Anu Miah – re Death investigation

TOWER HAMLETS PRIMARY CARE NHS TRUST
EAST LONDON AND THE CITY MENTAL HEALTH NHS TRUST
LONDON AMBULANCE SERVICE NHS TRUST

Clozapine

REPORT OF THE JOINT INVESTIGATION INTO THE DEATH OF ANU MIAH ON THE 4 SEPTEMBER 2003

(Serious Untoward Incident Inquiry)

Final Report
November 2004

Pemmel House, Stepney

ACKNOWLEDGEMENTS

TO THE FAMILY OF ANU MIAH

The panel would like to thank the family of Anu Miah for their co-operation and patience during the work of the investigation panel. In particular the panel would like to acknowledge their tolerance in the time it has taken to complete the piece of work. Due to the complexity of the issues that emerged the work took longer than originally anticipated. The panel hopes that the family will accept this as an indication of the thoroughness of the investigation.

The panel would like to record its sympathy and condolences at the sudden, unexpected and very sad loss of Anu Miah as a member of their family. We know that his loss can never be replaced but hope this report will go some way in helping them to understand what happened and why their loved one died.

TO OTHER CONTRIBUTORS

The panel would also like to acknowledge the additional help and advice given by the following contributors. The panel is grateful for their contributions and the expertise they contributed in the course of the investigation:

The family of Anu Miah and particularly:
Anwara Begum, Anu Miah's mother
Moymona Begum, Anu Miah's sister

Khasruz Zaman, PALS Officer, THPCT

Dr Ben Essex, Consultant in Primary Care Medicine

Dr Stephen Wright, Consultant in Primary Care Medicine

Dr Pritchard, Forensic Handwriting Expert

Dr Baithun, Coroner's Pathologist

Dr Sonia Payne, Medical Director, Novartis

Dr H Patel, Consultant Medical Adviser, Novartis

Dr J M Raine, Committee on Safety of Medicines

General Medical Council

Medicines Control Agency

Rachel Stevens, Pharmacy Technician

Professor of Surgery, Barts and the London Trust

Dr Fiona Moore, Medical Director, London Ambulance Service

Ralph Morris, Assistant Chief Ambulance Officer, LAS

THANKS TO STAFF

The panel would also like to offer their thanks to members of staff involved in this incident for their help and co-operation with the investigation. Events such as these are traumatic for the staff involved. It is recognised that most people working in the NHS (and particularly areas such as East London) are very committed to their work and want to ensure that patients receive the best possible care available within their resources. It is, therefore, important that investigations into adverse incidents and events are thoroughly investigated so that the NHS and the individual staff members can learn and improve services and practice as a result. This investigation is intended to achieve that end and the panel would like to acknowledge the contribution the staff involved have made to this report through their co-operation and contributions.

THANKS TO THE PANEL

Christine Carter, former Chief Executive of Tower Hamlets Primary Care Trust and Chair of the SUI Investigation Panel would like to thank the members of the panel for their work and commitment to this investigation. Panel members were exemplary in pursuing their enquiries and ensuring the investigation was thorough and that as much expertise and intelligence as possible has been sought. The panel members were:

Christine Carter (Chair)	*former Chief Executive, Tower Hamlets Primary Care Trust*
Dr Douglas Russell	*Medical Director, Tower Hamlets Primary Care Trust*
Ala Uddin	*Non Executive Director, Tower Hamlets Primary Care Trust*
David Whitmore	*Medical Directorate, London Ambulance Service Trust*
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Thanks also to Julie Dublin, Personal Assistant to Christine Carter, for the administrative support she gave to the panel.

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1. INTRODUCTION AND BACKGROUND

1.1. Anu Miah, a 23-year-old man died suddenly and unexpectedly on 4 September 2003 shortly after 4 pm. This summary of the death of Anu Miah is drawn from information obtained from the relatives of Anu Miah and the initial individual investigations carried out by Tower Hamlets Primary Care Trust and the London Ambulance Service. It is written as a narrative introduction to the Investigation Report in order to provide some context and scene setting. This section is intended to provide a factual summary of events on the day of the death of Anu Miah. The subsequent sections of the report will further investigate the details of events preceding, during and following the death, together with the findings, conclusions and recommendations of the Investigation Panel.

Immediate history

1.2. Anu Miah was a 23-year-old man of Bangladeshi origin, brought up and educated in Britain and living in Tower Hamlets. He had been married for just six months prior to his untimely, sudden death. For three years Anu had been under the care of the East London and the City Mental Health Trust and treated for mental illness (schizophrenia). He lived in community residential housing with warden support. Sometimes he stayed at his mother's home in a block of flats in Stepney Way E1 with other members of his immediate family (including his wife). Since 1 September (three days preceding his death) he had stayed with his mother.

The morning of the 4 September

1.3. According to his mother, Anu had been very constipated for three days prior to his death. At 4 am on 4 September Anu woke his wife up and complained of severe abdominal pain. She made him some rice pudding but the pain became much worse. It was a colicky pain, which came and went. At times it was so severe he screamed with pain.

1.4. At 9.15 am Anu vomited. His mother said the foul smell of the vomit was quite different from normal sickness. It was difficult to describe the smell but it was abnormal. His sister drove Anu, together with his mother and wife, to their General Practitioner's surgery. In the car he was shaking severely and was holding his stomach, as the pain was so bad.

Consultation with the General Practitioner (GP)

1.5. Anu Miah's regular GP, a partner in the practice, was fully booked that morning with appointments. Anu was given an appointment to see another doctor, a locum GP with the practice. The mother of Anu Miah reported that when they entered the consulting room Anu went to lie down on the examination couch. The locum GP speaks Bengali so there was no language difficulty during the consultation. (For the record, Anu was known to speak good English, as he was educated in this country but his mother who attended the consultation with him does not speak English; therefore the locum GP's ability to speak Bengali ensured no language difficulties for all present). Anu's mother was asked to get the patient's records from reception – which she did.

1.6. The locum GP asked Anu's mother about his medication and she told him he was treated by the mental health team who prescribed his drugs and did regular blood

tests. The locum GP then went with Anu's mother to ask his regular GP to confirm Anu was his patient and to clarify any medication he was taking. Anu's regular GP confirmed that Anu was his patient and advised the locum GP to telephone his consultant in the Mental Health Trust to find out about medication before prescribing further treatment for him.

1.7. The locum GP, accompanied by Anu's mother, returned to Anu in his consulting room and examined him. There is a dispute between the family and the locum GP about the thoroughness of the examination carried out. Anu's mother expressed concern about the absence of a thorough examination (she indicated that there was no abdominal palpation, use of stethoscope, taking of the blood pressure or pulse). Anu's mother reported that at one point during the consultation Anu was crying with the pain.

1.8. The locum GP then prescribed four drugs for Anu, including an antacid, a painkiller and an antibiotic. Anu's mother expressed concern about the absence of a thorough examination and the treatment prescribed. She was also worried about the psychiatric medication and the fact that the locum GP had not followed the advice of Anu's regular doctor and telephoned to check with the consultant psychiatrist before prescribing further medication.

1.9. The locum GP concluded the consultation by advising that if there was no improvement with the treatment then Anu should be taken to hospital. There was no indication of what to do if the pain, vomiting or constipation persisted within a specific period of time.

Following the consultation with the General Practitioner

1.10. Anu's mother reported that following the consultation with the locum GP they went to the chemist to collect the medication prescribed and Anu took some of it whilst in the chemist shop. They then walked to his residential accommodation to tell the staff that Anu would be staying with his mother and also collected his mental health medication. On the return journey Anu had episodes of severe abdominal pain forcing him to sit on the ground until the pain passed. This continued all the way back to his mother's home.

1.11. When he arrived back at his mother's home, Anu tried to have a bath with the help of his wife and mother. He was unable to do much for himself at this point. His mother thought he was very hot and shaking with a fever. She tried to cool him by bathing his forehead with cool water. He lay on the bed but appeared to deteriorate. His mother suggested that the staff at the residential housing unit might be asked to take Anu to hospital as they might get a higher priority. Anu called the unit to ask for help but was told he would have to go there for them to help. At this stage Anu was unable to get up to get dressed, even with the help of his wife and mother.

1.12. An uncle then arrived and saw how ill Anu was. At 3.25 pm (according to the family) an ambulance was called.

Attendance by the Ambulance Service

1.13. According to the records of the London Ambulance Service NHS Trust (LAS), at 15.36 the Central Ambulance Control (CAC) received a '999' emergency call. The call was categorised as 'Red 3' by the Advanced Medical Priority Dispatch System (AMPDS), requiring an eight-minute response. Again according to the LAS records, an ambulance was despatched from E2 postcode at 15.39 and arrived on scene at 15.43 (within four minutes of despatch).

1.14. A Rapid Response Unit (RRU) arrived on scene at 15.42. The LAS record shows that the RRU arrived on scene first, closely followed by the ambulance crew.

The family's report of events

1.15. The family reported that ten minutes after the 999 telephone call, an ambulance arrived with two men and also a separate car arrived with one man carrying a large bag. By this stage, according to the family, Anu could not even talk. The family reported that the ambulance crew asked if Anu had seen the GP and had been given any medication. The family told the crew what had been prescribed by the GP. According to the family, the ambulance crew indicated that 'this was correct and that going to hospital would be a waste of time as they would just give him the same medication'. He had to 'wait 24 hours to give the medicine a chance'. Again, according to the family, no physical examination was carried out and the 'man with the bag' then left.

1.16. At this point, Anu's younger brother arrived home from school. According to his account, he heard Anu screaming in pain and went upstairs to see the ambulance crew in the room. He asked what was wrong and was told that they did not know but that his brother was not co-operating with them. Again, according to the family, by the time the ambulance crew took the decision to take him to hospital, they also insisted that he got dressed and suggested he did not need a chair saying that he was 23 and looked fit and could walk to the ambulance. The family reported that at this stage, Anu could no longer speak and could not sit up or dress himself. The family was asked to dress him and help him stand. The family tried to do this but Anu collapsed back onto the bed. The ambulance crew then helped him but as soon as they let him go, Anu fell to his knees on the floor. Apparently Anu was now foaming at the mouth, according to his family's report of the events. The ambulance crew then decided to get a chair for Anu and his uncle and brother helped him into the chair. Anu was then taken to the ambulance. He was accompanied by his brother and mother, who were asked to wait outside the ambulance for a minute. This turned into four minutes according to the family and when the doors were opened to them they noticed that a 'heart monitor' had been set up. During the journey to the Royal London Hospital, Whitechapel (just a very short distance away) Anu's brother noticed that the normal heart trace suddenly became a straight line and he 'knew his brother had died'.

The Ambulance Service report of events

1.17. The incident summary prepared by the LAS records that on arrival, the ambulance crew and the Rapid Response Unit (RRU) driver had been given the information from Central Ambulance Control 'the patient was a 24 year old suffering from abdominal pain and difficulty in breathing.

1.18. The LAS reported that "The RRU entered the patient's room and assessed the patient. The patient had a Glasgow Coma Score of 15, was well perfused with no difficulty with his breathing and appeared uncomfortable. The RRU driver was shown the Ciprofloxin tablets that a GP had given the patient that morning. The ambulance crew arrived and the RRU gave a brief handover to the crew, ensured the crew were happy to deal and left the scene. The ambulance crew carried the patient down the internal stairs and down two flights of external stairs. Once in the back of the ambulance, the patient went into Pulseless Electrical Activity (PEA). The ambulance crew commenced Cardio Pulmonary Resuscitation, pre-alerted the Royal London Hospital at 16.09 and arrived at Accident and Emergency at 16.11, 28 minutes after arriving at the scene".

On arrival at The Royal London Hospital Accident and Emergency Department

1.19. On arrival at the Accident and Emergency department resuscitation attempts were continued but Anu Miah was finally declared to be dead at approximately 16.30.

1.20. His death was referred to the Poplar Coroner. A Coroner's post mortem was carried out. The post mortem report showed that the cause of death was 'natural causes'. The large bowel was found to have impacted faeces, with the small bowel distended with an area of gangrenous bowel and some intra-luminal haemorrhage. This finding implies that there was no frank perforation of the bowel and thus no peritonitis.

1.21. The 'Certified Copy of an Entry Pursuant to the Births and Deaths Registration Act 1953' states that the cause of death of Anu Miah was:

(a) Ischaemic bowel
(b) Impacted faeces

3.9. The report of the outcome of the investigation into the complaint details a large number of discrepancies between the version of events related by the family and that related by the ambulance crew and RRU (Rapid Response Unit). The report also states that the crew was on the scene for a total of 26 minutes and in hospital 2 minutes later, thus the patient was in hospital within 35 minutes of the original call.

3.10. Dr Fiona Moore, Medical Director for LAS, stated that, in her opinion, time was not wasted on scene or that the actions of the crew contributed to the sudden deterioration of the patient. She also stated as questionable as to whether a more rapid removal would have even been possible considering the location of the patient.

3.11. The recommendations of the investigation were as follows:

- **Recommendation for Ambulance Attendant**: Meeting with Sector Trainer to discuss correct completion of Patient Report Forms.
- **Recommendation for Ambulance Driver**: No further action to be taken.
- **Recommendation for Rapid Response Crew**: No further action to be taken.
- **Recommendation for the London Ambulance Service NHS Trust:** Full co-operation with the interagency panel in their investigation and report.

3.12. The SUI panel acknowledged the thoroughness of the investigation in terms of scrutinising the time lines relating to attendance at the scene and despatch of the patient to hospital, scrutiny of the available documentation and the detailed statements taken from the ambulance service staff involved in the incident. However, the panel was concerned that the report mainly described the differing versions of events and made no attempt to investigate why there might be these differences or whether there was corroborating evidence to support the versions.

3.13. In addition, whilst the report focused on the time lines associated with the incident, there does not appear to have been any scrutiny of the actual practice of the LAS staff relating to the management of the patient at the scene. The SUI investigation panel therefore felt the complaint investigation was not entirely conclusive and there were a number of additional unresolved questions requiring further scrutiny that needed to be explored as part of the SUI investigation.

Relating to the Mental Health Trust

3.14. The untimely death of Anu Miah was not initially identified as a serious or unexpected incident by the East London and the City Mental Health Trust (ELCMHT) and the Trust did not, therefore, initially declare it a Serious Untoward Incident. When the PCT identified that this was an avoidable death the ELCMHT agreed this to be the case and unequivocally agreed that the death should be investigated under the auspices of a Serious Untoward Incident. The Trust gave its full support to the work of the panel, which included the full involvement of the Medial Director and the Pharmacy Adviser – both of whom were panel members.

3.15. In addition the initial concerns raised by the family of Anu Miah related to the treatment he received from the GP and the Ambulance Service on the day of his death. Their feeling being that if both of these agencies had acted differently then Anu Miah would not have died. This meant that the ELCMHT received no complaints from the family. This together with the fact that they had not identified the death to be a SUI meant that no investigation was carried out immediately following the death or prior to the establishment of the SUI panel.

3.16. The panel initiated its investigation into the ELCMHT management of Anu Miah by carrying out the following:

- Secured the medical and CMHT (Community Mental Health Team) records of the patient
- Reviewed the medical and CMHT records
- Developed a summary chronology of the management of Anu Miah from the Clinical Notes
- Interviewed the consultant psychiatrist responsible for the care and treatment of Anu Miah.

Use of clozapine in patients with Schizophrenia

3.17. The panel reviewed a number of documents related to the use of clozapine. This included information on implementing NICE guidance, information from the manufacturers on prescribing and monitoring patients, literature for patient's and professionals and information contained in the British National Formulary (BNF), the medical practitioner's reference book for prescribing information.

3.18. The panel also looked into the side effects of clozapine under the following categories:

- those that are well recognized
- those that are less well recognized or about which there is less evidence

3.19. The Investigating Panel sought additional information from the Committee on Safety of Medicines regarding any adverse effects associated with clozapine. The panel was sent a print out listing all suspected adverse reactions reported to the Committee previously. This was in response to the Investigating Panel submitting to the Committee a suspected adverse drug reaction report. *(The Committee on Safety of Medicines has requested any additional information that may become available as a consequence of the inquiry report)*

Information from the pathologist who carried out the post mortem

3.20. The post mortem report stated that death was due to 'natural causes' – impacted faeces, ischaemic bowel with an area of gangrenous bowel. Dr Douglas Russell subsequently interviewed the pathologist who carried out the post mortem to try to gain more insight into the possible underlying causes of death.

3.21. The pathologist noted that the lungs were very congested, indicative of toxic shock and cardio-vascular shut down. The overall picture is one not uncommon in frail, bed-ridden older people, but is very unusual in a young man.

3.22. The build up of impacted faeces resulted in the bowel swelling (distension), leading to a reduction in the blood supply (ischaemia). As the bowel and other organs require blood to function, the reduced supply would lead to tissue death; the decaying dead tissue causing gangrene. This infection would then result in severe blood poisoning (toxic shock), overwhelming the body's defence systems and causing the heart and other organs to shut down.

4. FINDINGS OF THE INVESTIGATION PANEL

4.1. This section of the report summarises the panel's findings relating to the different elements of the investigation inquiry. It takes into account information and evidence gathered as part of investigations carried out by the individual agencies, as well as that gathered as part of the additional investigations carried out by the SUI investigation panel.

Relating to the Role and Actions of General Practice

4.2. The findings of the investigation panel in relation to the role and actions of General Practice in the management of the care and treatment of Anu Miah are considered as relating specifically to the practice of the locum GP.

4.3. Overall the panel expressed grave concerns about the standard and quality of the primary care consultation provided to Anu Miah by the locum GP on 4 September. It was felt that the care and treatment provided by this locum GP fell very short of what would have been expected as minimum good practice.

4.4. The panel in particular highlighted the failure to consider Anu Miah's psychiatric history and failure to carry out an appropriate examination and clinical assessment. The panel also expressed grave concern that the locum GP prescribed symptomatic treatment without properly diagnosing the underlying cause of the patient's symptoms, and provided minimal follow up advice.

4.5. As has already been noted, there was a difference of opinion between the family of Anu Miah and the locum GP as to whether the consultation on the morning of 4 September included the recording of the pulse and blood pressure. Dr Ben Essex's scrutiny of the notes suggested a possible irregularity in the recording of pulse and blood pressure in the notes (that the observations had been entered subsequent to the rest of the written record). The panel, therefore, decided to undertake a forensic examination of the record and to seek an expert opinion as to whether all of the record of the consultation, including the recording of the blood pressure and pulse readings had been entered contemporaneously in the record.

4.6. The forensic report indicated that entries had been made at different times into the record; that specifically the blood pressure and pulse readings had been entered at a different time from the rest of the text. But the examiner was not able to say what the time difference may have been between the entries. The panel found this to be totally unacceptable practice and constituted falsifying a record entry.

4.7. Since registering her complaint about the locum GP with the practice, Ms Begum did not get a satisfactory response. The acting Practice Manager suggested that perhaps a meeting with her brother's regular GP, one of the partners, could sort things out. Ms Begum did not accept this offer of a meeting. Subsequently the partner telephoned the family and spoke with Ms Begum. He described the side effects of clozapine (one of the drugs prescribed for Anu Miah's psychiatric condition) and wanted to deliver a leaflet about the drug to Ms Begum. Ms Begum by this time had made contact with PALS and indicated to the doctor that she would only allow him to meet with her if she were accompanied by a PALS officer. The doctor refused this arrangement and declined to meet with the family.

Relating to the Role and Actions of the Ambulance Service

4.8. As has been stated in paragraph 3.14 of this report, the SUI investigation panel thoroughly examined the practice of the Ambulance Crew and the Rapid Response Unit (RRU) man and was left with some unresolved concerns about their management of the patient at the scene prior to his movement to the ambulance.

4.9. In scrutinising the supporting evidence relating to the response rates of the ambulance service, the panel did not dispute the time lines as detailed in the LAS investigation report and accepted the times given as fact and consistent with the response time standards set by the service.

4.10. From the evidence presented, it appeared to the panel that the RRU man and the ambulance crew arrived within one minute of each other. The RRU man, according to his statement was the first on the scene, with the ambulance crew following close behind. The panel noted that the RRU man (from his own account) was with the patient for no more than six minutes within which time he carried out an assessment of the patient, took a brief history from Anu Miah himself, did an abdominal examination, asked some questions of the family regarding medication and handed over to the ambulance crew. The panel was however concerned that after responding to a Red 3 priority call, it appeared that the RRU crew member very quickly came to the conclusion that there was no real emergency to be dealt with and left the scene. The panel noted that in any emergency situation it is normal London Ambulance procedure for the RRU to handover to the ambulance crew and leave the scene.

4.11. The panel found that it had a number of overall concerns about the quality of the clinical assessment carried out by the RRU crew and ambulance crew, summarised within the conclusions in the next section of this report.

4.12. Although the timescales recorded suggest the patient was despatched to hospital within 35 minutes of the original call, the panel was concerned that there were delays associated with a lack of sensitivity to the condition of the patient. The panel noted, however, that once the patient collapsed in the ambulance and was without a pulse then the crew acted with all haste and the actions taken albeit unsuccessful were consistent with good practice in such a situation.

4.13. The panel, in deliberating its findings, considered the family's accusation of *discrimination/racism and total lack of compassion'*. The panel has already commented on its concerns around the assessment and management of Anu Miah by the RRU and ambulance crew. The panel did have some concerns that there did appear to be a lack of understanding in relation to dealing with people from different cultural and linguistic backgrounds. In addition the panel found that some comments made by the crew did suggest somewhat 'value judgement' statements and a lack of sensitivity. For example:
……the patient appeared to be either unwilling or unable to communicate effectively with me.' As referenced in the LAS report
' The patient was now murmuring but still had no apparent difficulty with his breathing and was not sweaty or hot to touch. When we got to the ambulance, the patient was now unresponsive and we asked relatives to wait outside.' As referenced in the LAS report.
'When I spoke to the patient he made eye contact with me, but did not respond verbally.' As referenced in the LAS report.

4.14. *'We had some difficulties getting a history, partly due to a language barrier, but also that no one seemed to want to answer us particularly.'* As referenced in the LAS report.

4.15. It is acknowledged that the above quotations are drawn from broader statements but they are not particularly taken out of context. It was felt that some of the comments seemed to suggest a view that the family and patient were not co-operative and gave the panel some cause for concern regarding the attitude taken towards this young man's serious condition. It was felt that the emphasis on *'language barrier'*, perceived unwillingness on the part of the family to give information, the fact that none of the family could tell the crew why the patient had been given antibiotics, (when they did not know themselves) seem to have influenced the crew's judgements in relation to the seriousness of the illness and taken precedence over carrying out a more thorough clinical examination of the patient.

4.16. The panel was concerned, as was the LAS, on speaking with members of the family, representatives of the local Bangladeshi community and others with experience in Tower Hamlets, to find such a strong perception of racism in the LAS within the ethnic minority community. This was based upon previous experiences and the death of Nasima Begum in 1994, which was cited as an example. The Wells report found that operational issues relating to inadequate numbers of ambulances and inadequate staffing levels caused delays which affected a number of patients including Nasima Begum, who lived in the same area. The perception of racism persists despite this case being 10 years old and the findings of the report reflecting operational failures rather than issues of racism.

4.17. From the statements given by the crew and family it does appear that information regarding Anu Miah's mental health background was not available until he was being carried down the stairs to the ambulance. The panel could find no evidence of this having affected the clinical assessment and treatment.

4.18. The post mortem confirmed the death of Anu Miah as being the result of impacted faeces and ischaemic bowel with gangrenous areas. This would have led to an absence of bowel sounds (the ambulance crew would not have been expected to identify this) and a 'tense' abdomen. Had the examination of the abdomen (the site of the acute pain) been more than cursory by both the RRU crew and the ambulance crew, this might have led them to identifying more serious clinical symptoms than they appear to have done with their limited physical examination of the patient.

4.19. In addition, the findings of the post mortem led the pathologist to be of the view that at the time the ambulance crew were with Anu Miah, such was his condition, that he would have been presenting at this stage (so near to his death) with a bradycardia (slow pulse). The pulse of 72 reported by the RRU crew is within normal average range for a healthy man of 23 (normal pulse being between 60 and 80 beats per minute). The panel found it difficult to reconcile these two positions.

4.20. In summary the panel found that the Ambulance service did not understand the severity of Anu Miah's illness, which led to delays in moving Anu to the ambulance. In addition, the panel had concerns about the attitude of the ambulance crew to Anu and his family.

4.21. The panel recognised from its investigation, scrutiny of testimonies by the crew and the reports from the investigating officers on the SUI panel, that the ambulance crew were very upset and shocked by the sudden death of Anu Miah and expressed their sorrow and sympathy to the family. The panel was encouraged to find that counselling and support services had been made available to the staff. The panel is keen to ensure that any findings and recommendations from this report will enable learning rather than blame.

4.22. The panel, in the course of its enquiry, became very aware of the difference in perception between members of the public and the LAS regarding the level of competencies to be expected from LAS ambulance staff. In scrutinising the practice of the LAS staff member, the panel was grateful for the advice of Bartholomew Wood and David Whitmore (both LAS officers). It was important to remember that the clinical skills and competencies of ambulance staff are not those of doctors and it was, therefore, important not to expect immediate diagnosis and treatment. The panel tried to ensure that scrutiny of their practice was consistent with agreed policies and practices. It is to the credit of the LAS that the public has such high expectations of the competencies of its staff. This is largely due to the fact that this is, by and large, a high performing, competent service in which the public generally has great confidence. This, no doubt, accounts for the very high expectation the public has about how the service will respond to any emergency situation.

Relating to the Role and Actions of the Mental Health Service

4.23. As previously mentioned in this report, the East London and the City Mental Health Trust (ELCMHT) was not the subject of any complaint by the family of Anu Miah following his death. They were, therefore, not immediately alerted to his death and did not carry out any internal investigation. Once the Trust did know about the death, it still did not initiate any investigation as to whether or not his use of mental health services had any impact on his death.

4.24. The panel was surprised to find that the ELCMHT had not identified this as an incident worthy of further investigation. It was only when it was declared a SUI by the PCT that ELCMHT became involved in investigating their role in the care and treatment of Anu Miah. This is significant as it suggests that deaths resulting from medication related conditions may go unrecorded and therefore opportunities to learn from these incidents lost.

4.25. Overall, the panel found the diagnosis, treatment and management of Anu Miah by ELCMHT reflected very good practice. The panel was impressed by its findings in that the patient was well managed, received good support from all elements of the service and was achieving good outcomes from his treatment in that he was rehabilitating back into mainstream living.

4.26. The panel was impressed also by the overall engagement of the multidisciplinary Community Mental Health Team (CMHT) in the care and treatment of Anu Miah. There was evidence of good communications between the consultant and other members of the CMHT through regular review and discussion of the case. Anu Miah had been in regular contact with the CMHT, which reviewed his mental health and established links with the supported residential accommodation in which he was living.

4.27. The panel found that there were good systems in place for primary care to get in touch with the consultant if advice and help was needed but as previously mentioned, on the day of Anu Miah's death this was not taken advantage of.

4.28. The panel also found evidence of good practice in keeping primary care informed and updated on the reviews and Care Programme Approach for the patient. Evidence of this was found in the GP records and also evidenced by the fact that his regular GP appeared to have a reasonable recollection and working knowledge that Anu Miah was a patient of a named consultant psychiatrist and known to be on medication.

4.29. The panel was concerned however, that despite the frequent contact between Anu Miah and the multidisciplinary team, no concerns were identified around his physical well-being.

4.30. The panel found poor mechanisms in place in ELCMHT for monitoring the short and longer-term physical health of patients. In addition there appeared to be a lack of awareness or understanding of the physical risks associated with the use of clozapine (other than those associated with neutropenia – low levels of a particular type of white blood cell).

4.31. The panel discovered that best practice suggests that the monitoring of patients on clozapine is best achieved through the establishment of a dedicated 'Clozapine Clinic'. The panel was concerned to find that although the PCT had commissioned the provision of a Clozapine Clinic and provided the necessary funding for it some two years prior to this investigation, ELCMHT had failed to set such a clinic up. The panel felt that it was a missed opportunity to develop the service and establish a model of good practice for patients using clozapine.

4.32. However, in considering the function of a Clozapine Clinic and its priority for monitoring the white blood cell count, the panel recognised that, even if such a clinic had been in place, it would not have picked up the side effects of clozapine that appear to have contributed to the death of Anu Miah. These clinics as currently practised monitor the white blood count of patients on clozapine; they do not currently monitor gastrointestinal symptoms such as constipation, which in rare cases has been implicated with fatalilty. The panel found that very little emphasis appears to have been placed (or is placed on) the side effects of clozapine other than the impact on the white blood cell count.

4.33. The panel found that whilst there was a variety of information sources available, common with each of these sources was the observation that information on the potential side effects (other than those affecting the blood) is largely 'buried' in the leaflets. In addition, the panel felt concerned that whilst reference was made to constipation, it made no reference to the consequences of ignoring the symptom or what to do if the symptom persisted. There is nothing to suggest that medical help should be sought if the symptoms persist.

4.34. The panel felt that a significant factor in the death of Anu Miah was that the patient, his carers, other healthcare professionals and the GP had not considered his prolonged constipation to be of any significance, nor did they proactively link it to his medication. Most importantly of all no one seemed to be aware of the

consequences of the constipation being untreated and persisting to the point of the development of impacted faeces and an ischaemic bowel.

4.35. The panel found that the number of patients registered since 1989 as users of clozapine is 36,000. The number of deaths of patients whilst taking clozapine and recorded as being associated with gastro-intestinal disorders is 15. That equates to approximately 1:2400. It is possible that there may have been others not known about because the cause of death may have been attributed to some other primary cause. However, the panel was concerned to find that as many as 1:2400 known deaths were attributed to gastro-intestinal disorders. It posed questions for the panel that warranted further research into causes of deaths of users of clozapine.

About the use of clozapine and related information available for patients and healthcare professionals

4.36. The panel reviewed a range of information, with the focus on identifying information on possible side effects, including patient information that would have been given to Anu Miah on at least one occasion.

4.37. The panel, in the light of the death of Anu Miah and its cause, found that the references to constipation in the literature were not given as much prominence as the effects the drug might have on the heart and the blood. Clearly this is likely to be related to the absence of any substantial body of evidence that is currently available relating to the reports of unexplained deaths. The panel felt that, in the light of the death of Anu Miah, there might be further exploration of any recurring causes of unexplained deaths reported in patients taking clozapine.

4.38. The panel was concerned that the presentation of the information would not lead the user, a carer or even a healthcare professional to be more alert to the problems of ongoing constipation.

British National Formulary (BNF)

4.39. The British National Formulary (BNF) is published jointly by the British Medical Association and the Royal Pharmaceutical Society of Great Britain; it is revised every six months, in March and September. Novartis Pharmaceuticals UK Ltd (the manufacturers of clozapine) wrote to the editor of the BNF on 9 April 2001 highlighting updates to the summary of product characteristics (SPC) for Clozaril (clozapine), including the statement "CLOZARIL can cause varying degrees of impairment of intestinal peristalsis.....On rare occasions these cases have been fatal". The current edition of the BNF (47, March 2004) does draw attention to the possibility of gastro-intestinal obstruction under "Cautions" and "Side effects"; however, it does not indicate that this has been fatal in some cases, neither does it give the same degree of emphasis to gastro-intestinal obstruction as it does to possible effects on the blood and heart.

Committee on Safety of Medicines

4.40. The Committee on Safety of Medicines were contacted by the investigation. They replied on 29 October 2003, enclosing a Drug Analysis Print (DAP) listing all spontaneously reported reactions on the Adverse Drug Reaction Online Information Tracking database (ADROIT) associated with clozapine. The panel found that there had been 10,491 adverse reaction reports, of which 368 had involved death. The panel found that there had been 1,909 adverse reactions related to haemopoietic disorders (to do with the formation of blood cells) but of those, 3 had been fatal. The panel found that there had been 1,040 adverse reactions reported relating to the gastro-intestinal system, of which 26 had been fatal, and 1,779 adverse reactions relating to the cardiovascular system (the heart), of which 166 had been fatal. The panel found that the Committee on Safety of Medicines had drawn the attention of prescribers to the cardiovascular risks of clozapine in their Bulletin "Current Problems in Pharmacovigilance", volume 28, October 2002. Having taken into account the fact that deaths might well be co-incidental in many of the adverse reaction cases reported, the panel was surprised that no advice from the CSM had been issued in relation to gastro-intestinal side effects.

Relating to the Post Mortem and following

4.41. The panel was both surprised and concerned to find that the unexpected death of a young man of 23 attracted so little attention in relation to the post mortem findings. Although ischaemic bowel and impacted faces are legitimately classified as 'natural causes', death from these symptoms is not an expected or natural scenario for a relatively physically healthy young man of 23 years.

4.42. The panel noted that the post mortem report was very brief, no tissues were retained for toxicology and no inquest was declared.

4.43. No one involved in his care raised any real concern about his sudden and unexpected death – not even to ask why he had such impacted faeces to cause an ischaemic bowel and subsequent death. No individual in any of the agencies involved appeared to recognise this as a potential SUI.

4.44. The panel was left wondering in what circumstances would the sudden and unexpected death of a young man generate an inquest? Whilst his death did not meet the accepted criteria for an inquest, neither did it really seem to sit comfortably with the notion of 'natural causes' – and thereby no further investigation required. This combination of circumstances in a young man was unusual.

4.45. The panel sought the view of Dr Baithun, who was the pathologist who carried out the post mortem on behalf of the coroner and who issued the death certificate. It was his opinion that the obstruction had been building up slowly, with gross faecal impaction that must have been accumulating over weeks. It was the view of Dr Baithun that the patient may well have presented atypically because of:

- the very slow accumulation and distension of the bowel
- the evidence suggests that patients with schizophrenia appear to have an altered (reduced) perception of physical pain and altered emotional and physiological response to pain.

Furthermore, the pathologist felt that even if the patient had presented to accident and emergency earlier on 4 September 2003, the chance of survival would have been very low, as the bowel was already non-viable. The terminal event would most likely have been electrolyte disturbance with a toxic shock syndrome developing in the last few minutes of life.

5. CONCLUSIONS OF THE INVESTIGATION PANEL

General conclusions

5.1. The general conclusion drawn by the panel was that by the time Anu Miah went to see health professionals on 4 September 2003, it is doubtful whether his death could have been prevented.

5.2. A Clozapine Clinic operating in accordance with currently accepted clinical standards would not have identified the constipation as a risk factor, as the function of these clinics is to monitor the patient's blood count for evidence of the development of a potentially dangerous fall in the circulating white blood cells. A clozapine clinic currently does not routinely monitor for gastro-intestinal symptoms such as constipation, nor for the other potentially serious side effects of this drug. Even if such a dedicated clozapine clinic had been established, the panel concluded on the balance of probabilities that it would not have prevented this untoward death. The panel makes recommendations about improving clozapine clinics later.

5.3. The panel found that the prescribing information available does not place sufficiently clear emphasis on the potential for fatality as a result of constipation associated with clozapine use.

5.4. In trying to understand the reasons for his death the family came to a conclusion that if the GP and the London Ambulance Service had reacted in a different way Anu Miah may have received essential treatment that might have saved his life. However, what was not known to the family were the wide ranging adverse effects of Clozapine, which was one of the material causes. They did not relate his symptoms to the drug treatment of his schizophrenia. They, therefore, believed that the GP and ambulance crew who treated him in his last hours were negligent and responsible for his death because, in their view, they did not treat him appropriately.

5.5. The panel, whilst recognising that it had no specialist expertise in pathology or post mortem analysis concluded that there were three contributing elements to the death of Anu Miah. These were:

- The increasing constipation due to grossly impacted faeces, led to massive bowel distension, the development of gangrenous and ischaemic bowel and terminal severe electrolyte disturbance and toxic shock with circulatory collapse. Constipation is a known side effect of the clozapine which had been prescribed for his schizophrenia.
- The locum GP failed to take an adequate history, failed to carry out a competent examination, failed to make a plausible set of differential diagnoses, failed to determine that the patient was acutely ill, failed to contact the consultant as instructed, and failed to refer to any prescribing literature. The panel did not expect GPs generally to be aware of any detail about clozapine, however the panel found the locum GP concerned did not display the level of general skill and competence normally expected of GPs.
- By the time he was referred to the ambulance service and they arrived on scene, Anu Miah was very close to death. The panel concluded that it was doubtful whether more rapid transfer to hospital would have saved him. But it did conclude that there was an apparent failure on the part of the ambulance crew to undertake a sufficiently complete assessment, including secondary survey.

5.6. The panel was not able to conclude at what point Anu Miah's decline became irreversible – regardless of any interventions from trained and well-equipped healthcare professionals. The panel found it impossible to conclude how long before he died surgical or other medical intervention would have been life saving.

5.7. But regardless of this, the panel concluded that the services that Anu Miah and his family sought (appropriately) to help him on that day failed him in a number of ways, regardless of whether intervention at this late stage would have ensured his survival and recovery. At the very least, the family could have expected competent and sympathetic support that would have made them feel confident that Anu Miah was receiving the best possible care.

5.8. Whilst there was clear evidence of poor performance on the part of the locum GP and some questions around the attitude of the ambulance staff, the panel was unable to conclude on the balance of probabilities whether more rapid action would have saved his life.

5.9. The panel concluded, from wider intelligence, that it is likely that Anu Miah's death was associated with toxic shock caused by metabolic instability from physiological changes resulting from a distended, gangrenous bowel. This in turn was caused by prolonged gradual distension resulting from severe faecal impaction.

5.10. The pathologist at Barts and the London Trust expressed a view that, in addition, the schizophrenia may well have resulted in altered pain perception, lack of awareness and failure to recognise the potential severity of the constipation on the part of the patient. By the time Anu Miah presented on 4 September 2003 the chances of rescue may have been unlikely or very limited.

The Mental Health Service

5.11. Anu Miah, had schizophrenia which was stable, and was responding well to treatment. He was beginning to develop a normally functioning lifestyle – attending college, married for six months and looking for full time employment. He was rehabilitating back into the community by living in supported residential accommodation. The mental health service is to be commended for this degree of progress is such a severe case of schizophrenia.

5.12. However, whilst the mental health outcomes were very positive, his death from a physical condition may still have had its origin in his mental health care and treatment. His death was from 'natural causes' resulting from impacted faeces and ischaemic bowel. The origins of the chronic constipation that led to these conditions is likely to have been a side effect of the drug regime he was prescribed as part of his mental health treatment.

5.13. Whilst he was appropriately registered and monitored for the toxic side effects of clozapine relating to the potential development of blood problems, other physical side effects were not monitored effectively by the service. In addition his carers were not made aware of the potentially serious side effects that could develop in relation to constipation so they, and Anu Miah himself, were unable to recognise the possible links with his mental health treatment.

5.14. Insufficient emphasis was placed on the wide range of physical side effects of clozapine and it appeared that whilst all healthcare professionals were very aware of the potential for blood problems to develop, none of them appeared to monitor for any other side effects. Certainly, in the light of Anu Miah's death, greater emphasis needs to be placed on the physical side effects relating to constipation.

5.15. There is a need to strengthen the monitoring processes relating to physical side effects. Unless more comprehensive monitoring is introduced, more deaths could occur resulting from constipation in other patients taking clozapine.

5.16. The absence of a dedicated 'Clozapine Clinic' is regrettable, particularly as it has already been commissioned and funded by the PCT. This could provide the basis for a comprehensive mechanism for not only blood monitoring, but also for the wider range of physical side effects of clozapine. A dedicated service could in future provide a vehicle and focal point for improved outreach to patients taking clozapine, providing dedicated staff with specific expertise on the drug and all its attendant side effects and up to date clear information on the full range of potential side effects.

5.17. The statistics suggest that a not insignificant number of deaths resulting from gastro-intestinal conditions occur in patients whilst taking clozapine - 1:2,400 are known to have occurred in the fourteen years since 1989. There may have been more not recorded or not categorised appropriately. This may be worthy of further study.

5.18. The literature available for both users and healthcare professionals does not appear to emphasise sufficiently the side effects of constipation and the possibility that this can lead to a serious condition (or even death) if untreated.

5.19. The protocols developed within the ELCMHT for management of patients on clozapine appear to be inadequate.

5.20. General awareness of the potential physical side effects of clozapine across the whole multidisciplinary team appears inadequate and uncoordinated (probably because of the absence of a dedicated clinic as a focal point for liaison).

Primary Care

5.21. Anu Miah presented to his GP at around 10 am on the day of his death, supported by his mother and family, following a night of increasingly severe pain and vomiting. They recognised that he was very ill and needed urgent treatment. Rather than taking him directly to the Accident and Emergency department, they took him to see his GP where they thought there would be knowledge and understanding of his medical history. They also expected help in a rapidly deteriorating situation.

5.22. The reception and consultation they experienced from the locum GP was far from the standard to be expected of modern primary care. Anu Miah was not competently examined, diagnosed or treated. Whilst it is recognised that any healthcare professional is not infallible and cannot always get it right, they may, at times, misdiagnose a condition. However, the public should be able to expect that at the very least, a thorough examination would be carried out and that the healthcare professional would have sufficient knowledge of their subject to be able to make a reasonable interpretation of the findings of their examination. If unable to

make an appropriate diagnosis (or treat the patient) then it would be usual to expect referral to be made to a level of expertise or diagnostic facilities not available in primary care. In most cases this would be the local acute hospital via the accident and emergency department.

5.23. In this case the absence of an appropriate and competent examination was a serious impediment to determining either a diagnosis or recognising that Anu Miah was indeed, very seriously ill. From the findings of the PCT investigation and that of the SUI panel, it would appear that the locum GP failed to meet a minimum standard of good practice in relation to examining the patient. He further compounded the outcome of his cursory examination by apparently falsifying entries into the record, suggesting that his examination had been more thorough than it had been.

5.24. The locum GP then went on to suggest a diagnosis that was inconsistent with his limited findings and not justified by the presenting signs and symptoms of the patient. A course of action that increases clinical risk and the potential to exacerbate the situation for the patient – in Anu Miah's case it was a very dangerous course of action. The clinical risk for the patient was further increased by the absence of any adequate follow up instructions.

5.25. Despite displaying a lack of competence and clinical reasoning and judgement the locum GP's actions probably did not increase the already high risk of fatality, as by the time he saw Anu Miah, it is unlikely that any intervention would have led to a different result.

5.26. From all of this and the fact that, on retrospective reflection, the locum GP demonstrated no insight into the inadequacy and inappropriateness of his practice with this patient, there must be grave concerns about the clinical knowledge, practice and clinical competencies of this locum GP. The panel found that the case of Anu Miah revealed general failures in clinical competence that would apply to his care of all patients. The panel do not expect any GP to be an expert in Clozapine and its side effects. They do expect any GP to be able to take an accurate history, carry out a competent examination, follow instructions from a more senior doctor, consult with specialist colleagues treating the patient, and to keep accurate contemporaneous records. In particular, after an untoward event the panel expect any doctor to exhibit insight and reflective learning. This locum GP's clear lack of insight and failure to reflect and learn led the panel to conclude that he poses a serious risk to patients such that his registration with the GMC should be called into question.

London Ambulance Service

5.27. The panel concluded that the evidence relating to the response times of the LAS supports the fact that it took 35 minutes in all to get the patient to hospital from the time the original 999 call was made. The panel accepted that this was an acceptable response time and met current standards expected of the service.

5.28. However, whilst the overall response time was within acceptable limits, the panel concluded that there were concerns around the approach the crew took to the management of Anu Miah and his family.

5.29. From the evidence available, the panel concluded that the assessment of the patient's condition was not as thorough as it might have been. Whilst getting a history from the patient is important, the emphasis placed upon this appeared to take precedence over thoroughly assessing the patient's clinical condition.

5.30. The panel noted that the crew had undertaken a GCS (Glasgow Coma Score) and approximated systolic blood pressure by palpating peripheral pulse, in line with normal assessment procedures. The panel felt that other observations such as accurate blood pressure and visible abdominal palpation would have been of greater relevance. The panel was therefore surprised that, in someone presenting with an acute abdomen, neither the RRU crew member nor the ambulance crew thought it important to obtain an early accurate systolic and diastolic blood pressure reading (the diastolic blood pressure reading being of greater significance than the systolic in determining any impending state of collapse of a patient).

5.31. Whilst the GCS is a worthy primary assessment tool to ensure the patient is conscious and breathing – it appears to be of limited value in assessing the condition of a patient with severe abdominal pain. The crew appropriately carried out the GCS assessment, which the panel understood to be standard practice as a 'primary assessment' *(terminology used by the LAS officers on the panel).* The panel concluded that their next stage of assessment, (secondary survey), of a patient presenting with severe abdominal pain was limited.

5.32. The abdominal examination reported to have been done by the RRU crew, of his own admission was limited, and no one else in the room saw him do it. On the balance of evidence the panel concluded that this was at best a cursory examination. The ambulance crew taking over appear to have paid very limited attention to trying to assess either the severity of his pain or the cause of it as no abdominal examination appears (from the evidence of their statements) to have been carried out by them – even though they took over after just six minutes of the RRU crew's initial assessment. The radial pulse of 72 reported to have been taken by the RRU crew is inconsistent with the assessment of the pathologist that with a gangrenous, ischaemic bowel Anu Miah's organs would have been going into 'shut down' and a bradycardia (slow pulse) is likely to have been present. None of the ambulance crew felt it necessary to take the patient's blood pressure, which the panel concluded was a significant omission from their assessment. This could have been a most useful indicator in determining the condition of Anu Miah.

5.33. The panel concluded, from the limited examination carried out by the ambulance crew and RRU crew, that within a very short time of appearing on scene they decided that Anu Miah's condition was not serious and not life threatening. There was no statement to this effect but their subsequent actions seem to suggest this to be the case and they certainly gave no impression that they treated him as a seriously ill young man. This view is supported by the fact that they at worst requested, and at best allowed, Anu Miah to be dressed before taking him to the hospital. This is despite the obvious discomfort and distress it caused Anu Miah, culminating in his initial collapse and their responding by giving him immediate oxygen.

5.34. It did appear from the statements and actions of the ambulance crew that they did not believe Anu Miah to be seriously ill and they appeared to doubt what limited history they got from the family, e.g. they were told he had been vomiting but did not see evidence of it.

5.35. The panel were unable to determine why, given that Anu Miah was so near to death, LAS staff did not recognise this, perhaps by undertaking a more detailed examination, such as a secondary survey. The panel concluded there was very likely to have been evidence of his serious moribund condition before he collapsed and died.

5.36. The way in which the crew managed this patient reinforced the family's perception that they were being discriminated against, for whatever reason. Whilst there is no evidence (or indeed suggestions from the family of Anu Miah) that the ambulance crew made racist comments during the incident this does not exclude the possibility of discriminatory behaviour in a more subtle form. From the comments reported in the crew's statements, the panel concluded that the crew did appear to have made some value judgements about the family suggesting they were 'difficult' or just did not want to answer questions. There did not appear to be any evidence or justification for these judgements.

5.37. There appeared to be a failure on the part of the crew to recognise this was a man who was very seriously ill with family who were extremely concerned about him, as would any other family be about a loved one. They appeared to perceive the family as being 'difficult' rather than 'experiencing difficulties' in getting healthcare professionals to understand and respond appropriately to their needs.

5.38. The ambulance crew appears to have made an assumption that Anu Miah would not be able to speak English. When he was unable to answer their questions because of his deteriorating condition they saw this as a confirmation of a perceived language barrier. This does appear to have been a stereotypical approach on the part of the crew – rather than considering that he could speak English but was not able to speak.

Other General Conclusions

5.39. The panel could not conclude that a more rapid removal to hospital could have been achieved by the ambulance crew and could have been life saving to Anu Miah at this late stage of his illness. Whether his deteriorating condition could have been reversed at this stage is doubtful but others may be better able to make a judgement. However, the perceptions of the family might be different if they had experienced a more proactive response from the ambulance crew that indicated they gave Anu Miah the benefit of the doubt and did treat him as someone who was very seriously ill. Clearly their actions did not convey this approach to the family and, indeed, neither did the actions of the locum GP.

5.40. The unexpected death of this young man, within minutes of arrival at the accident and emergency department, seemingly from natural causes but with no previous history of physical disease, attracted no attention from the health service or 'the authorities'. It was only when the complaint of the family about the GP and the ambulance service was made known to the PALS officers that concerns were raised. The post mortem result raised no questions and there was no request for an inquest. The panel concluded that this untoward death could have passed uninvestigated.

5.41. The panel concluded that the testimony and account of events given by the family of Anu Miah were generally supported by the findings of the investigation. The panel could not conclude whether verbatim reports of what was actually said were upheld, as this was a matter of one word against another. However, overall the panel concluded that the description of events given by family of Anu Miah were credible. Throughout the process, including their complaints, interviews with investigating officers and members of the SUI panel, the family acted with dignity and control.

i.e. they showed no anger

6. RECOMMENDATIONS OF THE INVESTIGATION PANEL

All organisations that were involved in the joint investigation should ensure this report is considered at their Board and that recommendations from this panel do not preclude further actions.

Relating to Primary Care

6.1. The PCT should pursue the outcome of its referral of the locum GP to the GMC.

6.2. The GMC has indicated that it is awaiting this report on the investigation into the death of Anu Miah before proceeding with its consideration of the case.

6.3. The PCT should ensure that access to the British National Formulary (BNF) is made available to all GPs, including locums, as this currently may not be the case.

6.4. The PCT should ensure that with the establishment of the new guidelines for responding to complaints in the NHS, that a mechanism is established to ensure that complaints made about individual practices are recorded and responses monitored, and that untoward incidents in a general practice setting are captured, analysed and learned from.

6.5. The PCT should ensure that GPs and practice staff are training in good practice in handling patient complaints.

6.6. The PCT should build upon the excellent PALS service that was responsible for bringing this incident to light. It is a testimony to the value of this user-friendly service.

6.7. The PCT should consider ways in which it can raise awareness amongst primary care regarding the physical side effects of clozapine. It is important to ensure that physical symptoms presented by users of this drug are fully assessed and treated.

6.8. The PCT should work with the ELCMHT to develop shared care protocols for the management of patients treated with clozapine and strengthen the links between primary care and the clinicians within the mental health service.

Relating to the Ambulance Service

6.9. The ambulance service should complete its response to the complaint from the family of Anu Miah, which appears to have been held in abeyance pending the outcome of this investigation. The service should consider offering an apology and acknowledging that the staff could have behaved in a more sensitive way to Anu Miah and his family. Complaint now being examined by Independent Review Panel.

6.10. The LAS should consider a debriefing/reflective practice session for the staff involved in the incident with a view to considering 'Could we have done it differently?' This should be facilitated and should be done within a learning context. Any learning should be shared with managers responsible for the service.

6.11. LAS should continue the work it is doing in equalities training available to staff and managers in the service. This should be reviewed and strengthened with a view to increasing the understanding of equalities and working with diverse communities.

6.12. The service should consider how it can work with local ethnic minority communities to improve relationships and change the perception of racism within the service – whether it is real or perceived.

6.13. As well as continuing to use the Glasgow Coma Score as a primary assessment tool, the service should ensure the secondary survey and other pain assessment tools are used.

6.14. The multilingual phrase book developed and used by the LAS should be shared as an example of good practice across other services, in particular Out Of Hours services. The service should also raise awareness of the availability of this tool and when to use it within its own service and amongst staff.

6.15. Support LAS through the Tower Hamlets Partnership to recruit local people into the service and to develop targeted training programmes for local people.

Relating to the Mental Health Service

6.16. The ELCMHT should consider the urgent establishment of a dedicated 'Clozapine Clinic'. A good model of service should include:

- Co-ordinating the care of patients across primary care, CMHTs and secondary care.
- At least monthly mental health assessments and monitoring of all side effects (not just neutropenia)
- Monthly educational sessions with patients and carers
- Backing up patient information leaflets with verbal advice or friendly patient information leaflets.
- Advise the UKPPG (United Kingdom Patient Prescribing Group) on clozapine patient information leaflet.
- Keeping all prescribers informed of up to date information relating to clozapine.
- Provide regular monitoring of temperature, pulse, blood pressure, blood glucose, patient's weight – ensuring baseline monitoring is in place and appropriate onward referral as necessary.
- Develop and implement a clozapine policy throughout the ELCMHT.
- Research and share best practice.

6.17. The ELCMHT should consider the introduction of alert bracelets for patients using clozapine (if the patient is willing to comply but recognising this may be considered stigmatising).

6.18. Develop a Trust wide policy for the management of patients on clozapine *(see 6.15 also as part of function of Clozapine Clinic)*. This will include:

- Development of protocols
- Shared care protocol with primary care
- Protocols for dealing with unresolved constipation

6.19. Establishment of a clozapine monitoring group. This will:

- Monitor overall patients on clozapine and outcomes

- Monitor adverse incidents associated with the use of clozapine
- Elicit data on death rates in East London and consider comparison with the national picture.
- Share good practice

6.20. Liaise with other mental health trusts and shape consistent policies and protocols based on best practice.

6.21. If GPs are involved in shared care then the patients on clozapine should be considered for inclusion on Severe Mental Illness Register.

6.22. Consider this case in the light of the reporting of SUIs within the Trust. Consider amending the SUI policy if necessary.

6.23. Review other serious or adverse incidents associated with the use of clozapine and collate information resulting from the incidents and report any recommendations to the Clinical Governance Committees of ELCMHT and THPCT.

General Recommendations

6.24. Report this incident and the outcome of the investigation to Novartis – UK manufacturers of clozapine.

6.25. Novartis should be encouraged to:
- Review patient and carer information relating to clozapine.
- Review prescriber information
- Review information for other healthcare professionals
- All information relating to the use of clozapine should be reviewed with a view to increasing the emphasis on the side effects relating to constipation, which is not given the same prominence as the monitoring of blood for neutropenia.

6.26. Novartis should consider more detailed monitoring of deaths of patients on clozapine and the causes.

6.27. The PCT would explore with the coroners' service the criteria that trigger an inquest and why this case did not meet those criteria.

6.28. The report on this case should be shared with the NPSA (National Patient Safety Agency) for consideration of wider national implications for the management of patients on clozapine.

6.29. The BNF information on clozapine should be reviewed, as at present it does not adequately reflect the possible physical side effects of clozapine such as to alert clinician to relevant symptoms.

6.30. The PCT and ELCMHT should report the findings of this investigation, relating to the management of patients on clozapine to the Committee on Safety of Medicines for their consideration.

-------- Report Ends --------