Oncology pharmacy practice in Lebanon; Old Challenges, New Insights

Racha Sabbagh Dit Hawasli, Pharm.D., PhD Researcher

Supervisors and co-authors:
Shereen Nabhani-Gebara, Pharm.D., BCOP
Stephen Barton, PhD, CSci, CChem, MRSC
Outline

- Session I: Interactive case discussions
- Session II: Dose banding
Case 1

Compounding sterile preparations

PS, an oncology pharmacist, walks in to the cytotoxic preparation unit (CPU) dressed in her white coat on top of her clothes. She dons a pair of latex gloves, and places the cytotoxic drug (CD) vials packaged in their cartons inside the Class II BSC along with other material needed to complete the preparation. She turns on the hood and starts the compounding process.
Case 1
Compounding sterile preparations

Q1: Is this an example of good practice?

A) Yes
B) No
Case 1

Compounding sterile preparations

“walks in to the cytotoxic preparation unit (CPU) dressed in her white coat on top of her clothes. She dons a pair of latex gloves”
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Case 1

Compounding sterile preparations

“places the cytotoxic vials packaged in their cartons inside the hood”

“Preparation of sterile cytotoxic drugs can be defined as an aseptic preparation.”
Case 1
Compounding sterile preparations

“Reduce the hazardous drug contamination burden in the Class II BSC by wiping down hazardous drug vials before placing them in the BSC.”
“Do not spray the cytotoxic drug vials as drug residues will be aerosolized and transferred to the air and other surfaces.”
Case 1
Compounding sterile preparations

“She turns on the hood and starts the compounding process.”

“the BSC shall be allowed to run for 30 minutes to purge before using for aseptic preparation”
Accuracy

Sterility

Spill

Case 2

Preventing occupational exposure

While withdrawing the cytotoxic drug from the vial, PS spills one drop of CD on the preparation pad placed within the BSC.
Case 2

Preventing occupational exposure

Q1: What engineering control measure would you suggest to PS?

A) N95 Mask
B) Isolator instead of a class II BSC
C) Closed System Transfer Device
**Recommendations**

1. **Level 1 – Elimination, substitution, replacement**
   Replace the product by a less or non-toxic one.
   
   *Level 1 is not an option for cytotoxic drugs as replacement would have a dramatic and undesirable therapeutic effects for the patients.*

2. **Level 2 – Isolation of the hazard/source containment**
   Use of closed systems to prevent the occurrence of any form of contamination.

3. **Level 3 – Engineering controls/ventilation**
   Use of local and general ventilation measures.

3b. **Level 3b – Administrative controls/organisation measures**
   Organise the work in such a way that the duration of exposure and the number of employees exposed is reduced.

4. **Level 4 – Use of personal protection measures**
   Use personal tools such as gloves, masks, gowns, goggles or face shields and other equipment to create a temporary barrier between the contamination and the operator.

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Recommendations

USP 800 requires the use of CSTD for CD administration
CSTD

NIOSH DEFINITION

“Closed system drug-transfer device (CSTD): a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.

CSTD
CSTD

Advantages

- Reduces surface contamination and occupational exposure to personnel with CD
- Preserves sterility of the preparation → Extending beyond use date *(microbiologically)*
- Eliminates needle stick injuries
- Reduces preparation time

Challenge: COST
Case 2

Preventing occupational exposure

The infusion bag is then delivered to the oncology ward. Nurse F.R connects the infusion set to the bag and primes the infusion at the nursing station. She then makes her way to the patient’s room for administration.
Case 2
Preventing occupational exposure

Q1: Is this an example of good practice?

A) Yes
B) No
Preventing occupational exposure

“Attach and prime the appropriate I.V. set to the final container in the BSC or isolator before adding the hazardous drug”

American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *AM J HealthSyst Pharm.* 2006; 63:1172934-
IV bag preparation with spiking and priming in pharmacy. YouTube. Available from [https://www.youtube.com/watch?v=8rs7IPEx9Kk](https://www.youtube.com/watch?v=8rs7IPEx9Kk). Accessed 31 March 2017
Case 3
Handling cytotoxic waste

Patient W.L was sent home connected to an ambulatory elastomeric infusion pump containing 5FU. 48 hours later, the nurse from the one day oncology ward presents to W.L’s house to disconnect the pump. She places the empty pump in a separate waste bag, and throws it in the waste bin by the patient’s bed. A couple of days later, the bag is taken along with the regular household waste and disposed of in the waste containers provided by the municipality.
Case 3
Handling cytotoxic waste

Q1: Which one of the below statements is correct?

A) Since the pump has fully emptied, it poses no risk of cytotoxic hazard, and could be discarded as described

B) The nurse should have used a cytotoxic waste bag and discarded it with similar waste at the hospital

C) The pump could have been kept in a bag for re-use during the next cycle
Case 3
Handling cytotoxic waste
Case Discussion

Conclusion

Need for national guidelines for the safe handling of cytotoxic drugs in limited resource settings
Session II: Dose banding

Definition

“A system whereby, through agreement, doses of SACT drugs calculated on an individualised basis, that are within defined ranges or bands are rounded up or down to predetermined standard doses(4). The maximum variation of the adjustment between the standard dose and the doses constituting each band is typically 5% or less. A range of syringes or infusions manufactured by pharmacy aseptic compounding unit staff or purchased from licensed manufacturers, can be used to administer the standard dose. “

BSA based banding

Doxorubicin 50mg/m2
BSA=1.73 m2
BSA rounded to 1.7m2
→ dose= 85mg

Reducing waste of remnants from 50 mg Doxorubicin vials

Target Dose Banding or Drug Centered Dose Banding

Doxorubicin 60mg/m²
BSA = 1.82 m²
Calculated dose = 109.2mg
→ 110mg is given
### Target Dose Banding or Drug Centered Dose Banding

#### DOXORUBICIN SYRINGES:
The dose bands used in this table are constructed based on a 2mg/ml concentration of doxorubicin.

<table>
<thead>
<tr>
<th>Dose Range (mg)</th>
<th>Banded Dose (mg)</th>
<th>Maximum variation range (%)</th>
<th>Maximum variation range (mg)</th>
<th>Suggested Syringe Sizes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>38 - 42</td>
<td>40</td>
<td>5.00% (Upr)*, -5.00% (Lwr)</td>
<td>2mg (Upr), -2mg (Lwr)</td>
<td>40mg</td>
</tr>
<tr>
<td>43 - 47</td>
<td>46</td>
<td>2.17% (Upr)*, -6.52% (Lwr)</td>
<td>1mg (Upr), -3mg (Lwr)</td>
<td>20mg, 26mg</td>
</tr>
<tr>
<td>48 - 52</td>
<td>50</td>
<td>4.00% (Upr)*, -4.00% (Lwr)</td>
<td>2mg (Upr), -2mg (Lwr)</td>
<td>50mg</td>
</tr>
<tr>
<td>53 - 57</td>
<td>56</td>
<td>1.79% (Upr)*, -3.39% (Lwr)</td>
<td>1mg (Upr), -3mg (Lwr)</td>
<td>30mg, 26mg</td>
</tr>
<tr>
<td>58 - 62</td>
<td>60</td>
<td>3.33% (Upr)*, -3.33% (Lwr)</td>
<td>2mg (Upr), -2mg (Lwr)</td>
<td>30mg x 2</td>
</tr>
<tr>
<td>63 - 67</td>
<td>66</td>
<td>1.52% (Upr)*, -4.55% (Lwr)</td>
<td>1mg (Upr), -3mg (Lwr)</td>
<td>40mg, 26mg</td>
</tr>
<tr>
<td>68 - 72</td>
<td>70</td>
<td>2.86% (Upr)*, -2.86% (Lwr)</td>
<td>2mg (Upr), -2mg (Lwr)</td>
<td>40mg, 30mg</td>
</tr>
<tr>
<td>73 - 77</td>
<td>76</td>
<td>1.32% (Upr)*, -3.95% (Lwr)</td>
<td>1mg (Upr), -3mg (Lwr)</td>
<td>50mg, 26mg</td>
</tr>
<tr>
<td>78 - 82</td>
<td>80</td>
<td>2.50% (Upr)*, -2.25% (Lwr)</td>
<td>2mg (Upr), -2mg (Lwr)</td>
<td>50mg, 30mg</td>
</tr>
<tr>
<td>83 - 87</td>
<td>86</td>
<td>1.16% (Upr)*, -3.49% (Lwr)</td>
<td>1mg (Upr), -3mg (Lwr)</td>
<td>40mg, 30mg, 26mg</td>
</tr>
<tr>
<td>88 - 92</td>
<td>90</td>
<td>2.22% (Upr)*, -2.22% (Lwr)</td>
<td>2mg (Upr), -2mg (Lwr)</td>
<td>40mg, 50mg</td>
</tr>
<tr>
<td>93 - 97</td>
<td>96</td>
<td>1.04% (Upr)*, -3.13% (Lwr)</td>
<td>1mg (Upr), -3mg (Lwr)</td>
<td>50mg, 20mg, 26mg</td>
</tr>
<tr>
<td>98 - 105</td>
<td>100</td>
<td>5.00% (Upr)*, -2.00% (Lwr)</td>
<td>5mg (Upr), -4mg (Lwr)</td>
<td>100mg</td>
</tr>
</tbody>
</table>

| 106 - 115       | 110              | 4.55% (Upr)*, -3.64% (Lwr)  | 5mg (Upr), -4mg (Lwr)       | 50mg, 40mg, 20mg        |
| 116 - 125       | 120              | 4.17% (Upr)*, -3.33% (Lwr)  | 5mg (Upr), -4mg (Lwr)       | 100mg, 20mg             |
| 126 - 135       | 130              | 3.85% (Upr)*, -3.08% (Lwr)  | 5mg (Upr), -4mg (Lwr)       | 100mg, 30mg             |
| 136 - 145       | 140              | 3.57% (Upr)*, -2.86% (Lwr)  | 5mg (Upr), -4mg (Lwr)       | 100mg, 40mg             |
| 146 - 155       | 150              | 3.33% (Upr)*, -2.67% (Lwr)  | 5mg (Upr), -4mg (Lwr)       | 100mg, 50mg             |
| 156 - 165       | 160              | 3.13% (Upr)*, -2.50% (Lwr)  | 5mg (Upr), -4mg (Lwr)       | 100mg, 30mg x 2         |

Suggested Syringe Sizes: 20mg, 26mg, 30mg, 40mg, 50mg, 100mg

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Stability data for batch preparation

Infusions/admixtures of 50-1000 mL in D5W or NS are stable for 48 hours at 25°C, protected from light.

Determinants of Dose banding

**Drugs**
- Stability
- High cost drugs
- High frequency drugs
- Oral drugs with variation in available strengths

**Dose Volumes**
- Compatible with agreed dose measurement limits
- Minimal number of syringes for each dose band
Examples of Drugs suitable for Dose Banding

Drugs

- Carboplatin
- Cyclophosphamide
- Docetaxel
- Doxorubicin
- Epirubicin
- 5-FU
- Gemcitabine
- Irinotecan
- Oxaliplatin
- Paclitaxel

Dose banding

Advantages

- Reducing patient waiting time

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Dose banding

Dose banding

Advantages

- Reducing patient waiting time
- Optimizing pharmacy services
- Reducing drug waste
  i- Remnants in vials
  ii- Re-assigning pre-filled syringes
- Reducing errors

Dose banding

Limitations

- Correct stock utilization to avoid wastage
- Correct labelling of preparations and training of personnel
- Not applicable to all drugs

Exceptions for use DB

- Pediatrics
- Cachexia and Obesity
- Clinical trials

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Conclusion

- Continuously evolving cancer care
- Need for guidelines catering to developing countries
References

1- American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *AM J HealthSyst Pharm.* 2006; 63:117293


References


10- IV bag preparation with spiking and priming in pharmacy. YouTube. Available from https://www.youtube.com/watch?v=8rs7IPEx9Kk Accessed 31 March 2017

