Standards Supporting Safety in Aseptic Compounding.

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Presenting on behalf of the ASSIG (HPAI) and MSF project committee.
Introduction

- Aseptic units have been operating in Irish Hospital Pharmacies since the early 1990s.

- Products reconstituted include:
  - Medications required in a ready-to-use form – *safety* (carcinogenic, teratogenic, mutagenic)
    - Traditional anti-cancer therapies (e.g. Cytotoxic medications - cisplatin)
    - Targeted Therapies (e.g. monoclonal antibodies – Mabthera®)
  - Medications that are *cost-effective* to produce in pharmacy
Aseptic Compounding Unit

- Aseptic suite
  - Trained staff operate in a controlled environment.
Benefits of an on-site Aseptic Unit

- Located close to wards – Service Flexibility
  - Emergencies
  - Dose changes
  - Fast turn around time
  - Short stability products
- Health and safety of patients and staff
- Reduced risk of error
  - Compounding complex products
- Clinical Trials medications
Other benefits

- **Cost savings**
  - High cost items, can be manufactured after individual patient assessment
  - Reduced wastage
    - One dose of monoclonal antibody €2000-€3000
  - Sharing vials between patients
    - Study - €343,580/year

Ref: Coughlan M et al. Analysis of cost efficiencies within the manufacturing process of an Aseptic Compounding Unit. Poster at HPAI conference 2011
Safety
“Manchester Incident” 1994
Death of 2 children following administration of contaminated TPN -

- Facilities
- Contamination
- Validation
- ? Poor technique
The Farwell Report (UK 1995)

- ‘Aseptic Dispensing for NHS patients’
- Identified need to ensure standards of practice are in place in pharmacy aseptic units
- Regular Audits
Current Situation

- No guidance document on Hospital Aseptic Compounding in Ireland

- WHY?
  - Exempt from Medicinal Products (Control of Manufacture) Regulations 2007
  - Do not fall under the remit of the IMB

- Need guidelines specific to practice in Ireland.
  - Hospital GMP
Guidance
Guidance

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Public Health and Risk Assessment
Pharmaceuticals

Brussels,
SANCO/C8/AM/sl/ares(2010)1064597

EudraLex
The Rules Governing Medicinal Products in the European Union

EU Guidelines to
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use
Dutch Model

- EU GMP
- Modified for hospital pharmacy use
- Applicable sections were adopted immediately
- Further clarification added to some sections to apply to manufacture in the hospital setting
Medication Safety Forum Project

- To develop National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice
Aims and Objectives

To ensure patient safety by the development of nationally recognised good manufacturing practice (GMP) standards for aseptic compounding in Hospital Pharmacy Departments.
Met with HIQA and IMB
Scope

“Aseptic reconstitution in isolators situated in a clean area, where licensed products or products from licensed manufacturers, are used to compound patient specific products, on receipt of a prescription, that are released by a responsible person”.
Key outcomes from project

- To ensure patient safety
  - by the provision of practical and achievable Irish hospital-GMP guidelines.

- To ensure patient safety
  - by the development of guidelines that assist in the implementation of the Irish hospital-GMP standards.

- To develop self-audit tool

- To identify training needs
Project Update

- PIC/S guidelines have been reviewed by 14 Irish Hospitals
  - Identified need for guidance statements

- Via the Medication Safety Forum – plan to liaise with the IMB to agree a guidance document.
Cancer Incidence is Increasing

Figure B.2 Number of new cancer cases (1994–2002) [solid line] with projected numbers to 2020

Source: National Cancer Registry
Factors affecting safety

- **Staffing**
  - Adequate numbers of suitably trained staff

- **Space**
  - Clean Room Standard

- **Equipment**
  - Quality Control Tests
Summary

- Most hospital pharmacies are currently working to UK or international best practice.

- Scope of the project is to define guidelines specific to Irish hospital pharmacies.
  - In conjunction with HIQA/IMB

- Need to get these standards recognised.

- Adequate resources to implement and maintain standards.
Questions?

Thank You