

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

Summary

Introduction

The Care Quality Commission carried out an investigation into the out-of-hours services provided by the organisation Take Care Now (TCN).

'Out-of-hours' refers to those times when GP surgeries are generally closed, from 6.30pm to 8.00am on weekdays and all day at weekends and bank holidays. TCN was commissioned by five separate NHS primary care trusts (PCTs) to supply out-of-hours care.

Reason for the investigation

The investigation followed the death of Mr David Gray, who was treated in February 2008 by a locum doctor, Dr Ubani, and died following the administration of 100mg of diamorphine, about 10 times the normal therapeutic dose. 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.

Scope of the investigation

We were asked by NHS East of England in June 2009 to review the out-of-hours arrangements in relation to TCN. Our terms of reference were:

- An assessment of current systems, including contractual and monitoring arrangements between TCN and the five PCTs.
- A review of events from 1 April 2007 to ensure that all appropriate factors have been identified and establish whether further improvements need to be made.

The organisations covered by our enquiries were:

Provider: Take Care Now (TCN)*

Commissioning PCTs: NHS Cambridgeshire

NHS Great Yarmouth and Wavenev

NHS South West Essex

NHS Suffolk

NHS Worcestershire

Strategic health authorities

(SHAs)

NHS East of England NHS West Midlands

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

We looked at TCN's handling of calls, staffing, medicines management, governance processes and leadership. We examined the arrangements for commissioning out-of-hours services by the five PCTs and also the strategic and performance management role of the two SHAs. Finally, we looked at the way that the PCTs administered their performers lists of GPs (the lists of doctors who are authorised to treat patients). The full terms of reference are set out in the appendix document.

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 also noted that the PCTs involved 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.

This summary

This summary of our final report draws together our main findings and conclusions. Our recommendations are listed at the end of this summary.

Contents:

Summary of main conclusions	4
The death of David Gray	6
Previous incidents involving overdoses of diamorphine	6
Provision of out-of-hours services by TCN	7
Commissioning and monitoring of out-of-hours contracts by the five PCTs	11
Strategic and performance management roles of the two SHAs	14
Administration of the performers lists by the PCTs	15
Overall conclusions	16
Recommendations	17

Summary of main conclusions

The death of David Gray and previous incidents involving overdoses of diamorphine

 Two previous incidents at TCN involving overdoses of diamorphine were warnings that a more effective system of governance could have identified and acted on earlier. Concerns had been raised in TCN and some steps taken, but the more fundamental changes that might have helped prevent a further incident did not happen until after Mr Gray's death.

Provision of out-of-hours services by TCN

- 1. TCN struggled to recruit local GPs and relied heavily on doctors flying in from Europe to work weekends. Some doctors worked long hours. TCN tolerated staffing levels that were potentially unsafe, with pressure on other staff.
- 2. TCN failed to recognise the importance of learning lessons from complaints and incidents. It was not sufficiently focused on clinical risk and did not adequately report or investigate serious incidents. In particular, it failed to act quickly enough on the concerns that emerged from the two overdoses of diamorphine in 2007, or on the National Patient Safety Agency alert in 2006.
- TCN's systems for medicines management were inadequate, leading among other things to controlled drugs being stored and administered inappropriately. Recently medicines management had improved and the system for accessing controlled drugs was more robust and easily monitored.
- 4. TCN reported activity in a way that was confusing and potentially misleading, and did not act to resolve this. The performance that TCN reported to the PCTs on the national quality requirements did not accurately reflect the actual performance of the organisation, and could potentially have concealed poor performance.
- 5. TCN grew too rapidly and the focus on expansion and business priorities was at the expense of governance and clinical services. Although clinical governance was well articulated by TCN, there was insufficient capacity to deliver it. It was not rooted in frontline patient services, nor demonstrated by clear accountability or local clinical leadership.
- 6. TCN failed to recognise problems in its own systems that might have helped prevent the death of Mr Gray. It was reluctant to admit its shortcomings and provided information to the PCTs and to us that was often inaccurate or incomplete.

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

- 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.

Strategic and performance management role of the two SHAs

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.

Administration of the performers lists by the PCTs

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

The death of David Gray

A number of factors led to the death of Mr Gray. Chief among these was the poor knowledge and practice of Dr Ubani, who did not understand the strength of diamorphine and administered such a large dose of the drug that it killed Mr Gray.

However, there were also shortcomings in TCN's systems that contributed to the failure to help prevent the death of Mr Gray. In 2006, the National Patient Safety Agency issued a safer practice notice because of a number of reports of deaths due to the administration of high doses (30mg or greater) of diamorphine or morphine injections. Organisations were asked to assess their procedures for the prescribing, labelling, supplying, storing, preparing and administering of diamorphine and morphine injections. TCN had special boxes for the pain relief of palliative care patients. These contained different strengths of diamorphine. TCN claimed that they had not known about this notice and so had not taken any action. However, the primary care trust NHS Suffolk had evidence which suggested that TCN had been notified. TCN's own drugs coordinator had also raised this matter internally.

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

Dr Ubani was working his first out-of-hours shift in England and should have had a full induction. The induction file he was given was poorly organised and the information in it about controlled drugs was not prominently displayed. The doctor who conducted the induction was an experienced GP but had never done an induction before and was already busy, both working a shift and supervising a GP trainee.

Previous incidents involving overdoses of diamorphine

There had been two incidents involving TCN in the previous 12 months of patients being given overdoses of diamorphine. Both cases involved doctors who trained and practised in Germany and who came to England to work shifts for TCN. Both the patients were taken to hospital following the overdoses and recovered. Neither of these events were reported as a 'serious untoward incident', although they should have been. The second, in August 2007, was notified to NHS Suffolk, but in the context of whether the doctor involved needed training. The PCT did not report it to its strategic health authority as a serious untoward incident.

On the day of the second incident, TCN's lead for clinical governance sent a memo to TCN clinicians, reminding them of safety issues when giving opiates by injection. The memo pointed out the different strengths of morphine and diamorphine, that normally no more than 5mg of diamorphine should be given and that it was hardly ever appropriate to open the 30mg ampoule of diamorphine available. This memo was in the

induction pack and available to clinicians who joined TCN after August 2007. However, the pack was poorly organised.

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

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

The clinical governance lead was to draw up a proposal for this scheme. On 15 January 2008, he proposed changes to the palliative care boxes to senior TCN staff, including the medical director, and staff at Ipswich Hospital Pharmacy. He raised concern that these two incidents had occurred as clinicians had inappropriately administered diamorphine, and considered that action needed to be taken to rectify their current system before a death occurred. The proposal suggested the introduction of smaller 'pain boxes' to be used to treat acute pain and discouraged the use of the palliative care boxes in these instances.

Following Mr Gray's death on 16 February 2008, the referee system was introduced within 48 hours. The pain boxes were introduced in May 2008 and the 100 mg vials of diamorphine were removed in September 2008.

We conclude that there were clear warning signs which an effective system of governance could have identified and acted on earlier.

Provision of out-of-hours services by TCN

In out-of-hours services, people usually contact the service by telephone. They are either given advice on the phone, asked to come and see a clinician at a base or health centre, receive a home visit or are transferred to another service.

Call handling

We found that TCN's standard of call handling was generally satisfactory. However, TCN did not ensure that calls related to symptoms of stroke were immediately diverted to 999 in line with national guidance. Although TCN said that this was because local staff had given us an out-of-date protocol, we found the same protocol still in use elsewhere.

Overall, the standard of clinical triaging for the calls that were audited was good. As with call handling, the area most in need of improvement was giving the caller advice about what to do if symptoms got worse.

If a call is deemed to be routine, the caller can be asked if they would like to go straight to a base, rather than talk first to a clinician. This name for this is 'call streaming'. It effectively bypasses the stage when a clinician assesses the urgency of the call. TCN introduced call streaming, initially for children, and then extended it to adults.

TCN was not consistent about its rationale for call streaming. Call streaming can be popular with patients and a useful approach, provided the system is audited. Although TCN told us that call streaming had been audited when it was introduced, there had only been one audit and then the change had been incorporated into practice without any further checking.

TCN did not undertake routine auditing of their call handlers. This was of particular concern because, when call streaming was in operation, call handlers were expected to ask callers whether they would like to go straight to a base. If the caller chose this option, it could be a considerable period before they saw or spoke to a clinician.

Reporting of activity

TCN's reporting to PCTs of its performance on the national quality requirements (NQRs) was not comprehensive or accurate, and did not reflect the actual performance of the organisation.

The way in which TCN reported its activity was confusing and potentially misleading. Most providers report activity such that for each patient there is just one record. The number of cases or 'patient journeys' is the same as the number of contacts.

However, at TCN, if a patient was triaged and given an appointment for a visit to a base, two patient contacts were created for this one case. This was sometimes referred to as 'double counting'. A PCT might be under the impression that total contacts meant total cases/patients and therefore have overestimated the level of activity in out-of-hours, which could have affected contract negotiations. For example, the value of the out-of-hours contract was increased by NHS Worcestershire by 9% seven months after TCN took over the contract.

TCN's client service managers did not fully understand the activity figures and neither did those in the PCT with operational responsibility for monitoring the contract. TCN did not take sufficient action to resolve the lack of transparency of its activity reporting.

Staffing

In some areas, TCN struggled to recruit local GPs. TCN's lead for clinical governance noted in 2008 that TCN was heavily reliant on the use of doctors coming over from Europe. In Worcestershire between August and November 2009, 31% of shifts were worked by GPs not on local performers lists and 28% of doctors working in Worcestershire in this period were supplied by agencies (although it should be noted that there was no contractual requirement to use doctors on local lists).

The difficulty with recruiting GPs and filling shifts meant that some doctors worked excessive hours. Clinicians were not supposed to work more than 12 hours consecutively, and more than 16 hours in a 24-hour period. There were 12 occasions between March and May 2009 where a clinician in the East Anglia area worked more than 16 hours in a 24-hour period. In Worcestershire in the same three months, there were over 100 occasions when a GP worked more than 12 hours consecutively.

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

Half of TCN's own staff thought that clinical staffing levels were poor or not good. Staff also told us that their concerns about poor staffing were ignored or dismissed.

This was an area we investigated in depth, using rotas, surveys and unannounced visits. All of these confirmed that clinical shifts were often unfilled. Our analysis of rotas in place in all TCN areas from March to May 2009 found that 8% of shifts were unfilled. This amounted to more than 3,000 hours. By September and October 2009 the situation had deteriorated, with 10% of clinical shifts unfilled in the East of England and 18% in Worcestershire (13% overall).

Our observations during a weekend in September 2009, when we visited bases in the East of England, reinforced the concerns of staff and our analysis of rotas. We found an unfilled doctor's shift at Wisbech on the Saturday morning, the base at Ely closed on the Saturday morning because there was no doctor available, the base at Newmarket closed at 6pm because there was no doctor available, and we learnt there was no doctor at Sudbury. Staff told us this was not unusual.

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

We later identified four other occasions in September 2009 between midnight and 8am where a nurse in Wisbech was providing the sole clinical cover for the East Cambridgeshire and Fenlands area. Since the out-of-hours base in Bury St Edmunds was closed from midnight and the Newmarket shift was unfilled, the nearest doctors on those occasions would have been more than 70 miles away. We also noted that TCN's bases were often poorly signposted and difficult to find.

The induction of front line clinical staff was poor in 2007 and much of 2008. It then gradually improved. In 2007 and occasionally in 2008, some doctors worked shifts before they had been inducted.

TCN acknowledged it needed to improve its records of the training that staff had attended. It had very limited records of attendance before the end of 2008. Over 90% of non-clinical staff reported that they had not had training in areas such as child protection and protection of vulnerable adults.

Medicines management

The National Patient Safety Agency issued a safer practice alert in 2006. It required that organisations took action in respect of prescribing, labelling, supplying, storing, preparing and administering of morphine and diamorphine. This went to all the PCTs and NHS Suffolk had evidence that it would have been sent to TCN. The drugs coordinator for TCN at that time also told us that she escalated this alert internally within TCN. TCN stated that they did not receive this alert and therefore did not take any action. Before January 2009, TCN did not have a formal system for ensuring staff were aware of alerts.

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

The first policy on the management of medicines issued in September 2007 was written by the clinical nurse lead with input from the medical director, but without any pharmaceutical advice. It had no supporting policies such as one for controlled drugs and was unsatisfactory in a number of respects. It did not provide sufficient detail and contained some incorrect information.

Other than in Cambridgeshire, there was no evidence that the original medicines management policy was reviewed by PCT pharmacy staff until subsequent revisions of the policy in spring 2009.

Governance and leadership

TCN did not have a robust system to learn from incidents and complaints and to identify risks and act accordingly.

We found that some serious events and situations had not been recognised and reported as serious untoward incidents, and there had been inconsistent reporting to PCTs of serious clinical problems. There was also an inconsistent approach to investigating some cases including deaths, where system failure or clinician performance could have been an issue.

In our survey of local GP's opinions in areas served by TCN, just over a third of respondents (36%) rated the standard of GPs used by TCN as "poor" or "very poor". TCN began to audit clinicians in 2009 and is to be commended for identifying the poor performance of some doctors through audit. However, it had not developed an effective system to feed back performance. Staff in bases reported that there was poor communication with senior management and we found there was a lack of clinical leadership for frontline staff.

TCN did not have strong governance arrangements and it was difficult to decipher a systematic approach to monitoring and improving clinical care. There was insufficient capacity to ensure good governance and the staff who were responsible for governance were either part-time in this role or had other significant responsibilities. Minutes of meetings often lacked detail and some were missing, which made it difficult to track the content of discussions and the type of decisions being made.

It was a matter of concern that TCN could not provide the minutes of meetings of its executive. Initially they stated that this was due to commercial confidentiality but their later position was that the minutes were not available as none had been taken.

Between 2005 and 2009 TCN experienced rapid growth, winning three more contracts and more than doubling the population they covered. The management and operational commitments required for such a significant growth in organisational size, combined with the demanding nature of the transition from the governance structure of a GP cooperative to the structure required of a large provider of NHS healthcare, put significant strain on capacity at TCN, particularly in the areas of middle management and clinical leadership.

We were concerned that TCN did not acknowledge that shortcomings in their internal systems may have contributed to the failure to prevent the incident in Cambridgeshire involving the death of Mr Gray. At our initial meeting, TCN provided some information that was incorrect, and omitted information that was clearly relevant to the investigation, particularly the previous two cases involving doctors from Europe who had given overdoses of diamorphine.

It was a serious concern to the CQC that despite two requests for any incident reports in relation to death of Mr Gray, TCN did not provide the one completed by the lead for clinical governance at the time. This report stated that it was the third time in a year that TCN had an overdose of diamorphine and that they had 'already identified that it presented a serious clinical risk to the unwary'. The report noted that many doctors from Germany had very little experience in palliative care and in the use of the drugs which were relevant in this area.

Surveys of TCN's performance

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

Overall conclusions about TCN

TCN failed on many fronts. It prioritised expansion over existing services, did not listen to staff or invest in governance, tolerated staffing situations that were potentially unsafe for patients or staff, and failed to recognise clinical failures and risk.

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

Primary care trusts (PCTs) are responsible for leading the NHS at a local level. If a 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 GPs, dentists, pharmacists, out-of-hours services and walk -in centres.

The five PCTs that commissioned services from TCN 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, NHS Worcestershire, was in the West Midlands. Four of them inherited significant financial deficits and needed to make savings. For some this meant either losing staff or not filling vacancies.

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

Procurement of contracts

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 the PCTs were advised that there would be a conflict of interest if local GPs were involved in the procurement process.

Although in retrospect PCTs told us they wished local GPs to be involved in providing the service, they did not take steps to ensure this happened, and the rates of pay offered by TCN acted as a disincentive to local GPs.

Contracts did not generally specify what type of clinician was required, nor how many should be on duty. Some of the PCTs did not consider it was their responsibility to monitor staffing levels routinely, providing the service met the national quality requirements.

Contract monitoring

It was a major concern to us that the staff in the PCTs with responsibility for routine monitoring of the contracts for out-of-hours did not understand TCN's reports on performance. These staff were not able to adequately explain the data or the basic activity figures, and they did not fully understand the national quality requirements (NQRs).

TCN reassured them 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

In a number of cases, the PCTs 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. The methodology used to calculate, and the precise nature of, the forecast figures presented to support the claim of an increase in activity levels were not clear.

Changes to services which could have significant implications were generally discussed and agreed by non-clinical staff with little or no clinical input from the PCTs. Some senior staff in PCTs were 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 national quality requirements.

In the PCTs there was generally little integration between staff in the quality department and those in routine contract monitoring. 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 considered that it was not necessary for them to monitor unfilled shifts and type of clinical staff on duty as long as the NQRs were being achieved. However, we established that PCT staff did not understand the way in which TCN reported compliance with the NQRs.

The 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. Even after that, there was little evidence that complaints or themes arising from them were routinely discussed, other than by NHS Great Yarmouth and Waveney. Similarly, PCTs did not identify that some concerns had surfaced through TCN's audits of clinical staff. None of the PCTs had robust established arrangements to share information on poorly performing clinicians.

The PCTs were not aware of serious incidents in the out-of-hours services they commissioned, except for NHS Great Yarmouth & Waveney which regularly discussed serious incidents in out-of-hours at its patient safety group and in NHS Cambridgeshire following the death of Mr Gray. NHS Suffolk did not report the second diamorphine incident as a serious incident, although it clearly should have been. It could not produce internal TCN investigation reports for two serious incidents that happened in out-of-hours in early 2009. NHS Worcestershire provided the initial reports but was unable to provide final investigation reports for any of the six serious incidents in out-of-hours.

Before the start of this investigation, the PCTs (other than NHS Cambridgeshire) had 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 had begun a programme of inspections of controlled drug procedures after the death of Mr Gray in 2008. NHS Great Yarmouth and Waveney had also visited all of TCN's bases in their area and inspected arrangements for controlled drugs. 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 PCT boards

Performance on out-of-hours services was not usually reported at board level, 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 exception was NHS Cambridgeshire following the death of Mr Gray. There was also evidence of discussion

of issues arising in out-of-hours at the board in NHS Great Yarmouth and Waveney. The board of NHS Worcestershire did not receive the findings of a critical external review of out-of-hours, and the report that went to the board in September 2009 focussed on the progress that had been made and gave little indication of the seriousness of the concerns expressed in the review.

The serious incident at TCN was reported to the majority of the PCT boards, although the non-executives in NHS South West Essex did not realise that part of their out-ofhours service was provided by the organisation involved in the death of Mr Gray until this was formally reported in October 2009.

The views of local GPs

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

In a survey we carried out, the percentage of GPs 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. This compares with the results in a similar survey of Devon GPs conducted in December 2006 by Devon doctors (where only 1% rated the service as poor or very poor).

Overall conclusions about the PCTs

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

Staff responsible for routinely monitoring contracts did not fully understand the activity data reported by TCN, or the national quality requirements, 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. The standard of commissioning and of contract monitoring in out-of-hours services did not provide reassurance that PCTs knew what they were receiving, 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 failure to commission appropriate out-of-hours services for the local population and monitor that these were being delivered.

By the end of 2009, there was evidence that all the PCTs were beginning to improve their commissioning and monitoring of out-of-hours services.

Strategic and performance management roles of the two SHAs

Strategic health authorities (SHAs) are the regional headquarters of the NHS and provide strategic leadership to all NHS organisations in their area. The two SHAs covering the areas served by TCN were NHS East of England and NHS West Midlands. Both were established in 2006.

Initial priorities at both SHAs reflected the national priorities of financial stability and achievement of national targets, and the performance of PCTs was managed against these national priorities. 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.

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. PCTs 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 potential for this to lead to fragmentation was not widely realised.

Neither SHA had a system to identify serious incidents in out-of hours services, which meant opportunities to identify risks had been missed. NHS East of England had identified concerns about TCN from serious incidents in late 2008, which influenced their decision to ask CQC to carry out an investigation. Both SHAs now have electronic systems to identify serious incidents in out-of-hours.

Since 2007 NHS East of England had supported a network for PCTs on urgent care which occasionally included issues in out-of-hours. In December 2009, NHS West Midlands established a primary care out-of-hours network. Both SHAs conducted baseline surveys of all PCTs in the autumn of 2009 and required action or improvement plans.

Overall, we conclude that initially there had been little strategic focus for out-of-hours services, particularly in the context of integrated urgent care. Recently, there has been more targeted activity at SHA level in respect of out-of-hours.

Administration of the performers lists by the PCTs

A GP must be on a performers list in order to treat patients. They can only be on one list for one PCT but, 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. Doctors must apply in writing to a PCT, including a range of information about their qualifications, registration and experience.

West Yorkshire NHS Central Services Agency had not automatically accepted Dr Ubani's application to join Leeds PCT performers list. This was because he achieved a lower score than needed on a language test, failed to supply evidence that he was going to work in the PCT area, and one of his references was not admissible. Dr Ubani withdrew his application before he was formally rejected and this meant that NHS Leeds was not required to alert the GMC to his application.

NHS Cornwall and Isles of Scilly, which accepted Dr Ubani on its performers list, did not require GPs from the EU to provide a certificate of competence in English or provide evidence that they intended to work locally. The only checking of his referees was to ascertain that they had written the reference.

After the death of Mr Gray in Cambridge, NHS Cornwall suspended Dr Ubani. However the PCT board did not at that time review the arrangements for approving doctors to join the list and the changes that were made were largely instigated by staff on the contracts team.

We found a range of different approaches to performers lists in the five PCTs. Some lists were administered by the PCT; others used an NHS support agency. Some required applicants to have a specific level of proficiency in English, others did not. The level of scrutiny of both applications and appraisals varied. Most of the PCTs checked annually that GPs had worked in their area. For those who checked, the doctor needed only to have worked one shift to satisfy their criteria.

Most of the 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 share concerns about clinical staff between out-of-hours and other services, or between PCTs.

The PCTs have all recently tightened their procedures and most have increased the level of clinician involvement in screening non-standard applications.

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, we did not find evidence to suggest that the PCTs were acting systematically to monitor care or 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.

Overall conclusions

Out-of-hours GP services are higher risk than the same services on weekdays. Clinical staff working out-of-hours often do not have local knowledge, treat patients they do not know and without access to the patients' notes, and work with unfamiliar colleagues in unfamiliar settings. Where the clinicians are tired, their first language is not English and they are not familiar with the NHS, then the pressures and risks are increased.

Out-of-hours services are an essential element of the urgent care service in a local area. Despite this, and although they cover more hours in total than 'in-hours', they have not until recently had a high priority. The tragic death of Mr Gray has played a large part in bringing these services to the fore.

The decision to relieve GPs of their responsibility for 24-hour care of their patients was a major change in policy. PCTs were given the responsibility to arrange out-of-hours

services. What we found in this investigation was that the PCTs involved did not know what they were buying. They had little understanding of out-of-hours and they did not scrutinise performance closely. The lack of transparency in the way TCN reported its activity did not help this. The PCTs did not understand or challenge what lay behind the pages of information on performance, or proposed changes to services such as call streaming.

TCN was dominated by an agenda of growth and focused on winning contracts, not on providing high quality care. It often had too few clinicians on duty. TCN did not have effective governance arrangements in place and failed to identify shortcomings and implement changes. In the case of Mr Gray, the failure to identify and mitigate the risks reduced the chance of averting the tragic outcome.

Recommendations

We focus on recommendations in those areas that were not part of the recent review by the Department of Health* or the coroner's recommendations.

Overall recommendation

1. Out-of-hours services present a high risk to both patients and staff. All parties involved in the provision and purchase of out-of-hours services need to ensure that there are sufficient suitably trained and experienced clinical staff, particularly doctors, engaged in planning and delivering these services.

Recommendations for those who commission out-of-hours services

- 2. Primary care trusts must consider out-of-hours services as a vital component of both primary care and of urgent care, and ensure they are procured and developed strategically, linking with other providers of these services.
- 3. Primary care trusts need to be aware of the risks in out-of-hours services and actively commission services to reduce these risks. In particular, they need to ensure adequate staffing by GPs.
- 4. We reiterate the recommendation from the interim statement that all PCTs should scrutinise out-of-hours services more closely and that staff responsible for monitoring out-of-hours contracts should be sufficiently senior and understand the information being reported by providers. There needs to be clarity on how and what activity is recorded.
- 5. PCTs should ensure that all serious incidents occurring in out-of-hours services are reported, thoroughly investigated and learning disseminated. Audits should be considered to identify under reporting.
- 6. PCTs need to seek and act on feedback from key stakeholders about out-of-hours services, and have clear governance structures in place for escalation of concerns.

^{*} Dr David Colin-Thomé and Professor Steve Field, *General Practice Out-of-Hours Services: Project to consider and assess current arrangements*, January 2010

- 7. PCTs must ensure that there is adequate support, including clinical support, for those administering the performers list so that only appropriately qualified, trained, experienced staff, with good English and knowledge of the NHS, can join and stay on the list.
- 8. PCTs must ensure an effective and timely two way flow of relevant information with out-of-hours services about poorly performing doctors, and appropriate action

Recommendations for those who provide out-of-hours services

- 9. Above all, providers of out-of-hours services need to have enough properly qualified, trained and experienced staff on duty, who have adequate support, can communicate effectively and are not working excessive hours. In particular there should be adequate GP coverage.
- 10. Providers of out-of-hours services need to have effective systems to record activity accurately and analyse data and performance.
- 11. Providers of out-of-hours services should have a robust governance system in place, including a clear hierarchy of committees and a high standard of minute taking, so that decisions and accountability are clearly recorded.
- 12. Providers of out-of-hours services must report all serious incidents, including those arising from complaints, and ensure these are thoroughly investigated, with analysis of underlying causes, high quality reports, and changes made at operational level.
- 13. Providers of out-of-hours services need to ensure that clinical audit is used to identify the quality of clinical performance, that feedback is timely, that poor performance is identified and dealt with, and that information is shared appropriately with the relevant PCT(s) and/or other authorities in a timely fashion.
- 14. Providers of out-of-hours services must have adequate advice and input from a pharmacist to ensure robust policies and procedures for the management of medicines, including controlled drugs.
- 15. Providers should audit their handling of calls in a routine and systematic way. Providers should conduct audits both of call handlers and clinicians using voice recordings as well as documented notes.
- 16. Providers of out-of-hours services need to have effective means to communicate with their frontline staff, particularly about clinical matters, and to listen to the views and concerns of staff.

Recommendations for SHAs

17. SHAs should ensure that their strategic frameworks, and their systems of performance management and support, reflect the pivotal role of out-of-hours services in the entire urgent care service in a local area, including ensuring learning from incidents in these services.