North West Independent Hospital
RQIA ID: 10624
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Ballykelly
BT49 9HS

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Announced Medicines Management Inspection of North West Independent Hospital

19 January 2016

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
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1. Summary of Inspection

An announced medicines management inspection took place on 19 January 2016 from 10.30 to 16.30.

The management of medicines was found to be safe, effective and compassionate. The outcome of the inspection found no significant areas of concern though some areas for improvement were identified and are set out in the quality improvement plan (QIP) within this report.

This inspection was underpinned by The Independent Health Care Regulations (Northern Ireland) 2005 and the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments, July 2014.

1.1 Actions/Enforcement Taken Following the Last Medicines Management Inspection

Other than those actions detailed in the QIP there were no further actions required to be taken following the last inspection on 14 January 2013.

The Review Directorate within RQIA had undertaken a review of theatres, including those in North West Independent Hospital, in October 2014 and this included the management of medicines.

1.2 Actions/Enforcement Resulting from this Inspection

Enforcement action did not result from the findings of this inspection.

1.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	2	3

The details of the QIP within this report were discussed with Mrs Finola Carmichael, Registered Manager and Mrs Elizabeth Dallas, Chief Executive, as part of the inspection process. The timescales for completion commence from the date of inspection.

2. Service Details

Registered Organisation/Registered Person: North West Independent Hospital/ Mr Philip Stewart	**Registered Manager:** Mrs Finola Patricia Carmichael
Person in Charge of the Hospital at the Time of Inspection: Mrs Finola Patricia Carmichael	**Date Manager Registered:** 6 April 2011
Categories of Care: AH, PT(E), PT(L), AH(DS)	**Number of Registered Places:** 35

3. Inspection Focus

The inspection sought to assess progress with the issues raised during and since the last medicines management inspection and to determine if the following standards have been met:

Standard 25: Management of Medicines
Standard 26: Medicines Storage
Standard 27: Controlled Drugs
Standard 28: Medicines Records

4. Methods/Process

Specific methods/processes used included the following:

The management of incidents reported to RQIA since the last medicines management inspection was reviewed.

Discussion with the registered manager, chief executive, and ward/theatre staff on duty.

The inspection included a review of the management of medicines on one ward, in one theatre and in the pharmacy.

The following records were examined:

- medicines requested and received
- personal medication records
- medicine administration records
- medicines disposed of
- medicines transferred
- medicine audits
- policies and procedures
- training records
- medicines storage temperatures
- controlled drug records

5. The Inspection

5.1 Review of Requirements and Recommendations from the Previous Inspection

The previous inspection of the hospital was an announced care inspection dated 5 October 2015. The completed QIP was returned and approved by the care inspector.

5.2 Review of Requirements and Recommendations from the Last Medicines Management Inspection

No requirements were made.

Last Inspection Recommendations		Validation of Compliance
Recommendation 1 **Stated:** First time	The registered manager should further develop the policies and procedures for theatre and pharmacy to ensure they include the management of recording errors in controlled drug records.	**Met**
	Action taken as confirmed during the inspection: There was evidence that up to date written procedures regarding the management of errors in controlled drug records were in place.	

5.3 The Management of Medicines

Is Care Safe? (Quality of Life)

There was an organisational and management structure in place that identified the lines of accountability and specific roles and responsibilities for medicines management within the hospital. Staff advised committees met each quarter, which included clinical audit, risk management, clinical governance and evidenced based care. Within the organisation, the pharmacist has overall responsibility for the safe, secure and effective management of medicines.

Staff had access to up to date information relating to relevant legislation, medicines reference sources and guidance with respect to the safe and secure handling of medicines.

Separate requisition forms were in use for general medicines and controlled drugs. A list of the names and sample signatures of consultants and staff authorised to request medicines was maintained.

Satisfactory arrangements were in place for the management of drug alerts, medical device alerts and safety warnings about medicines.

There were incident reporting systems for identifying, recording, reporting, analysing and learning from adverse incidents and near misses involving medicines and medicinal products. A risk matrix was in place.

Medicines were stored safely and securely. Specific storage arrangements were in place for medicine keys. The management of medicines for emergency use were reviewed. Medicines required for resuscitation or other medical emergency were clearly defined and have been regularly monitored. However, the stock checklist and records for emergency medicines should be reviewed and a recommendation was made.

The management of medicines which require cold storage was examined. Satisfactory systems were in place in the theatre but not in the ward or in the pharmacy. Although maximum and minimum medicine refrigerator temperatures were recorded, some records showed that the temperature had fallen below the recommended minimum temperature of 2^{o}C. There was no evidence that this had been recognised and reported to management. It was agreed that the suitability of use of the medicines held in these refrigerators would be reviewed in consultation with the pharmacist/manufacturers after the inspection. In the ward it was noted that the refrigerator temperatures had been the same for a number of consecutive days, indicating that the thermometer was not reset on a daily basis. A requirement regarding the cold storage of medicines was made.

The Accountable Officer for the hospital is responsible for all aspects of the management of controlled drugs and attends the local intelligence network meetings.

The receipt, storage, administration and disposal of all controlled drugs subject to record keeping requirements were maintained in a controlled drug record book (CDRB). Separate sections in the ward CDRB were maintained for hospital stock and any stocks of controlled drugs brought into the hospital by patients. However, in relation to transfer and disposal, some missing details and signatures were noted in the ward CDRB. It was also found that some single doses of refused or wasted controlled drugs were not denatured prior to disposal in the ward. A recommendation was made.

Since the last medicines management inspection there had been improvements in the management of controlled drugs in theatre. These improvements were acknowledged and highlighted as evidence of good practice during the inspection.

Appropriate arrangements were in place to reconcile quantities of Schedule 2 and Schedule 3 controlled drugs which are subject to safe custody legislation. The good practice of monitoring stocks of controlled drugs which are not required to be stored in the controlled drugs cabinet was acknowledged.

In the ward, the audit of one randomly selected controlled drug could not be completed as entries in the CDRB were incomplete and did not correlate with the record of medicines administered and the record of medicines transferred to the patient on discharge. The registered manager was advised that this must be investigated. A requirement was made.

The majority of medicine records were legible and accurately maintained to ensure that there was a clear audit trail. The organisation had recently adopted the use of the most recent regional hospital kardex. Records of medicines ordered by ward and theatre staff were incomplete; staff signatures and dates of receipt were noted to be missing on a number of occasions. A recommendation was made. Records of the transfer of medicines to patients at the time of discharge were incomplete and there was evidence of some incorrect entries. This issue had been identified by the registered manager following an audit in December 2015. The need for complete and accurate medicine records was discussed.

Is Care Effective? (Quality of Management)

There were written policies and procedures for the management of medicines. These had been reviewed every two years and updated to include the management of injectable medicines. Standard Operating Procedures (SOPs) were in place that covered all aspects of the management of controlled drugs.

Records showed that the management of medicines was undertaken by qualified, trained and competent staff and there was evidence that systems were in place to review staff competency on a regular basis. A staff training matrix was provided and reviewed during the inspection. The organisation's policy states that clinical supervision of staff should be completed at least every three months; however, this had not occurred for some time, due to a number of changes within the hospital. The registered manager advised that this had been identified and was to be implemented in the near future.

There were arrangements in place to audit most aspects of the management of medicines. These audits were undertaken by management and staff and included controlled drugs, patients' own drugs and injectable medicines. The outcomes of the audits were raised at staff meetings and were also discussed at the hospital committee meetings. In response to the findings of this inspection, the registered manager advised that the audit process would be reviewed and further developed to include the areas identified for improvement.

Is Care Compassionate? (Quality of Care)

Patients who wished to self-administer their medicines were supported to do so.

Detailed information regarding any medication prescribed and administered within the hospital was provided to patients.

Areas for Improvement

The management of medicines for emergency use should be reviewed. The medicine checklist on the emergency trolley should be up to date with respect to the strength of each medicine, the required stock level of each emergency medicine and records of any stock removal and replacement. A recommendation was made.

The management of medicines which require cold storage must be reviewed to ensure they are stored at the temperature specified by the manufacturer. A requirement was made.

The record keeping in relation to controlled drugs stored in the ward should be monitored, to ensure that records of administration and transfer are fully documented on every occasion and the disposal record clearly indicates that controlled drugs have been denatured prior to disposal, by two designated persons. A recommendation was made.

The discrepancies noted during the audit of a controlled drug in the ward must be investigated and details of the outcomes and any action taken must be forwarded to RQIA. A requirement was made.

The necessary arrangements should be made to ensure that records of the receipt of medicines in the ward and in theatre are fully and accurately maintained on every occasion. A recommendation was made.

Number of Requirements	**2**	**Number of Recommendations**	**3**

6. Quality Improvement Plan

The issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Mrs Finola Carmichael, Registered Manager and Mrs Elizabeth Dallas, Chief Executive as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

6.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on The DHPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, and The Independent Health Care Regulations (Northern Ireland) 2005.

6.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The Department of Health, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments, July 2014. They promote current good practice and if adopted by the registered person may enhance service, quality and delivery.

6.3 Actions Taken by the Registered Person/Registered Manager

The QIP should be completed by the registered person/registered manager and detail the actions taken to meet the legislative requirements stated. The registered person will review and approve the QIP to confirm that these actions have been completed. Once fully completed, the QIP will be returned to **pharmacists@rqia.org.uk** and assessed by the inspector.

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the hospital. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations. It is expected that the requirements and recommendations set out in this report will provide the registered person/manager with the necessary information to assist them in fulfilling their responsibilities and enhance practice within the hospital.

Quality Improvement Plan

Statutory Requirements	
Requirement 1 **Ref**: Regulation 15 **Stated:** First time **To be Completed by:** 18 February 2016	The registered person must ensure that all medicines which require refrigeration are stored in strict accordance with the manufacturers' instructions at all times. **Response by Registered Person(s) Detailing the Actions Taken:** All medicines requiring refrigeration are stored in strict accordance with the manufacturers' instructions. New temperature recording sheet reiterating the importance of action if outside parameters in Ward and Pharmacy.
Requirement 2 **Ref:** Regulation 15 **Stated:** First time **To be Completed by:** 18 February 2016	The registered person must investigate the discrepancies noted during the audit of a controlled drug in the ward and forward a written report of the investigation and any action taken to RQIA. **Response by Registered Person(s) Detailing the Actions Taken:** Investigation completed and report enclosed
Recommendations	
Recommendation 1 **Ref**: Standard 26 **Stated:** First time **To be Completed by:** 18 February 2016	The medicine checklist on the emergency trolley should be reviewed and revised to ensure that it is up to date with respect to the strength and the required stock level of each emergency medicine and details of stock removal and replacement are recorded. **Response by Registered Person(s) Detailing the Actions Taken:** Medicine checklist reviewed and revised to reflect up to date strength, expiry and required emergency stock amount. It also identifies when stock is removed and any replacement.
Recommendation 2 **Ref**: Standard 27 **Stated:** First time **To be Completed by:** 18 February 2016	The record keeping in relation to controlled drugs stored in the ward should be monitored, to ensure that records of administration and transfer are fully documented on every occasion and the disposal record clearly indicates that controlled drugs have been denatured by two designated persons. **Response by Registered Person(s) Detailing the Actions Taken:** A revised CD audit sheet has been developed to ensure that CD records are further monitored to ensure that records of administration and transfer and disposal are fully documented on every occasion.The disposal is completed by two designated persons

Recommendation 3 **Ref**: Standard 28 **Stated:** First time **To be Completed by:** 18 February 2016	The necessary arrangements should be made to ensure that records of the receipt of medicines in the ward and in theatre are fully and accurately maintained on every occasion. **Response by Registered Person(s) Detailing the Actions Taken:** Arrangements have been made to ensure that records of the receipt of medicines in the ward + theatre are fully completed on every occassion. Discussion with Pharmacist and all staff

Registered Manager Completing QIP	S Carmichael	**Date Completed**	16.02.16
Registered Person Approving QIP		**Date Approved**	16.02.16
RQIA Inspector Assessing Response		**Date Approved**	

Please ensure this document is completed in full and returned to pharmacists@rqia.org.uk from the authorised email address

RQIA Inspector Assessing Response	Judith Taylor	**Date Approved**	23 February 2016

Medicines management inspection to NWIH on 19 January 2016 - IN024073