Meeting of the Minds: Pharmacy Services and Integration

RICK ABBOTT - B.Sc (Pharm)
Regional Pharmacy Manager, Systemic Therapy, Eastern Health, Pharmacy Services

CAROLE R. CHAMBERS - B.Sc (PHARM), MBA
Pharmacy Director of Cancer Services with the Alberta Health Services

JAN ORUCK
Business Liaison Manager Pharmacy Services, Baxter CIVA

RACHEL E. WHITE - M.A. (Psych)
Human Factors Specialist, Healthcare Human Factors Group, University Health Network
Overview:

DELEGATES:

Chair:
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AGENDA:

1:00 pm  Introduction and Overview  
[Rick Abbott]

1:10 pm  Emerging Regulations and Guidelines  
[Jan Oruck]

1:25 pm  Preparation: Process – Efficiency – Volume vs. Accuracy  
[Rick Abbott]

1:40 pm  Handling; & Sterility  
[Carole Chambers]

1:55 pm  Technology: Human Factors & Automation  
[Rachel White]

2:30 pm  Q&A  
[Rick Abbott]
Emerging Regulations and Guidelines

JAN ORUCK
Business Liaison Manager Pharmacy Services, Baxter CIVA
UNITED STATES PHARMACOPIEIA (USP) 
CHAPTER <797>: 2008 and <1066>

STANDARD 11: PHARMACEUTICAL
SOCIETY OF AUSTRALIA: 2010

CANADIAN SOCIETY OF HOSPITAL

PHARMACEUTICAL INSPECTION
CONVENTION, PHARMACEUTICAL INSPECTION
COOPERATION SCHEME (PIC/s): 2008
WHY STANDARDS?

TO PREVENT PATIENT HARM

• From microbial / particulate contamination
• From incorrect or poor quality ingredients
WHY STANDARDS?

TO PREVENT HARM TO PERSONNEL + ENVIRONMENT

• From exposure to hazardous substances
USP CHAPTER <797>
THE EVOLUTION OF STANDARDS

- 1993
  ASHP - Quality Assurance for Pharmacy Prepared Sterile products

- 1995
  USP - Chapter <1206>
  Sterile Product for Home Use

- 2000
  ASHP – Quality Assurance Guidelines REVISED

- 2008
  USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations

INCREASED SAFETY
USP <797>

- Mandates a risk-level determination
- Mandates environmental controls for hazardous and non-hazardous substances
- Mandates documented, validated procedures + processes
SAFE PRACTICE ENVIRONMENTS (Proposed)

- Describes optimal physical environment for safe practice
- 5 Target areas
  1) Lighting  
  2) Interruptions  
  3) Noise  
  4) Organization of workspace  
  5) Medication Safety Zone
STANDARD 11

• Is applicable to Pharmacists who perform or supervise the preparation of sterile product

• Is applicable to the preparation and supply of a single unit intended for immediate use

• Is intended to be used in conjunction with fundamental Pharmacy Practice Standards
STANDARD 11

• Mandates that cleanrooms, Laminar Air Flow and most notably, Cytotoxic Safety Cabinets meet Australian Standards.

• Mandates validated and documented process for environmental monitoring and temperature control
PREPARATION OF STERILE PRODUCT IN PHARMACIES

- Applicable to the preparation of patient-specific sterile product and to “batch scale” production on non-commercially available preparations

- Mandates the creation and continuous improvement of policies and procedures
CSHP GUIDELINES

HANDLING and DISPOSAL of HAZARDOUS PHARMACEUTICALS (Including Cytotoxic Drugs)

- Defines Cytotoxics and Hazardous chemicals
- Requires that cytotoxics preparation be performed by specially trained staff
- Requires protective equipment and biological containment cabinets meet current safety standards (NSF 49)
PIC/s GUIDELINES

• GOOD PRACTICES FOR THE PREPARATION OF MEDICINAL PRODUCTS IN HEALTHCARE ESTABLISHMENTS

• Guidelines for Comprehensive Quality Systems
• Requirements for process validation similar to Good Manufacturing Practice (GMP) regulations
• Recommends documented assessment of risk and the creation of risk mitigation processes
“Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives”

William Foster
THANK YOU

Jan Oruck
Manager, Business Liaisons
Baxter CIVA Pharmacy Services
jan_oruck@baxter.com
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Preparation:
Process – Efficiency – Volume versus Accuracy

RICK ABBOTT
Regional Pharmacy Manager, Systemic Therapy, Eastern Health, Pharmacy Services
Preparation: 
processes, efficiency, volume versus accuracy

Processes

- Dispensing and preparing medications are core pharmacy functions
- How do Hospital Pharmacists spend their time?
  - 60% dispensing medications
  - 15% preparing injectable products
  - 15% clinical work
  - 10% other services (drug information, administrative ftns., etc)
- Medication Safety Literature: “errors do occur at the preparation stage”

Preparation: processes, efficiency, volume versus accuracy

PROCESSES

• In the chemotherapy suite, medications are either prepared or come from suppliers in a “ready to use” format
• The type of preparation process depends upon
  – nature of the product including stability
  – demand for the product
  – sterility of the product
  – dosage form and route of administration

Preparation:
processes, efficiency, volume versus accuracy

Processes

• There are 5 primary tasks in dispensing
  1. Communication of the order to pharmacy
  2. Review of the medication order by the pharmacist
  3. Verification of proper storage and handling
  4. Accurate preparation of the medication for dispensing (if not available commercially)
  5. Accurate and efficient dispensing and distribution of medication

Preparation:
processes, efficiency, volume versus accuracy

Efficiency:

• Challenges:
  – DO MORE with LESS, or
  – DO MORE with the SAME

• Solutions:
  – Technology
  – Out sourcing
  – Scheduling – i.e., next day chemotherapy, extend hours of service
Preparation: processes, efficiency, volume versus accuracy

Efficiency:

- **Technology**
  - Robotics - Cytocare®: improve patients safety and decrease operator’s risk while at the same time working more efficiently and containing costs.

  - Software - Chemocato®: Reducing the human interaction that contributes to errors during the preparation of chemotherapy, and using the software to electronically document each step of the preparation, provides unsurpassed accuracy for all forms of chemotherapy preparation in the IV room.
Preparation:
processes, efficiency, volume versus accuracy

Efficiency:

• Out sourcing
  – products manufactured by an external body
    • Ready to Use format; e.g. 5-FU infusors
    • Near Ready to Use; e.g. Reconstituted Cyclophosphamide
  – products purchased “Ready to Use”
    • e.g. Metoject syringes
Preparation: processes, efficiency, volume versus accuracy

Health Products and Food Branch Inspectorate: January 26/09

- Policy on Manufacturing & Compounding Drug Products in Canada
- Provides a framework to distinguish compounding from manufacturing
- Encompasses:
  - Schedule C: Radiopharmaceuticals
  - Schedule D: Biologics
  - Schedule F: Prescription Drugs
  - Schedule G: Controlled Substances
  - Over the Counter Drugs
Process for dealing with Manufacturing and Compounding Issues

- Pharmaceutical Company
  - Manufacturing
  - Federal Government
    - Discussions
    - Drug Identification Number, Establishment Licence, Notice of Compliance
    - Compliance with federal requirements
- Healthcare Professional
  - Compounding
  - Provincial/Territorial Regulatory Bodies
    - Meet applicable standards
    - Compliance with provincial/territorial requirements
Preparation:
processes, efficiency, volume versus accuracy

Health Products and Food Branch Inspectorate: January 26/09

• Compounding: Only if there is a “therapeutic need” or “lack of product” availability.

• Should not be done solely for economic reasons for the healthcare professionals.

• The compounded product must provide a customized therapeutic solution to improve patient care without duplicating an approved drug product.
Volume vs. Accuracy:

- Has your staffing levels evolved in the chemotherapy suite with the increased workload demands associated with the changes in therapy?

- Example – CRC
  - Adjuvant treatment
  - FOLFIRI – FOLFOX (1st and 2nd treatment)
  - Avastin
  - 3rd line treatment
Volume vs. Accuracy:

• What is the safe number of chemotherapy admixtures to prepare? Per FTE, per hour, etc

• Do you adjust your staffing levels throughout the week / day based on workload demands?

• At your peak production periods, do you or your staff ever cut corners? “doing all the wrong things for the right reasons!”
Volume vs. Accuracy:

- Do you have a 2\textsuperscript{nd} independent double check in place?

- Do you meet the ISMP definition for a 2\textsuperscript{nd} independent double check?

- Is the 2\textsuperscript{nd} independent check ever compromised because of high volume demands?
THANK YOU

Rick Abbott
Regional Pharmacy Manager
Systemic Therapy/Health Consultant
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Handling & Sterility

CAROLE R. CHAMBERS
Pharmacy Director of Cancer Services with the Alberta Health Services
St__ility

- Comfort zone – stABility of the chemical we are looking at, lots of references, charts, and what we share

- Uncomfortable – stERility
Common Assertions

• We do a visual check on our final products and they are NOT contaminated
## Calculated Microbial Growth

Cundell AM, USP Committee on Analytical Microbiology, Pharmacopeial Forum 2002; 28 (6) Stimuli to the Revision Process

<table>
<thead>
<tr>
<th>Time (Hours)</th>
<th>Microbial Count (CFU per mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>9</td>
<td>640</td>
</tr>
<tr>
<td>12</td>
<td>41,000</td>
</tr>
<tr>
<td>18</td>
<td>$1.7 \times 10^7$</td>
</tr>
<tr>
<td>24</td>
<td>$6.9 \times 10^9$</td>
</tr>
</tbody>
</table>
Common Assertions

• We are preparing Cytotoxic admixtures and no microorganisms can grow in our preparations – these are drugs that kill cells
Growth CAN happen

• Evaluation of growth of six micro-organisms in fluorouracil, bacteriostatic sodium chloride 0.9% and sodium chloride 0.9% media. Hosp Pharm 1983: 18: 348-349

• Viability of microorganisms in fluorouracil and cisplatin small-volume injections AmJHospPharm 1988:45-1089-91

BCG

• Larry Broadfield at earlier NOPS provided survey that showed 50% of respondents prepared BCG in same hood as chemotherapy
BCG

- Inadvertent BCG Meningitis; Hosp Pharm 1994:29: 885
Gene-Transfer Products

• Biologicals – not chemicals.
• First type of guidelines you may wish to check out:
• Handling of gene-transfer products by the National Institutes of Health Clinical Centre pharmacy department A J Heath-Sys Pharm 1997;54:1604-10
Guideposts

- Why should we follow professional guidelines or even USP?
- Only 13% of a Canadian Hospital Pharmacy survey are doing End Product testing
- Only 8% of same Canadian Hospital Pharmacy survey are using foot covers in cleanrooms…

CJHP 2009 62(3) 192-203

“The apparent superficial knowledge of clean room standards may point to a lack of overall attention to, or knowledge of, the CSHP guidelines and USP Standards among the survey respondents”.
“Since the environment in which sterile manipulations is never absolutely sterile, the product can easily become contaminated with micro-organisms”

William H Frieben was Research Head, Microbiological Process Control, The Upjohn Company and this material was presented at special session at the 40th ASHP Annual Meeting in June 1983
Old Expired BUD Paradigm

- Assume the compounded preparation is sterile
- Base the BUD solely on the drug’s chemical stability

BUD – Beyond Use Dating aka Expiry date
Microbiological BUD

• There is an ever-present chance, indeed likelihood, that some Admixtures will be inadvertently contaminated

• Time and warm temperatures are the enemy, speeding the potential for growth of dangerous amounts of microbial contamination

• Guidance for limits is needed to avoid unacceptable risks of harming patients
Chapter 797> BUD Paradigm

• Recognize the possibility that the preparation was inadvertently contaminated during compounding

• For patient safety, base the BUD on the drug’s chemical stability in conjunction with microbiological limits, whichever is shorter
USP 797 Market supports

• Steriquot – product sterility monitoring system

• Valiteq – Aseptic Technique validation system

• Without end product testing – Expiry Date or BUD has frameworks from USP797, ASHP and CSHP.
THANK YOU

Carole R Chambers B.Sc.(Pharm) MBA
AHS Pharmacy - Director, Cancer Services
Tom Baker Cancer Clinic Pharmacy

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Technology: Human Factors & Automation

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We cannot change the human condition,
but we can change the conditions under which humans work

James Reason
Hierarchy of effectiveness

1. Forcing Functions and Constraints
2. Automation and Computerization
3. Simplification and Standardization
4. Reminders, Checklists and Double-checks
5. Rules and Policies
6. Training and Education

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Time to think differently!
THANK YOU

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Q & A
THANK YOU

Please complete the Evaluation Form and leave on your table.