



Your ref G UW/TW/W2075.14
Our Ref JC/BS/GS/15052001

20 May 2015

Mr G U Williams
HM Senior Coroner for the County of Worcestershire
The Court House
Bewdley Road
Stourport on Severn
Worcestershire DY13 9XE

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H.M. CORONER

Dear Mr Williams

**The late Leonardus Adrianus Gerardus VRIES
Regulation 28 Response**

In response to your Regulation 28 Report To Prevent Future Deaths I wish to clarify the existing controls on drugs used within theatres and document the changes in the last six months.

With regard to "non controlled" drugs, the existing controls in place are:

- All medicines are prescribed by an authorised registered prescriber and an audit trail exists on the patient record. All administrations of medicines are documented on the patient drug chart or the anaesthetic record both of which are stored in the patient's notes. Throughout the UK, this is the standard method of control and monitoring of medicines use.
- Pharmacy staff manage all drug issues to theatres and all clinical areas by regularly assessing drug stock levels in the area and supplying stock to a minimum stock level previously agreed by the department manager and the pharmacy team. This minimum stock level is determined by the historical use of the drug and the time between stock replenishment (normally weekly in ward areas and daily in theatres). Pharmacy staff report any concerns regarding increased drug use picked up at this point to the Chief Pharmacist who will investigate in conjunction with the Trust's Local Security Management Specialist and the police if required.
- In theatres, all drug deliveries are placed into an Omnicell secure electronic storage system by pharmacy staff after running a report on what has been issued through the machine since the last assessment. Theatres staff can then access these medicines using an individual username / password or fingerprint recognition. Stock is then transferred from this central storage point into secure lockable cupboards in each anaesthetic room. Only registered staff may hold the keys to these cupboards. Individual staff have a professional responsibility for the safe, secure and legal storage of medicines under their control and only approved, registered staff may hold the keys. Registration is under the General Medical Council for doctors, Nursing and Midwifery Council for nurses and the Health and Care Professions Council for



Operating Department Practitioners. Pharmacy staff are regulated by the General Pharmaceutical Council.

- A monthly issue report is generated using the Pharmacy electronic stock control system. This is monitored by pharmacy, theatres management and finance looking for any unexplained changes in drug use. It is however unlikely that diversion by a single individual could be identified in this way because of the volume of legitimate drug use.
- Medicines incidents (“non controlled” drugs and Controlled Drugs) are reported electronically and the management / resolution of these incidents is monitored by the Chief Pharmacist and the Trust Medicines Safety Committee, which is a sub group of the Trust Drugs and Therapeutics Committee. Action and learning is shared across the organisation by involving all relevant staff groups including matrons and clinical directors, coordinated by the Trust Chief Pharmacist, the Lead Nurse for Medicines and the Trust Medication Safety Officer who is a senior doctor and also chairs the Drugs and Therapeutics Committee.

A letter was issued to all staff in February 2015 clarifying individual staff responsibilities regarding the safe and secure handling of medicines and Standard Operating Procedures (SOPs) were issued to each anaesthetic room. Staff have signed to confirm that they have received, read and understand the SOPs.

Since February 2015 a weekly audit of Controlled Drug documentation is carried out by theatres management. Since March 2015 the Chief Pharmacist has carried out unannounced snapshot audits (normally two per week) on drug storage (all drugs) and documentation in theatres. No concerns regarding diversion or theft of medicines have been identified through this audit cycle and all documentation is correctly completed.

Additional requirements for the safe and secure storage and use of Controlled Drugs are detailed in [The Controlled Drugs \(Supervision and Management of Use\) Regulations 2013](#). The Trust is compliant with these regulations and has an Accountable Officer for Controlled Drugs (the Director of Nursing and Governance) who delegates operational responsibility for this to the Chief Pharmacist. The trust is compliant with the legislation and best practice and contributes to the NHS England Birmingham Solihull and Sandwell Controlled Drugs Local Information Network.

The Chief Pharmacist audited the organisational governance structures for the safe and secure use of Controlled Drugs using the Care Quality Commission’s [audit tool](#) in March 2015 and has reported these audit findings, action plans and progress on action plans to the Accountable Officer for Controlled Drugs, the Trust Drugs and Therapeutics Committee and the Trust Clinical Governance Committee.

In summary, the controls around both Controlled Drugs and “non-controlled” drugs have been reviewed. Standard Operating Procedures for Controlled Drugs have been updated and audits conducted by the Chief Pharmacist have shown compliance with the standards required. Controls around “non-controlled” medicines have been reviewed and found to be compliant with or indeed exceed all national guidance. There remains a small risk that these medicines could be diverted as is the case in all hospitals. This is mitigated by the professional responsibilities of all staff regarding the use of medicines. To further mitigate



this risk the Chief Pharmacist will continue to monitor trends in usage of drugs in all areas of the Trust

Yours sincerely

[Redacted Signature]

Jo Chambers
Chief Executive Officer