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

Part 3:
Commissioning and monitoring of out-of-hours contracts by the PCTs, performance management, and administration of the performers lists

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 By then, TCN had completely withdrawn 100mg ampoules of diamorphine, significantly reducing the chance of the original mistake being repeated.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 Part 2, we report in detail on TCN and its provision of out-of-hours services.

- In this part, 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 3: Contents

Part 3: Main findings and conclusions

Findings

Commissioning and monitoring of out-of-hours contracts by the five PCTs

- The PCTs were established as part of a major re-organisation in 2006. Four of the five inherited significant financial deficits. Out-of-hours services were low priority and there was little strategic vision of how they should develop. This was a disadvantage when procurement was undertaken. Additionally, because PCTs were advised not to involve local GPs in the procurement process due to conflicts of interest if they were tendering for the service themselves, the clinical input to procurement was limited.

- The staff in PCTs with responsibility for routine monitoring of out-of-hours contracts did not fully understand TCN's reports on performance. They could not adequately explain the information in the reports or the basic activity figures, and they did not fully understand the national quality requirements (NQRs).

- Changes to out-of-hours services that could have significant implications were frequently discussed and agreed by non-clinical staff at PCTs. Senior staff were often unaware that call streaming was taking place. (This is the practice of offering patients the chance to go straight to a base without first having a clinical assessment.)

- Before the start of our investigation in May 2009, none of the PCTs robustly monitored staffing levels in out-of-hours services, the skill mix or whether the shifts were filled, and most did not monitor them at all. Some of the PCTs considered this would be inappropriate for any of their contracts, especially if quality standards were being achieved. However, we have noted above that the PCT staff did not fully understand the NQRs.

- Most of the PCTs did not have a clear picture of any problems in out-of-hours services. They were not generally aware of serious incidents. None of the PCTs had robust arrangements to share information on poorly performing clinicians.

- Before the publicity in spring 2009 about the death of Mr Gray, only in NHS Cambridgeshire was there interaction between PCT staff responsible for medicines management and TCN.

- Performance on out-of-hours services was seldom reported at board level in PCTs and non-executives were not well informed, other than in NHS Cambridgeshire and NHS Great Yarmouth and Waveney.

- Most of the PCTs had not invested in finding out the views of local GPs on out-of-hours services. In our surveys, GPs were highly critical. In three of the four PCT areas that obtained all their out-of-hours services from TCN, over 60% rated the services as poor or extremely poor.

Strategic and performance management role of the two SHAs

- Initially, priorities at both SHAs reflected the national priorities of financial stability and achievement of national targets. PCTs were managed against these priorities. The SHAs had encouraged another national priority which was increasing the range of providers, particularly in the commercial sector.

- Both SHAs referred to out-of-hours services in the overall strategic context of urgent care, rather than having a separate strategy specifically for out-of-hours. Recently, there has been more targeted activity at SHA level in respect of out-of-hours.

Administration of the performers lists by the PCTs

- We found a range of different approaches to performers lists in the PCTs, and different levels of scrutiny of applications and of proficiency in English. PCTs were not acting systematically to monitor care or ensure new performers were familiar with local structures and services. However, there was evidence that PCTs had recently tightened their procedures and increased clinician involvement in screening of applicants.

Conclusions

1. Out-of-hours services were low priority at the time and the PCTs had limited understanding of these services. There was a lack of leadership in commissioning and monitoring services as part of an integrated urgent care service.

2. Out-of-hours was a relatively new area of commissioning and there was a lack of experience in the PCTs in contracting with a commercial organisation. The staff with responsibility for routine monitoring of contracts did not fully understand the national quality requirements or TCN's reports on activity or performance. There was little interrogation or challenge at the contract monitoring meetings.

3. Some of the PCTs stated that it was unreasonable for them to monitor individual concerns or staffing levels, since this would not happen for other contracts. But we consider that these contracts should have been monitored more thoroughly.

4. Our assessment was that the PCTs did not have a high standard of commissioning or contract monitoring in out-of-hours. There was a failure to commission appropriate out-of-hours services for the local population and monitor that these were being delivered. All the PCTs had begun to improve their commissioning and monitoring arrangements.

5. SHAs in their early years focused on the national imperatives of targets and finances and, since out-of-hours was not a national priority until recently, placed less priority on monitoring PCTs' performance in out-of-hours services. There has been more targeted activity recently in both SHAs in respect of these services.

6. The PCTs had all recently tightened their procedures in respect of performers lists, although there were still different levels of scrutiny.

Primary care trusts and commissioning

Primary care trusts (PCTs) are responsible for leading the NHS at a local level. They ensure that people have access to health services by either providing services directly, or by agreeing and managing contracts with a range of NHS, voluntary and independent sector healthcare providers.

If the PCT does not provide the health service directly then it is responsible for authorising or 'commissioning' the services required to meet the health needs of the local community. These services include amongst others GPs, dentists, pharmacists, out-of-hours services and walk in centres. There are 152 PCTs in England and they manage about 80% of the total NHS budget. They are accountable to their local communities and to the Secretary of State through the Strategic Health Authorities.

PCTs control the funding for hospitals and make decisions about the type of services that hospitals provide. They are also responsible for making sure that commissioned services meet the needs of patients and are delivered to appropriate standards.

PCTs have been encouraged by the Department of Health to establish a clear focus on commissioning and to separate commissioning activities from the direct provision of services. This had led to significant organisational restructuring in a number of PCTs.

The trust board governs the work of the PCT and ensures the organisation is on track to meet aims and targets to improve health and deliver appropriate health services. The trust board also includes non-executive members who are local people appointed to the board.

Within each PCT there is either a professional executive committee (PEC) or a clinical executive committee (CEC). These committees consist of health professionals such as GPs, nurses and pharmacists who are elected by their profession to represent their views. The PEC/CEC should have a key role in advising the trust board on clinical strategy and should direct the local health services to meet the local health needs of the community.

Associated with each PCT is a local medical committee. The local medical committees (LMCs) are the statutory bodies representing and supporting local general practitioners (GPs). They are independent of PCTs.

Until 31 March 2008, each PCT had a patient and public involvement forum (PPI). This network was established to improve the quality of NHS services by bringing to trusts and PCTs the views and experience of patients, their carers and families. PPI forums were abolished in 2008 and replaced by local involvement networks (LINks).

Sources of evidence for primary care trusts and commissioning

- Interviews with PCT staff
- Minutes of meetings including the board, clinical governance and contract monitoring
- Logs of incidents and complaints
- Correspondence between the PCT and TCN
- Interviews with local medical committee representatives
- CQC survey of TCN staff
- CQC survey of GP practices
- TCN performance reports
- PCT contracts and service specifications
- Interviews with organisations in the health community, including local involvement networks, health overview and scrutiny committees

NHS Suffolk

History of the PCT and local out-of-hours services

NHS Suffolk is the primary care trust for the county of Suffolk (excluding Waveney) and cares for a population of around 585,000. The PCT was formed in October 2006 from an amalgamation of four predecessor primary care trusts. When NHS Suffolk was first formed it inherited a £36 million debt.

The former Suffolk PCTs first contracted with TCN (formerly SDOC) in October 2004. SDOC was originally the local GP co-operative out-of-hours service, Suffolk Doctors on Call. The current contract began in April 2007 and was extended to cover 2009/2010. NHS Suffolk announced in December 2009 that it would not renew the contract with TCN.

Senior TCN staff stated that the service was under funded by the PCT and that this affected the service they were able to provide. TCN claimed that there was a reduction in the contract value of £286,000 in 2006/2007, when the former PCTs merged. The PCT stated that the contract value had increased each year from 2006/2007 but were aware that prior to the merger of the former Suffolk PCTs, there had been some reduction in investment in the service by Suffolk West PCT. NHS Suffolk stated that the out-of-hours service was not included in their financial recovery plans.

The Primary Care Foundation estimated in November 2009 that the out-of-hours service in NHS Suffolk was a little above the national average for cost per head of population compared with other services involved in the benchmark at that time.

Finding of fact

- NHS Suffolk inherited a deficit of £36 million and was required to make savings. The PCT stated out-of-hours was not included in their financial recovery plans.
- Suffolk Doctors on Call, which gave rise to TCN, was originally the GP co-operative service for out-of-hours in Suffolk

Routine monitoring of the out-of-hours contract and the effectiveness of this monitoring

Monthly contract monitoring meetings between TCN and NHS Suffolk took place from October 2006 to January 2008. They were attended by a senior clinical representative from TCN but there was no record of a clinical representative from the PCT. The PCT stated the director of commissioning attended on occasions. Discussion was focused on reviewing performance, particularly failure, on the national quality requirements relating to response times.

NHS Suffolk was unable to provide minutes of the contract meetings held between January 2008 and September 2008 or a number of the performance reports produced by TCN during that time. This was due to a change in personnel at the PCT and files that could not be retrieved. From September 2008 to June 2009 the contract monitoring meetings were scheduled to take place every other month. Due to financial restraints which resulted in restrictions on recruitment, the PCT only held three contract meetings during this time although they stated that TCN performance information was reviewed monthly nonetheless. During this period the discussion of quality requirements as recorded in the minutes was noticeably briefer than in 2006 and 2007. The membership changed and a

clinical representative did not routinely attend these meetings until June 2009.

Staff responsible for contract monitoring were unable to explain some key aspects of the activity data in the performance reports. Towards the end of 2009 the performance team began to monitor the data being provided by TCN and they acknowledged that the information provided previously had been 'poor and at a very basic level'.

The policy for children under five to be given appointments at the base had been agreed earlier in the contract by the previous contract manager.
The call streaming, also called straight to base, protocol for adults and older children, was not understood properly by contract staff at Suffolk PCT and it was unclear whether it had been agreed with TCN. The director of commissioning and the contracts manager were not aware that TCN call handlers were directing patients straight to the bases or that these figures were not being included in the performance reports.

From the inception of the PCT until April 2008 there was no formal post of medical director at the PCT, although the PCT stated there were a number of medical advisers supporting the organisation at that time. Clinicians were also involved in the urgent care network but this was not responsible for monitoring out-of-hours services. The chief nurse and head of clinical quality was responsible for clinical governance. A number of staff told us that there was a lack of integration between the quality department and the routine contract management of out-of-hours services. The chief nurse/head of clinical quality, who had been responsible for clinical governance in 2007, told us that the workload in clinical governance was greater than had been anticipated and this had an impact on the governance capacity in the PCT. The matter was not raised formally with senior management. The person responsible for contract monitoring at that time stated that they had not reviewed the quality of the service in any depth.

The medical director currently in place at the PCT was given joint responsibility for quality with the chief nurse and head of clinical quality in March 2008. The PCT established the directorate of patient safety and clinical quality in April 2009 to emphasise their importance. When we interviewed staff in July 2009 the performance reports produced by TCN had not been routinely reviewed by the medical director nor were they reported to the clinical executive committee. The PCT's recently promoted director of patient safety and quality was responsible for reporting any problems in the delivery of the out-of-hours service on an exception basis. However she did not understand some of the quality requirements reported by TCN and acknowledged the limitations of her knowledge about the performance reports.

From June 2009 a member of the quality team at the PCT attended the contract monitoring meetings and the PCT began to develop a specific 'quality report' in order to collate the main quality indicators. However, in subsequent interviews in November 2009, the CQC team noted that those responsible for monitoring quality in the out-of-hours services were still uncertain about aspects of the service and its implications for monitoring performance. For example, neither the director of patient safety nor the medical director understood that as a result of the way the number of patients being sent straight to base was being recorded, TCN did not know how long patients waited to be seen after their initial call.

We were told that the PCT did not specify the numbers of doctors and nurses on the rotas. Staffing rotas in out-of-hours were not reviewed by clinical staff or contract staff at the PCT and there was no record of discussion of staffing cover at the contract meetings. Staff responsible for monitoring the contract told us in November 2009 that they would not expect to be told if TCN replaced a doctor with a nurse in the rota. The contract manager at NHS Suffolk told us that they did not define the number of doctors or nurses being used. He expected that Take Care Now would have the capacity to meet demand in terms of their staffing levels and it was their responsibility how they did it. The PCT stated this was consistent with their approach to all their contracted services including NHS hospitals.

In December 2009 the PCT stated that TCN could use nurses who had the appropriate additional qualification as nurse practitioners provided they had undertaken training in home visits and could refer to a GP. The director of patient safety told us that the PCT had very recently started to ask for information about the level of medical cover to support nurses as part of the quality report information. She also incorrectly told us that nurse practitioners did not make home visits.

In the autumn of 2009, CQC asked TCN staff who worked in the area covered by Suffolk PCT how they rated clinical staffing levels at TCN bases. 50% of the 101 staff who responded stated that clinical staffing levels were poor. In comparison, only 4% of the 99 staff who responded felt that non-clinical staffing levels were poor.

A number of doctors had been asked to leave the service by TCN as a result of concerns about their performance. 11 doctors were removed from TCN's service between November 2008 and November 2009, seven of these after the rollout of the RCGP audit in February 2009. The director of commissioning was aware of this but the contracts manager and director of patient safety were not.

The staff at the PCT we interviewed were not aware that the national guidelines for stroke were not being followed by the staff at TCN who handled calls. They did not know that patients phoning out-of-hours with symptoms of a stroke were not being immediately referred to 999. The director of commissioning acknowledged that the new national guidelines for stroke had not been raised with TCN and that, although there was a stroke network, TCN had not been invited to those meetings.

Findings of fact on routine monitoring by NHS Suffolk

- There were monthly contract monitoring meetings between October 2006 and January 2008 attended by a senior clinician from TCN.
- Between January 2008 and June 2009 there was limited clinical representation from the PCT or TCN at these meetings. This was although Mr Gray died in February 2008.
- The PCT could not provide minutes of the meetings between January and September 2008.
- Staff responsible for monitoring the contracts could not explain some key aspects of the data in the performance reports.
- Staff at all levels did not understand the effect of call streaming on the NQRs.
- Some staff had concerns about capacity in the early days of the PCT in terms of monitoring contracts, particularly the quality of services.
- There was little integration between staff in the quality department and those in routine contract monitoring.
- In July 2009 neither the medical director nor clinicians on the professional executive committee had reviewed the performance reports produced by TCN.
- The recently promoted director of patient safety and quality acknowledged the limitations of her knowledge about these reports.
- The PCT did not require information from TCN to enable them to monitor staffing levels or whether shifts were filled.
- The PCT was not aware that the guidelines for stroke were not being followed by call handlers in the out-of-hours service.
- From June 2009 the PCT began to develop a specific 'quality report' in order to collate the main quality indicators.

Systems in NHS Suffolk to identify and escalate areas of concern

National quality requirement 6 requires information about complaints to be regularly reported to the PCT. The minutes of the contract meetings recorded occasional reference to individual incidents but there was no evidence that they were discussed in any depth. Reports on complaints were tabled at the contract meetings but there was no evidence of discussion of individual complaints made to either the PCT or TCN. Before July 2008 TCN only reported on a monthly basis the number of incidents and complaints. At this time the PCT did not routinely receive any information about the actual detail of individual incidents or complaints. The PCT stated this was consistent with other contracts.

After July 2008 NHS Suffolk received a summary of individual incidents and complaints. However, there was very little record of discussion of individual complaints and incidents at the contract meetings, and no reference to the two serious untoward incidents that took place in out-of-hours in early 2009.

Two earlier incidents involving controlled drugs had taken place in Suffolk PCT in 2007. Both cases involved doctors who trained and practised in Germany working for TCN who had administered high doses of diamorphine. On both occasions patients stopped breathing properly and required a drug to counter the effects of an overdose of diamorphine.

The first incident involving diamorphine occurred in April 2007. There was no evidence that this incident was formally reported at Suffolk PCT until a written report was received from TCN two years later. This report in 2009 did not detail that the incident had involved a doctor practising in Germany. Although the report stated that processes were changed as a result of the incident, it did not describe what revisions to procedures had actually taken place.

The second incident involving diamorphine occurred in August 2007. The GP who was the governance lead for TCN contacted the chief nurse who was the lead for governance at the PCT. This was to discuss the need for the doctor involved in the incident to receive mentoring. In September the chief nurse for NHS Suffolk requested a report on this incident. They received it in early November 2007, labelled ‘serious untoward event’.

This second incident was not reported to the SHA as a SUI by the PCT, nor was the medicines management lead at the PCT informed. There was no evidence that this incident was ever formally reviewed, monitored or discussed at NHS Suffolk until the subsequent brief by TCN to the chief executive of NHS Suffolk on 13 May 2009.

This briefing in 2009 did not mention that the second incident had also involved a doctor practising in Germany, nor did it mention that the patient had required naloxone as a result of the dose of diamorphine that had been administered. The report by TCN stated that acute pain boxes were introduced to the service as a result of this second incident, however these boxes were not in operation until May 2008.

In 2008 Suffolk PCT was concerned about the proposed removal of the high dose of diamorphine from the palliative care boxes because the only mechanism they had at the time to replace syringe drivers for palliative care patients was through the out-of-hours service, and there were no pharmacies in the area open 24 hours. The PCT did not want to introduce the changes without consultation with other services.

The senior pharmacist was not aware of the death of Mr Gray from an overdose of diamorphine until six months after it happened. When she was interviewed in July 2009 the senior pharmacist stated that she was not confident that she would be told about an incident involving medicines that was reported at the contract monitoring meeting. It was noted that TCN did not attend the network for the safety of medicines although they had been invited. The focus of this network was to share incidents and review NPSA alerts. When we spoke to the PCT medicines management team in July 2009 the TCN medicines policies had not been reviewed. We were told that the PCT did not conduct any spot checks or

routine monitoring of pharmacy arrangements at the out-of-hours bases.

The medical director at the PCT was not clear about the events surrounding the earlier incidents. He stated that one of the incidents was the result of the patient having a bad reaction to the opiates and did not acknowledge that it was the size of the dose that had put the patient at risk. He stated that the GP involved in the second incident remained with the patient after they had administered the diamorphine, which was inaccurate.

In his initial interview the medical director at the PCT stated that TCN had provided additional training to the doctors involved in both of the 2007 diamorphine incidents. During the coroner's inquest in 2010, the clinical governance lead for TCN stated that although he had written to the first doctor personally, they had not accepted that the dose of diamorphine they had administered had caused the patient's respiratory collapse and the incident was not followed up any further.

Despite having the similarities in the earlier incidents outlined to him during a subsequent interview, the PCT's medical director was insistent that the earlier incidents were quite different in nature to the death of Mr Gray and that there was no pattern. He considered that the death of Mr Gray was entirely due to the error of an incompetent GP.

The chief executive of Suffolk wrote to the East of England SHA in May 2009 stating that actions had been agreed with TCN regarding the incident in August 2007 and that these had been monitored. There was no evidence that the PCT had checked the changes to practice that TCN stated they had made in relation to either of the earlier diamorphine incidents. The PCT also assured the SHA in an earlier letter in May 2009 that there were safe systems in place at TCN. The letter stated that TCN had provided a portfolio of evidence to support this. Initially the PCT could not provide us with a copy of this evidence, reporting it had been forwarded to the SHA and that a copy had not been kept. In April 2010, the PCT was able to retrieve the evidence as supplied by TCN the previous year. This evidence included TCN policies on recruitment, induction, controlled drugs and alerts. There were also examples of weekly checks of controlled drugs, clinical bulletins sent to clinicians and an extract from the alerts database. The PCT stated in the letter to the SHA that they would follow up these areas through the contract monitoring process. In the June 2009 contract meeting the PCT began to develop a quality reporting template with TCN.

The changes TCN stated they made as result of the death of Mr Gray were not challenged by Suffolk PCT until May 2009. This was despite the fact that Dr Ubani was operating from the TCN base at Newmarket, which was in Suffolk, and a history of two earlier diamorphine incidents involving TCN. NHS Suffolk stated there was an agreement that NHS Cambridgeshire would lead the review and follow up after the death of Mr Gray.

NHS Suffolk with NHS Cambridgeshire carried out a joint annual performance review of TCN in May 2008. The review focused on the national quality requirements but there was no record of detailed discussion about compliance with the standards. There was no record of a reference to the death of Mr Gray which had taken place three months earlier. However TCN was asked by NHS Cambridgeshire for reassurance that their SUI policy had been fully implemented. There was no reference to any earlier incidents involving diamorphine in the minutes of this meeting. NHS Suffolk did not carry out the review the following year and there was no evidence of follow up of the issues raised.

The PCT's medical director said that any major incident before September 2008 would have been brought to the attention of the executive team by the chief nurse. We were told that, between September 2008 and May 2009, clinical risks arising in out-of-hours were identified by the patient safety and quality network. They were then raised with the patient safety committee before being brought to the clinical executive committee and trust board. Members of the clinical executive committee were not formally advised about any problems in out-of-hours until February 2009, although the medical director chaired this committee and was aware of the incidents involving TCN in 2008.

At the first meeting of the patient safety committee in September 2008 it was noted that Cambridgeshire PCT had given formal notice to TCN that they needed to improve. There was no reference to TCN or out-of-hours in any of the subsequent meetings. It was noted in January 2009 that SUIs were to be a standing item on the agenda to ensure that learning points were disseminated.

The medical director stated that one of the functions of the patient safety committee was to ensure that SUI information reached the board of the PCT. There were two SUIs in out-of-hours in Suffolk PCT in the first six months of 2009 and neither was recorded having been reported at the patient safety committee. During his interview the medical director told us that the TCN performance report would have gone to the patient safety committee and any problems would have been raised with the clinical executive committee. There was no evidence of the TCN performance reports being presented at the patient safety committee. In June 2009 the patient safety committee merged with the clinical executive committee because of concerns that the latter did not have a sufficient remit in terms of the safety of patients.

The first meeting of the patient safety and quality network took place in September 2008. The aim of the network was to bring together the lead clinicians and managers with responsibility for clinical quality from across the county. In March 2009 the group identified that it needed to identify a TCN representative to attend. There was no record of discussion of out-of-hours in the meetings between September 2008 and July 2009. A TCN representative first attended in September 2009. The PCT's head of clinical governance and patient safety stated that these meetings were designed to share and support good practice, not to monitor out-of-hours performance. The medical director told us that the patient safety network was their preferred option for engaging with TCN on the safety of patients.

In early 2009 NHS Suffolk reported to the SHA two serious untoward incidents that occurred in out-of-hours. The PCT was not able to provide an internal TCN SUI report for either of these incidents. In the first case TCN provided a series of letters written by TCN in response to the incident. The PCT did not provide evidence of any further enquiry in to the events.

The second SUI involved TCN, NHS Direct and the East of England Ambulance Service. Suffolk PCT commissioned a review by an independent clinician. There were some discrepancies in the information provided by the family involved in the incident and the clinical notes as recorded by the TCN doctor. The clinician carrying out the review was satisfied that the resulting investigation carried out by TCN was sufficient. No further evidence was provided relating to the internal investigation as carried out by TCN.

The board was formally informed about an incident relating to TCN in September 2008. In November 2008 the NHS Cambridgeshire review of non-compliance at TCN and associated action plan were presented to the board. TCN were compliant against three of the 22 requirements. In March 2009 the board received an update on TCN's progress against the action plan and it was stated that NHS Suffolk's medical director would prepare the terms of reference for a more focused review of TCN's clinical and quality standards. In May 2009 the board noted that action would be taken to ensure more effective monitoring of out-of-hours providers and a clinical quality manager was appointed by the PCT. The main responsibilities of this post were to review SUI monitoring and develop a database to ensure the capture of key actions and learning. In July the board was notified that CQC was undertaking an investigation into the out-of-hours services provided by TCN and a further update was provided in September.

Findings of fact on systems in NHS Suffolk to identify and escalate areas of concern

- NHS Suffolk with NHS Cambridgeshire carried out a joint annual performance review of TCN in May 2008.

- The PCT did not routinely receive any details about individual incidents or complaints received by TCN until July 2008.
- The first diamorphine incident was not reported to the PCT. Neither it nor the second were designated as SUIs by TCN. The PCT did not report the second incident as a SUI to the SHA. It was not reported to the PCT lead for medicines management.
- In July 2009 the medical director did not recall the facts fully or accurately in respect of the earlier incidents involving diamorphine.
- The PCT's medical director was confident that the death of Mr Gray was solely because of the actions of an incompetent GP.
- The PCT assured the SHA in May 2009 that changes had been agreed with TCN and that these had been monitored. There was no evidence of that monitoring having taken place.
- There were two SUIs in the out-of-hours service in the first six months of 2009. There was no evidence that either of these had been reported to the patient safety committee.
- The PCT could not provide a TCN report for either of the two SUIs referred to above.
- In November 2008 the NHS Cambridgeshire review of non-compliance at TCN and associated action plan were presented to the board.

Local perspectives on TCN's out-of-hours services

Local GPs

We were told by a member of the local medical committee that the PCT met with the LMC at least monthly and that they would discuss TCN when necessary. In a statement to CQC on 19 August 2009 the head of the primary medical services stated that no formal concerns had been raised by local GPs. Members of staff we interviewed at the PCT made reference to concerns that had been raised by local GPs in relation to coverage of coastal areas of Suffolk and the distance patients had to travel to reach the bases. The director of commissioning stated that the PCT had tried to find evidence that TCN referred more patients to hospital from coastal areas but had been unable to substantiate this. The director of commissioning said she had not heard any GP concerns about the clinical quality of the service. The opinion of local GPs had not been formally collated or actively surveyed by the PCT.

CQC sent a survey to GP practices in Suffolk PCT in October 2009 asking them for feedback concerning the out-of-hours service provided by TCN to their patients. We compared these figures to a similar survey sent out by 'Devon Doctors' out-of-hours service in December 2006. The response rate for the Devon Doctors survey was 47%. We are 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. Devon Doctors covers a large rural area with a similar population density to the areas covered by TCN. 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.

We received responses from 71 GPs in total which represented 17% of total GPs in Suffolk. 35% of those that responded stated that the service provided by TCN was good or excellent. 24% stated it was poor or very poor. In comparison to the same question asked of Suffolk GPs only 1% of Devon GPs rated the out-of-hours service as poor or very poor. Specific concerns raised by Suffolk GPs were related to understaffing and waiting and response times for patients.

49% of Suffolk GPs responded that they did not have concerns about any particular groups of patients and of those that did have concerns

the majority of comments were relating to those patients who needed home visits.

35% of Suffolk GPs felt that the telephone response times to patients were good or excellent (71% at Devon Doctors) and 27% stated that the standard of GPs utilised by TCN was good (79% at Devon Doctors). 32% felt that ease of access to a local treatment centre was good or excellent (64% at Devon Doctors) and 28% thought that the length of time patients had to wait to be seen was good or excellent (65% at Devon Doctors). 38% stated that the ability for patients to receive home visits when clinically required was good or excellent (63% at Devon Doctors).

The majority of Suffolk GPs were happy with the reliability and content of the patient information sent to practices. 73% stated that the general standard of communication with their practice was good or excellent (80% at Devon Doctors).

Suffolk GPs were generally more positive about the out-of-hours service than those GPs who responded from other PCT areas. Suffolk PCT was effectively the 'home' of TCN.

CQC interviewed a representative of the local medical committee (LMC). He remembered concerns being discussed by GPs that foreign doctors working in out-of-hours did not have sufficient local knowledge. He also commented on the level of clinical staffing coverage in out-of-hours and the pay rates offered to clinicians. He expressed the opinion that the pay rates were a result of the economic restraints as a result of the PCT funding of out-of-hours. We have noted earlier that the Primary Care Foundation found the level of investment in out-of-hours to be slightly above average.

Local consultation on out-of-hours services

NHS Suffolk carried out a public consultation between 23 February and 22 May 2009 in order to collect views on the proposed changes to out-of-hours care. There was a mixed response from respondents in relation to the service they had received from out-of-hours. The executive summary of the consultation noted that feedback showed 'strong support for the out-of-hours service' although also commented that 'there were many issues raised where the service could be improved'.

Health overview and scrutiny committee

On 11 November 2009, a paper was presented at the health overview and scrutiny committee outlining the information gathered in a review of the out-of-hours service provision in Suffolk. Local concerns raised in the resulting report were around the lack of GP cover, including overnight, and access to drugs for severe pain relief. Issues were also raised about the distance that patients had to travel to reach a base and waiting times to see a clinician.

Findings of fact on local perspectives

- The opinion of local GPs had not been formally collated or actively surveyed by the NHS Suffolk.
- 35% of GPs who responded to the CQC survey stated that the service was good or excellent.
- 24% said it was poor or very poor.
- The results compared unfavourably with a survey in Devon in 2006.
- Suffolk GPs were generally slightly more positive about the service than GPs in other TCN areas.
- The executive summary to the report on public consultation carried out by NHS Suffolk in the spring of 2009 said there was strong support for the out-of-hours service.
- The Health Overview and Scrutiny Committee in November 2009 noted local concerns including lack of GP cover and distances patients had to travel.

Developments

The head of clinical governance and patient safety told us that patient survey indicators were now included in the monthly quality report recently developed by the PCT to monitor their out-of-hours contract. The PCT had increased the unannounced visits they made to call centres and primary care facilities. They had also begun to ask for more information

concerning the percentage of GPs filling shifts. However staff acknowledged that as they did not have a view of what shift cover should be in place it was difficult for them to come to any conclusions.

In November 2009 the clinical executive committee considered the TCN medicines management policy, controlled drug policy and standard operating procedures for the supply of drugs.

NHS Suffolk provided an action plan in December 2009 which included a number of the key areas where concerns had been raised. These included recruitment, induction, appraisal, medicines management and management of SUIs. The action plan also made reference to reviewing patient experience, capturing GP views of the service and the PCT reporting and risk management structures.

The PCT stated that performance reports were now being presented to the clinical executive committee every three months. CQC also noted that the performance team was now involved in contract monitoring and were meeting with representatives of TCN regularly to discuss the information provided in the performance reports. In November 2009 the PCT appointed a deputy director for patient safety and clinical quality to support the development of safety and quality monitoring.

The PCT acknowledged that their management of records in some sections of commissioning had not been sufficiently robust to provide evidence of sound contract management and arrangements for staff handover of work had been weak. The PCT stated that handover protocols had been established.

The PCT commented that they may have been perceived to be protecting the local GPs because of their competency in their core services and because TCN was largely owned and led by local GPs. The PCT accepted that it must demonstrate objective assessment even when familiar with the provider, particularly when operating under different management regimes especially commercial companies.

In December 2009 NHS Suffolk terminated the contract with TCN. Harmoni began providing out-of-hours services to NHS Suffolk from 1 April 2010.

NHS Cambridgeshire

History of the PCT and out-of-hours services

NHS Cambridgeshire was formed in October 2006 from an amalgamation of four earlier primary care trusts. One of these was East Cambridgeshire and Fenland PCT. In the early days of the PCT there was a deficit of £52 million and the PCT was required to make significant savings to decrease the deficit. There were a number of interim appointments, some posts were frozen pending restructuring and some senior staff told us it was a difficult time. The performance of the PCT was being managed by the SHA.

In 2004 East Cambridgeshire and Fenland PCT contracted with SDOC to deliver out-of-hours services. Cambridgeshire PCT was not aware until much later that SDOC had subsequently handed the responsibility of running the services to TCN. The contract was not formally agreed and signed until March 2009.

The out-of-hours service delivered by TCN in East Cambridgeshire covered an area of approximately 650 square kilometres with a population of around 80,000. The district of Fenland covered around 500 square kilometres with a population of around 90,000. East Cambridgeshire and Fenland is a largely rural district with some areas of high deprivation.

The PCT also commissioned out-of-hours services from Camdoc (Cambridgeshire doctors on call) and Huntsdoc (Huntingdon doctors on call). The Huntsdoc service was provided directly by the PCT. A small part of the north of the PCT was covered by Pdoc (Peterborough doctors on call).

The PCT reduced the value of the out-of-hours contract during the time the service was provided by TCN. According to a statement by NHS Cambridgeshire, TCN was 20% more costly per head than Camdoc or Huntsdoc out-of-hours services. The PCT recognised that Cambridgeshire and Huntingdon both had a central urban acute hospital. The PCT reported that they curbed the annual inflationary increase that TCN might have expected to receive and reduced the contract by a total of £20,412 between 2006 and 2009. They reported that these savings were partly as a result of a reduction in opening hours at the minor injuries unit. The PCT acknowledged that the population in East Cambridgeshire and Fenland had increased over the years which meant that TCN would have had to have cut costs in order to continue running the service at the same level. TCN disputed the figures above and claimed the reduction had been significant.

We noted that in the autumn of 2007 the PCT had served notice on all of their out-of-hours contracts. The minutes from the professional executive committee meeting in February 2007 suggested that the PCT tried to renegotiate all their out-of-hours contracts in order to save £500,000.

The Primary Care Foundation estimated in 2009 that the TCN service in Cambridgeshire was well above the average for cost per head across all out-of-hours services involved in the benchmark. It found that there was also a high cost per head compared with those services categorised as rurally based.

NHS Cambridgeshire served a formal notice to TCN on 18 September 2009, requiring it to remedy its services. The weekend following the release of the CQC interim statement on 6 October, the PCT carried out unannounced spot checks of the TCN out-of-hours bases and found shortfalls in the number of clinical staff and coverage of shifts. The PCT issued a termination notice ending the contract with effect from 1 December 2009. Camdoc provided the out-of-hours cover until the new contract began in April 2010.

Findings of fact

- NHS Cambridgeshire inherited a deficit of £52 million and was required to make significant savings.
- The PCT had reduced the value of the contract with TCN between 2006 and 2009.
- The Primary Care Foundation estimated that the cost of the service by TCN in Cambridgeshire was well above average for cost per head generally and compared with rural services.
- NHS Cambridgeshire issued a remedial notice in September 2009 and a notice of termination on the 9 November 2009.

Actions taken by NHS Cambridgeshire in response to the death of Mr Gray

TCN did not inform the PCT directly about the death of Mr Gray. On 19 February 2008 the medical director of NHS Cambridgeshire was informed of the death of Mr Gray by the patient's GP. This was three days after the incident on 16 February 2008. She reported the incident to the SHA and spoke to the medical director at TCN.

The immediate response by NHS Cambridgeshire was to establish the actions TCN had taken as a result of the incident. The PCT contacted the GMC and arranged for an alert to be issued nationally by the SHA to reduce the likelihood that Dr Ubani could come back to the UK and treat patients in the NHS. The medical director joined the police team on 22 February 2008 as the health link. NHS Cambridgeshire was involved in the visits to the other patients that had been treated by Dr Ubani, to ascertain if there had been any further problems.

The Langdale Review

The 'Langdale' review was a multi-agency process set up initially to assist the police following the death of Mr Gray but was then developed to investigate aspects of the incident, learn from the case and monitor change in TCN.

From March 2008 onwards, visits were carried out at TCN bases as part of the first phase of the Langdale review. On an unannounced visit to the Newmarket base at the beginning of September 2008, the PCT found that three different strength vials of diamorphine were still in place. This was a serious concern to the PCT and from then on the monitoring became more intense (including more unannounced visits). The relationship with TCN became strained. On 10 September 2008 the PCT wrote to TCN and insisted that they provide written assurance that all the 100mg vials of diamorphine had been removed. The PCT also requested regular clinical briefings, a list of all practitioners working in the PCT area, and a named contact in TCN.

Between 22 September and 22 October 2008 the assistant director for quality and governance at the PCT provided weekly updates to the chief executive and medical director of the PCT. There were weekly meetings involving the PCT and TCN until December 2008. In total Cambridgeshire PCT carried out 16 unannounced visits between 12 March and 22 December 2008. Updates were reported regularly at the private sessions of the board after it was discovered that TCN had not removed the 100 mg of diamorphine from the palliative care boxes.

Steps were taken to inform key individuals about the serious incident. The PCT's medical director wrote in September 2008 to the medical directors in Great Yarmouth and Waveney, NHS Suffolk and the Chief Executive of South West Essex. Presentations were made to the Local Intelligence Network that had representatives of all the out-of-hours providers including TCN.

From January 2009 the Langdale group met on a monthly basis. The minutes of these meetings recorded detailed scrutiny of TCN. The PCT requested and reviewed substantial amounts of evidence from TCN in order to feel confident that TCN was providing a safe service.

NHS Cambridgeshire only became aware in May 2009 of the two diamorphine incidents

that had taken place at Suffolk PCT in 2007. At a clinical engagement meeting in May 2009 the PCT challenged TCN about these. TCN did not acknowledge that both of the incidents had involved doctors who practised in Germany. Cambridgeshire PCT did not receive a written report of these earlier incidents.

Findings of fact on the Langdale review

- Cambridgeshire PCT learnt about the death of Mr Gray three days after it happened. The PCT learnt from his GP, not from TCN.
- NHS Cambridgeshire wrote to the medical directors of NHS Suffolk, NHS Great Yarmouth and Waveney and NHS SW Essex on 22 September 2008 to inform them of the incident.
- As part of the Langdale review, the PCT undertook 16 unannounced visits between March and December 2008.
- In September 2008 the PCT discovered that vials of 100mg of diamorphine were still in use in the Newmarket base.
- The PCT insisted that the vials of high strength diamorphine should be removed by TCN.
- Between September and December 2008 there were weekly meetings between TCN and the PCT, subsequently they met monthly.
- The PCT became aware of the earlier diamorphine incidents in May 2009. TCN did not inform the PCT that these incidents also involved doctors who practised in Germany.

Routine monitoring of the out-of-hours contract and the effectiveness of this monitoring

The urgent care network began to receive information from the out-of-hours services in January 2007. The purpose of the urgent care network was to monitor and review urgent and emergency care standards. Minutes of the first meeting of this network in January 2007 stated that formal monitoring of activity and quality reporting would take place in separate review meetings. However the PCT was only able to provide the minutes for monthly business meetings held with TCN in December 2007 and January 2008. The Langdale review considered many aspects of the service but did not monitor activity.

In November 2008 the terms of reference of the urgent care network were revised to include monthly monitoring of the performance of urgent care services. Statements by staff at the PCT and documentary evidence made it clear that the urgent care network was meant to be the main forum for the routine monitoring of out-of-hours services in Cambridgeshire. The representative that TCN sent to these meetings was not a clinician and there was no local clinical lead for the TCN service in Cambridgeshire.

In October 2007 the urgent care network began to receive information on performance from the various out-of-hours services. There was no reference to compliance with the national quality requirements until January 2008. Monitoring of out-of-hours at these meetings largely consisted of noting the standards that each out-of-hours service had failed that month. There were occasional references to specific issues in out-of-hours, for example in September 2007 it was noted that reassurances had been received from out-of-hours services that they were implementing the recommendations of the Penny Campbell report. There were slightly more detailed reviews of out-of-hours performance following the Christmas periods.

The assistant director for performance told us that information on TCN's performance was only reported at the urgent care network. The medical director of the PCT told us that the head of governance and the former medical director had not been aware of the reports on performance in out-of-hours as they went to the contract performance meetings. There was no record of the information on performance being reported at the trust board or PEC. The former medical director stated that regular routine reporting from TCN did not come to the governance committees at that time. A member of the PCT contracting team attended

the Langdale review regularly from June 2009 and contracts staff attended meetings intermittently in 2008. The national quality requirements were not considered at the Langdale meetings until May 2009. The assistant director of governance told us in interview that they could see that TCN had been reporting 'green' and yet from the Langdale process they knew that this was not the case and this had proved a 'painful' lesson for the PCT.

The PCT's monitoring of out-of-hours services at the urgent care network did not appear to be any more thorough after the death of Mr Gray. There was no record of discussion about any of the specific issues in the incident or how they might apply to the other out-of-hours services, and there was no reference to the Langdale review. The SUI was reported to the urgent care network in April 2008 but, as there was a police investigation, there were issues of confidentiality. The new head of the urgent care network who took over in January 2009 was unaware of the death of Mr Gray until the publicity in the spring of 2009. The PCT stated that they held a meeting with the directors at Camdoc and Huntsdoc to discuss learning from the SUI and the medical director at NHS Peterborough.

The information on performance received from each of the out-of-hours services was amalgamated in a single report. The urgent care network did not query the activity data reported by TCN. Those we spoke to in 2009 who were responsible for monitoring this information, were unclear about which requirements were important. They acknowledged that it was difficult to monitor this information effectively through the urgent care forum. The assistant director of governance and performance admitted that TCN had previously reported 100% achievement for a number of the national quality requirements. This had not been challenged at the urgent care network, although at the Langdale meeting in July 2009 the PCT requested further details about the information in the performance report.

Staff who were responsible for monitoring out-of-hours had other significant areas of responsibility. One told us that they had not received any training in monitoring contracts despite it being a major part of their job. During the follow up interviews in November 2009 we found that staff responsible for monitoring out-of-hours contracts were still unclear about some of the anomalies in the information reported by TCN.

In December 2008 the PCT agreed to call streaming or the 'straight to base' initiative for children under five at weekends and bank holidays. The PCT had not formally agreed that this could be rolled out to the general population. Staff responsible for monitoring the contract were unaware of the impact this had on reporting the quality requirements. Staff were also unaware that TCN had not been directing patients with symptoms of stroke to 999.

At the meetings of the urgent care network there was no record of discussion of numbers or skill mix of staff in out-of-hours services. When we discussed the auditing of clinicians (NQR 4) with those responsible for monitoring the contract, we were told that TCN listened to the calls made by the clinicians when in fact they did not.

CQC asked TCN staff who worked in the East Cambridgeshire and Fenland area how they rated clinical staffing levels at TCN bases. 44% of the 25 TCN staff who responded who worked in the area of Cambridgeshire PCT stated that clinical staffing levels were poor. In comparison, none of the 24 staff who responded felt that non-clinical staffing levels were poor. 83% reported that non-clinical staffing levels were good or excellent.

In June 2009 the assistant director of performance told us that contract monitoring and governance were coming together routinely for TCN, but not for the other providers. In May 2009 the medical director, assistant director for governance and professional performance drafted an out-of-hours rapid response template to be completed by Huntsdoc and Camdoc. Routine performance monitoring was still taking place at the urgent care network but the PCT instigated monthly clinical quality review meetings with Camdoc and Huntsdoc from June 2009. There were still some concerns about information received from services, and we were told in November 2009 that Cambridgeshire PCT had not received a report on compliance with standards from Peterborough doctors-on-call since April 2009.

In April 2010 NHS Cambridgeshire stated that routine monitoring of all out-of-hours providers including Peterborough doctors-on-call was now reported to the board.

Findings of fact on routine monitoring by NHS Cambridgeshire and its effectiveness

- The urgent care network was the mechanism for routine monitoring of out-of-hours services.
- The monitoring at the urgent care network was restricted to the distribution of reds and greens provided by the various out-of-hours services. The underlying data were never examined or queried.
- No lessons from the death of Mr Gray were taken formally to the urgent care network.
- There was no discussion of staffing levels or unfilled shifts at the urgent care network.
- None of the governance structures or committees at the PCT received reports on performance from TCN although some issues were brought on an ad hoc basis.
- Staff in the PCT with responsibility for monitoring the contract did not understand key aspects of the information on activity provided by TCN.
- The PCT never queried the activity data provided by TCN.
- Staff in the PCT with responsibility for monitoring the contract did not understand the impact of call streaming on reporting the NQRs.
- Staff in the PCT were unaware that TCN was not directing patients with symptoms of stroke to 999.
- The PCT instigated monthly clinical quality review meetings with its other out- of-hours providers from June 2009.

Systems in place in NHS Cambridgeshire to identify and escalate issues of concern

The death of Mr Gray was formally reported and discussed at the private part of the PCT's board meeting in March 2008 and a special meeting was held the following month. The board subsequently received regular updates on the Langdale review.

The assistant director of hospital care at the PCT was responsible for monitoring incident reporting. She stated that there had been a number of business meetings and discussions with TCN which were not continued because the topics became the responsibility of the Langdale review. The only formal record that Cambridgeshire PCT provided of these business meetings were the minutes of two monthly meetings held with TCN in December 2007 and January 2008. Neither of these meetings was attended by a clinical representative from either TCN or the PCT, although there was some discussion of incidents and complaints. At the January 2008 business meeting the PCT representative raised the issue of the 'steady flow of incident and near miss reporting from nurses at Wisbech'.

Some PCT staff told us in interviews that they had been aware of specific concerns relating to foreign doctors. The chief pharmacist stated that she had raised concerns with the clinical governance lead for TCN a couple of years earlier. These involved the difficulties foreign doctors had with understanding the British National Formulary. It did not appear that this was followed up any further. The chief pharmacist told us that before the death of Mr Gray the PCT had not inspected TCN's arrangements for the management of medicines or reviewed their policies. However this had changed after the death of Mr Gray and when we interviewed the chief pharmacist in late June 2009 the PCT had given TCN detailed advice on how to improve their policies and procedures. At this time the policies had still not been approved by the PCT. The PCT also made unannounced inspections of controlled drugs at Camdoc and Huntsdoc in August and October 2008.

The former medical director of the PCT acknowledged to CQC that before the death of Mr Gray the PCT had no direct involvement with TCN other than by exception reporting. This meant that the PCT would only be contacted by the service provider if there was an issue that TCN decided the PCT should be aware of. She commented that this system did not work. The PCT did not receive detailed information about specific incidents or complaints in the TCN performance report until May 2008.

The medical director told us that after the death of Mr Gray, complaints and clinical incidents were reported to the routine contract management meetings and the Langdale monthly meetings. There was evidence of substantial review of complaints and incidents at the Langdale meetings. There was no record however of discussion of individual complaints or incidents at any of the subsequent meetings of the urgent care network.

In June 2008 Cambridgeshire PCT declared a SUI because TCN continued to provide inadequate and late information about incidents. Cambridgeshire PCT was already aware of the problems with incident reporting at TCN, as they had not immediately reported the death of Mr Gray to the PCT. TCN and Cambridgeshire PCT met on 4 August 2008 to discuss this SUI and TCN presented evidence to support the actions they had taken in response. There was no reference to this SUI being discussed at the urgent care network.

Cambridgeshire PCT had a record of incidents and complaints raised directly with the PCT relating to out-of-hours since 2007. They also kept a log of concerns raised with PALS relating to out-of-hours between July 2007 and March 2009. The outcome of complaints was usually that they had been forwarded to TCN. There was no update on whether these complaints were resolved. There were ten incidents in total relating to TCN, three of which related to inadequate levels of staff in out-of-hours bases. Generally these incidents were copied to TCN to investigate although more recently further action by the PCT had been detailed.

Findings of fact on systems to identify and escalate areas of concern

- Before the death of Mr Gray in February 2008 the PCT had limited direct contact with TCN.
- The PCT did not receive information about specific incidents or complaints in TCN's performance report until May 2008.
- Complaints and incidents were discussed at the Langdale meetings, but there was no record of discussion of complaints or incidents at the urgent care network.
- NHS Cambridgeshire declared a SUI in June 2008. This was about TCN's system for reporting and dealing with incidents. This matter was not discussed at the urgent care network.
- Before the death of Mr Gray in February 2008 the PCT had not reviewed TCN's policies for managing medicines.
- Following the death of Mr Gray the PCT made unannounced controlled drug inspections at all of their out-of-hours providers.

Local perspectives on TCN's out-of-hours services

Patient and Public involvement forum

In January 2008 the patient and public involvement forum (PPIF) published a report into the out-of-hours services following visits made to the out-of-hours bases in the winter of 2007.

The report stated that some patients experienced difficulties visiting out-of-hours services because of the distances involved. It was noted that most doctors came from abroad but had excellent English and relevant experience. It was noted that staff in Ely and Wisbech had been informed about proposed service changes and there was an obvious reduction in morale and uncertainty as to how the new system would work. It was also noted that one doctor from Germany and the doctor booked for the previous day had not turned up.

The PPIF team had met with TCN and commented that there was a lack of understanding of the new care model, poor relationships between management and staff, and poor internal communications. The report noted that TCN had agreed to provide the team with information relating to these concerns but that the information had not subsequently been provided.

In addition to visits to the bases, the PPIF review team acting as patients phoned the out-of-hours service during May 2007. The service had been advised this would happen. They found that the service was slow in answering calls and that there was an inappropriate message diverting patients to the minor injuries unit at Ipswich. Following recommendations made in this report Cambridgeshire PCT stated that TCN had agreed to improve the speed at which they answered calls and removed the message about the minor injuries unit. The PCT responded formally to the overall report from the PPIF but did not refer to its concerns about poor communication and relationships between management and staff.

Local GPs

We were told by the representative of the local medical committee that concerns had been raised by local GPs working in out-of-hours about clinical isolation, lack of teamwork and the distances GPs had to travel to get to work. TCN had lost many local GPs because of concerns they had about the quality of the clinical staff that TCN was using to supplement the workforce.

The majority of local medical professionals that CQC spoke to about TCN's service were generally satisfied that the majority of clinical care was of an acceptable standard and GPs were generally positive about the information on consultations sent to their practice. There were, however, concerns expressed that at times the service was too stretched with staffing levels too low to cover such a wide geographical area and a number of GPs commented that they would prefer to see more bases open during the evenings and overnight. Concern was expressed that overnight there might only be a nurse or ECP in the area and parts of the county, such as Ely, were a long way for the doctor based at Newmarket to cover. Some GPs were concerned with the lack of local doctors encouraged into the service and that the quality of some of the unfamiliar doctors brought in at short notice was not of the highest standard, although most said that this practice had reduced.

NHS Cambridgeshire asked the local medical committee (LMC) to survey local GPs about the out-of-hours services. The LMC ran the survey in the summer of 2009 and 262 out of 714 GPs replied. 10 out of the 19 GPs who worked for TCN made critical comments. 40% of GPs in the East Cambs and Fenland area of Cambridgeshire thought the service needed more medical cover. This was higher than for the other areas surveyed by the LMC, and this area had the lowest proportion of local GPs working in the out-of-hours service.

The CQC sent a survey to GP practices in Cambridgeshire PCT in October 2009 asking them for feedback about the out-of-hours service provided by TCN to their patients. We received responses from 20 GPs which represented 18% of total GPs in East Cambridgeshire and Fenland. We compared these figures to a similar survey sent out by 'Devon Doctors' out-of-hours service in December 2006. The response rate for the Devon Doctors survey was 47%. We are 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.

65% of those that responded stated that the services provided by TCN were poor or very poor. In comparison only 1% of Devon GPs rated the out-of-hours service as poor or very poor. Cambridgeshire GPs raised specific concerns about understaffing, waiting and response times and the quality of care provided.

30% of the responding Cambridgeshire GPs said they did not have concerns about any particular groups of patients. 70% of respondents did. These concerns included

treatment for the elderly, those requiring palliative care, and patients who needed home visits.

10% of the responding Cambridgeshire GPs felt that the telephone response times to patients were good or excellent (71% at Devon Doctors) and 10% stated that the standard of GPs utilised by TCN was good (79% at Devon Doctors). 30% felt that ease of access to a local treatment centre was good or excellent (64% at Devon Doctors) and 5% thought that the length of time patients had to wait to be seen was good or excellent (66% at Devon Doctors). None of the responding doctors stated that the ability for patients to receive home visits when clinically required was good or excellent (63% at Devon Doctors).

In general Cambridgeshire GPs were happy with the reliability and content of individual patient information sent to practice. Less than half of Cambridgeshire GPs stated that the general standard of communication with their practice was good or excellent (80% at Devon Doctors).

Findings of fact on local perspectives of TCN's out-of-hours services in Cambridgeshire

- In 2008 the PPIF noted that some patients had problems in using the out-of-hours services because of the distances involved.
- Local GPs who worked for TCN had concerns about clinical isolation and poor teamwork.
- In 2009 NHS Cambridgeshire asked the local medical committee (LMC) to survey local GPs about the out-of-hours services.
- In the LMC survey, 40% of GPs thought that the service needed more medical cover.
- In the CQC survey of GPs, 65% of the doctors who responded considered that the services provided by TCN were poor or very poor.
- In Cambridgeshire, GPs' views of TCN compared very unfavourably to Devon GPs' views of Devon Doctors.

Developments

The PCT issued a termination notice ending the contract with effect from 1 December 2009. Camdoc provided the out-of-hours cover until the new contract began in April 2010.

NHS Great Yarmouth and Waveney

History of the PCT and out-of-hours service delivery

NHS Great Yarmouth and Waveney covers an area that is broadly aligned with Great Yarmouth Borough Council and Waveney District Council. It serves a population of around 230,000. The region is more deprived than other areas of the East of England. Compared with Suffolk, life expectancy is lower and there are marked inequalities. The trust was established in October 2006 following the merger of Great Yarmouth teaching PCT and Waveney PCT.

The new PCT inherited significant financial problems and ended the 2006/2007 £1.3 million in debt, having repaid £7million. In 2007/2008 it ended the year in surplus but received poor ratings for the local auditors evaluation, the Healthcare Commission's annual health check and the assessment of World Class Commissioning. The consequence was a radical change in the board with a new chairman being appointed and a replacement director of finance, and the chief executive. Since that time the PCT has made steady progress, achieving scores of fair and good in the 2008/2009 annual health check rating. There was an interim chief executive at NHS Great Yarmouth and Waveney from May 2009 until the new chief executive took up post in November 2009.

Originally SDOC provided the out-of-hours service in Great Yarmouth and Waveney. In 2004 the contract was awarded to Anglian Medical Care (part of the East Anglian ambulance service) which provided the service for three years. The service was then put out to tender in 2007 and TCN was awarded the contract in October 2007. The PCT continued to have financial problems and we were told by the interim chief executive that the PCT had undertaken a competitive tender. The contract with TCN was less expensive than its predecessor.

The director of public health told us that the specification for the contract had focused on access times to treatment centres, because of the rural nature of the area. The PCT wanted every resident to have no more than a 30 minute drive to see a clinician. Staff from the PCT described the TCN proposal as having a comprehensive number of bases.

Representatives from the local medical committee told us they had concerns that there had been inadequate clinical involvement in the specification of the services. NHS Great Yarmouth and Waveney held a three month consultation on the draft out-of-hours specification which was publicised widely. There was evidence that the PCT considered concerns raised by GPs as a result of this consultation. Members of the PEC were given time to consider the specification and approved this document in April 2007. The PCT received legal advice that GPs should not play any part in the tender process. It was not clear whether Great Yarmouth and Waveney approached other PCTs for references for those bidding to provide the out-of-hours services as part of the tender process.

The district nursing service In NHS Great Yarmouth and Waveney was not available 24 hours a day. Patients requiring services when the service was not available in the early morning and early evening may well have relied on the out-of-hours services. There were two '100 hour' pharmacies. The provision of pharmacy services was said to be adequate in urban areas during out-of-hours periods but not as good in rural areas.

The PCT had not reduced the value of the out-of-hours contract over the last three years; it was a three-year contract at a fixed price. The medical director of the PCT stated that he thought the contract value was not adequate to cover the quality of service that TCN wanted to provide.

The Primary Care Foundation found that the out-of-hours service was below the average for

cost per head. The cost per head was well below the median compared with other PCTs that were categorised as rurally based, according to their population density.

Findings of fact

- There had been considerable turnover at board and senior manager level since the creation of the PCT.
- The procurement process led to an out-of-hours contract which was less expensive than its predecessor.
- The PCT held a three month consultation on the draft specification, recorded GPs' concerns about the specification and made changes as a result.
- The LMC did not think there had been enough clinical involvement in the development of the specification.
- The cost per head of the out-of-hours service was well below the median compared with other PCTs that were categorised as rurally based.

Routine monitoring of the out-of-hours contract and the effectiveness of this monitoring

During the implementation stage of the new out-of-hours contract in 2007, the contract monitoring team met weekly. From January 2008 the contract monitoring meetings took place monthly. The commissioning manager and the head of performance routinely attended on behalf of the PCT. In March 2009 the director of commissioning and planning also began to attend the meetings in order to emphasise that the PCT was strongly managing the performance of the contract.

We were told that every three months staff from clinical governance at the PCT attended the contract and performance meeting. From the minutes of the meetings supplied by the PCT it appeared that these joint directorate meetings had not taken place regularly. There were no clinical representatives from the PCT at these meetings between September 2008 and May 2009. The PCT contract manager attended the committee responsible for monitoring patient safety issues twice during this time and quality in out-of-hours was discussed but there was no representative from TCN at these meetings.

In July 2009 the minutes recorded that the medical director and nursing director of the PCT had attended the contracts meeting. This was the first time they had done so. The medical director for TCN had attended the clinical review meetings held in 2008 and the lead nurse for TCN started to attend the clinical meetings in 2009. TCN client managers attended the routine monthly meetings.

It was not clear how long the TCN performance reports had been routinely reviewed by clinical staff at the PCT. The patient safety and clinical quality manager told us in July 2009 that she now saw the monthly reports on performance but did not know how long those reports had been produced by TCN. When asked what monitoring took place of the quality of the out-of-hours service, the director of nursing told us that she did not scrutinise the reports on performance since that was the responsibility of the contracts team. The director of public health did not routinely see these reports but thought that they occasionally went to the executive team or the board.

We queried whether a clinician was required to understand the figures fully and make a decision about whether TCN's explanations were valid. The director of public health stated that he thought this was undertaken by the medical director. However the medical director did not routinely receive the performance report. The medical director told us that he relied on the contracts team to bring him any problems in the report and that they had not come to him with any concerns. He stated that the role of monitoring contracts was split between staff in commissioning and performance with some clinical input, but that clinical staff did not take the lead responsibility for the contract. The interim chief executive told us in October 2009 that the chief nurse and medical director were in charge of monitoring the achievement of the national quality requirements in the contract

Despite the confusion about the responsibility for clinical involvement in the monitoring of out-of-hours, there was more in-depth discussion recorded in the minutes of the contract monitoring meetings than in the other PCTs that CQC reviewed. On more than one occasion the PCT requested that TCN provide them with the raw data that supported the performance information. TCN had agreed to start processing the information through a data warehouse in order to comply with these requests.

The minutes of the meeting to monitor the contract and performance in January 2008 noted that the PCT had major concerns about the service and had received numerous complaints from patients, staff and clinicians working in the service. For example, patients had been told by the call centre to attend Beccles base without specific appointments. Other patients were given appointments but arrived to find the doctor was not there. The staff of the minor injuries unit at Beccles base had complained they had to deal with TCN's patients because they had to wait so long.

The head of inpatient and day services at the PCT stated that she had had complaints regarding a number of different areas, including:

- No feedback to the PCT about incidents reported.
- No communication between Ipswich and the bases.
- Delays in answering telephone calls.
- Doctors not following policies for admissions
- Encouraging 'walk-in' patients.

As a result of the concerns raised in the contract monitoring group in January 2008, the PCT gave TCN one week to produce an action plan for improvement. The PCT followed up the specific concerns at the meeting in February 2008 which was attended by senior members of staff from TCN and the PCT's director of commissioning

The national quality requirements were discussed at contract meetings in greater detail than at the other PCTs. However, when we spoke to staff at the PCT there were still some uncertainties around what the information actually meant. The director of nursing was not aware that calls were streamed and patients were being sent 'straight to base'. The director of performance was aware of this protocol but was not aware of the details. The commissioning manager stated that she had been informed by TCN that call handlers were booking patients straight to base and that she was unhappy that TCN had not discussed this with the PCT before it was implemented. There was a general lack of awareness that the number of patients sent directly to the base were not reported in the quality requirements.

Staff responsible for monitoring the contract had not been aware that the call handlers were not following the national guidelines for patients with symptoms of a stroke. Following interviews with CQC staff where this was raised, the PCT told us that when they followed this up, TCN told them that they were following national guidance. In observation visits in August 2009 CQC found that this was not the case. TCN was officially part of the stroke network but the medical director told us in July 2009 that TCN had not attended in the last year. The PCT had not had an explicit conversation with TCN about developments in stroke services and what their expectations were for their residents.

Neither the staff responsible for monitoring performance or the clinical staff we spoke to at the PCT could explain why the number of emergency calls reported by TCN was consistently zero. Those responsible for monitoring TCN's activity against the national quality requirements were not aware of the categories used by TCN and clinical staff were not aware that the number reported was zero. The PCT stated that the commissioning manager and the performance manager visited TCN in August 2009 to improve their understanding of how calls were handled and data recorded.

Great Yarmouth and Waveney PCT put pressure on TCN to routinely audit the clinicians working in their service. In July 2008 TCN started auditing using the RCGP toolkit. This was earlier than for the other PCTs. CQC brought to the attention of the PCT that the audit of clinicians carried out by TCN indicated that between July and September 2008, 45%

of TCN clinicians were not 'safety netting' their patients. This meant not giving advice about the circumstances under which they should contact the service again. The PCT's medical director and director of nursing were not aware of these results.

In June 2009 the medical director wrote to TCN for the names of all GPs working in out-of-hours who were not on a local performers list and the details of which performers list they were on. He received a list of 10 GPs from TCN and wrote to each of the PCTs listed and asked whether the GP was on their list, whether they had had an appraisal and whether there were any outstanding concerns about their performance. After six weeks the medical director had still not heard from three of the PCTs and he had received some responses which stated that the named GPs were not on the specified performers list. He then wrote to TCN to see how they were going to check whether a GP was on the list in the future and whether this would entail a rolling programme of checks. The PCT's medical director stated that he was working with TCN to ensure that all GPs were appraised.

In an annual review of quality in 2008 the PCT raised concerns about unfilled shifts. The commissioning manager was aware that if a shift was unfilled then TCN asked a clinician from another base to attend. For example if the base at Lowestoft had no clinical staff, TCN would move a clinician from Great Yarmouth to Lowestoft. The PCT informed TCN that this was unacceptable.

TCN did not initially report the percentage of shifts that were unfilled. However in July 2009 the PCT requested this information. The director of nursing stated her expectation that TCN would inform them if a GP shift was covered by a nurse practitioner or an emergency care practitioner. There was no example in the minutes of the contract monitoring meetings of an occasion when TCN had given this information. The PCT did not know whether GPs in out-of-hours worked too many shifts or worked too may hours.

The PCT's assessment of compliance at the end of 2009 found that shifts were not always adequately filled. It also found that times of predictable demand such as Saturdays were not sufficiently covered. The report in December 2009 stated that TCN's escalation plan was superficial, lacked detail and was not robust. TCN was to develop a joint action plan with the PCT to match capacity to meet demand. The status of this plan in January 2010 was 'ongoing'.

CQC asked TCN's staff who worked in the area of Great Yarmouth and Waveney PCT, how they rated clinical staffing levels at TCN bases. Nine of the 13 staff who responded (69%) stated that clinical staffing levels were poor. In comparison, only one (7%) of the 14 staff who responded to a separate question felt that non-clinical staffing levels were poor and 12 (86%) reported that non-clinical staffing levels were good or excellent.

Findings of fact on NHS Great Yarmouth and Waveney's routine monitoring of out-of-hours and its effectiveness

- From January 2008 there were monthly contract meetings
- Meetings to review performance and governance were meant to take place quarterly but had not happened on a regular basis. No clinical PCT staff attended the contract monitoring meetings between September 2008 and May 2009.
- In July 2009 the medical director and nursing director attended the contract meeting for the first time
- There was confusion at the PCT over who was responsible for scrutinising clinical aspects of the performance reports
- There was more detailed discussion minuted at the contract meetings than for the other PCTs
- The PCT carried out an annual assessment of compliance
- Staff responsible for monitoring the contract did not understand the way in which activity was reported in the performance reports; two senior managers

visited TCN in August 2009 to improve their understanding

- PCT staff did not understand the effect of call streaming on the reporting of the NQRs
- When we interviewed staff responsible for monitoring the contract, they were not aware that TCN was not following national guidance for stroke.
- In July 2008 the PCT ensured that TCN audited its clinical staff. This was earlier than in the other PCTs.
- 45% of clinicians were found to be providing inadequate 'safety net' advice to patients. The directors of medicine and nursing at the PCT were not aware of these results.
- The medical director took pro-active steps to check which GPs working for TCN were on which PCT's performers list. He worked with TCN to ensure that all GPs had had an appraisal. This action was not seen in other PCTs.
- In the annual review of 2008 the PCT raised concerns about unfilled shifts. In July 2009 the PCT asked for performance reports to include details of unfilled clinical shifts.
- In our survey of TCN's staff, 69% of those who responded who worked in Great Yarmouth and Waveney reported that clinical staffing levels were poor.
- In January 2008 the PCT required TCN to produce an action plan to address concerns raised in the contract monitoring meeting.
- The PCT's annual audit of compliance at the end of 2009 found that shifts were not always filled. TCN was required to develop an action plan.

Systems in place to identify and escalate issues of concerns in NHS Great Yarmouth and Waveney

The PCT's patient safety and clinical quality group was responsible for monitoring and reviewing matters relating to patient safety and clinical quality in services the PCT commissioned. From January 2008 this group met monthly. The medical director, the director of nursing and the integrated governance manager attended the meetings. There was feedback from out-of-hours at every meeting with specific discussion of individual incidents and complaints that had taken place at TCN. This committee reported to the integrated governance committee which included executive and non-executive members of the board. Reports about TCN were received in three successive months in 2008.

The serious incident in Cambridgeshire (death of Mr Gray) was reported to the patient safety and clinical quality group in October 2008. It was stated that the incident would be raised at the next contract monitoring meeting. However there was no record of the details of the SUI in Cambridgeshire being discussed at the contract monitoring meetings. In September 2008 the minutes of the contract monitoring noted that the medical director for TCN stated that 'some palliative care drugs are about to be changed in order to conform to new guidelines. Phials of opiates will be mostly 10mg, with a special procedure available for those on higher doses'. There was no further discussion or details provided.

The minutes of the patient safety and clinical quality group recorded a number of occasions where it was agreed that the information reviewed by the group should be shared with the contract monitoring team. Complaints and incidents were regularly discussed at the contract meetings. There were also specific requests for complaints and incidents logs to be provided to the PCT's commissioning manager. The commissioning manager attended all the contract meetings. On occasion the group asked for sight of the performance reports from TCN but there was no formal record in the minutes of the

performance reports being reviewed at these meetings.

The team for managing medicines did not immediately hear about the death of Mr Gray. Each PCT has its own local intelligence network and there was no requirement for Cambridgeshire PCT to be part of the network which Great Yarmouth and Waveney hosted across Suffolk and Norfolk. Although TCN had been invited they did not attend. The deputy head of medicines management stated that TCN had reported the incident in the annual declaration of controlled drugs 2008/2009. The details were not received until March 2009 and led to the PCT making a series of visits to TCN locations in May 2009.

The deputy head of prescribing and medicines management had not seen TCN's overarching policy for medicines management but was aware that there had been considerable input from Cambridgeshire PCT. She said that the PCT had had a meeting with TCN in order to review their standard operating procedures. The PCT had copies of all TCN's operating policies for controlled drugs.

The medical director stated that the prescribing team had made sure that 100mg of diamorphine was no longer being stored anywhere at the PCT. The deputy head of prescribing and medicines management confirmed that they had visited all TCN's bases and noted the arrangements for storage of controlled drugs. We were told that the head of medicines management attended the group that considered untoward incidents and if appropriate action had not been taken, it would be followed up with TCN. The PCT's deputy head of prescribing and medicines management said the PCT kept a watch on prescribing in out-of-hours services.

NHS Great Yarmouth and Waveney reported two SUIs in out-of-hours in 2009 which TCN also recorded internally as SUIs. Both of these SUIs were discussed at the contract monitoring meetings and the patient safety and clinical quality monitoring group.

The board noted in July 2008 that there were problems with TCN but that these were being dealt with by the assistant director of commissioning. There was no further update in later board meetings until May 2009, when the board received a comprehensive briefing on TCN. This included details of the other serious incidents in out-of-hours and the actions taken in relation to these. In the autumn of 2009 the board was regularly informed of the situation in NHS Cambridgeshire following the serious incident.

The performance committee, which first met in April 2007 and until October 2008 was known as the finance and performance committee, received a report in relation to TCN in September 2009 when an overview of the national requirements was presented. The committee reviewed the specific issues that the PCT had had with TCN. These meetings were attended by non executive directors of the PCT and the interim director of performance. A further report was presented the following month.

Findings of fact on NHS Great Yarmouth and Waveney's systems to identify and escalate concerns

- Out-of-hours was discussed at every meeting of the patient safety and quality group. Reports went to the integrated governance group in 2008.
- The death of Mr Gray was reported in October 2008 but the death of Mr Gray was not discussed at the contract monitoring meetings.
- The SUIs in out-of-hours in 2009 were discussed at contract monitoring meetings and at the patient safety and quality group.
- The PCT had visited all the bases and noted the arrangements for controlled drugs.
- The board received a detailed report on TCN in May 2009 that included details of all the serious incidents in out-of-hours.

Local perspectives on the out-of-hours service

Local GPs

The PCT had not formally surveyed the opinion of local GPs but the chief executive stated that the medical director had held meetings in different areas and contacted a number of GPs. The director of commissioning and the medical director said that local GPs had raised concerns that service was stretched. The chairman of the clinical executive committee stated that GP colleagues had informed him that there had been occasions overnight where there was only one GP covering the entire area of Great Yarmouth and Waveney.

Representatives from the LMC told us that GPs reported they had stopped working for the out-of-hours service because they were unhappy about the staffing levels.

CQC sent a survey to GP practices in Great Yarmouth and Waveney PCT in October 2009 asking them for feedback concerning the out-of-hours service provided to their patients. We compared these figures to a similar survey sent out by 'Devon Doctors' out-of-hours service in December 2006. The response rate for the Devon Doctors survey was 47%. We are 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.

We received responses from 35 GPs in total which represented 21% of total GPs in Great Yarmouth and Waveney. 66% of those that responded stated that the services provided by TCN were poor or very poor. We compared these figures to a similar survey sent out by 'Devon Doctors' out-of-hours service in December 2006. Devon Doctors cover a large rural area with a similar population density to the areas covered by TCN. In comparison to the same question asked of Great Yarmouth and Waveney GPs only 1% of Devon GPs rated the out-of-hours service as poor or very poor. Great Yarmouth and Waveney GPs raised concerns about understaffing (15 GPs), quality of patient care (eight GPs), waiting times (three GPs), and the quality of the clinicians employed by TCN (three GPs).

34% of the GPs said they did not have concerns about any particular groups of patients, whereas 60% did and 6% did not respond. These concerns included care for elderly patients (seven GPs) and patients requiring home visits (five GPs).

11% of the GPs felt that the telephone response times to patients were good or excellent (71% at Devon Doctors) and 6% stated that the standard of GPs utilised by TCN were good or excellent (79% at Devon Doctors). 14% felt that ease of access to a local treatment centre was good or excellent (64% at Devon Doctors) and 6% thought that the length of time patients had to wait to be seen was good or excellent (66% at Devon Doctors). 17% stated that the ability for patients to receive home visits when clinically required was good or excellent (63% at Devon Doctors).

57% of GPs who responded stated that the reliability of individual patient information sent to practice was good or excellent (79% at Devon Doctors). 26% stated that the content of this information was either good or excellent (71% at Devon Doctors). 34% of Great Yarmouth and Waveney GPs stated that the general standard of communication with their practice was good or excellent (80% at Devon Doctors).

Findings of fact on local perspectives

- The chairman of the CEC stated that GPs reported that that there had been occasions overnight where there was only one GP covering the entire area of Great Yarmouth and Waveney.
- In the CQC survey, 66% of GPs that responded said that TCN's services were poor or very poor. The most common concern was understaffing, which 43% mentioned.

- Generally, GPs were highly critical of TCN's services and the responses compared unfavourably with Devon Doctors.

Developments

It was clear when CQC spoke to senior staff at Great Yarmouth and Waveney late in 2009 that the PCT had spent some time reviewing the information provided by TCN. We have already referred to their audit of compliance at that time. The interim chief executive told us that what TCN told them was often different to what they heard from local GPs. The PCT had started to request details of any closures of bases as they felt it was happening more frequently than TCN reported. The PCT increased its requirements for TCN to provide details of shift coverage and during the period of winter pressures the reports were received weekly.

The PCT undertook a review of its systems for governance with the patient safety and clinical quality committee now reporting directly to the board. The Medical Director and Nursing Director were given joint responsibility for scrutinising clinical aspects of performance reports and feeding into the contract monitoring process.

Non executive directors had been involved in carrying out unannounced inspections at the out-of-hours bases and the PCT focussed on building relationships with the local GPs and seeking their views of out-of-hours service delivery.

Great Yarmouth and Waveney had problems developing an alternative out-of-hours service in place of TCN and were especially concerned about the impact to their service if the TCN contract was terminated in Suffolk. The PCT gave notice to TCN in October 2009 that there would not be an extension to the contract beyond October 2010.

From 1 April 2010 the out-of-hours services at NHS Great Yarmouth and Waveney were provided by Harmoni.

NHS Worcestershire

History of the PCT and out-of-hours services

NHS Worcestershire was formed in October 2006 from a merger of Wyre Forest PCT, Redditch and Bromsgrove PCT and South Worcestershire PCT. Wyre Forest has a population of around 100,000, Redditch and Bromsgrove a population of around 170,000 while South Worcestershire has a population of around 280,000. The northern part of the county includes the beginnings of the urban sprawl of the Midlands agglomeration, while the south of the county is largely rural. The county has pockets of relative urban and rural deprivation. All of the existing PCTs had financial pressures when they merged and NHS Worcestershire inherited a significant deficit of £16 million. As a result of the merger the PCT was expected to make savings of £2 million on management costs.

Since 2004 out-of-hours services had been provided by South Worcestershire PCT on behalf of the three PCTs in the county. The service consisted of three GP co-operatives aligned with the original PCTs. We were told that each of these services worked in different ways, even after the service went county wide.

Senior PCT staff told CQC that the previous out-of-hours service delivered by the local GP co-operatives provided poor care and that there had been a number of complaints in relation to out-of-hours, mainly around poor telephone access. The service was rated as having performed poorly in the Healthcare Commission's review of urgent care published in September 2008. However this was mainly because the service was unable to provide the information that was requested and was not necessarily a reflection of the treatment being provided by clinicians. The manager at the PCT who had been responsible for receiving incidents about the Worcestershire GP led service did not consider there had been significant concerns.

The report to the commissioning board by the interim director of commissioning in February 2007 stated that ''the service is being faced with steadily increasing call volumes with a fixed number of phone lines to cope with this. Consequently, the service is unable to meet Department of Health (DoH) standards in terms of phone pick up time and faces the possibility of patients with significant pathology not being able to receive appropriate timely advice. This had led to increasing numbers of complaints and some increasing clinical risks within the service". The report also stated that "there is no option in terms of continuing the current level of service. The PCT cannot continue to fail to deliver below the standards required by the DoH". This statement was based on the level of investment perceived to be necessary to continue the PCT-led service.

The recommendation of the report was to develop a service specification for the urgent primary care service with a view to market testing the service. The minutes of the commissioning board meeting noted that the management team recommended market testing the service. The trust board in March 2007 noted the decisions made at the commissioning board meeting in February 2007.

There was little evidence that the decision to market test the service had been part of a wider strategy for urgent care, nor was it evident that the PCT had considered other options such as a replacement provider for the telephone service. The commissioning board noted there were opportunities to develop innovative working in partnership with the local acute trust A&E departments and the Minor Injury Units.

At the time the decision was made to market test the service, the post of medical director did not exist and there was no head of primary care. The director of public health and director of clinical development provided clinical leadership. The head of primary care was appointed in September 2007. The PEC met

for the first time in February 2007 and before this the commissioning board provided clinical leadership.

The draft specification was presented to the commissioning board in June 2007 and there were several GPs on this committee including the interim PEC lead. This document was broadly based on national documentation and an out-of-hours specification developed by NHS Norfolk. The procurement approach taken by the PCT was the 'competitive dialogue' model. This meant that the specification was non-prescriptive as they wanted the suppliers to suggest how they would provide the service. The commissioning board received regular updates on the tender process and was given an opportunity to comment on an early draft of the specification.

The PCT stated that the working group established to investigate the risks in out-of-hours had a specific brief of ensuring that any new service was integrated with the rest of the urgent care system. There was no evidence from the out-of-hours project board meeting minutes that integration with the urgent care system was discussed and the minutes of the November 2007 meeting stated that "the service specification has not been overly prescriptive at this stage in order to understand the service potential and influence the future shape of the service specification and ultimately the OOHs service".

Some of those involved in the procurement felt there was a lack of vision from the PCT. A member of the project board involved in key stages of the procurement process commented that until the final stages of the decision making process there was a lack of involvement from the steering group and that 'an understanding of any real vision from the PCT was absent'. The PPI representative stated that it may have been useful for the team to have had an agreed brief from the board at the beginning of the process in terms of their vision for the future. Of the six feedback forms received in the evaluation of the procurement process, two made reference to the lack of long term vision shown by the PCT. One described the adherence to the procedure and protocols as exemplary.

The specification for out-of-hours was presented to the PEC in January 2008 at which stage it was stated that 'a tailored service specification needed to be developed to inform the last stage of the process and one of the key aims was overall coherence in the provision of urgent care and out-of-hours services'.

A risk noted at the project board meeting in January 2008 was the concern around the lack of local knowledge/integration. An email was sent in March 2008 from a manager involved in the final stages of the procurement process about the level of clinical input in the final round of discussions. This correspondence expressed concerns that the 'direction of clinical services would not be adequately represented'. CQC was told by the LMC secretary that there appeared to be little GP involvement in the procurement panel and award of the contract.

The PCT had recruited a recently retired GP to join the procurement panel rather than the representative that the local medical committee requested. The other clinical representative on the panel was another retired GP with experience of working in out-of-hours, although not in Worcestershire. The local GPs were making their own bid for the contract and the PCT was advised by the Healthcare Purchasing Consortium that inclusion of local GPs in the procurement process would present a conflict of interest. The chair of the PEC joined the panel at the final stages of the procurement process.

It was not apparent from the evidence reviewed by CQC that the local strategic fit of the out-of-hours service was considered until the latter stages of the procurement process.

The PEC chairman told us that the main selling points of TCN was that the computer system was reportedly more efficient and the call answering system was more robust. In the extraordinary board minutes of 28 April 2008 the then director of commissioning stated that although TCN was the most expensive bid they had been able to demonstrate that the additional expense related to higher numbers of staff and skill mix. The scoring matrix for the final four bidders confirmed that TCN was the second most expensive bid.

NHS Worcestershire stated that as part of the tendering process they requested from all organisations on the final short list a complete list of all serious incidents and references from one established commissioner. They also undertook site visits to interview commissioners and staff who worked with the supplier. In the case of TCN how they dealt with a selected serious incident formed part of the submission to the panel with specific reference to lessons learned and improved procedures.

NHS Worcestershire was informed of the death of Mr Gray before they awarded TCN the contract. The PCT they contacted was NHS Suffolk. The lessons learned and improved procedures implemented as a result of this incident were not verified with NHS Cambridgeshire. Members of the procurement panel visited the operational bases of each of the tender applications but these visits took place 'in hours'.

We were told that keeping local GPs involved in delivering out-of-hours was an objective of the procurement exercise and that TCN had provided the most convincing bid in that respect. The project manager for the procurement and implementation phase told us that the model that TCN had presented was fairly non prescriptive in terms of precise structure and numbers of staff. They also commented that a further model presented by another bidder was rejected as the panel felt that there were too few GPs. TCN was not specific about what they intended to pay their staff if they won the contract and the deputy director of finance told us that TCN had only provided a global figure for staffing costs.

On 28 April 2008 TCN was awarded the contract for out-of-hours. In July 2008 they took over management of the service and the implementation of the new TCN model of delivery started in October 2008. Those doctors who had previously been working in the out-of-hours service in the PCT lost their entitlement to NHS pensions and sessional pay rates were reduced, resulting in a net reduction in income from working in out-of-hours of 20-30%

The LMC raised concerns about staffing levels and pay rates with TCN at a meeting in September 2008. TCN produced revised staffing rotas at this meeting but did not renegotiate the pay rates. The LMC continued to raise concerns about the quality of out-of-hours services and their relationship with TCN deteriorated. The PEC chair told us that many local GPs left the service as a result. The PCT was not aware when they awarded the contract that TCN intended to reduce pay rates for GPs and they did not think it was appropriate to become involved in the subsequent discussions between TCN and the GPs.

The value of the variable elements of the out-of-hours contract was increased by NHS Worcestershire by 9% in 2009/2010, backdated to October 2008 and to be in operation until October 2010. 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 also confused ‘contacts’ with ‘patients’. We have already noted that TCN’s client service managers did not fully understand the activity figures. In the next section we note that neither did many of the PCT staff responsible for monitoring the contract, although the PCT’s director of delivery did. TCN’s proposal for the contract uplift included definitions of ‘patient calls’, ‘patient contacts’ and ‘patient events’. While these definitions would have alerted the PCT to the fact that patient contacts were not equivalent to call volumes or patient episodes/cases they incorrectly stated that

patient contacts would count every event that required reporting against the NQRs, i.e. that every call ending in a face to face consultation would count as two contacts. However, as noted previously, only base visits where an appointment was made generated two contacts whereas home visits and base visits without an appointment only generated one contact. Therefore despite the definitions provided by TCN the PCT would still not have had a full understanding of the activity being regularly reported.

The period over which the increase in activity was calculated included a Christmas period with unusually high demand across healthcare services nationally. This made it especially difficult for the PCT to assess whether any increase was due to a long term trend or the result of seasonal variation in demand. The PCT also made an additional one-off payment of £44,032 to allow TCN to provide additional clinical hours over Christmas. Given that the PCT had implemented payments to assist TCN with managing the period of highest demand it is unclear why a two year non-recurrent uplift was agreed to using this short period of demand data rather than waiting and evaluating any uplift against a longer and more stable period of demand. This is further supported by the fact that when the PCT reviewed the volume of calls after a 12 month period they found that there had only been a 2.2% increase, rather than the 19% increase forecasted by TCN, which resulted in the PCT having to seek further renegotiation of the contract in 2010.

The primary care foundation stated in their November 2009 out-of-hours benchmarking report that the cost per head of the service in Worcestershire was average.

Findings of fact on the context of out-of-hours services in Worcestershire and the procurement process

- The PCT was formed in 2006 and needed to make significant savings on management costs.
- The decision to market test the service was discussed at the commissioning board in February 2007. This was noted at the PCT board in March.
- The rationale for change was poor performance and the cost of providing new telephony.
- The commissioning board report that went to the trust board in March 2007 stated that the risks identified in out-of-hours were mainly in relation to call pick up times.
- The poor performance of the previous service in the Healthcare Commission's review of urgent care was because of failure to provide information.
- At the time the decision was made to change service providers the PCT had no medical director or head of primary care.
- There were several GPs on the commissioning board that discussed the broad specification for the new service.
- The LMC considered there had been little clinical involvement in the procurement panel.
- The PCT was advised not to involve local GPs in the specification or procurement because of potential conflicts of interest.
- The PCT considered that TCN would provide good clinical cover although the PCT did not monitor what structure or staffing levels would be in place or what doctors would be paid.
- The PCT only contacted NHS Suffolk for references for TCN. The PCT was aware of the SUI in Cambridgeshire but did not contact them for information about the circumstances of the incident.
- TCN's bid was the second most expensive.
- Net income for local GPs continuing to work in out-of-hours fell by 20-30%.
- The cost per head of the service in Worcestershire was average.

- NHS Worcestershire increased the value of the contract by 9% in 2009/2010. The methodology used by TCN to forecast the activity increase was unclear and was based on data that included a period of unusually high demand.

Routine monitoring of the out-of-hours contract and the effectiveness of this monitoring

The formal relationship between TCN and the PCT was through the contract management board. The board met monthly with quarterly meetings aligned with the quality review group. The head of non-acute commissioning routinely attended the monthly meetings for the PCT, and the lead executive nurse attended the quarterly clinical meetings. TCN's clinical lead for the Worcestershire out-of-hours service began attending the monthly contract meetings in March 2009; before that the meetings were only attended by TCN operational staff.

The national quality requirements were reviewed at these meetings but there was no evidence of interrogation of the information. It was not until September 2009 that the team started to ask for the figures underpinning the percentages. The lead executive nurse stated that she thought there had been some confusion between the monitoring of quality and the monitoring of performance and accountability for both.

It was clear from the interviews with the staff who were responsible for monitoring the contract with TCN that they were unsure about what the total activity figures in the performance reports represented. The project manager at the PCT with responsibility for implementation of the new out-of-hours contract stated that he had been particularly keen to develop the reporting framework with TCN. When presented with a performance report in the interview he told us that he had no idea how many individual patient calls were made to the service as it was not his job to evaluate the figures. He stated that that was the responsibility of the other members of the PCT contract monitoring team. The other members of the contract team were not able to interpret the information from the performance reports. The head of non acute commissioning was aware that TCN produced a record of all parts of the contact with a patient (although TCN only created a second contact for base visits by appointment) and commented that that was why people thought they had multiple patients. The lead executive nurse was aware that the activity figures did not actually represent the total number of calls but she was unable to explain the figures or other aspects of the information. NHS Worcestershire stated that the director of delivery understood the output of the HMS reporting system however he did not attend the contract monitoring meetings. We have already noted that from the start of the contract until March 2009 the front page of the report to the PCT stated that the number of calls made to the service was the same as the total number of contacts. There is no record of these figures being challenged. The chairman of the PEC told us that there had been an increase of 50% in patients being seen out of hours.

NHS Worcestershire stated in a letter to CQC in December 2009 that call streaming was not normal practice in Worcestershire PCT and that TCN had piloted the appointment system for children under five during Easter 2009. The results of the pilot were discussed in the contract management meeting in May 2009. This meeting was not attended by the lead executive nurse although a clinical representative of the PCT was present. There was no evidence that the implications of the straight to base protocol were discussed from a clinical perspective. The PCT was unaware that these patients would not be reported against a number of National Quality Requirements and that TCN was unable to report how long these patients waited to be seen after the initial call. In an unannounced visit by CQC to the Worcester call centre in August 2009 the reviewer was shown a copy of the protocol for management of children under five dated and stamped 22 July 2008. This protocol stated that the call handler should book a child under five 'straight to base' if they presented for advice. TCN also sent us a protocol dated September 2009 for the management of children under five which told call handlers to offer visits to bases for routine calls.

PCT staff had not been aware that the stroke protocol did not follow the national stroke guidelines i.e. that callers were not transferred to 999 if patients had symptoms of a stroke. TCN had not been challenged about their declaration of 100% compliance with the requirement to transfer life threatening conditions to 999.

TCN in NHS Worcestershire did not have the facility for call handlers to transfer emergency calls directly to the ambulance service and in practice the call handler told the patient to put the phone down and call 999. This meant that TCN could not be certain that the patient had contacted the emergency services. The PCT had been aware from October 2008 that there were problems transferring calls to 999 but these were not rectified until November 2009. 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) .

From the analysis CQC carried out of the TCN rotas, covering the period March-May 2009, 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. There were 103 occasions In Worcestershire where a clinician worked more than 12 hours consecutively in the three month period between March and May 2009. In the first ten months that TCN managed the out-of-hours contract the PCT had not asked TCN to produce this type of data. Nor had the PCT reviewed the staffing rotas or monitored the extent to which shifts were filled, or which profession filled them. The PCT considered that this was not something they would routinely review as long as the service met the National Quality Requirements. After the independent review in May 2009 the PCT began to ask for rotas and assurances around staffing.

In the autumn of 2009, CQC asked TCN staff who worked in the area of Worcestershire PCT, how they rated clinical staffing levels at TCN bases. 61% of the 62 staff who responded stated that clinical staffing levels were poor and 25% of the 59 staff who responded felt that non-clinical staffing levels were good or excellent.

TCN declared themselves compliant against NQR 4 (auditing of staff on clinical quality) from February 2009 onwards but had not actually provided any audit data to the PCT. The overall summaries of TCN's reports on performance for February, March and April 2009 stated that the audit had been completed. Later on in the same reports however it was stated that the action plan was currently being drafted for rollout throughout March and April. Compliance continued to be reported during summer 2009 but no results were presented. The lead executive nurse acknowledged in interviews in June 2009 that the PCT had not started to monitor this information. There was no evidence in the minutes that TCN were ever challenged about their declared compliance with this standard.

CQC were provided with copies of e-mail correspondence between staff responsible for contract monitoring and TCN. Some of these emails were repeated requests for information. A clinical staff member on the contract monitoring team told us that she had been disappointed by the response of TCN to her requests. She did not receive the information that she had requested and she had raised this a number of times. In July 2009 a member of the contract monitoring team listed actions that TCN should have taken that were still outstanding. These included management of complaints and incidents, quality monitoring (mandatory training and registration), and the 'patchy' delivery of the weekly performance data.

Findings of fact on arrangements for routine monitoring and its effectiveness

- There were regular contract monitoring meetings chaired by the head of non-acute commissioning
- The NQRs were considered at the contract management board but there was no interrogation or challenge
- Staff responsible for monitoring the contract did not fully understand the activity figures.
- Staff did not understand the effect of call streaming on monitoring the NQRs.
- The PCT believed that the appointment system for children under five had been piloted during Easter 2009. However TCN staff routinely sent children under five directly to bases at other times.
- Staff did not know that TCN did not follow the national stroke guidelines.
- TCN declared they were compliant on auditing clinical staff (NQR4). They did not provide any information and the PCT did not challenge the absence of information subsequently provided.
- The PCT did not routinely monitor staffing levels or skill mix.
- In July 2009 there were still concerns about the management of complaints and incidents, monitoring of mandatory training and registration, and the 'patchy' delivery of the weekly performance data.

Systems in place in NHS Worcestershire to identify and escalate issues of concern

In early 2009 the local MP for Wyre Forest and the local medical committee both separately approached the chief executive of NHS Worcestershire on two occasions. They expressed concerns about quality and safety issues in out-of-hours services. The MP for Wyre Forest stated that the chief executive of NHS Worcestershire was initially sceptical. The MP then wrote on 26 March 2009 with details of complaints he had received about the service. After the second, more formal approach from the LMC, senior staff at the PCT met with representatives of TCN. The PCT wrote formally to TCN on 26 March and on 30 March 2009 decided to commission an independent review of the service.

The review took place in April and May 2009. It was led by a senior GP from another area and two management consultants with considerable operational experience of out-of-hours. The reviewers were so concerned about some of their observations during the course of their visits to TCN bases that they issued an interim report to the PCT on 18 May 2009.

The report covered a number of operational issues but the main concerns were that staffing was inadequate with some GPs working unacceptably long hours. The team reported that nurses were performing triage without formal guidelines and protocols. There were concerns about the inappropriate prioritisation of calls, which the review team felt was a result of the pressure that staff were under to enhance statistics and meet targets. There were also concerns about the morale of staff working in the service and a lack of management support from TCN to address staffing shortfalls.

TCN contested many of the findings in this report. They stated that they 'over provided' clinical hours against the rota and commented that although they had reduced nursing hours they had introduced call handlers. In relation to the criticism that there was little management support or escalation on the day the review team visited the base, TCN commented that there was clear evidence of escalation. TCN did not accept the findings of the review team that overnight shits were often unfilled and challenged any assertion that they had been manipulating the statistics.

The PCT served TCN with a remedial notice on 21 May 2009 and presented key areas of action that TCN must implement with immediate effect to address the findings of the review. These involved assurances about call handling and triage, rotas and staff induction, and access to TCN operational arrangements

by PCT staff over the forthcoming May bank holiday weekend. The PCT also required TCN to ensure that the primary care centres would be staffed by experienced Worcestershire based GPs over the bank holiday weekend. The final requirement by the PCT was for TCN to ensure that they addressed any areas of unsatisfactory practices identified in the report.

The chief executive put together a clinical reference group with representatives from the GPs, chair of the LMC, PEC chair and emergency care lead. The full independent report was shared with this group. A series of visits were carried out by members of this group to TCN primary care centres over the May bank holiday weekend. In a meeting on 1 June 2009 the group reported on the findings of the visits. A number of concerns were raised by the GP members of the group.

The PCT held a further meeting with TCN later the same day (1 June) where they responded to the independent review and presented an action plan to address the remedial notice. The chief executive and director of delivery were satisfied with the TCN response to issues raised in the review and believed that TCN had improved. The PCT stated that at a meeting on 19 June the GP clinical reference group advised the director of delivery that the assurances received from TCN were sufficient. GP members of the group told us they were not fully reassured but accepted the PCT's argument that terminating the contract with TCN would pose a greater risk than its continuation. Minutes were not taken of this meeting. The director of delivery for the PCT wrote to TCN on June 26 2009 stating that the meeting held in response to concerns that had been raised about the out-of-hours service was 'satisfactory' and that the PCT 'welcomed the approach taken by TCN and the efforts put in to responding to their concerns'. The letter stated that the PCT would monitor the actions taken by TCN and move the discussions back into the formal contract management process. We noted earlier that operational staff were less confident with the information being provided to the PCT at that time.

The independent review was not published and none of the non-executive directors who we spoke to had seen copies of the report. The PCT have stated that the report was not published because it was clinically and commercially sensitive and they had to consider the impact of a loss in confidence in the service on other providers at a time when swine flu was having a significant impact on urgent care services. However an email sent by the director of delivery to TCN on 20th May 2009 suggested that the PCT did initially consider that 'Given the public interest in the matter, the final report will undoubtedly end up in the public domain '.

There was no evidence that non executive directors were aware of the extent of criticisms in the report. The PCT stated that the review had been discussed at an informal board meeting on 16 June 2009 although the non-executive directors that were interviewed by CQC did not refer to this meeting. The chairman was not certain that he had seen a copy of the final report, although the PCT gave us evidence that the chairman was sent a copy of the letter that specified the key issues from the review that TCN needed to address**.**

The director of delivery took a report on the out-of-hours service to the board in September 2009. It was for information only and stated that the key performance indicators had significantly improved. The report did not provide details of the findings of the independent review but said the review had identified 'some areas of agreed service improvement'. As a result of the review an action plan was put in place which included monitoring of working hours and greater participation by local clinicians in service delivery. The report said that formal patient complaints continued to be at a low level and that there had been much greater activity levels than previously recorded. As noted earlier, when the PCT reviewed the volume of calls after a 12 month period they found there had only been a 2.2% increase in activity.

No specific details of individual complaints or incidents were reported to the PCT by TCN until July 2009. There was no evidence of discussion of specific incidents or complaints taking place at the contract monitoring meetings held with TCN at that time.

Incidents and serious untoward incidents (SUIs) that occurred in out-of-hours and were reported by PCT staff, were discussed at the

risk working group. There was some confusion as to whether this group was responsible for monitoring these matters since its main focus was on services that the PCT itself provided. In the minutes we reviewed up to July 2009, out-of-hours services were never discussed at the quality and safety committee despite the concerns that had been raised about TCN.

The executive lead nurse stated in her interview in June 2009 that the PCT had been having quarterly meetings with all their providers to go through incidents but that TCN had not been included.

The PCT had agreed with TCN in November 2008 that until 31 March 2009 PCT would keep a dual log of all complaints and incidents. There was to be a weekly catch up with TCN operational managers to make sure they were recording everything. The PCT also agreed not to count complaints other than those made by service users. This meant that any concerns or feedback from health care staff such as district nurses would be recorded and managed separately. TCN assured the PCT that they would still manage the complaints to the same time frames.

NHS Worcestershire provided a record of complaints received about out-of-hours in the preceding three years and stated that there was no firm evidence that the number of complaints about TCN were greater than those received in relation to the previous PCT provided service. Between October 2006 and June 2007, 53 complaints were received altogether and between October 2007 and June 2008 the number of complaints fell to 23. The TCN service delivery model commenced in October 2008 and between then and June 2009 the PCT received 22 complaints. These figures however are not directly comparable to the earlier information because they only reflected those complaints received directly by the PCT. CQC analysis of the internal TCN complaints log indicated that there were a further 21 complaints received directly from patients or relatives in Worcestershire between October 2008 and June 2009. This meant that altogether 43 complaints were made against TCN between October 2008 and June 2009. These figures indicate that the number of complaints about the out-of-hours service initially increased after TCN took over the service although there was not enough historical information for CQC to determine whether this represented a continuing trend.

In March 2009 an internal email from the patient safety manager to the head of commissioning of community services stated that the number of incidents reported had increased since TCN took over the service. Three incidents had been reported when the PCT ran the service compared to 25 in the same period with TCN. The patient safety manager commented that this may have represented better reporting but that there was no evidence that TCN had actively encouraged increased reporting. Analysis of a further summary of incidents provided by the PCT indicated that between October 2006 and June 2007 there were 15 incidents recorded and between October 2007 and June 2008 there were a total of 11 incidents. After TCN took over the service the PCT log recorded a total of 16 incidents between October 2008 and June 2009. CQC analysis of the internal TCN incident log found that a total of 77 untoward incidents actually took place in this time. These figures indicate a considerable increase in incident reporting after TCN took over the service.

In an email dated May 2009 the PCT followed up the requirement in the contract that they receive a breakdown of each individual incident and complaint. They realised that they had not routinely received this information since TCN took over the contract. The PCT complaints and incidents team created a report cross referencing the number of complaints and incidents logged by the PCT against the number of complaints and incidents reported to the PCT by TCN. There was a mismatch between PCT and TCN records with considerably more incidents and complaints logged by the PCT.

The report stated that the detailed information relating to incidents and complaints reported to the PCT was poor and that they did not receive sufficient information about the response to complaints made by healthcare staff. The report was presented to the contract monitoring board in May 2009 and the minutes recorded that responsibilities for reporting were identified.

Senior managers were not convinced there had been an increase in the number of complaints and incidents received in relation to the out-of-hours service provided by TCN. In a further statement NHS Worcestershire commented that they did not receive detailed information on incidents and complaints from the other services they commission although following the increase in concerns about TCN in April 2009 they increased scrutiny of the total service including complaints.

In early May 2009 NHS Worcestershire logged a serious untoward incident following the death of a baby at a TCN out-of-hours base. The PCT was initially told by the clinical lead for TCN in Worcestershire that the call had been placed in urgent triage by the call handler and that the triage nurse had told the parents to come directly to the out-of-hours base as they lived nearby to the hospital where the base was located. The family arrived at the base ten minutes after the phone conversation at 4:40am and were booked in to see an out-of-hours GP. The incident report recorded that within a few minutes the father raised the alarm that the baby was not breathing and at that point the family were taken directly to the doctor. The GP commenced CPR and it was recorded at 4:46 that the arrest team was called.

In a further letter to the PCT on the 26 June 2009 the clinical lead for TCN acknowledged that the call handler had not categorised the call as urgent as previously stated and that the call had actually been processed as routine. The call was picked up by the triage nurse after 15 minutes which was within the 'urgent' timeframe. It was confirmed that the family had actually been waiting to be seen by a doctor in the waiting room for 10-12 minutes rather than the 3-5 minutes previously stated. The resuscitation team was not called until 4:55am.

In response to this incident the clinical lead for TCN acknowledged that the error lay with the call handler not following the appropriate protocols for classification of 'urgent' cases. He stated that a review of call handler protocols was being undertaken across the organisation and that a percentage of all calls were routinely audited. In fact, as we noted in Part 2 of our report, routine audits of call handlers did not take place at TCN. TCN stated that mandatory training for all staff in basic life support would be completed by all staff by the end of September 2009.

This incident was not recorded as a SUI by TCN and the internal TCN incident log did not record any actions taken as a result. A staff member who had dealt with TCN in relation to clinical incidents told us that she was not confident that anything would change as a result of this incident.

In response to a request, NHS Worcestershire provided an updated out-of-hours SUI log dated October 2009. The log recorded the incorrect details in relation to the categorisation of the call and the length of time the family were waiting before the baby died. The PCT log stated that they were waiting for a final report from TCN following the outcome of the inquest. The coroner's verdict was given as death by natural causes as a result of a heart defect. The final information sharing and planning meeting took place on October 7 2009. TCN was not invited to this meeting. The minutes of the quality and patient safety assurance committee (with board membership) noted on 6 November 2009 that 'Approval was given for formal closure of the one SUI reported by TCN to date, with assurance that continued monitoring is in place'. The investigation report was not provided and no evidence was provided in support of the actions that TCN reported they had taken in response to this incident. The CQC could not find any evidence that this incident had been reviewed or formally discussed at any other PCT meeting. Nor had it been reported to the PCT's board, although concerns about out-of-hours services were known at this time.

NHS Worcestershire supplied a record of six SUIs that had taken place in the out-of-hours service between October 2008 and May 2009. These were all after TCN had taken over the service. None of the SUIs logged by NHS Worcestershire was logged internally as SUIs by TCN. The PCT was not able to provide a final investigation report for any of these incidents. The forms completed by the PCT to report the incidents included a summary of the events leading up to the incident although it was not clear if these accounts had been verified. Certain cases provided a brief summary of actions taken by TCN. There was

no evidence that root cause analysis had been carried out and in one case the form completed by the clinical lead for TCN stated that 'although the triage process was weak it was far from clear that a better triage would have made very much difference and this, combined with the emotive power of the situation, disinclines me to draw the attention of the triage nurse to these weaknesses on this occasion. It is to be hoped that the general standard of triage will improve as time moves on'. This analysis by the TCN clinical lead does not appear to have been challenged by the PCT.

The head of medicines management at the PCT stated that she had not been informed about the serious untoward incident in Cambridgeshire involving the death of Mr Gray. She had a number of concerns in relation to TCN including difficulty in obtaining the relevant policies she had requested. For example she did not receive their medicines policy until April 2009 although she had requested it before TCN took over the contract over six months earlier. When she received it, she noted it did not include details of supply and labelling of medicines, which would be necessary for their service. The policy for handling controlled drugs was only approved by TCN and sent to the PCT following the identification of a discrepancy in the controlled drug stock before Christmas 2008.

The head of medicines management confirmed that there was a local intelligence network but TCN did not attend these meetings. A systematic audit of prescribing of controlled drugs in the out-of-hours service had not been carried out. However the PCT received monthly data on prescribing and met TCN quarterly to discuss this.

Findings of fact on systems to identify and escalate concerns

- In response to formal concerns from the LMC, the PCT commissioned an independent review in the spring of 2009.
- The reviews findings included inadequate levels of staffing, some GPs working unacceptably long hours, nurses performing triage without formal guidelines and protocols, inappropriate prioritisation of calls, and pressure on staff to enhance statistics and meet targets. TCN contested many of the findings.
- This review was not published and the non-executive directors had not seen it, nor were they aware of the seriousness of the concerns. A paper to the board in September stated it had identified 'some areas of agreed service improvement'.
- The PCT issued a remedial notice in late May 2009 and TCN drew up an action plan.
- The executives in the PCT considered TCN to have responded to concerns; some other staff with more operational contact with TCN expressed concerns about TCN's failure to provide information or take action.
- TCN was not included in the system the PCT had to discuss incidents with the services they commissioned.
- There was confusion concerning which committee was responsible for monitoring incidents and complaints occurring in out-of-hours.
- The number of complaints rose after TCN took over the service.
- The number of incidents reported also rose. This could have been because of increased reporting.
- The PCT did not receive details of individual incidents or complaints until July 2009.
- None of the six SUIs logged by NHS Worcestershire were logged internally as SUIs by TCN. The PCT could not find the final reports for any of these incidents.
- There was a SUI involving the death of a baby in May 2009. Although there were inaccuracies in how TCN described what had happened, the PCT did not formally discuss this matter and the SUI was not reported to the board. TCN was not invited to the final meeting on sharing lessons.
- The head of medicines management at the PCT stated that she had not been informed

about the serious untoward incident in Cambridgeshire involving the death of Mr Gray.

- TCN did not send the PCT their medicines policy until April 2009 although it was requested before TCN took over the contract over six months earlier.
- The PCT received monthly data on prescribing and met TCN quarterly to discuss this.

Local perspectives on out-of-hours services

Local GPs

Local GPs had consistently expressed concerns about the medical cover in out-of-hours and the length of the shifts that some staff were working. The PCT was sceptical of these views because of perceived conflicts of interest and poor relations with TCN. The CQC made an unannounced visit in August 2009 and found evidence that both clinical and operational staff were working back-to-back shifts. Staff we spoke to expressed concerns about the number of unfilled shifts and the number of agency doctors that were used.

The majority of local GPs that CQC spoke to regarding TCN's service were generally satisfied that the majority of clinical care was of an acceptable standard and GPs were generally positive about the information on out-of-hours consultations sent to their practice. There were, however, concerns expressed that the staffing levels overnight and in particular the number of GPs had been reduced too far to cover such a wide geographical area. Concerns were also raised around the lack of local GPs working in the service. The explanations given for this were that TCN reduced pay rates too far and a general dissatisfaction with the consultation that occurred when TCN took over the service.

The PCT had not formally sought the views of local GPs about the quality of the out-of-hours service until after the independent review was carried out. It was at this point that local GPs became involved in the review of the service. It was not clear to what extent their views were incorporated in the further decisions the PCT made. We noted that the minutes of October 2009 meeting of the Local Medical Committee recorded that the LMC should ask the PCT "to stop publicity about TCN to maintain objectivity, particularly as the LMC has studiously kept to our part of the agreement not to go public with our concerns".

The CQC sent a survey to GP practices in Worcestershire PCT in October 2009 asking them for feedback about the out-of-hours service provided by TCN to their patients. We compared these figures to a similar survey sent out by 'Devon Doctors' out-of-hours service in December 2006. The response rate for the Devon Doctors survey was 47%. We are cautious of making judgements of 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.

We received responses from 72 GPs in total which represented 19% of the GPs in Worcestershire. 63% of those that responded stated that the services provided by TCN were poor or very poor. In comparison to the same question only 1% of Devon GPs rated the service as poor or very poor. Worcestershire GPs raised concerns about long waiting times for patients (19 GPs), the quality of clinicians used by TCN (nine GPs), the quality of care provided to patients (nine GPs), prescribing issues (five GPs), and patients being inappropriately redirected back to GP practices (four GPs).

46% of Worcestershire GPs who responded stated that the reliability of individual patient information sent to practice was good or excellent (79% at Devon Doctors). 14% stated that the content of this information was either good or excellent (71% at Devon Doctors). 13 % of Worcestershire GPs stated that the general standard of communication with their practice was good or excellent (80% at Devon Doctors).

LINks

The LINks representative reported that they had visited out-of-hours sites in the winter of 2009 and heard concerns and complaints from TCN staff in every location. Some expressed concern regarding the quality of the doctors with one GP commenting that the service was unsafe and others raised concerns about unfilled shifts.

There was a worry that patients thought they were seeing a GP when the clinician was an ECP. LINks were unhappy that ECPs were seeing babies and children.

The CQC was told by representatives of the health overview and scrutiny committee that there was a debate about the new service model and the use of ECPs rather than doctors. The committee was split on whether they were happy with this model.

Findings of fact on local perspectives

- The PCT had not formally sought the views of local GPs concerning the quality of the out-of-hours service until after the independent review
- In the CQC survey of GPs, there was a 19% response rate and 63% of those that responded stated that the services provided by TCN were poor or very poor.
- LINks had concerns in the autumn and winter of 2009 and found that TCN staff were worried about unfilled shifts and the quality of some doctors with one GP commenting that the service was unsafe.

Developments

In further interviews with the PCT in October 2009 we learnt that the PCT had agreed to the number of doctors on overnight reducing to two, working with an ECP. NHS Worcestershire supplied the notes of a meeting held with TCN on 22 October 2009. At this meeting TCN was asked to provide additional information about how ECPs were being used by TCN. This included details of induction, training, home visit statistics and all details of incidents and complaints involving ECPs. In addition the PCT asked for escalation plans, reports of the number of shifts worked by local GPs, percentage of unfilled shifts and call handler prioritisation protocols. The PCT also requested a demonstration of the HMS system and reinstated the weekly volume sheet including 999 and A&E referrals.

As a result of concerns raised by TCN staff and the LMC, the PCT asked TCN to postpone the introduction of ECPs. The PCT stated they had no concerns about the use of ECPs but only about the timing of their introduction. TCN responded by agreeing to suspend the plan for further ECP deployment for the immediate future. The main reason for the delay was to maintain public confidence in the service as winter approached.

A paper focusing on key strategic and quality issues in out-of-hours was taken to the Worcestershire clinical senate on 8 December 2009. Following a difficult Christmas period the PCT met with the TCN executive team to discuss the future of TCN in Worcestershire. The PCT was particularly concerned about the loss of the Suffolk contract and the impact that would have on TCN's ability to meet its other obligations. At this meeting it was agreed that TCN could not continue providing the Worcestershire out-of-hours service and that TCN's preferred option was to sell a controlling interest to another out-of-hours provider. It was agreed that the TCN contract with NHS Worcestershire would transfer to this new provider.

The PCT started a due diligence process and stated that this would focus on the need to put local GPs at the centre of the proposed model. The PCT required the new service provider to

support a GP management board in order to monitor GP engagement in the process.

The PCT provided evidence that the final decision to support the request from TCN to transfer the contract to a new out-of-hours provider was supported by senior clinicians.

From 1 April 2010 the out-of-hours services at NHS Worcestershire were provided by Harmoni.

NHS South West Essex

History of the PCT and out-of-hours service delivery

NHS South West Essex was formed in October 2006, following the merger of the former Basildon; Billericay, Brentwood and Wickford; and Thurrock PCTs. The organisation is responsible for the healthcare of more than 420,000 people across the boroughs of Basildon, Brentwood and Thurrock.

The PCT started with financial problems and was under close scrutiny by the SHA. The following year, money that was due to the PCT was released more quickly than had been expected and had to be spent. Some of this money was spent on management consultants to bring about faster improvement in aspects of the PCT's functioning, including world class commissioning.

The PCT did not have a medical director until May 2009 and there had been little spending on the infrastructure for primary care.

The delivery of out-of-hours services in NHS South West Essex was complex. This was because about 40% of the GPs decided to continue to provide their own out-of-hours service. The 33 GP practices that did not opt out, provided out-of-hours services through South Essex Emergency Doctors Service, covering a population of 151,296.

The other 60% (48 out of 81) of GP practices had opted out of out-of-hours care and this service was originally provided by the East of England Ambulance Service Trust (the ambulance trust) serving a population of 262,196.

The ambulance trust had previously contracted with South Essex Emergency Doctors Service to provide medical care and run some of the primary care centres. PCT staff told us that following a breakdown in the relationship, the ambulance trust approached TCN to tender a joint bid in 2007.

The PCT's overarching objective for strategic procurement was to extend the range and quality of providers and services, including the private and voluntary sectors. The PCT awarded a three-year contract to the ambulance trust from January 2008 until January 2011. The ambulance trust had a sub contract with Take Care Now to deliver the face-to-face medical service to patients in parts of South West Essex. The ambulance trust did all the call handling and triage, and patients were then transferred to TCN to provide the doctors at the bases and home visits. This service applied in Basildon and Thurrock whereas in Brentwood the ambulance service also provided the face-to-face assessment. TCN was responsible for the management of their staff.

There had not been any input from PCT staff involved in governance in the development of the service specification for out-of-hours. A manager involved in developing the specification conceded that there were 'grey areas' in the specification. For example although it was the expectation of the PCT that all clinical telephone triage be carried out by GPs the service specification referred to a clinician with the 'skills of a GP'.

We were told that the PCT had not received any legal advice about the development of the specification although they had received an example specification from the contract procurement hub at the SHA. A senior GP was involved in the service specification and procurement process, and there was evidence of discussion of the specification and procurement process at the board.

The Primary Care Foundation report dated November 2009 found that the cost of the out-of-hours service was below average overall and close to the median in comparison with other organisations categorised as mixed rural/urban based.

NHS SW Essex had not reduced the contract price with the ambulance trust but they stated that they were aware that the ambulance trust in 2009 withheld the sum of £13,761 from TCN in relation to problems with filling shifts.

Findings of fact on the context of out-of-hours services in South West Essex

- From January 2008 the ambulance trust had a sub contract with Take Care Now to deliver the face-to-face medical service to patients in South West Essex.
- The cost of the out-of-hours service was below average overall and close to the median in comparison with other mixed rural/urban based services.
- In 2009 the ambulance trust withheld money from TCN because of problems with filling shifts.

Routine monitoring of the out-of-hours contract and the effectiveness of this monitoring

There were monthly out-of-hours meetings about the implementation of the contract between October 2007 and February 2008. These meetings were attended by representatives from the PCT, TCN and the ambulance trust.

The first PCT out-of-hours meeting to monitor performance was held in March 2008 and was attended by the PCT, South Essex Emergency Doctors Service and the ambulance trust. The subsequent meetings between the PCT and the ambulance trust took place in May and October 2008. At the next meeting, in February 2009, it was agreed to meet quarterly from then on. Minutes of these meetings stated that a representative from TCN would also attend these meetings. It was not clear when TCN began to attend this meeting.

The ambulance trust held two different types of meetings with TCN. The partnership board meetings were attended by operational staff from TCN and the manager at the ambulance service with responsibility for the subcontract with TCN. They took place every three months. There was general discussion about performance on the national standards at these meetings, with TCN providing an operational report for the ambulance service. The clinical governance meetings between TCN and the ambulance trust were attended by the ambulance trust's medical advisor and contract managers and senior clinical staff from TCN. The first clinical governance meeting took place in March 2008, and subsequently meetings took place every two months. There was no representative from the PCT at these meetings although the ambulance service stated that they were formally invited. These meetings regularly discussed poorly performing doctors, training, working time directives, prescribing, incident reporting and some reference to specific complaints.

The PCT did not receive performance reports from TCN. They received weekly and monthly reports on performance from the ambulance trust in relation to the overall contract. Until April 2009 there was little routine, formal discussion of national quality requirements at the PCT led contract monitoring meetings.

The outgoing and interim associate directors of quality and commissioning at the PCT were interviewed together in July 2009. Neither had attended a contract monitoring meeting or seen report on out-of-hours performance at that time.

The manager at the ambulance trust with responsibility for the contract with TCN, stated that the ambulance trust had assured the PCT that the service was clinically robust primarily based on the fact that they were meeting targets, but with further assurances from other sources. He commented that he had no contact with the staff responsible for clinical quality in the PCT, until the head of integrated governance began to attend the contract meetings in July 2009.

The ambulance service told us they were assured of the quality of the service at the clinical governance and partnership board meetings held with TCN. When asked about the assurances the ambulance trust received that TCN staff were appropriately checked and

trained, the contract manager stated he had no assurances that TCN was doing what they should be. The ambulance service did, however, conduct some of their own audits of the performance of TCN clinicians.

SW Essex had had problems with poorly performing GPs who worked for a number of different out-of-hours services. 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 we have referred in Part 2 of our report to the fact that 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.

In April 2009 there was a further update and a doctor who had been removed by the ambulance trust from their service was found to still be working for TCN. The matter of poorly performing doctors was not raised at the contract monitoring meeting held with the PCT until July 2009, so the PCT was not aware of this matter before then. The PCT did not routinely review the minutes of the meetings held between the ambulance trust and TCN.

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.

TCN only began carrying out audits of clinicians undertaking face-to face consultations in South West Essex in the second half of 2009, with results available in the autumn. Before this the ambulance trust conducted some audits of face-to face consultations.

Concerns were noted regularly in the contract monitoring meetings that GPs were working back-to-back shifts in out-of-hours. It was difficult to identify GPs working excessive hours because they worked for both TCN and South Essex Emergency Doctors Services.

In February 2009 the new associate director of commissioning of primary care took up post. In July 2009 a representative from the PCT attended the ambulance service partnership board meeting for the first time since March 2008. This meant from July these meetings included representation from the ambulance trust, TCN and the PCT. When we interviewed staff at the PCT in July 2009 the head of integrated governance told us that she had just started to attend the quarterly monitoring group meetings with TCN.

Findings of fact on routine contract monitoring and its effectiveness

- TCN did not attend the out-of-hours contract monitoring meetings held by the PCT. The PCT received performance reports from the ambulance trust.
- The PCT did not routinely send clinical or governance staff to their own contract monitoring meetings until April 2009.
- National quality requirements were not discussed routinely at the PCT's contract monitoring meetings until April 2009.
- A representative from the PCT did not attend the contract review meeting held between the ambulance service and TCN until 2009.
- A representative from the PCT contract team attended the partnership board meeting between TCN and the ambulance service for the first time in July 2009.
- The PCT had relied on the ambulance trust to monitor TCN.
- TCN used some doctors despite having been advised to the contrary by the ambulance trust. The PCT was not aware of this matter until July 2009.

- There was no integrated system to raise and resolve concerns about poorly performing clinicians.

Systems in place at NHS South West Essex to identify and escalate issues of concern within the PCT

Complaints and incidents were not routinely monitored at the contract monitoring meetings held by the PCT. In the meeting in April 2009 it was noted that they needed to agree a format for regular reporting of complaints, SUIs and matters to do with patient safety. This would allow trends over time to be monitored. The group agreed to set up a monthly meeting from September 2009 between the PCT and the ambulance trust to review incidents.

The PCT's clinical quality and safety sub group was responsible for the safety of patients and for reviewing SUIs, incidents and complaints to ensure appropriate action was taken by the PCT. Out-of-hours was first mentioned in July 2009 when it was noted that several complaints had been received about the service.

CQC asked the PCT for details of any changes made to provision of services as a result of incidents that had occurred since April 2007. The PCT stated in June 2009 that they were not aware of any incidents that had occurred in relation to TCN. After further requests in August 2009 the PCT provided an action plan written by the ambulance service in response to a number of incidents involving TCN which had been logged monthly since February 2009. All of the incidents logged were in relation to doctors, ECPs or driver/receptionists either not turning up or being late for work. The actions taken in response to these incidents were that TCN was aware or that TCN had written to the GP concerned. Since the PCT was not initially aware of the incidents, it had not considered the effect that the failure of staff to turn up on time or at all, could have had on shifts and the pressure on other staff. We were told by the ambulance service that they generally filled these shifts using their own staff and then billed TCN.

SUIs, incidents and complaints were all managed separately in different departments in the PCT. We were told in July 2009 that they planned to bring all these elements together under the director of nursing. At the same time the PCT's head of integrated governance told us she did not routinely see complaints about the out-of-hours service, and that incidents had recently come to light of which they were previously unaware.

The complaints manager at the PCT who attended the contract review meetings stated that there were not many patient complaints relating to TCN. The PCT provided CQC with a log of complaints received directly by the PCT in relation to out-of-hours since January 2007. The majority of complaints were noted to be the responsibility of the ambulance service although a few in 2009 were assigned to TCN as well as the ambulance service. There was very little detail provided in terms of the outcome of the complaints.

The PCT also provided CQC with a log of complaints they had received from the ambulance service relating to out-of-hours services since December 2006. From September 2008 there were references to complaints being passed to TCN. The log did not include any feedback about the outcome of these complaints and noted that they were 'waiting for their report'.

The medical advisor to the ambulance trust with responsibility for out-of-hours in SW Essex stated that complaints about out-of-hours came in by different routes but the ambulance service dealt with them, because it held the contract. The acting medical director for the ambulance trust stated that they had been trying to integrate out-of-hours so that all SUIs, incidents and complaints went through the ambulance trust's central system. This would mean that they could compare and analyse different incidents.

During the time of the contract a SUI had never been declared in respect of out-of-hours. Some PCT staff were not clear about the process for reporting out-of-hours SUIs and stated that they 'suspected or thought they

would follow whatever process the ambulance service had'. The associate director of commissioning of primary care who started at the PCT in February 2009 was clear about this process. The manager at the ambulance service with responsibility for the subcontract with TCN stated that if a serious incident were to occur, TCN would report it to the ambulance trust and they would inform the PCT. However he commented that they had learnt about some incidents involving TCN from sources other than TCN, including their own staff.

The head of medicines management for the PCT commented in July 2009 that he had only just started to attend the contract monitoring meetings and that his relationship with TCN was 'non existent'. The accountable officer for controlled drugs for the ambulance service told us at the end of July 2009 that she had only found out five days earlier that the ambulance trust had a sub contract TCN. She stated that there was very little written documentation about how the subcontract and interaction between TCN and the ambulance trust. At the meeting on clinical governance in March 2008 between TCN and the ambulance service it was reported that TCN had tightened up their protocol on the use of controlled drugs following a recent SUI. The meeting also discussed GP pre-employment checks, training and induction provided to new GPs.

In the partnership meeting between TCN and the ambulance service in September 2008 it was stated that the contents of the boxes containing controlled drugs had been called into question by the SHA and that 100mg of diamorphine should be removed from the boxes. The SHA wanted the new procedure in place by the end of the week. There were no clinicians from TCN at this meeting. At the contract meeting between the PCT and the ambulance service in October 2008 it was noted that 100mg vials of diamorphine were not carried by the ambulance trust. It was also recorded that the controlled drug policy was still being developed at that time.

The medical advisor to the ambulance trust carried out an audit of prescribing in April 2009 and reported that the results demonstrated a 'reasonable rate of compliance with 40% of prescriptions falling outside of the OOHs formulary'. This meant that 40% of the drugs prescribed were not on the standard list of out-of-hours medications. These results were not benchmarked against any similar audits taking place in out-of-hours.

There was an extraordinary meeting between the PCT and the ambulance trust in May 2009. The PCT asked the ambulance service for assurance that robust processes were in place for monitoring TCN following the recent publicity about the death of Mr Gray in Cambridgeshire. The ambulance trust responded that agency doctors were never used in SW Essex and also that all the out-of-hours doctors used were on the Essex performers list. The death of Mr Gray in Cambridgeshire was not discussed at the PCT contract meetings until July 2009.

In October 2009 the board of NHS South West Essex was formally notified about the CQC investigation and the PCT's relationship with TCN. When CQC interviewed the non-executive directors in December 2009 it became clear that at the time the death of Mr Gray was made public, they had not been aware that the out-of-hours organisation that had treated Mr Gray was the same organisation that served their PCT population.

Findings of fact on systems to identify and escalate concerns

- Complaints and incidents were not on the agenda of the contract monitoring meetings held by the PCT until April 2009.
- In July 2009 concerns about the out-of-hours service were referred to for the first time at the clinical quality and safety group. This group did not routinely receive reports from out-of-hours.
- The PCT initially informed us there had not been any incidents in relation to TCN since April 2007, but this was not accurate.
- An action plan in relation to a number of incidents logged since February 2009 showed that all the incidents related to doctors, ECPs and drivers not turning up or being late for work.
- The arrangements to manage complaints, incidents and serious untoward incidents in

the PCT were not integrated. Some senior staff were not clear about the process for SUIs in out-of-hours services.

- The death of Mr Gray was not discussed at a contract meeting until July 2009.
- In October 2009 the board of NHS South West Essex was formally notified about the CQC investigation and the PCT's relationship with TCN. Before this, the non-executive directors had not been aware that the out-of-hours service came from the organisation that had been involved in the death of Mr Gray.

Local perspectives on out-of-hours services

The local medical committee reported that few concerns around out-of-hours had been reported. Members had not been surveyed about out-of-hours.

The PCT carried out a residents' survey with Ipsos Mori between 28 July and October 2008. Of those that responded to the question relating to out-of-hours, just over 50% reported that they were fairly satisfied or very satisfied with out-of-hours services. Just under 50% responded that there was a 'fair amount or a lot of' need for improvement.

The PCT had benchmarked individual results for practices in the 2008/09 patient survey against the East of England results. An area where a number of practices were highlighted as scoring below the East of England average was about patients knowing how to contact an out-of-hours service.

SW Essex was initially included in CQC's survey, however as a result of the differences in the way the services were configured in SW Essex compared to the other PCTs and the low level of response from SW Essex GPs, the results for this PCT have not been included in the report.

Developments

NHS SW Essex issued a remedial notice to the ambulance trust in November 2009 and the remedial action plan was formally agreed with the PCT on 25 January 2010. The PCT stated that they would monitor the action plan through formal monthly meetings with ambulance trust representatives. It was noted that the ambulance trust had been meeting TCN weekly to monitor implementation of the specific actions. The chief executive told us in December 2009 that two associate directors now attended the contract monitoring meetings and they were routinely looking at the quality of the service.

The PCT reported that South Essex Emergency Doctors Service and East of England Ambulance Service Trust (EEAST) now share rotas and monitor the hours that doctors are working, and the PCT receives a report.

The PCT served notice on EEAST to terminate their sub-contract with TCN on 2 February 2010, in view of ongoing concerns about the filling of shifts in SW Essex. This took effect on 1 April 2010. EEAST has now entered into a new sub-contract with South Essex Emergency Doctors Service.

Conclusions about the PCTs and commissioning

Summary of findings

- The PCTs were established as part of a major re-organisation in 2006. Four of the five inherited significant financial deficits. Out-of-hours services were low priority and there was little strategic vision of how they should develop. This was a disadvantage when procurement was undertaken. Additionally, because PCTs were advised not to involve local GPs in the procurement process due to conflicts of interest if they were tendering for the service themselves, the clinical input to procurement was limited.

- The staff in PCTs with responsibility for routine monitoring of out-of-hours contracts did not fully understand TCN's reports on performance. They could not adequately explain the information in the reports or the basic activity figures, and they did not fully understand the national quality requirements (NQRs).

- Changes to out-of-hours services that could have significant implications were frequently discussed and agreed by non-clinical staff at PCTs. Senior staff were often unaware that call streaming was taking place (This is the practice of offering patients the chance to go straight to a base without first having a clinical assessment).

- Before the start of our investigation in May 2009, none of the PCTs robustly monitored staffing levels in out-of-hours services, the skill mix or whether the shifts were filled, and most did not monitor them at all. Some of the PCTs considered this would be inappropriate for any of their contracts, especially if quality standards were being achieved. However, we have noted above that the PCT staff did not fully understand the NQRs.

- Most of the PCTs did not have a clear picture of any problems in out-of-hours services. They were not generally aware of serious incidents. None of the PCTs had robust arrangements to share information on poorly performing clinicians.

- Before the publicity in spring 2009 about the death of Mr Gray, only in NHS Cambridgeshire was there interaction between PCT staff responsible for medicines management and TCN.

- Performance on out-of-hours services was seldom reported at board level in PCTs and non-executives were not well informed, other than in NHS Cambridgeshire and NHS Great Yarmouth and Waveney.

- Most of the PCTs had not invested in finding out the views of local GPs on out-of-hours services. In our surveys, GPs were highly critical. In three of the four PCT areas that obtained all their out-of-hours services from TCN, over 60% rated the services as poor or extremely poor.

Summary of conclusions

1. Out-of-hours services were low priority and PCTs had limited understanding of these services. There was a lack of leadership in commissioning and monitoring services as part of an integrated urgent care service.

2. Out-of-hours was a relatively new area of commissioning and there was a lack of experience in the PCTs in contracting with a commercial organisation. The staff with responsibility for routine monitoring of contracts did not fully understand the national quality requirements or TCN's reports on activity or performance. There was little interrogation or challenge at the contract monitoring meetings.

3. Some of the PCTs stated that it was unreasonable for them to monitor individual concerns or staffing levels, since this would not happen for other contracts. But we consider that these contracts should have been monitored more thoroughly.

4. Our assessment was that the PCTs generally did not have a high standard of commissioning or contract monitoring in out-of-hours. There was a failure to commission appropriate out-of-hours services for the local population and monitor that these were being delivered. All the PCTs had begun to improve their commissioning and monitoring arrangements.

Context

The five PCTs that were the focus of part of this investigation were established as part of a major NHS re-organisation in 2006. Four of them were in the East of England: NHS Cambridgeshire, NHS Suffolk, NHS Great Yarmouth and Waveney and NHS South west Essex. One PCT, NHS Worcestershire, was in the West Midlands. Four of the organisations commissioning services from TCN inherited significant financial deficits (£52 million in the case of NHS Cambridgeshire) and had been required to make savings. For some this had meant either losing existing staff or not filling or holding vacancies, and organisational memory was lost. The later initiative to separate the commissioning function from the provision of services directly delivered by PCTs, meant that there was increased pressure on scarce staffing resources, for example in governance.

PCTs had large and expensive contracts with acute, mental health and ambulance trusts. Contracts with out-of-hours services were small by comparison and not a national priority at that time. Some PCTs saw potential savings arising from these services either by tendering for a new service or taking money out of the existing contract.

There was encouragement nationally to increase the number and type of providers of health services, and PCTs were not obliged to ensure that a newly commissioned out-of-hours service was integrated more generally with other urgent or unscheduled care services.

Procurement

We have seen above that developing the market and establishing a range of providers was being encouraged nationally. PCTs did not have a strategic vision of how out-of-hours services needed to link with other services. In the case of Worcestershire, the justification for tendering the service rested on assumptions about the quality of the service. We established however that concerns had mainly related to access by telephone not clinical quality, but the PCT did not consider seeking a replacement for the telephone element of the service.

For those PCTs that undertook procurement of their out-of-hours services and encouraged organisations to tender for these, local GPs were concerned about the extent of clinical

involvement in drawing up the original specification and in awarding the contract. On occasions this was difficult since some GP practices were involved in tendering for the service, and PCTs were advised that there would be a conflict of interest if they involved them in the procurement process.

Although in retrospect PCTs told us they wished local GPs to be involved in providing the service, generally they did not take active steps to ensure this happened. TCN won the bid in NHS Worcestershire despite being more expensive than most other bidders. The director of commissioning at that time told us that TCN had demonstrated that they would provide a higher quality service including higher numbers of staff and a better skill mix. There was no evidence that the clinical quality of the service improved following the re tender of services in Worcestershire. One of consequences of TCN winning the contract was a net reduction in income for GPs working in out-of-hours of 20-30%. This had a negative effect on retaining local GPs in the service. As a result many of the GPs who worked for the service came from outside the local area.

Contracts did not generally specify what type of clinician was required or how many should be on duty. Where a staffing model was illustrated in the contract it was generally accepted to be an indicative model and was not used by contract staff to monitor the number of staff on duty. Not all PCTs considered it their responsibility to monitor staffing levels or skill mix in their contracted services.

Contract monitoring

As we noted above, out-of-hours services were small contracts in financial terms especially when compared with other PCT commissioned services. However they still involved considerable sums of public money and the impact of these services when they are poorly managed on other elements of urgent care provision and on patient safety is much greater than the size of the contract might indicate.
It was a major concern to CQC that those staff in PCTs with responsibility for routine monitoring of the contracts for out-of-hours did not fully understand TCN's reports on performance. These staff could not adequately explain the data; they did not fully understand the NQRs, or the basic activity figures. NHS Great Yarmouth and Waveney were the most informed in this respect but even they had limited understanding of the information on activity.

Reassurance was given by TCN that the NQRs had been achieved, but the level of compliance reported was often based on small numbers of patients. As the PCTs were not aware that the percentage compliance reported by TCN did not include the total number of patients treated, they were not in a position to challenge the accuracy of these figures.

PCTs generally did not realise that TCN had dealt with far fewer patients than the total number of contacts reported. This was because one patient often generated two contacts. This was particularly worrying in the case of NHS Worcestershire since the value of the out-of-hours contract was increased and the PCT agreed to pay TCN more money for the service. 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.

Changes to services which could have significant implications were often discussed and agreed by non-clinical staff. Senior staff in PCTs were often unaware that call streaming (offering patients the opportunity to bypass triage and go straight to a base) was taking place. Staff did not understand the implications of call streaming on the reporting of the NQRs, nor did they understand the possible implications of call streaming on patient safety especially if protocols were not clear and rigidly followed.

PCTs were not aware that the number of calls reported by TCN as being 'emergency' did not reflect the total number of calls that had been transferred to 999 by call handlers. In Worcestershire for the first year of the contract, call handlers were unable to transfer emergency calls directly to 999. PCTs were not aware that national guidelines for patients with symptoms of stroke were not being followed.

In SW Essex the PCT relied on the ambulance service to monitor the service provided by TCN. The ambulance service held the main contract and had a subcontract with TCN. The PCT did not review the meetings taking place between the ambulance service and TCN. The PCT met the ambulance trust but did not always send clinical staff to these meetings. Discussion about quality was limited to percentage compliance on the NQRs. The PCT began to routinely monitor the contract with TCN from April 2009.

In the PCTs there was generally little integration between staff in the quality department and those in routine contract monitoring. In some PCTs the monitoring of quality was hampered by lack of staff, or involved staff with other significant responsibilities. It was often unclear who was responsible for monitoring quality and clinical aspects of the performance reports. Most of the PCTs had patient safety groups or their equivalent but only in NHS Great Yarmouth and Waveney was out-of-hours discussed regularly at such meetings.

Before the start of this investigation none of the PCTs robustly monitored staffing levels, skill mix or whether shifts were filled. Some of the PCTs told us that this would be inappropriate for any of their contracts and considered that unfilled shifts and details of staffing were not something they would routinely monitor if quality standards were being achieved. However these issues are significant in the context of PCT staff not understanding the way in which TCN reported compliance with the NQRs. PCTs did not ask TCN to monitor the hours that staff worked, although we found that some staff worked excessive hours. Great Yarmouth and Waveney alone expressed concerns about the closure of bases as a result of relocating clinicians to cover unfilled shifts.

The CQC found that PCTs did not have a clear picture of problems in out-of-hours services. TCN did not supply PCTs with information on individual complaints until the summer of 2008 and even after that, there was little evidence that complaints or themes arising, were discussed internally at PCTs, other than by NHS Great Yarmouth and Waveney. NHS Cambridgeshire declared a SUI because of TCN's poor handling of incidents and complaints but this was identified through the Langdale process that followed the death of Mr Gray, not routine contract monitoring. Some PCTs considered it unrealistic to expect them to review complaints and incidents unless specific concerns had been raised about a service. CQC is concerned that since many of the PCTs were unaware of the content and number of complaints and incidents in out-of-hours, it would be difficult for them to identify that there were specific concerns.

PCTs were not generally aware of serious incidents that happened in out-of-hours services, other than NHS Cambridgeshire and the death of Mr Gray. NHS Great Yarmouth and Waveney regularly discussed serious incidents at their patient safety group. Suffolk PCT did not report the second diamorphine incident as a SUI, although it clearly should have been and could not produce internal TCN investigation reports for two serious incidents that happened in out-of-hours in early 2009. Although NHS Worcestershire was aware of some of the inaccuracies in the details TCN provided of the serious incident that involved the death of a baby, there was no evidence that this incident had been reviewed or formally discussed at any PCT meeting. NHS Worcestershire had declared six SUIs in out-of-hours but were unable to provide final investigation reports for any of these.

PCTs did not identify that some concerns had surfaced through TCN's audits of clinical staff. NHS Great Yarmouth and Waveney alone had put pressure on TCN to audit clinicians (but even they were unaware of poor performance on 'safety netting'.) TCN stated in their performance reports that between February and May 2009 they were auditing clinical staff in Worcestershire. However they did not provide the results and the PCT had not challenged this. None of the PCTs had robust established arrangements to share information on poorly performing clinicians.

The staff in PCTs with responsibility for medicines management had had little interaction with TCN until the publicity in the spring of 2009, a year after the death of Mr Gray. Before the start of this investigation they had little input into TCN's policies in respect of

drugs and had not inspected TCN's arrangements for the management of medicines. NHS Cambridgeshire began a programme of inspections of controlled drug procedures following the death of Mr Gray as part of the Langdale review and carried out spot checks of controlled drugs at their other out-of-hours providers. The external review carried out in NHS Worcestershire in April 2009 considered the arrangements for controlled drugs and the head of medicines management at the PCT had visited the TCN bases. NHS Great Yarmouth and Waveney had also visited all of TCN's bases in their area and inspected arrangements for controlled drugs since the death of Mr Gray. There had been no inspections of controlled drug arrangements at NHS Suffolk when we spoke to senior pharmacy staff at the PCT in July 2009. The accountable officer for controlled drugs for the ambulance trust in SW Essex told us in July 2009 that she had only just learnt about the subcontract with TCN and therefore would have been unaware of the responsibility to monitor TCN's controlled drug procedures.

Out-of-hours services and the boards of PCTs

Generally, performance on out-of-hours services was not reported at PCT boards unless it was in relation to procurement or the circumstances of the CQC enquiry. The non-executives were not well informed about these services. The exceptions were NHS Cambridgeshire because of the death of Mr Gray, and NHS Great Yarmouth and Waveney.

There was little mention of out-of-hours services at the board in NHS Suffolk until September 2008 when the findings from the Langdale review of compliance were reported. The senior staff in NHS Worcestershire did not notify the board in May 2009 of the findings of the external review, nor of the death of a baby who had been treated during out of hours in that same month. When a report went to the board in September, it focussed on the progress that had been made and gave no flavour of the seriousness of the concerns.

The board in South west Essex was not informed about the investigation into TCN until October 2009 and that part of their out-of-hours service was provided by TCN.

Relationships with TCN

Suffolk was the original home of TCN, and relationships between the PCT and TCN were well established. NHS Suffolk appeared reluctant to recognise there were shortcomings in out-of-hours services. Senior staff at NHS Worcestershire also sought to maintain good relationships with TCN despite continuing concerns from local GPs and those expressed in the external review they commissioned.

NHS Cambridgeshire had an increasingly fraught relationship with TCN as the Langdale review exposed the delays in changing processes and arrangements at TCN. NHS Cambridgeshire was also frustrated by the difficulty in obtaining full and accurate information from TCN. In the initial interviews with staff at NHS Great Yarmouth and Waveney in July 2009 we were told that staff found TCN responsive to concerns that had been raised. However, later in the year the interim chief executive stated that they had begun to question the accuracy of some of the information provided by TCN. NHS South West Essex did not have a direct relationship with TCN and there was little evidence that there was any meaningful interaction between the PCT and TCN until 2009.

PCTs and the views of local GPs on out-of-hours services

Most of the PCTs had not invested in finding out the views of local GPs on the out-of-hours services, although they were key stakeholders. NHS Cambridgeshirewas the exception, having asked the Local Medical Committee in 2009 to survey local GPs about out-of-hours services.

In CQC's survey, GPs in Suffolk were slightly more positive about the services than GPs elsewhere but all were critical. The percentage rating the out-of-hours service as poor or very poor ranged from 24% in Suffolk to 63% in Worcestershire, 65% in Cambridgeshire, and 66% in NHS Great Yarmouth and Waveney.

These ratings are extremely worrying in themselves. Although not directly comparable, a similar survey undertaken in Devon in December 2006 rated the Devon Doctors out-of-hours service as poor or very poor in 1% of responses. Particularly critical views of aspects of the service were expressed by local GPs in Cambridgeshire, Worcestershire and Great Yarmouth and Waveney.

Overall conclusions about the PCTs and their commissioning of out-of-hours services

The PCTs had all made improvements towards the end of 2009.

Before that, out-of-hours services were low priority, reflecting the national position, and PCTs had limited understanding of these services and the national quality requirements. In the early days, PCTs struggled with financial and capacity problems and some wished to disinvest in out-of-hours. There was a notable absence of vision and leadership in commissioning and monitoring out-of-hours services by PCTs as part of an integrated urgent care service. There were challenges for PCTs to obtain sufficient local clinical involvement in procurement when local GPs were bidding for the service.

Staff responsible for monitoring contracts did not understand key components of the activity data or the NQRs and there was little interrogation or challenge at the meetings to monitor contracts. There was very little knowledge about unfilled shifts, skill mix or the quality of the service. This meant PCTs in reality could not determine outputs, let alone outcomes, in terms of impact on other elements of urgent healthcare in this area and on patient safety.

Some of the PCTs stated that it was unreasonable for them to monitor individual complaints, incidents, or staffing levels since this would not happen for other contracts unless there were concerns. The CQC however considers that these were contracts that should have been monitored more thoroughly. This was a relatively new area of commissioning for the PCTs and there was a general lack of experience in contracting with a commercial organisation with a major emphasis on business priorities. In many cases they were newly implemented contracts which should have initiated closer scrutiny from the outset. Finally, CQC was not assured that the PCTs had the governance systems in place to identify that there were issues with the services and react accordingly.

PCTs had to develop their standards of commissioning as part of the ‘world class commissioning’ initiative. The CQC’s assessment of the standard of commissioning and of contract monitoring in out-of-hours services did not provide reassurance that PCTs knew what they wanted, whether they were receiving it, what the public thought, or how much they should be paying. With the exception in some respects of Great Yarmouth and Waveney there was a widespread failure to commission appropriate out-of-hours services for the local population and monitor that these were being delivered.

Strategic and performance management role of the strategic health authorities

Summary of findings

- Initially, priorities at both SHAs reflected the national priorities of financial stability and achievement of national targets. PCTs were managed against these priorities. The SHAs had encouraged another national priority which was increasing the range of providers, particularly in the commercial sector.

- Both SHAs referred to out-of-hours services in the overall strategic context of urgent care, rather than having a separate strategy specifically for out-of-hours. Recently, there has been more targeted activity at SHA level in respect of out-of-hours.

Summary of conclusions

1. SHAs in their early years focused on the national imperatives of targets and finances and, since out-of-hours was not a national priority until recently, placed less priority on monitoring PCTs' performance in out-of-hours services. There has been more targeted activity recently in both SHAs in respect of these services.

Strategic health authorities (SHAs) were originally created in 2002 to manage the local NHS on behalf of the Secretary of State. Each SHA is responsible for developing a strategic framework for the local health and social care community, and managing the performance of providers of healthcare within its boundaries. This includes having in place arrangements for monitoring and improving the quality of healthcare provided to individuals in the area.

The responsibility of SHAs to manage the performance of providers of healthcare does not apply in the case of foundation trusts, where Monitor has this role.

Sources of evidence
- Minutes of meetings
- Interviews with senior staff
- Documents and correspondence provided by the SHAs

NHS East of England

Background

NHS East of England was established on 1 July 2006 as the Strategic Health Authority for the east of England, covering Bedfordshire, Cambridgeshire, Essex, Hertfordshire, Norfolk and Suffolk.

NHS East of England is the regional headquarters of the NHS, and provides strategic leadership to all NHS organisations across the six counties. It is ultimately accountable to the Secretary of State for Health. The SHA notes on its website that it is also responsible for ensuring that the £8.1 billion spent on health care in the region delivers the best services and value-for-money for both patients and the taxpayer.

Early in 2009 when Dr Ubani was found guilty of manslaughter in Germany, the SHA

considered that the case needed independent investigation and referred it to CQC.

The SHA acknowledged that, overall, much of its focus had been on acute hospitals, targets and finances. There had been less concentration on primary care, particularly out-of-hours services. This had changed more recently.

Out-of-hours

The SHA did not have a specific strategic framework for out-of-hours services. Primary care trusts had the responsibility to ensure adequate provision of these services and the freedom to commission the means to do this, provided the services met the national quality requirements. Particularly in the first three years after the inception of SHAs, there was national encouragement to 'test the market' and develop a range of different providers. The director of commissioning acknowledged there was a risk that PCTs could have procured out-of-hours services independently.

Actions at the SHA in respect of out-of-hours before, or unrelated to, the death of Mr Gray

Penny Campbell died from septicaemia at the end of the Easter bank holiday weekend in 2005 following contact with eight doctors from Camidoc, a North London out-of-hours service. In December 2006 in response to this report, the Department of Health issued new 'directions' which 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.

In June 2007 the director of public health and director of commissioning at the SHA wrote to all the PCTs in the east of England area to check that they had robust procedures for reporting serious incidents that happened in out-of-hours services and ascertain whether there were any deficiencies in their out-of-hours services. The PCTs responded, the SHA followed up with specific queries and the information was shared at a meeting of the PCT leads for urgent care in September 2007. The director of commissioning told us that they had to make careful judgements about what matters to pursue.

The SHA set up various regional meetings for PCTs to encourage good practice in its area. These included clinical quality and risk forums but out-of-hours services were not on the agenda of these. The meetings of urgent care leads occasionally discussed matters relating to out-of-hours.

PCTs were performance managed on national priorities which were national targets and finances. The SHA held regular meetings with PCTs and the main topics covered at these meetings were the national priorities of waiting time targets, finances, healthcare-associated infections, choose and book, cancer, GUM, smoking, mental health and obesity. Out-of-hours services were not a standing item at the meetings between 2006 and 2008, including at Cambridgeshire, where the death had occurred. However, the SHA took account of the Healthcare Commission's review of urgent and emergency care in September 2008 and asked for improvement plans in those PCTs who received poor ratings. Cambridge had received the second best score in the East of England in the out-of-hours section of this review.

There were no specific support mechanisms established for PCTs in respect of commissioning or monitoring of out-of-hours services, although PCTs could access support from various areas in the SHA. The SHA had facilitated workshops associated with national benchmarking and offered a support service for procurement, with a generic out-of-hours service specification. The SHA acknowledged that PCTs' capacity and capability to monitor all contracts was still developing during the period in question and contracts in out-of-hours had not always been well understood or adequately monitored.

The SHA acknowledged that there were challenges and risks for staff working out-of-hours, and that they now recognised it was an area of concern.

We were told that it had taken time to bring together the serious untoward incident policies from the predecessor SHAs, and to ensure that SUIs were sent to the SHA via the appropriate PCT. The governance team ensured that particularly serious incidents, such as the death of Mr Gray, were drawn to

the attention of the chief executive and executive directors of the SHA.

The SHA had invested time in supporting PCTs to undertake root cause analysis of serious incidents. However it had not tracked serious untoward incidents occurring in out-of-hours services other than that of Mr Gray in Cambridgeshire. NHS East of England had identified concerns about TCN from serious incidents in late 2008 and early 2009 which influenced their decision to request CQC to undertake an investigation. The SHA acknowledged it was a challenge to monitor action taken as a result of SUIs and ensure there was learning from these incidents. An electronic system was being set up.

The head of clinical quality and patient safety told us that not all PCTs had adequate capacity for governance, and the separation of provider functions had in some instances exacerbated this.

Actions at the SHA in response to the death of Mr Gray in Cambridgeshire in February 2008

The incident happened on 16 February 2008; the PCT was informed on 19 February; and the SHA learnt the following day.

The immediate action taken was that the GMC suspended Dr Ubani's registration and the Cornwall and Isles of Scilly PCT suspended him from their performers list. The regional director of public health for the SHA issued an alert letter across England to reduce the risk that Dr Ubani could return and work in other areas. An immediate review of the other patients seen by Dr Ubani was undertaken.

The SHA was part of the Langdale review process involving the police and Cambridgeshire PCT in the weeks after the death of Mr Gray. Because of concerns that the case was sub-judice, the SHA considered that information could not be shared in case it prejudiced any legal proceedings. The SHA therefore did not take steps in 2008 to alert other PCTs generally as to what had happened and the lessons that could be learnt. However the head of clinical quality and patient safety told us that the network of the PCTs' officers accountable for controlled drugs had been informed about the incident, although the matter was not put in writing until March 2009. The SHA acknowledged that this network had generally concentrated more on day-time GP services. In July and November 2008 the SHA also discussed matters relating to patient safety and medication in out-of-hours services, with the network of PCT pharmacy leads

The police told CQC that the nature of the incident could have been shared as long as precise details of individuals were not released. They accepted however that staff in the NHS may have felt constrained.

In September 2008, when NHS Cambridgeshire were having difficulty in ensuring that the 100mg vials of diamorphine were withdrawn, the head of clinical quality and patient safety at the SHA joined their contract meeting with TCN to emphasise the seriousness of the situation. The head of clinical quality and patient safety also contacted the chief pharmacist at the Ipswich hospital NHS trust.

In March 2008 the SHA invited NHS Cambridgeshire to join the Department of Health's review of performers lists, and later that year the SHA also followed up with PCTs about the implementation of NHS safety alerts.

In March 2009, after the completion of the trial in Germany at which Dr Ubani was convicted of causing death by negligence, and having cleared the letters with the police, the director of public health at the SHA wrote to all the PCTs in its area, although there was a particular focus on those with contracts with TCN. This was for assurance about the safety of their out-of-hours services especially in respect of induction, controlled drugs and the handling of national safety alerts.

At this time the SHA learnt about the two earlier overdoses of diamorphine. Some of the information TCN provided to the SHA was inaccurate, such as claiming that they had reported the first overdose of diamorphine. It was the East of England ambulance service which reported it, although not as a SUI.

At the start of April 2009 the SHA contacted West Midlands SHA to draw their attention to the imminent publicity in the light of the fact

that NHS Worcestershire also commissioned its services from TCN.

In May 2009 the director of public health wrote a follow up letter to the PCT chief executives enclosing the rapid performance assurance process which NHS Cambridgeshire had developed, which he thought other PCTs could use. He asked for action in the four areas of incident reporting, induction, high dose opiates, and the performers list.

Developments after the CQC interim statement

The SHA had conducted a baseline survey of all PCTs against a number of standards of commissioning of out-of-hours services. The SHA formally required PCTs to develop action plans where there was a shortfall. The SHA had a particular focus on those PCTs that commissioned services from TCN. The SHA intended to ensure adequate surveillance of all the out-of-hours contracts.

The SHA had also requested the East of England network, a facility established by the 14 PCTs, to undertake a review of current arrangements for accepting GPs on to medical performers lists in the East of England. In February 2010 the SHA instructed PCTs only to employ GPs on an East of England performers list, or that of a neighbouring PCT. The review identified a number of recommendations to help standardise and improve the process. These included that all applications should be reviewed by a clinician. The SHA recommended that the application form developed by NHS Cambridgeshire be adopted as good practice by others PCTs in the East of England.

The SHA invested in expanding the clinical quality and patient safety team in late 2009 in response to the CQC report. It also gained agreement at the regional Operations Board in February 2010 to develop a set of minimum standards for out-of-hours services that complement the National Quality Requirements. There was additional agreement to establish a programme of support team visits to all PCTs and OOH providers.

An electronic system to identify serious incidents in out-of-hours will be in place in summer 2010.

Findings of fact on NHS East of England

- The SHA took action after Penny Campbell case by writing to all their PCTs.
- Initially priorities at the SHA reflected the national priorities of financial stability and achievement of national targets. PCTs were performance managed on these national priorities. Out-of-hours was not a national priority until recently.
- The SHA supported PCTs in ‘managing the market’ in line with government policy at that time.
- The SHA had not had any concerns initially that out-of-hours services would develop piecemeal and in a fragmented way.
- The SHA set up regional meetings for PCTs to improve clinical quality and risk but out-of-hours was not on the agenda of any of these. At the meetings of urgent care leads, out-of-hours was occasionally discussed.
- The SHA recognised the need for a more effective system to identify and track SUIs in out-of-hours services. An electronic system will be in place in summer 2010.
- The SHA was cautious in the year after the death of Mr Gray because of concerns the case was sub judice, but it took a number of steps to respond to the death, including developing a generic out-of-hours specification and attending the network of pharmacy leads.
- The SHA supported Cambridgeshire PCT in resolving the matter of removing the high doses of diamorphine.
- The SHA considered the death of Mr Gray and the issues it raised, needed independent investigation and referred it to CQC.

- In March 2009 the SHA contacted all PCTs about the safety of their services especially re induction, CDs and safety alerts.
- The SHA conducted a baseline survey of all PCTs in autumn of 2009 and required an action plan.
- In autumn 2009 the SHA requested the East of England network to undertake a review of current arrangements for accepting GPs on to medical performers lists in the East of England. The SHA instructed PCTs to only employ GPs on an East of England list or that of a neighbouring PCT.
- The operations board for the East of England has agreed to develop a set of minimum standards for out-of-hours services and set up a programme of visits to PCTs and out-of-hours services.

NHS West Midlands

Background

NHS West Midlands was established on 1 July 2006 as the Strategic Health Authority for the West Midlands, covering an area of 5.4m people across Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Shropshire, Solihull, Staffordshire, Stoke on Trent, Telford and Wrekin, Walsall, Warwickshire, Wolverhampton and Worcestershire.

As the local headquarters of the NHS in the West Midlands, it provides strategic leadership and is accountable to the Secretary of State. It is responsible for ensuring that the £7 billion spent on health and health care across the West Midlands delivers better services for patients and better value for money for tax payers.

Our analysis showed that, overall, much of the SHA's focus had been on acute hospitals, targets and finances. There had been less concentration on primary care, particularly out-of-hours services, until more recently.

Out-of-hours

The SHA did not have a specific strategic framework for out-of-hours services, but made reference to several aspects of out-of-hours in its strategic framework in 2007and the revision a year later. The SHA acknowledged that with the creation of primary care centres, GP led health centres, Darzi centres and extended hours for GP practices, there was increasing demand on GP's time. This could impact on the availability of GPs to work in out-of-hours services. While the SHA had conducted analytical work around medical workforce planning across primary care this work did not specifically address out-of-hours and the impact that increased demands on GPs time would have on their willingness to work in these services. Discussions also took place within the workforce directorate including the deanery, which was responsible for post-graduate medical education. Issues around the primary care workforce were linked to the strategic priorities of the SHA. The director of commissioning thought the SHA might not yet have resolved the workforce shortfall and that the matter needed to be addressed nationally.

Following the death of Penny Campbell in 2005, the Department of Health had issued new 'directions' which 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. The SHA staff we interviewed were uncertain as to what action had been taken in respect of out-of-hours services in the West Midlands, as they were not in post at that time. The Director of Commissioning added that the Medical Director and Nursing director at that time would have been precise about the remedial action to be undertaken.

In the spring of 2009 the East of England SHA contacted West Midlands SHA about the forthcoming publicity about the death of Mr Gray and the conviction of Dr Ubani, and the terms of reference of the potential investigation. The West Midlands SHA took action to check the position in Worcestershire PCT which had contracted with TCN for out-of-hours services. The SHA also sent an email in May 2009 checking the situation in other PCTs. In September 2009 the SHA required all

its PCTs to complete a baseline assessment of their out-of-hours services and commissioning arrangements, using a standard proforma. The results from this were used to write a briefing report for the chief executive.

The deputy medical director thought that the policy for serious untoward incidents (SUIs) was different across PCTs in West Midlands. The SHA had tried to achieve a common approach in 2009 but was hampered by the lack of a national definition of a SUI. The SHA focussed on categorising SUIs largely in terms of the organisations reporting them and had not looked at SUIs in particular service areas such as out-of-hours to identify if there were any common themes. The director of commissioning agreed that commercial providers might be reluctant to report serious incidents and might fear exposure if they carried out a thorough investigation.

Performance management and out-of-hours

The director of performance and information explained that PCTs were performance managed mainly on national priorities which were national targets and finances.

In early 2007, the director of nursing and director of public health established a patient safety and clinical quality group. Out-of-hours services were not mentioned in the sets of minutes we reviewed, up to June 2009 and the SHA explained there had not been any concerns during that time.

Before the incident involving the death of Mr Gray the main interest of the SHA in out-of-hours was around winter planning, and avoiding patients being sent inappropriately to A&E. Although the SHA closely monitored the performance of acute hospitals and the ambulance service during the pressure on the services in winter, they had not included out-of-hours services in this scrutiny. The director of performance and information noted there was a relative paucity of data on out-of-hours services. Those aspects of out-of-hours that were in the SHA's strategic framework were not specifically monitored.

The SHA acknowledged that most of their PCTs needed to strengthen their monitoring of contracts. The SHA expected to see a model where 'quality' was part of the routine monitoring meetings or was considered in a separate quality meeting.

The director of commissioning stated it was the PCTs responsibility to monitor NQRs, and they did not monitor them at SHA level. He commented that part of the job of the SHA was to support the understanding of the information at PCT level. The director of performance and information told us the SHA had strongly encouraged all the PCTs to become part of the Primary Care Foundation benchmarking club.

The SHA acknowledged that out-of-hours services were often not as integrated as they should be with other providers of urgent care. The director of performance and information added that some of the work being done to set up separate urgent care centres had not had the impact on A&E and out-of-hours services that they would have anticipated.

Some of the out-of-hours services, especially in the commercial sector, initially resented any intrusion in their business. The SHA had met with the out-of-hours providers and relationships were better than previously. However the director of performance and information noted that they had not yet got to the position where all PCTs had an effective contracting relationship and partnership with out-of-hours services.

NHS Worcestershire

The SHA knew that NHS Worcestershire had plans in early 2007 to tender out-of-hours services. The SHA considered that primary care trusts had the responsibility to ensure adequate provision of these services and the freedom to commission the means to do this, provided the services met the national quality requirements. The SHA stated that developing the market and a range of different providers had been encouraged nationally at that time. The main principles espoused nationally were competition, contestability, plurality and choice. This created an environment where the expectation was that PCTs would review services and go out to tender if the service was not satisfactory.

The SHA expected any tendering to be conducted in accordance with the law on procurement. It encouraged PCTs to use the

West Midlands Healthcare Purchasing Consortium to help them achieve this. When the results of the Urgent Care Review were published in 2008, and NHS Worcestershire had performed poorly on out-of-hours services, the SHA considered it a positive step for the PCT to have procured a new service.

When asked about the lack of local GPs in the service, the director of commissioning acknowledged that one of the fundamental problems in out-of-hours services was that they did not have an oversupply of GPs. They were critically dependent on the local workforce.

The PCT informed the SHA in April 2009 that there were local concerns about the out-of-hours service from GPs. The MP for Wyre Forest had also written directly to the SHA. The SHA commented on the terms of reference of the external review and the PCT sent the report of the review to the deputy medical director. The SHA considered that NHS Worcestershire had dealt with matters in a very satisfactory manner.

Developments after the CQC interim statement in October 2009

Although urgent care had been a priority, out-of-hours had not been perceived as a risk and was not on the SHA's risk register. The director of commissioning told us in January 2010 that the SHA now saw out-of-hours as a risk and was focusing on it. He acknowledged that CQC's interim statement in October 2009 had contributed to a change of view and led to a number of changes.

On 8 December 2009 the SHA held a local regional workshop with the Primary Care Foundation including out-of-hours providers and commissioners. There was a particular focus on the results on patient experience. The workshop involved consideration of benchmarking, the quality review programme described below and the launch of the new primary care out-of-hours network.

This new out-of-hours network came into being in December 2009 with plans to hold meetings every three months. Aimed at staff in PCTs who commissioned out-of-hours services, it was to be a conduit for sharing key messages and best practice. At the December meeting PCTs gave presentations on areas where they were performing well, based on results of the baseline assessment. NHS Worcestershire was asked to present on their experiences in out-of-hours. At the second meeting in February the discussion included the inquest verdict on Mr Gray and the Department of Health report,

In 2009 the SHA set up the West Midlands Quality Reviews Service (WMQRS) as a collaborative venture involving NHS organisations in the West Midlands. The aim was to develop quality standards, with peers carrying out quality reviews and then producing comparative information and learning. The first review was scheduled for the spring of 2010 and the director of commissioning told us that this would focus on urgent care, including out-of-hours services. All the PCTs were signed up to the programme and the out-of-hours services needed to join in.

On 20th January 2010 the SHA required PCTs to produce improvement plans for out-of-hours services in partnership with their providers. These plans had to be submitted in March and address shortfalls from their baseline position and recommendations from the coroner and Department of Health.

From February 2010 out-of-hours services was included on the agenda of the SHA's patient safety and clinical quality group. The coding system for SUIs had been revised making it easier to identify if a serious incident occurred in out-of-hours services.

More generally the SHA had been working closely with NHS Primary Care Commissioning and identified a training need around entry and removal from the performers list. The completion of training was scheduled to be in early summer of 2010. The training included courses for operational staff as well as senior managers and non-executive directors.

Findings of fact on NHS West Midlands

- Initially priorities at the SHA reflected the national priorities of financial stability and achievement of national targets. PCTs were performance managed on these national priorities. Out-of-hours was not a national priority until recently.
- The SHA referred to out-of-hours services in the overall strategic context of urgent care, rather than having a separate strategy specifically for out-of-hours.
- The SHA supported PCTs in 'managing the market' in line with government policy at that time.
- The SHA had not had any concerns initially that out-of-hours services would develop piecemeal and in a fragmented way.
- Out-of-hours had not been on the agenda of the SHA's patient safety and clinical quality group until February 2010.
- In early 2010 the SHA introduced a system to identify serious incidents in out-of-hours services.
- At the time of the national publicity about the death of Mr Gray, the SHA requested information on the position in out-of-hours in the PCTs.
- The SHA considered that NHS Worcestershire had dealt satisfactorily with the problems in out-of-hours.
- In September 2009 the SHA conducted a baseline survey of out-of-hours in all PCTs which was used to brief the chief executive. In January 2010 the PCTs were asked to develop improvement plans.
- In December 2009 it established a primary care out-of-hours network.
- The SHA reported that the first service to participate in the programme of peer reviews of quality would be urgent care, including out-of-hours.

Conclusions about the SHAs and performance management of PCTs

SHAs are the regional headquarters of the NHS and provide strategic leadership to all NHS organisations in their area. For NHS East of England, there were four PCTs that contracted for part of all of their out-of-hours service with TCN; for NHS West Midlands it was one PCT, NHS Worcestershire.

NHS East of England considered the death of Mr Gray and the issues it raised, needed independent investigation and referred it to CQC.

Initially priorities at SHAs reflected national priorities of financial stability and achievement of national targets, and PCTs were primarily performance managed on these national priorities. Since out-of-hours was not a national priority until recently, the SHAs had not performance managed PCTs on these services.

Both SHAs referred to out-of-hours services in the overall strategic context of urgent care, rather than having a separate strategy specifically for out-of-hours. Particularly in the first three years after the inception of SHAs, there was national encouragement to 'test the market' and develop a range of different providers. Primary care trusts had the responsibility to ensure adequate provision of these services and the freedom to commission the means to do this, provided the services met the national quality requirements.

Neither SHA had an electronic system to identify SUIs in out-of-hours services. NHS West Midlands introduced this in early 2010 and it will be in place in East of England this summer. NHS East of England had identified concerns about TCN from SUIs in late 2008 and early 2009 which influenced their decision to request CQC to undertake an investigation.

Because of concerns the case was sub judice, NHS East of England was cautious about informing or checking other PCTs in the year after the death of Mr Gray. The SHA however took steps in the early summer of 2008 to inform the network of accountable officers for

controlled drugs about the incident in Cambridgeshire and it helped NHS Cambridgeshire resolve the matter of removing the high doses of diamorphine. In March 2009 it contacted all PCTs in the East of England about the safety of their services especially re induction, CDs and safety alerts.

NHS East of England informed NHS West Midlands about the forthcoming national publicity about the death of Mr Gray. NHS West Midlands was aware of the local concerns about out-of-hours services in Worcestershire and was content that the PCT had dealt with these satisfactorily.

Both SHAs conducted baseline surveys of all PCTs in the autumn of 2009 and required action or improvement plans. In December 2009 West Midlands established a primary care out-of-hours network. Since September 2007 the East of England had supported a network for PCTs on urgent care, which from time to time included issues in out-of-hours services. NHS East of England had also initiated a review of performers lists and tightened up regulations locally. NHS West Midlands reported that the first service to participate in the quality review programme would be urgent care, including out-of-hours.

Overall we concluded that there had been considerable recent activity at SHA level in respect of out-of-hours but prior to that there had been little strategy or leadership for out-of-hours services, particularly in the context of integrated urgent care

Administration of the performers lists

Summary of findings

- We found a range of different approaches to performers lists in the PCTs, and different levels of scrutiny of applications and of proficiency in English. PCTs were not acting systematically to monitor care or ensure new performers were familiar with local structures and services. However, there was evidence that PCTs had recently tightened their procedures and increased clinician involvement in screening of applicants.

Summary of conclusions

1. The PCTs had all recently tightened their procedures in respect of performers lists, although there were still different levels of scrutiny.

A general medical practitioner (GP) must be listed as a primary medical performer in order to treat NHS patients in a primary care setting. This applies whether a practitioner is a general medical services (GMS) contractor, a personal medical services (PMS) provider, a doctor who has been engaged or employed by a contractor or provider to perform the services (whether directly or via some other body or agency), or a practitioner who is employed to perform the services by a PCT. The list is called the performers list and is administered by PCTs.

In 2004, revised NHS regulations were issued. The Department of Health produced accompanying guidance for primary care trusts (PCTs) on the management of the list[1]. The NHS (Performers Lists) Regulations also provided a framework within which PCTs could take action if a doctor's personal and/or professional conduct, competence or performance gave cause for concern.

GPs can only be on one list for one PCT. Once they are on a list, they can work in the area of any other PCT in England. They must do some work "periodically" in the area of the PCT where they are on a list, which is normally the area where they do the most work. PCTs have discretionary power to remove GPs from their lists if the GPs cannot demonstrate that they have performed primary medical services for patients over any 12-month period.

The regulations include information about the grounds on which a PCT must refuse to include a performer in its performers list. These could be if the doctor has not provided satisfactory evidence that they intend to work in its area, or if the PCT is not satisfied that the doctor has sufficient knowledge of English to perform services in its area. If a PCT refuses to admit a GP, then they cannot perform services and they must declare this if they apply to join the list of another PCT.

Doctors who want to join a performers list must apply in writing to a PCT in the locality where they intend to perform services. They need to include a range of information and copies of evidence about their qualifications, registration and experience. The PCT is expected to take reasonable steps to verify the information.

In 2009 a review of the arrangements for the performers list was undertaken by the Department of Health. The review found that there were considerable variations both in processes and outcomes between PCTs. It noted there was considerable potential to improve the operation of the performers list

[1] 'Tackling Concerns locally: The performers list system – 20th March 2009 (10883 – Gateway Ref)

and in particular to improve the consistency of decisions taken by different PCTs.

The review noted that practitioners who have qualified and trained in other EU countries who intend to practice in the UK, posed a challenge. Under EU legislation any suitable primary care qualifications must be recognised by the UK national regulators. However, such practitioners would still need to be admitted to a performers list in order to be able to practise in primary care. The review considered that PCTs may therefore wish to ensure that they have adequate English to communicate effectively with their patients. The review also recommended that PCTs may also want to consider some sort of induction training so that practitioners are familiar with local clinical structures and processes including information systems, before they start work.

It concluded that PCTs should retain the responsibility for monitoring the conduct and performance of each primary care practitioner providing care to NHS patients, and for taking any action needed if there was a threat to patient safety. The review recommended the continuation of the performers list but with a number of improvements. These included more detailed guidance to promote greater consistency, fairness and transparency over initial admissions to the list and over the processes leading to possible suspension or removal from the list, with greater clarity over the safeguards for the practitioner.

The review considered that one of the primary benefits of the list being held by local organisations is that they are already responsible for monitoring the quality of care commissioned from primary care contractors. They have access to local intelligence about the nature of services provided and the needs of the population. By managing entry to the lists they can ensure that all new performers are suitable to provide services for the particular community, for example that they are familiar with local structures and protocols. Through monitoring or complaints, concerns, etc they can be alerted to problems. In the conclusion section to this investigation we consider this further.

Local PCT arrangements for management of the performers list

NHS Cornwall and the Isles of Scilly

Dr Ubani applied to join NHS Cornwall and the Isles of Scilly performers list on 4 July 2007. No concerns were raised in relation to Dr Ubani's application and he was accepted on to the performers list on 18 July 2007. Dr Ubani did not work at NHS Cornwall and the Isles of Scilly while he was registered with the PCT.

The application was received, processed and approved by an administrative member of staff at the PCT. The PCT did not require EU GPs to provide an IELTS certificate or provide evidence that they intended to work locally. The information that Dr Ubani supplied in support of his application did not detail how much of his time was spent actually working as a GP and what kinds of patients he treated. During the inquest in to the death of Mr Gray the director of the primary care support agency at the PCT stated that they had written to the referees Dr Ubani had provided asking for further details of his work experience. In fact the letters that were sent to the referees simply asked them to confirm that they had written the reference.

Dr Ubani had initially applied to join Leeds PCT performers list, via the West Yorkshire NHS Central Services Agency. He was not accepted as he had only achieved a score of six on the IELTS language test and he had failed to supply evidence that he was going to work in the PCT area. Dr Ubani was contacted during the application process and informed that one of his references was not admissible as the doctor had no experience of Dr Ubani's working as a GP. He was also advised to offer a referee with previous experience of the NHS. Dr Ubani withdrew his application in July 2007 at around the same time he was accepted on the performers list at NHS Cornwall and the Isles of Scilly.

Following the death of Mr Gray on 16 February 2008, the GMC suspended Dr Ubani from the medical register and NHS Cornwall and the Isles of Scilly suspended him from their performers list on 26 February 2008.

There was no evidence that the arrangements for approving doctors to join the performers list were formally reviewed by the board of NHS Cornwall and the Isles of Scilly. Many of the changes that were made as a result of this incident were instigated by staff on the contracts team.

During the inquest, the director of the primary care agency at the PCT stated that they had received 48 applications from foreign GPs to join the performers list during the year that Dr Ubani applied. The high number of applications was a result of the local out-of-hours provider losing the contract which meant that local GPs were less willing to work in the service. The contracts manager at the PCT told us that the PCT had subsequently removed around 40 GPs from the performers list, a number of whom were from overseas.

The contracts manager and a senior GP were now responsible for signing off all applications to the performers list. Candidates for the performers list at NHS Cornwall and the Isles of Scilly were required to present a language test certificate to support their application and they had also to provide proof that the majority of clinical work would be carried out in the PCT area. Referees were required to complete a proforma rather than relying on a general letter and the PCT also checked the status of the referees. If a referee had conditions attached by the GMC then the applicant would be asked to supply a third reference. All doctors who lived outside Cornwall and had not worked in Cornwall for the past 12 months were removed from the list. We were told that the contracts team checked this annually and would also follow up on the progress of any GP who responded that they had applied to a different performers list.

The PCT was running a revalidation pilot aimed at strengthening the appraisal system for doctors on the performers list. We were told that they were trying to make the system more about the fitness to practise of the clinician. If a GP had not had an appraisal after 15 months, then they would be informed that they would be removed from the performers list within 28 days. The contracts manager at the PCT told us that she had not been confident in the past that she would be notified if an individual had not had an appraisal but that this had been tightened up.

NHS Suffolk

Applications to the NHS Suffolk performers list were processed by the Anglia Support Partnership (ASP). The ASP was hosted by the Cambridgeshire and Peterborough NHS Foundation Trust and the organisation offered a range of support services to the NHS.

We were told by the ASP managers of the performers list at NHS Suffolk that there was a checklist against which applications were reviewed to ensure the correct documentation had been presented. If the applicant was already on another PCT performers list when they applied to NHS Suffolk then they would check with that PCT that everything was in order. It was acknowledged that the requirement for EU GPs to achieve level seven of the IETLS language test had been introduced relatively recently. The ASP managers reviewed the work history of the applicant and there was a GP medical advisor responsible for reviewing and following up the references from the applicant's most recent posts. Final acceptance to the performers list was signed off by the ASP manager.

The PCT reviewed the locum GPs on the list annually and a clinician would be removed if they could not provide evidence that they had worked in the PCT. GPs on the NHS Suffolk performers list only had to work one shift per year in Suffolk in order to remain on the local list. A letter from TCN that stated that the clinician had worked a shift in Suffolk in the last year would be accepted as evidence for that GP to remain on the performers list. Individuals were removed if they could not provide proof and CQC was told that one or two individuals were removed per year. The managers responsible for the performers list acknowledged that it was more problematic to check that salaried doctors were working in Suffolk. The practice managers were supposed to notify them when a salaried GP left but in practice that did not always happen. It was thought that around 20% of the GPs on the performers list were not resident in Suffolk.

We were told that there were occasions when TCN had phoned to check that a GP was on the NHS Suffolk performers list. It was also

commented that in the past TCN had attempted to get someone on to the list at short notice but that those requests had stopped after they were told it was not possible to fast track applicants. The expectation of the managers was that TCN would do the same checks of their own staff as NHS Suffolk would make for an applicant to the performers list. It was said that following the Dr Ubani incident TCN checked that all of their doctors were on a performers list.

There had been two previous occasions where NHS Suffolk had discovered doctors working in the PCT who were not on a performers list. It was reported that these were agency doctors working out-of-hours who had taken themselves off their previous performers list as they thought they had been accepted on to NHS Suffolk's list.

The managers of the performers list stated that a GP working in the PCT on a list other than their own would receive appraisals from the 'owner' of the performers list. The ASP managers were not responsible for recording whether GPs working in NHS Suffolk received annual appraisals from their 'home' list. They stated that they would be notified by NHS Suffolk if there was an issue with a GP on the list.

The managers responsible for the performers list stated that they knew what they were doing was broadly the same as other areas as they were in close contact with Norfolk and Cambridgeshire PCT and that they used the same processes and the same form.

NHS Cambridgeshire

Applications to the performers list were managed by the Anglia Support Partnership. We were told that the medical advisor at the PCT checked the clinical references of each applicant, rather than just referring to the GMC registration. There was a checklist which was used to ensure and record that all relevant checks of new applicants were made.

CQC were told that following the Dr Ubani incident Cambridgeshire reviewed their performers list application process extensively and contacted NHS Cornwall and the Isles of Scilly to establish where the improvements could be made. In June 2008 the PCT held a meeting to decide what changes to make locally. The PCT took legal advice concerning some of the proposed changes such as whether they could ask an applicant for a UK based clinical reference. They were interested in a scheme that had been recommended by the RCGP for foreign doctors whereby all applicants were given an assessment and induction in order to identify any gaps in their skills.

The PCT also wished to ensure that an applicant had to obtain at least a score of seven overall on the IELTS test. After the SUI the PCT learnt that Dr Ubani had scored poorly in the speaking and listening elements of the test. The PCT wanted to specify that a high score was achieved for the speaking and listening elements of the test because otherwise an individual could score poorly on this section but gain an average over seven due to performing well on another part of the test. However had Dr Ubani applied to the NHS Cambridgeshire performers list he would not have been accepted as he did not achieve a score of seven overall. In April 2009, the PCT stated they now had in place detailed requirements for a satisfactory language test.

NHS East of England recommended that the application form developed by NHS Cambridgeshire be adopted as good practice by others PCTs.

The PCT had a system in place for appraisal since 2006. The PCT contacted all the GPs on their performers list to ascertain when they were due an appraisal, and if they did not respond then they were sent a second letter and informed that they would be removed from the list if they did not contact the PCT. It was acknowledged that it was difficult to keep up with locum doctors but we were told that they had introduced a new process whereby practice managers were asked to complete exit reports when a locum left. This was to gather evidence for revalidation. We were told that as a result of the review following the SUI the PCT had realised that TCN did not record when a clinician had last received an appraisal.

The PCT used the Oasis database to keep a record of appraisal and performers list

registration of all the GPs who worked in NHS Cambridgeshire.

As was the case in Suffolk it was only necessary for a GP to work a minimal amount of time in the PCT in order to qualify to remain on the performers list. Around 10% of the GPs on the Cambridgeshire PCT performers list did not live in Cambridgeshire.

NHS Great Yarmouth and Waveney

The PCT had an agreement with Anglia Support Partnership (ASP) to provide support services to primary care. As part of this agreement ASP managed all applications to the PCT's performers lists in liaison with the PCT and in line with relevant national regulation and guidance. Where there was anything untoward in the application, such as questionable qualifications, incomplete career history or poor references it was stated that the application would be referred to the primary care lead within the PCT. The medical director was responsible for making the decision to refuse admission to a list, or conditionally include, suspend, remove or contingently remove a practitioner. After May 2009 the medical director personally examined all applications.

The PCT had developed a spreadsheet of all clinicians on the performers list so that they could tag incidents and complaints. They specifically requested the names of clinicians involved in complaints from TCN.

The contract monitoring team were collating the names of all individuals on the Great Yarmouth and Waveney performers list who worked in out-of-hours. The PCT had recently asked TCN to notify them whenever a new GP started work in the area so that they could do their own checks on that individual.

In May 2009 the medical director wrote to TCN to obtain a list of all the GPs who worked out-of-hours shifts for TCN in Great Yarmouth and Waveney and who were not on a local performers list. He received a list of ten individuals and he wrote to each of the relevant PCTs to ask whether they were on the list, whether they had had an appraisal and whether there were any outstanding performance concerns. In some cases he was told that the GP was not actually on the list. In response to this the medical director wrote to TCN to ask them how they were going to check that GPs belonged to a performers list in the future.

NHS Worcestershire

The performers list at NHS Worcestershire was managed, monitored and maintained by the primary care department. A senior member of staff was responsible for overseeing the application of clinicians on to the performers list whilst an administrative officer was responsible for implementing the process. Both of these individuals had received training and we were told that the senior member of staff had attended a regional West Midlands group which looked specifically at the performers list. If there was any reason for concern about a GP then the application had to be signed off by the medical advisor before they were accepted on to the list. As part of the checklist for acceptance on to the performers list, all applications were reviewed by the professional executive committee.

There was a proforma for checking the references and we were told that these had always to be in writing. The PCT always checked with the previous PCT the GP had been registered with before they were accepted on to NHS Worcestershire's list. We were told that with regard to language proficiency the PCT expected any GP applying to the list to meet nationally and locally agreed guidance. Applicants were not required to have taken the IELTS language test. The head of primary care stated that the procedure for foreign doctors joining the list was not any different as it was felt that the process was robust enough.

It was unclear whether the list was routinely updated other than when they were notified of a change in circumstances. The appraisal team at the PCT were notified when a GP was accepted on to the list. The head of primary care was unclear how they monitored the appraisal record of a GP who had been on the list for years and had not worked in the PCT. If a GP had not had a regular appraisal then they would be removed from the list but this had never occurred at the PCT.

Any complaints about a doctor from either a patient or the appraisal team were referred to

the director of public health. It was commented that when the new medical director started in December 2009 the PCT planned to hold a workshop to discuss how any concerns would be brought together in the future. The PCT did not have a list of the doctors on the performers list who were working for out-of-hours. We were told that part of the focus of the workshop would be around making links with out-of-hours in terms of sharing concerns about clinicians working in the system.

The PCT had reviewed their performers list process in June 2009 in light of recent guidance issued by the strategic health authority. They had not found it necessary to change the process they had in place.

NHS South West Essex

NHS South West Essex performers list was the responsibility of the performers list officer at the PCT. We were told that the application form was based on the current performers list regulations and that there was a standardised check list for applications to the list. The performers list officer told us that the PCT checked whether there were any restrictions on practice at the PCT where the GP was previously registered and the GMC website. If they were alerted to any issues relating to an applicant then the decision to accept the clinician on to the list would be made at a more senior level in the PCT. Applicants were not required to have taken the IELTS language test.

Applicants for South West Essex performers list were required to come in to the PCT in person to deliver their documents. This was the only PCT where we observed this practice.

There was a process for checking annually whether a GP had worked in the area. A GP would be removed from the list if they had not worked locally in the past 12 months. It was commented that this process was less robust at first but they had since tightened up the procedures.

The performers list officer did not know how many GPs working in the SW Essex area worked in out-of-hours and was not sure that she had ever been contacted by TCN to confirm an individual was on the performers list. The PCT would only find out if a GP worked in out-of-hours if an incident relating to that individual was reported.

The PCT had an appraisal scheme in place which a GP had to take part in or they would be removed from the list. This scheme included locum and salaried GPs who worked for agencies such as TCN. The date of the last recorded appraisal was recently added to the application form and the PCT appraisal team were sent a list of all GPs on the performers list.

Conclusions on performers lists

Dr Ubani's application was received, processed and approved by an administrative member of staff at NHS Cornwall and Isles of Scilly.
The PCT did not require GPs from the European Union to provide an IELTS certificate or provide evidence that they intended to work locally. The only checking of his referees was to ascertain that they had written the reference. There was no assessment of his application by a clinician.

This was in contrast to the West Yorkshire NHS Central Services Agency which assessed Dr Ubani's application to join Leeds PCT performers list and did not accept him. This was because he only achieved a score of six on the IELTS language test, he had failed to supply evidence that he was going to work in the PCT area, and one of his references was not admissible, as the doctor had no experience of Dr Ubani's working as a GP.

After the death of Mr Gray in Cambridge, although NHS Cornwall suspended Dr Ubani, the PCT board did not review the arrangements for approving doctors to join the performers list. The changes that were made as a result of this incident were largely instigated by staff on the contracts team.

As with the review by the Department of Health in 2009, CQC found a range of different approaches to the performers list in the PCTs we reviewed. This had not been an area of priority for PCTs until recently, when all had tightened their procedures and most had increased the level of clinician involvement in screening non-standard applications. Some

lists were administered by the PCT; others used a NHS support agency. Some required applicants to have a specific level of proficiency in English, others did not. One PCT required applicants to deliver their applications in person.

The level of scrutiny of both applications and appraisals varied. The medical director in Great Yarmouth and Waveney actively checked the performers list status of GPs working in out-of-hours and whether there were concerns about the GP in their 'home' PCTs. Most PCTs now checked annually that GPs had worked in their area but Worcester did not. For those that checked, the doctor needed only to have worked one shift to satisfy their criteria.

Most PCTs did not know which doctors on their list worked in the out-of-hours service and, more particularly, who worked only in this service. None had clear cut systematic arrangements to ensure concerns about doctors were shared between out-of-hours and other services, and between PCTs.

The review by the Department of Health considered that one of the primary benefits of the performers list being held by local organisations was that they were already responsible for monitoring the quality of care commissioned from primary care contractors. However, CQC did not find evidence to suggest that the PCTs were acting systematically to ensure that all new performers were suitable to provide services for the particular community, for example that they were familiar with local structures and protocols. Nor was there evidence that PCTs had effective mechanisms to identify and respond to problems by monitoring complaints, concerns or incidents.