

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

Part 1:

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

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, 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. 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 By then, TCN had completely withdrawn 100mg ampoules of diamorphine, significantly reducing the chance of the original mistake being repeated.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 which 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. 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 this part, 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 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.

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Part 1: Main findings and conclusions

Findings

- Mr Gray was killed by an injection of 10 times the normal dose of diamorphine.
- The coroner determined he had been unlawfully killed. Dr Ubani was convicted of manslaughter in Germany and struck off the medical register in the UK.
- In the year before Mr Gray's death, there had been two incidents at TCN involving overdoses of diamorphine, both involving doctors flying in from Europe to work shifts in the out-of-hours services.

Conclusions

The previous incidents 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.

The death of David Gray and the coroner's inquest

The coroner's inquest

Due to the circumstances surrounding the death of David Gray in February 2008, an inquest was held by HM Coroner for North & East Cambridgeshire from 14 January to 4 February 2010.

The coroner determined that David Gray was unlawfully killed. He concluded that the cause was injection of 100mg diamorphine. This is about 10 times the normal therapeutic dose. The actions of Dr Ubani killed Mr Gray, although the coroner was satisfied that Dr Ubani did not mean to kill Mr Gray. The coroner stated that, as there was a duty of care, there was negligence. The coroner took into account Dr Ubani's lack of induction, his unfamiliarity with the area and his tiredness. This did not excuse his actions. Dr Ubani had the British National Formulary (a medical reference book that contains wide information on medicines), instructions and documents. He should not have administered the diamorphine if he was unsure and he could have sought advice.

Under Rule 43 of the Coroners Rules 1984, the coroner also made 11 recommendations that were to form part of a report to the Secretary of Health, and one recommendation each to NHS East of England and the Royal College of General Practitioners (see appendix G in the appendix document).

At the same time, the Department of Health published its review of out-of-hours services containing 24 recommendations. This is described in Part 2 of our report.

David Gray

David Gray was born in 1937 and at the time of his death was living with his partner, Linda Bubb. He suffered from renal colic and had a history of kidney stones, although none were found post mortem.

Mr Gray's GP tended to treat Mr Gray's pain with pethidine 100mg. Pethidine is a strong painkiller. Between 2006 and 2008 Mr Gray was treated on a number of occasions by the out-of-hours service. He received injections of pethidine and diamorphine and non-opiate analgesics. Mr Gray's doctor had not sent the out-of-hours service any special notes about Mr Gray's medication. At the inquest, he said this was because Mr Gray was a chronic patient.

On Saturday 16 February 2008, Mr Gray was in discomfort and he took some brandy. At lunchtime, when he asked his partner to call the out-of-hours service, it was suggested that he be taken to the community hospital in Ely. Ms Bubb could not do this due to her own reduced mobility and so a doctor was sent to their home.

Dr Ubani arrived in the afternoon. Ms Bubb described Dr Ubani as in good health but subsequently said that he said that he was tired and was not as alert as he should have been. Ms Bubb told Dr Ubani that, in these situations, Mr Gray received 100mg pethidine. This was confirmed by Mr Gray. She also told Dr Ubani that sometimes the out-of-hours service did not carry pethidine. The coroner had no doubt that it was the mention of the 100mg pethidine which led to Dr Ubani's grave error.

Ms Bubb did not see Dr Ubani examine Mr Gray. She says that Dr Ubani returned with the green palliative care box and she witnessed him looking at a card. She saw Dr Ubani administer the two injections, diamorphine and buscopan, a drug that relieves spasm of the urinary tract. Dr Ubani went downstairs to complete records and then left. He did not re-examine Mr Gray and left syringes on the window sill. The records indicate that 100mg diamorphine was administered intramuscularly at 16.45 hours.

Ms Bubb subsequently checked on Mr Gray and realised that something was wrong. She called the emergency services and two

paramedics arrived followed by a third. Death was pronounced at 18.36 hours. The cause of death was recorded as a) diamorphine poisoning b) hypertensive heart disease and myocardial fibrosis. The coroner concluded that Mr Gray died as a result of administration of 100mg diamorphine.

Dr Daniel Ubani

At the time Dr Ubani was aged 65 years. He went to school in Nigeria and attended universities in Russia and Germany. He registered with the General Medical Council (GMC) and went on the GP register and the specialist register in 2006.

In December 2006 Dr Ubani applied to join the medical performers list of Leeds PCT via the West Yorkshire NHS Central Services Agency. He supplied references and proof of GMC registration. However, West Yorkshire CSA required a score of seven on the International English Language Testing System (IELTS), and Dr Ubani scored only six.

He abandoned this application and in May 2007 made an application to join the Cornwall and Isle of Scilly performers list, producing the same documents as before. Cornwall and Isle of Scilly PCT did not at that time require doctors to pass the IELTS test and did not ask whether Dr Ubani had previously failed this. Cornwall accepted him onto their medical performers list in July 2007. Dr Ubani was then able to work for any PCT in England.

His services were engaged by an agency called Cimarron who supplied his services to TCN. TCN provided out-of-hours services to the East Cambridgeshire and Fenland area of NHS Cambridgeshire, as well as to three other PCTs. Cimarron engaged Dr Ubani for the weekend of 16-17 February and also 23-24 February 2008. He was to work from 8am to 7.59pm, a 12-hour day on each day, at a rate of £45 per hour. He was to pay for his own accommodation.

Dr Ubani flew from Germany and arrived in the UK on Friday 15 February 2008. He hired a car and travelled to the Cimarron offices at 2pm. He was met there by a company director of Cimarron. He did not have an induction but a

conversation was had about the key locations in the area. The company director said that he appeared fit and healthy. They gave him a copy of the Monthly Index of Medical Specialities (MIMS, a prescription medicine database and prescribing guide) and their personal satellite navigation system. He left about 4.30pm.

At 6pm Dr Ubani arrived at the offices in the Riverside clinic, the call centre and operational centre for TCN in Ipswich. He was seen by a support trainer from TCN, who provided a staff training support role. Dr Ubani received training on the HMS computer software system used by TCN but no clinical training. The support trainer said that he was not tired and she had no problems communicating with him. She also said that Dr Ubani took a lot of notes and, although these sessions usually last one and half hours, Dr Ubani's session lasted two hours.

The GP who was undertaking a shift that evening then gave Dr Ubani an induction session from 8pm to 9.50pm. He was a GP in practice and worked part time for TCN. He had been sent an email to ask him to induct Dr Ubani but was taken by surprise as he had not had a chance to read his emails. He also had a registrar shadowing him and his own out-of-hours duties to undertake. Although an experienced supervisor and trainer of GP registrars, he had not undertaken an induction before.

The GP had no problems communicating with Dr Ubani but was concerned about his lack of experience in the NHS and lack of knowledge of the local area. In the light of these he gave Dr Ubani his mobile number and advised he could contact the duty manager with any queries. He took Dr Ubani through the HMS software system and used the induction checklist to check the areas covered.

One area that was dealt with was the palliative care box. The GP on duty went through the documentation relating to the palliative care box. However, no actual box was produced at this session. Dr Ubani would not have seen the accompanying documentation or the vials. At that induction there was no discussion about the use of diamorphine or naloxone (a drug that counteracts the effects of diamorphine).

However he would have received an induction pack that should (according to the clinical governance lead) have included guidance to clinicians on prescribing diamorphine and stated that it was 'never appropriate to open 30mg of diamorphine unless it was to help set up a syringe driver'. It was noted at the inquest that the induction pack was not well organised and important documents were not highlighted.

The GP who had inducted Dr Ubani had to complete an induction report which was simply a checklist. On the report he wrote that he was not happy about being asked to assess a fellow practitioner without protected time and that the assessment was not enough to assess his competence. He noted he was also supervising a registrar and providing cover for two nurse practitioners. The form was submitted on 18 February 2008, after the death of Mr Gray. Dr Ubani's induction form had not been formally signed off before he undertook his first shift. The GP who inducted Dr Ubani said that the session was an induction only and there was no mentoring. It is unlikely that Dr Ubani left Riverside before 10pm. He travelled to his accommodation, arriving at 00.40 hours and had to start work in Newmarket at 8am that day.

The car provided by TCN had a lockable pilot bag containing diagnostic equipment, the silver box with medicines, the sealed palliative care box and the British National Formulary. Dr Ubani also had his copy of MIMS. The pilot bag itself contained injectable drugs but not controlled drugs, which were in the palliative care box. The palliative care box was sealed both by the manufacturers and TCN. Physically attached to the palliative care box was the list of medications it contained including cyclizine 1ml, diamorphine 10mg, diamorphine 100mg and other medication. Attached in the plastic coating was a palliative care order form for restocking. There was also a form with instructions for doctors on the palliative care box. After breaking the seals, inside the box was a blank prescription form and a document called opioid potency ratios, which listed the relative potencies of the controlled drugs. The vials or ampoules of drugs sat in recesses in a foam bed. There was one much larger vial of diamorphine inside the box at the top; this was the 100mg diamorphine.

On 17 February 2008, the lead for clinical governance at TCN got a call about 2.15pm from the senior duty manager at TCN. This alerted him to a potential problem in which a patient had died. The lead for clinical governance contacted Dr Ubani, stood him down and suggested that he go home.

The GMC referred the matter to their Interim Orders Panel and suspended Dr Ubani's registration on 29 February 2008. Cornwall and the Isles of Scilly PCT also suspended him from their medical performers list. The GMC formally struck Dr Ubani from the medical register in June 2010.

On 20 March 2009 the district court in Witten in Germany imposed a suspended prison sentence of nine months on Dr Ubani, for having caused death by negligence. Extradition to the UK was refused because he had already been through the judicial process in Germany. Dr Ubani declined to attend the inquest.

Concerns expressed by the coroner

The coroner considered the induction process Dr Ubani underwent to be insufficient and inadequate. He also considered that Dr Ubani would have been tired.

The coroner noted that the GP who was the lead for clinical governance at TCN sent an email on 15 January 2008 about the use of the palliative care boxes, because two previous overdoses of diamorphine had occurred. This was sent to the following staff at TCN: nurse consultant, operations development lead, the operations manager, and duty manager. It was copied to TCN's medical director and drugs coordinator, and the manager of the manufacturing unit at Ipswich hospital pharmacy.

The lead for clinical governance advised in the accompanying discussion paper that the dosages should be kept separate and there should be a different box for the provision of acute pain relief. He also proposed the introduction of a referee system, whereby the doctor could not open the box without permission from the duty manager at base.

These suggestions were not put in place prior to the incident.

After the incident the referee system was put in place the next working day and in due course the boxes for acute pain relief were introduced. However, the 100mg doses of diamorphine were not removed until September 2008, at the insistence of NHS Cambridgeshire.

Previous incidents involving overdoses of diamorphine

On 25 May 2006, the National Patient Safety Agency (NPSA) issued a safer practice notice because of a number of reports of deaths due to the administration of high dose (30mg or more) diamorphine or morphine injections. Organisations were asked to assess the risk of their procedures for the prescribing, labelling, supplying, storing, preparing and administering of diamorphine and morphine injections. This was to be complete by October 2006. The matter of whether TCN was aware of this notice is considered in Part 2 of our report.

The first overdose took place in Suffolk in April 2007. A call was received by TCN, triaged and it was decided that the patient needed a home visit. The triage notes recorded that the patient had been suffering severe back pain and had a history of this type of complaint. The patient had other medical conditions and was on medication. The TCN doctor, who trained and practised in Germany, attended the patient at home and entered the notes of the face-to-face consultation on the HMS system. The records show the doctor administered 30mg of diamorphine over ten minutes via an intravenous line. The patient was then referred by the doctor to West Suffolk A&E for management.

On arrival at the A&E department the patient required resuscitation and intravenous naloxone. Naloxone is a drug that counteracts the effects of diamorphine. The clinical governance lead for TCN received a verbal report from the East of England Ambulance service (EEAST) raising concerns about the treatment of this patient.

In the coroner's court TCN's lead for clinical governance said that TCN was only notified in writing of this incident a couple of months after it happened. The document from the ambulance service noted the A&E sister's confirmation that the patient should have received 2-5mg diamorphine, not the 30mg administered by the TCN doctor.

TCN acknowledged receipt of this incident from the ambulance service in July 2007. It

was recorded as an untoward incident on the TCN log. It was summarised as a query from the ambulance service regarding management of a patient. The outcome was recorded as 'passed to CGL' meaning to the clinical governance lead. No actions or analysis and outcome were included in the log.

The TCN clinical governance lead wrote to the doctor who had treated this patient, alerting them to the concerns raised by the ambulance crew and asking for clarification as to their actions regarding the patient in question. An assurance was given that this was not a formal complaint from a patient but a concern from the ambulance service.

The doctor who had given the diamorphine replied stating that if they were to use diamorphine again they would use a 10-15mg dose, and preferably subcutaneously. During the coroner's inquest in 2010, the lead for clinical governance stated that although he had written to the doctor personally, the doctor who had given the diamorphine had not accepted that the dose of diamorphine had caused the patient's respiratory collapse and the incident was not followed up any further.

After the second incident (see below) the clinical governance lead wrote to the manager of clinical field operations for the East of England Ambulance service apologising for the delay and informing them that he had written to all TCN clinicians about the use of opiates and recommending that they use lower doses of diamorphine in future.

The next overdose happened in August 2007 when a call was received by TCN and logged as 'routine'. The patient, who lived in Suffolk, was recorded as suffering from back pain and being unable to sleep. The call was designated as requiring a home visit. The TCN doctor who visited the patient trained and practised in Germany. They noted the patient was hyperventilating and in pain. The doctor administered 30mg diamorphine. The route of administration is disputed. It appears the injection was initially intravenous i.e. into a

vein but was finished as intramuscular i.e. into muscle.

A second call was received by TCN as the patient was struggling to breathe; the call was logged as 'urgent' and transferred to the ambulance service. East of England Ambulance staff arrived and found the patient unconscious and not breathing properly; the antidote naloxone was administered to the patient by the ambulance crew. The patient was taken to Ipswich Hospital. The East of England Ambulance Service called TCN about the medication that had been given. TCN recorded this as an untoward incident.

Correspondence between the clinician who treated the patient and TCN indicated that the clinician acknowledged their error in mistakenly administering more than the advised dosage of diamorphine. This was attributed to confusion about the relative strengths of morphine and diamorphine.

The TCN clinical governance lead sent a memo to TCN clinicians the same day, reminding them of safety matters when giving opiates by injection. The memo pointed out the different strengths of morphine and diamorphine, suggested that normally no more than 5mg of diamorphine should be given, that it should be administered subcutaneously and that it was hardly ever appropriate to open the 30mg ampoule of diamorphine. The exception would be to set up a syringe driver to administer pain relief to a terminally ill patient.

The lead for clinical governance said that this memo should have been in the induction pack and available to clinicians who joined TCN after August 2007. The PowerPoint presentation that subsequently became part of the induction process included most of the content of the memo. It warned about opiate strengths and mentioned that normally no more than 5mg of diamorphine administered subcutaneously should be used.

The clinical governance lead for TCN wrote to the patient concerned a week later to apologise for the error and explain the doctor's mistake. A week after that, the patient's sister raised a formal complaint with TCN. TCN subsequently 'upgraded' the incident to a complaint.

In subsequent correspondence with the PCT regarding the incident another matter came to light. An ampoule of oxycodone (another opioid pain killer) and the accompanying paperwork were missing from the palliative care box used to treat the patient. The paperwork and the ampoule were never found or accounted for, although TCN took statements from those involved.

The lead for clinical governance at TCN contacted the chief nurse and head of clinical quality at NHS Suffolk to discuss the second overdose in the context of possible re-training for the doctor. The incident was not reported to the SHA as a serious untoward incident by the PCT. In late September the chief nurse and head of clinical quality at NHS Suffolk wrote to the lead for clinical governance at TCN asking him to fully investigate and provide a report within 14 days.

In November 2007, in response to the request from the PCT, TCN provided a report on what it called 'the serious untoward incident', although it was never recorded as a serious untoward incident in the TCN internal system. The report stated that reminder notices were to be placed with palliative care boxes. However there is no evidence that this happened. The former TCN drugs co-ordinator told us that changes were not made to the documentation until after the death of Mr Gray in February the following year.

TCN stated in the report that the clinician involved in this incident received a period of mentoring following the incident arranged by TCN, at the request of the PCT.

In early December 2007, following the incidents in April and August, the lead for clinical governance at TCN raised the matter at the TCN clinical management group meeting. He was concerned that the two incidents had occurred under similar circumstances and the group should consider if it was indicative of an internal systemic problem. The group decided that it was not.

It was agreed and recorded in the minutes of the December meeting that extra documentation should be placed with the boxes. However, as noted above, there was no evidence that this happened.

The minutes of the governance meeting on 3 January 2008 recorded that the doctor who had mentored the doctor concerned, felt strongly “that there is a systematic problem inherent in the current set-up and that, if we do not address this, it is only a matter of time before a patient is killed by an overdose of morphine from one of our palliative care boxes”.

The proposed solution was to remove the palliative care boxes from the TCN cars and to issue them only on direction from the control centre, following approval from a second GP. It was felt by control centre staff that removing the boxes from the cars would pose an unacceptable burden on the service. They were willing to accept that a second GP should act as referee but with the boxes continuing to be available in the cars. The clinical governance lead was to draw up a proposal for this scheme, including the proposed acute pain boxes and present for discussion.

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

The proposal suggested the introduction of smaller ‘pain boxes’ to be used to treat acute pain and discourage the use of the palliative care boxes in these instances. The pain boxes were introduced in May 2008.

Following the death of Mr Gray on 16 February 2008, the referee system was introduced within 48 hours.

Findings of fact on incidents involving overdoses of diamorphine

- On 25 May 2006, the NPSA issued a safer practice notice relating to risks associated with higher doses of morphine and diamorphine, and the actions to be taken. TCN said that it had not been notified of this.
- There were two incidents within TCN involving overdoses of diamorphine in 2007. They both happened in Suffolk. Both involved doctors practising in Germany and flying in to undertake shifts for TCN.
- Neither incident was notified as a serious untoward incident by TCN.
- In Part 2 of our report, we note that the second incident was not notified to senior pharmacy staff at NHS Suffolk by TCN or the PCT.
- After the second incident, the GP lead for governance sent a memo to clinicians advising about the administration of opiates.
- Although the two incidents had certain key factors in common, the clinical governance group did not consider that there was a systemic problem.
- Although the clinical governance group agreed that extra documentation should be provided, there is no evidence that action was taken in respect of labelling the palliative care boxes.
- The clinical governance lead sent an email warning that the next incident could result in a death.
- The acute pain boxes were introduced in May 2008.