



Care Quality Commission
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Private & confidential

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8 January 2010

Ref: 0511/as

Dear Dr Goldman,

Concerns about Governance and the Safety of Patients

I am writing in relation to the concerns about governance and the safety of patients which you brought to the attention of the Care Quality Commission in April 2009. The findings of our enquiries into the concerns are detailed in this letter. I am grateful for the assistance of your staff in providing the extensive documentation for our enquiries and during the feedback visit on the 23 October 2009.

Concerns in details

As you know, the concerns were raised following the death of a [REDACTED] who underwent an appendectomy in 2007. [REDACTED] death was subject to a coroner's inquiry between 20 and 24 April 2009. The trust reported that at this time it was acknowledged that there were a number of other Serious Untoward Incidents across the trust, however the trust did not identify any specific trends from these incidents. In agreement with Monitor the trust referred the matter of governance and the safety of patients to the Care Quality Commission for review.

As a result of this, to ensure the safety of patients and make certain that lessons have been learnt, the Investigations team agreed to:

- Review the steps that have been taken by the trust to ensure that each Serious Untoward Incident was investigated thoroughly and the appropriate learning opportunities were identified
- Review the governance arrangements in place at the trust
- Assess whether sufficient steps have been taken to ensure that the culture, the reporting tools and the information escalated to the Board are appropriate in relation to the safety of patients

The Commission has not conducted a formal investigation, but have considered the information carefully in order to decide if any further action is necessary, and if so, the appropriate course of action. Having reviewed and discussed the information available to us, we are now in the position to provide the trust with the findings of our enquiries.

Findings in detail

1. Review the steps that have been taken by the trust to ensure that each Serious Untoward Incident (SUI) was investigated thoroughly and the appropriate learning opportunities were identified

The trust has provided information relating to 27 SUIs which have occurred at the trust between March 2007 and June 2009. Of these SUIs 16 occurred at Birmingham Heartlands Hospital, six at Good Hope Hospital and two at Solihull Hospital. Two of the SUIs were in relation to the loss of confidential data and do not specify which hospital the incident occurred at. Furthermore, there was an additional SUI relating to the overmedication of a baby, the report does not specify at which hospital this incident occurred.

The following themes arose from the 27 SUIs:

Theme	Number where present
Medication error (all but 1 resulted in death)	6
Delay in recognising clinical picture – Junior staff not escalating concerns in a timely manner	6
Lack of appropriate training	6
Inappropriate discharge of patient	3
Poor record keeping	3
Poor communication	3
Delay in appropriate medical input	2
Insufficient staffing levels	2
Insufficient monitoring of patient	1

All SUIs had a root cause analysis and an action plan which included identified action and learning from the incident. The review of the 27 SUI action plans provided by the trust found the majority of actions to be clear with timescales and details of individual responsibility for implementing the recommendation. There are, however a number of recommendations which are ambiguous with limited indication of how the recommendation will be achieved, for example:

The Nursing Directorate should consider a mechanism which will deter staff from routinely raising integral bed rails unless bed rails are specifically required.

The trust should ensure that clear recommendations are made in all cases.

On review of the action plans, a considerable number of the recommendations did not appear to have been signed off despite the date of completion having lapsed. There are slightly different forms for some of the action plans which may have influenced the level of detail provided. The trust clarified the system in place for checking the implementation of recommendations from SUI investigation is as follows; all identified actions are submitted to the Governance team. The details of each action are collated centrally and the identified lead is required to provide a progress update against their actions on a monthly basis to the Governance team and then to the appropriate business unit Quality and Safety Committee.

The progress against actions is monitored by the relevant Quality & Safety Committee on a monthly basis, who in turn provides assurance to the Business Unit Executive Committees (monthly) and Governance & Risk Committee (bi-monthly). When agreement is reached by the Business Unit and Governance directorate that the action is complete it is removed from the report.

We note that the trust acknowledges that their action plans are in a variety of formats, which, they report is representative of the evolution of the SUI process and their efforts to make the action planning and implementation process more effective. The trust SUI process is currently under revision, led by the Director of Medical Safety which includes a review of how the trust is monitoring and ensuring that recommendations are implemented. The trust needs to ensure it has a clear mechanism to track how and when each recommendation is implemented.

The trust has undertaken a review of the SUI's to ascertain the trends and themes arising from them. The review looked at 16 incidents reported between November 2007 and December 2008. The review identified the top four underlying causes to be:

- Poor documentation
- Lack of escalation to senior colleagues
- Lack of recognition of a deteriorating patient
- Non compliance with guidelines.

The SUI review was presented to the Governance and Risk Committee in February 2009 and subsequently the trust has demonstrated the following actions:

- The new Modified Early Warning Scoring (MEWS) System and Paediatric Early Warning System (PEWS) policies now contain guidelines on escalation of abnormal physiological parameters.
- Consultants to advise their junior and middle grade doctors at induction to contact more senior colleagues when a patient shows signs of deterioration or if they are concerned.

The minutes of this meeting also indicate that the trust have identified a need to improve communication about learning from adverse events across the trust. Subsequently, the trust report to be in the process of developing a Safety Communications Strategy. It was also recorded that patient stories are being incorporated into patient safety training.

The trust has identified a cluster of SUIs within the paediatric service, as such they commissioned an external review of Paediatric Services within the trust led by the Royal College of Paediatrics and Child Health. The aim of the review is to provide assurance to the trust in relation to the systems currently in place in those clinical areas, the actions taken to remedy prior root cause identified in the previous 12-24 months and to identify any further areas of improvement in clinical practice, managerial arrangements or governance.

2. Review the governance arrangements in place at the trust

The trust board committee and membership's structure is in line with Monitor's Code of Governance. The trust has a dedicated board level lead, Director of Governance and Standards to lead on safety and governance across the organisation.

The trust appears to have clear boundaries and lines of accountability within each Committee which should serve to assist with decision making and timely sharing of information. There appears to be clear accountability and delegation of responsibility within the structure. Furthermore, at each board meeting the board considers the minutes of the sub-committees.

The trust has evidenced that they have a full Governance Committee framework in place to support it with the delivery of the trust's organisational safety arrangements. Whilst the board retains overall responsibility for safety, risk and governance across the organisation, it is supported in discharging these duties via the board level Governance and Risk Committee, chaired by the Deputy Chair. This Committee oversees trust wide programmes of work relating to these areas. The sub-committees to whom specific aspects of work are delegated from the risk committee are:

- Safety Committee
- Patient Quality Committee
- Clinical Standards Committee
- Information Governance Committee
- Mortality & Morbidity Group
- Equality & Diversity Committee

The Risk Committee is supported by a full range of technical sub-committees who advise on specialist aspects of the trust governance and safety programme and provide reports to the Risk Committee as necessary.

The trust's safety programmes are overseen by three key groups:

- Safety Committee- corporate safety programmes
- Medicine Quality and Safety Committee- clinical operational safety within the business units/directorates
- Surgery Quality and Safety Committee- clinical operational safety within the business units/directorates

The clinical business units monitor their safety and quality programme through their own Safety and Quality Committees. Progress is monitored against: risk registers, safety alerts, local risk management issues, incidents, complaints and business cases. Operational reports are presented to the Governance and Risk Committee on a bi-monthly basis and issues of concern would also be escalated to the trust's Executive Directors Committee, the Surgical and Medical Executive Committees.

Implementation and delivery of effective risk management is monitored using the Assurance Framework and the trust's governance reporting framework. The committee structure of the trust is aligned to the Integrated Governance Framework. Internal audit concludes that the trust's 2008/2009 assurance framework was comprehensive. The Assurance Framework is used to monitor strategic risks and these are linked to the achievement of the trust's

corporate objectives, monitored by reports to the trust board and through the performance monitoring framework. The purpose of the dual system is to monitor how well the trust are performing against the quality and safety measures and managing risks.

In October 2008, the trust report that it was agreed that more formal arrangements were required to monitor their performance against the quality indicators in the NHS Contract between the trust and the Commissioners. The Clinical Quality Review Group was established and chaired by the lead Commissioners, Birmingham East & North PCT and this superseded the Health Economy Joint Patient Safety and Quality Advisory Group.

The trust has gained National Health Service Litigation Authority Risk Management Standards for Acute Trusts at Level 2 and in January 2008 the maternity service within the trust achieved compliance with Level 3 of the Maternity risk management standards.

3. Assess whether sufficient steps have been taken to ensure that the culture, the reporting tools and the information escalated to the Board are appropriate in relation to the safety of patients

Board Involvement

The trust has evidenced that the Executive Directors along with the Patient Safety Team have conducted a number of patient safety walk-around within clinical areas of the trust. The walk-arounds are a way of ensuring that executives are informed first hand regarding the safety concerns of frontline staff. The trust also views the walk-around as a way of demonstrating visible commitment by listening to and supporting staff when issues of safety are raised. The trust has stated that walk-arounds are instrumental in developing an open culture where the safety of patients is seen as the priority of the organisation.

The trust has evidenced that Patient Safety Walk-arounds commenced in January 2008. Since then a total of nine walk-arounds have been conducted and the process has been refined. Action plans are developed after every walk-around and are followed up by the patient safety team. Feedback meetings to individual wards on progress are also conducted. Furthermore, the trust reports that action plans from all future walk-arounds will be presented to the Governance and Risk Committee and medical/ surgical quality and safety committees.

Walk-arounds are monitored in the following ways:

- Number of walk-arounds performed
- Number of actions identified and completed
- Reassessment of the safety culture of frontline workers and managers
- Increase in reporting of patient safety incidents/prevented incidents
- A decrease in risk/severity of outcome of adverse events identified through case note review using the Global Trigger Tool.

There have been several common themes identified from walk-arounds which include Communication issues between Accident and Emergency and Ward areas, Environmental concerns relating to Mixed sex accommodation, provision of oxygen and air points, congestion within A&E, provision of a high risk of falls area and Training concerns in relation to access and availability of training.



Reporting Tools

The trust implemented a Being Open Policy in 2009. They state that they have encouraged incident reporting by staff over the years through training of junior doctors, senior sisters, at induction and clinical governance meetings. The reporting of incidents is undertaken by either completing a paper incident IR1 or electronic form. The use of electronic reporting is currently being phased in across the trust with training being provided to all relevant staff. The trust has recognised that reporting by doctors needs to be strengthened and this is being addressed within the Safety Strategy.

The Commission considered surveys undertaken by Post Medical Education Training Board in relation to junior doctors at the trust. The sample size is very small but highlights concerns regarding supervision, consent and how incidents are reported. It is suggested that the trust consider undertaking a similar survey using a larger sample to explore this area further.

As previously stated, the minutes of the Governance and Risk Committee in February 2009 indicate that the trust has identified a need to improve communication about learning from adverse events across the trust. As a result of this, the trust is developing a Safety Communication Strategy.

Information Escalated to Board

As detailed in the previous section regarding governance, the trust has demonstrated clear lines of accountability in order to escalate concerns in relation to the safety of patients to the board.

Conclusion

In summary the trust has robust governance processes in place and a clear mechanism to investigate and learn from incidents that occur. The Trust has been proactive in identifying any trends with regards to incidents and has commissioned internal reviews in areas of concerns such as the Paediatric and Neonatal review. There are improvements to be made with regards to the SUI process which the trust have recognised and is working to improve. The Trust is also continuing to work on improving the culture at the trust, ensuring that incidents are reported and any serious concerns are escalated to the Board for action.

On the basis of the information provided, the Commission does not have any immediate concerns relating to the safety of patients and will close this case. Thank you again for the assistance of your staff in our enquiries.

If you would like to discuss any of these issues, please do not hesitate to contact me on [REDACTED] or at [REDACTED]

Yours sincerely

[REDACTED]
[REDACTED]
Investigations Manager



CC: William Moyes, Chairman, Monitor
Sophia Christie, Chief Executive, Birmingham East and North PCT
Andrea Gordon, Regional Director, Care Quality Commission