

**The Report of the Panel Overseeing the
Serious Untoward Incident Investigation into
the Death of Penny Campbell**

18 May 2007

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Panel members were drawn from the healthcare organisations involved in Penny Campbell's care. These were the local GP out of hours service (Camidoc) and the four primary care trusts (PCTs) who commission this service: Camden, City & Hackney, Haringey and Islington. The investigation was conducted by independent experts with no links to these organisations.

Members of the panel	
Pam Constantinides	Non Executive Director, Haringey Teaching PCT (Lay Chair)
Dr Lesley Mountford	Acting Director of Public Health, City & Hackney Teaching PCT
Dr Peter Reader	Medical Director, Islington PCT
Tony Hoolaghan	Locality Director, Islington PCT
Graham MacDougall	Head of Primary Care, Camden PCT
Trish Galloway	Head of Primary Care Practitioner Performance, Enfield PCT and Haringey Teaching PCT
Dr Ivor Robinson	Retired GP and Chairman of Camidoc
Dr Jonathan Sheldon	Camden GP and Camidoc Medical Board
Dr Nick Brand	Islington GP and Chair of Camidoc Clinical Governance Group
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"On behalf of the organisations that bear a public duty to protect and promote the health of the local population, the members of the panel overseeing this investigation wish to express their deepest regret and sympathy to Penny Campbell's family for her untimely death. Penny's death is a tragedy that a public health service must respect and respond to in the fullest possible way."

Contents

- Executive summary 2
- 1. Introduction..... 3
- 2. The events prior to Penny Campbell's death 4
- 3. The response of local health services 4
- 4. Terms of reference for the investigation..... 5
- 5. Key findings of the panel 7
- 6. Key recommendations of the panel 11
- 7. Glossary 14
- Appendix: The Independent Investigators' Report 15

Executive summary

This report presents the findings from a Serious Untoward Incident investigation into the death of Penny Campbell on 29th March 2005. Her death followed complications from a routine surgical procedure carried out six days earlier at the London Independent Hospital. Over the four days of the 2005 Easter bank holiday weekend, as she felt increasingly unwell, Penny Campbell made an initial contact with the consultant surgeon who carried out the procedure, and subsequently with eight doctors working with Camidoc, the local GP out of hours service. None of the doctors identified the septicaemia that led to her death.

A coroner's inquest in October 2006 concluded that Penny Campbell died as the result of an accidental adverse healthcare event to which the non-recognition of the seriousness of her condition contributed.

This investigation has been overseen by a panel with membership from Camidoc and the four PCTs that commission the out of hours service. The investigation itself was conducted by independent professionals with no links to these organisations. Its aim was to investigate the events leading up to Penny Campbell's death and to make recommendations that will help to reduce the possibility of a similar incident occurring in the future. The investigation focused on the out of hours GP service and did not consider the care provided at either the London Independent Hospital or the Royal London Hospital where she died.

The independent investigators found that the failure of the out of hours doctors to recognise the seriousness of her condition was partly due to practical problems involved in getting hold of notes from her previous consultations. Although Camidoc had begun to implement a fully computerised system for note-taking, the risks inherent in the paper-based system had not been adequately assessed. They concluded that Camidoc's failure to address these risks, together with its failure to undertake an immediate formal review following Penny Campbell's death, is indicative of weaknesses in the organisation's systems for monitoring clinical performance and improving the quality of their service.

These failings should be seen against the context of changes to the GP contract in 2004 which included a crucial shift in responsibility for out of hours care from individual GPs to PCTs. Camidoc's roots as a small GP co-operative meant that it was not fully prepared for its rapid transformation into a major provider of out of hours care.

Camidoc and the four PCTs which commission their services are committed to learning from the serious issues raised by this case. This report recommends that:

- **Camidoc** should improve its organisational governance and clinical leadership and ensure that it has appropriate systems in place to monitor and improve the quality and safety of its services. It should put clear protocols in place for responding to untoward events.
- The **doctors** involved should reflect on this case and consider its implications for every aspect of their personal clinical practice.
- The **primary care trusts** should recognise the importance of the out of hours service and develop action plans to fully respond to the findings of this investigation. They should ensure that any questions about the practice of individual GPs are addressed through their established mechanisms for maintaining the quality and safety of patient care.
- All **out of hours providers and commissioners** should consider the implications of this case for their own organisations.
- The **Department of Health** should clarify national expectations of the role and performance of out of hours care services.

1. Introduction

On 29th March 2005 Penny Campbell died from multi-organ failure due to septicaemia, six days after a routine surgical procedure conducted at the London Independent Hospital. Over the long Easter weekend prior to her death, Penny repeatedly contacted the local out of hours GP service as her health deteriorated. Her partner, son, family and friends now live with her loss and want to know what went wrong.

On behalf of the organisations that bear a public duty to protect and promote the health of the local population, the members of the panel overseeing this investigation wish to express their deepest regret and sympathy to Penny Campbell's family for her untimely death. Penny's death is a tragedy that a public health service must respect and respond to in the fullest possible way.

The membership of this panel has a lay chair and includes professionals from the healthcare organisations involved in Penny's care between her discharge from the London Independent Hospital and her admission to the Royal London Hospital. The organisations represented on the panel will now act on the findings of the investigation. The investigation itself was conducted by independent experts with no links to these organisations.

A serious untoward incident investigation is an established investigative method within the NHS. The purpose of such an investigation is not to apportion blame or identify liability but to understand better what went wrong in a particular incident and to identify ways of remedying problems for the future.

This report describes the panel's response to the investigation and sets out recommendations for change. The investigators' report is included in full as an appendix. As the focus of the investigation was limited to the care Penny Campbell received from the out of hours GP service, this report does not address her experience with the London Independent Hospital or the Royal London Hospital, where she died.

This report is the end of one journey and the beginning of another. The new journey is of learning and change, a process that reaches from the details of how the local service is run to questions of national policy and practice. This report is recommended to everyone involved in the commissioning and delivery of health services, at every level.

*Members of the Panel Overseeing the
Serious Untoward Incident Investigation into the Death of Penny Campbell*

May 2007

2. The events prior to Penny Campbell's death

Penny Campbell was a 41 year old journalist who lived with her partner and young son in Islington. On Wednesday 23rd March 2005, two days before the Easter weekend, Penny Campbell visited the London Independent Hospital for a routine surgical procedure.

Two days later, on Good Friday, Penny Campbell contacted the consultant surgeon who had carried out the procedure, complaining of feeling unwell. The surgeon told her that her symptoms were unlikely to be related to the earlier procedure but that if they persisted she should contact her GP as she, the surgeon, would be unavailable over the Easter weekend.

Later that day Penny Campbell contacted Camidoc, the out of hours service for her GP practice. She discussed her symptoms with a doctor who invited her to attend a Camidoc clinic. Following this assessment, Penny Campbell continued to manage her symptoms at home but contacted Camidoc on each day of the Easter bank holiday. In total she had contact with eight different Camidoc GPs, including a face-to-face assessment at the Camidoc clinic and one assessment at her home. None of the Camidoc GPs identified the signs or symptoms that would have suggested a diagnosis of septicaemia, a very uncommon complication of this procedure that few GPs would expect to see in their lifetime.

During a telephone consultation with a Camidoc GP on the morning of Easter Monday, Penny Campbell decided to go to the Accident & Emergency department at the Royal London Hospital. She was lucid on arrival but by mid afternoon her condition had deteriorated and, with her consent, she was moved to the intensive care unit. Penny Campbell died at approximately 7.00am the following morning.

The cause of death was recorded as multi organ failure following septicaemia from a perirectal abscess due to a haemorrhoid injection. Following an inquest on 6th October 2006, the coroner recorded that Penny Campbell died as the result of an accidental adverse healthcare event to which the non-recognition of the seriousness of her condition contributed.

The coroner's verdict is accepted in full by the members of the panel.

3. The response of local health services

A death in such circumstances ought to have triggered an immediate investigation within Camidoc. It is a matter of great regret that this did not happen and that Camidoc decided that they should wait until after the coroner's inquest before pursuing their own investigation.

A range of local organisations and individuals were involved, directly or indirectly, in the care of Penny Campbell. These were the London Independent Hospital, Camidoc and its GPs, the four primary care trusts that commission the service and the Royal London Hospital. This report focuses on the role played by Camidoc, its GPs and the primary care trusts.

Primary care trusts are the local NHS organisations responsible for securing an appropriate range of health services to meet the needs of their population. In London most PCTs are coterminous with boroughs. PCTs can provide services themselves but they also commission services from other organisations, predominantly NHS trusts such as hospitals but also independent organisations.

Camidoc is an independent not-for-profit organisation that provides a GP service when GP surgeries are closed (an out of hours service). Camidoc is commissioned by four PCTs to provide an out of hours service to local people in their catchment areas: Islington, Camden,

Haringey and City & Hackney. Most of Camidoc's consultations take place over the phone but Camidoc also runs its own out of hours clinics and offers home visits.

Camidoc was originally established in 1996 as a GP co-operative providing urgent care during the out of hours period. At this time GPs bore 24 hour responsibility for their patients but since the end of 2004 GPs have been able to opt out of this responsibility, with the responsibility for ensuring the provision of out of hours care falling on PCTs. The four PCTs have sought to meet this challenge by commissioning the service from Camidoc. Camidoc does not employ the GPs that provide its services. The GPs are registered on approved Primary Medical Performers Lists held by the PCTs and provide services for Camidoc on a sessional basis.

The response of local services to Penny Campbell's death should be seen against this background of nationally negotiated changes to the GP contract and the demands these changes placed on local organisations. This neither excuses nor explains events but provides additional context for understanding why mistakes were made.

In November 2006, following the coroner's verdict, the PCTs and Camidoc convened a multi-disciplinary panel to oversee an investigation into the events leading up to Penny Campbell's death, now designated a 'serious untoward incident' (SUI). Investigations into SUIs are a common means within the NHS of learning from mistakes and minimising the risk of their reoccurrence. The membership of this panel is made up of key individuals from within the affected organisations, people who must ensure that practical action follows from the findings of the investigation.

In consultation with Penny Campbell's partner, the panel developed the terms of reference for their investigation. These terms of reference defined a range of questions in order that local health organisations and the NHS as a whole might draw lessons from the event. The panel recruited independent investigators with no links to Camidoc or the commissioning PCTs to conduct the investigation.

The organisations that participated in the investigation sought to engage with the investigators in a spirit of openness and with a determination to ensure that the risk of such an event happening again is significantly reduced.

4. Terms of reference for the investigation

The following are the terms of reference for the investigation agreed by Camidoc and the four primary care trusts that commission the out of hours service. They were developed in consultation with Penny Campbell's partner. Although these terms of reference are broad, they remain focussed on the events within the out of hours service prior to Penny Campbell's death and the subsequent response of local services. The investigation should not be seen as a general appraisal of the organisations or individuals involved.

Aim of the investigation

To investigate the events surrounding the unexpected death of Penny Campbell on 29th March 2005 and to make any recommendations that will help to reduce the possibility of a similar incident occurring in the future.

The clinical investigation panel should address the following issues:

1. The clinical care received by Penny Campbell

- a. What was the sequence of events from the surgical intervention at the London Independent Hospital to the death of Penny Campbell?
- b. Was the clinical care offered by each of the 8 Camidoc GPs who treated Penny Campbell over the Easter Bank Holiday 2005 of a reasonable standard?
- c. What access did Camidoc GPs have to information or notes of any previous consultations, including the earlier surgical intervention?
- d. Was access to information or previous notes a significant factor in the clinical decision-making process and if so how much did it impact upon the clinical diagnosis and therefore the final outcome?

2. The systems in place at Camidoc over Easter 2005

- a. What was the system for recording, storing retrieving and accessing clinical notes?
- b. Were all staff and clinicians trained and familiar with the use of the system?
- c. Were the systems for ensuring Clinical Governance at Camidoc fit for purpose?
- d. Was Camidoc adequately staffed over the Bank Holiday weekend?
- e. Were the systems in operation over Easter 2005 significantly different to the systems that usually operated at Camidoc?

3. Investigation reporting and responses following the death of Penny Campbell

- a. How did Camidoc become aware of the death of Penny Campbell?
- b. What actions were taken as a result of this information, including reports to other agencies such as the commissioning PCTs or the NPSA?
- c. Were the arrangements for reporting serious incidents and serious concerns over clinical performance clear and adhered to?
- d. What were Camidoc's contractual obligations in relation to reporting sudden or unexpected deaths to its PCT commissioners, and did this take place in relation to Penny Campbell?
- e. How appropriate were the actions taken by Camidoc following the death of Penny Campbell?
- f. What is the system for monitoring sudden or unexpected deaths in Camidoc?

4. The systems in place at the PCTs over Easter 2005

- a. Were the commissioning, performance monitoring and working relationship between the 4 PCTs and Camidoc appropriate and effective?
- b. How appropriate were the actions taken by PCTs following the death of Penny Campbell?

5. The systems currently in place at Camidoc

- a. What access do clinicians working at Camidoc have to the notes of previous patient consultations?
- b. What training do clinicians have on the use of this system and what support is available to them; including telephone work with patients?
- c. Are there a minimum number of shifts required to ensure a safe working knowledge of the clinical and other systems?
- d. Are the systems for ensuring Clinical Governance e.g. identification and review of incidents when they occur, at Camidoc fit for purpose?

5. Key findings of the panel

The following findings should be read in conjunction with the recommendations set out in the next section. The recommendations define the actions required of local services to address the issues identified here.

The detailed findings of the investigators and the context in which they reached their conclusions are cited in their report in the appendix.

	The investigators' view (summarised)	The panel's comments
1.	The clinical care received by Penny Campbell	
1.1	Of the eight Camidoc doctors whom Penny Campbell consulted, six provided a reasonable standard of care. One did not provide a reasonable standard of care. One provided a standard of care which cannot be adequately assessed in retrospect.	The panel agrees with the investigators' view. The panel notes that, for each doctor, these judgements relate only to the care received by Penny Campbell.
1.2	The doctors did not have easy access to the notes of previous consultations. The failure to ensure that notes were available was a major system failure and a direct factor leading to Penny Campbell's death.	The panel agrees that the lack of easy access to notes was a contributing factor in the failure to diagnose the seriousness of Penny Campbell's condition.
2.	The systems in place at Camidoc over Easter 2005	
2.1	The system for recording clinical notes was known by Camidoc to be unwieldy and unpopular with clinicians. However Camidoc had already initiated a transfer to computerized records. The speed of this transfer was constrained by the supplier of the system.	The panel agrees that there were limitations in the computer system, despite it being the best available, and that Camidoc did not do enough to overcome these limitations.
2.2	Staff and clinicians were familiar with the systems in operation at Camidoc at Easter 2005. However Camidoc did not have systems in place to assess the risks of the paper-based method for recording clinical notes.	The panel agrees with the investigators' view.
2.3	The systems for ensuring clinical governance at Camidoc were not fit for purpose.	The panel agrees with the investigators' view in relation to some areas of Camidoc's practice at the time.
2.4	Camidoc was adequately staffed over the bank holiday weekend.	The panel agrees with the investigators' view.

3. Investigation reporting and responses following the death of Penny Campbell		
3.1	The arrangements for reporting serious untoward incidents within Camidoc, and for informing a PCT about them, were not clear.	The panel agrees with the investigators' view.
3.2	The actions taken by Camidoc following the death of Penny Campbell were made in good faith. However there was a lack of established process within the organization for responding to adverse events.	The panel agrees with the investigators' view.
3.3	The doctors involved in the case were poorly supported by Camidoc prior to the coroner's inquest.	The panel agrees with the investigators' view.
3.4	There is no formal system for monitoring deaths in Camidoc. This is consistent with primary care services in general.	The panel agrees with the investigators' view.
4. The systems in place at the PCTs over Easter 2005		
4.1	There was a system in place for the PCTs to monitor the performance of Camidoc. However the basis for this monitoring did not provide the detail necessary for the clinical oversight of Camidoc's work.	The panel agrees with the investigators' view.
4.2	The PCTs were not immediately aware of the death of Penny Campbell and the commissioners for the out of hours service were informed belatedly.	The panel agrees with the investigators' view.
4.3	The Islington PCT commissioner for the out of hours service should have obtained clear assurance from Camidoc that an internal investigation was taking place.	The panel agrees with the investigators' view.
4.4	The actions of the Islington PCT were not completely appropriate. They were limited by lack of clarity about the role of the coroner and the approach Camidoc was taking to internal investigation.	The panel agrees with the investigators' view.
5. The systems currently in place at Camidoc		
5.1	There is little overt clinical leadership of performance management within Camidoc.	The panel agrees with the investigators' view.
5.2	Details of previous patient consultations are now available to Camidoc doctors on the computer system. Doctors can also give patients appointments to be seen at one of the Camidoc clinics. All clinicians are trained in the use of the computer software.	The panel agrees with the investigators' view.

5.3	There is no minimum number of Camidoc shifts that GPs need to work to maintain competence. Few out of hours providers have a policy on this.	The panel agrees with the investigators' view.
5.4	The registration of a doctor on a PCT's Primary Medical Performers List is assumed to be an adequate qualification for a doctor to provide an out of hours service. Camidoc does not assess the skills of the doctors prior to them starting work for the organisation.	The panel agrees with the investigators' view.
5.5	Camidoc's approach to clinical governance has not taken proper account of the changed role of the organisation since GPs gave up their 24-hour responsibility for patient care. Clinical governance within Camidoc is not yet appropriate for the scale of the service it provides.	The panel agrees with the investigators' view.
5.6	Camidoc's serious untoward incident guidance lacks clarity in its definitions and methodology.	The panel agrees with the investigators' view.
5.7	Camidoc have introduced a system of clinical co-ordinators and have produced guidance on call prioritisation.	The panel agrees with the investigators' view.
6.	General findings	
6.1	Camidoc's rapid transition from being a GP co-operative to a healthcare organisation with a multiplicity of services has not been followed through with the development of effective and appropriate systems and processes.	The panel agrees with the investigators' view.
6.2	Camidoc is in effect the employer of the doctors who provide services to it yet it does not carry out any of the functions which might be expected of an employer such as clinical appraisal or clinical referencing. It relies on the fact that GPs are on a Primary Medical Performers List.	The panel agrees with the investigators' view.
6.3	If a GP is registered on a Primary Medical Performers List of a PCT that does not commission Camidoc, Camidoc would not necessarily be informed if this doctor was suspended from the list. This is a weakness of the Medical Performers List system in general.	The panel agrees with the investigators' view.
6.4	Camidoc can no longer rely on the informal systems of a small organisation, especially in identifying and responding to problems.	The panel agrees with the investigators' view.
6.5	Camidoc provides out of hours support over long periods, especially during bank holidays. A culture of keeping things going until morning comes is not sustainable over these periods.	The panel agrees with the investigators' view. The panel notes that the future of out of hours care is currently the subject of national debate.

6.6	Camidoc has suffered from a lack of strategic vision and a rather inward-looking culture that has not responded fully to changes in the NHS.	The panel agrees with the investigators' view in relation to some areas of Camidoc's practice. The panel notes that Camidoc has actively engaged with national debate in the development of out of hours care.
6.7	The failure of Camidoc to carry out an immediate investigation into Penny Campbell's death and its inappropriate deference to the coroner's inquest are rooted in its culture. Even a rapid appraisal would have shown that there were major system problems within the organisation that needed to be addressed.	The panel agrees with the investigators' view.
6.8	Camidoc had little external scrutiny, such as is offered by non-executive directors in NHS trusts, but is planning significant changes to its corporate structure.	The panel agrees with the investigators' view.
6.9	Camidoc needs to find ways to increase the engagement of a wider cross section of the GPs who provide the service to ensure that there is less of a gap between the board and the GPs.	The panel agrees with the investigators' view.
6.10	Camidoc and the PCTs have been under pressure to deliver an agenda of change in primary care focussed on access and unscheduled care. The speed of this change has encouraged a reliance on mutual co-operation between the organisations, based on established professional relationships, without proper risk assessment of the changes being introduced.	The panel agrees with the investigators' view.
6.11	The support and resources that PCTs have devoted to the commissioning of out of hours services has not been commensurate with the out of hours services' expanded role and the increased time over which they operate.	The panel agrees with the investigators' view.

6. Key recommendations of the panel

The following are the key recommendations of the panel. The detailed recommendations of the investigators are cited in the appendix.

Recommendations	
1. Recommendations for Camidoc	
<i>The investigators' recommendations (summarised)</i> <i>The panel's comments</i>	
1.1	Camidoc should formally review its organisational governance.
	The panel supports this recommendation.
1.2	Camidoc should review its medical leadership and accountability and consider appointing a medical director.
	The panel supports this recommendation. The panel recommends that this review should cover all clinical roles.
1.3	Camidoc should consider commissioning an independent clinical risk assessment of its policies and processes to identify how it will manage its clinical risks.
	The panel supports this recommendation.
1.4	Camidoc should review its clinical governance and work with the PCTs to bring its systems into line with other healthcare providers.
	The panel supports this recommendation.
1.5	Camidoc should agree with commissioners a definition of a serious untoward incident and make clear how, and by whom, investigations into such incidents will be conducted.
	The panel supports this recommendation.
1.6	Camidoc should review its approach to complaints and its ability to investigate and respond directly to complainants.
	The panel supports this recommendation.
<i>Additional recommendations of the panel</i>	
1.7	Camidoc should produce an action plan to fully address the findings and recommendations within this report.
2. Recommendations for the doctors involved	
<i>The investigators' recommendations (summarised)</i> <i>The panel's comments</i>	
2.1	The doctors involved should meet the Medical Director and lead officer for primary care in their PCT to discuss the findings of the report and any other concerns and outstanding issues.
	The panel supports this recommendation.
<i>Additional recommendations of the panel</i>	
2.2	The panel recommends that all the doctors involved should reflect on this case and consider its implications for every aspect of their personal clinical practice.

3. Recommendations for the four primary care trusts that commission Camidoc		
	<i>The investigators' recommendations (summarised)</i>	<i>The panel's comments</i>
3.1	All four PCTs should recognise the role of the out of hours service and the part it plays in the care of their populations. They should adopt a lead commissioner approach and resource this jointly.	The panel supports this recommendation.
3.2	The lead commissioner should ensure that Camidoc adopts performance procedures that promote patient safety and meets the Standards for Better Health.	The panel supports this recommendation.
3.3	The PCTs should ensure that commissioners are aware of any concerns that reach them about a service provided by a non-NHS body, whatever the route.	The panel supports this recommendation.
3.4	The PCTs should have an explicit procedure agreed with their out of hours providers about how an SUI should be investigated and how information is shared when an investigation is in progress.	The panel supports this recommendation. The panel notes that this procedure must include a clear definition of an SUI.
3.5	Medical directors and lead officers of primary care should ensure that each of the doctors involved in this incident attends an interview with them to discuss this report and its findings to ensure that any concerns and outstanding issues are addressed.	The panel supports this recommendation.
<i>Additional recommendations of the panel</i>		
3.6	The PCTs should engage with the GPs whose care was not considered to be satisfactory to ensure high standards of care in the future. They should employ their formal procedures for assessing and improving the quality of clinical care to ensure that any questions about the GPs' wider clinical practice are fully addressed.	
3.7	The PCTs should consider the implications of this report in detail and at the highest level within each organisation. PCT boards and clinical governance committees should articulate a full response and develop a detailed action plan to address all these recommendations.	
3.8	The PCTs should assure themselves that Camidoc also has an action plan in place to address the findings and recommendations within this report.	

4. Recommendations for the wider NHS		
	<i>The investigators' recommendations (summarised)</i>	<i>The panel's comments</i>
4.1	All out of hours providers and commissioners should read this report and learn the lessons identified within it.	The panel supports this recommendation. The panel recommends that all out of hours providers and commissioners consider the implications of this report for their own organisations.
4.2	The perception of an out of hours service as a 'holding bay' until the patient's GP resumes care needs to be addressed.	The panel supports this recommendation.
4.3	The profile of out of hours services needs to be raised nationally and the professional reputation of the doctors working for the service should be recognised.	The panel supports this recommendation.
4.4	Policy confusion over whether an out of hours service is for urgent or unscheduled care should be addressed and resolved.	The panel supports this recommendation.
<i>Additional recommendations of the panel</i>		
4.5	The Department of Health should consider the implications of this report and help to clarify national expectations of the role and performance of out of hours care.	
4.6	The London Independent Hospital should consider conducting a review of its own role in the events that led to Penny Campbell's death, focussing on communication and post-procedural support.	

7. Glossary

Camidoc

An independent not-for-profit organisation that provides a GP service when GP surgeries are closed (an out of hours service). Camidoc is commissioned by four PCTs to provide this service to people in their catchment areas: Camden, City & Hackney, Haringey and Islington. Most of Camidoc's consultations take place over the phone but Camidoc also runs its own out of hours clinics and offers home visits.

Clinical audit

A clinical audit is an investigation of a clinical service to assess its performance against defined targets or standards.

Clinical care

The healthcare provided by doctors, nurses and the many other health professions within the NHS. Medical care, provided by doctors, is one form of clinical care.

Clinical governance

The systems and processes used within healthcare organisations to monitor and improve the quality of their clinical care.

Commissioner

Within PCTs commissioners are the individuals responsible for agreeing contracts with different providers to make sure the right range of local health services is provided. PCTs are commissioning organisations and a PCT may be described as a 'lead commissioner' for a service if it takes responsibility for commissioning a service on behalf of several PCTs.

Fit for purpose

Having the appropriate range of systems, procedures, policies and personnel to deliver a defined service to an agreed standard.

National Quality Requirements

A service standard set by the Department of Health for out of hours services.

Out of hours service

A service that provides support when the main service provider is closed. In primary care, out of hours services operate when ordinary GP surgeries are closed.

Primary care

The professionals and services that people typically turn to first such as GPs (general practitioners), dentists, opticians and pharmacists.

Primary care trust

Primary care trusts (PCTs) are the local NHS organisations responsible for securing an appropriate range of health services to meet the needs of their population. PCTs can provide services themselves but they also commission services from other organisations, predominantly NHS trusts such as hospitals but also independent organisations.

Primary Medical Performers List

This is a register of accredited GPs held by a primary care trust. GPs have to be accepted on a Primary Medical Performers List in order to provide care within the NHS.

Serious untoward incident investigation

An established method for investigating the circumstances of unexpected adverse healthcare events. The purpose of such an investigation is not to apportion blame or identify liability but to understand better what went wrong in a particular incident and to identify ways of remedying problems for the future.

Appendix: The Investigators' Report

Serious Untoward Incident Investigation into the death of Penny Campbell

SheeYlar Macey

Sadru Kheraj

Wendy Fisher

May 2007

Introduction

Penny Campbell was a 41 year old woman who lived in Islington. On March 23rd 2005 she underwent a minor surgical procedure which set in chain events which led to her death on March 29th 2005. The cause of death was recorded as multi organ failure following septicaemia from a perirectal abscess due to haemorrhoid injection. This is an uncommon and very unusual complication of a very simple and commonly undertaken procedure. Following an inquest on 6th October 2006, the coroner recorded that Penny Campbell died as the result of an accidental adverse healthcare event to which the non-recognition of the seriousness of her condition contributed.

After the completion of the coroner's inquest, Dr Sadru Kheraj and Sheeylar Macey were commissioned to carry out a Serious Untoward Incident Investigation by the multi agency panel convened to review the case. The purpose of a Serious Untoward Incident (SUI) review is to examine in detail the events and place them in the context of the system in which they operated. Unlike a trial it is not focussed on attributing blame but on identifying underlying cause and the effect which that had on the specific case. SUI reviews would normally be carried out internally and as soon as practicable after the events occurred to maximise the learning from the case. Why this was not done in this case is a question we try to answer in this review.

At the request of the reviewers the terms of reference for the inquiry were broadened to allow us to consider any wider implications of the way in which out of hours care is delivered.

Reviewers

Sheeylar Macey is a trained nurse and specialist practitioner in primary care. She holds an MSc in primary care development. She has also been a primary care adviser to a health authority. Sheeylar Macey has worked as a clinical director in primary care and as Head of Governance to a strategic health authority. She is fully trained in root cause analysis and has extensive experience of investigations in primary care and community based settings.

Dr Sadru Kheraj is a general practitioner. He is senior partner in a large practice in south east London. For the last twelve years, he has also been Medical Adviser to Lambeth, Southwark and Lewisham Health Authority and then the South East London Strategic Health Authority. He is fully trained in root cause analysis and has extensive experience of investigations in primary care settings, including out of hours services.

Wendy Fisher is a psychologist with an MSc in statistics and is a trained nurse and midwife. Until recently Wendy worked as Head of Research for the South East London Strategic Health Authority. Fully trained in root cause analysis techniques, Wendy has extensive experience in working within a team conducting reviews of GP practices and investigating untoward incidents and concerns.

None of the reviewers are, nor ever have been, employees of Camidoc or the PCTs who have commissioned this review. The reviewers have considered any conflicts of interest and have none to declare.

Methodology

We have used a root cause analysis approach. Root cause analysis is a problem solving methodology used as an integral part of investigation management for identifying the underlying reasons for events.

As part of our investigation we have reviewed the transcript of the coroner's inquest and all of the statements sent to that inquest from Camidoc and the individual doctors.

As the individual doctors had already made statements they were asked to review these when we met with them. Each of these interviews was held at the doctor's surgery and was conducted by at least two members of the team. We reviewed a sample of each doctor's out of hours recording sheets. We reviewed a sample of doctors' in hours records for benchmarking purposes. Our point of reference for considering the reasonableness of the clinical action is the General Medical Council publication *Good Medical Practice* and the Royal College of General Practitioners/General Practitioners Committee interpretation of this, *Good Medical Practice for General Practitioners*¹.

We visited the Camidoc base at St Pancras and 'walked through' the organisation while it was operational.

We interviewed key members of staff and board members at Camidoc. All of the interviews at Camidoc were conducted by three reviewers. This was important to establish what it was like to work at Camidoc and to get a feel for 'what things are like around here'.

We interviewed the Consultant surgeon who carried out the procedure.

We met Angus MacKinnon, the partner of Penny Campbell.

We reviewed all of the available clinical policies at Camidoc.

Where available we reviewed the doctors' applications to join a Primary Medical Performers List. These were not available for those who had been in practice for many years as they were simply transferred to the Primary Medical Performers List from a historic list and had not been required to complete an application.

We reviewed the records of the performance management meetings with Camidoc and interviewed the Islington commissioner of the service. We read the Camidoc contract.

Current and historic Department of Health guidance on out of hours services was reviewed along with *Raising Standards for Patients: New Partnerships in Out of Hours Care* (the Carson Report).

The National Audit Office (NAO) report and the Public Accounts Committee reports were considered as was the NAO report on clinical governance in primary care and Camidoc's self assessment against the Healthcare Commission's core standards.

The reviewers considered all the data individually and then used a nominal group technique to establish the consensus of our findings and to establish the priority of the themes. We used the National Patient Safety Agency's decision support tree and guidance on systems failure to group the themes.

In compiling this report we have chosen to answer the questions in the terms of reference directly. It is deeply regrettable that this, the first complete internal inquiry into Penny Campbell's death, commenced over 18 months after the events. Inevitably, the review of

¹ http://www.rcgp.org.uk/PDF/Corp_GMP06.pdf

events will be tainted by hindsight. We have compiled the themes which emerged from this review and our conclusions. Finally we have made our recommendations.

We would like to thank everyone who co-operated with this inquiry for their openness, patience and honesty.

1. The clinical care received by Penny Campbell

a. **What was the sequence of events from the surgical intervention at the London Independent Hospital to the death of Penny Campbell?**

The following timeline identifies the known facts from Penny's injection until her death.

Wednesday 23rd March 2005

Daytime Penny Campbell undergoes injection of haemorrhoids at London Independent Hospital. The injection is carried out by Miss Susan Clark, consultant surgeon.

Thursday 24th March

Penny Campbell went into work but at sometime felt unwell enough to return home.

Friday 25th March

am Penny Campbell calls the surgeon who undertook the procedure, who advises her after discussion that a connection with the procedure is unlikely and to consult her GP should her symptoms worsen.

19.17hrs Call received by Camidoc from Penny Campbell.

19.50hrs Dr El-Kinani telephones Penny Campbell, advises attendance at Camidoc base.

20.28hrs Penny Campbell arrives at Camidoc's St Pancras Base.

20.30hrs Penny Campbell is seen by Dr Fitzpatrick.

Saturday 26th March

14.38hrs Call received by Camidoc from Penny Campbell.

15.40hrs Dr Vucevic telephones Penny Campbell and gives telephone advice.

22.24hrs Call received by Camidoc from Penny Campbell.

22.46hrs Dr Wenaden calls Penny Campbell, advises to call tomorrow to be seen.

Sunday 27th March

11.40hrs Call received by Camidoc from Angus MacKinnon* partner of Penny Campbell.

11.51hrs Dr Laqueur telephones Penny Campbell advises non-urgent home visit.

15.45hrs Dr Beyzade** arrives at Penny Campbell's home and examines Penny Campbell.

*Mr Angus MacKinnon reported that Penny Campbell herself had called Camidoc on the morning of March 27th prior to his telephone call of 11.40. The investigators were unable to confirm or deny this. Calls prior to the 11.40 call are disputed by Camidoc.

**Dr Beyzade recalls that the whole of the presenting complaint was not filled in when he saw Penny Campbell and he did not have access to the information there. Camidoc dispute this.

Monday 28th March

04.09hrs Call received by NHS Direct from Penny Campbell, passed to Camidoc.
04.50hrs Dr Chuah telephones Penny Campbell and gives telephone advice.
09.58hrs Call received by Camidoc from Penny Campbell.
10.15hrs Dr Choudary telephones Penny Campbell, who decides to attend A&E (Accident & Emergency).
10.50hrs Arrives at Royal London Hospital A&E, alert and orientated but with obvious clinical signs of sepsis and shock.
15.00hrs Moved to ITU and ventilated in view of multi organ failure.

Tuesday 29th March 2005

07.50hrs Penny Campbell died.

b. Was the clinical care offered by each of the eight Camidoc GPs who treated Penny Campbell over the Easter Bank Holiday 2005 of a reasonable standard?

Each of the doctors had to place themselves in a position where they could be sure that their own assessment of her clinical condition was adequate. We therefore looked at each consultation as though it stood alone.

Dr El-Kinani

Dr El-Kinani spoke to Penny Campbell and because she had undergone a surgical procedure and he could not be certain what was causing her symptoms, he asked her to come into the base to be seen. He had correctly advised her that she should contact the surgeon who had performed the procedure. She had done so and the surgeon had reassured her that her symptoms were probably coincidental and not related to the surgical procedure that had been undertaken. Dr El-Kinani's notes reflected his actions and at this stage the presenting problem appeared to be constipation and general malaise.

Our opinion is that the care provided by Dr El-Kinani to Penny Campbell on Friday the 25th March 2005 was of a reasonable standard.

Dr Fitzpatrick

Dr Fitzpatrick saw Penny Campbell at St Pancras Hospital. He took a reasonable history and performed an examination that would allow him to complete his assessment. He made a reasonable assessment of the problem, which he judged to be a viral infection, and arranged appropriate safety netting: she was told to call back if she needed to.

Our opinion is that the care provided by Dr Fitzpatrick to Penny Campbell on Friday the 25th March 2005 was of a reasonable standard.

Dr Vucevic

Dr Vucevic gave telephone advice to Penny Campbell. Dr Vucevic responded to the information provided to him by Penny Campbell. He obtained sufficient background information to put himself in a position to give reasonable advice about the presenting complaint and he provided appropriate safety netting.

Our opinion is that the care provided by Dr Vucevic to Penny Campbell on Saturday the 26th March 2005 was of a reasonable standard.

Dr Wenaden

Dr Wenaden gave telephone advice to Penny Campbell. Dr Wenaden took a reasonable history over the telephone and determined that Penny Campbell needed to see a doctor. Dr Wenaden agreed with her that she would be seen the next morning. The methods of working in place at that time meant that Dr Wenaden could not arrange for Penny Campbell to be seen the next morning. It was necessary to start a whole new episode of care.

Our opinion is that the care provided by Dr Wenaden to Penny Campbell on Saturday the 26th March 2005 was of a reasonable standard.

Dr Laqueur

Dr Laqueur gave telephone advice to Penny Campbell. A recording was made of this telephone consultation and the interview with Dr Laqueur included a review of the transcript of her telephone consultation. Dr Laqueur took a reasonable history, allowing the patient to describe her problems without interrupting her and also picking up on the patient's cues about her clinical condition, and arranged for Penny Campbell to be seen by another doctor at home.

Our opinion is that the care provided by Dr Laqueur to Penny Campbell on Sunday the 27th March 2005 was of a reasonable standard.

Dr Beyzade

Dr Beyzade visited Penny Campbell at home. He has a clear memory of the consultation despite the passage of time. He found her to be lucid and alert; she did not appear distressed although she was "clearly not well". He examined her abdomen and recorded his findings. He recalls taking her pulse but did not write this down nor did he record the medication which he prescribed. He did not take a blood pressure. He was aware that her symptoms "did not fit" and recommended that she see her own doctor about the oral thrush. He recalled that he did not look in her mouth.

Dr Beyzade's recollection was that he had discussed the rash with Penny Campbell but that it had not been there when he examined her. This is not consistent with Mr MacKinnon's recollection. Dr Beyzade responded to Penny Campbell's overall condition and her ability to respond and articulate by which he judged that she was not "acutely very unwell".

There are inconsistencies in the accounts of this clinical consultation with Penny Campbell. There are clear gaps in both the processes of the clinical encounter and the recording of the event. Additionally, the significant passage of time between the events we were reviewing and the interview with Dr Beyzade has unfortunately compounded the difficulties in this retrospective review.

We are therefore unable to reach any conclusions about the standard of care provided by Dr Beyzade to Penny Campbell on Sunday the 27th March.

Dr Chuah

Dr Chuah spoke to Penny Campbell; we have the transcript of this conversation. The fact that we have a transcript and a recording of this conversation allows us to be more definitive in our opinion of this clinical encounter. At over 11 minutes, it was a long conversation at 4.50 in the morning. The balance of the conversation is that Dr Chuah spoke for much more of the time than Penny Campbell. Reviewing this transcript, it is apparent that Penny Campbell was articulate and coherent. In the course of the conversation she describes her symptoms quite clearly. It is also evident that Dr Chuah did not pick up the cues offered by her or further explore any of these symptoms to clearly and definitively exclude any serious pathology that could have accounted for these symptoms. When she checked with him that it was "not

anything serious", Dr Chuah replied that if it was more serious, she would be a lot more sick and "wouldn't be talking to me like this".

Dr Chuah offered safety netting in the form of "Call us back in the daytime and we will try to see you".

Given the overall context of the time of day that this telephone consultation took place and the description of the symptoms provided, our opinion is that Dr Chuah had not effectively put himself in a position to be certain that Penny Campbell did not have a significant acute illness that needed a face to face consultation at that time.

Our opinion is that the care provided by Dr Chuah to Penny Campbell on Monday the 28th March 2005 was not of a reasonable standard.

Dr Choudary

Penny Campbell did call back and spoke to Dr Choudary at 10.15am. During the conversation she decided to go to the A&E department and was driven there by Mr MacKinnon. Dr Choudary was clear that the patient needed reassessment and he had offered her a home visit. It seems unlikely that as Penny Campbell arrived at A&E at 10.50am she would have arrived more quickly had an ambulance been called. Her care beyond this point is outside the scope of this review.

Our opinion is that the care provided by Dr Choudary to Penny Campbell on Monday the 28th March 2005 was of a reasonable standard.

c. What access did Camidoc GPs have to information or notes of any previous consultations, including the earlier surgical intervention?

The Doctors did not have easy access to the notes of the previous consultations. It would have been possible to retrieve the call sheets but there was no simple system apparent to the doctors that could have made this possible. The only information about the surgical intervention came from Penny Campbell. Penny Campbell appears to have made it clear to the doctors to whom she spoke that her conversation with them was not her first contact with Camidoc.

d. Was access to information or previous notes a significant factor in the clinical decision-making process and if so how much did it impact upon the clinical diagnosis and therefore the final outcome?

Eight contacts by an individual to a service in a short period of time is unusual. It seems probable that, had the doctors realised the sheer number of clinical contacts made by a clear, lucid and articulate woman over such a short period, they might have escalated her care more rapidly, especially as, viewed as a whole, none of the consultations 'fit' to provide an adequate explanation of her continuing condition. However, we cannot be certain of this.

Information was available to the doctors as Penny Campbell was such a clear historian. However this is not the same as access to the notes of a colleague with evidence of consideration of differential diagnosis.

It is our opinion that failure to ensure that notes were available was a major system failure and a direct factor leading to Penny Campbell's death.

Each doctor told Penny Campbell to call back if she did not recover, however as a system for safety netting this was seriously flawed as each call was treated as an individual episode of care. Each time she called back Penny Campbell had to start her narrative all over again. Most of the doctors did not benefit from the experience of the preceding colleague's account except as part of Penny Campbell's explanation of her reason for calling.

The two doctors who examined Penny Campbell would have had access to the notes of the doctor who immediately preceded them but no-one had easy access to all of the consultations prior to the one with which they were engaged. Dr Beyzade disputes that the details were complete on the sheet he received, citing the fact that the printer in the car was not working, thus the usual process was interrupted. Camidoc dispute that the call sheet was not completed prior to the visit and point out that it would be a serious deviation from the usual method. The investigation uncovered no further information about this.

It is correct to say that there was no readily accessible system to access notes which would have allowed the doctors to know how many of their colleagues had spoken to Penny Campbell. The significance of this increased the further along the line the doctor was. We believe that the coroner was correct in identifying that lack of ready access to notes had an effect on the clinical decision making. However hindsight bias cannot be ignored in this investigation, as everyone interviewed by us knew what the coroner had said this and therefore must have been affected by it. Had an investigation taken place prior to the coroner's inquest a clearer answer to this question might have emerged.

2. The systems in place at Camidoc over Easter 2005

a. **What was the system for recording, storing retrieving and accessing clinical notes?**

At Easter 2005 the system for recording clinical notes was paper based. The call sheets were completed and then faxed to the patient's own GP practice. So notes were kept, reviewed and stored but retrieval was a major problem. We are aware that a system existed through the evidence of the clinical audits carried out in compliance with the National Quality Requirements². Evidence came from the clinical governance lead that legibility was a problem in carrying out the audits, but that they were indeed completed.

The unwieldiness of the system and its unpopularity with the clinicians was a fact known to the Camidoc board. We acknowledge that Camidoc acted rapidly to upgrade the clinical records system to a fully computerised version after Penny Campbell's death. The move to the new computerised system had commenced prior to the events of Easter 2005 and the ability to move to this system was governed by the supplier's ability to support organisations in the transition.

b. **Were all staff and clinicians trained and familiar with the use of the system?**

Staff and clinicians were familiar with the systems in operation at Camidoc at Easter 2005. Training records are not detailed to each individual doctor. However, as this was a paper based system little training should have been required. Each doctor and Camidoc staff told us of the information books at the Camidoc sites providing contact information for various services and some internal policies.

What is less clear is what steps Camidoc took as an organisation to assess the safety of their systems after the death of Penny Campbell.

We heard varying accounts of how people had attempted to deal with the limitations of the paper based system. We saw no evidence to suggest that the risk had been discussed with the commissioner in explicit terms or that a formal, structured risk assessment had been carried out. As Camidoc did not have the systems which exist in an NHS trust to support a properly constructed risk register it is not clear how the board was made aware of the

² http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137271

situation. As Camidoc is a more diverse organisation than a general practice it is not clear that the more informal systems at work in such an environment were appropriate here.

c. Were the systems for ensuring clinical governance at Camidoc fit for purpose?

Apart from the clinical audit requirements of the National Quality requirements, there were few explicit systems to define or assure clinical governance. We found that this was attributable to Camidoc's view that as they were not legally the employer of the doctors providing the service, they did not have to comply with aspects of good employment practice as would be expressed through a clear clinical governance system. Whilst this may be strictly correct, it is not good practice. A similar analogy might be volunteers in a school setting: just because they are not employed by the school, the school cannot ignore the requirement for Criminal Records Bureau checks for anyone working with children. This is not a point of bureaucratic nicety. Lack of systems meant that Camidoc was not able to demonstrate that the board had considered their responsibilities to their members or to the community they served.

Our opinion is that the systems for ensuring clinical governance at Camidoc were not fit for purpose.

d. Was Camidoc adequately staffed over the Bank Holiday weekend?

The charts attached as appendix B shows the number of clinical staff available over the Easter weekend. These charts were kindly prepared by Mr Michael Golding.

Camidoc call rates for the period are available and they are included in appendix C. Comparing the information provided by Camidoc for the previous and subsequent years, both the staffing and activity levels appear to be fairly constant.

Our opinion is that Camidoc was adequately staffed over the bank holiday weekend.

e. Were the systems in operation over Easter 2005 significantly different to the systems that usually operated at Camidoc?

Over the Easter period of 2005 Camidoc provided cover from 6.30pm on Thursday night until 8am on Tuesday morning, a total of 109.5 consecutive hours. During a normal weekend Camidoc provides cover for 61.5 hours.

Camidoc's stated view of the service is that they provide support to practices in providing out of hours care. The difficulty with this view is that the service is designed to offer support over short periods when patient demand is at its lowest.

3. Investigation reporting and responses following the death of Penny Campbell

a. How did Camidoc become aware of the death of Penny Campbell?

Camidoc received a telephone call from St Peter's Street Medical Practice informing them that Penny Campbell had died and advising them that the coroner would be in contact.

Penny Campbell's GP records indicate that the practice was informed of her death by telephone on 4th April 2005. A letter from Barry Newbury, the coroner's officer based at Poplar, dated 5th April was sent to Penny Campbell's GP. This states that she had died on 29th March and that the subsequent post mortem showed the cause of death to be '1a Histology, Microbiology, Virology' and indicates that there will be an inquest at Poplar at a

date to be arranged. The letter also notes that she was seen by Camidoc on several occasions and that reports are being obtained from them.

b. What actions were taken as a result of this information, including reports to other agencies such as the commissioning PCTs or the NPSA?

Following a telephone call from the coroner's office, on 15th April 2005 Michael Golding, Chief Executive of Camidoc, wrote to all eight doctors informing them that she had died. From this letter it seems apparent that there was little clinical information provided about Penny Campbell's death. The doctors were asked to record 'all the details that you think might be relevant to a coroner's enquiry'. The doctors were advised that they might be asked to attend the inquest. A reminder letter was sent out on 30th June for the outstanding reports. A letter was sent to the coroner's office on 4th July with a timeline of contacts from Camidoc with Penny Campbell and seven of the GP reports. On 18th July a letter was sent to the coroner's office enclosing the final report.

In September 2005 Islington PCT received a letter from Parlett Kent solicitor acting for Mr MacKinnon. This letter was forwarded from the Chief Executive's office to the Clinical governance team in Islington who deal with legal matters. The PCT complaints department contacted Camidoc by telephone. Camidoc confirmed that they were aware of the case and that a coroner's inquest was pending.

Camidoc advised the PCT and Parlett Kent by letter dated 27th September 2005 that they would carry out an investigation after the coroner had made a judgement.

At some point between April and September Camidoc's board had made a decision not to investigate. We saw no evidence that this decision was minuted at a meeting. It was asserted to us that the board agreed this approach.

It was not until December 2005 that the commissioner became aware of Penny Campbell's death. He was advised that any investigation would be delayed until the coroner had made a judgment. He was advised that Camidoc's legal experts thought this a reasonable course of action and that the board had agreed to take no further action until after the inquest which was scheduled for early March 2006.

The inquest was originally set for March 2006 but was delayed; the reviewers have been unable to establish the cause for the delay. The inquest actually took place in October 2006.

We saw no evidence to suggest that between March 2006 and October 2006 there was any review of the Camidoc board decision in relation to an internal review. Neither have we seen any evidence that they were asked to review this by the PCT.

Camidoc at no stage regarded the letter from Mr MacKinnon's solicitors as a complaint and did not therefore investigate using their complaints process.

The case was not reported to the National Patient Safety Agency's anonymised National Reporting and Learning System (NRLS). Camidoc is not linked to the NRLS and it is not clear to the reviewers if other out of hours services are. Even if it had been, the anonymisation of this system is such that it would have formed part of a data set for learning after analysis rather than forming part of a management tracking system.

c. Were the arrangements for reporting serious incidents and serious concerns over clinical performance clear and adhered to?

The arrangements for reporting serious incidents within Camidoc were not clear. We were shown a protocol which was noted as having been revised in January 2006 but this was not in place at the time.

The Camidoc process for informing a PCT of a Serious Untoward Incident was not clear.

d. What were Camidoc's contractual obligations in relation to reporting sudden or unexpected deaths to its PCT commissioners, and did this take place in relation to Penny Campbell?

In March 2005 the relationship between Camidoc and the PCTs was in the form of service level agreements rather than in its present form of a contract. This contained no explicit requirement to report sudden or unexpected deaths. As detailed above, Camidoc did not inform the PCT of Penny Campbell's death until they were approached by Islington PCT in September 2005.

e. How appropriate were the actions taken by Camidoc following the death of Penny Campbell?

We believe that the actions taken by Camidoc following the death of Penny Campbell were made in good faith. They were not however based on a clear understanding of the role of the coroner. Equally there were no embedded clinical governance processes for demonstrating quality in the organisation and for explicitly stating what the organisation would do when something went wrong, as it had in this case. If there had been it would have been clear that an explicit internal review as soon as possible after the event was vital. Such a review would not have been prejudicial to the coroner's inquest. For example a maternal death in hospital is reported to the coroner, to the local supervisor of midwives and to the Confidential Inquiry on Maternal Deaths; it would be a serious untoward incident and would be investigated internally by the trust. All of these processes are clear and formal but would not wait upon the other.

As it was, from the evidence supplied we believe that the internal review was fragmented into discussions about various aspects of the case with no clear overview. The review was not clearly documented by the board of Camidoc. Neither the failure to carry out a local review nor the failure to clearly document discussions was appropriate.

We found that all of the doctors involved in the case had received little regular contact with Camidoc in the lead up to the inquest. This meant that they were poorly prepared to answer the questions put to them and had a poor understanding of the process of the coroner's inquest. Whilst it is strictly correct that the individual liability sits with each of the practitioners, this only becomes truly relevant if any of the practitioners are sued for negligence or if they are required to undergo investigation by the regulator. We found that, as a consequence of the narrow view of liability rather than responsibility in Camidoc, there was a general lack of pastoral support running through Camidoc for the clinicians performing shift work.

f. What is the system for monitoring sudden or unexpected deaths in Camidoc?

Since October 21st 2003, all deaths which occur on general practitioners premises must be reported to the PCT. This is part of the changes following the Shipman Inquiry.

Camidoc have information folders at their bases with information about reporting deaths to the coroner. The website also contains information including contact numbers and this is easily accessed.

The contract from 1st April 2005 does require Camidoc to report the death of any patient of which it is aware³. However there is no formal system of monitoring deaths in Camidoc; this is in line with other out of hours services and primary care in general.

³ Contract between Camidoc and Islington PCT for the provision of primary medical services during the out of hours period

4. The systems in place at the PCTs over Easter 2005

a. **Were the commissioning, performance monitoring and working relationship between the four PCTs and Camidoc appropriate and effective?**

The National Audit Office (NAO) report *The Provision of Out of Hours Care in England*⁴ published in 2006 identified many of the problems which are germane to the relationship between out of hours services and PCTs. The change to the service was introduced as part of the new GMS contract. We agree with the NAO report's conclusion that 'Despite upgrades and improvements to IT systems, management information is still poor'.

Setting aside the paucity of management information we found that there was a system in place for commissioning and performance monitoring between Camidoc and the four PCTs. There is evidence in the form of meeting agendas and minutes that a process exists for Camidoc and the commissioners to meet regularly and discuss the service. There is a nominated lead for each PCT and this provides an effective working relationship. This system was in place over Easter 2005 although the service was not governed by a contract but by a much looser Service Level Agreement (SLA). The basis for the performance monitoring of quality was and is the National Quality Requirements. These do not provide the sort of fine detail to give specific clinical oversight into Camidoc's work.

In comparison to the management of contracts with the voluntary sector, the process of contract monitoring with Camidoc is quite formalised, although in monetary terms this is not a very high cost contract.

There appears to be little overt clinical leadership of performance management at Camidoc. Instead this is assumed to be a management function. This is an inappropriate assumption.

b. **How appropriate were the actions taken by PCTs following the death of Penny Campbell?**

The PCTs were not immediately aware of the death of Penny Campbell. A letter from Parlett Kent dated 11th August was sent to Islington PCT at Goswell road, This was not addressed to any particular individual. A reply from the Chief Executive indicates that the inquiry was treated as a matter for Camidoc who were awaiting the coroner's inquiry. In the reply Islington PCT note that they had not received the letter until 13th September. Islington PCT did not request any further information from Camidoc following the email from Camidoc's chief executive to the clinical governance department of Islington PCT. There was limited communication within Islington PCT and the PCT commissioner for the out of hours service was not informed until December 2005. At this stage the inquest was planned for March 2006.

Once it was evident after the inquest that an explicit internal review of systems and clinicians had not taken place, all four PCTs were involved in creating the terms of reference for this investigation.

In our opinion Islington PCT should have shared the information about Penny Campbell's death internally sooner than they did.

Islington PCT commissioner for the out of hours service should have obtained clear assurance from Camidoc that an internal investigation was taking place.

The actions of Islington PCT were limited by the lack of clarity about the role of the coroner and the approach that Camidoc were taking to their internal investigation.

⁴ http://www.nao.org.uk/publications/nao_reports/chronindex.asp?type=vfm

In our opinion the actions of Islington PCT were not completely appropriate.

5. The systems currently in place at Camidoc

a. **What access do clinicians working at Camidoc have to the notes of previous patient consultations?**

All previous patient consultations are now fully available on the computer system. There have been other innovations by Camidoc to allow doctors to give patients appointments to come in to be seen at any one of the centres. There is also the facility to provide appointments for the next day.

b. **What training do clinicians have on the use of this system and what support is available to them, including telephone work with patients?**

All clinicians are required to undertake formal training in the use of the clinical software with Camidoc before they are able to undertake shifts.

Telephone consultation skills courses are available but not mandatory as the ability to undertake telephone consultations is considered a part of the core skills required of any general practitioner.

However there is an overall system assumption on the part of the National Health Service that being on a Primary Medical Performers List is sufficient to enable doctors to work in an out of hours service. Normally the adequacy or otherwise of an individual for a post is judged by an employer as part of a contract for service or by joining a partnership. However none of this was considered for the individuals working for Camidoc.

There is detailed national and local guidance on training for GP registrars in out of hours work. It is beyond the scope of this report to comment on the adequacy of this.

c. **Is there a minimum number of shifts required to ensure a safe working knowledge of the clinical and other systems?**

There is no formal system for monitoring the numbers of shifts worked at Camidoc. The rota is run by a capable and experienced manager and there is a limited number of shifts which we were assured were always filled. We found that reliance on an individual rather than an explicit system is the normal method of operating at Camidoc.

There is no minimum number of shifts that need to be worked to maintain competence. Few out of hours providers have a policy on this.

There is no set maximum number of shifts that a GP can undertake but the ratio of the number of available shifts to the number of available duty doctors limits this. For all of the doctors working shifts at Camidoc this is one of perhaps several jobs. There is no policy for the maximum number of shifts worked and Camidoc cannot monitor what other work doctors are performing. A doctor can normally only do one shift per day but, if there is a special arrangement, two are possible. This is rare and there would have to be a four to six hour gap between the shifts.

Except for the policy on training in the use of the clinical software, no special requirements are in place to join the Camidoc rota; being a GP on a Primary Medical Performers List is enough. This is in line with many other providers but may not be a satisfactory arrangement especially if the GP is not on a local performers list. Although Camidoc report good informal links with other out of hours providers there is nothing to link them to PCTs who do not commission services from them. A GP could in theory be suspended from the Primary Medical

Performers List in one PCT and continue to work at an out of hours service. This is not a problem just for Camidoc but is a limitation on the Primary Medical Performers List system and is an issue which should be addressed.

d. Are the systems for ensuring clinical governance, such as identification and review of incidents when they occur, fit for purpose at Camidoc?

Camidoc has a clinical governance lead. There is a clinical governance group and the work carried out here is reviewed by the medical board. We saw no evidence of a formal articulation of what clinical governance meant to Camidoc or how they would assess its effectiveness in relation to the totality of its service.

The underlying difficulty with Camidoc's approach to clinical governance is that it appears to have been developed on the basis that, as there is no registered population and the doctors who work there are not direct employees, many aspects of organisational clinical governance do not apply.

This may have been appropriate when the complete responsibility for 24 hour care sat directly with GPs but that is no longer the case. The PCTs commission the service from Camidoc as an organisation and not from each individual who works there. It is understandable that the model for governance has developed from a GP perspective but, given the changes in the service and the scale of the service, this is not an appropriate model. Nor is it possible for the PCT to adequately performance manage the contract for service if basic systems are in not in place.

Camidoc have made some progress in changing their approach. For example they now have a risk management policy and a risk register but it is not clear when this was approved by the board of Camidoc or when it is due to be reviewed. The risk register has more of a corporate rather than a clinical focus dealing mainly with estates issues and commercial competitors.

There is an SUI policy which was revised January 2006 but it is unclear when it was introduced. This states that a senior manager will carry out an investigation but it does not include the definition of what the Camidoc board sees as an SUI. We were offered no evidence that the board or the clinical governance group had discussed the definition of an SUI for the organisation and then formed conclusions which were translated into policy and process.

We saw no evidence of SUI reporting embedded in the organisation. For example we were offered no evidence of training for staff or clinicians in SUI analysis or reporting . We were offered a protocol for investigation which is a series of questions which could act as prompts. This made no reference to methods usually used in SUI investigation or links to supportive systems such as the NPSA decision support tree.

In May 2005 Camidoc carried out a self assessment of the organisation using the *Core standards for better health* from the Healthcare Commission. This was repeated in August 2006. The process was conducted in collaboration with Camden PCT.

Camidoc is not required to make a direct submission of this assessment to the Healthcare Commission.

In NHS trusts the board is required to assure itself of the state of the organisation's compliance with each of the standards. This means not only having a process but knowing that it works and is effective. In its self-assessment, Camidoc reports compliance to all standards but this assessment is limited to its own directly employed staff.

From this year PCTs are required to sign off the Core standards with regard to how they are met in commissioned services.

Camidoc have also introduced a system of clinical co-ordinators, 'a clinician working outside of the duty doctor rota who can take an over-view of the call list'⁵. They have also produced guidance on call prioritisation for call handlers and clinicians.

At present we do not accept that the Camidoc systems for clinical governance are adequate. This is in part rooted in the assumptions of both the provider and the commissioner that they have a mutually agreed understanding of the terms which they use and the processes which sit behind these. Yet when, for example, the question of an investigation was raised it clearly meant one thing to Camidoc and another to the commissioner. This in turn makes the monitoring of the contract extremely difficult.

Themes

It was impressed on us many times that Camidoc had been a small organisation, set up as a GP co-operative that had grown rapidly in a short space of time. Although to a patient a doctor from Camidoc comes from a single organisation, Camidoc still operates on the basis that the responsibility for the service lies with the individual GPs. There are no contracts between the GPs and Camidoc. Whilst this might have been appropriate in a small organisation where everyone knew one another it is not in a commercial company. The transition from being a GP co-op to being a healthcare organisation which offers a multiplicity of services such as support for community matrons, district nurse messaging, dental emergencies and supporting 'Choose and Book' has not been followed through with development of effective and appropriate systems and processes. This is most noticeable in the governance of the organisation.

Camidoc is in effect the employer of the doctors who provide services to it, yet it does not carry out any of the functions which might be expected of an employer such as clinical appraisal or clinical referencing of doctors. Rather it relies on the fact that GPs are on a Primary Medical Performers List. Whilst this is not unreasonable in itself, because Camidoc does not recognise its responsibilities as an employer it lacks many of the systems and processes which would allow it to rely on third party information. For example it relies on doctors telling them if they have changed from one PCT's list to another. We saw no evidence that it is was linked in to any PCT's systems for detecting and ameliorating clinical underperformance. Equally Camidoc does not formally monitor the number of shifts carried out by individuals. Whilst we recognise the experience and expertise of the Camidoc manager who runs the rota, it remains a system dependent on an individual and such systems are inevitably vulnerable.

The board members at Camidoc stressed their knowledge of their doctors and the out of hours work. We do not doubt their sincerity in this. In small organisations, like general practices, informal systems are still common but not always acceptable. It is reasonable (if not always accurate) to say in a small practice "we would know if there was a problem" but it is not reasonable for personal knowledge to be a substitute for a system in an organisation the size and complexity of Camidoc.

Camidoc's view was that their purpose was to support patients until they could see their usual GP.

The view of the four PCTs was they were meeting their obligation for the opted out practices by purchasing a telephone advice service, capacity for patients to be seen at a base (for example Whittington or St Pancras) and home visiting.

⁵ Specification for the role of clinical co-ordinator May 2006- Camidoc internal document

Whilst these views are not contradictory it should be remembered that Camidoc are actually providing this service for 115.5 hours per week which equates to 69% of the week. As well as removing the clarity of 24 hour responsibility, the new GMS contract introduced the concept of core hours, these being Monday to Friday 8.00-18.30 excluding bank holidays. At Easter 2005 Camidoc provided cover for 109.5 consecutive hours. The culture of keeping things going until morning comes is in our opinion not sustainable over such a prolonged period.

The opinion of the reviewers is that Camidoc has been dominated by the operational need to move on and do the next thing rather than vision and planned strategic development with the concomitant infrastructure considerations which this would require. Whilst we recognise that the NHS modernisation agenda is moving quickly it seemed to us that Camidoc relied on historical assessment of its worth, such as the accreditation process, rather than continuing to challenge itself, checking if it was fit for purpose and having clear systems to demonstrate this. For example we saw no evidence of an organisational strategy or a clinical governance plan. We found a rather inward looking culture which was not linked to developments in the outside world. An example of this can be found in the absence of any linkage of the assessment of medical records by the clinical governance group. Although there are many tools to assist in standard setting in this area, they were not used. The team felt that further evidence of the lack of overall vision was shown by the organisation's reliance on simply meeting the National Quality Requirements⁶ for the service. This misses the need to define what local service requirements might be for GPs and patients. We note that Camidoc carries out patient surveys and that these rate the service as generally very satisfactory.

It is the opinion of the reviewers that the failure to carry out an SUI investigation after Penny Campbell's death was rooted in the culture of Camidoc. The role of the coroner is distinct. An inquest is not a trial but a limited investigation. The role of the coroner is to find out who has died, and how, when and where they died⁷. The expectation that the inquest would follow shortly after Penny Campbell's death was in fact irrelevant as an SUI investigation is a totally separate thing. It adds to the distress of all concerned that the opportunity to investigate was lost when memories were fresh. From the evidence which we have seen there was no process for anyone at Camidoc to follow to investigate an SUI in March 2005. The Camidoc board had not defined an SUI nor had they ratified a process for investigation and escalation. There is no national definition of an SUI, instead the board of an organisation should define what they mean and what action needs to be taken to investigate via an SUI policy.

Our interviews have led us to conclude that Camidoc were waiting for the coroner's inquest to offer them information rather than assuring themselves of the strengths and weaknesses of their system. Believing that there was a need to wait for the coroner before investigating and being wrong footed by the delay is the only explanation the reviewers have been offered. To us this is another example of an inward facing culture as advice is readily available on the role of the coroner. It is possible that Camidoc were trying to avoid an accusation of double jeopardy by carrying out an internal investigation prior to that of the coroner. This would again be an incorrect understanding of the role of the coroner and the role of Camidoc as an organisation.

The absence of a robust SUI investigation meant that Camidoc was in a poor position to assist the coroner's inquest and the doctors involved were unsupported by the organisation. Even a rapid appraisal would have shown that there were major system problems, not only with a partially paper based system, which was acknowledged, but with the absence of key policies and procedures.

⁶ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137271

⁷ CORONERS RULES 1984, SI 1984 No 552 Rule 36

We saw little evidence of the sort of external scrutiny offered for example, in NHS trusts from non-executive directors. We acknowledge that Camidoc are planning significant changes to their structure. We also heard of the difficulties of getting GPs to engage with much of the corporate agenda and the perceived lack of enthusiasm for meetings. However, Camidoc needs to find ways to increase the engagement of a wider cross section of the GPs who provide it with service to ensure that there is less of a gap between the board and the general practitioners.

Part of the culture for Camidoc and the PCTs is a focus on delivering an access and unscheduled care agenda that is dependent on providing a range of services where GPs are involved. As many of these services have to be introduced rapidly and as the PCTs and the providers are known to one another it becomes easy and often effective to add things on to a contract without consideration of the risk involved or clarity about what systems are needed to sort things out should it all go wrong. The agreements and relationships between the PCT and the provider were often at the level of 'colleagues helping out' rather than at a more business orientated level. This has suited everyone as it is relatively convenient and cheap to provide services in this way. The development of the out of hours dental triage system would be an example of this.

Just as Camidoc has not developed sufficient robust infrastructure to ensure good governance, so the PCTs have not supported the commissioners of their out of hours service to provide the capacity and resource to ensure that they can devote the time to the detail of the work required. Out of hours is usually a part of a commissioner's work load in the same way that out of hours is part of a doctor's. Given the risks associated with this service and the greatly expanded role and time for which the service operates, PCTs need to consider how they can effectively monitor out of hours services contract for quality.

Recommendations

The PCTs contract with Camidoc to provide an out of hours service. No contracts exist between Camidoc and the doctors who provide the service.

A decision needs to be made on whether Camidoc are service providers or whether they act as introduction agents for GPs to provide service to the PCT. This has huge implications for the way in which the Camidoc and other out of hours services are run and for their costs. If the basic tests used by the Inland Revenue to identify whether or not a person is self employed applied to the doctors who work shifts at Camidoc, it is likely that they would be regarded as employees. An alternative approach to acting as an employer would be for Camidoc to act as a commissioner with each of the doctors who provide the service to patients on their behalf. The service could be specifically contracted and many of the issues around responsibility could be clarified.

Recommendations for Camidoc

There is insufficient segregation of duties for effective governance. Despite the executive board structure, the Chief Executive of Camidoc is in effect required to be chief operating officer, finance director, director of strategy, director of human resources and day to day clinical director. These functions need to be formally separated and reviewed to comply with the basics of good corporate governance. This should include a director of finance who holds a Consultative Committee of Accountancy Bodies qualification and a chief executive with a defined job description and clear accountability for the duty of quality of care.

There is little clarity around medical leadership and accountability and this should be reviewed immediately. Consideration should be given to appointing a medical director who could lead the development of a robust and professional clinical culture into the organisation.

Camidoc should consider commissioning an independent clinical risk assessment of its policies and processes to identify how it will manage the large areas of clinical risk identified in this review. Camidoc should consider how it would meet the standards expected of the NHS Litigation Authority's Clinical Negligence Scheme for trusts as a starting point to being able to provide assurance of their ability to meet the core standards declaration.

Camidoc must review its approach to Clinical Governance and work with the PCTs to bring its systems and processes into line with that of other providers in being able to demonstrate that it is fit for purpose and can demonstrate this in a formal manner. As a matter of urgency the Camidoc board should decide and agree with the commissioners a definition of a serious untoward incident.

Camidoc needs to be explicit in its description of how to investigate an SUI and clarify exactly who should do this. At present the lack of segregation of functions makes it difficult to do this effectively.

Camidoc should revisit their approach to complaints and consider again what a complaint is as well as their ability to investigate and respond directly to complainants.

Camidoc should invest time in clarifying their business and commercial objectives as a method of providing greater clarity about exactly what it is that can be expected of the service.

Recommendations for Commissioners

The four PCTs should adopt a lead commissioner approach to out of hours services and resource this jointly. The work should no longer be simply an add-on to a job. There has been some excellent work done in this area and this can be built upon. Commissioning PCTs should recognise the role of the out of hours service and the part it plays in the total care of their populations. We believe that even with effective benchmarking and tighter commissioning it is likely that the costs for providing, commissioning and monitoring the service are likely to rise if quality systems are to be brought in line with the best levels in the NHS, this will require clear financial planning on all parts.

The lead commissioner should ensure that Camidoc links to a PCT and adopts performance procedures that will promote patient safety, such as more robust credentialing and linkage in appraisal systems. The lead commissioner needs to identify how the out of hours provider is meeting the standards for better health.

PCTs should ensure that commissioners are aware of any concerns that reach them about a service provided by a non NHS body, whatever the route. The segregation by organisation in the NHS complaints procedure is no reason not to carry out a joint investigation. Equally within NHS organisations any information about a serious concern should be shared with the commissioner of the service.

PCTs should have an explicit procedure agreed with their out of hours providers whether they are opted in or opted out on how an SUI should be investigated and how information is shared when an investigation is in progress.

Medical directors and directors of primary care should ensure that each of the doctors involved in this incident attends an interview with them to discuss this report and its findings to ensure that any concerns and outstanding issues are addressed. This has been a stressful process.

Recommendations for each of the doctors

Each of the doctors should seek a meeting with the medical director or director of primary care of the PCT to discuss the findings of this report. We acknowledge that the process that

they have gone through has been stressful and they should be offered an opportunity to discuss any concerns and for any outstanding issues to be addressed.

Recommendations for the wider NHS

We believe that all out of hours providers and commissioners should read this report and learn the lessons identified here. Many of the issues raised are of national significance.

The perception of the out of hours service as a 'holding bay' until the patient's GP resumes care needs to be addressed. The profile of the out of hours service needs to be raised nationally and the professional reputation of doctors working for the service should be recognised. Provision of out of hours care is now much broader than it was seven years ago when the Carson Report led to the recommendations for change. It may no longer be reasonable to assume that because a doctor is equipped to work in general practice, she or he is automatically able to undertake out of hours care.

Equally it may no longer be sufficient to assume that Monday to Friday 8am until 6.30pm are the hours when a GP service with continuity of care is offered.

The NAO report on out of hours care pointed out the policy confusion caused by the lack of clarity between urgent care and unscheduled care:

Many providers and commissioners told us that there was ongoing confusion about whether out-of-hours was supposed to be an urgent or unscheduled care service, and that the difference was not merely linguistic.

A truly urgent primary care service would likely treat patients classified as either 'emergency' or 'urgent' and all others would be asked to make an appointment to see a GP in hours the next working day. Demand would be cut and providers could focus on meeting Quality Requirements for patients requiring advice or care within short time frames. An unscheduled care service, however, would be more responsive to patients and would not seek to restrict access, no matter how minor the injury or illness. Since access would be unrestricted, this service could be more costly, but might provide more flexibility for patients and could interact better with existing daytime primary care services by allowing continuity of care.

Commissioners and providers would like the Department to decide which kind of service they should provide, as they feel that currently they are providing a hybrid model, with resulting confusion for commissioners, providers and patients.

There is no doubt in our minds that Penny Campbell required unscheduled care.