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

Appendices

July 2010

Appendix A: Care Quality Commission's criteria for investigation

Our functions include conducting investigations into the provision of NHS care, the provision of adult social services and the exercise of functions of strategic health authorities and special health authorities performing functions in respect of England. We are required to publish a report of any such investigation.

We will conduct an investigation where we become aware of specific concerns. An investigation involves obtaining evidence on, and developing an understanding of, the reasons for a serious failing in the provision of care. We can make recommendations to prevent the failing happening again. When conducting an investigation, we will take account of accepted standards and criteria or, in their absence, other statements of good practice (for example from professional bodies).

Triggers that might alert us to the potential need for an investigation include:

- Direct contact from service users, the public, staff or the media.
- Issues brought to light during our other regulatory activities.
- Requests from the Secretary of State for Health, or from other regulatory bodies.

We have a wide discretion as to the circumstances in which we will undertake an investigation in relation to NHS care or adult social services.

Generally, this will only be where we have credible information that suggests that there may have been, or there may be, a serious failing in the provision of care or the exercise of functions by a strategic health authority or special health authority*, that has, or may result in, a negative impact on the safety of service users, the effectiveness of the service, or responsiveness to people who use the service.

If a case does not feature such a serious failing, we will nevertheless consider whether an investigation should be started, having regard to the particular facts of the case.

- Factors which might trigger us to commence a formal investigation include:
- A higher number than anticipated of unexplained deaths.
- Serious injury or permanent harm, whether physical, psychological or emotional.
- Events which put at risk public confidence in the care provided, or in the NHS or adult social services more generally.
- A pattern of adverse effects or other evidence of high-risk activity.

- A pattern of failures in service(s), or team(s), or concerns about these.

- In line with multi-agency procedures, allegations of abuse, neglect or discrimination against service users, particularly those less able to speak for themselves or assert their rights.

* Where the authority is performing functions only or mainly in respect of England.

When we are deciding whether to investigate, we will consider the extent to which local resolution, referral to an alternative body, or other action might offer a more effective solution.

Generally, we will not investigate:

- Individual incidents that have not been pursued through the appropriate complaints procedure, unless it raises an immediate concern.

- Individual complaints about professional misconduct.

- Changes to service configurations (such as mergers).

- Employment or disciplinary matters.

- Matters being considered by legal process.

- Specific matters already determined by legal process.

This does not prevent us from investigating circumstances surrounding such matters. A matter that has been determined under one of the processes outlined above may raise general concerns about the safety of service users or suggest that organisational systems are flawed.

We will consider all allegations of serious failings, identify whether rapid action is required (for example, enforcement action to suspend the service for the protection of people who use services), and liaise with the body concerned and other bodies where necessary. It may be more appropriate in some cases for us to refer the matter to another agency, such as the police.

Appendix B: Terms of reference for the Take Care Now enquiry

The Care Quality Commission is to investigate out-of-hours services provided by an organisation called *Take Care Now (TCN)*, following a number of cases in which patients have suffered harm. *TCN* is an independent provider commissioned by several Primary Care NHS Trusts (PCTs) to supply doctors as general practitioners providing out-of-hours care.

The incident which triggered immediate concern was that of a patient, who was treated by a locum doctor and subsequently died following the administration of 100mg of diamorphine. This happened in February 2008. The doctor practised in Germany, and through a locum agency worked at *TCN* to cover some out of hour's shifts. He was admitted onto the performers list of Cornwall and the Isles of Scilly PCT, in July 2007, but did not work for the PCT. Subsequently, other Primary Care trusts identified further incidents involving *TCN.*

All of these incidents have been investigated by the Primary Care trusts and they and *TCN* state they have reviewed their processes and implemented changes where improvements were deemed necessary.

The Care Quality Commission has been asked to review the out-of-hours arrangements in relation to these specific cases and generally, in order to be assured that all lessons have been identified and appropriate action taken.

The Care Quality Commission's enquiries will encompass:

- An assessment of current systems including contractual and monitoring arrangements between Primary Care Trusts and *TCN,* including changes made after recent incidents*.*

- A retrospective 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

And will include a particular examination of:

a) management of calls and the response by TCN

b) staffing arrangements at TCN, to include recruitment, induction, supervision, training and how poor performance is identified and addressed

c) governance arrangements at TCN including the management of, and learning from : audits, complaints, incidents, near misses and serious untoward incidents

d) pharmacy arrangements in place at TCN including therapeutic protocols, medicine supply & storage, arrangements for controlled drugs, and pharmaceutical advice and support

e) commissioning arrangements, and performance management of these, particularly the governance and quality checks in place for monitoring the contract with TCN, including the National Quality Requirements for the delivery of Out of Hours Service. How PCTs identify and act upon patient safety incidents at TCN and mechanisms for lessons arising from incidents or complaints to be shared between commissioners and providers of out-of-hours services

f) the arrangements in Cornwall and Isles of Scilly PCT for their performers list and their responsibility as a holder of this list

g) any other matters that the Care Quality Commission considers arise out of, or are connected with, the matters above.

Additional Information

The investigation will be conducted by the Care Quality Commission under powers set out in the Health and Social Care Act 2008. The Care Quality Commission's purpose in investigating a care provider is to help it improve the quality of the care that it provides, build or restore public confidence in the service, and to help the organisation and the wider care sector to learn lessons about how best to ensure the safety of people who use services.

As part of the investigation, the Care Quality Commission will conduct face to face and telephone interviews with individuals both from within and outside TCN and primary care trusts who have information that is relevant to the issues listed above. Anyone with relevant information who is not able to participate in interviews may, subject to the agreement of the Care Quality Commission in any particular case, provide written submissions, statements or copies of relevant correspondence.

The Care Quality Commission will publish a report on the findings of the investigation, and will make recommendations as appropriate to TCN and other relevant bodies.

Where recommendations are made, the Care Quality Commission will assist all interested parties in the preparation of an action plan, in order to make any necessary improvements.

June 2009

Appendix C: The investigation team

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Appendix D: Interviews

The investigation team formally interviewed 158 current and former TCN, PCT and SHA staff.

The investigation team interviewed 52 stakeholders (members of the public, TCN and PCT staff who contacted us independently or members of external organisations associated with out-of-hours care). They were interviewed face to face or by telephone either as a result of contacting the investigation team or in response to an invitation from the investigation team. The following shows a breakdown of those interviewed and who contacted the CQC in writing:

Table 1: TCN staff and former TCN staff interviewed	
Chief executive and executives	3
Chairman, non-executive directors (including SDOC)	7
Heads of service	5
Clinical managers	7
Operational managers	9
Senior administrative / support staff	4
Frontline OOH staff	14
Total	**49**

Table 2: PCT staff and SHA staff interviewed	
NHS Cambridgeshire	18
NHS Great Yarmouth and Waveney	15
NHS South West Essex	23
NHS Suffolk	19
NHS Worcestershire	23
NHS Cornwall & Isles of Scilly	3
NHS East of England Strategic Health Authority	4
NHS West Midlands Strategic Health Authority	4
Total	**109**

Table 3: **Stakeholders interviewed or who contacted us in writing**	
Patients, relatives, carers and members of the public	25
West Midlands Ambulance Service	3
East of England Ambulance Service	2
Ipswich Hospital Pharmacy	4
Cambridgeshire Constabulary	2
GP locum agencies	3
Health Overview and Scrutiny Committees	4
Local Involvement Networks	2
Patient & Public Involvement Forums	1
Members of Parliament	2
External reviewers	4
Total	**52**

Appendix E: CQC update on enquiry into Take Care Now and out-of-hours services

Introduction
On 10 June 2009, CQC announced an enquiry into Take Care Now's (TCN's) provision of out-of-hours services. This is an update on progress following completion of the first phase of our work.

Background
The incident which triggered concern was a patient who was treated by a locum doctor. The patient was given 100mg of diamorphine, 10 times the normal recommended dose, and subsequently died. The doctor practised in Germany, and was engaged by TCN through a locum agency to cover some shifts out of hours in East Cambridge and Fenland. He was registered on the performers list of Cornwall and the Isles of Scilly PCT, in July 2007, but never worked in that area.

This incident happened in February 2008 and court proceedings in Germany relating to the incident were concluded on 15 April 2009. The doctor was given a nine-month suspended sentence for causing death by negligence in the UK. There will be an inquest in Cambridgeshire later this year or early in 2010.

The enquiry
The terms of reference for this enquiry are attached to this update. They include, in respect of TCN, an examination of its management of calls (that is, initial call handling and prioritisation, and subsequent decision-making about whether to advise patients on the phone, arrange a home visit or ask them to come in for treatment), as well as arrangements for governance, staffing and pharmacy. They also include an examination of the commissioning arrangements by the primary care trusts (PCTs) that use TCN to provide their out-of-hours services for their patients, and performance management of these – particularly the governance and quality checks in place for monitoring contracts with TCN.

This is a challenging enquiry because of the complex provision and commissioning of the out-of-hours services, the need to have an objective measure of the quality of the service, the fact that TCN provides all or part of the out-of-hours services to five PCTs, the range of stakeholders, and the number and geographical spread of the bases from which services are provided.

We obtained expert advice from within CQC and more widely and in the next phase may use additional external advisers as required. We recruited as external advisers to our team:

- A GP with extensive experience in out-of-hours services at operational and strategic levels.
- The operational manager of Devon Doctors – a not-for-profit organisation owned by GP practices across Devon who have been providing out-of-hours care since 1996, originally as a GP co-operative.
- A pharmacist with considerable experience in out-of-hours services.

- A PCT manager with extensive experience of commissioning out-of-hours services.

Progress so far
In the initial phase of the investigation, we requested documents and visited the five PCTs where TCN provides out-of-hours services. These are:

- Worcestershire
- Cambridgeshire
- Suffolk
- Great Yarmouth & Waveney
- South West Essex.

We obtained information to put the services into context, to compare the services and arrangements in the different areas and to scope further work. We interviewed PCT and TCN staff and visited some of TCN's facilities, including some visits at weekends when the services were busiest.

We have also sought the views of those who had used the service and other providers of urgent care. We will continue this in the autumn.

Observations
We note that TCN has completely withdrawn 100mg ampoules of diamorphine and that schedule 2 controlled drugs[1] are stored and dispensed more securely. Removing 100 mg ampoules of diamorphine has significantly reduced the chance of the original mistake being repeated.

We also observed that TCN at times has difficulty in filling shifts, particularly for doctors. This puts pressure on other staff and could affect the quality of the service.

We have asked TCN to ensure that patients with symptoms of stroke are transferred without delay to the 999 service.

Our other considerations at this stage are preliminary, as we still have work to undertake and complete. They include that:

- TCN needs to complete its work on its policy for managing medicines, as it includes some information that is currently too generic or not appropriate for out-of-hours. It should be tailored to the actual out-of-hours services that the organisation provides.
- The PCTs need to improve their routine monitoring of out-of-hours services. This means more detailed scrutiny of what is being provided, particularly the quality of the service that their patients receive.

Although some PCTs had taken some action in advance of this enquiry, we noted this last point for all of the PCTs involved, and we believe that this may be a lesson that needs to be learned nationally. We recommend that:

All PCTs should scrutinise out-of-hours services more closely. They should look in detail at the services that they commission, including the efficiency of call handling and triage, the number of unfilled shifts, the proportion of shifts covered by non-local doctors, the induction and training those doctors receive, and the quality of the decisions made by clinical staff.

The next phase of the enquiry

In the second phase, we will carry out further more detailed diagnostic work including:

- Visiting most of the remaining facilities from which TCN operates. Most of these will be unannounced or short notice visits.
- An audit of call handling, triaging and face-to-face assessment to establish the quality of interactions and decision-making.
- A survey of TCN staff to hear their views on induction, training, support, equipment and so on.
- Visiting key agencies who supply clinical staff to TCN.
- Continuing the examination of the original incident to establish whether all necessary lessons have been learned.
- Seeking the views of stakeholders, including other urgent care providers and local GPs in some areas.
- Closer scrutiny of arrangements for the managing medicines.
- Consideration of how doctors are admitted to performers' lists and arrangements to monitor and maintain these lists.
- Further scrutiny of arrangements to commission and monitor out-of-hours services.

We plan to publish our final report early in 2010. If there are other messages for TCN or the PCTs in the meantime, we will provide a further update.

Some terms used in this report

Commissioning: The buying of services on behalf of the people living in a particular area.
Governance: The system for administering an organisation or a specific process.
Locum: A doctor who stands in temporarily for a colleague who is absent or ill.
Out-of-hours services: Services provided outside core hours (most often 8.00am to 6.30pm, Monday to Friday, and weekends).
Triage: Sorting patients according to the seriousness of their illnesses or injuries, so that their treatment can be prioritised.

[1] Any doctor who wants to perform general or personal medical services for NHS patients must be on a performers list. The NHS (Performers Lists) Regulations provide a framework within which PCTs

can take action if a doctor's personal and/or professional conduct, competence or performance gives cause for concern.

[1] Schedule 2 controlled drugs include the opiate-based drugs used in acute and palliative care. They are subject to regulations determining their supply and storage.

Appendix F: Sources of information

- Observations during visits to TCN bases and call centres
- Interviews with TCN staff
- Interviews with PCT staff
- Interviews with SHA staff
- Interviews with members of the public
- Minutes of meetings at TCN, including
    - TCN Board
    - SDOC Board
    - Executive Committee
    - Remuneration Committee
    - Audit Committee
    - Clinical Management / Governance Group
    - Clinical Staff Development Group
    - Business Performance Group
    - Clinical Excellence meeting
    - Operational Metrics meeting
    - Evidence Based Practice Group
- TCN induction and training documentation and records
- TCN clinical pathways and guidelines
- TCN internal memos, alerts and bulletins
- TCN complaints and incidents records
- TCN records of disciplinary actions against staff
- Minutes of PCT meetings including
    - PCT Boards
    - Contract Monitoring meetings
    - Professional / Clinical Executive Committees
    - Local Medical Committees
    - Urgent Care Networks
    - Monthly Business meetings
    - Clinical Engagement meetings
    - Healthcare Governance meetings
    - Langdale meetings
    - Joint Directorate meetings
    - Patient Safety and Clinical Quality Groups
- Correspondence with and between TCN & PCTs

- TCN Documents including structure charts, governance strategies and briefing documents, policies and procedures
- CQC survey of TCN staff
- CQC survey of GP practices
- CQC audit of call handling
- CQC audit of telephone triage
- TCN performance reports
- TCN statements
- PCT Contracts and service specifications
- TCN shift rotas and reports
- TCN call centre statistics
- Minutes of meetings of East of England and West Midlands SHAs
- Interviews with senior staff at East of England and West Midlands SHAs
- Documents and correspondence provided by East of England and West Midlands SHAs
- Interviews with organisations in the health community, including: -

    - local involvement networks,
    - patient and public involvement forums,
    - health overview and scrutiny committees
    - Ipswich Hospital pharmacy

- Interviews and correspondence with members of parliament
- Interviews and correspondence with Cambridgeshire Constabulary
- Information on relevant incidents (including reports of serious untoward incidents)
- Reports of external governance reviews
- TCN standard operating procedures
- TCN staff rotas
- Manual and protocols for call handlers
- Controlled drugs regulations
- Reports by the Audit Commission
- Out-of-hours audit toolkit, Royal College of General Practitioners (RCGP)
- Information from the Primary Care Foundation (PCF)
- Information from Cambridgeshire Coroners Office

- Patient Public Involvement Forum and Local Involvement networks for Suffolk West, Worcestershire and Cambridgeshire
- Evidence presented at the coroner's inquest
- Report of the Independent Review of Out-of-Hours care (the 'Carson review')
- National Quality Requirements and commentary
- Minutes of HMS user group

Appendix G: Coroner's recommendations, made under Rule 43 of the Coroners Rules 1984

Recommendations to the Secretary of State:

1) Having regard to specific training in medical practice and the variation in status of general medical practitioners across member states of the EU, that he undertake a review of the Council Directive 93/16/EEC, within the United Kingdom.

2) Guidance be given to all PCTs reminding them that all PCTs must be satisfied under regulation 6 (2) (b) of the National Health Service (Performers List) Regulations 2004 ("Performers List Regulations") that each PCT must be satisfied that performers have sufficient knowledge of English to be able to work as a doctor.

3) Guidance must be given to all PCTs that in assessing applications to join performers' lists, they must be able to demonstrate that they have applied regulation 6 of the Performers List Regulations robustly and that they have an appropriately qualified person responsible for ensuring this is done in each PCT.

4) Steps be taken to ensure that each PCT follows nationally drawn up protocol (to avoid variation in standards) before deciding to admit a practitioner to a performers list.

5) That steps be taken to remind PCTs that it is a mandatory requirement under Regulation 6 (2) (a) that the PCT concerned must be satisfied that performers intend to deliver services in its area.

6) That guidance be given to all PCTs recommending that PCTs should, when considering an applicant's suitability to join the Performers List, consider whether he has failed to progress other applications by him to other PCTs and whether any such other applications have been turned down.

7) That guidance be given to all PCTs requiring risk assessment in respect of every non-UK based doctor in out of hours care such risk assessment to include assessment of a) the doctors degree of experience working in the NHS, and b) whether the doctor gained accreditation to do general practice in his home state under any acquired rights system, rather than by examination or accreditation.

8) That guidance be given to PCTs ensuring that quality assurance in recruitment should be the responsibility of the relevant out of hours provider and should not be delegated to commercial agencies who provide doctors.

9) That guidance to ensure all PCTs have written contracts with their out of hours provider, containing detailed requirements concerning standards to be observed by out of hours providers in the recruitment, training and induction of staff for out of hours work, and that such contracts have robust clinical governance and risk management structures in place.

10) That guidance to ensure that all contracts between PCTs and their out of hours providers are regularly and robustly monitored to ensure quality service standards.

11) That the department of health institute a national database of doctors from abroad who apply for inclusion on any performers list, such database to hold information on language skills, levels of medical competence (including qualifications and appointments), criminal record checks and records of any malpractice, and whether any doctor has been registered by, or had withdrawn his application to any PCT.

Recommendation to NHS East of England:

1) That the SHA recommends to all out of hours providers that no doctor should undertake out of hours work unsupervised, unless he has been through a proper induction with a clinician employed by the same out of hours provider who has been suitably trained in undertaking inductions.

Recommendation to the Royal College of General Practitioners:

1) Inviting the RCGP to draw up a national training and assessment programme for doctors, qualified abroad, who have never worked in general practice in the United Kingdom.

Appendix H: National Quality Requirements for out-of-hours (OOH) services

1. Providers[2] must report regularly to PCTs on their compliance with the Quality Requirements.

2. Providers must send details of all OOH consultations (including appropriate clinical information) to the practice where the patient is registered by 8.00 a.m. the next working day. Where more than one organisation is involved in the provision of OOH services, there must be clearly agreed responsibilities in respect of the transmission of patient data.

3. Providers must have systems in place to support and encourage the regular exchange of up-to-date and comprehensive information (including, where appropriate, an anticipatory care plan) between all those who may be providing care to patients with predefined needs (including, for example, patients with terminal illness).

4. Providers must regularly audit a random sample of patient contacts and appropriate action will be taken on the results of those audits. Regular reports of these audits will be made available to the contracting PCT.
   The sample must be defined in such a way that it will provide sufficient data to review the clinical performance of each individual working within the service. This audit must be led by a clinician with suitable experience in providing OOH care and, where appropriate, results will be shared with the multi-disciplinary team that delivers the service.
   Providers must cooperate fully with PCTs in ensuring that these audits include clinical consultations for those patients whose episode of care involved more than one provider organisation.

5. Providers must regularly audit a random sample of patients' experiences of the service (for example 1% per quarter) and appropriate action must be taken on the results of those audits. Regular reports of these audits must be made available to the contracting PCT.
   Providers must cooperate fully with PCTs in ensuring that these audits include the experiences of patients whose episode of care involved more than one provider organisation.

6. Providers must operate a complaints procedure that is consistent with the principles of the NHS complaints procedure. They will report anonymised details of each complaint, and the manner in which it has been dealt with, to the contracting PCT. All complaints must be audited in relation to individual staff so that, where necessary, appropriate action can be taken.

7. Providers must demonstrate their ability to match their capacity to meet predictable fluctuations in demand for their contracted service, especially at periods of peak demand, such as Saturday and Sunday mornings, and the third day of a Bank Holiday weekend. They must also have robust contingency policies

[2] A provider is any organisation providing OOH services under GMS, PMS, APMS or PCTMS

for those circumstances in which they may be unable to meet unexpected demand.

8. **Initial Telephone Call:**

Engaged and abandoned calls:

- No more than 0.1% of calls engaged
- No more than 5% calls abandoned.

Time taken for the call to be answered by a person:

- All calls must be answered within 60 seconds of the end of the introductory message which should normally be no more than 30 seconds long.
- Where there is no introductory message, all calls must be answered within 30 seconds.

9. **Telephone Clinical Assessment**

Identification of immediate life threatening conditions

Providers must have a robust system for identifying all immediate life threatening conditions and, once identified, those calls must be passed to the ambulance service within 3 minutes.

Definitive Clinical Assessment

Providers that can demonstrate that they have a clinically safe and effective system for prioritising calls, must meet the following standards:

- Start definitive clinical assessment for urgent calls within 20 minutes of the call being answered by a person
- Start definitive clinical assessment for all other calls within 60 minutes of the call being answered by a person

Providers that do not have such a system, must start definitive clinical assessment for all calls within 20 minutes of the call being answered by a person.

Outcome

At the end of the assessment, the patient must be clear of the outcome, including (where appropriate) the timescale within which further action will be taken and the location of any face-to-face consultation.

10. **Face to Face Clinical Assessment**

Identification of immediate life threatening conditions

Providers must have a robust system for identifying all immediate life threatening conditions and, once identified, those patients must be passed to the most appropriate acute response (including the ambulance service) within 3 minutes.

Definitive Clinical Assessment

Providers that can demonstrate that they have a clinically safe and effective system for prioritising patients, must meet the following standards:

- Start definitive clinical assessment for patients with urgent needs within 20 minutes of the patient arriving in the centre
- Start definitive clinical assessment for all other patients within 60 minutes of the patient arriving in the centre

Providers that do not have such a system, must start definitive clinical assessment for all patients within 20 minutes of the patients arriving in the centre.

Outcome

At the end of the assessment, the patient must be clear of the outcome, including (where appropriate) the timescale within which further action will be taken and the location of any face-to-face consultation.

11. Providers must ensure that patients are treated by the clinician best equipped to meet their needs, (especially at periods of peak demand such as Saturday mornings), in the most appropriate location. Where it is clinically appropriate, patients must be able to have a face-to-face consultation with a GP, including where necessary, at the patient's place of residence.

12. **Face-to-face consultations** (whether in a centre or in the patient's place of residence) must be started within the following timescales, after the definitive clinical assessment has been completed:

    - Emergency: Within 1 hour
    - Urgent: Within 2 hours
    - Less urgent: Within 6 hours

13. Patients unable to communicate effectively in English will be provided with an interpretation service within 15 minutes of initial contact. Providers must also make appropriate provision for patients with impaired hearing or impaired sight.