

Meeting of:
Lanarkshire NHS Board
28 July 2010

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SUBJECT: CLINICAL GOVERNANCE

1. PURPOSE

This purpose of this paper is to provide a progress report to Lanarkshire NHS Board on quality assurance, with a focus on Clinical Quality and Research and Development.

2. MONTHLY REPORT TO THE BOARD ON QUALITY ASSURANCE

2.1 NHS Scotland Quality Strategy

NHS Lanarkshire has and will continue to support the implementation of the NHS Scotland Quality Strategy and representatives attended an event on the development of the Quality Improvement Hub on 29 June 2010.

2.2 NHS Quality Improvement Scotland Activity

The following activity has taken place in relation to QIS peer review visits, QIS Standards, SIGN guidelines and NPSA alerts.

NHS QIS Peer Review Visits

Sexual Health Services

QIS will be reviewing NHS Boards' compliance with the standards for Sexual Health Services, which were published in March 2008 as part of the 2010/11 peer review programme. NHS Boards have been asked to evaluate their services and collate evidence to support the self assessment, which was issued to Boards in July 2009.

NHS QIS Standards

Draft standards for HIV Services

The main project group and three sub-groups met in April and May to further develop 10 standards for HIV services in Scotland. A new performance assessment methodology was agreed by NHS QIS which uses a quality improvement scale to assess standards at the standards level as opposed to the criteria level.

Heart Disease Improvement Process

NHS QIS are streamlining their approach into a new way of working. Boards will not receive a QIS review visit, instead Evaluation Panels made up of clinical peers, patient representatives and governance staff will review evidence that is submitted. Boards will then be given the opportunity to meet with the review panel, which for NHS Lanarkshire is in January/early February 2011, to explore the results of the panel evaluation and to discuss plans for improvement.

Neurological Health Services Clinical Standards

Neurology Improvement Leads in each board have been asked to complete a baseline self evaluation and identify a top ten of the criteria which their neurological services team considers to be the priority areas for improvement support within their Board area.

SIGN Guidelines

The following SIGN guidelines activity on guidelines has taken place.

Guideline No	Guideline Name	Publication Date	Process
SIGN 120	Management of Chronic Venous Leg Ulcers	September 2010	Leads to be identified
SIGN 119	Management of Patients with Stroke: Identification and Management of Dysphagia	June 2010	Minor update of guideline SIGN 78, issued for consideration
SIGN 118	Management of Patients with Stroke	June 2010	Leads have recommended full implementation and a financial impact is not expected

National Patient Safety Programme (NPSA)

The following NPSA alerts have been received and circulated; these are advisory for NHS Scotland:

- NPSA/2010/RRR013 - Safer administration of insulin

2.2 Other Reviews and Inspections

Healthcare Environment Inspectorate

The report of the Healthcare Environment Inspectorate announced inspection of Hairmyres Hospital on 25 and 26 May 2010 was published along with NHS Lanarkshire's Action Plan in response to the inspection on 8 July 2010.

Her Majesty's Inspectorate of Education (HMIE)

HMIE Inspectors will be undertaking an inspection of South Lanarkshire's services to protect children and young people over two full weeks from 30 August to 3 September and 13 September to 17 September 2010. The inspection team of 12 will be multi agency including inspectors with a variety of work backgrounds.

Prior to the team's arrival they will have scrutinised previous inspection reports from HMIE, Social Work Inspection Agency, Care Commission and any inspection reports relating to the NHS, Social Work and Police. The Child Protection Committee completes a pre-inspection return, detailing structures and services in the area.

HMIE will also be inspecting North Lanarkshire and the three phases of the fieldwork inspection activity – scoping, core and proportionate will take place over the two week period beginning 22 November 2010.

Mental Welfare Commission (MWC) for Scotland Visit

For the first time the MWC will be conducting visits outwith Mental Health and Learning Disability wards and have chosen dementia as the focus of their visit. The visit will focus on care and treatment of patients with dementia.

3. UPDATE ON CLINICAL QUALITY

3.1 Clinical Quality Service Development

The restructuring of Primary Care Clinical Governance and Acute Clinical Effectiveness services was completed on 1 July 2010. Four Performance Quality Coordinators will be retained within Primary Care to support performance management and service evaluation within the localities and Mental Health / Learning Disabilities. The remaining staff will make up the newly established Clinical Quality Service, comprising of six clinical quality work streams aligned to local and national priority areas and the Healthcare Quality Strategy for NHS Scotland.

The focus for the new teams in the next quarter will include:

- Staff induction into new teams and agreeing and implementing a programme of training and development
- Formal handover of work to appropriate work streams
- Scoping exercise to identify unnecessary clinical quality support for legacy audits, inefficient methodologies and duplication, to create a more efficient, quality driven service.
- Redevelopment of the acute online project register to capture local and national Clinical Quality work across NHS Lanarkshire, improving feedback mechanisms and allowing audit tracking of information
- Development of an NHS Lanarkshire-wide audit information pack to aid clinicians in undertaking high quality audit.
- Formal launch of the new Clinical Quality Service including actively promoting the new team through agreed branding/website, and by targeted promotion with an emphasis on a single team, core services and a new way of working.

3.2 2010/11 Work Programme

The draft Clinical Quality Service Work Programme for 2010/11 has been subject to review and prioritisation by representatives from the Acute and Joint CHP Clinical Governance and Risk Management Committees (on the 25 June 2010 and 8 July 2010). This document will go out to service leads for consultation prior to final sign off and approval by the committees in July/August 2010.

Part of the review process for the primary care element of the work programme included an exercise to determine which work currently being supported by Primary Care Clinical Governance should continue, if it should be carried out by Performance Quality or Clinical Quality and whether the work should be treated as essential or desirable priorities. There was also discussion around developing more efficient and improved ways of working in relation to providing Clinical Quality support.

3. UPDATE ON RESEARCH AND DEVELOPMENT

3.1 Chief Scientist Office (CSO) Research Governance Standards (Fifth Review)

The CSO operates a set of research governance standards to ensure that rigorous research governance systems are in place and being applied across the NHS in Scotland. NHS Boards are required to complete a self assessment reporting tool annually.

As research governance is part of the NHS in Scotland quality agenda, initially NHS QIS included research governance as part of the Clinical Governance and Risk Management (CGRM) standards assessment. Since 2006 the CSO has developed a more detailed set of research governance standards to underpin the CGRM standard and the CSO provides feedback to QIS on levels of attainment against these standards for each NHS Board annually.

NHS Lanarkshire has recently received its report from the CSO on its attainment against the research governance standards. The outcome of this is set out below and from this it can be seen that there has been a significant improvement attainment.

The scoring system is:

Level 1	Development	The NHS Board is developing a system for research governance that includes systems, policies and procedures.
Level 2	Implementing	The NHS Board is implementing its research governance systems, policies and procedures across the organisation.
Level 3	Monitoring	The NHS Board is monitoring the implementation of its systems, policies and procedures for research governance across the organisation.
Level 4	Evaluating	The NHS Board is evaluating the impact of its systems, policies and procedures for research governance across the organisation.

Standard	Score awarded Review 4	Score awarded Review 5	Improvement
1. Describe the management and reporting structures within the organisation for research governance.	Level 2	Level 4	Improvement
2.1 Describe the R&D Management Approval procedures in place in the organisation for all research and provide evidence which verifies this. 2.2 Describe the Audit and Monitoring arrangements in place to enable scrutiny of the recruitment practices of researchers in relation to obtaining informed consent and adherence to the project Protocol.	Level 2	Level 3	Improvement
3.1 Provide evidence of communication systems and training in place to ensure awareness of the Research Governance Framework and associated guidance. 3.2 Provide a copy of a written agreement and an Honorary Research Contract agreed in the last financial year. 3.3 Provide a copy of a Research Passport granted and a copy of a letter confirming you have accepted a Research Passport during the last financial year.	Not Met	Level 2 following submission of further evidence	Improvement
4. Describe the systems that are in place for the costing, financial management and accounting of all research activity.	Level 1	Level 4	Improvement
5. How does the organisation ensure that all research undertaken by the organisation complies with statutory legislation and guidance?	Level 2	Level 3	Improvement
6.1 Describe the procedures in place for recording and reporting adverse events arising from research including clinical trials covered by the Medicines for Human Use (Clinical Trials) Regulations 2004.	Level 2	Level 3	Improvement

Standard	Score awarded Review 4	Score awarded Review 5	Improvement
<p>6.2 How is the policy disseminated to all areas in order to facilitate staff adoption and use of the process?</p>			
<p>7.1 Describe the procedures that are in place to ensure agreement is reached on the identification of Sponsors for all research activity.</p> <p>7.2 Provide a copy of a Sponsorship agreement/ documentation from the last financial year confirming Sponsorship arrangements for an agreed study/ trial.</p>	Level 3	Level 3	Maintained
<p>8.1 Describe the monitoring and reporting systems in place to ensure that research misconduct and fraud are detected and acted upon.</p> <p>8.2 What training is in place to enable staff to recognise and deal appropriately with the types of research misconduct and fraud that may arise?</p>	Level 2	Level 3	Improvement
<p>9.1 Describe how the organisation involves consumers in the research process.</p> <p>9.2 Provide evidence of the range of information formats used to let service users and the public know about research undertaken by the organisation.</p>	Level 1	Level 2 following submission of further evidence	Improvement
<p>10.1 Describe the measures in place to ensure that the findings of research are appropriately disseminated, recorded and followed up.</p> <p>10.2 What requirements are placed on researchers to ensure that research findings are disseminated and made available to research subjects?</p> <p>10.3 Provide evidence of the publication of research findings from the last financial year.</p>	Level 2	Level 2 following submission of further evidence	Maintained
<p>11.1 Describe the mechanisms in place to ensure the identification of Intellectual Property as it arises, either through approval, monitoring or end of project routines.</p> <p>11.2 Describe the Intellectual Property policies in place in the organisation that demonstrate compliance with current guidelines and set out arrangements for ownership, exploitation and income sharing with internal staff and internal bodies.</p>	Level 2	Level 3 following submission of further evidence	Improvement
<p>12.1 Describe how the organisation monitors/ reviews/ evaluates the system for research governance and ensures that improvements are made where necessary.</p> <p>12.2 Provide evidence of the research governance indicators the organisation has developed and implemented.</p>	Level 2	Level 2	Maintained

Standard	Score awarded Review 4	Score awarded Review 5	Improvement
<p>13.1 Provide the number of single-site studies for 2009-10, the mean number of approval days, the median number of approval days, the number of studies that took more than 30 days and the number that took more than 60 days.</p> <p>13.2 Provide the number of multi-site studies for 2009-10, the mean number of approval days, the number of studies that took more than 30 days and the number that took more than 60 days.</p> <p>13.3 Describe how the organisation monitors/ reviews/ evaluates the system for R&D approval and ensures that improvements are made where necessary.</p> <p>13.4 Describe how the organisation participates in the NRS approval process and provide training on the agreed Standard Operating Procedures.</p>	N/A	Level 2	New Standard more work required.

3.2 Medicines and Healthcare Products Regulatory Agency (MHRA) Statutory Good Clinical Practice Inspection of Clinical Trials of Investigational Medicinal Products

The MHRA's Good Clinical Practice (GCP) Inspectorate is part of the Inspections and Standards Division of the MHRA. It assesses the compliance of organisations conducting clinical trials using investigational medicinal products with UK and EU legislation. On the 9 and 10 June 2010 the MHRA inspected an NHS Lanarkshire primary care clinical trial.

The finding from this inspection will be provided in a report which is expected to be received at the end of July 2010. Once NHS Lanarkshire is in receipt of this report we will have 30 days to respond to the Inspector regarding his findings

4. FURTHER INFORMATION

For further information or clarification of any issues in this paper please contact:

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