Nursing Homes and Residential Care settings for older people

provision of safe and appropriate patient care and pharmacy Services

PSI/ICCPE Joint Initiative Citywest 19th Jan 2012

Cora O'Connell MPSI – Inspection & Enforcement Unit, PSI

- Legislative Provisions
- Inspection Process
- •Inspection Process with regard to patients in nursing home/residential care settings

Legislative Provisions

- The Pharmacy Act 2007 gives the PSI significant powers of inspection, investigation and enforcement
- 7 (1) (e) Pharmacy Act:
 "To supervise compliance with this Act and the instruments made under it"
- Part 7 Powers of Investigation
 Section 67

Inspection Process

Assess compliance with:

- Pharmacy Act 2007
- Regulations
 - Regulation of Retail Pharmacy Businesses 2008
 - Medicinal Products (Prescription & Control of Supply) 2003 as amended
 - Misuse of Drugs Regulations 1988 as amended
 - European Communities Animal Remedies Regulations 2007 as amended
- Guidance Issued by PSI

Inspection Process

- Certificates of Registration
- Policies & Procedures
- Duty Register
- Prescription Register/ Daily Dispensing Report
- Controlled Drugs Register
- Controlled Drugs Inventory
- Controlled Drugs Safe
- Storage of Medicines
- Authorisation of Medicines
- Premises
- Extemporanoeus Preparation
- Veterinary Medicines (storage & record keeping)
- Clinical waste management
- Supply to Nursing Homes/Community Care/ Residential Care Homes

Dispensing to Patients in Nursing Homes/Residential Care Centres

- Dispensing Process
- Standard Operating Procedures
- Record keeping

Same Process For All Patients?

Receipt of the Therapeutic Preparation of medicines prescription review Transfer to Medicines Prescription Check **Patient** Counselling

Receipt of Prescription

Medicines are dispensed on foot of an original valid prescription

 Controlled Drugs (CD2/3) prescriptions are valid (14 days)

Emergency Supply

Reminder

- A Faxed prescription is <u>not</u> an original prescription
- Kardex is <u>not</u> an original prescription
- A medication administration record is <u>not</u> an original prescription
- A 'requisition' from a nurse is **not** a prescription/requisition

Do I ensure that <u>all</u> medicines are dispensed on foot of a valid prescription?

Therapeutic Review

- Regulation 9(1) & 9(2) of the Regulation of Retail Pharmacy Businesses Regulations 2008 SI No. 488 of 2008
- Clinical assessment may include
 - screening for any potential drug therapy problems which may arise out of the use of medicines prescribed
 - therapeutic duplication
 - clinical misuse/abuse
 - drug-drug interactions including OTC medicines, food-drug interactions
 - incorrect drug dosage or duration of treatment
 - known drug allergies

Do I ensure that every prescription is reviewed by a pharmacist for its therapeutic appropriateness for each patient?

Preparation of Medicines: Facilities, Equipment, Resources

- Facilities
 - Area for preparation
 - Cleaning Schedule
- Equipment
- What equipment is in place
 - Manual
 - Automated
- Maintained/Serviced/Calibrated
- Resources(Pharmacist supervision and Staffing)
- Pharmacist Supervision
- Procedures
- Personnel training

How do you satisfy yourself that the preparation of medicines is carried out in a way that minimises risk to patient health and safety?

Preparation of Medicines: Monitored Dosing Systems

- Suitability of MDS for each Patients
- Stability of all medicines
- Hygiene
- Batch traceability
 - Lot Number & Expiry
 - Date
 - Procedure for recall

How do you satisfy yourself that MDS <u>is</u> the most suitable method for the Patient.....and not the Nursing Home?

How do you satisfy yourself that medicines are suitable for inclusion in MDS systems?

Prescription Check

- Number of checks in the process
 - In-process check
 - End-of-process check
- Where is it carried out?
- How many Rx?
- How long (hours)?
- Who does it?
- Who checks the checker?
- Accountability throughout the process?

How do I design a system of checking that considers and addresses the risk of error?

Medicines Counselling

- Regulation 9(3) of the Regulation of Retail Pharmacy Businesses
 Regulations 2008
- PSI Practice Notice 01/2010
 - How is counselling is provided? What intervals?
 - Records of visits to attend on patients

How do I ensure that every patient receives the appropriate counselling on the use and storage and all relevant matters relating to the medicines prescribed and dispensed?

Do I visit my patients?

Transfer to Patient

- Secure
- Maintain medicines stability
- Confidentiality
- Records Traceability

How do I ensure that every patient receives the medicines prescribed and dispensed for them? How do I ensure that the quality, safety & efficacy of medicines is not compromised in transit?

Standard Operating Procedures

- Written procedures e.g.
 - Authority to supply (including management of Rx changes etc.)
 - Disposal of returned medicines
 - Delivery
 - Counselling
 - Error & Incident management
- Records of all staff training
- Process improvement/Audit

Are all SOPs are compliant with all pharmacy legislation and current PSI Guidance?

How can I assure myself that all staff working in the pharmacy carry out their duties in accordance with the legislation?

Do I have a robust Quality System in place?

Record Keeping

Records = Legal activity Records = Proof of an activity

- •SOPs
- Patient consent
- Prescription Register
- Records of Delivery
- Records of Visits by the Pharmacist
- Error logs & corrective actions

How do I manage my dispensing such that I know exactly......

- •what I have dispensed?
- •To whom it was dispensed/delivered?
- •When it was dispensed?
- •That it was dispensed in the most appropriate manner for that patient?
- •That each patient's medicine therapy has been reviewed?
- •That each patient has received appropriate counselling?

Preparation For Inspection

- Self Audit/Self Assessment Tool
- •thepsi.ie
- •info@thepsi.ie

Thank You