

Summary of the intervention at Milton Keynes Hospital NHS Foundation Trust

December 2008

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The Healthcare Commission

The Healthcare Commission works to promote improvements in the quality of healthcare and public health in England and Wales.

In England, we assess and report on the performance of healthcare organisations in the NHS and independent sector, to ensure that they are providing a high standard of care. We also encourage them to continually improve their services and the way they work.

In Wales, the Healthcare Commission's role is more limited. It relates mainly to national reviews that include Wales and to our yearly report on the state of healthcare. In this work, we collaborate closely with the Healthcare Inspectorate Wales, which is responsible for the NHS and independent healthcare in Wales.

The Healthcare Commission aims to:

- Safeguard patients and promote continuous improvement in healthcare services for patients, carers and the public.
- Promote the rights of everyone to have access to healthcare services and the opportunity to improve their health
- Be independent, fair and open in our decision-making, and consultative about our processes.

Introduction

In June 2007, a baby was born at Milton Keynes General Hospital who died the same day. The case was referred to the coroner and an inquest held in February 2008. Following this, the Deputy Coroner for Milton Keynes (under Rule 43 of the Coroner's Rules 1984) reported the case to the Secretary of State for consideration. In his letter, the Deputy Coroner stated that his verdict was that both a system and a communication failure had contributed to the baby's death. His concerns centred on telephone calls between a consultant obstetrician and a registrar prior to the baby's birth, and his finding was that concerns expressed by an experienced midwife at the time appeared to have been disregarded. The midwife had challenged the decision of the registrar but had not raised concerns directly with the consultant obstetrician. He asked the Department of Health to consider the circumstances in which a consultant is required to attend at a hospital before clinical decisions are made.

As a result of the Deputy Coroner's letter, Department of Health officials met representatives of the trust, Milton Keynes Primary Care Trust (PCT) and South Central Strategic Health Authority on 8 May 2008, to discuss the concerns. The meeting failed to alleviate concerns about whether the trust had adequate processes in place for incident reporting and risk management. There was particular concern about the lack of evidence of learning from incidents to prevent the same mistakes happening again. Concerns were also expressed about the trust's ability to look at all the aspects and components of an incident in a comprehensive way.

The trust's chief executive subsequently wrote to the Healthcare Commission on 20 June 2008, asking the Commission to review the clinical governance processes and procedures within the trust's maternity services and to determine whether the principles of clinical governance were embedded.

Investigating serious failings in healthcare

The Healthcare Commission is empowered by section 52(1) of the Health and Social Care (Community Health and Standards) Act 2003 to conduct investigations into the provision of healthcare by, or for, an English NHS body. As part of this function we undertake 'interventions' when this is considered to be the most proportionate and practical means of identifying the need for, and bringing about, sustainable improvements in the service concerned.

We aim to help organisations to improve the quality of care that they provide, to build or restore public confidence in healthcare services, and to ensure that the care provided to patients is safe throughout the NHS.

Our approach

As the trust had already begun to restructure the governance arrangements within its maternity services, we considered that, in this case, an intervention was the most effective way of determining the effectiveness of the trust's clinical governance processes.

Our remit was not to re-investigate the original incident. Instead, our focus was to look at the systems in place to investigate and learn from incidents, in order to prevent the same thing happening again.

We did not examine evidence in relation to all the core standards set out in the Healthcare Commission's annual health check, as the focus of our visits was to establish what was the situation in relation to the areas of concern in maternity. However, we did take the opportunity to look at the trust's wider governance arrangements and specifically where the governance arrangements within the maternity service fitted into the overall arrangements.

We considered:

- Whether the underlying principles of clinical governance are understood and properly embedded within maternity services.
- Whether clinical governance systems and processes within maternity services (antenatal care, care during delivery, and postnatal care) are effective.

Our investigation team worked with the trust to establish the extent of the concerns and to make recommendations for improvement where appropriate.

As part of this process, we called for documents from the trust for review, conducted two visits to the trust, interviewed 14 staff directly associated with the work of the maternity unit, and interviewed those involved with the trust-wide governance arrangements, including the chief executive. We also spoke to a number of others including Milton Keynes PCT and the Deputy Coroner. We also spoke to members of staff during our visits to the maternity unit. The investigation team included expert maternity advisors who provided advice and guidance throughout.

As a result of the findings, we have made 12 specific recommendations to the trust. The recommendations and the rationale leading to them are set out below.

Background

Milton Keynes Hospital NHS Foundation Trust is a hospital of around 500 beds. It became an NHS Foundation Trust on 1 October 2007. The current chief executive was appointed in 2001.

The trust's turnover for 2007/08 was £129 million. Its main commissioning body is Milton Keynes PCT (accounting for 70% of the trust's turnover). Other commissioners include Bedfordshire PCT, Buckinghamshire PCT, Northamptonshire PCT and Oxfordshire PCT. The trust ended the financial year 2007/08 with a surplus of £3.1 million.

Milton Keynes is one of the fastest growing districts in the country, with a relatively young population. Between 2003/04 and 2006/07, whereas the population rose by 3% to 222,350, the number of births rose by 5.4% to 3,637 per year.¹ This increase is predicted to continue and the annual number of births is expected to exceed 4,000 in 2016.²

The complexity and case mix of deliveries is also changing. The proportion of women in Milton Keynes giving birth in hospital who do not classify themselves as White British has risen, from 27% in 2004/05 to 35% in 2006/07.² In addition, there is an increase in the number of obese women giving birth (and who are more likely to have diabetes and complications in pregnancy), very young and older mothers, and more subsequent deliveries where the previous delivery was assisted or where it was by caesarean section.¹

In the Healthcare Commission's 2007/08 annual health check, the trust was scored "good" for quality of services and "excellent" for use of resources respectively.

However, our 2007 national review of maternity services, which provided a comparative assessment of those services against a range of 25 indicators, rated the trust's maternity services as falling within the "least well performing" trusts in England (a category which contained 21% of all trusts). The trust was ranked (where 1st = best):

- 135th overall in England out of 148 trusts.
- 104th for "having strong processes and practices to ensure the maternity service is safe and effective".
- 105th for "are women informed, counselled and supported to ensure that they have a positive maternity experience".
- 141st for "adequate funding to provide an acceptable service and management and improvement processes ensuring women get the best care for the money spent".

¹ Milton Keynes PCT: *Review of Maternity Care in Milton Keynes*, September 2007

² Milton Keynes PCT and Council: *Joint Strategic Needs Assessment 2008* (draft)

Maternity services

Maternity services at the trust include antenatal care, care during labour, immediate postnatal care and community-based care, as well as early pregnancy assessment, health promotion and screening.

The service provided antenatal and postnatal care for 3,782 women in Milton Keynes during 2007/08. Over 90% of the births took place under the care of Milton Keynes General Hospital, which is also responsible for the delivery of antenatal care through its community midwives. Of the remaining births, approximately half are homebirths.

The NHS Litigation Authority is responsible for handling negligence claims made against NHS bodies in England. It has an active programme of risk management to help raise standards of care and reduce incidents that may lead to claims. It has a specific set of standards for maternity services and, currently, the trust has been awarded level 2 (where level 3 is the highest rating).

Monitor, which is responsible for regulating NHS foundation trusts, considers the three-year plans submitted by all NHS foundation trusts. As part of this, each NHS foundation trust is required to self-certify its expected compliance over the next 12 months in each of the areas related to governance. Based on the trust's self-certification, it was assigned with a risk rating of 'green' (fully compliant) for 2008/09.

External reviews undertaken in the maternity service

Review of stillbirths 2005 (published in 2006)

Towards the end of 2005, the clinicians and managers of the trust's Women and Children's Services Division noted a cluster of stillbirths at Milton Keynes General. There were 32 stillbirths in the year, a significant increase on the 17 stillbirths in each year, 2003 and 2004.

As a result, the trust commissioned a team from Southampton University Hospitals NHS Trust to undertake an external review into the stillbirths. The team consisted of a consultant obstetrician and a consultant midwife. As well as the stillbirths, the reviewers also looked at all aspects of safety and the quality of care on the labour ward.

The review recognised that there was a good level of skill in dealing with these cases among maternity staff in the multidisciplinary team. However, the review found that most of the deaths (19 out of 32) occurred in pregnancies in which one would have expected a good outcome. The team made a number of recommendations including:

- Clinicians and managers should develop shared values and a clear vision for the maternity service under confident, proactive leadership.
- Leadership in clinical governance and involvement of clinicians at all levels should be made a priority, with a multi-professional approach to clinical governance and midwifery.
- Clinical leadership (both medical and midwifery) should be considerably strengthened, including giving real consideration to the appointment of a consultant midwife.
- A programme for joint guidelines and audit, adhering to recognised standards, should be instigated immediately.
- An urgent need for provision and monitoring of multi-professional education and development for doctors and midwives, including emergency drills undertaken as a team.
- New models of midwifery care should be developed.
- Midwives should feel confident to query decisions that they are not comfortable with.

Following the review, the trust devised an action plan, dated May 2006, to carry out the recommendations. We note that there are recommendations outstanding from this review.

PCT maternity review 2007

The public health team at Milton Keynes PCT undertook a review of the maternity service, published in September 2007. Its aim was to review evidence of best practice in maternity care, determine the needs of the people of Milton Keynes, and build the best models of maternity care for the district. It also assessed the extent to which the current services matched up to these models and recommended how care could be commissioned in future.

This review also found no shortage of skill within the maternity, obstetric and midwifery team and noted that the department was committed to making the changes needed to deliver on the Government's 2009 targets. (These say that choice should be guaranteed for all women and their partners in four areas: access to maternity care; type of antenatal care; place of birth, and postnatal care.)

However, the review noted that the leadership and morale needed in the department to carry such changes through was in shorter supply. The recommendations included:

- The need for the trust to recognise the increasing numbers of births in Milton Keynes and to resource its service to meet these growing needs.
- Maternity staffing levels needed to rise, as soon as possible, to meet the nationally recommended levels for a hospital with the birth rate in Milton Keynes.

- Reconfiguration of the midwifery team to improve teamwork. In particular, greater prominence and time should be given to educating, counselling and giving public health advice to pregnant women.
- To meet the Government's 2009 guarantees of choice, options for an adequately staffed midwife-led delivery unit should be explored, next to the consultant-led delivery unit.
- Indicators were needed to monitor the quality of maternity services, including documented evidence of risk assessments, rates of perineal trauma during delivery and rates of post-partum haemorrhage.

Our findings

In order to check whether the underlying principles of clinical governance were understood and properly embedded within the trust's maternity services, and to assess whether the clinical governance systems and processes were appropriate, we looked at the trust's structure for clinical governance and its arrangements for learning from incidents.

We also looked at the trust's maternity guidelines, its audit arrangements, the management of serious untoward incidents in maternity, resources, leadership and training.

Clinical governance structure

An integral role of a trust's board is to examine critically a trust's functions and be assured that the trust operates the highest possible clinical standards. Where there is room for improvement, it is the board's responsibility to make sure action is taken to achieve those improvements.

The trust has a new clinical governance structure in place, formed of Clinical Information Groups (CIGs) within each division. The purpose of these groups is to discuss issues relating to the experience of patients, risk management, information for patients, guidelines, audit, training, clinical effectiveness and, where appropriate, safeguarding children. It was acknowledged that the CIGs had only been in place for about six months.

The CIGs report incidents to the Divisional Governance Board, which provides quarterly reports to the trust's Healthcare Governance Committee. Clinical directors are accountable for what happens within each CIG. Also, as part of the overall structure, there is a trust-wide clinical risk management committee and a separate trust-wide non-clinical risk management committee.

The trust has a healthcare governance support unit managed by the Head of Clinical Governance, who also acts as secretary to the Healthcare Governance Committee. We were told that there are healthcare governance facilitators in each of the divisions, working with the divisions to ensure that governance matters are placed firmly at operational level.

The formal link between the divisional clinical governance structure and the trust's board is the Healthcare Governance Committee, which meets bi-monthly. Typical recent agenda items have included checks on the competency of locum staff, updates from PALS (Patient Advisory Liaison Service) quarterly reports, equality and diversity steering group updates, divisional risk reports, reports on clinical negligence scheme for trusts and audit reports.

The maternity department has several regular meetings associated with clinical governance. These include delivery suite meetings, weekly unit risk meetings,

clinical risk management committee meetings, community midwives meetings, weekly cardiotocograph (CTG) meetings, local directorate and specialty governance group meetings, joint consultant/matron meetings and a CIG meeting. From the evidence obtained, none of these meetings had compulsory attendance requirements. Actual attendance was variable, and the frequency of meetings ranged from weekly to bi-monthly.

The weekly CTG meeting was set up by the trust in response to a need to learn about CTG interpretation. The CTG was introduced nationally as a screening test in the 1970s to monitor pregnant women. It simultaneously measures foetal heart rate and uterine contractions, and produces a printout: the CTG trace. The baby's heart rate is monitored throughout labour so that stress can be detected early. The contractions are monitored so that the midwife and mother know when the contraction is occurring and to check for distress in the baby during the contraction. The use of CTG monitoring in labour is recommended for women with identified risk factors.

The CTG meeting appeared to be well attended because it suited the shift patterns of both doctors and midwives. It was described as a good learning opportunity, as the meeting discussed current cases and incidents on the unit. In February 2008, a proforma for the meeting was developed to include a description of any incident, identifying problems, learning opportunities and actions to be undertaken. The Practice Development Midwife maintains a record of attendance and staff are expected to attend at least one CTG meeting a year, as part of a wider programme of case study and practitioner skills training.

Learning from incidents and reviews

We interviewed members of maternity staff to gain an impression of how clinical governance arrangements were understood and implemented at ward level. A few members of staff mentioned that reported clinical incidents were discussed at weekly risk meetings. These meetings have an agreed core membership and are not compulsory, but other members of staff are invited to attend. Attendance at them seemed to depend on a member of staff's availability. There also appeared to be a problem securing the attendance of some doctors, where their attendance would place them above the 48-hour working week limit. One person mentioned that they were unable to attend the weekly risk meeting because it clashed with a clinic that they ran. Some midwives said that they were unable to attend due to pressure of work and that they often only found out about incidents through chatting to colleagues on the wards.

The midwives we spoke to, either in interviews or on visits to the maternity unit, knew how and when to report a clinical incident. What was less clear was whether individuals routinely received feedback from any incidents raised. One midwife said that the only feedback she had received was when she had attended a risk meeting. Figures for the trust from the 2007 national NHS staff survey show that only 23% of staff strongly agreed that the trust informs staff of

incidents, compared with 30% for all trusts. In addition, 26% strongly agreed that the trust provides feedback about any changes made (31% for all trusts).

On a more positive note, we found that a bi-monthly newsletter called “Risky Business”, whose aim was to raise awareness and provide feedback on risk issues and serious untoward incidents among other issues, had recently been re-instated in June 2008. We found that there was a clinical risk notice board and black risk boxes, designed to contain risk forms (audit, trigger, verbal complaints and drug errors), on the labour ward and the antenatal day unit.

While there were some positive initiatives at ward and departmental level, we did not see evidence that any of the meetings described to us – with the exception of the CTG meeting – were sufficiently well attended to provide an effective channel for clinical governance issues to have the high profile required among all front line staff and managers. It was not clear how information discussed at these various meetings was passed on to staff not able to attend.

Since November 2007, non-executive directors have occupied the posts of chair and deputy chair on the Healthcare Governance Committee. From this time, divisional reports have been given more prominence on the agenda and have stimulated discussion. Previously, they were included in the trust’s quarterly governance report.

It was clear from interviews and from evidence in Healthcare Governance Committee minutes that individual trends in incidents had been reported. However, in all the clinical governance reporting structure, we could find no evidence of serious untoward incidents from the maternity department or elsewhere in the trust having been highlighted and traced all the way up from ward level, through the divisional structure, to the Healthcare Governance Committee and the trust’s board. We could also find no evidence of the resolution of issues, learning or other feedback being passed back down the line to ward level.

Another issue concerned the two reviews into maternity services at the trust mentioned above. From evidence we have seen from the minutes, the review of stillbirths at Milton Keynes in 2005 was presented as a report to the trust’s Healthcare Governance Committee on 5 June 2006. It was noted that an action plan was in the process of being reviewed in order to address the key issues.

In the Healthcare Governance Committee meeting minutes of 7 August 2006, it was noted that the action plan had been signed off. We found no evidence that this was fed up to the board or subsequently monitored.

The 2007 PCT maternity review came to the formal attention of the trust’s board at its meeting in November 2007. At that meeting, it was agreed that an action plan be drawn up. Subsequently, it was agreed that the PCT would produce a service specification of maternity services for 2008/09. This was published in March 2008, setting out the minimum standards required.

In summary, at ground level the individual clinical governance and risk meetings and initiatives appear uncoordinated and, because of fluctuating levels of attendance, are not addressing clinical governance issues in a reliable and systematic way.

At the same time, at a higher level there has appeared to be little effective critical intervention or monitoring of clinical governance issues, and little clear evidence of how clinical governance issues are effectively passed up the line and then passed back down again in the form of improvement action at ward level. While we recognised that the trust is making strenuous efforts to improve clinical governance, those issues need to be more deeply embedded within the trust's structure and continued efforts are required for this to happen.

The trust does not have the type of effective clinical governance arrangements that one might now expect in a maternity service in 2008. There has been a belated recognition on the part of the trust of the need to make significant improvements. There had been deficiencies in the way that the trust had managed clinical governance within the maternity department, and the new clinical governance structure was a step forward in addressing some of these deficiencies.

Recommendation 1

The trust must take steps to further embed its clinical governance arrangements to ensure that they are observed in its daily operation. For example, it must ensure that all members of staff who need to attend clinical governance meetings are able to do so as part of their normal duties, and not as an addition to them.

Maternity guidelines

We examined a series of guidelines relating to maternity and found a number of deficiencies. The dates on some of the guidelines we saw were inconsistent and several were overdue for review.

Some of the guidelines were not always referenced to the appropriate national standard or guidelines. For example, there was a guideline in relation to post-partum haemorrhage. However, this did not appear to be in line with the Confidential Enquiry into Maternal and Child Health (CEMACH) recommendation relating to surgical intervention. It referred to the unit's Massive Obstetric Haemorrhage guideline, but this was not found on the trust's intranet or in the policy and guideline folder on the ward. As this guideline concerns the management of a serious medical emergency and is a requirement for level 1 of the clinical negligence scheme for trusts, we wrote separately to the trust on this omission and ensured that swift and appropriate action to remedy this was in hand.

We found no evidence of a multidisciplinary approach to the production of guidelines. Instead, the process appeared to be that one or two individuals would write them within their own specialism.

Recommendation 2

The trust should ensure that its maternity guidelines are updated regularly, using a multidisciplinary approach across midwives, junior and middle grade doctors, and consultants, to help gain multidisciplinary ownership of them.

Audit

Audit at the trust appears to be largely led by doctors, with little involvement of other professionals in either choosing or even in participating in the audit meetings. We are concerned that this could lead to difficulties in recommendations being converted into actions and in learning across the disciplines being properly 'owned'.

From interviews and other evidence, we found that medical and midwifery audits tended to be conducted separately. We were told that audit was seen more as an educational tool, which might improve practice. There appeared to be a lack of systematic approach as to what might be audited and it depended more on an individual having an idea about what could be audited. We found no evidence, for example, that the audit programme was informed by trends in clinical incidents. There is, however, discussion at quarterly audit meetings in different departments about future possible audits.

We expected to find more evidence of a systematic audit framework than we actually did, and more evidence of a multidisciplinary approach. While audit meetings were described as being moderately well attended, there is no mandatory attendance requirement.

Recommendation 3

The trust should put in place a more formalised audit programme, covering all its divisions including maternity. This should be multidisciplinary in approach, and focused on adherence to recognised standards.

Serious untoward incidents (SUIs)

In order to see how another aspect of clinical governance was operating in practice, we examined a number of SUI reports concerning stillbirths.

We found that the overall standard of documentation of the SUI reports we studied was poor, with significant inconsistency in levels of completeness. In

terms of investigation of the SUIs, we found this to be mainly midwifery-led, with very little medical obstetric input. The SUI summaries that we reviewed did not enable the reader to easily see what actions were being taken, by whom, or to what timescale. At times, issues highlighted by an investigation, when actually documented, did not appear to be addressed by the proposed actions.

There was no evidence of lessons learnt from one SUI to another. For example, CTG misinterpretation (monitoring of the baby's heartbeat) appeared to be a common feature, as was evidence of midwives not calling for consultant input if there was some disagreement with the registrar regarding management of the CTG. The SUIs also raised questions about a lack of appropriate consultant presence on the labour ward. There were also repeated issues in relation to poor record-keeping.

Overall, the documentation and management of the SUIs that we saw was poor, with little evidence of root cause analysis and, for the period that the SUIs covered (2006 to 2008), of effective clinical governance in the maternity division.

Staff interviewed appeared unclear of the system for monitoring SUIs and the responsibility for signing off the investigation report and action plans. We asked several members of staff at different levels to describe what they thought the process was, once an SUI had been reported. The answers varied in detail and indicated that knowledge of the process was not widespread. Several mechanisms were highlighted, but key post holders that were said to be responsible were actually not aware of their role in the SUI process. Documentation showed that one SUI in maternity had occurred in January 2008, but had only come to light in April 2008. There was also little documentary evidence of any co-ordinated learning from SUIs, apart from some ad hoc responses to individual incidents.

Section 8 of the trust's SUI policy states that all incidents will be recorded on the trust's database and regular reports provided to the relevant clinical governance groups, including the Healthcare Governance Committee and the trust's board. Section 9 of the policy states that reviews of untoward incidents, ensuring that lessons learned are cascaded appropriately and monitoring action plans, are the responsibility of the relevant risk management committee, with updates provided to the Healthcare Governance Committee and trust board.

Given the poor state of the SUIs examined, we can find no evidence that any of the above happened in such a way as to alert the trust's board or the Healthcare Governance Committee to the true nature of incidents in maternity services. This may go some way to explain why nobody in the trust took action over the unacceptable standard of SUI reporting in these instances.

We noted that the terms of reference of the Clinical Risk Management Committee includes reference to its duty to monitor and receive reports on serious incidents and to monitor action plans. In our review of the minutes of

this committee's meetings held between January and July 2008, we found no evidence of such activity having taken place.

There was evidence of some SUIs being notified to the trust's board and Healthcare Governance Committee as part of quarterly governance reports. However, this was not in detail and there was no minuted evidence that they were discussed. This is despite the fact that we were told in interview that such items were regularly reviewed at the Healthcare Governance Committee.

We noted that, from 1 July 2008, Milton Keynes PCT took over from the strategic health authority in monitoring SUIs at the trust. The PCT's system to manage SUIs includes a weekly review to discuss any new incidents and the level of investigation and specialist advice required. A review group to review all incidents meets bi-monthly to ensure there is learning and that action plans are implemented. If there are any concerns, these are escalated through the clinical quality review group meeting and the PCT clinical concerns group.

Following the appointment of a new Head of Midwifery at the trust, maternity SUIs are being discussed at the weekly labour ward risk meeting. The PCT states that it is still investigating the level of current reporting at the hospital. We were also told that, under the new SUI system within the maternity department, an investigation panel will be appointed for investigating SUIs including an obstetrician, midwife lead and risk lead. An investigation template is also being developed. Although this system is still in its infancy, it represents encouraging evidence of a co-ordinated approach to the monitoring of SUIs at the trust.

Recommendation 4

The trust should continue to work with the PCT to help develop its system of monitoring of serious untoward incidents and ensure that they are appropriately reported, investigated and audited, and that lessons are learnt.

Recommendation 5

The trust's board should assure itself that it is receiving adequate information on clinical incidents and serious untoward incidents, so that it can take any appropriate action to protect the safety of patients at the trust.

Resources

In 2003, a 'birth rate plus' assessment of the physical capacity and staffing levels was conducted. It was estimated that, to run a service to meet the needs of the local population, the unit would need 47 beds in total (15 antenatal and 32 postnatal)

According to the latest information provided by the trust, the maternity unit at Milton Keynes General currently comprises:

- A labour ward of 11 rooms (10 single-bedded and a two-bedded high dependency unit).
- Ward 9 containing 30 antenatal and postnatal beds, in separate areas on the same ward.
- A day antenatal assessment unit for women, in case of problems related to their pregnancy (from 20 weeks onward).
- An early assessment unit run from the outpatients department.

The 2007 PCT maternity review had identified a significant operating shortage of midwives, and a midwife workforce too heavily dominated by highly skilled, high band staff. The PCT and the trust jointly agreed as part of the resulting action plan to the recruitment of an additional 18 whole-time equivalent (WTE) midwives in March 2008. The results of the recruitment campaigns have, so far, failed to sufficiently increase the number of midwives in post when natural wastage is taken into account.

During the course of our interviews with members of staff within the maternity service, and from our own observations on the wards, we noted an enthusiastic, mutually supportive team keen to perform efficiently and effectively, beset by the symptoms of a workforce operating under pressure. These symptoms include concentrating primarily on day-to-day issues, with little or no protected time to attend training sessions or clinical audit meetings, for example, in order to learn from previous incidents.

There appeared to be a high degree of pressure on bed occupancy. More than one midwife expressed concern about mothers and babies being discharged early to make way for other deliveries. This appears to be borne out by the postnatal care statistic in the Healthcare Commission's review of maternity services for 2007. This shows a 12.8% re-admission rate of mothers within two weeks of giving birth at Milton Keynes, against an average for England of 4.5%. Similarly, the trust had only 59% of mothers who considered their length of stay in the maternity unit was about right (compared to 73% of mothers on average in England).

Members of staff made reference, on more than one occasion, to the unit nearly closing to new patients on several recent dates, and only being kept open because adjacent maternity units could not take patients. There were also descriptions of community midwives being drafted in to the maternity unit and of very senior midwives, up to and including the Head of Midwifery, coming in and "rolling their sleeves up" to deliver babies due to the shortage of staff. Some of this is laudable devotion to duty, but it also suggests an element of urgent, unplanned operation caused by an overall lack of resources. It is in such an environment that mistakes can be made and clinical incidents can happen. The pressure of work and time is also not conducive to members of staff devoting additional time to clinical governance issues, such as learning from incidents.

From speaking to members of staff, both in interviews and when visiting the maternity unit, it became clear that shortage of staff and the lack of beds was placing individuals and the system under continued and continual stress. The

external reviews in 2005 and 2007 highlight concerns about capacity that do not appear to have been addressed. Lack of sufficient resources, principally in the number of midwives in post but also in the lack of provision of sufficient bed capacity, is placing a risk to the safe delivery of maternity services at the trust. Despite the recommendation in the birth rate plus review in 2003 that the unit would need 47 beds, the actual number of beds has been reduced to 30 because of a lack of midwives and despite the number of women using the service continuing to increase.

In the course of our visits, we learned that there is a discrepancy between the differing systems used to count the number of deliveries (upon which funding is based). It is understood that the newly appointed Divisional Manager for maternity is now in active discussion with the PCT to resolve this issue.

Recommendation 6

While recognising the trust's previous efforts to increase its number of midwives in post, the trust needs to take immediate further steps to remedy these shortages.

Recommendation 7

It is recognised that the trust is committed to developing a capital building project within the next five years to increase the capacity of the maternity unit. However, in the short term, the trust needs to urgently review and reassess the number of beds likely to be required to run the service and ease the current pressure on beds, and also to take into account the predictions of future growth in the birth rate until the capital building project is completed.

Leadership

On the trust's website, the board lists among its responsibilities: to set the direction of the trust; to oversee the delivery of planned results by monitoring performance against objectives and ensuring corrective action is taken where necessary; and to ensure that there is effective dialogue between the trust and the local community on its plans and performance and that these are responsive to the community's needs.

This sets the tone for leadership throughout the trust and depends on there being a board with all its necessary officers, non-executive directors, chief executive and chair in place. It also implies that, where designated posts are listed as necessary to the functioning of the trust, those posts will be filled either substantively or via other means.

In the course of our intervention, we identified gaps in the trust's structure and in the maternity division through vacancies, and one person occupying two or even three roles. This would place stresses and strains not only on the efficient working of the trust's various functions (not least the functioning of its

operations and clinical governance), but also on the leadership structure, with similar detrimental effect.

The picture of vacancies in substantive posts, and one person covering more than one post between the period January 2006 to early 2008, is a complex one. However, in summary the following seems to be the situation from evidence we obtained and people we spoke to.

There was a Director of Nursing actively in post throughout 2006 and up to July 2007. The Divisional General Manager covered elements of the Director of Nursing role from July 2007 up to 31 August 2008, when the post holder resigned. Since then, the post of Director of Nursing has been vacant although, during our visit, we were told that it is hoped to fill this in the near future.

One of the key recommendations of the 2005 stillbirths review was to strengthen the clinical leadership (both medical and midwifery) at Milton Keynes. A specific recommendation was to give real consideration to the recruitment of a consultant midwife. We note that this recommendation has been considered but that it has been decided, so far, not to recruit to this post.

Another serious gap in leadership in the trust has been the absence of a trust risk manager, apart from a six-month period from December 2007 to June 2008, despite unsuccessful attempts by the trust to recruit to this post. Had there been a risk manager in post, this role could have acted as a focal point to drive forward best practice in risk assessment, clinical risk management, SUI reporting and documentation, investigation including root cause analysis, programmes to ensure learning from incidents and driving forward a programme of multi-disciplinary audit.

The key post of Head of Midwifery originally became vacant in August 2006. It was noted in a local supervisory authority audit visit of November 2006 that “there is no Head of Midwifery and this is very noticeable”. Despite recruitment campaigns, this post was not successfully filled on a substantive basis until March 2008. The arrival of the current Head of Midwifery has been regarded as a very positive move both at the trust and at the PCT, and we agree with that view. However, the gap of the best part of two years means that the current post holder, along with the newly appointed divisional manager and the newly appointed labour ward lead, has much to put right.

Supervisors of Midwives

The role of the Supervisor of Midwives is formally recognised as part of the leadership structure of any maternity unit, and can be described as helping to ensure that midwives and midwifery students practise safely and effectively. The Supervisor of Midwives is a source of sound professional advice on all midwifery matters and is accountable to the local supervisory authority for all supervisory activities.

From interviews and evidence provided by the trust, we found that the level of Supervisors of Midwives at Milton Keynes was low. The recommended ratio of Supervisors of Midwives to midwives is 1:15 (Nursing and Midwifery Council) and we found that the ratio at Milton Keynes varied from 1:12 to 1:23. There appear to be several reasons for this. At Milton Keynes, Supervisors of Midwives receive no additional remuneration for the role, whereas it is understood that in adjoining areas they receive an additional £2,000 to £3,000 a year for performing Supervisor of Midwives duties. Linked to this, the 2005 stillbirth review found that some Supervisors of Midwives at Milton Keynes did not feel that their role was valued. This view was echoed by a number of people whom we interviewed. On the other hand, several midwives said that they felt that the Supervisors of Midwives provided them with valuable support.

We have been impressed, overall, by the level of dedication of the current midwifery workforce. Until recently, they have worked with significant gaps in leadership. We found that, over a considerable period of time, the trust has allowed not only significant gaps in the leadership to happen – directly affecting the maternity division in terms of operational effectiveness and clinical governance – but also has tolerated periods where individuals have been spread too thinly over more than one area of responsibility. The result has been to render them less effective than they would otherwise have been.

Recommendation 8

The trust should take steps to increase the number of Supervisors of Midwives to reach the recommended national ratio of Supervisors of Midwives to midwives, and to ensure that their value to the trust is suitably recognised and rewarded.

Recommendation 9

The trust should ensure that it takes the necessary steps to fill all vacant posts that have a significant impact on the operational and clinical governance effectiveness of the maternity division and the wider trust.

Training

One essential way to ensure that best practice and clinical governance policy and procedures becomes the lifeblood of an organisation is to have a comprehensive training programme, and an organisational commitment to the time and money necessary to make sure that any such training programme is implemented.

We have already made mention of the shortage of midwives and gaps in the nursing management structure within the division and in the trust. The maternity unit at Milton Keynes benefits from having a highly skilled and trained midwifery force with a preponderance of midwives at Band 6. However, shortages of

midwives have placed strains on any activity, which might be not directly operational.

The new Head of Midwifery has already recognised that training and development is another large area of development, particularly in view of the recruitment drive to add an additional 18 whole-time equivalent midwives to the establishment and the need to ensure that they receive support to develop. It is also with a view to the fact that the Healthcare Commission's maternity review found the trust to be one of the 21% of trusts to be in the "least well performing" category for maternity services.

Other issues that will require training in order to change ways of working include the above-average rate of caesarean section at Milton Keynes (26% in 2006/07, as against 24% in England). In 2007, the Healthcare Commission's maternity review found that the trust's maternity service did not meet any of the requirements in relation to the appropriate use of caesarean sections. This assessment was due to the trust's inability to submit sufficient data.

We were told that training was currently being reorganised, with a proposal to allocate one week a year to staff during which they would undertake all mandatory training, such as practitioner skills and drills, CTG interpretation and action, basic life support and general obstetrics and gynaecology. It was noted that the new labour ward lead intended to resurrect a workshop to promote normal birth, which had previously been cancelled due to pressure of work and staff shortage. We note that the service specification for maternity services 2008/09 specifies the requirements for multi-professional team training.

Recommendation 10

The trust should undertake a review of its training provision, including the provision of protected time for doctors, midwives and maternity care assistants to attend normal birth workshops and multi-professional mandatory and developmental training, including training as outlined in the service specification for maternity services 2008/09.

Other issues highlighted during the intervention

While the primary focus of our intervention was to review the trust's clinical governance processes and procedures and to determine the factors that had influenced it, we naturally became aware of other issues during the course of our visits and through studying evidence given to us. We have summarised these issues below, on the grounds that they, too, have an influence on clinical governance and hence the operational and clinical outcomes that may be affected.

Lack of dedicated 24-hour obstetric theatre

In order to qualify for level 1 of the clinical negligence scheme for trusts, consultant obstetric units must have a dedicated 24-hour obstetric theatre and a dedicated resident obstetric anaesthetist. From the evidence provided by the trust, its theatre policy, and from speaking to individuals, this does not appear to be the case. Whilst there is a dedicated theatre, the situation outside the hours of 9am to 5pm is that the resident obstetric anaesthetist may be called to other areas in the hospital “to help out”. We were told that this results in delays to this anaesthetist being available, and debates as to what qualifies as an emergency serious enough for this anaesthetist to return to obstetric anaesthetist duties. This could lead to serious delays in an obstetric emergency.

Recommendation 11

The trust should review its anaesthetic rota and theatre arrangements, to ensure that it complies with the requirement to have a 24-hour dedicated obstetric theatre, and 24-hour immediate availability to an anaesthetist.

The role of the PCT

The situation at Milton Keynes is unusual in that Milton Keynes PCT is by far the main commissioner of the hospital services provided by Milton Keynes NHS Foundation Trust. This places the PCT in the position of having an overwhelming interest and influence over the services provided by the trust.

There is ample evidence to indicate that the PCT is taking this position and its influence as commissioner and monitor of the various services extremely seriously. The PCT decided to commission its own review into the maternity service at the trust, which was published in September 2007. From this review, the trust has formulated its own action plan and the PCT has produced the service specification for maternity services, which the acute trust has signed up to.

In our interviews with various members of staff at the PCT, we came away with the view that, given its high volume commissioning role of the trust’s services, the PCT is keen to be regarded more as a “critical friend” to work in partnership with the trust.

From our analysis of the evidence and from what we saw on our visits, it is apparent, while some progress has been made, there are still outstanding actions from both reviews into the maternity service and there is still work to be done to achieve the requirements of the service specification.

Recommendation 12

We recommend that the acute trust and PCT increase their collaboration in order to enable the recommendations of the two previous reviews into maternity services at Milton Keynes and the requirements of the service specification for maternity services 2008/09 to be successfully completed.

Conclusions

The Healthcare Commission has carried out other investigations and interventions into the maternity services of other trusts, which suggest that, if there are weaknesses in the governance of an organisation, performance in maternity services is likely to be an indicator of wider governance issues.

We were invited to examine the trust's clinical governance processes and procedures because of concerns expressed by the trust and other external bodies.

We have examined the trust's governance systems with regard to maternity to check whether they were effective. We conclude that there are a number of improvements that need to be made in maternity. As part of our scrutiny of maternity, we have looked at some aspects of the wider trust clinical governance arrangements. Where appropriate, our recommendations highlight improvements that need to be made more widely across the trust.

Recent improvements have been made. There is a new leadership team in place at senior levels within the maternity division, but there are still gaps in positions of leadership that require filling. A new clinical governance structure has been agreed. It is important that the trust makes strenuous efforts to ensure that this becomes firmly embedded.

It is essential that the new team in maternity, and in particular the new Head of Midwifery, receive sufficient support from the board and senior managers to bring about an improvement in clinical governance and new ways of working within the unit. We recognise that there are significant challenges and we have made formal recommendations for improvement.

The trust has been open and co-operative with the Commission, has demonstrated a willingness to make improvements, and has accepted the recommendations in this report. It is the responsibility of the trust's board to set in motion the necessary action to achieve those improvements and to keep a close watch over them. Ongoing responsibility for managing the performance of the trust continues to be with Monitor, with whom we have discussed the content of this report. In addition, we will conduct a follow-up visit to the trust in September 2009 to assess progress against these specific recommendations.

Summary of recommendations

Recommendation 1

The trust must take steps to further embed its clinical governance arrangements to ensure that they are observed in its daily operation. For example, it must ensure that all members of staff who need to attend clinical governance meetings are able to do so as part of their normal duties, and not as an addition to them.

Recommendation 2

The trust should ensure that its maternity guidelines are updated regularly, using a multidisciplinary approach across midwives, junior and middle grade doctors, and consultants, to help gain multidisciplinary ownership of them.

Recommendation 3

The trust should put in place a more formalised audit programme, covering all its divisions including maternity. This should be multidisciplinary in approach, and focused on adherence to recognised standards.

Recommendation 4

The trust should continue to work with the PCT to help develop its system of monitoring of serious untoward incidents and ensure that they are appropriately reported, investigated and audited, and that lessons are learnt.

Recommendation 5

The trust's board should assure itself that it is receiving adequate information on clinical incidents and serious untoward incidents, so that it can take any appropriate action to protect the safety of patients at the trust.

Recommendation 6

While recognising the trust's previous efforts to increase its number of midwives in post, the trust needs to take immediate further steps to remedy these shortages.

Recommendation 7

It is recognised that the trust is committed to developing a capital building project within the next five years to increase the capacity of the maternity unit. However, in the short term, the trust needs to urgently review and reassess the number of beds likely to be required to run the service and ease the current pressure on beds, and also to take into account the predictions of future growth in the birth rate until the capital building project is completed.

Recommendation 8

The trust should take steps to increase the number of Supervisors of Midwives to reach the recommended national ratio of Supervisors of Midwives to midwives, and to ensure that their value to the trust is suitably recognised and rewarded.

Recommendation 9

The trust should ensure that it takes the necessary steps to fill all vacant posts that have a significant impact on the operational and clinical governance effectiveness of the maternity division and wider trust.

Recommendation 10

The trust should undertake a review of its training provision, including the provision of protected time for doctors, midwives and maternity care assistants to attend normal birth workshops and multi-professional mandatory and developmental training, including training as outlined in the service specification for maternity services 2008/09.

Recommendation 11

The trust should review its anaesthetic rota and theatre arrangements, to ensure that it complies with the requirement to have a 24-hour dedicated obstetric theatre, and 24-hour immediate availability to an anaesthetist.

Recommendation 12

We recommend that the acute trust and PCT increase their collaboration in order to enable the recommendations of the two previous reviews into maternity services at Milton Keynes and the requirements of the service specification for maternity services 2008/09 to be successfully completed.

Appendix: Statistics

Type of delivery

Since 2004/05, caesarean section rates at the trust have risen by 6% to 28% (2006/07). Although increasing caesarean section rates are a national problem, local elective and emergency caesarean section rates (10.6% and 17.9%) are above the national averages (9.5% and 14.7%).³

Table 1: Types of delivery at Milton Keynes Hospital NHS Foundation Trust, 2004/05-2006/07

Type of delivery	2004/05	2005/06	2006/07
Spontaneous vaginal delivery	65%	66%	61%
Caesarean section	22%	24%	28%
Vacuum deliveries	8%	6%	5%
Forceps deliveries	5%	3%	4%

Source: HES online – NHS Maternity Statistics, England (based on declared records)

Outcomes – maternal morbidity

As can be seen from table 2 below, postpartum haemorrhage rates for the trust have been consistently lower than the national average, throughout 2006/07 and 2007/08.⁴

³ HES online– NHS Maternity Statistics, England 2006/07

⁴ Hospital Episode Statistics, Healthcare Commission

Table 2: Percentage of delivery spells where a post partum haemorrhage occurred – Milton Keynes Hospital NHS Foundation Trust (April 2006-March 2008)

	Milton Keynes General Hospital NHS Trust	All trusts
06/07 Q1*	3.4%	7.5%
06/07 Q2*	3.0%	7.8%
06/07 Q3*	2.8%	8.3%
06/07 Q4*	5.2%	8.6%
07/08 Q1*	9.2%	9.4%
07/08 Q2*	4.4%	9.1%
07/08 Q3*	5.6%	9.2%
07/08 Q4*	4.7%	9.0%

Source: Hospital Episode Statistics, Healthcare Commission

* Q1 = Quarter 1 April to June; Q2 = Quarter 2 July to Sept; Q3 = Quarter 3 Oct to Dec; Q4 = Quarter 4 Jan to March.

Rates of third and fourth degree perineal tears are high, consistently running at (above) 2% (RCOG Green-top Guideline no. 29 states that 1% births are associated with third or fourth degree tears).⁵

Table 3: Third and fourth tears as a percentage of all births – Milton Keynes Hospital NHS Foundation Trust (2005/06-2007/08)

	Percentage of all births		
	2005/06	2006/07	2007/08
Third degree perineal laceration during delivery	2.3	2.8	1.8
Fourth degree perineal laceration during delivery	0.1	0.2	0.2
Third or fourth degree perineal lacerations	2.4	3.0	2.0

Data provided by Milton Keynes PCT

⁵ Data Provided by Milton Keynes PCT using SUS

Outcomes – perinatal mortality

The perinatal mortality rate is calculated as the number of stillbirths plus number of deaths at ages less than one week, per 1,000 live births and stillbirths. Analysis of standardised mortality rates by quarter, from April 2005 until March 2008, shows the trust to have higher than expected numbers of deaths between April and December 2005, and between July 2006 and March 2007.⁶ However, from April 2007 onwards, perinatal mortality at the trust is lower than expected.⁷ Figures 1 and 2 below show an overall downward trend for stillbirths, perinatal and neonatal death rates within the trusts, with rates of stillbirths currently being on par with other trusts within the strategic health authority region.

Figure 1: Trust mortality rates, 2005-2007

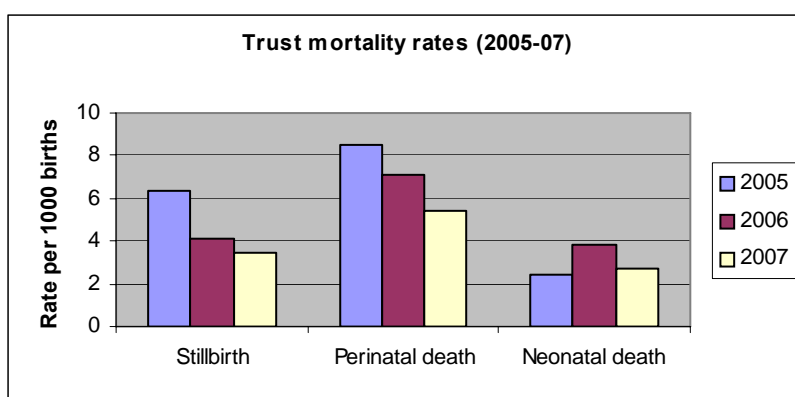
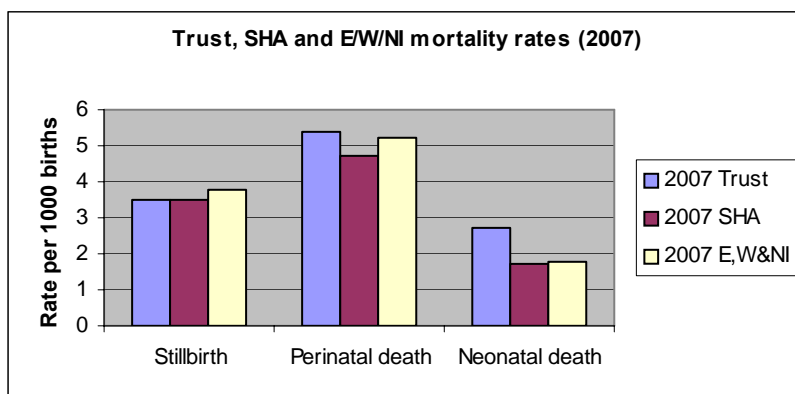


Figure 2: Trust, SHA and England/Wales/Northern Ireland mortality rates, 2007



Source: CEMACH – Perinatal Mortality Report 2007 (2008)

Notes:

- All rates are adjusted by removing terminations, lethal malformations, gestation <22 weeks and birth weight <500g.
- Perinatal death rate is per 1,000 total births.
- Neonatal death rate is per 1,000 live births.
- A χ^2 test revealed that there is no statistically significant difference between the rates over the three years.

⁶ 'Expected' values are produced from a comparison against other trusts in England, standardised by sex

⁷ Hospital Episode Statistics, Healthcare Commission