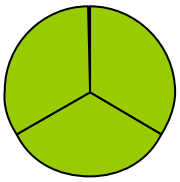
Internal Audit

Clinical Governance

January 2015

Report Assessment



Distribution List

- Chief Executive
- Director of Finance
- Chair of the Healthcare Governance Committee
- Medical Director
- Executive Director of Nursing, AHPs and Unscheduled Care
- Director of Human Resources & Organisational Development
- Employee Director
- Deputy Executive Nurse Director
- Director of Communications & Public Affairs
- Clinical Governance & Risk Manager
- Audit Scotland, External Audit

Contents

Page 1	Introduction
Page 2	Executive Summary
Page 4	Management Action Plan
Page 8	Appendix 1: Definition of ratings

Introduction

The concept of clinical governance was introduced to NHS Scotland in the Scottish Executive white paper *Designed to Care* (SEHD, 1997) to ensure that quality of care is given the same prominence as other key drivers such as finance and staffing. It has been described as 'corporate accountability for clinical performance' and is the system for making sure that healthcare is safe and effective, and that patients and the public are engaged in decision making.

The Healthcare Governance Committee, a sub-committee of the NHS Lothian Board, was established to provide assurance that the quality of all aspects of care in NHS Lothian is person-centred, safe, effective, equitable and in line with current standards.

The implementation of clinical governance standards is an organisational responsibility and is delivered through the monitoring, reporting, review and continuous improvement of all aspects of quality and safety of clinical care. Under the Board's Scheme of Delegation, the Medical Director and Executive Director of Nursing, AHPs & Unscheduled Care are responsible for ensuring sound frameworks and effective assurance systems are in place for healthcare governance and risk management.

The Clinical Governance and Risk Management Support Team facilitate and advise on appropriate methodology to support quality improvement work across NHS Lothian. The overall role of the Clinical Governance & Risk Management Support Team (CGRMST) is to support staff to improve the outcomes of care. CGRMST work with teams at all levels within the organisation to help them develop and improve their systems and processes.

Scope

We reviewed arrangements in place for the management of Clinical Governance within NHS Lothian. The control objectives for this audit, along with our assessment of the controls in place to meet each objective, are set out in the summary of findings.

Acknowledgements

We would like to thank all staff consulted during this review, for their assistance and cooperation.

Executive Summary

Conclusion

The controls NHS Lothian has in place to manage clinical governance are adequate and operating effectively. This review has identified a number of opportunities for improving processes and practices which will benefit future clinical governance activities.

Summary of Findings

The table below summarises our assessment of the adequacy and effectiveness of the controls in place to meet each of the objectives agreed for this audit. Definitions of the ratings applied to each action are set out in Appendix 1.

No.	Control Objective	Control objective assessment	Number of actions by action rating			
			Critical	Significant	Important	Minor
1	The Healthcare Governance Committee receives appropriate assurances over clinical governance.	Green			1	
2	Risks associated with clinical governance are clearly identified, with action plans to address any exposures	Green		1		
3	Significant adverse events are actioned appropriately	Green			1	

Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention. (60 points and above)
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points)
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less)

Main Findings

We noted a number of areas of good practice during the review.

The remit of the Healthcare Governance Committee is clearly defined in its terms of reference. A Statement of Assurance Need was developed by the Committee to identify the information required in order to gain assurance that clinical areas are managed effectively and to ensure its terms of reference have been met. Processes are in place to identify whether the information sources documented in the Statement of Assurance Need provide sufficient assurance and to highlight areas where additional information is required.

The Clinical Governance & Risk Management Support Team (CG&RMST) provides advice and support to the Healthcare Governance Committee and clinical areas. It has advised on the review of corporate and divisional risk registers using the Best Value Toolkit as well as the implementation of the Significant Adverse Events Improvement Plan.

We identified one significant and two important areas for improvement during the review:

- As part of its annual self assessment, the Healthcare Governance Committee should review the draft Statement of Assurance Need for 2014/15 alongside the 2013/14 version to determine whether the additional sources of assurance are sufficient or whether further assurance sources should be sought.

- Quarterly alerts should be issued to remind managers to update divisional risks and routine risk reporting to the Healthcare Governance Committee should identify whether divisional risks are being reviewed and updated. Routine reporting should also address the outcomes of the ongoing review of divisional risk registers due for completion in summer 2015.

- The outcomes of the diagnostic review process for Significant Adverse Events and explanations for any reviews that exceed the 66 day limit should be routinely reported to the Healthcare Governance Committee.

Further details of each of these points are set out in the Management Action Plan

Management Action Plan

The Healthcare Governance Committee receives appropriate assurances over clinical governance	
1.1: Statement of Assurance Need	**Important**
Observation and risk At the end of 2013/14 the Healthcare Governance Committee implemented a process to review its work using a Statement of Assurance Need. The Statement of Assurance Need sets out the areas for which the Healthcare Governance Committee requires assurance as part of its remit and Terms of Reference. It captures the processes and information sources used by the Healthcare Governance Committee to gain assurance that these areas are being managed effectively. It also concludes on the assurance provided by those processes, and identifies several areas where the Healthcare Governance Committee doesn't currently have sufficient assurance. These areas are reflected in the Committee's annual work plans for 2014/15. Progress against the plans is reported at each meeting of the Healthcare Governance Committee. As the process has not yet completed a full annual cycle, the Healthcare Governance Committee has not yet assessed the Statement of Assurance Need in full to determine whether the additional work included on the action plans has given the necessary assurance or whether further information is required. There is a risk the additional information will also fail to provide adequate assurance unless a follow-up review is conducted to determine whether it is sufficient or whether further assurance is necessary.	
Recommendation As part of its annual self assessment, the Healthcare Governance Committee should review the draft Statement of Assurance Need for 2014/15 alongside the 2013/14 version to determine whether the additional sources of assurance are sufficient or whether further assurance sources should be sought.	
Management Response and action: As part of the completion of HCG annual report the HCG Committee will undertake the above recommendation.	
Responsibility: Clinical Governance and Risk Manager	Target date: March 2015

Control Objective 2: Risks associated with clinical governance are clearly identified, with action plans to address any exposures	
2.1: Review and update of divisional clinical governance risks	**Significant**
Observation and risk Controls are in place to ensure that Corporate clinical governance risks are reviewed, updated and reported to the Healthcare Governance Committee at bi-monthly meetings. However this process is not replicated at divisional level. The Audit & Risk Committee agreed a proposal to carry out a self-assessment of the Risk Management System using the Audit Scotland Best Value Toolkit for Risk Management in order to highlight areas for improvement at a service level. A report showing the outcome of the review process will be provided to the Audit and Risk Committee in the Summer of 2015. We reviewed the risk management processes of 23 service areas and found that four were not updating divisional risk data in Datix. Although the service areas advised that risks had been considered, reviewed and actions had been taken to manage them, Datix records had not been updated to reflect this. There is a risk that NHS Lothian will be unable to demonstrate that it has identified new or changing divisional risks or that it has taken mitigating actions to address them at service level.	
Recommendation Quarterly alerts should be issued to remind managers to update divisional risks. Service areas should also be reminded that the NHS Lothian Risk Management Policy requires that divisional risk reviews are updated on the Risk Register System (datix) Routine risk reporting to the Healthcare Governance Committee should identify whether divisional risks are being reviewed and updated. Routine reporting should also address the outcomes of the ongoing review of divisional risk registers due for completion in Summer 2015.	
Management Response and action: We are reviewing the corporate and divisional risks as part of the ongoing risk review which will be completed and reported on to the Healthcare Governance Committee in summer 2015.	
Responsibility: Clinical Governance and Risk Manager	Target date: July 2015

Control Objective 3: Significant Adverse Events	
3.1 Significant adverse event reporting	**Important**

Observation and risk

NHS Lothian's Adverse Event Management Policy requires that formal reviews of significant adverse events (SAEs) causing death or major harm commence within 10 working days and be completed within 66 working days of an incident. We found that reviews had not been completed within the 66 day limit for 186 of the 261 open Significant Adverse Events at November 2014.

All departments have access to the Datix dashboard which provides managers with details of any SAE reviews that have exceeded the 66 day limit and diagnostic information is available that demonstrates the reasons for the delay in real time. This process was implemented as part of the Significant Adverse Events Improvement Plan.

Details of Significant Adverse Events are currently reported to the Healthcare Governance Committee, including the number of reviews that haven't been completed within 66 days. However explanations for any delays are not routinely reported to the Healthcare Governance Committee.

There is a risk that further adverse events could occur if causes of SAE's are not identified and managed within the 66 day limit defined in the policy.

Recommendation

The outcomes of the diagnostic review process and explanations for any reviews that exceed the 66 day limit should be routinely reported to the Healthcare Governance Committee. Where common causes, issues or themes emerge the Healthcare Governance Committee should identify opportunities to improve performance.

Management Response and action:

The Clinical Governance and Risk Management Support Team have been using diagnostic information available in Datix to get a better understanding of the reasons for delays in the SAE review process and will report findings of the review to the Healthcare Governance Committee in March 2015. Routine reporting will also be introduced from March 2015.

Responsibility: Clinical Governance and Risk Manager	Target date: March 2015

Appendix 1 - Definition of Ratings

Management Action Ratings

Action Ratings	Definition
Critical	The issue has a material effect upon the wider organisation – 60 points
Significant	The issue is material for the subject under review – 20 points
Important	The issue is relevant for the subject under review – 10 points
Minor	This issue is a housekeeping point for the subject under review – 5 points

Report Ratings

Issue Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention. (60 points and above)
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points)
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less)