCN told us that they had repeatedly raised concerns and queries about the anomalies in the data but these "fell on deaf ears".

Some TCN staff were aware that ShropDoc (Shropshire Doctors on Call), which also used HMS, had managed to resolve these matters with HMS and no longer had 'double-counting' in its reports. They could not provide a clear explanation as to why TCN had not done this. TCN subsequently told us that that the solution used by Shropdoc was not available to TCN. One ex-member of staff said it was because TCN "had failed to give a clear specification to HMS".

TCN rarely classified patients as requiring 'emergency' home visits, i.e. did not designate visits that had to be completed within an hour. The performance reports showed either no calls recorded against this standard or very low numbers. However TCN regularly reported that this standard was achieved even when no calls were recorded. The Primary Care Foundation's report on lessons learnt stated that some other services did not identify any emergency visits in their 4 week samples.

TCN's policies on home visits and target times made no mention of emergency visits or the one hour standard. This issue was raised in the review of out-of-hours services conducted by Worcestershire PCT. In response TCN stated that where an emergency visit was required, calling an ambulance was generally more appropriate.

We could not find evidence that the other commissioning PCTs had approved TCN's interpretation of this requirement.

We noted when visiting the Riverside Call Centre that, as part of the home visiting process, calls were held in dispatch and no more than five were assigned to a clinician in a car. This meant the dispatcher had to assign calls appropriately to cars, based both on location and priority, rather then allowing the clinician in the car to determine which call they attended first. TCN did not have a system whereby the location of clinicians in cars could be seen on an on-screen map. Discussions with HMS confirmed that holding calls in dispatch did not 'stop the clock' or otherwise assist in meeting performance targets.

Examination of the performance reports indicated that in addition to the issue of 'double counting' (discussed above) there were a number of other disparities between the figures in the appendices to reports and those under the individual NQRs (the numbers did not add up in the way a reading of the NQR standards would indicate).

According to the review of clinical governance undertaken by David Carson in early 2009, TCN's clinical induction document gave advice to clinicians to 'always downgrade the priority allocated to calls'. Carson identified this, in combination with the high use of agency doctors, as presenting a risk to the safety of patients. TCN subsequently explained that the instruction was poorly worded and related to downgrading, where appropriate, after triage. TCN acknowledged it was open to misinterpretation. In the induction documents that we subsequently received from TCN there was no mention of altering dispositions, indicating that TCN had taken steps to remove this instruction.

Findings of fact on reporting of activity and NQRs

- The HMS system, as used by TCN, generated two contacts for every patient given an appointment to visit a base. This did not happen for those who had home visits, received advice or visited a base without an appointment.
- Those who were given appointments were not counted in the calculation of NQR12.
- TCN's reports of activity did not make either of the above clear.
- Most PCT and TCN staff did not fully understand how activity was reported or what was included in NQRs.
- The reported performance of TCN against the NQRs was not comprehensive or accurate, and did not reflect the actual performance of the organisation. This meant that possible poor performance could have gone unnoticed.

- Some senior staff at TCN identified problems in 2008 with reporting activity.
- The way activity was reported 'changed' the proportion of cases that were treated with advice.
- TCN acknowledged the original induction documentation which advised doctors to downgrade priority, was poorly worded and open to misinterpretation. It was changed after the review by Dr Carson in early 2009.
- The number of calls transferred to the emergency services by call handlers was not being recorded.

Special patient notes

During a visit to the Worcester call centre in October 2009 we observed that GP practices were not directly entering notes into the TCN system about patients with specific needs. Such patients could include those with a disability or requiring end-of-life care. Instead practices were sending faxes, the notes from which were then added to the system by TCN. This increased the risk that incorrect patient information could be recorded on the clinical notes referred to by the clinician when treating a patient.

We were concerned that not all the faxes were being kept and were instead being destroyed. This meant that if mistakes were made there was no record to check and it would not be possible to audit the input of special patient notes. From some faxes that had been kept we noticed that details had been incorrectly entered on the HMS system. Some of these involved incorrect or incomplete information on medication.

We wrote immediately to TCN and were assured that the administrative staff involved in entering special patient data onto the HMS system had been interviewed by managers. The staff had asserted that, in line with their training, they did not shred originals of special patient notes but kept them in a file for future reference.

When the CQC investigation team visited Riverside in November 2009 we found that faxes of special notes were being kept, and the details entered in HMS, corresponded correctly with the faxed information.

Findings of fact on special patient notes

- At the Worcester call centre we observed that information about patients, sent by GP practices, was not entered correctly on the system and was not being stored.
- At the Riverside call centre we observed that the information was being entered correctly and was being stored.

Staffing

Summary of findings in this chapter

- TCN struggled to recruit doctors and relied on doctors coming from Europe to work shifts, particularly in 2007 and 2008. Some doctors worked excessive hours, including in 2009.
- TCN frequently failed to fill large numbers of clinical shifts. The resultant shortfall put pressure on other staff and potentially compromised the care of patients. In one PCT, the rate of unfilled shifts in autumn 2009 was 18%. Unfilled shifts were not reported to PCTs. Although TCN said they had a flexible system to ensure adequate coverage, we found several instances in September 2009 when the nurse on duty overnight at Wisbech was the only clinician for more than 70 miles.
- Communication with front line clinical staff, and their induction and training, were poor in 2007 and much of 2008. They then gradually improved. In 2007 and occasionally in 2008, some doctors worked shifts before they had been inducted. There was insufficient local clinical leadership.
- The out-of-hours bases were generally poorly signposted and often difficult to find.

Sources of evidence

- Observations
- Interviews with TCN staff and managers; PCT staff
- Records of induction and training, induction protocol
- Statements by TCN
- Minutes of meetings at TCN, and of contract monitoring meetings
- Contracts and service specifications
- Performance reports
- Correspondence
- Shift rotas, shift reports
- TCN clinical audit reports
- List of Doctors with background information

Survey of TCN staff - As a further source of evidence CQC conducted a survey of TCN staff involved in out-of-hours services. The online survey was distributed to staff on 14 September 2009 by email via TCN's information champion, and via a link on the Sharepoint system. Staff received reminders in their payslips on 28 October.

Overall 222 responses were received to the survey. TCN directly employed 416 staff, excluding doctors, who were involved in the out-of-hours service. They directly employed 9 doctors and had 307 freelance GPs. The survey received 57 responses from doctors, an 18% response rate for this staff group, and 165 responses from other staff, a response rate of 40%.

Of the 222 responses, the majority came from staff based in Suffolk (51%) then Worcestershire (29%). With regard to staff groups, drivers and receptionists accounted for

the most responses (30%) followed by doctors (26%) and nurses (16%).

Appointment and induction

Clinical

In 2007 and early 2008, TCN's appointment and induction procedure for clinical staff involved a three step process. The first step involved relevant documentation checks. For GPs this would include checking the GMC register, their status on a PCT performers list and their medical insurance. The second step was an induction in the use of the HMS system, at which they would be provided with TCN's clinical manual. The third step was a clinical induction session with a TCN supervising clinician.

Mr Gray died on 16 February 2008. In March 2008 TCN revised their induction protocol and then reviewed it in November 2008. CQC were provided with the November 2008 version of the protocol. This new protocol introduced two new steps to the process and enhancements to two of the existing steps.

The documentation checks were expanded to include a MRCGP, JCPTCP or PMETB certificate, CV and references, date of their last GP appraisal, a signed statement by the applicant that there were no outstanding adverse issues from that appraisal, evidence of CPR and Child Protection training, CRB check and confirmation of English Language competence at International English Language Standard (IELS) Level 7 or higher. The HMS induction session remained unchanged but the clinician also had to watch a PowerPoint presentation detailing some important aspects of TCN's clinical processes. This included a warning about opiate strengths. The clinical induction session was renamed the familiarisation session and greater clarity was given on the competencies that the doctor undertaking the induction needed to assess. A fifth step was then added whereby the first three shifts of the new clinician were audited using the RCGP audit toolkit. TCN revised its induction protocol again in March 2010.

During 2007 the minutes of the clinical management group showed that robust processes were not in place to ensure that all clinical staff underwent inductions. The minutes of the clinical management and governance group in 2007 confirmed that there were occasions when doctors undertook shifts before they had received induction. For example, in April 2007 they recorded "This is still a rather hit and miss process with far from all doctors being inducted". Steps were taken to improve this, but the minutes in August 2007 recorded that problems remained for doctors brought in to cover shifts at short notice. In 2008 there were still problems with the proper recording of induction dates. In July 2009 TCN told us that all new clinical staff now underwent induction.

From the induction lists provided to us by TCN there were only 4 doctors identified as having an induction in 2007 compared to 132 in 2008 and 25 in 2009 (up to 23/11/2009). We noted that Dr Ubani was not included on the list for 2008 although we know that he attended an induction session.

For agency staff TCN often relied on the agencies to perform the background checks, but during 2009 TCN started to independently verify this information. During a visit to TCN's management and administration centre (Jackson House) in November 2009 we found details of GMC registration and CRB checks in personnel files for doctors. During the summer of 2009 TCN began to verify doctors status on performers lists and to check that they had had an up-to-date appraisal. From the records it appeared that these checks were often done after the doctors began working shifts for TCN. From May 2009 TCN had recorded the performers list number of every GP. The head of human resources at TCN told us that all of the relevant documents and checks would be present for the more recent personnel files but she was less confident about older files as they had just started to audit these. Appropriate information was now being kept on electronic employee records which would be easier to audit.

Doctors supervising the familiarisation session did not have dedicated time in which to do this; the role was additional to their normal shift duties. We found this still to be the case at the end of 2009, although a new policy in March

2010 said the doctor would be supernumerary "wherever possible".

Non-clinical
The induction process for call handlers involved a training course involving eight sessions totalling about 32 hours of training. It was usually completed within 4 weeks. The sessions covered an introduction to TCN, the role of a call handler, the HMS system, guidance on recording symptoms and prioritisation, and culminated in 'live' call handling with a supervisor. Following the induction sessions call handlers automatically progressed, after 10 weeks, to the consolidation course. Handlers were then reassessed at their probationary review which occurred three months after their first induction session. For other non-clinical staff the initial introduction to TCN and their role was similar with further training on HMS and other aspects varying according to their specific role.

The major check for non-clinical staff was a Criminal Records Bureau (CRB) disclosure. References were also requested and checked. We were told that when TCN used an agency driver at short notice a CRB check would not necessarily have been performed. We were also informed that on occasion TCN used taxi services to take clinicians to home visits. The taxi drivers would not necessarily have had a CRB check and there were concerns about the security of medications as clinicians often left their bag in the TCN car when inside the patient's home, and only came out to collect it if equipment or medication was required.

All staff, clinical and non-clinical, who had started employment with TCN in the previous 12 months were asked about induction in the CQC staff survey. They were generally positive about induction, as shown in the results. 43% of respondents rated the value of induction as either good or excellent, 33% rated it as average and 24% rated it not good or poor. 43% of respondents rating the relevance of the process to their role as either good or excellent, 38% as average and 19% rated it not good or poor.

Findings of fact on appointment and induction

- Inductions for clinical staff became routine during 2008; they were not routine in 2007, when some doctors started work without induction.
- Before the death of Mr Gray TCN checked a doctor's GMC status, medical insurance and registration on a PCT performers list in good standing.
- Induction included training on the HMS software, and a clinical handbook, followed by a familiarisation shift. Extra time was not included for the supervising clinician. This was still the case at the end of 2009.
- A month after the death of Mr Gray TCN changed the induction of doctors by checking more documentation, developing a presentation and auditing the first three shifts of new clinicians.
- Call handlers received eight sessions totalling about 32 hours of training. It was usually completed within 4 weeks. The sessions covered an introduction to TCN, the role of a call handler, the HMS system, guidance on recording symptoms and prioritisation, and culminated in 'live' call handling with a supervisor.
- Handlers were then reassessed at their probationary review which occurred three months after their first induction session.
- The major documentary check for non-clinical staff was a Criminal Records Bureau (CRB) disclosure. When TCN used an agency driver at short notice or a taxi service, a CRB check would not necessarily have been performed.
- Our survey found that most staff who had started employment recently considered that induction was useful and relevant.

Skill mix

The skill mix of staff in the team in this context refers to which clinician advises or sees the patient. National quality requirement 11 requires that "Where it is clinically appropriate, patients must be able to have a face-to-face

consultation with a GP, including where necessary, at the patient's place of residence".

For the PCTs in East Anglia that used TCN to triage calls, this was mainly conducted by doctors. For Worcestershire triage was carried out almost exclusively by nurses in the call centre, as had been the practice when TCN took over the contract. All clinicians in bases in both areas however were asked to triage calls between appointments, so some doctors were involved in Worcestershire and some nurses in the East of England.

For home visits TCN on occasions used nurse practitioners and in some areas emergency care practitioners (ECPs) as an alternative to GPs. However in the staff rotas these shifts were designated as 'doctor' shifts and although the staff group of the individual was documented on RotaMaster, it was not immediately apparent. Unless the duty manager knew the individual clinician it appeared as if a doctor was filling the shift when actually it could be another practitioner. We describe this situation more fully in the description of our weekend visit to Cambridgeshire and Suffolk bases.

According to their job descriptions there were restrictions on the types of patients that could be seen by nurse practitioners or ECPs. For ECPs these exclusions were palliative care patients, patients requiring screening for mental health, pregnant women past the three month stage of pregnancy, women less than six weeks after giving birth and babies younger than six weeks old. ECPs could see patients with abdominal pain but had to discuss the diagnosis and management routinely with the GP before closing the call. A similar list of exclusions applied to nurses except they could not see any pregnant women with pregnancy related conditions. However nurses were able to see patients with abdominal pain without reference to a doctor, because of their generally higher level of training. There were no restrictions on nurse practitioners or ECPs seeing babies or young children over six weeks of age. Nurse practitioners are accountable to the NMC for the scope of their practice. There is no national set of restrictions on the types of patients that can be seen by ECPs.

TCN stated that nurse practitioners were only used in a doctor's role when there was a nearby doctor to provide support. However evidence from the staff rotas and our visits showed that this was not always the case. At times a nurse practitioner was the only clinician for more than 50 miles. We noted from analysis of the rotas in September 2009 that there were four occasions overnight when there was only a nurse at Wisbech and there was no doctor at Newmarket or Bury St Edmunds (that is, this nurse would have been the only clinical cover for more than 70 miles). When we raised this at the time as a concern, TCN sought to re-organise the geographical coverage.

We saw instances in shift reports where concerns were raised by clinical staff over these arrangements. For example nurse X "would like it noted that she feels that it is dangerous and unacceptable to expect nurses to cover without a Dr in base".

Using a nurse practitioner to fill a doctor's shift involved approval from the clinical team at TCN, but was not formally recorded anywhere. It was not clear what criteria, aside from willingness, were used to decide that a particular nurse practitioner or ECP had the requisite skills to cover for a GP. For example, on the visit to Wisbech and Newmarket in late September 2009 there was a solitary nurse practitioner at Wisbech for the shift from 6pm to midnight. The duty manager at Riverside incorrectly believed this person to be a doctor. When we examined this nurse's personnel file there was no documentation to show that she had been approved to perform the functions of a GP.

The list of clinicians with their professional registration (i.e. doctor, nurse or ECP) that TCN sent to the CQC did not match all the names in the rota for March to May 2009. We found names on the rota that were not on TCN's list. Using the list that TCN sent and only counting shifts by those staff members, 74 out of 5566 GP shifts (or about1%) were covered by a nurse or ECP. Nurses undertook 71 shifts and three were carried out by an ECP. CQC's analysis of clinical staff rotas in September and October 2009 showed that 245 out of 3224 GP shifts (or 8%) were covered by a nurse or ECP with this proportion rising

to over 40% of doctor's shifts in East Cambridgeshire and Fenland.

From performance reports and service specifications in the out-of-hours service contracts it was clear that all of the PCTs knew that nurses and ECPs were used in the service. TCN stated that NHS Worcestershire, Cambridgeshire and Great Yarmouth and Waveney were perfectly aware that ECPs and nurse practitioners were visiting patients in their homes. However, we did not see any documentary evidence of clinical approval by any PCT of the use of ECPs and nurse practitioners for home visits, or to be the only clinical member of staff at a base.

Interviews with PCT staff showed that most were unaware that nurse practitioners and ECPs were being used to cover GP shifts, although some of the PCTs, like Worcestershire and Suffolk, did not see it as part of their remit to determine the staff composition on shifts provided TCN met the NQRs and gave assurances.

Findings of fact on skill mix

- In East Anglia, TCN mainly used doctors to triage calls. In Worcestershire they mainly used nurses.
- TCN used ECPs and nurse practitioners for some home visits.
- There were no written criteria to decide what skills were needed by other clinical staff to cover for a GP.
- Personnel records did not show that non-medical staff had been approved to undertake home visits. There was no other record of formal approval of nurse practitioners to undertake home visits.
- There were some restrictions on the types of patients that nurse practitioners and ECPs could see. Both could see babies more than six weeks old.
- The rota had a column headed 'doctors shifts'. It was not easy for staff to identify which staff on that list were, and were not, doctors.
- The CQC was incorrectly informed by the duty manager that a doctor was on duty in Wisbech. The individual was actually a nurse practitioner.
- Between March and May 2009, 74 out of 5566 GP shifts (or about 1%) were covered by a nurse or ECP. Only 3 of these were covered by an ECP.
- In September and October 2009 over 40% of doctors' shifts in East Cambridgeshire and Fenland were covered by a nurse or ECP.
- TCN stated that there was always a doctor nearby for support. However, nurses and ECPs on occasions worked without a doctor nearby; we observed a situation on a Saturday evening where there was no doctor for 50 miles.
- PCTs were generally unaware that nurse practitioners and ECPs were being used to cover doctors' shifts at short notice. Worcestershire and Suffolk PCTs did not consider it relevant provided TCN met the NQRs and gave assurances.

Staffing levels and filling of shifts

In the following section unless otherwise specified, all vacancy rates or unfilled percentages given are for shifts rather than hours, i.e. number of unfilled shifts divided by total number of shifts.

Our analysis of clinical staff rotas for March, April and May 2009 showed that TCN had filled 92% of all clinical shifts across the five PCTs. The 8% that were unfilled amounted to more than 3000 unfilled clinical hours (note, this was during the swine flu epidemic of that time). Analysis of the position in September and October 2009 showed an increase in unfilled shifts with an overall vacancy rate of over 13%.

The proportion of unfilled shifts in the spring of 2009 varied by PCT with SW Essex showing the lowest rate (2%, more than 76 hours) and Great Yarmouth & Waveney having the highest rate (16%, more than 799 hours). In the autumn, SW Essex still had the lowest rate but Worcestershire had the highest (18%, more than 1460 hours). Across the East of

England, the overall vacancy rate in the autumn was 10% (totalling almost 1400 hours).

Vacancy rates also varied according to the different types of clinical staff. In the spring of 2009 doctors had the lowest overall vacancy rate as measured by unfilled shifts but a considerable number of lost hours (5% unfilled shifts, more than 1225 hours). This was because doctors worked more shifts than the other clinical staff. Nurses were high on both (15%, more than 1287 hours) and ECPs had the highest rate but fewest lost hours (29%, more than 649 hours). In the autumn the vacancy rates had all increased with 8% for doctors, 21% for nurses and the highest vacancy rate was still for ECPs, but now at 45%.

We examined shift vacancy rates by day of the week and by location from March to May 2009, excluding bank holidays. This showed that vacancy rates were highest at weekends, rising to just over 9%.

The base with the highest clinical shift vacancy rate over this period was Wickham Market (59%) and the base with the highest number of unfilled shifts was Great Yarmouth (119 out of 448). The base with the highest vacancy rate for doctors was again Wickham Market (59%), for nurses it was Great Yarmouth (66%) and for ECPs it was Kidderminster (92%).

Problems with filling shifts were discussed internally in various meetings at TCN during the period under investigation including the Business Performance Group, Operational Metrics meetings and Clinical Management/Governance Group. They were also mentioned in shift reports, in summaries of near-misses and untoward incidents and SDOC board minutes.

Discussions in TCN about unfilled shifts began at least as early as the second half of 2007 with discussions at board level of how best to use agency staff and concern about the preoccupation of managers and clinical leaders with filling shifts. There were particular concerns about levels of cover in East Cambridgeshire and Fenland in the latter half of 2007. This was because the staffing model was changed, with fewer GP shifts at Doddington. In December 2007 an untoward incident was reported about pressure on cover in the Cambridgeshire area.

Due to the number of unfilled shifts TCN had on occasions closed bases, extended clinician shifts, paid higher rates for short notice shifts, used nurse practitioners or ECPs to cover for GPs, or brought in agency staff at short notice to try and improve cover for areas. However there was little evidence that TCN took a fundamental approach to reducing the number of unfilled shifts. From early 2008 there was continuing discussion around problems with filling shifts. An untoward incident was reported in March 2008 about difficulties in filling doctors' shifts across all areas. It was noted to be a challenge at the April meeting of the board. In August 2008 it was noted at the board that, although not by design, unfilled shifts contributed to savings. Minutes of a range of meetings showed that frequent discussions around difficulties with filling shifts continued throughout 2009. There were some discussions about increasing the rates of pay. For example it was decided at the meeting of the business performance group in May 2009 that increasing the shift rate by £10 an hour was financially untenable. There was comparatively little discussion about the effect of unfilled shifts on workload pressure or increased risk for patients or staff.

The shift reports for the Ipswich Call Centre for March, April and May 2009, documented 21 occasions when a base was closed due to lack of clinical staff. Calculations indicate that the Worcester base was most affected by unfilled clinical shifts, followed by the Great Yarmouth base. This calculation was further supported by results from the CQC survey of TCN staff where the ratings of clinical staffing levels at bases were most critical amongst respondents who worked in the Great Yarmouth and Waveney (69% rating not good/poor) and Worcestershire (61% not good/poor) areas. Shutting a base was not perceived as a potential risk to patients and was not routinely reported to PCTs, nor was the need to shut bases formally defined as a risk and entered on the risk register.

The shift reports also recorded a number of clinicians expressing their concerns over the levels of staffing. For example one wished to state his dissatisfaction with the current

staffing levels and said the under-resourcing was 'dangerous'. The duty manager advised him that he needed to deliver this message through higher channels but the doctor said he had tried this already and it was a waste of time. He also said he was not alone in his views.

Results from the CQC survey of TCN staff indicate that just over half of TCN's staff had concerns about the levels of clinical staffing and skill mix on shifts. As part of the survey, staff were asked to rate the staffing levels at TCN bases and 53% of all staff who responded (109 out of 206 responses) and 52% of clinical staff who responded (47 out of 91 responses) rated clinical staffing levels at bases as not good or poor.

In response to the question asking what could be done to improve the service to patients, 100 comments were received suggesting that staffing levels and skill mix on shifts could be improved. For example:
"*Regular under-resourcing is the main problem in compromising the service to patients. Weekends are of particular concern. It is very often an extreme challenge for duty managers and the control room staff to 'pull it together' and provide a reasonable service out of the resources available. In many cases it just can't be done, and in my view we fail as a service. I recently worked a Saturday overnight shift. The evening had several clinical shifts short. The triage callback time was 5 hours at 2300 and 7 hours at 0300. Not a good service for a regular Saturday*"

For the question asking what staff would you most like to change about TCN, there were 47 responses that referred to staffing levels and said that they would most like this to change by increasing the number of staff. For example,
"'Fire fighting' mentality with regard to getting clinical staff to fill sessions." – Doctor, Suffolk.

"I strongly feel that the service has been reduced to the absolute minimum and that there is no capacity to cope with the normal fluctuations in demand seen out hours, it is stressful, demoralising and at times dangerous work" -Doctor, Worcestershire.

Results from the CQC survey of local GPs, in the areas TCN provided out-of-hours services, indicated that some GPs had concerns about staffing levels at TCN bases. In response to the question asking for further comments, a total of 124 responses were received. Of these 41 raised concerns about staffing; GPs in Great Yarmouth & Waveney showed the greatest concern with 40% of responding GPs from this area expressing a concern about understaffing.

GPs also expressed concern about the ability of the out-of-hours service to provide home visits to those patients who clinically required a visit. 50% of respondents rated this as not good or poor. GPs in Cambridgeshire showed the greatest concern with this aspect of the service, with 75% of respondents from this area rating it as not good or poor. This may have related to the fact that there was normally only one clinician to cover the whole of the East Cambridgeshire and Fenland area overnight. Additional clinical cover had to come from the Newmarket base located in Suffolk.

The minutes of the business performance group in May 2009 recorded a judgement that: "if we believe that we can deliver our metrics with the current rota pattern being 95% full, then we should refer to this as the clinically safe model". In other words, provided they were meeting the NQR targets, it was not necessary to fill every shift in their rotas and 95% coverage would be clinically safe. However, earlier we noted that the rate of unfilled shifts was 8% between March and May 2009 and more than 13% of shifts were unfilled in September and October 2009. The latter was more than twice the 5% rate that TCN had declared as the clinically safe limit.

TCN responded to external concerns about unfilled shifts, including those raised by CQC, by describing their ability to respond flexibly to demand by using a centralised triage system and getting clinicians to cross cover areas. This system meant that triage could be conducted from any location, including some clinicians' homes, and any spare capacity at one base could be used to make up for shortfalls in capacity at other bases. They argued this meant that vacancy rates for individual bases did not represent a corresponding shortfall in available care for

patients. Despite this, evidence from rotas, visits and concerns from clinicians showed that at times the level of clinical cover for quite large geographical areas resulted in extra pressure being put on clinicians working in the service. Even with their flexible staffing system these low levels of clinical cover across large areas meant that at times the entire system was stretched potentially resulting in lower levels of care for patients. An example is documented in the shift report for April 3, 2009 which recorded "*NO ALDEBURGH, NO HAVERHILL (EXCEPT 90MINS) NO WISBECH FOR 2HRS NO WAVENEY NURSES - ISSUES AFFECTING TRIAGING TONIGHT".* Another, later in the same month, recorded that there were no base clinicians at Beccles or Great Yarmouth overnight, so one Lowestoft GP covered the whole area.

Non-clinical shifts

For the East Anglia area (Suffolk, Cambridgeshire, Great Yarmouth & Waveney and South West Essex) there were very few unfilled shifts for drivers and receptionists during the period March-May 2009. There was a 31% vacancy rate for shifts for call handlers (operators) over this period. For Worcestershire the only complete rotas available were for March 2009, and during this month the shift vacancy rate for call handlers was 22% and 30% for dispatchers.

Results from the CQC survey of TCN staff showed a positive impression of the staffing levels of non-clinical staff at TCN bases with 61% of respondents rating this as good or excellent, 31% average and 8% not good or poor. Call handlers did not work in bases, but at the call centres in Worcester and Ipswich.

The high vacancy rates for call handlers could have resulted in slower answering of calls and increased pressure on the remaining call handlers. In the operational metrics meetings TCN frequently referred to poor performance i.e. slow response to answering calls because of staffing problems. Although we did not receive any evidence of formal analysis, TCN examined the effect of staffing levels on meeting access times and NQRs.

Staff were generally positive about the system for the rotas at TCN. In the staff survey:
55% of respondents rated fairness of allocation as good or excellent, 22% average and 24% not good or poor ;
57% of respondents rated the electronic timesheet as good or excellent, 25% average and 18% not good or poor ;
53% of respondents rated adequate notice of available shifts as good or excellent, 20% average and 27% not good or poor;
and 46% of respondents rated the effectiveness of the rota team as good or excellent, 28% average and 26% not good or poor.

Findings of fact on staffing levels and filling of shifts

- TCN filled 92% of clinical shifts between March and May 2009 (some of this period overlapped with the outbreak of swine flu).
- The 8% that were unfilled amounted to more than 3000 unfilled clinical hours.*
- 21 bases were closed during this period in the East Anglian area.*
- In September and October 2009, 13% of clinical shifts were unfilled overall.
- Analysis of clinical staff rotas for September and October 2009 showed that 18% of the total clinical shifts across NHS Worcestershire were unfilled.
- Wickham Market was the base with the highest vacancy rate for clinical staff.
- Vacancy rates were highest for ECPs, but most of the lost clinical hours were unfilled doctors shifts.
- Managers at TCN had been aware of unfilled shifts since 2007.
- Untoward incidents of problems with unfilled shifts had been reported in 2007 and 2008, and shift reports in 2009 continued to record concerns about staffing levels.
- Shutting a base was not perceived as a potential risk to patients and was not routinely reported to PCTs.
- TCN's view was that they had a flexible response which allowed adequate coverage despite staff not being available.
- In May 2009 the business performance group agreed that 95% coverage of clinical

shifts was clinically safe if the NQRs were achieved.

- In our survey, 52% of clinical staff at TCN rated staffing levels in the two lowest categories (not good/poor).
- In our survey of GPs, 41 out of 124 comments related to concerns about staffing.
- Staff were generally positive about the system for rotas at TCN.

Observations of staffing levels at out-of-hours bases in East Cambridgeshire and Fenlands and NHS Suffolk

During a weekend in late September 2009, the CQC team carried out a series of unannounced visits to the TCN out-of-hours bases across East Cambridgeshire and Fenland, and Suffolk. The purpose of the visits was to observe the operation of the out-of-hours services first hand.

On the Friday evening the team visited the out-of-hours base in Wisbech which is situated on the northern border of NHS Cambridgeshire. Staff told us that they had struggled to fill doctor's shifts over the last year. They said that nurses or ECPs covered doctor shifts including home visits. The team examined the weekend rota for the Cambridgeshire area and observed some significant gaps.

We returned to the Wisbech treatment centre the following morning at 8am. According to the rota there should have been two doctors at the base that morning, one out in the car carrying out home visits and another based at the centre. As indicated by the rota the previous evening one of these shifts had not been filled. Staff at the base told us that most weekends they were generally missing a doctor and expressed concerns about working Saturdays as it was so stressful. The GP working that morning also expressed concerns about the number of shifts that were unfilled.

The nurse practitioner working in Wisbech that morning was also booked to cover the six pm to midnight shift that evening. She commented that she had been asked to do this 'at the last minute'. She stated that she hadn't yet been out on a home visit in out-of-hours but that she was expecting to do so that evening. The nurse commented that she did sometimes feel that she was at the borderline of her competencies but she could contact a doctor if she was concerned. The nearest doctor scheduled to work that evening was at the Newmarket base in NHS Suffolk.

The CQC team then travelled approximately fifteen miles south to Doddington to the next available out-of-hours base. This base was used for patient appointments only. The base coordinator told us that when a GP did not turn up for work the shifts were left unfilled. The nurse practitioner here stated that they were very rarely fully staffed and they were mostly understaffed at weekends. She commented that even when the GP shift was unfilled TCN call handlers still sent patients to Doddington for an appointment. The GP working that morning stated that there had been many occasions when she had turned up at the Wisbech base and found there was no doctor. She gave the example of the previous weekend when the other GP working the 9am-12pm shift had not turned up and then the GP covering the 1pm to 6pm shift had not arrived either.

The CQC team then travelled south to the out-of-hours base in Ely. We arrived at 4pm and the receptionist confirmed that the base had been closed earlier that day because there were no doctors available. The GP carrying out home visits had started at 1pm and the base GP had started at 2pm. There were no nurse practitioners working in this base but the PCT operated a minor injuries unit in the same location. The receptionist stated that it was getting more common recently to be short of a doctor. The minor injuries nurse stated that the previous weekend the afternoon GP had not turned up. The team spoke to the GP carrying out the home visits and he stated that TCN had asked him if he would come in earlier to cover the unfilled shift but he had declined. He commented that he stopped doing the base shift about two months ago because of the pressure.

The team left Ely and travelled north-east over the border to NHS Suffolk to the Newmarket out-of-hours base. This was the centre that Dr

Ubani had been based at on the day that he treated Mr Gray. The team arrived at approximately 5:55pm and met the GP driver who stated that the centre was closed that evening as there was no doctor available. This meant that the nurse practitioner who was working at the Wisbech base that evening would have no GP support over a considerable area.

As a result of these concerns the CQC investigation manager phoned the TCN base at Riverside to confirm what clinical cover was in place that evening. The CQC team was told by the duty manager that Doctor 'JH' was based in Wisbech and would be covering the GP shift that evening. The CQC team stated that they were aware that 'JH' was actually a nurse and were subsequently told that someone from TCN would get back to them shortly.

By approximately 7:05pm the CQC team had not heard from TCN and so contacted the medical director of TCN directly. The medical director stated that there was a GP in a car based at the Haverhill base, and a GP and a nurse practitioner at the Bury St Edmonds base. He commented that they were trying to activate the second on-call doctor and that following a successful recruitment drive the rotas would improve from the following weekend. In a later phone call he stated that the doctor at the Ely base had agreed to work until 9pm and there would be a GP starting at midnight at Wisbech.

The CQC team drove east to the Bury St Edmonds base to confirm that staffing cover was in place. The team arrived at approximately 7:45pm and there was a receptionist and GP working as normal until midnight, and an additional nurse practitioner who had been asked the day before to come in to work that evening. Members of staff told us that there had been no GP at Newmarket the previous evening either. The driver who arrived in Newmarket was supposed to be working in Sudbury but had been redirected to Bury St Edmonds as the GP scheduled to work in Sudbury had not turned up.

On Sunday morning the CQC team visited the Haverhill out-of-hours base which is situated in the south of Suffolk PCT. The team arrived at around 10:30 am and spoke initially to the base co-ordinator. We were told that lately there had been more gaps in clinician coverage and at times there had been clinicians missing from both Newmarket and Sudbury. The day before the base at Haverhill had been closed between 2pm and 6pm because of a lack of doctors. There were two GPs working that morning and we were told that there were concerns about the available medical cover and the fact that nurse practitioners and ECPs were visiting patients.

The CQC team then drove east to the out-of-hours base in Sudbury. The base should have been open but was closed when we arrived. The team then travelled to the base in Stowmarket but were unable to enter the centre as the doctor was out visiting patients at home.

On Monday evening the team visited the Stowmarket base again. We were told that the filling of shifts had been getting worse over the last three to four months and the previous Saturday there had been no doctor at the base in the evening despite the fact that the regular GP had given 3-4 weeks notice that he was unable to work. Staff told us that drivers were often told to work at another base or stood down at the last minute if a GP had not turned up.

In general CQC found that there was good staff morale at the bases they visited. This seemed to be a result of the commitment of the staff operating the bases, rather than the support provided from TCN head office, which staff described as poor. Staff had not consistently had appraisals and many of the staff working in Cambridgeshire stated that it was difficult for them to access the team meetings given the locations they were held at and training was also problematic in that respect.

A number of staff were not aware of the SharePoint software system and commented that communication from head office was poor. This was supported by the fact that a number of staff were not aware of the CQC staff survey despite the fact that TCN assured CQC that they had sent round communications to all staff informing them of the survey. The CQC

team were unable to find the link for the staff survey on the SharePoint system.

Staff stated that they were aware of how to report incidents although there were mixed messages concerning whether they felt that TCN responded. Generally staff reported that there had been fewer foreign doctors in the last six months and did not seem to feel that the use of foreign doctors was a problem. Clinical staff were unhappy about the way the RCGP audit results had been fed back to them and none of the staff that we spoke to were aware of any changes to the stroke guidelines.

CQC found that generally the out-of-hours bases were poorly signposted and we were especially concerned that at some of the bases there was no information concerning what a patient should do if they turned up and there was nobody there.

On 5 October 2009 CQC wrote to TCN to inform them that there were serious concerns that an isolated nurse practitioner had been providing the sole clinical cover for the East Cambridgeshire and Fenland district on the Saturday night that the TCN bases were visited. The CQC review team found it unacceptable that the nearest clinician available to provide support to the nurse practitioner in Wisbech was located 50 miles away in Bury St Edmonds.

The TCN medical director stated in response that the TCN resources and operation teams had activated the normal TCN escalation process as a result of the shift being cancelled in Newmarket. This meant that an additional nurse had been scheduled to work in Bury St Edmunds allowing the GP and car based at Bury to move to the Newmarket area.

We were told that there had been a delay in contacting the doctor at the Ely base to extend his shift to cover Wisbech because the duty manager at TCN had to deal with requests for information from the visiting CQC team. CQC considers that the doctor in Ely was only contacted to extend his shift because CQC queried the clinical cover available. When the CQC team spoke to the doctor in Ely at approximately 5pm he did not mention that he had been asked to work late that day – despite commenting that he had been asked to come in earlier to cover another unfilled shift.

CQC requested information from the duty manager at approximately 6pm when it became apparent that the Newmarket base was closing. The duty manager would not have been prevented from contacting the Ely GP earlier in the day to extend his shift. CQC carried out further staffing analysis of the rotas supplied by TCN and found that there were four other occasions in September 2009 between midnight and 8am where the nurse in Wisbech was providing the sole clinical cover for the East Cambridgeshire and Fenlands area with no supporting clinician at Newmarket. Since the out-of-hours base in Bury St Edmonds was closed from midnight the nearest doctors on those occasions would have been the GP in Great Yarmouth (79 miles from Wisbech) and another in Beccles (76 miles from Wisbech) and 2 car GPs based out of the Ipswich base (77 miles to Wisbech). On two of these occasions the second GP car at Ipswich was covered by a nurse practitioner and on one occasion the Great Yarmouth GP shift was also unfilled.

We note that without CQC's intervention there had been no escalation put in place to cover unfilled shifts on these occasions.

TCN acknowledged that the nurse had been identified inappropriately as a home visiting nurse and that the version of the rota available to the duty manager identified the nurse as a doctor. TCN stated that they would take steps to ensure in future the duty manager's version of the staffing spreadsheet contained fuller and more appropriate information.

TCN stated in their letter to CQC that they felt they had illustrated that they had robust and effective escalation mechanisms in place to ensure reasonable services and clinical cover are maintained. CQC obtained a print off of the shift log for the Saturday night of our unannounced visits. This log was completed by the TCN duty manager and clearly documented serious internal concerns about the level of clinical cover that was available throughout that night. The duty manager recorded that he was 'very concerned for operational and clinical safety'.

Findings of fact from our observations

- Staff reported that shifts were frequently unfilled.
- There was an unfilled doctor's shift at Wisbech on Saturday morning.
- The base at Ely had been closed on Saturday morning because there was no doctor available.
- The base at Newmarket closed at 6pm because there was no doctor available. We learnt there was no doctor at Sudbury either.
- The nurse practitioner at Wisbech on Saturday evening was the only clinical member of staff. She had not done home visits before. She expected there to be a doctor at Newmarket.
- The duty manager at Wisbech thought the nurse practitioner was a doctor.
- TCN responded when we raised concerns.
- The duty log for the Saturday night clearly recorded serious concerns about staffing levels and the safety of patients.
- The out-of-hours bases were generally poorly signposted and often difficult to find.

Source of doctors working for TCN

According to the results of an internal TCN audit of 177 doctors who worked shifts for TCN in Suffolk or Cambridgeshire over the period 1 Dec 2008 - 1 May 2009, 82% were resident in the UK. 9% were agency staff, all from abroad and they covered 5% of the shifts. However, 14 doctors did not complete the agency question, so the proportion of agency doctors may have been higher. 41% of shifts were covered by doctors who were members of the Suffolk Guild.

Our own analysis of doctors working shifts in the East of England between 1 October 2008 and 30th November 2009 suggested that 10% of the doctors came from agencies and worked 4% of shifts, 30% were Guild doctors working 33% of shifts and 60% were locums or free lance, working 63% of shifts. This analysis used the list of doctors provided by TCN covering the four PCTs in the East of England. From the analysis we also found that of the 281 GPs with their performers list PCT recorded, 79% (covering 80% of shifts) were on the Suffolk, Norfolk, Great Yarmouth & Waveney, Essex or Cambridgeshire PCT performers lists. 20% of shifts were covered by doctors not on any of these local performers lists. It should be noted there was no contractual requirement for TCN to employ doctors on local performers lists.

For doctors that worked in the Worcestershire area TCN was only able to provide details for those that worked during the period 1 August 2009 to 30th November 2009. This was due to the upgrade in the software system that occurred at the start of August. This meant that the sample size for the Worcestershire area was smaller than for the East of England. The analysis of this list suggested that 28% of doctors came from agencies and worked 18% of shifts, with the rest of the doctors being freelance or locums. We found that of the 67 GPs 64% (covering 69% of shifts) were on the Worcestershire, Birmingham, Solihull, Wolverhampton, Gloucestershire, Herefordshire, Shropshire, Staffordshire or Warwickshire PCT performers list. 31% of shifts were covered by doctors not on any of these local performers lists.

TCN stated that they made efforts to reduce the use of agency doctors, and in particular those from outside the local area. However these clinicians formed an important part of TCN's workforce pool. This is demonstrated by a statement from TCN's clinical governance lead in the initial report into the death of Mr Gray where he commented that despite many doctors from Germany lacking experience in palliative care and the associated drugs, "these matters cannot be resolved over night as the OOH service would be brought to its knees if these doctors could not continue to form part of the workforce".

Hours worked by individual clinicians

According to the manager of the rota team at TCN, the limits imposed on hours worked by clinicians were that they could not work more than 12 hours consecutively, and could not work more than 16 hours in a 24 hour period

(there were also more specific rules for triage shifts).

The contract for freelance GPs contained a clause that stated "You are responsible for ensuring that whilst working for TCN you do not exceed the directive for working to a maximum of 15 hours with an 11 hour rest period." A clinical briefing in September 2008 set out the more restrictive rules for triage shifts, "It is therefore now TCN policy that (a) triage shifts shall not exceed three hours in length and (b) an individual clinician shall not commence a second triage shift without having had a break of at least two hours after the first." It was recorded at the Ops Metrics meeting in November 2008 that 12 hours was the maximum continuous shift length.

Our analysis of the hours worked by individual clinicians for the period March-May 2009 showed that the longest period worked by individuals in the East Anglia area (Suffolk, Cambridgeshire, Great Yarmouth & Waveney and South West Essex) in a 24 hour period was 18 hours and 57 minutes. These hours were worked by two doctors; one in SW Essex in March and one in Ipswich in May. Both did two consecutive day shifts and had a 5-6 hour break between that and working a night shift. There were 12 occasions across this three month period where a clinician in the East Anglia area worked more than 16 hours in a 24 hour period.

The longest period worked in a 24 hour period in Worcestershire was 17 hours with one doctor working from 13:00 -22:00 then 23:59 - 07:59 at the Redditch primary care centre. This clinician also did the most number of shifts over this three month period completing 102 in total (over 655 hours). This was the only occasion in the Worcestershire area where a clinician worked more than 16 hours in a 24 hour period, over these three months.

We noted that the incidents of the largest number of hours worked in a 24 hour period all occurred on weekends or bank holidays.

With regards to consecutive hours* worked, there were 67 occasions in the E. Anglia area where a clinician worked more than 12 hours consecutively and 103 occasions where this occurred in the Worcestershire area, over this three month period.

TCN told us that there was no systematic retrospective checking of the hours worked by individual clinicians. We noted that the minutes of the clinical excellence meeting in January 2009 recorded that one of the poorly performing clinicians was working too many hours. TCN's summaries of near misses and untoward incidents also mentioned doctors possibly working too many hours. There was no evidence this led to a systematic process to identify and address this.

In terms of implementing the European Working Time Directive (EWTD) on working hours, TCN did not monitor the number of hours a clinician was working elsewhere, e.g. other shifts for different out-of-hours services or daytime practice hours. This would in practice be difficult to monitor. TCN relied on clinicians signing to say that they were not breeching the EWTD or had opted-out.

Aggregated hours reported

For the three PCTs with clinical hours shown in their May 2009 performance reports (Suffolk, Cambridgeshire, and Great Yarmouth & Waveney) , we compared the filled clinical hours from the rota with the clinical hours reported against NQR 11 in the performance reports for the three months March-May 2009. Bank holidays and corresponding weekends were excluded.

NQR 11 is a requirement that patients are treated by the clinician best equipped to meet their needs in the most appropriate location. There is nothing in this requirement that necessitates the service to report clinical hours but as TCN reported these hours, the PCTs would have been under the impression that these were the hours worked.

The results showed a shortfall in actual clinical hours that were filled by TCN in comparison with expected hours from the performance reports:

1) Suffolk: total shortfall of over 643 hours

* Hours were counted as consecutive if the shift length was more than 12 hours, or consecutive shifts were worked totalling more than 12 hours with less than a 30-minute break between shifts.

2) Cambridgeshire: total shortfall of over 664 hours
3) Great Yarmouth & Waveney: total shortfall of over 1670 hours.

The difference for Cambridgeshire was because there were ECP hours listed in the performance report but none in the rota (Cambridgeshire was under covered for doctors but over covered for nurses). The large number of hours difference for Great Yarmouth & Waveney was also partly due to no ECP hours in the rota, but was also due to 44% of nurse shifts being vacant.

Findings of fact on source of doctors, individual hours worked and hours reported

- Approximately 10% of doctors used by TCN in the East of England came from agencies. They covered about 4% of shifts.
- Between August and November 2009, 28% of doctors used by TCN in Worcestershire came from agencies and worked 18% of shifts.
- European doctors formed an important part of the TCN workforce.
- About one third of shifts in the East of England were covered by Suffolk Guild doctors.
- 75-80% of GPs used by TCN in the East of England were on one of the local PCTs' performers lists and 20-25% were not. About 80% of shifts were covered by doctors on these lists while 20% of shifts were not.*
- In Worcestershire 64% of GPs used by TCN were on 'local' lists and 36% were not. About 69% of shifts were covered by doctors on these lists and 31% were not.*
- There were 12 occasions between March and May 2009 where a clinician in the East Anglia area worked more than 16 hours in a 24-hour period. There was just one occasion in Worcestershire.
- There were 67 occasions in the E. Anglia area and 103 occasions In Worcestershire where a clinician worked more than 12 hours consecutively in the three month period between March and May 2009.
- The incidents of long hours worked
- TCN, like other out-of-hours providers, relied on clinicians to sign to say they were not working excess hours.
- Hours worked by clinical staff according to rotas were less than those reported in performance reports.

* Note: there was no contractual requirement to use doctors on local lists

Pay rates

Pay rates for doctors at TCN varied from £45-50 per hour for day shifts, £50-55 per hour for the overnight shift and up to £75 per hour on bank holidays when enhanced pay rates were in operation. TCN also offered bonus payment schemes for some bank holiday weekends and when there was high demand caused by swine flu.

A variety of sources including interviews, visits, minutes of meetings, evidence given at the Inquest and the CQC staff survey all indicated that there had been considerable dissatisfaction with these pay rates and that they were lower than most other comparable out-of-hours services.

Discontent with TCN's rates of pay appeared to be exacerbated in areas where another nearby out-of-hours service was offering greater rates. For example on a visit to Ely we were informed by staff that other providers in Cambridgeshire and Norfolk were offering hourly rates up to double those offered by TCN. TCN's own meetings with staff raised similar concerns in other areas such as South West Essex.

From the concerns articulated by doctors, pay rates had a significant effect on their desire to work for TCN and therefore on TCN's ability to fill shifts. This issue was also raised at the inquest into the death of Mr Gray where it was suggested that at these rates TCN would struggle to find good UK doctors and may have been forced in some areas to rely on greater proportions of foreign doctors. In some urban areas out-of-hours services are able to recruit doctors at rates of £45 per hour or lower.

However the nature of rural localities (fewer local doctors, greater distances to cover, increased risk, travelling times) often necessitates paying higher rates to attract clinicians.

In response to the need to fill certain shifts, particularly when a PCT insisted on this as happened during summer 2009 in Worcestershire, TCN offered much higher rates for shifts (£85 or more) that had to be filled at short notice. This caused some destabilisation of the market for doctors with some doctors intentionally waiting for the higher rates of pay before agreeing to work.

Although they offered some short term enhanced pay schemes, TCN did not conduct any systematic analysis of the effects of these. However, looking at the minutes of the operational metrics meetings for April and May 2009, we noted that TCN had reviewed and then increased bank holiday pay for bank holiday shifts between the Easter bank holiday and the first bank holiday in May. An examination of the clinical rotas for Easter Monday and the bank holiday on Monday 4 May shows that the vacancy rate for shifts in East Anglia fell from 9% to 7%.

Another area of concern for some doctors was that doctors who were members of the Suffolk Guild received a contribution to their NHS pension in addition to their pay via SDOC, whereas other doctors did not, as TCN was not eligible to provide this.

The evidence indicated that pay rates were not just an issue for doctors but also affected nursing staff. The rates for nurses were even more variable than doctors and depended on the clinical activities being undertaken by the nurse – e.g. a nurse practitioner was paid more than a minor injuries nurse as they could treat a wider range of conditions.

While there were no direct questions in our staff survey on pay rates, one question allowed staff to comment on anything they would like to change about TCN. Of the 182 responses to this question there were 25 comments relating to the desire for increased pay rates with one nurse commenting:

"*Better pay - pay and conditions are worse than those of my colleagues in other areas, though I welcome the recent abandonment of complex pay rate."*

Results from the CQC survey of local GPs showed that some GPs, particularly in Suffolk, felt that the service was under-funded by the PCTs.

Findings of fact on rates of pay

- TCN's rate of pay for general shifts for doctors was £45-55 per hour, which was lower than in most comparable and neighbouring out-of-hour services.
- At times TCN paid higher rates in response to pressure from PCTs to fill shifts.
- Rates of pay for nurses were also variable and staff told us they were lower than other out-of-hours services.

Arrangements to identify and manage poorly performing doctors

According to the policy dated March 2009, TCN's process to improve clinical standards in respect of individual doctors could be triggered by three upheld complaints; three incidents; one serious untoward incident, concerns raised by other organisations or in shift reports, or poor performance identified by clinical audit. Following any of these triggers the clinician was reviewed either by a clinical lead or senior auditor and the findings were brought to a decision panel. The panel decided if further action was needed and whether the clinician needed training, monitoring of practice, suspension or withdrawal.

In October 2008 the minutes of the performance management of clinicians group noted: "There is no infrastructure for poor performers, therefore a 'three strikes' policy is now to be used". At the meeting of the group in January 2009 it was noted that for serious cases the medical director was responsible for discussing the issue with the clinician. For less serious cases it would be either the nurse consultant, clinical governance or education

lead who would be responsible for conducting any recommended training.

The CQC requested details of all clinicians who had been removed from TCN's service since January 2008. TCN sent a list of 12 clinicians (11 doctors and one nurse) with dates of removal ranging from November 2008 to November 2009. These had been identified from a variety of sources as described above.

TCN sent us a document called performance management of clinicians, with dates from January to June 2009. During the first half of 2009 TCN identified 25 clinicians with problems in respect of their performance. Four of these clinicians were removed from TCN's service. For the remaining 21 clinicians various mechanisms were used including writing to or speaking to the clinician, additional supervision or training, and further review of their practice. These clinicians were identified as poorly performing via complaints, untoward incidents or significant events. A number of the complaints, untoward incidents and significant events were dated either 2008 or 2007 indicating long standing concerns with some of these clinicians.

There were particular issues with the identification and management of poorly performing clinicians in the SW Essex locality due to the subcontract between TCN and the ambulance service. We were told that when the contract between the ambulance service and TCN was first set up, the ambulance service advised TCN against using certain doctors. However TCN employed those doctors. The matter of doctors who were performing poorly was discussed from December 2008 onwards at the clinical governance meetings between the ambulance trust and TCN. TCN gave assurances that they had written to poorly performing doctors and that they were no longer using certain GPs. In January 2009 it was noted that there was no integrated system to raise and resolve concerns about poorly performing clinicians.

TCN could not directly access the out-of-hours software that was used by the ambulance service and therefore all reports of any problems on a shift had to be retrospective. Consideration was given to transferring the management of TCN's clinical staff to the ambulance service but it was thought that the clinicians would be unwilling to accept this. In January 2009 seven clinicians were identified and a random sample of printed call sheets was audited. In April 2009 there was a further update in relation to each of these clinicians and a doctor who had been removed by the ambulance trust from their service was found to still be working for TCN. The minutes noted that there was a culture of 'not wanting to tell tales'.

The medical director for TCN reported in the meeting with the ambulance trust in July 2009 that 'more than half of TCN Doctors had responded very well to intervention, around a quarter have been removed from service and the rest are ongoing'. He stated that this was having a significant impact on filling shifts but that new initiatives were underway.

Although there was some sharing of information, particularly with NHS Suffolk, TCN did not have a formal system for informing a PCT when a poorly performing doctor was registered on the PCT's performers list. At the April 2009 meeting of the TCN board it was noted that 'there is a robust system within TCN for dealing with poorly performing clinicians however, no mechanism for feedback to the PCT and Performers List'. In July 2009 TCN's medical director wrote to the four main commissioning PCTs suggesting the establishment of a formal process.

Results from the CQC survey of TCN staff indicated some dissatisfaction with the quality of clinicians that were employed by TCN, in answer to question 3 (Are there any areas you feel could be improved to enhance the service to patients?) 21 out of 168 respondents referred to improving the quality of clinicians working in TCN's out-of-hours services.

Results from the CQC survey of local GPs, in the areas TCN provided out-of-hours services, indicated that there was some concern with the quality of clinicians at TCN. Concerns with the quality of clinicians were expressed in the responses to the question asking staff to rate the standard of GPs utilised by TCN, where just over a third of respondents (36%) rated the standard of GPs used by TCN as poor or very poor. 13% rated them good with no-one rating them excellent. GPs in the

Worcestershire and Great Yarmouth & Waveney areas were the most negative about the quality of GPs used by TCN with 43% of respondents (in both areas) rating them as poor or very poor. We compared these figures to a similar survey sent out by 'Devon Doctors' out-of-hours service in December 2006. The CQC is cautious about making judgements on the differences between the results of two surveys, however the Devon Doctors survey provides a measure against which to consider the responses to the TCN survey. CQC acknowledges that the Devon Doctors survey of GPs views was conducted in a neutral environment whereas the CQC survey was carried out as part of a CQC enquiry at a time when there was negative press concerning out-of-hours.

Devon Doctors covers a large rural area with a similar population density to the areas covered by TCN. Devon Doctors had 0% rating the quality of GPs as poor or very poor and 79% rating them as good or excellent.

In response to the question asking staff to add any further comments they believed to be helpful, a total of 124 comments was received. Of these 124 comments, 20 raised concerns with the quality of clinicians employed by TCN. GPs in the Worcestershire area had the highest proportion of respondents raising concerns about the quality of clinicians (17% of responding GPs raised this concern). The concerns included: poor quality care to patients; information passed by the TCN doctors was not clear; that TCN relied heavily on locum and foreign doctors; that there was often a language barrier and that doctors lacked local knowledge.

Findings of fact on arrangements to identify and manage poorly performing doctors

- Before autumn 2008 TCN did not have a consistent system for handling poorly performing clinicians or for recording clinicians removed from service.
- TCN operated a 'three strikes' policy, depending on the severity of the concerns raised, with evidence of poor performance coming from complaints, incidents, clinical audits and concerns raised by other sources.
- TCN used some doctors despite having been advised to the contrary by the ambulance trust.
- In 2009 TCN took steps to identify and manage poorly performing doctors.
- 12 clinicians (11 doctors and 1 nurse) were removed from TCN's service between November 2008 and November 2009.
- There was no formal system for sharing information on poorly performing clinicians with the relevant PCTs.
- In our survey of local GPs 36% rated the standard of GPs used by TCN as poor or very poor. 13% rated the standard as good and none rated the standard as excellent.

Feedback to staff on performance

At interview both the chief executive and medical director at TCN mentioned that there had been a poor response from GPs to the initial results from the audit toolkit. They acknowledged this was in part because TCN sent the scores to staff without formal feedback or appraisal sessions, although there were announcements in advance about the audit and a covering letter was sent to each GP.

This lack of formal feedback was also noted in a document giving details of training and audit in Worcestershire stating that "There is no formal process for feedback". The original intention was to use the audits both to identify poor performance and to form part of the appraisals process as stated in a clinical governance briefing in September 2008. However as TCN only had appraisals for full time staff (see appraisals and PDP sections), this excluded the majority of clinical staff working in TCN's out-of-hours service.

The matter of the feedback on performance for clinical staff was highlighted by the results from the CQC survey of TCN staff where over a third (36%) of clinicians who responded to the question "Do you receive formal feedback from TCN on your clinical performance?" said that

they had never received formal feedback on clinical performance from TCN.

Results from the CQC survey of TCN staff also indicated that non clinical staff did not get feedback on their performance with 55% out of 129 respondents saying that they 'Never' received formal feedback on their performance.

Findings of fact on feedback of performance to all staff

- The results of the audit were initially sent out to GPs with a covering letter but without formal feedback or appraisal sessions.
- 36% of clinical staff and 55% of non-clinical staff reported they never received feedback on their performance.

Appraisal and PDP

An internal memo at TCN in March 2009 announced the introduction of a new system of internal annual appraisal for all clinicians working in TCN. The appraisals would involve a face to face meeting with peer appraisers in the out-of-hours service, based on the data from the quarterly review of performance.

TCN stated in October 2009 that 30% of TCN staff had completed an appraisal in 2009/2010. We understand that this referred only to staff directly employed by TCN, not to locum, agency or freelance staff. TCN had relied on doctors receiving training and appraisal by their in-hours employer. The head of HR told us that appraisals were primarily for substantive staff. She also reported that drivers/receptionists, who mainly worked part time for TCN as a second job, did not see this as a worthwhile process and looked for development opportunities elsewhere. In our survey 65 drivers/receptionists responded to the question about whether they had regular appraisals and 94% of them responded that they did not.

TCN employed about 490 full time staff. We compared this number with the appraisal records for 2009, and calculated that they had only appraised 20% of staff during 2009/2010 (up to December 2009). This was further supported by results from the CQC survey of TCN staff where out of the 216 responses to a question about whether they had regular appraisals with their manager at TCN, 75% said that they did not have regular appraisals.

TCN reported that 115 staff had an appraisal during 2009. The list included no doctors, one ECP, 18 nurses, two homecare practitioners, and eight radiographers. Some of these staff would not have worked in out-of-hours egg radiographers. There were no doctors on the list of staff who had appraisals in either 2008/2009 or 2009/2010.

Results from the CQC survey of TCN staff showed that for those staff that had appraisals, 49% either agreed or strongly agreed that it was beneficial and 21% disagreed or strongly disagreed.

The survey also showed that clinical staff were generally positive about the level of support from fellow clinicians at TCN. 54% of respondents agreed or strongly agreed with the statement that they felt supported by clinicians at TCN in their clinical work; 28% disagreed or strongly disagreed.

According to the minutes of the clinical staff development group in October 2008 and the induction protocol, a PDP folder was to be created for all staff at induction. However, TCN told us that PDPs were voluntary and TCN did not monitor their uptake.

Findings of fact on appraisal and PDP

- A new system of appraisal for clinical staff was announced in March 2009.
- In October TCN stated that 30% of their staff had so far completed an appraisal during 2009/2010.
- Our analysis in December 2009 found that by that time 20% of TCN's permanent staff had completed an appraisal in 2009/10.

Training

TCN did not keep centralised training records until late 2008 and therefore had very limited records of training events and attendance before this.

In 2009 much of TCN's training was conducted through self-learning online courses and there was no policy in place to monitor non-completion or non-attendance. Overall TCN had incomplete records of who had completed what training but had identified the need to improve this process as part of their work on Standards for Better Health.[*] TCN identified the need for a training and development manager to coordinate this area.

Results from the CQC survey of TCN staff indicated that call handlers were positive about the training they had received about call categorisation. 85% of the 33 respondents rated the training as good/excellent and 91% of these respondents rated their confidence in categorising as good/excellent. However, clinicians' rating of categorisation by call handlers was less positive with 38% rating it as good /excellent, 40% rating it as average and 21% rating it as not good/poor (total of 93 responses).

Results from the survey showed that clinical staff were generally positive about the operation of the triaging system but had more mixed views on the training related to this:

- 47% of respondents rated the operation of the triage system as either good or excellent (39% average and 14% rated it not good or poor).
- 31% of respondents rated their training in phone triage as either good or excellent (42% rated it average and 27% not good or poor).
- 38% of respondents rated the guidance they receive on clinical decision making as either good or excellent (39% rated it average and 24% not good or poor).

As much of TCN's clinical workforce was part time, TCN expected that most clinicians would receive relevant training from their in-hours employers. Where TCN was the clinician's primary employer, greater attention was paid to their training requirements.

In early 2009 the minutes of the clinical staff development group recorded that TCN began to monitor the completion of mandatory training by clinicians. Mandatory training included child protection, health and safety, manual handling and basic life support. These courses were also applicable to non-clinical staff, although we had no evidence that TCN ensured the completion of these courses by non-clinical staff. During visits to both the Worcester and Ipswich call centres, we were told by non-clinical staff that they had not received, and were unaware of, some standard training courses such as equality and diversity, child protection, protection of vulnerable adults and health and safety.

Results from the CQC survey of TCN staff indicated that a high proportion of call handlers, drivers/receptionists and base coordinators had not received some of the basic training that would be expected of staff in these roles:

- Child Protection: out of 85 responses 94% had not received this training.
- Protection of Vulnerable Adults: out of 87 responses 94% had not received this training.
- Equality and Diversity: out of 88 responses 98% had not received this training.

Findings of fact on training

- TCN did not keep centralised training records until late 2008 and had very limited records of training events and attendance before this. They identified the need to improve this.
- Call handlers were positive about their training and competence in prioritisation but clinicians were less positive about the prioritisation by call handlers.

[*] Standards for Better Health were first published by the Department of Health in July 2004 (updated in 2006). They set out a series of standards applicable to all healthcare organisations building upon the NHS Improvement Plan (June 2004) and part of the Government's plans for the modernisation of the health service.

- In 2009 TCN began to monitor the completion of mandatory training by clinicians.
- Over 90% of non-clinical staff reported that they had not received standard training courses such as equality and diversity, child protection and protection of vulnerable adults.
- Staff had mixed views on the quality of their training on triage and on the guidance they received on clinical decision making.

Communication with staff and staff morale

In 2007 and 2008, relevant important information referred to as 'alerts' was faxed to the bases and critical alerts were sent out as memos. When clinical issues arose the lead for clinical governance would write to clinicians on an ad hoc basis. TCN confirmed that "The introduction of the clinical bulletins commenced in December 2008. Prior to this, notices were sent to bases when required. These have not been systematically saved and available notices have been provided." CQC was therefore unable to ascertain exactly what the earlier alerts had covered.

The medical director distributed a briefing on clinical governance to staff in September 2008; this noted that clinical governance matters had previously been shared with staff by occasional mailings.

Folders for paper alerts were kept in bases until August 2008 and relevant alerts and memos were faxed to bases. This 'hard copy' system was replaced with an electronic system following the introduction of Sharepoint. Microsoft SharePoint is a software package that was used by TCN to host their internal website. It acted as an intranet for TCN staff where they could access shared workspaces, information stores and documents.

The information champion for TCN led discussions about implementing the Sharepoint system. These discussions took place at the meetings of the operational metrics group after December 2008. The minutes of this group indicated that Sharepoint was not installed and working across all bases until March 2009. During our visit to the base at Doddington in Cambridgeshire in September 2009, staff told us that they had only just been given access to the Sharepoint system. During a visit to the base at Wisbech in September, we found that neither the receptionist nor the GP were able to access Sharepoint**.** Two doctors at the Haverhill base were not aware of the Sharepoint system and another doctor at the Wisbech base was unaware of and had no access to Sharepoint**.**

The views of TCN staff that we talked to about Sharepoint were mixed; most thought it easy to use, some did not. The results of the CQC survey of TCN staff were more positive: of the 195 staff who responded to the question about the Sharepoint system, 51% rated it as excellent/good, 30% rated it average and 19% rated it not good/poor.

As well as being placed on the Sharepoint system, alerts were included in the Clinical Bulletin produced fortnightly and sent to some staff via personal emails. Special Critical Alert Bulletins were also produced when required and emailed to staff. TCN stated this was also sent to some staff via personal emails, although we were told by the TCN information champion that they discouraged the use of personal emails to contact TCN staff. These alerts did not contain confidential personal information

The patient safety group produced a flowchart for alerts which was implemented in November 2008 and the policy for alerts was also produced in January 2009. Clinicians were to be asked to sign to say they had read alerts; they were informed of this new policy via the TCN clinical governance briefing in September 2008. The minutes of the operational metrics meeting in February 2009 however noted it was not plausible to obtain receipts for reading alerts or to monitor that clinicians had signed them. The clinical coordinator in Ipswich also told us that it was difficult to ensure people signed to say they had read the alerts. Some TCN staff told us that doctors were not good at reading their emails.

In April 2009 the minutes of the business performance group recorded problems with

communication and the difficulties with having a geographically spread workforce. The operational metrics group decided to instigate regular meetings for clinicians and these were held in May and June 2009 in Ipswich and South West Essex. The main issues relating to communication which emerged were:

- Clinicians felt the Clinical Bulletin was good but they did not get time on shift to read it and embedded documents were not easy to access.
- They had never been asked to confirm they had read updates or sign a log.
- Clinicians were unable to access Sharepoint at home.
- Bulletins and updates were not ordered by date on Sharepoint and therefore difficult to review.
- A large number of administrative emails were received by clinicians and hence sometimes important clinical information was overlooked.

The CQC survey of TCN staff asked individuals to rate different types of written communication from TCN. 191 individuals rated the clinical bulletins. 108 respondents (57%) rated them as excellent or good, 56 respondents (29%) rated them as average and 27 respondents (14%) rated them as not good or poor.

The CQC survey of TCN staff asked respondents to rate different types of verbal communication within TCN. 189 individuals rated 'briefings from your manager'. 78 individuals (41%) rated these as not good or poor. 53 individuals (28%) rated them as average and 58 individuals (31%) rated them as excellent or good.

The CQC survey of TCN staff also asked respondents to rate 'staff meetings'. 168 individuals responded to this question, 93 individuals (56%) rated them as not good or poor, 40 individuals (24%) rated them as average and 35 individuals (21%) rated them as excellent or good.

Morale

The CQC survey of TCN staff involved in out-of-hours services asked them what they most liked about working for TCN. 189 responses were received to this question.

The main themes arising from the comments received were:

- TCN colleagues.
- Working with patients and providing a useful service.
- Flexibility of shifts.

Seventy-five of 182 respondents said that their colleagues were what they most liked about working for TCN. 54 of the comments received said that they most liked working with patients and providing a useful service. 36 responses commented on the flexibility of shifts that fitted easily around their lives. 18 respondents in response to this question said that there was nothing they liked about working for TCN.

Results from the CQC survey of TCN staff also indicated a few had concerns about the level of morale. 14 of the 182 comments in response to the question about what they would most like to change, mentioned low staff morale amongst TCN staff and that they felt neglected by the management team.

Many TCN staff in bases told us that they felt there was a distance between the senior management of the organisation and the front line staff and there were problems with some staff not feeling part of the organisation as a whole**.**
Some staff told us morale amongst front line staff was poor, due to the lack of communication from senior management, feeling that they were not engaged or consulted.

We asked all TCN staff participating in the survey whether they had given feedback on any information or instruction that came from senior management within TCN. There were 213 responses to this question. 70 respondents (33%) said yes and 143 respondents (67%) said no. Of the 70 individuals who made comments or had given feedback, 34 respondents (49%) said they were satisfied with the response and 35 respondents (51%) said no. One person did not respond.

Findings of fact about communication and morale

- In 2007 and 2008 clinical update information was sent as faxes or memos.
- The notices were not saved.
- In December 2008 a fortnightly clinical bulletin was introduced.
- Some information was sent to staff's personal email addresses.
- Sharepoint was introduced in spring 2009 but some staff could not access it in September 2009.
- In the staff survey, 51% of staff rated Sharepoint as excellent or good.
- The CQC survey of TCN staff asked individuals to rate different types of written communication from TCN. 191 individuals rated the 'clinical bulletin'. 57% rated it as excellent or good, 29% rated it as average and 14% respondents rated it as not good or poor.
- 41% of 189 respondents rated briefings from their managers as not good or poor, 28% rated them as average and 31% rated them as excellent or good.
- 56% of 168 respondents rated staff meetings as not good or poor, 24% rated them as average and 21% rated them as excellent or good.
- TCN had struggled to find an effective system to record whether staff had read information.
- When we visited bases, staff reported to us that communication was poor.
- Some staff told us morale amongst front line staff was poor.

Medicines management

Summary of findings in this chapter

- TCN had inadequate governance for medicines management, with limited pharmaceutical advice or support, no service level agreements or contracts, and policies that lacked clarity and detail. This resulted in an environment where controlled drugs were being stored and administered inappropriately. There was little knowledge of controlled drugs procedures, and limited opportunity to monitor and address concerns or staff awareness of controlled drugs.

- The NPSA issued a safer practice alert in 2006 about prescribing, labelling, supplying, storing, preparing and administering morphine and diamorphine. TCN did not take action in respect of this alert. The death of Mr Gray from an overdose of diamorphine happened in February 2008 and the 100mg vials of diamorphine were not removed until September 2008, and then at the insistence of NHS Cambridgeshire.

Medicines management can be defined as a system that determines how medicines are used by providers of healthcare and patients. It encompasses all aspects of the way medicines are procured, stored, prescribed, supplied, administered, disposed of and reviewed to optimise outcomes of patient care.

Sources of evidence

- Minutes of meetings
- Interviews with staff at TCN, their external pharmacy consultant, PCTs, Ipswich Hospital Pharmacy and the manufacturing unit for the pharmacy
- Controlled drugs regulation
- Reports by the Audit Commission and Healthcare Commission
- Memos and statements by TCN
- TCN's policies for medicines management and for controlled drugs
- Standard operating procedures
- Observations
- CQC's survey of TCN staff

Due to their potential for harm and for abuse, controlled drugs are subject to legislative control. The Misuse of Drugs Act 1971 and its regulations control the availability of drugs that are considered sufficiently 'dangerous or otherwise harmful', with the potential for diversion or misuse. Many controlled drugs (CDs) are essential to modern clinical care. Legitimate clinical use of these drugs is governed by the regulations which divide drugs into five schedules according to the level of control they need.

An opiate is a naturally occurring narcotic derived from opium. An opioid is a synthetic narcotic that resembles the naturally occurring opiates. Opioid analgesics are prescribed for moderate to severe pain. Diamorphine is an opioid and is a Schedule 2 controlled drug.

Following the inquiry into Harold Shipman and the reports produced by Dame Janet Smith which raised concerns about the system for regulating controlled drugs, new legislation concerning controlled drugs came into effect in January 2007. This strengthened monitoring

arrangements for organisations involved in prescribing, supplying or the administration of controlled drugs, which were described as 'controlled drug designated bodies'. It required these organisations to appoint accountable officers to take responsibility in their organisation for the safe and secure management of controlled drugs. It became a statutory obligation under the Health Act 2006 for all NHS trusts and independent hospitals to appoint an accountable officer, who must either be an executive director or report directly to an executive director and should not personally be involved in the routine prescribing, supply, administration, or disposal of controlled drugs.

Accountable officers in PCTs were responsible for establishing 'local intelligence networks' where information could be shared. Non statutory drug services, including TCN, were not included as responsible bodies in the regulations. Many are involved in local intelligence networks but they are not formal members.

Arrangements for the supply of medicines and for pharmaceutical advice

The medicines manufacturing unit of the pharmacy at Ipswich Hospital NHS Trust supplied medicines and controlled drugs (through the palliative care boxes) to SDOC originally and then TCN in 2005. The manufacturing unit of Ipswich Hospital Pharmacy holds a manufacturer's license which allowed them to supply TCN with packs of medicines in appropriate quantities, labelled and fit for out-of-hours clinicians to supply to patients to take home. The pharmacy took orders approximately every three weeks from the out-of-hours service and supplied them on a 'make to order' basis.

TCN reported that it contracted with the manufacturing pharmacy at the Ipswich Hospital NHS Trust (an NHS Manufacturing Pharmacy for the East of England Region) for its supply of medicines and also for relevant support on medicines management and the governance of this process. However TCN also told us that there was no formal contract in place with the manufacturing unit of Ipswich Hospital Pharmacy. Staff at the pharmacy told us that there was no service level agreement with TCN and that the pharmacy acted purely to supply medication. It was not contracted to provide pharmacy advice or to advise on governance matters in medicines management. The interface pharmacist for Ipswich PCT had provided some advice in the past for SDOC when it was a GP co-operative.

TCN did not have a pharmacy advisor for some time. An external pharmacy consultant, also sometimes referred to as the lead pharmacist, was referred to in the board minutes in July 2007, as if he were already in post. He told us he joined TCN part-time, on average one day a week, in September 2007 to provide advice. The adviser told us that he was brought into the organisation to look at medicines management and the initial focus was on the GP practices that TCN managed rather than out-of-hours. There was more emphasis on the out-of-hours services after the incident in February 2008.

Staff that we interviewed at TCN told us that the adviser had little practical hands-on involvement. They and the staff at Ipswich Hospital Pharmacy were of the view that one day a week was insufficient time to provide pharmacy advice. TCN acknowledged this and in late 2009, had planned to recruit more advice.

In August 2008 the minutes of TCN's clinical excellence group and the evidence based practice group noted that Ipswich Hospital Pharmacy would not be able to meet TCN's requirements in respect of the supply of medicines. The minutes recorded that this was because of the rapid expansion in TCN bases and the new contract with Worcestershire PCT. TCN told us that the main reason for the change to another supplier was difficulty in obtaining supplies for the Worcestershire area. The view was that Ipswich hospital pharmacy did not have the capacity to respond quickly enough. TCN said it was also a consequence of a review of medicines management systems across all TCN sites and because TCN wanted to implement a more robust control system to manage restocking and supplying of drugs, as well as improving the data available about their use.

The minutes of the clinical excellence group stated that a full appraisal of potential supply options would take place before any plans were finalised. However, no formal tender process took place. The Fairview pharmacy system was initiated in Worcestershire and East Cambridgeshire & Fenland in March 2009. A memo was sent to all clinical staff in March 2009 informing them that TCN had introduced the new medicines supply and management system. The memo stated that TCN was considering rolling this out to all areas.

TCN planned to extend the new system to parts of the East of England over the period April to May 2009. Listed as a dispensing chemist, the pharmacy is based in Edgware, Middlesex and provides pharmacy services to other out-of-hours services.

Following the switch to Fairview Pharmacy as the supplier of medicines, the standard operating procedure for supply and replenishment of drugs in March 2009 indicated that clinicians were required to label medicines. NHS Cambridgeshire identified that the new system was inconsistent with national guidance and good practice and insisted that the arrangements needed to change. This policy was revised in July 2009 and stated that ready-labelled medicines were now available.

Fairview provided TCN with their medicines apart from morphine and diamorphine, which continued to be supplied by Ipswich Hospital Pharmacy. The pharmacy was responsible for delivery and restocking of the drug cases supplied to TCN. Medication administration sheets attached to each drug case provided a better record of the drugs used than happened under the previous system.

In our survey of views of TCN staff, we asked about supply of medicines. We asked clinical staff and base staff (167 respondents to the survey) about who supplied medicines. Of the 155 responses received, 46% knew and 54% of respondents did not know who supplied their medicines.

Clinical and base staff were then asked to rate the access to medicines when needed. Of the 144 responses received, 49% of respondents rated access to medicines as excellent or good, 31% as average and 19% as not good or poor.

These staff were then asked to rate the availability of medicines in terms of range and dosage. Of the 135 responses received, 39% rated the availability of medicines as excellent or good, 39% as average and 22% as not good or poor.

These staff were also asked to rate the arrangements for restocking medicines. Of the 136 responses received, 38% rated restocking arrangements as excellent or good, 32% as average and 31% as not good or poor.

Findings of fact on the supply of medicines and pharmaceutical advice

- TCN had no pharmacy adviser until September 2007. In 2007 TCN appointed an external consultant to provide advice one day per week.
- There was no formal contract in place between TCN and Ipswich Hospital pharmacy to define responsibilities. The manufacturing unit of Ipswich Hospital pharmacy supplied TCN with drugs until TCN changed supplier to Fairview pharmacy in the spring of 2009.
- The lack of a service level agreement between the pharmacy manufacturing unit and TCN resulted in confusion regarding accountability.
- The change to Fairview pharmacy was driven primarily by supply problems in the Worcestershire locality and a desire to improve controls in the TCN medicines management system.
- Initially with the new supplier, clinicians had to label medicines that they gave to patients. By July 2009, ready labelled drugs were supplied.
- Staff were generally positive about access to and availability of medication, with nearly 80% rating both as average or better.
- The views on restocking were more divided with 38% rating it as good or excellent but 31% rating it as not good or poor.

Policies for the management of medicines

The first policy on the management of medicines at TCN was issued in September 2007. No other policies such as for controlled drugs accompanied it and it was not shared with the PCTs that commissioned services from TCN. There was no evidence that any PCT other than Cambridgeshire reviewed this policy until subsequent revisions had been made.

It was written by the clinical nurse lead (later promoted to nurse consultant) with input from the medical director. The board minutes in July 2007 noted that the lead pharmacist/ external pharmacy consultant would undertake a review of medicines management and that TCN would have a comprehensive medicines management policy in two months. However he told us he took up post in September and did not have any role in the creation of this policy.

Our judgement is that this policy was not satisfactory in a number of respects. These included a lack of clarity when referring to prescription forms and providing insufficient detail. For example the policy stated that the Medicines Act required the prescription of certain drugs and drug classes to be hand written and hand dated, but there was no guidance on what these drugs were.

The flowcharts within the policy were also inaccurate in several respects. For example the flowchart to explain the arrangements for medicines when the pharmacy was open, showed that the nurse saw the patient and then either asked the GP to write the script, or wrote the script and asked the GP to sign it. Nurses should transfer the patient to a doctor if they are not able to prescribe the medication.

TCN stated that these arrangements were common practice in primary care. However, CQC considers that out-of-hours care is significantly different in that there is limited access to patient's records and a lack of knowledge of the competency and experience of the staff working on a particular shift. Due to these differences the flowcharts were considered inaccurate in the context of out-of-hours.

TCN's external pharmacy consultant reviewed the medicines management policy following the death of Mr Gray incident in February 2008. He considered that it needed to be entirely re-written and became involved in writing the new policies in late 2008/early 2009. Subsequently the medicines management policy was reviewed and a revised policy was issued in April 2009. NHS Cambridgeshire told us that it obtained the policy in May 2009, provided TCN with a detailed critique of the arrangements and ensured the amendments were made.

We found that the April 2009 policy referred to out-of-date legislation. It stated it was to be read in conjunction with a number of supporting policies including for controlled drugs, the standard operating procedure for the supply and replenishment of drugs and some other standard operating procedures including one for patient group directions. Patient group directions (PGDs) are documents which are used to enable staff other than doctors (for example paramedics and nurses) to give medicines legally. In July 2009 during a visit to Riverside we were told by staff that there was one central medicines management policy available on Sharepoint. The staff we interviewed at Riverside were not aware of the controlled drugs policy and standard operating procedures although these had been produced by this time.

The role of emergency care practitioners was not covered in this policy. The policy had sections that had been copied from a PCT policy egg in section 1.4 Application the policy stated 'it is the responsibility of all managers employed by the PCT to ensure that copes of this and related documents are available and that they meet the skills and competencies required by the policy as a minimum..."

The September 2009 policy for medicines management referred to the policy for controlled drugs. However the policy for controlled drugs also referred to itself as a standard operating procedure. TCN's external pharmacy consultant told us that there was a lack of clarity in general about what constituted

a standard operating procedure and what constituted a policy.

Parts of the controlled drugs policy looked as if they had been taken from a policy from a GP practice. The TCN pharmacy advisor confirmed that they used practice policies as a reference.

The policy for medicines management was updated again in September 2009. This was more comprehensive and applicable to out-of-hours services. It still cited the out of date legislation and lacked clarity in references to prescription forms.

In October 2009 TCN established a medicines management group.

Findings of fact on policies for the management of medicines

- The first policy on the management of medicines was issued in September 2007.
- This policy was written by the nurse consultant with input from the medical director. TCN did not have any pharmaceutical advice on this policy. It had no supporting policies.
- The 2007 policy was unsatisfactory in a number of respects. It did not provide sufficient detail and had some inaccurate information.
- TCN's pharmaceutical adviser reviewed the policy after the death of Mr Gray in February 2008 and deemed it should be entirely re-written.
- A revised policy was produced in April 2009 and updated in September 2009.
- Sections of the April 2009 policy on medicines management had been copied from a PCT policy.
- Parts of the 2009 controlled drugs policy were taken from a policy designed for a GP practice.
- Policies for the management of medicines were not routinely shared with commissioning PCTs until April 2009.

Controlled drugs – licensing, storage and availability

TCN told us that as far back as 2004 both the Home Office and Ipswich Hospital Pharmacy were consulted about the need for a licence. Because the boxes containing controlled drugs were made up and sealed in the pharmacy at Ipswich they were considered 'manufactured medicines'. Thus while the manufacturing centre at Ipswich Hospital Pharmacy required a Home Office Licence, the TCN bases did not. If TCN had been carrying "loose" CDs not contained within sealed manufactured palliative care boxes then TCN would have required a Home Office Licence. However, no documentary evidence could be found for this agreement and the TCN staff involved at that time were no longer employed by the organisation. In the first half of 2009 TCN applied for licences for their bases and the licences were received in August 2009.

The policy on medicines management of September 2007 provided a list of locations where spare palliative care boxes should be kept. These included areas that we considered were not sufficiently secure such as the 'white injectables cupboard in the TV room' in …and 'lower right in the drugs cupboard in consulting room one'.

The original 2007 policy on medicines management lacked detail on aspects of controlled drugs such as how activity should be witnessed, entries registered, and how and when the safe codes should be changed. There was no reference to standard operating procedures and no separate controlled drugs policy. In 2009 the minutes of the evidence based practice group in March, April and May noted 'on-going issues' with the Riverside drugs cupboard and assessment of the arrangements in place there.

Problems with the palliative care boxes were minuted at the clinical management (governance) group as far back as March 2007. In April 2007 the police were involved in an incident when diamorphine was lost and reported to them by the TCN clinical governance lead. The police did not take further action but there were losses from two palliative care boxes where it was clear that TCN could not account properly for the drugs.

In the original system the boxes were removed when they needed restocking and taken to the Riverside clinic. Receipts/returns were recorded in the base journal. The boxes arrived sealed with a yellow Ipswich hospital pharmacy seal. The drugs coordinator logged the contents and the log book was completed noting the box numbers, the expiry dates and the date received. Red TCN seals and documentation were added at the Riverside clinic. The drugs coordinator delivered boxes to specific bases at a specified date and time. TCN documentation included notes on what to do once the box had been opened and a re-order form. The seal had a number correlating to the paperwork the clinician needed to complete should they need to open the box. Another seal was included in the documentation pack for the doctor to re-seal the box after use.

The new system for accessing controlled drugs was introduced as part of the policy for controlled drugs in November 2008. It removed the controlled drugs from the palliative care boxes and kept them in special safes in the bases. All the palliative care boxes were removed from circulation by February 2009. The new system involved a weekly audit of the contents of the controlled drugs case including the register, key log, stock check and re-ordering. Re-stocking was done via an order book. Stocks of controlled drugs were collected by a TCN driver from Ipswich hospital pharmacy. Duplicates from the order book were retained by the pharmacy and the TCN accounts department.

When there was a delivery of controlled drugs, the driver and GP signed out the keys to the safe in the corresponding log book and the GP signed the order book to confirm receipt. The drugs were stored in the controlled drugs safe and an entry made in the controlled drugs register. The GP and the driver signed the CD register and checked and recorded the type, quantity and strength of drugs received. The order book was locked in the controlled drugs safe, the key in the key safe and an entry made in the log. In order to access controlled drugs the keys to the safe had to be signed out by the GP and base coordinator.

The revised TCN policy in September 2009 specifically prohibited GPs from carrying their own stocks of controlled drugs from their own dispensaries. During visits we observed however that some GPs doing precisely that and hence were practising outside of the procedures for controlled drugs that TCN had in place. This was confirmed by some TCN staff.

As an independent organisation TCN was not required to have an officer accountable for controlled drugs. TCN informed us that the lead for clinical governance in East of England and the clinical lead in Worcestershire acted as designated accountable officers. However there was no reference to this responsibility in their job descriptions.

The CQC survey of TCN staff working in out-of-hours services, asked clinical staff and base staff (167 respondents to the survey) to rate a number of statements around the issue of controlled drugs.

The first question was in respect of their awareness of controlled drugs. 78% of respondents rated it as excellent or good, 16% as average and 6% as not good or poor.

The second was their view of the availability of controlled drugs in terms of range and dosage. 52% of respondents rated availability as excellent or good, 30% as average and 18% as not good or poor.

The third question asked their opinion about how safely controlled drugs were stored. 84% rated this as excellent or good, 10% as average and 6% as not good or poor.

Findings of fact on controlled drugs

- In 2007 some controlled drugs were kept in locations that were not sufficiently secure.
- The policy for medicines management in 2007 had insufficient detail on the proper procedures for controlled drugs.

- Diamorphine was lost and could not be accounted for in April 2007.
- Before the removal of the palliative care boxes from the TCN system and the introduction of the controlled drugs policy in November 2008, guidance and procedures surrounding access to controlled drugs were insufficient.
- The revised system for accessing controlled drugs was more robust and easily monitored.
- Some GPs carried their own stocks of controlled drugs from their own dispensaries, in contravention of TCN's policy.
- In the staff survey, staff were generally positive about the availability and security of controlled drugs.

The national alert system and how TCN responded

NHS Central Alerting System (CAS)

In September 2008 the Central Alerting System (CAS) brought together the chief medical officer's Public Health Link (PHL) and the Safety Alert Broadcast System (SABS). CAS is maintained by the Department of Health and serves to distribute safety information throughout the NHS. It is a web based system which enables alerts and urgent specific guidance on the safety of patients to be accessed at any time. The website includes information such as safety alerts, emergency alerts, drug alerts, Dear Doctor letters and Medical Device alerts.

The NPSA safer practice notice 'Ensuring safer practice with high dose ampoules of diamorphine and morphine' was issued on 25 May 2006. The notice was issued as for 'action' (the other categories of notice being immediate action, update and information request). The notice stated that there had been a number of reports of deaths due to the administration of high dose (30mg or greater) diamorphine or morphine injections.

The major risks were identified as:

- The packaging of different strengths of diamorphine and morphine, which look similar.
- The storage of higher strength ampoules alongside lower strength in clinical areas.
- The insufficient therapeutic training and understanding of healthcare staff of the risks.

Organisations were asked to complete a number of actions by October 2006. These included risk assessing procedures for the prescribing, labelling, supplying, storing, preparing and administering of diamorphine and morphine injections. They were also to review therapeutic guidelines, update information concerning the safe use of diamorphine and morphine injectable products, and ensuring naloxone injections were available in clinical locations where diamorphine and morphine injections were stored or administered.

TCN told us that as an independent provider they did not receive via their PCTs the safer practice notice issued by the NPSA in 2006. Their pharmaceutical adviser also informed us that his understanding was that TCN had not received this alert. TCN's drugs co-ordinator told us that on her own initiative she subscribed to the NPSA electronic alerts. She received this safer practice notice and escalated it at the time to the nurse consultant at TCN. The former medical director for Cambridgeshire PCT also provided us with evidence that SDOC was on the circulation list that NHS Suffolk used to distribute safer practice notices to all their providers at that time.

There was no documented evidence of a formal system at TCN to disseminate 'alerts' to staff before July 2008. At that time there was a paper based system at the Riverside which management expected staff to read. Information was relayed using faxes and there were folders containing alerts in the bases.

The first TCN briefing on clinical governance was distributed in September 2008. This informed staff that they would be asked to sign to confirm they had read any alerts distributed to bases. The patient safety group produced a

flow chart for ‘alerts’ which was to be implemented by November 2008. It stipulated that shift managers should visit all bases during operational times to ensure all recommendations from all streams were adopted correctly.

From December 2008 ‘alerts’ were sent out in clinical bulletins. TCN told us that alerts relevant to TCN were also sent out via personal emails and were faxed to the bases and placed in the folders. Special alert critical bulletins were sent out immediately to the bases and via personal emails. Later they were added to the next clinical bulletin.

In January 2009 TCN produced a policy for ‘alerts’ outlining how these would be distributed to relevant staff. It also introduced a database of alerts. The minutes of the clinical excellence group for March 2009 noted potential problems with staff not having signed to say they had read alerts. They noted that measures needed to be put in place to ensure that this was happening. At this time the alerts were not available on Sharepoint.

Findings of fact on TCN’s system for handling alerts

- The NPSA issued a safer practice alert in 2006. It required that organisations took action in respect of prescribing, labelling, supplying, storing, preparing and administering of morphine and diamorphine. This went to all the PCTs.
- Cambridgeshire PCT stated they had evidence the alert had been sent by NHS Suffolk to SDOC/TCN. The drugs co-ordinator for TCN at that time told CQC that she escalated this alert internally within TCN.
- TCN stated that they did not receive this alert.
- TCN did not take any action in response to this alert.
- In 2007 and 2008 TCN did not have a formal system for disseminating alerts and ensuring these were received by staff.
- In January 2009 TCN produced a policy and database for alerts.

Incidents involving diamorphine and changes made by TCN

The incidents have been covered in detail in Part 1 of our report. A summary follows below, highlighting changes made by TCN.

There were two incidents involving overdoses of diamorphine in Suffolk in 2007. These happened in April and August 2007. At the time of the second incident the GP lead for governance circulated a memo to clinicians giving advice on the administration of opiates by injection.

These incidents were raised by the GP lead for governance at the clinical management group on December 2007. The minutes of this meeting indicated that the group felt there was no systemic problem. It was agreed and recorded in the minutes that extra documentation should be placed with the boxes. However there was no evidence that this happened. We were told by the person who had been TCN’s drugs co-ordinator at that time that no additional documentation was placed with the palliative care boxes until after the death of Mr Gray in February 2008.

After the December 2007 meeting the GP lead for governance continued to be concerned that there was a systemic problem and on 15 January 2008 wrote an email to that effect to colleagues including the medical director and nurse consultant at TCN, warning of the potential consequences of inaction.

The fatal overdose to Mr Gray happened on 16 February 2008. On 18 February TCN introduced a second GP ‘referee’ system for administering controlled drugs. GPs were required to complete an entry on the HMS system and then phone the relevant duty manager to ask for a second GP review. The duty manager appointed a reviewing GP who made a decision as to whether administration of the drug was appropriate. This decision was also recorded on the HMS system. If approved, the duty manager informed the GP and the bag containing the controlled drug was released to the GP. The CQC’s survey of TCN staff asked them to rate the requirement to contact a second doctor. 67% of respondents

rated the requirement as excellent/good, 25% as average and 8% as not good/poor.

The senior pharmacist at NHS Suffolk with responsibility for out-of-hours was not aware of the two previous diamorphine incidents that took place in 2007 and she was not informed of the serious untoward incident in Cambridgeshire until over six months after it took place. She chaired the PCT's medicines safety group.

TCN told us that they were in liaison with the manufacturing unit of the pharmacy at Ipswich Hospital before Christmas 2007 to introduce separate boxes to contain appropriate pain relieving drugs for patients with acute pain. This was to remove the need for doctors to open the palliative care boxes in these circumstances. The minutes of the clinical management group recorded this matter had been discussed in late 2007. The pharmacy told us they did not receive an order for the pain boxes until March 2008 and the boxes were introduced in May 2008.

We were told by the TCN operations development manager, who was part of the Langdale process (set up to identify what had happened in the case of Mr Gray and learn lessons), that phase one involved removal of the palliative care boxes and removal of the 100mg diamorphine.

In the brief prepared for the TCN board in May 2009, TCN stated that in the weeks following the incident Cambridgeshire PCT identified that having 10, 30 and 100mg diamorphine vials in the palliative care boxes was in contravention of the NPSA safer practice notice 12 in May 2006. TCN stated that they consulted immediately with the manufacturing unit at Ipswich Hospital Pharmacy after the incident, but that development and implementation of new cases was complex. The pharmacy told us that the development was straightforward but the logistics of implementation by TCN was complex. TCN described the need to maintain access to palliative care drugs during the changeover period to a new supply. The briefing also stated that "removing 100mg from the cases in each frontline base rather than in a licensed site is considered by expert advice as potentially in contravention of controlled drug legislation and guidance, therefore requires return of cases to Ipswich Hospital for re-manufacture on pharmacy site".

The external pharmacy consultant for TCN told us that the continued presence of the 100mg vials had gone unnoticed and that this would not happen now. The former drugs coordinator for TCN told us that she was surprised the 100mg vials had not been removed from the system earlier.

The vials of 100mg diamorphine were finally removed from the palliative care boxes in all areas in September 2008, after an unannounced visit by Cambridgeshire PCT that month found that they were still in existence. TCN informed staff in a clinical governance briefing in September that the opiate content in the palliative care boxes would be made up of 10mg vials of diamorphine. The minutes of the clinical excellence minutes of 11th November 2008 noted that all the palliative care boxes were to be removed and morphine and diamorphine were to be kept in the manufacturer's boxes. The palliative care boxes were removed in February 2009.

Findings of fact on the overdoses of diamorphine and changes made

- There were two incidents involving overdoses of diamorphine in 2007. These both happened in Suffolk.
- After the second incident the GP lead for governance sent a memo to clinicians advising about the administration of opiates.
- Although the clinical governance group documented it as having happened, no action was taken in respect of labelling the palliative care boxes.
- The introduction of the second doctor check was instigated on Monday 18 February, within 48 hours of the death of Mr Gray.
- The acute pain boxes were introduced in May 2008.
- The 100mg vials were removed from the palliative care boxes in September 2008.

- The palliative care boxes were removed in February 2009.

TCN's arrangements to audit the use of medication and prescribing, and to provide support to clinicians

Before March 2009 TCN was unable to audit the use of medication or determine prescribing rates. The minutes of the clinical management group in May 2007 stated there was no audit facility on the use of the formulary. This was also mentioned in the minutes of the evidence based practice group in early 2009.

TCN's position statement in July 2009 reported that TCN had introduced a programme of monthly audits of drugs usage in Cambridgeshire and Worcestershire PCT localities in March 2009, which was rolled out to West Suffolk in June 2009. This was an audit of overall drug usage, not of individual prescribing by clinical staff.

The clinical coordinator at Riverside told us that she had no access to individual prescribing data for appraisals and that this information was only picked up when she did individual audits. When we visited the Riverside clinic, the doctor on duty told us he had never received feedback on his out-of-hours prescribing from TCN.

The CQC survey of TCN staff asked clinical staff only (doctors, nurses, ECPs) to rate whether they felt supported by clinicians at TCN in their clinical work. Of the 85 responses, 20% of responses strongly agreed and 28% disagreed or strongly disagreed.

Software used in out-of-hours usually records who prescribed (through log in), so service providers should be able to access reports on the prescribing of individual prescribers, linked where possible to a diagnosis (which is also recorded). However the HMS system was not able to support this at that time.

Findings of fact on arrangements to audit use of medication and prescribing

- TCN had introduced an audit programme of monthly drugs usage.
- TCN was not able to use their software system to audit prescribing by individual clinicians.

Governance arrangements

Summary of findings in this and the following chapter

- TCN was poor at recording and handling both complaints and incidents, and trends were not consistently identified and acted on. TCN was poor at identifying clinical risk and failed to consistently identify serious incidents that required reporting and investigating. TCN did not investigate serious incidents thoroughly or learn lessons from them. In particular, although there were two overdoses of patients in 2007 involving diamorphine, operational changes were not introduced until after the death of Mr Gray.

- TCN had flawed governance systems – it was not able to provide the minutes of some important meetings, and the minutes of others were poor quality. Some of the information TCN provided to the CQC and PCTs about the events associated with the death of Mr Gray was incomplete or inaccurate. TCN appeared reluctant to accept its shortcomings, whether in respect of activity reporting, filling of shifts or governance systems.

- Between 2005 and 2009, TCN grew rapidly, winning three contracts and more than doubling the population they covered. This growth in business was not matched by an expansion in capacity in governance.

Clinical governance has been described as a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.[*] The principles also apply to commercial organisations that are commissioned to provide care for the NHS,

Sources of evidence

- Interviews with TCN staff and managers; PCT staff; external reviewers
- Statements by TCN
- Minutes of meetings at TCN and SDOC
- Observations
- Documents including structure charts, governance strategies and briefing documents, policies and procedures
- Reports of external governance reviews
- Correspondence
- Survey of TCN staff
- Results of audits of clinicians

[*] Gabriel Scally, regional director of public health, and Liam J Donaldson, regional director, NHS Executive (Northern and Yorkshire), *Clinical governance and the drive for quality improvement in the new NHS in England*, BMJ 1998;317:61-65 (4 July).

Structural arrangements for clinical governance and the management of risk

During the period covered by the investigation there were two main changes to the governance arrangements. One of these happened between April and October 2008 as a series of revisions. The other changes happened in about the same period in 2009. The arrangements and the changes were complex, with committees with more than one name, or instances where, after a committee ceased, the same name was used for another group. CQC also noted that minutes of meetings were sometimes lacking in detail or missing. What follows is a summary.

Originally there was a clinical management group, also known as the clinical governance group, or the clinical management governance group. The GP with the lead for clinical governance chaired the group and wrote the minutes. This group met monthly and reported to the executive committee until the latter was replaced by the TCN executive in April 2008. TCN did not provide us with minutes of the executive committee or the renamed executive for either 2007 or 2008. They informed us there were no minutes before March 2009.

The medical director, who had lead responsibility at executive level for clinical governance, took up post in May 2007. There was also a doctor, who worked locally as a GP and was a director of SDOC, who was the operational lead for clinical governance from 2005. The medical director was only employed part time initially, making the clinical nurse lead (later the nurse consultant) the only full time member of staff in clinical governance at that time. Both had other roles in TCN. Following the retirement of the original nurse co-ordinator who had been in post since 2006, a new nurse co-ordinator, with some responsibilities for governance, was appointed in April 2008.

The clinical management/governance group was replaced by the clinical excellence group in June 2008. It had a number of sub groups, known as 'workstreams' including one called clinical governance. The other sub groups included patient safety, which began in September 2008, and clinical operations, which began in October 2008.

The operational metrics group was formed in October 2007 in Ipswich. Operational metrics meetings were held weekly and involved reviewing operational measures, such as compliance with the NQRs, numbers of unfilled shifts, shift reports and audit results. The aim of these meetings was to identify any concerns or trends highlighted by these measures and then propose actions or escalate to an appropriate level. After the formation of the business performance group in April 2008, the operational metrics group reported to this committee. There was no clear reporting line before this. Minutes were not taken until October 2008.

As well as the TCN board, the audit and remuneration committees met throughout the period of this investigation, although not at regular intervals.

The minutes of the business performance group in October 2008 noted the need to review governance at TCN. This resulted in reviews by Carson and Tobin in 2009. More details of their findings are provided later in this part of the report. Carson criticised the separation between clinical and operational structures and systems in TCN. Tobin considered TCN needed operational clinical leaders to build effective links with frontline operational staff. This is covered further in the section on strategic capacity.

Following the reviews by Carson and Tobin in 2009, new arrangements for integrated governance were developed. A working group called 'the Standards for Better Health delivery group' was set up in June 2009. A strategy for integrated governance was developed to bring together clinical and corporate governance. The central committee was the committee for integrated governance and risk management which was established in July 2009. This was chaired by a non-executive director. The medical director was responsible for clinical governance and the finance director for financial and corporate governance.

Risk

Before June 2008 risks were not formally identified and did not feature regularly in board

minutes. TCN told us that historically risks were reported through the executive directors to the board and that risk management operated 'at all levels and across functions, both formally and informally'. However we noted that some risks that had been identified in the governance committee did not appear on the agenda or in the minutes of the board. These included the two previous diamorphine incidents in 2007. Others such as reduction in clinical cover and unfilled shifts were sporadically discussed, but not in a framework of clinical risk. In October 2008 the matter of unfilled rotas was discussed as part of the finance report. The incident that led to the death of Mr Gray happened in February 2008, and was discussed at the SDOC board later that month, but there was no record of it being discussed at a formal meeting of the TCN board until July 2008. A draft risk register was discussed at the board meeting in June 2008 and the board reviewed business risks in December 2008. The Carson review of May 2009 found that although TCN had a risk register 'it does not seem to feature high on management team or board agendas'. By early 2010 progress had been made with the risk register being reviewed at meetings of the board.

The minutes of the clinical governance group in February 2008 noted that the executive committee was to identify a risk management pathway. TCN told us in July 2009 that they did not have a strategy or policy for risk management.
When the integrated governance and risk management committee was established in July 2009, one of its functions was to develop a strategy for the management of risk and a risk register. A draft strategy had been produced by September, and was approved in December 2009.

Findings of fact about arrangements for clinical governance and arrangements to manage risk

- In 2008 there were major changes to governance arrangements. These involved the number and hierarchy of committees. The arrangements, and the changes, were complex.
- In early 2009 two external reviews criticised the split between operational and clinical matters and there was a further
- Minutes of meetings often lacked detail and some were missing.
- The medical director was the executive with the lead for clinical governance.
- There was a doctor, also working as a local GP, who had operational responsibility for clinical governance. He was supported by the clinical nurse lead who became the nurse consultant.
- TCN did not have a formal strategy or policy for managing risk until December 2009, and did not have a functioning risk register until early 2010.
- A draft risk register was discussed at the board meeting in June 2008 and the board reviewed business risks in December 2008.
- Although the incident that led to the death of Mr Gray happened in February 2008, there was no record of it being discussed at a formal meeting of the TCN board until July 2008.

External reviews of governance arrangements

The non-executive director who joined the board in early 2008 advised that TCN's governance arrangements needed to be reviewed. The minutes of the TCN Board in December 2008 noted that an independent assessment of clinical governance was to be undertaken by David Carson and Alex Tobin.

The review was originally intended to be conducted jointly, but the precise remits of the reviewers and how this was to work, were unclear. The two reviewers met only once in mid January 2009, after Tobin had produced an interim report, with a follow up call in February. The medical director reported to the clinical excellence group in March that both reviews had been completed. He explained that the Carson review focused on governance in out-of-hours services and the Tobin review

focused on the leadership and culture of clinical governance across TCN as a whole.

Alex Tobin completed her initial review which was noted by the board in January 2009 and was considered to be positive. The minutes of the board in January noted that David Carson was to add his chapters to the overall report. Dr Carson told CQC that the new non-executive director at TCN initially approached him to undertake this work. He developed the scope of the review himself and his brief from TCN was to look at governance structures in out-of-hours.

The two separate reports were completed by May 2009 and taken to the board. Some of the conclusions from these reports are also considered in the chapter on strategic capacity and leadership at TCN.

Both reports were short and consisted mainly of their conclusions rather than describing the evidence on which these views had been based. In the case of Tobin, it did not appear that the views of senior leaders at TCN, or the written frameworks they had produced, had been challenged or balanced against the experience of front line staff and other evidence of shortcomings in services and governance. Tobin told us that this was outside the scope of her review.

The Tobin review found that “senior leaders can articulate and recognise common core values about their staff, patients and business model. These core values are about excellence in patient care and patient experience”. Later in the report however Tobin noted that clinical governance had to be rooted in frontline patient services. She added that there was “insufficient evidence of effective and reliable clinical leadership at the operational frontline”.

She noted that the senior leaders were disappointed by the serious incident in February but reported that they had used this to understand what more they needed to do to achieve their core values. She reported that the two PCTs were not confident that TCN fully understood the seriousness of the failures in their clinical governance systems at the time of the incident.

The Tobin report noted that the clinical excellence framework was an exemplary document that clearly described a vision for clinical governance that would be recognised by experts in the field both nationally and internationally. She added that TCN was at an early stage in implementing the structure and processes.

She reported that TCN faced a significant challenge to communicate effectively with its frontline staff.

Carson recommended that TCN improved its risk register, ensuring it was not cluttered up with trivial items. He also suggested that TCN supplement the RCGP toolkit audit with an analysis of trends and reporting of individual performance.

Carson noted that the organisation had been working hard to develop its governance function coupled with a significant expansion by winning a number of new contracts. He considered this had placed some strain on the structures and staff working within the organisation.

In response to the Carson and Tobin reports, the medical director presented a paper to the board in May 2009. The paper noted the appointments of the information champion, the head of clinical services and further recruitment in HR and finance as steps towards increasing capacity. It noted that improvements were required in middle management capacity.

The head of clinical services started in post in June 2009 and produced a draft action plan that month in response to the recommendations made in their reports. A more detailed plan was produced in August.

She also undertook a baseline assessment of TCN against the Standards for Better Health to gain an overview of the service and areas for development. Initial recommendations, including the need for an audit lead, education and training lead, and a patient services manager, were accepted by the board in August 2009. Following this assessment she produced project plans and identified areas for improvement. This included establishing a group to deliver the Standards for Better

Health to underpin all of the governance work done in the organisation and to improve working between different areas.

The head of clinical services recognised that work needed to be done to improve accountability within TCN. She devised a new structure for integrated governance, and the integrated governance and risk committee was created, which reported to the board. The head of clinical services acknowledged that work still needed to be done to ensure work was joined up and well documented. She told the CQC that TCN was planning to put in place a governance assurance manager, a clinical audit and education lead and a coordinator for practice and policy development. The complaints policy was updated and the head of clinical services had planned to revise the incident reporting policy, ensuring it was modelled on the RCA toolkit from the NPSA, but due to changing priorities this work was not undertaken.

Findings of fact on external reviews

- Two independent reviews of clinical governance were conducted in late 2008/early 2009.
- The reviews were meant to be joint but the reviewers worked separately and two reports were produced.
- Both reviews were short and consisted of mainly of conclusions rather than the evidence on which they were based.
- The reviews had some common findings eg problems in communicating with the clinical workforce.
- The Tobin review found that clinical governance was well articulated by TCN but needed to be rooted in frontline patient services.
- The Carson review found that that there was not enough emphasis on clinical matters.
- An action plan was produced in response to the reports.
- The head of clinical services was appointed in June 2009 to improve capacity in clinical governance.
- The head of clinical services established a group to deliver the Standards for Better Health. She devised a new structure for integrated governance, and the integrated governance and risk committee was created, which reported to the board.

Defining and reporting incidents

In March 2009 the TCN policy and reporting procedure for adverse incidents stated that: "TCN identifies that hazards may be reported as potential incidents, hazards should also be subject and identified by a formal Risk Assessment as per the TCN Risk Policy". However, we have noted above that TCN did not have a risk policy. The head of clinical services intended to revise the policy for reporting incidents but this work was not completed.

Incidents

The most recent policy and reporting structure for adverse incidents was produced in March 2009 and approved by the medical director in May 2009. The original version, written by the nurse consultant, was released in September 2007.

The policy addressed near misses, untoward incidents, and serious untoward incidents (SUIs) as defined below:

- An **incident** is an actual occurrence or near miss occurrence that has or could cause harm to patients, staff, or members of the public. A **near miss** is where an incident may have occurred and is usually an indication of underlying risk.
- An **untoward incident** is any significant event that causes unintended harm or injury, loss or damage to TCN or the public.
- A serious untoward incident (**SUI)** is any unexpected event which:
  - causes death or serious injury, or was life threatening
  - contributes to or indicates a sustained reduction in standards of care below the agreed minimum safe standards
  - involves a hazard to public health
  - involves the absconding of a detained mental health patient deemed at risk to themselves or others

- causes significant disruption to services
- causes significant reputation damage (including data protection issues)
- relates to fraud or other criminal activity
- could, or did, give rise to a significant claim for litigation
- has involved the suspension of a member of clinical staff for reasons associated to clinical care
- raises concerns following an inquest or coroners inquiry
- involves an episode of restraint which does not comply with policy involves significant healthcare associated infections (excluding MRSA).

All incidents had to be reported within 24 hours via the customer relations administrator to the clinical governance lead and patient safety lead. Any incident classified as an SUI had to be reported via the commissioning PCT within 24 hours and recorded by the SHA.

TCN stated that they linked in with the commissioning PCT's own incident reporting procedures and that the customer relations team was responsible for agreeing arrangements with PCTs. The policy outlined that 'if necessary' a report or response would be made to the PCT within three working days and a full investigation completed within a further 25 days.

TCN provided CQC with details of 1,460 events from 2007 to 2009. This total was made up of 536 near misses, 577 untoward incidents, 6 SUIs and 341 complaints. The data below shows there was either an increase in overall reporting rates or an increase in incidents over the three years.

		2007	**2008**	**2009**
Near misses	536	44	157	335
UI	577	168	224	185
SUI	6	0	2	4
	1119	**212**	**443**	**524**

Until August 2008 TCN used a paper based system to record and track incidents and complaints. This was changed because Cambridgeshire PCT rated this system as being so poor as to constitute a serious untoward incident. At this time an electronic system was introduced.

The CQC survey of TCN staff in November 2009 asked 'In the last six months have you witnessed or been aware of an incident that has caused you concern?' Of the 220 responses to this question, 113 (51%) respondents indicated that they had witnessed or been aware of an incident that caused them concern. Of these 113, 63 (56%) had completed an incident form and 50 (44%) had not.

The survey also asked 'Would you know how to complete an incident form if you needed to?' 156 responses were received to this question, of which 102 (65%) respondents said they would know how to complete and incident form and 54 (35%) would not.

Findings of fact on defining and reporting incidents

- TCN had a policy which defined incidents, near misses, untoward events and SUIs and laid out the reporting arrangements.
- Cambridgeshire PCT considered the system for recording and managing incidents and complaints was so poor it raised a SUI.
- Until Cambridgeshire PCT raised concerns, TCN's system for recording and tracking incidents and complaints was largely paper based.
- In the staff survey, of the 113 staff who reported having witnessed or been aware of an incident, 56% had reported it and 44% had not.
- 65% of staff reported they knew how to complete an incident form and 35% said they did not.

Reporting and responding to complaints

The TCN complaints procedure was produced in October 2007 and updated and revised in January 2010.

Before it was revised at the end of 2008 the complaints policy stated that the 'patient

complaints would be handled in accordance with the NHS Complaints procedure'. The NHS complaints policy at that time stated that an organisation should provide a written response to a complaint within 25 working days. The specification in three of the five commissioning PCT contracts stated that TCN should make an initial response in the first two to three days of receiving a complaint and that the final response should be made within 10 days. The timescales in the remaining two contracts were in line with the TCN policy.

The complaints policy was updated in November 2008. The introduction to the policy stated that TCN would acknowledge a complaint within two working days and that the complainant would be given a written summary of the investigation and its conclusions within ten working days. The process outlined later in the policy stated that the customer relations manager would send a full written response to the complainant within twenty five working days of receipt of the complaint.

The November 2008 policy provided the details of who the complainant should contact if they were unhappy that their complaint had not been adequately responded to. The details given in this document referred to the patient advice and liaison service (PALS) for NHS Cambridgeshire. These details would not be relevant to complainants resident in the other PCTs served by TCN. Patient advice and liaison services had been abolished by the time this document was updated, and had been replaced by local involvement networks. These networks took time to be fully established in the PCTs that commissioned services from TCN.

National quality requirement 6 states that all complaints must be audited in relation to individual staff so that where necessary, appropriate action can be taken. Before 2009 the TCN internal complaints logs did not record the details of the individual clinician involved in specific complaints.

National quality requirement 6 also states that the out-of-hours provider must report anonymised details of each complaint, and the manner in which it was dealt with, to the contracting PCT. TCN began to provide PCTs with information about individual complaints in May 2008. Before this time, TCN had only reported details of the total number of complaints received and had not routinely provided any information about actions taken in response.

CQC reviewed the appendices on complaints attached to the PCT performance reports for three months in 2008/09 (July 2008, September 2008 and January 2009). CQC sampled these months in order to review the information recorded in relation to individual complaints and the response provided by TCN. The information provided in these reports generally outlined a brief summary of the complaint, the date at which it was resolved and whether or not it was upheld. The details outlining the context of the complaint were sparse and it was difficult to make a judgement about how serious a complaint was from the information recorded. There was very little detail about what action TCN had taken to review the complaint or as a result of the findings of the investigation.

CQC cross referenced the complaints recorded in the internal TCN log against those provided in the performance reports. During the three sample months reviewed it was found that generally most complaints recorded in the internal TCN log were also recorded in the corresponding performance report. There were some inconsistencies regarding the dates by which complaints were resolved. The dates recorded in the internal TCN log did not always reflect the date recorded in the PCT performance report. CQC also found that on the occasions where individual complaints received directly by PCTs had been forwarded on to TCN, those complaints were not recorded in the TCN internal complaints log.

CQC reviewed the time it had taken TCN to respond to complaints during three sample months in 2008 (January, July and September). TCN did not resolve any of the reported complaints in NHS Cambridgeshire, NHS Suffolk or NHS Great Yarmouth and Waveney area within the ten days specified in the contract. The majority of the complaints were resolved within the 25 days required by the internal TCN complaints policy in operation at that time.

Findings of fact on responding to and reporting on complaints

- The TCN complaints policy in operation until November 2008 did not reflect the timescales for response to complaints detailed in contracts with three of their commissioning PCTs.
- The complaints policy was updated in November 2008 but the timescales for responding to complaints were not clear.
- Incorrect contact details were provided for those complainants who were unhappy that their complaint had not been adequately addressed.
- The details of individual clinicians who were the subject of complaints made by patients were not routinely recorded until 2009.
- Information about individual complaints was not reported to PCTs until May 2008. Subsequent reports lacked sufficient detail for the PCT to undertake any meaningful analysis of the action taken in response by TCN.
- For the sample of months reviewed by CQC, complaints recorded in the TCN internal log were reported accurately to the PCTs although there were inconsistencies in the reporting of the dates by which complaints were resolved.
- For the sample of months reviewed by CQC it was found that complaints forwarded to TCN by the PCTs were not recorded in the complaints log.
- TCN responded to complaints in line with the timescales detailed in their internal policy but CQC found that TCN was not responding to complaints in line with the timescales specified in the individual PCT contracts.

Monitoring, analysing and learning from complaints, incidents and SUIs

The summary log for incidents and near misses in 2007 did not put incidents in categories; they were simply grouped together. Although the log for untoward incidents in 2007 included columns for actions taken and analysis and outcome, these were blank. The log in 2008 initially categorised incidents as 'clinical' or 'operational', as well as other categories such as 'other', 'response time' and 'attitude'.

TCN began coding the incident logs from mid-2008 onwards using the TCN incident coding card. This used codes based on a common classification system. The original coding card was added to TCN's adverse incident policy at the end of July 2008 and more codes were added in November 2008. Further codes were added in March 2009. The customer relations team, which was responsible for coding incidents, was not informed about changes to the coding card and therefore continued to use an outdated version.

Complaints detailed in the 2008 log were the earliest events to be coded by TCN. TCN did not code near misses and untoward incidents until the 2009 logs. However, the coding was incomplete and there were many incidents in 2009 for which a code was omitted. Full analysis of trends by TCN would therefore not have been possible with these logs.

A number of issues were apparent when looking through the codes TCN had used for incidents. Firstly, events recurring over a number of days were recorded as one incident, rather than as separate incidents. Secondly, it seemed a small number of incidents was repeated in the logs. Additionally, there were some incidents which we considered were not coded appropriately and there was also a lack of consistency in the allocation of codes.

CQC's analysis of complaints, near misses and untoward incidents

We coded all of the events (complaints, near misses and untoward incidents) recorded in TCN's internal logs for 2007, 2008 and 2009. The coding card from November 2008 [version

2.4] was used. We retrospectively coded the 2007 and 2008 logs.

The most frequently used coding category was 'Clinical Assessment & Treatment' (221 untoward incidents, 71 near misses, 215 complaints). This category accounted for 35% of total events. 'Operational Errors' made up 20% of all events (290), 'Medication Errors' 13% (187) and 'Staffing Issues' 8% (115).

The most frequently used code was 'Clinical Assessment & Treatment – Other'. This was used for 230 events (16%). This code was used when an event regarding clinical assessment and treatment could not be coded to a more specific code in the category. All events regarding the attitude of clinicians were coded to this. 'Delay/Difficulty in obtaining clinical assistance' was the second most frequent code (157 occurrences, 11%).

Other notable codes were;

'Diagnosis - Delay/Failure to' and 'Diagnosis – Wrong' 65 (4%)

'Confidentiality breach' 16 (1%)

'Incorrect or inappropriate prescription' 54 (4%)

'Controlled drugs issue' 33 (2%)

'Call wait time' 62 (4%)

'Inadequate [staffing] levels' 63 (4%)

'Unexpected or suspicious death' 17 (1%)

The codes that were added in March 2009 included 'attitude of clinician 'and 'refusal or failure' to visit. Had they been in use since 2007 they would have accounted for 182 incidents. Over three years there had been 65 (almost 20%) complaints about the attitude of clinicians, plus 32 untoward incidents and near misses.

TCN's analysis of incidents and complaints

CQC did not find any evidence that TCN had undertaken any analysis of the type described above, before April 2009.

The patient safety group was formed in September 2008. Before that it was unclear if any analysis and monitoring of complaints and incidents had occurred. Individual complaints and incidents appeared on the agendas for the clinical management (governance) group from 2007 but there was no evidence that trends or themes were analysed at these meetings. The TCN procedure for handling complaints stated that the customer relations manager would prepare weekly reports for discussion at the operational metrics meeting. There were no minutes available for Riverside operational metrics group before October 2008 to enable us to confirm this.

Until August 2008 TCN used a paper based system to manage incidents and complaints, which, combined with the lack of detailed incident coding, made analysis of themes difficult. The minutes of the operational metrics in December 2008 stated that untoward incidents and complaints would now feature as an agenda item.

The operations development manager told us that incidents were acknowledged with individuals who raised them and any relevant outcomes from the investigation shared with them. During a visit to the Riverside clinic we were told by the doctor on duty that he had never received feedback from an incident he had reported. In the CQC staff survey, 63 staff responded that they had witnessed or been aware of an incident that caused them concern, and had completed an incident form. These 63 individuals were asked if they were satisfied with the response they received. 26 respondents (41%) were satisfied and 35 (56%) were not.

SUIs and incidents did not appear in the minutes of TCN Board until July 2008, when it was noted that these should be brought to the board's attention in future. The SUI involving the death of Mr Gray first appeared in these July board minutes and it was referred to as the 'recent Cambridgeshire SUI', although the SUI occurred in February 2008. From September 2008 the board received updates on SUIs

The Clinical Bulletins contained information under a number of different headings and although these varied slightly from bulletin to bulletin, in the main the areas covered were; what's new, medication updates, clinical governance issues, clinical delivery and evidence based medicine. The bulletins did not contain information on individual incidents, serious incidents or complaints. There was no

discussion or presentation of analysis of trends in complaints or incidents. They did however contain clinical information relating to some recurring incidents, for example the clinical bulletin of 18 December 2008 stated that there had been some untoward incidents involving sharps and provided guidance on the management of contaminated sharps. All the bulletins contained information regarding alerts and relevant documentation was provided as embedded documents.

Findings of fact on monitoring, analysing and learning from complaints and incidents

- In the 2007 log of incidents, the columns for actions taken and analysis and outcome were blank.
- Until November 2008, TCN had a very basic system of classifying incidents. This made it difficult for TCN to identify themes.
- Until August 2008 TCN had a paper based system for managing complaints and incidents. This made it difficult to analyse and identify trends.
- Individual complaints appeared on the agenda of various minutes but there was no evidence of analysis of themes.
- The most common themes CQC identified were clinical assessment and treatment, delay or difficulty in obtaining clinical assistance, wrong diagnosis, incorrect prescription and inadequate staffing levels.
- TCN did not undertake any detailed analysis of themes. This reduced the possibility of learning and rectifying matters.
- 40% of staff in the staff survey were happy with the response to incidents they had reported. 56% were not happy.
- The clinical bulletins provided information on some recurring incidents.

Serious untoward incidents

We have previously considered the categories of incidents that were defined as SUIs. The policy stated that SUIs should be reported immediately to the designated TCN manager who was responsible for ensuring the relevant internal and external bodies such as the SHA, were informed. The policy also stated that SUIs should be reported via the commissioning PCT and recorded using the appropriate SHA SUI form. The customer relations team was responsible for completing this and informing the PCT within 24 hours of the incident being reported. The policy was not explicit on responsibility for contacting the PCT and ensuring the SHA was duly informed.

Before Mr Gray's death in February 2008, TCN had not reported any serious untoward incidents. There had been two previous incidents involving diamorphine as described earlier, but these had not been reported as SUIs. The first had not been reported to the PCT. The second was, but not as a SUI.

Serious incidents that had not been formally declared as SUIs

In our analysis of complaints and incidents described earlier, we identified a number of other instances that we considered could have been potentially reported as SUIs. These included the previously described diamorphine incidents. There were 10 other events which (based on the brief summaries in the logs of untoward incidents, near misses, and complaints) CQC considered could potentially have been categorised as serious untoward incidents (SUIs). Of the 10, five were complaints, four were untoward incidents and one was a 'near miss'. One of the 10 occurred in 2007, five in 2008, and four in 2009.

TCN provided us with investigation files for each of the events. These did not contain written final investigation reports as would be expected had they been designated as SUIs. They consisted of a collection of letters, emails, system call records, transcripts, call recordings and other related documentation that were produced or acquired during TCN's enquiry into the incident. The files ranged from 4 to 99 pages in length and contained variable amounts of detail. Each file contained a one page incident log showing summary

information such as dates, persons involved, the nature of the incident, a record of action taken, and the outcome. There was little evidence of root cause analysis, lessons learnt or recommendations.

A non-executive director (until mid-2009) led the investigation of complaints, and the lead for clinical governance investigated the untoward incidents and near misses. Both of these were GPs with limited administrative support. There was some collaboration between the two regarding closing incidents. All complaints were acknowledged by a customer relations administrator and referred to the investigation lead within 24 hours.

Response times in general were within acceptable standards; there were a few occasions where a case was extended over a number of months but only one where there was no explanation recorded for the delay.

There were three files which we considered to constitute a poor record of the incident. One was only four pages long and did not include any details or information following the incident being reported. Another contained only an email trail; no further information or documentation was provided.

In the other seven files, the two doctors who led on this work wrote to the person who reported the incident and obtained relevant information from any member of staff involved. Correspondence between the lead, staff, and patients' relatives was all well documented in the files. There were two cases where the insurance company was contacted and made aware of the incident and there was evidence of their involvement.

Only two files had evidence of the case being notified to the relevant PCT. TCN acknowledged one of these should have been declared a SUI but pointed out that the PCT had not raised this as a concern. TCN provided performance reports to show that a list of complaints and incidents were regularly sent to the PCTs.

The incidents were assessed against the specification of a SUI in TCN's incident policy. CQC considered that seven of the 10 cases probably should have been designated as SUIs. In the remaining three cases there was insufficient evidence to confirm they should have been designated as SUIs.

Our assessment was that:

1. There was inadequate reporting to the PCTs of significant clinical issues
2. Some investigations were inadequate and consequently there was inaction or inappropriate reassurance after completion of the investigation
3. Decisions were made by TCN governance and clinical leads without adequate checks or systems in place
4. There was an inconsistent approach to following good clinical governance in investigating some cases including deaths, where system failure or clinician performance may have been an issue

There was very little evidence from the files that any follow up actions were recorded. None of the files contained a resulting action plan. For only one incident was it clear that the clinician at fault was monitored afterwards. Other than specific professional development for a clinician, there was no reference in any of the files to further and widespread learning from the incident. The exception to this was one incident which apparently led to the introduction of a new protocol on checking patients due home visits when there were delays.

TCN stated that serious incidents or investigations of incidents declared or held by PCTs were on a number of occasions not reported to TCN by the PCT nor were the eventual reports shared with TCN. TCN commented that they tried to obtain these investigations and reports but that the PCTs did not provide this information.

Findings of fact on our analysis of serious incidents not declared as SUIs

- CQC considered that seven of the 10 cases that it looked at, should have been designated a SUI. This called into question the process by which SUIs were determined.

- TCN had only informed the PCTs in two cases, in the others PCT would have been unaware of significant clinical concerns.
- The investigations were conducted by two GPs with limited administrative support. The time taken to respond to incidents was within acceptable standards.
- Seven files contained reasonable records, three constituted a poor record of the incident.
- The approach taken to investigating cases was not consistently grounded in good governance. This included cases where system failure or clinician performance may have been an issue.
- There was little evidence of root cause analysis, lessons learnt or recommendations.

Investigating and writing reports on serious untoward incidents

TCN's policy and procedure for reporting adverse incidents stated that 'all serious incidents will be (internally) investigated using root cause analysis which will result in improvement strategies being designed and implemented, with outcomes and effectiveness measured'.

The policy stated that all incidents would require some investigation and these would usually be instigated by the designated incident manager and be completed within a day. A more comprehensive investigation might be requested which would be conducted by the clinical governance lead and might include the analysis of underlying causes. There was no guidance in the TCN policy on how to conduct an investigation or what an investigation report should include or how it should be presented.

TCN's clinical lead in Worcestershire told the CQC that SUIs within the Worcestershire area were referred to him and if he was unsure about the incident he would contact TCN's medical director or the head of clinical services. He stated that he had been given some guidance and had some administrative support at Ipswich to investigate incidents. When questioned about inaccuracies in a report about a particular incident he agreed that there was probably a lack of detail. He had not been aware of the level of scrutiny that would be required, it was the first SUI he had investigated and he acknowledged he was a 'bit naïve about the scale of the investigation'.

The NPSA guidance provides a toolkit to support the writing of patient safety Root Cause Analysis (RCA) investigation reports. This includes a comprehensive list of matters to include in investigation reports. Not all of these may be practical in out-of-hours services, but we took them into account as good practice in our analysis of TCN's reports on the SUIs they declared.

When we first requested information on SUIs, TCN had recorded six. TCN provided us with the accompanying 'reports' for these serious incidents. The first was the draft internal TCN report regarding the death of Mr Gray. Two others appeared as letters, one as email correspondence, one as a PCT report and one as a TCN report. We consider these in more detail below. Subsequently TCN reported two further SUIs and provided us with information on these.

First reported SUI – the death of Mr Gray

The TCN draft report of 'an internal clinical governance investigation' into SUI01 contained some of the features outlined in the NPSA's guidance but did not follow the format outlined in the guidance. The aim of the investigation was stated as 'to report on the investigation of the serious untoward incident (SUI) in a prompt timescale to the TCN board, the commissioning PCT and the strategic health authority (SHA) in line with the East of England SHA guidance on SUIs'.

The investigation team was identified in the report under a section headed 'clinical governance and patient safety staff involved in reviewing the SUI'. The TCN medical director was identified as the TCN reviewing clinician. The clinical governance lead for TCN carried out the initial investigation into the incident and the patient safety lead was involved in correspondence with the family related to the complaint they made.

The incident, its consequences and TCN's response were described. There was no executive summary, nor a pre-investigation risk assessment. The objectives of the investigation report included 'identify any factors contributing to the SUI' but there were no terms of reference for the investigation. The scope and level of the investigation was not explained, nor the type of investigation or the process and methods used. Reference was made in the report to evidence and information gathered and reviewed by the clinical governance lead, such as the voice recordings from calls but these were not documented in the report in a separate section. It was not possible to identify if all documents and evidence had been cited. No information was given as to whether relatives were involved or the involvement and support provided for staff.

The report listed the issues raised by the incident, which may be considered as problems with care or service delivery but they were not identified as such. The report made no reference to a root cause analysis being undertaken, although it identified 'findings' arising from each area and actions taken by TCN.

The NPSA guidance indicates that the report should connect root cause(s) in organisational processes with how these directly resulted in specific care and service delivery problems and how these led to the documented actual or potential affect on the patient. It was not clear from the report if the findings identified in the report constituted problems with care and service delivery in TCN, contributory factors or root cause conclusions. Actions taken by TCN also included recommendations for work to be undertaken. No action plan was outlined in the report and no timescales for actions were given.

Second reported SUI

NHS Cambridgeshire reported a SUI on 20th June 2008 relating to the management of untoward incidents by TCN. In response to this SUI TCN reviewed their internal processes and completed an interim report in July 2008 proposing actions to be completed by the 4 August 2008.

In response to the CQC request for the final investigation report TCN provided a letter to NHS Cambridgeshire, dated 4 August 2008. The letter is titled 'final report in response to declaration of SUI relating to management of untoward incidents: SUI02-2008'.

The letter acting as the investigation report did not include an executive summary or a description of the incident, or in this case, the nature of the concerns raised by Cambridgeshire PCT. There was no mention of a pre-investigation risk assessment, the investigation team, the scope and level of the investigation, the type of investigation, process or methods used. Problems were not linked to contributory factors, root causes or recommendations. The report consisted of a list of actions that had been taken or were being undertaken by TCN. An action plan was provided by TCN outlining actions to be taken and giving timescales and identified leads for action.

Third reported SUI

This incident happened in NHS Great Yarmouth and Waveney. On 26 December 2008 the mother of a 19 year old patient contacted the out-of-hours service in the early evening as the patient had a high temperature and loss of appetite. The call was logged as routine. A TCN clinician telephoned the patient under an hour later and ascertained that the patient had been unwell for over a week. The clinician advised that the patient take paracetamol and ibuprofen. The patient was unable to attend a TCN base for an appointment due to lack of transport. On 29th December the patient's mother called an ambulance as the patient had collapsed. The patient arrived in the A&E department of the James Paget Hospital and was pronounced dead shortly afterwards. The post mortem report identified the cause of death as bronchopneumonia. Great Yarmouth and Waveney PCT was informed about the incident by the BBC, as the story was to feature on a local news programme. The PCT contacted TCN on the 6 January 2009 informing them of the incident and requesting information for a statement for the programme.

TCN provided CQC with a document entitled 'final report SUI 688/2008'. This document, which was not dated, was produced by NHS

Great Yarmouth and Waveney. The report identified the PCT investigation team and included an action plan for TCN. However, CQC have not had any evidence that TCN conducted its own internal investigation of the SUI or produced any recommendations or action plan.

Fourth reported SUI

In the evening of 17 March 2008 the mother of an 11 year old patient contacted the out-of-hours service because her child had a sore throat, stiff neck, photophobia and a headache. The call was triaged by a TCN doctor who arranged a base visit for the patient. The patient was assessed by a TCN nurse who discussed the case with the doctor on duty. The patient was assessed again by a TCN doctor at the base who recommended paracetamol and ibuprofen. The patient was subsequently admitted to hospital by ambulance the following day and admitted to the HDU with suspected meningitis.

The SUI investigation report submitted by TCN was an internal letter from the lead for patient safety to the clinical governance lead, dated 13 February 2009. The letter referred to the SUI as a complaint. The patient safety lead indicated that the complaint had not been upheld clinically. The letter contained a description of the incident and the patient safety lead's interpretation of events. There was no reference to any form of investigation, of root cause analysis, identification of care or service delivery problems, recommendations or actions.

Fifth reported SUI

The only information given in TCN's summary of SUIs in their out-of-hours services is "9 month old baby boy seen at base. Patient died hours later suspected meningitis." This occurred in March 2009 and was in Suffolk. CQC have no further details of this SUI.

For this SUI we received copies of email correspondence between the TCN clinical governance lead and Suffolk PCT. In this correspondence the PCT were in the process of completing their final report and did not require a separate report from TCN. The last email from TCN to the PCT dated July 2009 requested a copy of the report. We have seen no evidence that TCN conducted an internal investigation into this SUI.

Sixth reported SUI

In the evening of 2 February 2009 the son of a 76 year old patient contacted the out-of-hours service because the patient was confused, had slurred speech and severe back pain. The call was triaged within 15 minutes. A home visit was conducted later that day by a TCN clinician who assessed the patient and prescribed medication for a chest infection. The following day the patient's condition had deteriorated and the family requested a home visit by the patient's GP. On arrival the GP contacted emergency services and the patient was admitted to A&E that afternoon. The patient's GP was unable to locate the call record of the TCN home visit. TCN provided this the following day. The patient was pronounced dead in the afternoon on 4 February.

On 19 February 2009 the surgery wrote to TCN raising concerns about the lack of communication with the patient's GP and the apparent deficiency of the TCN clinical consultation. On 17 March 2009 this letter was reviewed at the Great Yarmouth and Waveney patient safety reporting group, where it was decided this incident should be reported as an SUI.

The SUI investigation report provided was completed by the TCN clinical governance lead and dated 16 May 2009. Details of the incident were given and a summary of the evidence reviewed. There was no pre-investigation risk assessment, the investigation team was not identified, nor the scope and level of the investigation, the type of investigation, process or methods used. There was no information regarding the involvement and support of patients and relatives or the staff involved. Two issues were identified as arising from this incident. Although the issues identified were discussed and remedial actions taken by TCN were mentioned, there was no consideration of contributory factors, root causes nor were recommendations made. The report and consideration of the issues appears to have been solely undertaken by the clinical governance lead. No action plan was provided.

SUIs reported after CQC interim statement in October 2009

The investigation report following the SUI involving a cancer patient who experienced a nine hour wait in October 2009, was completed following the NPSA guidance on root cause analysis and investigation reports. It provided relevant information relating to the scope and level of the investigation, as well as identifying care and service delivery problems and root causes. An action plan was submitted.

There was a SUI in January 2010 about a patient who died following assessment at a TCN base. The investigation report was completed using the root cause analysis report template and covered all the areas denoted in the NPSA guidance. Sections relating to root cause analysis and recommendations were incomplete pending completion of the root cause analysis work. A seven day briefing of the initial investigation was submitted.

Findings of fact on investigating SUIs and producing reports

- Of the original six SUIs reported, the investigations led to two TCN reports, two generated letters, email correspondence and one a PCT report.
- Where reports were produced, they were incomplete and did not fully explore contributory factors or contain recommendations.
- There was little evidence of thorough investigation or root cause analysis in the TCN documentation on SUIs until autumn 2009.
- The two later SUIs in October 2009 and January 2010 were investigated much more thoroughly and detailed reports were produced.

Strategic leadership and quality of management

Sources of evidence

- Interviews with TCN and PCT staff
- External reviews of governance
- External review of service in Worcestershire and TCN response
- Transcript of initial meeting with TCN
- Minutes of meetings
- Correspondence with TCN
- TCN briefing on the death of Mr Gray provided to Suffolk PCT
- CQC survey of TCN staff

Growth, capacity and quality of management

When TCN was created in 2005 the organisation (in partnership with SDOC) held two contracts for out-of-hours services covering a population of over 600,000 people across Suffolk and East Cambridgeshire and Fenland. Between 2005 and 2009 TCN won three more out-of-hours contracts expanding their coverage to a population of over 1.7 million people, with TCN/SDOC responsible for the entire service for over 1.4 million.

The expansion to cover Great Yarmouth & Waveney was a natural extension of TCN's operations in the east of England and in the South West Essex service TCN only provided clinicians. Winning the Worcestershire contract was a significant expansion of the organisation into a geographically separate location. During this time period TCN also secured contracts in other services such as sexual health and dental health.

The organisation more than doubled in size over four years. Some of the board however did not think the rate of growth was remarkable, and pointed out that it was the nature of winning contracts. The growth occurred in an environment of increasing regulation of the NHS. There was growing recognition that out-of-hours services should operate similar governance standards to other providers of health care.

The strain that these changes placed on middle managers was identified by TCN, PCTs and by independent reviewers. Both the Carson and Tobin reviews of clinical governance at TCN identified problems with the capacity and capability of middle management at TCN. Tobin noted that the growth of TCN's business portfolio over the past year had outpaced the clinical governance skills and experience of staff. She wrote that Suffolk and Cambridgeshire PCT remained concerned that TCN continued to expand and might not be investing sufficiently in its operational infrastructure to sustainably support safe systems of care.

Tobin recommended "that TCN ensures that the senior leaders address some of the shortfalls in existing middle management capability". The executive director of business strategy and performance at TCN told us that middle managers were not strong enough. Other members of senior staff both at TCN and the PCTs were worried that the organisation had grown too fast and needed a period of consolidation.

Results from the CQC survey of TCN staff revealed concerns from some staff that operational priorities were being placed above clinical ones. There were 19 comments, out of 182 responses, to a question about what they would most like to change about TCN, which raised concerns about the balance between operational and clinical priorities.

Some staff were clearly stressed by the size of their workload. Some said that senior managers generally did not want to hear about problems and were reluctant to consider staff concerns. Examples included problems with

filling shifts and the complexity of the data on activity. Many TCN staff in bases told us that they felt there was a distance between the senior management of the organisation and the front line staff and there were problems with some staff not feeling part of the organisation as a whole**.** Some staff told us morale amongst front line staff was poor, due to the lack of communication from senior management. Staff felt that they were not engaged or consulted.

When asked in our survey of TCN staff whether they felt supported by senior management, 23% of the 215 staff who responded agreed or strongly agreed whereas 56% disagreed or strongly disagreed. The CQC tried to find comparative data but the Ipsos Mori public sector normative data did not contain a directly comparable question.

The most critical comments came from staff in the Worcestershire area where 55% strongly disagreed that they felt supported and Great Yarmouth & Waveney where 72% either disagreed or strongly disagreed. In terms of roles, the most satisfied were corporate staff where 52% agreed or strongly agreed that they felt supported, whereas over 50% of base co-ordinators, drivers, and duty managers disagreed or strongly disagreed. For doctors and nurses, 48% and 49% respectively disagreed or strongly disagreed that they felt supported by senior management.

The result for support from their line manager was that 37% of the 193 staff who responded agreed or strongly agreed they felt supported whereas 41% disagreed or strongly disagreed.

As mentioned above, the CQC survey of TCN staff gave respondents an opportunity to state what they would most like to change about TCN. Of the 182 responses received, 68 said they would most like to the change the management of TCN.

"I'll be honest and say that I would like to change the entire senior management team because I think that they are so disconnected from front line staff and as a result of this I think that morale is very low across the board" – Doctor, Suffolk.

14 of the comments mentioned low staff morale amongst TCN staff and that they felt neglected by the management team.

Findings of fact on growth, capacity and quality of management

- Between 2005 and 2009 TCN experienced rapid growth, winning three more contracts and more than doubling the population they covered.
- External reviewers and internal staff recognised the strain this had put on middle managers.
- 23% of TCN's staff who responded to the CQC survey agreed or strongly agreed that they felt supported by senior management, 56% disagreed or strongly disagreed.
- Just under half the doctors and nurses who responded did not feel supported by senior management.
- In the staff survey, 68 out of 182 respondents said what they would most like to change about TCN was the management.

Clinical leadership and communication with frontline staff and local GPs

The vast majority of the clinical workforce at TCN was not employed by TCN but worked as contract staff. This arrangement is common in out-of-hours services. It allowed for flexibility but made communication difficult, as described earlier, and made it difficult for TCN to develop clinical leaders. This issue was identified in Carson's review of clinical governance at TCN which stated "This is a major problem as the current level of clinical leadership and capacity at a local level is woefully inadequate". In interviews, this view was supported by several senior staff in TCN.

Carson was concerned that there was not enough operational capacity to deliver clinical quality. He recommended that the organisation should increase the capacity by developing clinical leadership roles within existing doctors and nurses.

TCN's lack of clinical leadership at the frontline was also identified in the Tobin review. The report stated "At the time of this review, there was insufficient evidence of effective and reliable clinical leadership at the operational frontline across the full scope of TCN's patient services".

During standard out-of-hours periods at TCN the duty manager was effectively responsible for overseeing operations. Any incidents or issues had to be reported to them. The duty manager was able to reach a senior clinician on the telephone, but generally there was not a senior clinician on shift with the responsibility of assisting the operational manager in overseeing the delivery of the service.

One of the recommendations of the Carson report was that a lead clinician role be created to share responsibility for overseeing operations with the operational managers. TCN had not been able to implement this due to problems with defining the remit of the role and a shortage of available appropriately experienced staff to fill the position. Additionally there were financial implications with adding a new higher paid clinical post to a rota that TCN was already struggling to fill.

TCN made efforts to ensure that one of its few full time senior clinical staff was available on-call. However they had a limited number of personnel at this level, all of whom had other commitments to the organisation. This meant they could only respond to incidents and events rather than providing a 'real-time' clinical overview of the delivery of the service.

Senior members of staff such as the executive director of business strategy and performance and one of the non executive directors confirmed that there was need for more integrated corporate and clinical governance. They noted a need to improve communication between the clinical and operational sides of the organisation.

In her review of governance in early 2009, Tobin noted that TCN faced a significant challenge to communicate effectively with its frontline staff. She considered that the senior leaders shared a coherent view of clinical governance but it was challenging for them to communicate this effectively across widespread geographical clinical locations and their mainly part-time workforce. She considered that significant progress had been made in addressing this challenge but more work still needed to be done to develop and implement an effective communications plan that would consistently connect the top and the bottom of the organisation together. Carson told us his view was that there was no effective structure within TCN to feed back clinical and operational performance to front line staff.

To try to improve communication with staff and the relevant PCT, the board had allocated different contracts to non-executive directors. In their 'patch' the directors were expected to visit services, talk to local GPs and liaise if necessary with the PCT. Only one of them, the chairman, had taken action to visit the patch and communicate with GPs and TCN staff in their area. We also noted that only one of the GP non executive members of TCN's board had ever worked a clinical shift for TCN. This was in June 2009.

Findings of fact on frontline clinical leadership and communication with the frontline staff and local GPs

- The Carson review considered that there had been a concentration on operational matters to the detriment of clinical quality.
- Tobin found that senior leaders shared a coherent view of clinical governance.
- The Carson and Tobin reviews were critical of the lack of frontline clinical leadership and Carson concluded that the current level of clinical leadership was 'woefully inadequate'.
- TCN had not been able to implement having a lead clinician to oversee shifts with the duty manager.
- TCN had problems communicating with frontline staff.
- The plan for non-executive directors to link with specific areas had not been fully implemented.

- Only one of the GP non-executive members of TCN's board had worked a clinical shift for the company.

Strategic aspects of governance and clinical quality

TCN had effective business leadership, as evidenced by their ability to win a succession of NHS contracts. There was a historic lack of clinical capacity, particularly in the area of clinical governance, at TCN. They had between one and two full time equivalent staff working in governance and these had multiple roles, including revising the induction system and ensuring that shifts were filled. This meant that there was less progress in developing clinical quality than in other areas such as operations.

We noted in the previous chapter the frequent changes to the governance structures. The reporting lines were not clear and the frequent changes exacerbated this. It was not clear that the structural changes, particularly in 2008, brought a step change in the effectiveness of the system. For example, the head of clinical services appointed in June 2009 told us that the individual work-streams for clinical governance had largely worked in isolation.

The board decided it needed to strengthen its understanding of clinical governance and appointed an experienced non-executive director who had previously been a chief executive of an ambulance trust. He began to make an input from February 2008 and officially joined the board in April.

The Carson report noted that the operational team had made significant progress in ensuring the service met the required access and response standards. Carson considered this had been at the expense of governance and clinical quality. He said that the organisation had placed operations and finance at the top of its hierarchy. "This had resulted in the clinical quality side always playing catch up."

Tobin thought that TCN was at an early stage of implementing the clinical excellence framework. She recognised the commitment of the senior leaders in clinical governance but recognised that the expanding business portfolio had outpaced their clinical governance skills.

Carson did not consider that the identification and management of clinical risks featured prominently on the agenda of the management team or the board. We have noted earlier that the failure to fill shifts appeared to be seen more in the context of finance rather than as a potential clinical risk. In July 2009 TCN still did not have a strategy or policy for the management of risk.

Following the Carson and Tobin reviews TCN appointed a new head of clinical services in June 2009. This strengthened the leadership capacity in clinical governance. The head of clinical services at TCN told us that she felt that governance was a 'bit of a lone voice', as the clinical governance lead was only part time and the nurse consultant's role covered a wide remit. We have seen that the head of clinical services took active steps to strengthen all of the governance work done in the organisation and to improve working between different areas. She recognised that work was needed to improve accountability within TCN. She devised a new structure for integrated governance and was actively involved in updating key policies. Her work was recognised by her colleagues.

The medical director was viewed by colleagues as having good ideas and describing them well, but being less skilled at implementation. A non-executive director said he was frustrated that decisions that had been taken by the board were not implemented. The medical director said that he was aware when he took up post in June 2007 that governance needed to improve. He considered that it had, but acknowledged that it was not embedded in the organisation. The CQC noted that he sometimes gave an inaccurate or incomplete assessment of situations or description of events. This is covered in more detail later in this part of our report.

The clinical governance lead at TCN told us that he did not think there had been enough investment in clinical governance and that there should have been a more structured

governance group with senior members involved. The lack of an effective interface between operations and clinicians had been an issue since 2004.

One of TCN's non-executive directors stated that the board in early 2009 had recognised the need for more comprehensive governance arrangements. As previously mentioned two external governance reviews and a subsequent internal paper to the board were completed. The appointment of the head of clinical services in June 2009 served as a catalyst in establishing a new, more robust, structure through which the executives would be held to account by better engagement of the non executive directors.

One of the non-executive directors, who resigned from the board of TCN in June 2009, had had responsibility for investigating and learning from complaints. In July 2009 he resigned as chair of the patient safety group and relinquished his complaints role. He said that he had not had sufficient time or support to undertake this work to his satisfaction. He praised the administrative staff but said they were over-burdened.

There were differing views from non-executive directors on the level of challenge at the integrated governance and risk committee.

Findings of fact on strategic aspects of governance and clinical quality

- There was a historical lack of capacity in clinical governance.
- The Carson review considered the focus on operations had been at the expense of governance and clinical quality.
- Tobin considered that the expansion of business had outpaced clinical governance skills.
- TCN appointed a head of clinical services in June 2009 to strengthen clinical governance; she had been active in her efforts to achieve improvement.

TCN and information provided on the diamorphine overdoses, including the serious untoward incident in Cambridgeshire in February 2008 involving the death of Mr Gray

CQC was concerned about the extent to which TCN acknowledged that shortcomings in their internal systems may have contributed to the failure to prevent the incident in Cambridgeshire involving the death of Mr Gray.

Tobin noted in her report that both NHS Cambridgeshire and NHS Suffolk were not confident that TCN fully understood the seriousness of the failure of their clinical governance system at the time of the significant untoward incident in February 2008. They considered that TCN had appeared naïve and complacent at the outset although when interviewed in January 2009 they thought this had changed.

TCN did pursue a number of improvements following the incident. We found, however, that TCN had frequently not recognised that failures in their systems may have played a part in failing to prevent Mr Gray's death. For example, in the meeting with Cambridgeshire PCT in November 2008, TCN's chief executive stated that the incident had been a straightforward error and not a systematic failure. The director of business strategy stated that that this had not been a system failure but an individual cause and it was important to use appropriate language.

The medical director described events leading to the death of Mr Gray during CQC's initial meeting with TCN in June 2009. The medical director reported that an ECP had called in sick for that shift, the implication being that Dr Ubani had been taken on at short notice. That was not correct. He said that when Dr Ubani accessed the palliative care box he needed to contact the duty manager first and let them know he was accessing it. That was not correct. The medical director also said that Dr Ubani had been on the performers list for Cornwall and the Isles of Scilly for over a year before he came to TCN. That was not correct either. No mention was made of the previous

diamorphine incidents. TCN also reported at this meeting (and to others) that it had not been informed of the NPSA Safer Practice Notice issued in 2006. Two other sources disputed this. One was Cambridgeshire PCT which stated at the inquest that Suffolk PCT had shared alerts with TCN and had email evidence of this.

The TCN's brief in May 2009 for the medical and nursing directors at NHS Suffolk did not include key details relating to the circumstances surrounding the earlier diamorphine incidents or the death of Mr Gray. It again included material inaccuracies.

For example, TCN stated that the first incident was investigated using a GP peer review system of assessment and shared with the East of England ambulance service. In fact it was the ambulance service that had raised the concern and the peer review was simply that the clinical governance lead was a GP. It was stated that alerts re diamorphine and other opiates were provided to all clinicians working in system, but this did not happen until after the second incident. No processes were changed at this point, although the report claimed they were.

In the description of the second incident, the summary omitted that it was a family member who had summoned the ambulance. TCN stated that as a result of the second diamorphine incident they implemented 'Very specific opiate drug warnings to all bases and placed on the palliative care box. Acute pain boxes containing 1 dose of Cyclimorph were developed with the manufacturing unit of Ipswich Hospital pharmacy department and introduced to the service in early 2008. However, CQC cannot find evidence that specific warnings were placed on the palliative care boxes before the third incident and the acute pain boxes were not in place until May 2008. The report claimed that this was fully investigated with the PCT and ambulance service, but the involvement with the PCT amounted to a phone call to the PCT followed by a report by TCN, requested by the PCT. CQC has not seen any evidence that the ambulance service was involved in the investigation of this incident.

This report did not record that both the doctors who had been involved with the earlier diamorphine incidents practised in Germany, or even that they were foreign. This obscured the fact that some GPs practising in Europe were unfamiliar with diamorphine and struggling with the appropriate dosage.

In the case of Dr Ubani, the report stated that 'A SUI was raised and submitted through the PCT'. TCN did not immediately inform Cambridgeshire PCT about the death of Mr Gray. The PCT learnt via the patient's GP.

Although the report stated that the clinical governance team recognised that this was the third diamorphine related incident, this was apparently not shared with Cambridgeshire PCT at the time. They found out over a year later.

The report stated that Dr Ubani had received an induction at the agency that had recruited him. However Dr Ubani did not have formal training or an induction session with the agency. TCN did not mention in the report that the GP responsible for carrying out the familiarisation session with Dr Ubani did not formally sign off this session until after the incident had taken place. Neither did it report that he had raised concerns that he was not able to carry out a proper familiarisation session with Dr Ubani due to the pressures of his work commitments at the time the session took place. Nor that it was his first induction.

The report again said that PCTs did not include TCN in all alert cascade systems until 2008. TCN stated that it relied on Ipswich hospital pharmacy for advice and guidance for the drugs and medicines it supplied to TCN. However this was not the view of the chief pharmacist at Ipswich, and there was no contract between TCN and the pharmacy for advice on medicines.

In the initial report on the incident following the death of Mr Gray, the clinical governance lead for TCN stated that it was the third time in a year that TCN had an overdose of diamorphine and that they had 'already identified that it presented a serious clinical risk to the unwary'. The report noted that many doctors from Germany had very little experience in palliative care and in the use of the drugs which were

relevant in this area. It was unclear to the CQC who had received a copy of this report. NHS Cambridgeshire only appeared to become aware of the earlier diamorphine incidents in May 2009 and the CQC obtained this document from the evidence presented at the coroner's enquiry in February 2010. TCN however stated that the report was shared with the PCT shortly after the incident. CQC had asked TCN on two occasions to provide any incident reports in relation to death of Mr Gray and had not been provided with this version.

Findings of fact

- TCN did not recognise there were failures in their internal system in relation to the serious incident in Cambridgeshire, despite the evidence to the contrary.
- At TCN's initial meeting with CQC, some of the information given about the events preceding the death of Mr Gray was incomplete or inaccurate.
- TCN produced a briefing for NHS Suffolk in May 2009 which was materially inaccurate in many respects. Some of the claims made about how incidents were dealt with were exaggerated or incomplete.
- There had been an initial report on the incident which mentioned the earlier overdoses and the inexperience doctors from Germany in respect of palliative care. TCN provided this report to the coroner but, despite requests, did not provide it to CQC.

The culture and maturity of the organisation and board

Carson's overall conclusion was that the organisation needed a "fundamental shift in direction to place clinical quality and response at the heart of its function with finance, operations and HR in support rather than the reverse".

A GP of many years experience was representative of several when he said that he had watched the decline of a good service, and that private companies like TCN only provided the bare minimum of standards. A member of staff who left at the end of 2008 said that, after the appointment of a new director in spring 2008 the organisation changed: "the commercial element took over and began to cut corners in the pursuit of profit." TCN in their view did not want to listen to clinical concerns.

Some current and past non-executive directors of TCN or SDOC told us that many GPs who had been in SDOC considered the culture of TCN had changed and it no longer felt like their organisation. Some felt that the TCN 'brand' was now irretrievably damaged. GPs working for TCN frequently said they felt undervalued.

CQC has concerns that TCN did not recognise problems with aspects of its performance and sometimes gave inaccurate or incomplete information. We have referred earlier to statements made about there being no system failures in connection with the death of Mr Gray.

In his paper to the board in May 2009, the medical director stated that Carson's view of the gap between clinical quality and operations is 'a statement for which no specific evidence is proffered and which is strongly at odds with the findings of Tobin'. Yet Tobin did refer to this matter in her report, noting that the business portfolio had outpaced clinical governance.

When concerns were first raised in Worcestershire by the whistle blowers via the LMC, TCN wrote a response in April 2009 that in places put the responsibility for problems on the calibre of its staff. For example the report stated that the nature of the challenge was severe in Worcestershire in terms of the competence, engagement and willingness of certain staff to be open to training, change and performance management. The perspective of staff was they had not had the support and training they had been promised. In the CQC's survey, 71% of respondents in Worcester disagreed or strongly disagreed that they felt supported by senior management.

In April 2009 TCN also told NHS Worcestershire, in response to a concern, that this problem had been the responsibility of a named member of staff who no longer worked for TCN in that area. In September 2009 when

CQC reported that a nurse had been mistakenly identified to us as a GP, a member of staff with the same name was identified as the person who had given us the incorrect information. This was in the East of England. TCN's chief executive told us in November 2009 that the person no longer worked for the organisation.

In their response to concerns about staffing and unfilled clinical shifts in the external review in Worcestershire in May 2009, TCN reported that they provided more hours than had been agreed in the contract. This was odd since TCN told the CQC that the rota in the contract was for illustrative purposes only. TCN also said the reviewers' claims were not supported by TCN's analysis of rotas. However our analysis showed that 11% of shifts were unfilled between March and May 2009. Our own observation visits and analysis of rotas have shown that despite the many assertions of TCN about the flexibility of their system and ability to respond, they frequently failed to fill shifts across wide geographical areas thereby compromising the capacity and responsiveness of the entire system.

In respect of call streaming, and how it was introduced, TCN constantly referred to trials yet there was only one set of audit data and the 'trials' ran for unspecified periods of time. This policy clearly stopped being a trial and became an operational process.

We wanted to gain insight into the workings of the TCN executive and their priorities by looking at the minutes of their meetings. We were initially told that this would not be possible because the minutes contained commercially sensitive information. CQC confirmed in writing that it would be careful not to put anything of this nature in our report unless it was clearly relevant to this investigation. TCN then sent the minutes from March to October 2009. After further communication and two months delay TCN stated that no record had been taken of the meetings of the executive before 2009. The minutes from March to October indicated the group met at irregular intervals. They were of variable quality and for the meeting on 1 September there were two different sets. As mentioned previously, we considered that TCN generally did not have a high standard of minute taking.

There was evidence in the board minutes of the need to make savings and ensure that the interests of shareholders were met. In January 2008 the chief executive noted there would be further savings associated with skill mix and doctors pay. In August 2008 it was noted at the board that, although not by design, unfilled shifts contributed to savings. A GP who had worked shifts for TCN said the whole structure was "designed to cut costs to the bone". Despite cost cutting TCN's accounts did not show a profit in 2007/2008 or 2008/2009.

In October 2008 the board discussed the different legal responsibilities for public bodies and limited companies. It noted legal advice that they could do anything that was not explicitly forbidden by law. In setting key performance indicators they needed to ensure they were looking after shareholders interests, and to "do enough to comply without damaging shareholder value through over bureaucratisation".

In December 2008 the board agreed there could be no reduction in clinical service; that they needed to performance manage the weaker clinicians and that shifts must not be overloaded. In respect of Worcestershire, it was noted that the revenue was to be increased. They claimed that rotas had initially been overstaffed (i.e. more staff put on than required) but this had been addressed.

One of the non-executive directors told us that although he felt the executive team were comfortable being challenged by the non-executive directors, he was not sure the non-executive directors had the sufficient financial and governance skills to ask the right questions.

Information provided by TCN to PCTs and the CQC about activity was ambiguous about the fact that the total activity figures produced via the HMS reports did not equate to the number of patients. This was apparent in responses to us, for example when asked for total calls handled at each of the call centres broken down by PCT, TCN sent total contacts in a file called "calls by month by pct". Moreover the front page of the original performance reports

for Worcestershire from the start of the contract until March 2009 stated that the total number of calls made to the service was the same as the total number of contacts.

TCN stated in their response to CQC in December 2009 that in terms of using activity and performance data to negotiate with their clients, they believed they had been open around how they accounted for activity in any reporting or requests for uplifts in revenue. In interviews with TCN's client support managers however it was clear that they did not fully understand the activity data or the reporting of performance when call streaming took place. In Part 3, we will show that the managers in PCTs responsible for monitoring the contracts did not fully understand the figures either. When we interviewed TCN's non-executive directors, they did not understand the problems with the activity data in TCN's performance reports. When it was explained to them, they acknowledged that the lack of transparency could misrepresent TCN's performance and was potentially serious, especially if linked to clinical safety or financial reward.

We noted that TCN and its commissioning PCTs in the east of England, generally had not developed mature relationships such that they were able to discuss staffing problems and financial pressures. For an out-of-hours organisation such as TCN a large proportion of its budget was devoted to paying clinicians and therefore a small increase in hourly wages translated into a large increase in operational expenditure. There was, however, a lack of evidence to indicate that TCN had articulated these concerns to the commissioning PCTs. Given that TCN was not significantly cheaper than other rural out-of-hours organisations, as shown by the PCF benchmarking reports, it was unclear why TCN's rates of pay were lower than neighbouring services.

Findings of fact

- Carson stated that finance, operations and HR were at the heart of TCN's function, rather than clinical quality and response.
- Many clinical staff considered that the culture of the organisation had changed.
- TCN failed to provide minutes of the meetings of the executive before March 2009, first on the grounds of commercial confidentiality and then stating that no record had been taken of the meetings of the executive before that date.
- TCN on occasion provided information that was incomplete or at variance with the facts.
- Information provided by TCN to CQC and the PCTs was ambiguous about the fact that the total activity figures produced via the HMS reports did not equate to the number of patients. Neither TCN's staff nor those in the PCTs responsible for monitoring contracts fully understood the figures.
- The non-executive directors did not understand the activity data that TCN entered in its performance reports. The non –executives acknowledged the lack of transparency could be serious, if finance or patient safety was involved.

Surveys and benchmarking of TCN's performance and the views of people who used their service

Summary of findings in this chapter

- In local surveys, TCN performed well on quantitative measures of satisfaction, with an 88% overall satisfaction rate. Using the relevant questions in the 2008/09 GP national survey, TCN achieved a score very close to the national average, and it was ranked 63rd out of 101 out-of-hours services.

In 2004 Suffolk West PPI Forum, worried about the changes to out-of- hours services, began conducting surveys of people who used out-of- hours services in the Suffolk area. This programme of surveys was conducted by a retired consultant from Suffolk. Surveys were conducted three times a year during the months of March, July and November. In March 2008 the surveys were expanded to cover users of TCN's out-of-hours services in the Great Yarmouth and Waveney and East Cambridgeshire and Fenland areas.

The surveys were conducted by choosing a Saturday in the relevant month and sending a questionnaire to all patients who contacted the service on that day. TCN knew the date of the survey in advance as it was responsible for sending out the questionnaires. TCN received the responses in special envelopes which were originally forwarded unopened to the forum member for independent analysis. This practice was later changed with TCN opening the envelopes first and checking for any issues that were inappropriate such as prescription payments or queries that might require immediate action. Response rates for these surveys have generally been around the 33% but varied from 26% to over 40%. On average there were about 360 responses to each survey equating to just over 1000 per year.

The surveys were split into two parts. The first involved individuals rating their level of satisfaction against seven areas: getting through on the telephone, way initial call was handled, time before they spoke to a clinician, manner of clinician, explanation given to the patient, treatment or advice given and overall satisfaction. The second was descriptive where respondents were encouraged to comment about their experience of the service. Results for the first, quantitative element of the survey indicated a high level of satisfaction with the service with the vast majority of respondents (88%, taking all the surveys into account) rating their overall satisfaction as either 'satisfied' or 'very satisfied'. The qualitative comments presented a more varied picture of the service with around half of the comments being positive and the other half being negative. For both elements of the survey the area of greatest dissatisfaction was with waiting times and in particular waiting time to speak to a clinician.

In addition to the independent surveys referred to above, as part of national quality requirement 5 TCN also conducted its own surveys, in Suffolk, Cambridgeshire, Great Yarmouth & Waveney and Worcestershire. For the East of England PCTs these surveys were conducted monthly with results presented as rolling quarterly summaries in the monthly performance reports (e.g. in the May report there would be total results for the February, March and April surveys) while for Worcestershire a single survey was conducted each quarter. The TCN surveys mirrored the independent ones but only had a quantitative section, the results were also similar with over 80% of respondents rating their overall

satisfaction as either 'satisfied' or 'very satisfied' and waiting time to speak to a clinician being the area of greatest dissatisfaction.

These surveys provided useful information but did not provide comparisons with other out-of-hours services. As part of their national benchmarking exercises the Primary Care Foundation, working in partnership with an organisation called CFEP UK Surveys, surveyed patients' views of out-of-hours services. The surveys were conducted by CFEP who used a confidential mailing system to send them to service users. Responses were returned to CFEP who analysed them while protecting patient anonymity.

The survey consisted of four main questions relating to people's experience of out-of-hours services. CFEP analysed the responses and provided a report both for the commissioner and provider, showing comparisons with national averages as well as breakdowns based on factors such as the outcome of calls (e.g. advice, base or home visit).

We looked at results from the CFEP surveys in September 2009 for each of the PCT areas in which TCN provided all of the out-of-hours service. In summary, the results show:

1. Great Yarmouth & Waveney: TCN achieved their best scores in this PCT area with only one question (rating of time for call back) falling below the national mean.
2. Suffolk: For five of the twelve benchmarked questions the results were equal to the national mean, for the remaining seven questions Suffolk fell below the national mean.
3. Worcestershire: scores for every question were below the national mean and fell within the lower quartile of scores nationally.
4. Cambridgeshire: as with Worcestershire the TCN scores for this area were all within the lower quartile nationally.

The 2008/2009 National GP Patient Survey contained seven questions relating to out-of-hours services. Questionnaires for this survey were sent out in January 2009. Using the results for the question which rated the care received from the out-of-hours GP service, PCTs can be ranked according to the percentage of respondents who scored the quality of care from the out-of-hours service as good or very good.

Below are the rankings for the 3 PCTs where TCN was the sole out-of-hours provider:

1. Suffolk: Rank 78th (out of 152) - 65% good or very good
2. Great Yarmouth & Waveney: Rank 73rd (out of 152) - 66% good or very good
3. Worcestershire: Rank 79th (out of 152) - 65% good or very good

Using the same ranking method, TCN as an organisation was ranked 63rd out of 101 out-of-hours providers with a score of 65% good or very good, compared to a national average of 66%. The highest ranked PCT achieved a score of 78% good or very good, the lowest 46%, and there was an overall national score of 66%.

The 2009/2010 National GP Patient Survey also contained seven questions relating to out-of-hours services with results of these currently available for the first two quarters. The PCTs were again ranked according to the percentage of respondents that rated the care they received from the service as good or very good. The three PCT rankings for the first 2 quarters of 2009/10 were as follows:

1. Suffolk: Rank 85th (out of 152) - 65% good or very good
   2. Great Yarmouth & Waveney: Rank 36th (out of 152) - 70% good or very good
   3. Worcestershire: Rank 76th (out of 152) - 66% good or very good

The highest ranked PCT achieved a score of 77% good or very good, the lowest 48% and the overall national score was 66%. Results for individual out-of-hours providers have not yet been released for the 2009/2010 survey.

Other than for patient experience, in their benchmarking report in March 2009 for Suffolk PCT the Primary Care Foundation stated that they were unable to benchmark TCN in a number of areas due to TCN's inability to provide an appropriate data extract. This was also the case in November 2009. This was an

issue for all of the PCTs that commissioned out-of-hours from TCN and was due to the HMS system being unable to provide a compatible extract of data at that time.

Experiences of people who used TCN's services

Some common themes emerged from relatives and patients who contacted the CQC or sent us information and from discussions with local stakeholders. These themes can be broadly grouped as follows:

- The apparent lack of concern shown by some clinicians particularly when it came to requests for home visits. While in many circumstances a home visit may be unnecessary and not the best use of clinical resources, we heard some accounts where important symptoms were missed due to patients not being seen face to face.
- A major concern in some localities, particularly Wickham Market, was that on occasions people would turn up to a TCN base, sometimes with an appointment, only to find the base closed and a note directing them to a different base several miles away.
- As noted in some of the survey work conducted in TCN's localities, waiting times, particularly for a clinician to call back, were an area of discontent. Some members of the public also complained of occasions when they never received a call back from a clinician.
- There were some concerns that rather than speaking to a GP as they expected the clinician was actually a nurse or ECP.
- Others expressed dissatisfaction with responses to complaints by TCN, incorrect prescribing advice and diagnoses being missed.

It should be noted that there were also some complimentary accounts of TCN's service praising the quality of staff and timeliness of the service.

The Healthcare Commission's review of urgent and emergency care

In September 2008 one of our predecessor organisations, the Healthcare Commission, published a national review of urgent and emergency care services in England. This review looked at out-of-hours GP services, A&E services and urgent care centres, emergency ambulance services and, to a lesser extent, urgent GP services delivered during usual surgery opening hours and NHS Direct. Data was gathered from all these services to produce a combined assessment of urgent and emergency care across each local area, based on the boundaries of each of the 152 primary care trusts (PCTs) in England. The headline results from this review for the five PCTs that commissioned services from TCN are given below. Results were grouped into three main themes of 'Can people access services in a timely fashion, and in ways which meet their needs?', 'Are services working together to provide effective care?' and 'How well are urgent and emergency care services are managed?'. It should be noted that at the time of this review TCN was not yet providing the out-of-hours service in Worcestershire. Also, the results are based on PCTs, so it is not possible to identify the specific effects of different out-of-hours providers.

- NHS Suffolk scored overall in the best performing category for urgent and emergency care, where 'best' is described as "found that the urgent and emergency care services in this area were better in a number of aspects than services in most other organisations". The PCT received above average scores for each of the three main themes.
- NHS Cambridgeshire scored overall in the best performing category for urgent and emergency care. The PCT received above average scores for each of the three main themes. *NB These scores were for all urgent and emergency care providers in Cambridgeshire not just TCN*
- NHS South West Essex scored overall in the least well performing category for urgent and emergency care, where 'least well' is described as "services in this area did not perform as well as those in many

other areas in a number of key aspects, and they need to improve". The PCT received low scores for indicators across all three main themes, and performed below average overall for all three themes. *NB These scores were for all urgent and emergency care providers in South West Essex not just TCN*

- NHS Great Yarmouth and Waveney PCT scored overall in the best performing category for urgent and emergency. The PCT received above average scores for each of the three main themes.
- NHS Worcestershire scored overall in the least well performing category for urgent and emergency care. The PCT received below average scores for each of the three main themes. It should be noted that one of the main reasons for this was that the service provider (the PCT) did not supply the necessary data and was therefore automatically given the lowest score for a number of indicators.

Findings of fact on results of surveys

- In the locally conducted surveys, TCN performed well on quantitative measures of satisfaction, with an 88% overall satisfaction rate.
- Half the descriptive responses were positive and half negative. The latter largely reflected concerns about delays.
- In respect of the CFEP surveys, the results were mixed. They were good for Great Yarmouth and Waveney with only one score below the national average. For Suffolk about half the scores were equal to the national average, and half were below. For Cambridgeshire and Worcestershire, the scores for every question were below average and in the lowest quarter nationally.
- Using the relevant questions in the 2008/09 GP national survey , TCN achieved a score very close to the national average, with a score 65% 'good' compared to 66%, and it was ranked 63rd out of 101 out-of-hours services.

Conclusions

Summary of conclusions

1. TCN struggled to recruit local GPs and relied heavily on doctors flying in from Europe to work weekends. Some doctors worked long hours. TCN tolerated staffing levels that were potentially unsafe, with pressure on other staff.

2. TCN failed to recognise the importance of learning lessons from complaints and incidents. It was not sufficiently focused on clinical risk and did not adequately report or investigate serious incidents. In particular, it failed to act quickly enough on the concerns that emerged from the two overdoses of diamorphine in 2007, or on the NPSA safer practice alert in 2006.

3. Systems for TCN's medicines management were inadequate, leading among other things to controlled drugs being stored and administered inappropriately. Recently medicines management had improved and the system for accessing controlled drugs was more robust and easily monitored.

4. TCN reported activity in a way that was confusing and potentially misleading, and did not act to resolve this. The performance that TCN reported to PCTs on the national quality requirements did not accurately reflect the actual performance of the organisation, and could potentially have concealed poor performance.

5. TCN grew too rapidly and the focus on expansion and business priorities was at the expense of governance and clinical services. Although clinical governance was well articulated by TCN, there was insufficient capacity to deliver it. It was not rooted in frontline patient services, nor demonstrated by clear accountability or local clinical leadership.

6. TCN failed to recognise problems in its own systems that might have helped prevent the death of Mr Gray. It was reluctant to admit its shortcomings and provided information to the PCTs and to us that was often inaccurate or incomplete.

Events preceding the death of Mr Gray

A number of factors were associated with the death of Mr Gray on 16 February 2008. Chief among these was the poor knowledge and practice of Dr Ubani, who did not understand the strength of diamorphine and administered such a large dose of the drug that it killed Mr Gray. This was the judgement of the coroner, who decided Mr Gray had been unlawfully killed.

However, there were also failures in the internal systems at TCN that could have helped prevent the death of Mr Gray. In 2006 the NPSA issued a safer practice notice because of a number of reports of deaths due to the administration of high dose (30mg or greater) diamorphine or morphine injections. Organisations were asked to assess their procedures for the prescribing, labelling, supplying, storing, preparing and administering of diamorphine and morphine injections. This

was to be complete by October 2006. TCN claimed they had not known about this notice and so had not taken any action. However Suffolk PCT had evidence which suggested that TCN had been notified. Their own drugs coordinator had also raised this matter internally.

TCN did not have enough local doctors to fill its shifts and so was reliant on doctors, many of them practising in Germany, flying over to work weekends. Diamorphine is not widely used in Germany. Dr Ubani was one such doctor. We now know that there were problems with his referees and that he was not automatically accepted when he tried to join the performers list of NHS Leeds. Dr Ubani withdrew his application before he was formally rejected and this meant that NHS Leeds was not required to alert the GMC to his application. NHS Cornwall was not aware of this when it accepted him onto its performers list in summer 2007.

Dr Ubani had not been recruited at short notice, so should have had a full induction. It was his first shift working in the out-of-hours service in England. The induction file he was given was poorly organised and the information about controlled drugs was not prominently displayed. The doctor who conducted the familiarisation shift had never done this before and was already busy, both working a shift and supervising a GP trainee.

Perhaps most significantly, there had been two previous incidents in the previous 12 months of patients being given overdoses of diamorphine. In both instances the doctors involved had been practising in Germany and had come to England to work shifts in the out-of-hours service. Both the patients involved were taken to hospital, given an antidote and survived. Neither of these events was reported as a serious untoward incident, although they should have been. The second in August 2007 was notified to Suffolk PCT, but in the context of whether the doctor involved needed training. The PCT did not report it to the SHA as a SUI.

The day that the second incident occurred TCN's lead for clinical governance sent a memo to TCN clinicians, reminding them of safety matters when giving opiates by injection. The memo pointed out the different strengths of morphine and diamorphine, suggested that normally no more than 5mg of diamorphine should be given, that it should be administered subcutaneously and that it was hardly ever appropriate to open the 30mg ampoule of diamorphine. This memo was in the induction pack and available to clinicians who joined TCN after August 2007. However, the pack was poorly organised.

After the second incident the lead for clinical governance at TCN asked the clinical governance committee in December 2007 whether this should be considered as a system problem in TCN. The group did not think so. It was agreed and recorded in the minutes of the December meeting that extra documentation should be placed with the boxes, but there was no evidence that this happened.

The minutes of the governance meeting on 3 January 2008 recorded that the doctor who had mentored the doctor concerned in the second incident, felt strongly that "that there is a systematic problem inherent in the current set-up and that, if we do not address this, it is only a matter of time before a patient is killed by an overdose of morphine from one of our palliative care boxes". The proposed solution was to remove the palliative care boxes from the TCN cars and to issue them only on direction from the control centre, following approval from a second GP. It was felt by the staff in the control centre that removing the boxes from the cars would pose an unacceptable burden on the service. They accepted the proposal for a second GP to act as a referee but with the boxes continuing to be available in the cars. The clinical governance lead was to draw up a proposal for this scheme, including the suggested boxes containing medication to relieve acute pain.

On 15 January 2008 the lead for clinical governance at TCN, emailed a discussion paper proposing changes to the palliative care boxes to senior TCN staff, including the medical director, and staff at Ipswich Hospital Pharmacy. He raised concern that these two incidents had occurred as clinicians had inappropriately administered diamorphine. He considered that action needed to be taken to rectify their current system before a death occurred. The email did not mention that both

doctors in the previous incidents trained and practised in Germany.

The proposal suggested the introduction of smaller 'pain boxes' to be used to treat acute pain and discourage the use of the palliative care boxes in these instances.

On 16 February 2008, there was a further serious untoward incident in Cambridgeshire services, resulting in the death of Mr Gray. The pain boxes were introduced in May 2008.

It is easy to be wise after the event. However, we consider there were clear warning signs that an effective system of governance could have identified and acted on earlier, possibly helping to prevent the tragedy that occurred.

What were TCN's arrangements for staffing and handling calls ?

Before the death of Mr Gray, clinicians did not always have an induction before they started working shifts. Those doctors who had the responsibility to familiarise new clinical staff with arrangements, had to undertake this role in addition to their other duties on a shift.

The arrangements to recruit and induct non clinical staff were reasonable, but the CQC was concerned that TCN on occasions used drivers obtained from agencies or even taxi drivers to transport clinical staff to patients' homes. There was no certainty that these staff had been checked for a criminal record or that confidentiality could be guaranteed.

TCN had no centralised training records before late 2008 and had very limited records of training events and attendance before this. It was a matter of concern that virtually no non-clinical staff including receptionists, drivers and call handlers, had received standard training on equality and diversity, child protection and protection of vulnerable adults

TCN did not undertake routine audit of their call handlers, even though they used them to establish whether calls were routine or urgent. The CQC found the standard of call handlers to be generally reasonable. The handlers were very good at greeting patients although particularly in Ipswich, the tendency to read potentially sensitive demographic details off the screen to the caller, in contravention of TCN's guidance, was worrying. Another area of concern was that the call handlers had not made a full record of all the relevant symptoms in a number of calls.

In terms of outcomes for patients, it was a matter of concern that our audits found 12% of calls (where call handler prioritisation could be assessed) had not been given sufficiently high priority. This was particularly because when call handlers rated the priority as routine, they could be expected to ask callers whether they would like to go straight to a base, rather than talk first to a clinician. If the caller chose to go to a base, it could be a considerable period before they saw or spoke to a clinician.

The decision to introduce call streaming and bypass triage in this way had been agreed with PCTs at contract monitoring meetings. In many cases, clinical staff from PCTs did not attend these meetings.

TCN was not consistent about the rationale for call streaming. Initially it was explained to us as increasing patient choice, but we noted it was only introduced for busy periods. It was likely that at least part of the rationale was to improve the figures for triaging calls. As noted by PCF, call streaming can be a useful approach, provided the system is audited. Protocols operated by call handlers need to be clear and consistently applied, and the change in practice and outcomes audited. Although TCN told us that call streaming had been audited when it was introduced, there had only been one audit and then the change had been incorporated into practice without any further checking.

TCN did not ensure that when calls came in that related to symptoms of stroke, the call was immediately diverted to 999. Although TCN told us when we found this to be the case in Ipswich that it was because staff had given us an out-of-date protocol, we found the same protocol still in use in the call centre in Worcester a month later.

Out-of-hours services, particularly in rural areas, face challenges with communication and difficulties with having a geographically spread workforce. When CQC visited the

bases, staff told us that communication was poor and there was a distance between the senior management of the organisation and the front line staff. There was a lack of communication from senior management and staff felt that they were not engaged or consulted. TCN staff considered the Clinical Bulletins as helpful and about half thought that the electronic system, Sharepoint, was useful, although it could have been better organised. Staff did not rate team meetings highly.

Clinical coverage at TCN

In some areas TCN struggled to recruit local GPs. This was in part because their pay rates were low compared to neighbouring out-of-hours services. TCN's lead for clinical governance noted in 2008 that TCN was heavily reliant on the use of overseas doctors. The CQC found that in the East of England between October 2008 and November 2009 about 20% of shifts were worked by doctors who were not on local PCTs' performers lists. It was not a contractual requirement for TCN to use doctors on local lists. In Worcestershire between August and November 2009 the proportion of shifts worked by GPs not on local PCTs' performers lists, was over a quarter, at 31%. 28% of doctors working in Worcestershire in this period were supplied by agencies.

The difficulty with recruiting GPs and filling shifts meant that some doctors worked excessive hours. Clinicians were not supposed to work more than 12 hours consecutively, and more than 16 hours in a 24 hour period. The CQC considers that these standards were set at a level that could lead to doctors being tired. In the event they were exceeded, and there were 12 occasions between March and May 2009 where a clinician in the East Anglia area worked more than 16 hours in a 24 hour period. In Worcestershire in the same three months, there were over 100 occasions when a GP worked more than 12 hours consecutively.

While these rules might be implemented by the rota team in planning shift coverage, all the problems with long hours occurred on weekends or bank holidays. Given the operational pressures on duty managers during shifts it was entirely possible that they extended a clinician's hours or increased their number of shifts without reference to the number of hours that clinician was working.

TCN did not monitor these hours effectively and the CQC has concerns that tired doctors were working particularly at times of intense activity or when they were not enough GPs working, posing a risk to patients.

One of the concerns of staff working in the service and local stakeholders was the failure of TCN to fill clinical shifts, with consequent closure of bases and pressure on remaining staff. This was an area the CQC investigated in depth, via rotas, surveys and unannounced visits. All of these methods confirmed that clinical shifts were often unfilled.

TCN considered that 95% coverage was satisfactory, and did not report to PCTs those occasions on which bases were closed. However clinical staff were concerned that the areas they were responsible for, were too large to cover safely and they had too little support.

Our analysis of rotas in place in TCN's bases from March to May 2009 found that 8% of shifts were unfilled. This amounted to more than 3000 hours. By September and October 2009 the situation had deteriorated with 10% of clinical shifts unfilled in the East of England and 18% in Worcestershire.

The survey of TCN's staff that the CQC conducted found that 52% thought that clinical staffing levels were not good or poor. Staff also told us that their concerns about poor staffing were ignored or dismissed.

Our weekend at the end of September spent visiting bases in the East of England reinforced the information derived from staff and our analysis of rotas. In summary, we found an unfilled doctor's shift at Wisbech on Saturday morning, the base at Ely closed on Saturday morning because there was no doctor available, the base at Newmarket closed at 6pm because there was no doctor available, and we learnt there was no doctor at Sudbury either. Staff told us this was not unusual. The duty log for the Saturday night clearly recorded serious concerns about staffing levels and the safety of patients

The nurse practitioner at Wisbech on Saturday evening was the only clinical member of staff for the entire East Cambridgeshire & Fenland area. She expected there to be a doctor at Newmarket and had not done home visits before. When we contacted the duty manager at Ipswich with our concerns, he mistakenly informed us that the nurse practitioner was a doctor. In response to the CQC, TCN took steps to try and spread the coverage. However, we remained concerned.

TCN responded to external concerns about unfilled shifts, including those raised by CQC, by describing their ability to respond flexibly to demand by using a centralised triage system and getting clinicians to cross cover areas. This system meant that triage could be conducted from any location, including some clinicians' homes, and any spare capacity at one base could be used to make up for shortfalls in capacity at other bases. Even with their flexible staffing system, we found low levels of clinical cover across large areas which meant that at times the entire system was stretched, potentially resulting in poorer responses or lower levels of care for patients.

We later identified that there were four other occasions in September 2009 between midnight and 8am where a nurse in Wisbech was providing the sole clinical cover for the East Cambridgeshire and Fenlands area, with no supporting clinician at Newmarket. Since the out-of-hours base in Bury St Edmonds was closed from midnight the nearest doctors on those occasions would have been the GP in Great Yarmouth (79 miles from Wisbech) and another in Beccles (76 miles from Wisbech) and 2 car- based GPs working from the Ipswich base (77 miles to Wisbech). On two of these occasions the second GP car at Ipswich was covered by a nurse practitioner and on one occasion the Great Yarmouth GP shift was also unfilled. We also noted that in September and October 2009, 40% of doctors' shifts in East Cambridgeshire and Fenland were covered by a nurse practitioner or ECP, with no supporting clinician within at least an hour's drive away. The pressure on staff was increased when they were also expected to support minor injuries units.

Using a nurse practitioner to fill a doctor's shift involved approval from the clinical team at TCN, but was not formally recorded anywhere. It was not clear what criteria, aside from willingness, were used to decide that a particular nurse practitioner or ECP had the requisite skills to cover for a GP. Although there were some restrictions on the types of patients ECPs and nurse practitioners could see, they were able to see babies and young children over six weeks of age. There are no national restrictions on this issue.

Given that duty managers (non-clinical staff) were responsible for allocating calls while on shift, often in a time pressured environment, there was the potential for patient safety to be compromised with the duty manager expecting a GP to be present when actually it was a nurse practitioner or ECP.

Due to the number of unfilled shifts TCN had on occasions closed bases, extended clinician shifts, paid higher rates for short notice shifts, used nurse practitioners or ECPs to cover for GPs, or brought in agency staff at short notice to try and improve cover for areas. We noted these were all reactive measures. TCN seemed to accept shortage of local GPs working as fixed and was engaged in 'fire fighting', rather than anything more fundamental. Shutting a base was not perceived as a potential risk to patients and was not routinely reported to PCTs, nor was the need to shut bases formally defined as a risk and entered on the risk register. It was troubling that, in August 2008 it was noted at the TCN board that, although not by design, unfilled shifts contributed to savings.

How TCN reported its activity

The way in which TCN reported activity was confusing and potentially misleading. Most providers report activity such that for each patient there is just one record. The number of cases or 'patient journeys' is the same as the number of contacts, whether or not the patients receive advice, visit the base or have a home visit.

However, in the HMS appointment booking system, as used by TCN, if a patient was triaged and given an appointment for a visit to

a base, two patient contacts were created for this one case (one patient). These were one for the call handling and triage stage, and one for the visit to a base. This was sometimes referred to as 'double counting'. Additionally, the system was inconsistent because when patients received home visits or attended the base without an appointment, it did not generate another contact.

The activity tables presented by TCN in the monthly performance reports gave the figure for total contacts which was significantly higher than the total number of actual cases/patients. In Worcester, the performance reports for Worcester even stated on the front page a figure for 'total calls' which was actually total contacts, *not* total calls. This changed in April 2009. In August 2009 when we initially requested numbers of calls handled at each call centre broken down by PCT, TCN sent a table showing total contacts.

A PCT might be under the impression that total contacts meant total cases/patients and therefore have overestimated the level of activity in out-of-hours, which could have affected contract negotiations. For example, the value of the out-of-hours contract was increased by NHS Worcestershire by 9% in 2009/2010, backdated to October 2008. This was a result of the claim by TCN that there had been an increase in activity levels above that predicted for the service when the contract was negotiated. The original activity baseline was derived from the number of calls that had been handled by the previous out-of-hours service. TCN presented a forecast increase in call volumes for a 12-month period based on the activity experienced from 1 October 2008 to 18 January 2009, and requested a two-year non-recurrent uplift of 20%. The exact methodology used to calculate these forecasts is unclear particularly in regards to how the effects of high seasonal demand and the availability of only a short period of demand data were accounted for.

Alongside the proposals for a contract uplift TCN also provided weekly volume reports. These, however, only gave figures for total contacts and would not have allowed the PCT to accurately assess changes in call volumes. The activity in the performance reports confused 'contacts' with 'patients'. We have already noted that TCN's client service managers did not fully understand the activity figures and neither did those in the PCT with responsibility for monitoring the contract. Some staff in TCN raised concerns about the way activity was represented but, although senior staff in TCN were aware of these problems, the matter had not been resolved.

Given the separation of the CMS system (call management system) from HMS, it was not clear why TCN did not also regularly report the total number of incoming calls to each of the PCTs and thereby reduce the potential confusion around the total contacts figure.

Since a large proportion of base visits was not recorded against NQR 12, (the time from definitive triage to being seen face to face), TCN's reporting of performance on this standard was based on small numbers and therefore inaccurate. Although there was no evidence to suggest TCN was systematically utilising this feature to improve compliance against this standard, as TCN was unable to produce waiting times for these calls it was not possible to tell whether patients had been waiting for inappropriate lengths of time.

The reported performance of TCN against the NQRs was not accurate and did not reflect the actual performance of the organisation which meant possible poor performance could have gone unnoticed.

TCN's arrangements for the management of medicines

Ipswich Hospital pharmacy supplied TCN with drugs until TCN changed supplier to Fairview pharmacy in the spring of 2009. There was no formal contract in place between TCN and Ipswich Hospital pharmacy. TCN had no pharmacy adviser until September 2007, when TCN appointed an external consultant to provide advice one day per week.

The first policy on the management of medicines was issued in September 2007. This policy was written by the clinical nurse lead with input from the medical director, but without any pharmaceutical advice. It had no supporting policies such as for controlled drugs

and was unsatisfactory in a number of respects. It did not provide sufficient detail and had some inaccurate information.

TCN's pharmaceutical adviser reviewed the policy after the death of Mr Gray in February 2008 and deemed it should be entirely re-written. A revised policy was produced in April 2009, but this needed further revision since parts were inappropriate, having been copied from a PCT policy. There is no evidence that policies for the management of medicines were shared with commissioning PCTs, other than NHS Cambridgeshire, until April 2009.

Before the removal of the palliative care boxes from the TCN system and the introduction of the controlled drugs policy in November 2008, guidance and procedures surrounding access to controlled drugs were insufficient. In April 2007 diamorphine was lost and could not be accounted for. The revised system for accessing controlled drugs was more robust and easily monitored.

The revised TCN policy in September 2009 specifically prohibited GPs from carrying their own stocks of controlled drugs from their own dispensaries. However, during visits we observed some GPs doing precisely that.

The National Patient Safety Agency issued a safer practice alert in 2006. It required that organisations took action in respect of prescribing, labelling, supplying, storing, preparing and administering of morphine and diamorphine. This went to all the PCTs and NHS Suffolk had evidence that it would have been sent to SDOC and hence TCN. The drugs co-ordinator for TCN at that time also told CQC that she escalated this alert internally within TCN. TCN stated that they did not receive this alert and hence did not take any action. Before January 2009 TCN did not have a formal system for ensuring staff were aware of alerts. We also noted that the manufacturing unit of Ipswich Hospital pharmacy, in its role as producer of the palliative care boxes, had not acted on the alert. The pharmacy considered its role as solely that of manufacturer and assumed TCN had its own governance arrangements. As there was no formal service level agreement between the two organisations their responsibilities for such matters were unclear.

By January 2009 TCN had produced a policy for alerts, but there had not previously been a formal system for disseminating alerts and ensuring staff were aware of these.

TCN was not able to use their software system to routinely audit prescribing by individual clinicians

Clinical governance at TCN

Incidents and complaints

Because the system for recording and tracking incidents and complaints had been paper based, and the initial classification scheme was so simplistic, it was difficult to identify themes in incidents or complaints. Because TCN did not undertake any detailed analysis of themes, there was less possibility of learning and rectifying matters.

The CQC found that some serious events and situations had not been recognised and reported as serious untoward incidents, and there had been inconsistent reporting to PCTs of serious clinical problems. There was also an inconsistent approach to investigating some cases including deaths, where internal system failure or clinician performance could have been an issue. There was little evidence of root cause analysis, lessons learnt or recommendations.

Of the six original serious untoward events that were reported, only two generated reports. There was little evidence of thorough investigation or root cause analysis in the TCN documentation on SUIs until autumn 2009.

The identification and management of clinical risks did not feature prominently on the agenda of the management team or the board. In July 2009 TCN still did not have a strategy or policy for the management of risk. The failure to fill shifts was seen more in the context of finance rather than as a potential clinical risk.

We have noted above that incidents and complaints were not logged or dealt with efficiently, and themes were not consistently identified so lessons were learnt. It was a major failure that SUIs were not identified, reported and investigated adequately, and that

PCTs were not always informed about significant clinical failures.

Audit of clinicians and dealing with poor performance

TCN did not start to audit the clinicians working in its service until February 2009. The CQC considered that the random generation of calls for auditing purposes that TCN's software system could generate, was an example of good practice. TCN audited what the clinician had recorded on the system, but did not listen to voice recordings of the call. Overall TCN judged that 83% of calls met or partially met the required standard. CQC also undertook an audit of the standard of triage and, for one sample, compared our findings with the results obtained on the same sample of doctors and nurses by TCN. There was reasonable agreement on the proportion of those who had not met the required standard, but CQC considered that a higher proportion had only partially met the standards, than did TCN. It was interesting that in our audit the scores were better when clinicians were assessed using a tape recording of the call as well as their notes, to assess their performance.

The area where clinicians were most likely to under perform, was in telling callers what to do if the patient's symptoms got worse, and recording that they had done this. In TCN's initial audit, 54% of the calls audited did not have a record of adequate 'safety netting'.

TCN sent the scores to staff without formal feedback or appraisal sessions, although a covering letter was sent to each clinician. It was understandable that clinicians presented with audit scores and a brief explanation but with limited or no follow up would not be appreciative of the process.

The CQC noted that the poor performance of some doctors had been identified through audit. This was to be commended. In our survey of local GPs in areas served by TCN, just over a third of respondents (36%) rated the standard of GPs used by TCN as poor or very poor.

TCN used some doctors in the SW Essex locality despite a warning from the ambulance service about their performance. Although TCN gave assurances in December 2008 that they had written to poorly performing doctors and that they were no longer using certain GPs, in April 2009 one of these doctors was found to still be working for TCN.

In respect of poorly performing doctors, TCN introduced a 'three strikes and you're out policy' in March 2009. Between November 2008 and November 2009, 12 doctors were removed. There was no system to share information with PCTs about poorly performing doctors, although TCN took steps to try and introduce this in summer of 2009.

Strategic aspects of governance, strategic capacity and overall priorities

TCN did not have strong governance arrangements and it was difficult to decipher a systematic approach to monitoring and improving clinical care. There was insufficient capacity to deliver good governance and the staff who were responsible for governance were either part time in this role or had other significant responsibilities. Minutes of meetings often lacked detail and some were missing, which made it difficult to track the content of discussions and the type of decisions being made.

It was a matter of concern that TCN could not provide the minutes of meetings of its executive. Initially they stated that this was due to commercial confidentiality whereas their later position was that the minutes were not available as none had been taken. We wanted these minutes to examine the decisions made by executives, their priorities and the traction between the executives and the rest of the organisation, particularly since TCN lacked a clear hierarchy of committees and decision making. We were unable to determine whether the failure to provide us with minutes was a case of failure of governance in not taking minutes, or reluctance to provide minutes because of their content. We have already noted the lack of transparency in TCN's reporting of activity and performance

When shortcomings were identified in governance arrangements, the response by TCN was to restructure committees. In 2008

there were major changes to governance arrangements, involving the number and hierarchy of committees. The arrangements, and the changes, were complex, and made it difficult to identify a clear hierarchy of committees and track how concerns had been dealt with. Despite these changes, in early 2009 two external reviews criticised the split between operational and clinical matters. Although clinical governance was well articulated by TCN it was not rooted in frontline patient services, and there was insufficient emphasis on clinical matters. These reviews led to a further extensive change in arrangements. The reporting lines were not clear and the frequent changes exacerbated this.

Between 2005 and 2009 TCN experienced rapid growth, winning three more contracts and more than doubling the population they covered. The management and operational commitments required for such a significant growth in organisational size combined with the demanding nature of the transition from the governance structure of a GP co-operative to the structure required of a large provider of NHS healthcare put significant strain on capacities at TCN particularly in the areas of middle management and clinical leadership. As Carson noted in his review, the growth of TCN's business portfolio over the past year had outpaced the clinical governance skills and experience of staff. Some PCTs were concerned that TCN had not invested sufficiently in its operational infrastructure to sustain safe systems of care.

Both Carson and Tobin considered in early 2009 that there was insufficient clinical leadership at a local level. By the end of that year the situation had not improved as TCN had not been able to implement having a lead clinician to oversee shifts with the duty manager. Only one of the GP non executive members of TCN's board ever worked a clinical shift for TCN.

The potential conflict between the interests of patients and those of shareholders is beyond the terms of reference of this investigation. It was difficult however to find evidence that clinical quality and clinical governance had been top priorities, particularly compared to business expansion. In August 2008 the board noted that, although not by design, unfilled shifts contributed to savings. Later that year the board in a discussion on the difference between the commercial and public sectors, noted legal advice that they could do anything that was not explicitly forbidden by law, and in setting key performance indicators they needed to ensure they were looking after shareholders interests. There were references at the end of 2008 to 'no reduction in clinical service' but we found continuing reduction in the levels of clinical staffing and an increased number of unfilled shifts. There was no evidence of concern at board level about the situation we encountered where the sole clinician on duty for over 50 miles was a nurse. This was not safe for either staff or patients.

Although GPs on a board can provide invaluable insight into specific clinical priorities, most will lack the necessary management experience to implement governance processes in an organisation the size of TCN. The leadership was not able to provide the appropriate skills for implementing NHS style governance changes. Over time TCN made efforts to resolve this leadership shortfall but given the operational pressures on the organisation the implementation of governance changes to the front line was difficult and other priorities took precedence.

We were concerned that TCN did not acknowledge that shortcomings in its internal systems may have contributed to the failure to prevent the incident in Cambridgeshire that led to the death of Mr Gray. In his initial meeting with the CQC, TCN's medical director provided some information that was inaccurate, and omitted information that was clearly relevant to the investigation, particularly the previous two cases involving doctors from Germany who had given overdoses of diamorphine.

It was a serious concern to the CQC that despite two requests for any incident reports in relation to death of Mr Gray, TCN did not provide the one completed by the lead for clinical governance at the time. This report was damning since it stated that it was the third time in a year that TCN had an overdose of diamorphine and that they had 'already identified that it presented a serious clinical risk to the unwary'. The report noted that many doctors practising in Germany had very little

experience in palliative care and in the use of the drugs which were relevant in this area.

The TCN's brief in May 2009 for the medical and nursing directors at NHS Suffolk did not include key details relating to the circumstances surrounding the earlier diamorphine incidents and the death of Mr Gray, and included material inaccuracies.

Overall conclusion about TCN

TCN did make changes after the death of Mr Gray, but too few and too slowly. It failed on many fronts. It grew too fast, prioritised expansion over existing services, did not listen to staff or invest in governance, tolerated staffing situations that were potentially unsafe for patients or staff, and failed to recognise clinical failures and risk.