

## **User-testing guidelines to improve the safety of intravenous medicines administration: a randomised in-situ simulation study**

### **Supplementary file 2**

#### **Data collection tools**

##### Structured observation forms

As there were differences between the requirements of the intravenous medicines administration policies of each NHS trust, there were small differences between the structured observation forms used at each research site. The four versions of this form are shown on the following pages.

## Trust 1 Observation recording form

## Effects of User Testing Injectable Medicines Guidance – Phase 2

Department of  
Pharmacy &  
Pharmacology

Participant ID:

Participant randomisation code:

Date:

Time taken:

| Expected preparation/administration step  | No error | Error | Error description/other notes | Error code     |
|---|----------|-------|-------------------------------|----------------|
| Wash hands with soap & water, or alcohol gel  |          |       |                               | N3             |
| Clean plastic tray with sporicidal detergent wipe, or soap and water. Allow to dry                      |          |       |                               | N3             |
| Wash hands with soap & water or alcohol gel. Put on gloves & apron                                      |          |       |                               | N3             |
| Remove seal from bathicillin vial & wipe septum with alcohol wipe. Allow to dry for 30 seconds          |          |       |                               | N1<br>N3       |
| Draw up reconstituting fluid:   |          |       |                               | N2             |
| • WFI or saline 0.9%  |          |       |                               | I1             |
| • Fluid has not expired   |          |       |                               | N4             |
| • Volume = 9.5 mL (8.6-10.5 mL)   |          |       |                               | I2             |
| Inject all the reconstituting fluid into the bathicillin vial:  |          |       |                               | I1<br>I2<br>N2 |
| • Use bathicillin 400mg vial  |          |       |                               | I3<br>N1       |
| • Bathicillin has not expired   |          |       |                               | N4             |
| With syringe in place, gently swirl until fully dissolved   |          |       |                               | I6<br>N2       |
| Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution  |          |       |                               | I3<br>N1<br>N2 |
| Wipe rubber septum of additive port on infusion bag with alcohol wipe & allow to dry for 30 seconds     |          |       |                               | N3             |
| Inject 8.6-9.5 mL reconstituted bathicillin solution into infusion bag through centre of injection port |          |       |                               | I3<br>N1<br>N2 |
| • Infusion bag is saline 0.9% or glucose 5%   |          |       |                               | I4             |

| Expected preparation/administration step  | No error | Error | Error description/other notes | Error code     |
|---|----------|-------|-------------------------------|----------------|
| <ul style="list-style-type: none"> <li>• Infusion bag volume is <b>100/250/500 mL</b></li> </ul>  |          |       |                               | I5             |
| <ul style="list-style-type: none"> <li>• Infusion bag has not expired</li> </ul>  |          |       |                               | N4             |
| Withdraw needle and invert bag at least 5 times to mix  |          |       |                               | N2             |
| Final infusion for is free of particles, cloudiness and discolouration  |          |       |                               | N2             |
| Draw up <b>saline 0.9% or glucose 5% flush</b>  |          |       |                               | I8             |
| <ul style="list-style-type: none"> <li>• Fluid has not expired</li> </ul>   |          |       |                               | N4             |
| Hang infusion bag. Attach administration set to infusion bag and prime. Replace cap on end of administration set. (Close roller ball if using gravity set).   |          |       |                               | N2             |
| Remove gloves, clean hands with alcohol gel, put on new gloves  |          |       |                               | N3             |
| Clean hub of cannula with alcoholic chlorhexidine 2% wipe   |          |       |                               | N3             |
| Flush cannula with <b>saline 0.9% or glucose 5% flush</b>   |          |       |                               | I7<br>I8       |
| Attach giving set to cannula. Open roller clamp/start pump & set infusion rate to give infusion over 2-3 hours ( $\pm 10\%$ ): <ul style="list-style-type: none"> <li>• <b>59 mL = 0.30-0.55 mL/min = 6-10 drops/min = 17.9-32.8 mL/hour</b></li> <li>• <b>109 mL = 0.55-1.01 mL/min = 11-20 drops/min = 33.0-60.6 mL/hour</b></li> </ul> |          |       | Rate of infusion:             | I7<br>I9<br>N2 |
| Use ANTT throughout, e.g: <ul style="list-style-type: none"> <li>• Don't touch syringe tips</li> <li>• Don't touch needle</li> <li>• Don't put down syringe with unsheathed needle</li> </ul>   |          |       |                               | N3             |

## Trust 2 Observation recording form

## Effects of User Testing Injectable Medicines Guidance – Phase 2

Department of  
Pharmacy &  
Pharmacology

Participant ID:

Participant randomisation code:

Date:

Time taken:

| Expected preparation/administration step  | No error | Error | Error description/other notes | Error code     |
|---|----------|-------|-------------------------------|----------------|
| Clean plastic tray with detergent wipe  |          |       |                               | N3             |
| Clean hands and put on gloves.  |          |       |                               | N3             |
| Use ANTT throughout, e.g: <ul style="list-style-type: none"> <li>• Don't touch syringe tips or needle</li> <li>• Don't put down syringe with unsheathed needle</li> </ul> |          |       |                               | N3             |
| Remove seal from bathicillin vial & wipe septum with 2% chlorhexidine/70% alcohol wipe. Allow to dry for 30 secs  |          |       |                               | N1<br>N3       |
| Draw up reconstituting fluid:   |          |       |                               | N2             |
| <ul style="list-style-type: none"> <li>• WFI or saline 0.9%</li> </ul>  |          |       |                               | I1             |
| <ul style="list-style-type: none"> <li>• Fluid has not expired</li> </ul>   |          |       |                               | N4             |
| <ul style="list-style-type: none"> <li>• Volume = 9.5 mL (8.6-10.5 mL)</li> </ul>   |          |       |                               | I2             |
| Change needle on syringe  |          |       |                               | N2             |
| Inject all the reconstituting fluid into the bathicillin vial:  |          |       |                               | I1<br>I2<br>N2 |
| <ul style="list-style-type: none"> <li>• Use bathicillin 400mg vial</li> </ul>  |          |       |                               | I3<br>N1       |
| <ul style="list-style-type: none"> <li>• Bathicillin has not expired</li> </ul>   |          |       |                               | N4             |
| With syringe in place, gently swirl until fully dissolved   |          |       |                               | I6<br>N2       |
| Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution  |          |       |                               | I3<br>N1<br>N2 |
| Change needle on syringe  |          |       |                               | N2             |
| Wipe rubber septum of infusion bag additive port with 2% chlorhexidine/70% alcohol wipe & allow to dry for 30 secs  |          |       |                               | N3             |

| Expected preparation/administration step   | No error | Error | Error description/other notes | Error code     |
|--|----------|-------|-------------------------------|----------------|
| Inject <b>8.6-9.5 mL</b> reconstituted bathicillin solution into infusion bag through centre of injection port   |          |       |                               | I3<br>N1<br>N2 |
| • Infusion bag is <b>saline 0.9% or glucose 5%</b>   |          |       |                               | I4             |
| • Infusion bag volume is <b>100/250/500 mL</b>   |          |       |                               | I5             |
| • Infusion bag has not expired   |          |       |                               | N4             |
| Withdraw needle and invert bag at least 5 times to mix   |          |       |                               | N2             |
| Final infusion for is free of particles, cloudiness and discolouration   |          |       |                               | N2             |
| Draw up <b>saline 0.9% or glucose 5% flush</b>   |          |       |                               | I8             |
| • Fluid has not expired  |          |       |                               | N4             |
| Attach administration set to infusion bag and prime.   |          |       |                               | N2             |
| Remove gloves, wash hands  |          |       |                               | N3             |
| Wipe cannula with 2% chlorhexidine/70% alcohol wipe  |          |       |                               | N3             |
| Put on new gloves  |          |       |                               | N3             |
| Flush cannula with <b>saline 0.9% or glucose 5% flush</b>  |          |       |                               | I7<br>I8       |
| Attach giving set to cannula. Open roller clamp/start pump & set infusion rate to give infusion over 2-3 hours ( $\pm 10\%$ ):<br>• <b>59 mL = 0.30-0.55 mL/min = 6-10 drops/min = 17.9-32.8 mL/hour</b><br>• <b>109 mL = 0.55-1.01 mL/min = 11-20 drops/min = 33.0-60.6 mL/hour</b> |          |       | Rate of infusion:             | I7<br>I9<br>N2 |

**Trust 3 Observation recording form****Effects of User Testing Injectable Medicines Guidance – Phase 2**Department of  
Pharmacy &  
Pharmacology

Participant ID:

Participant randomisation code:

Date:

Time taken:

| Expected preparation/administration step  | No error | Error | Error description/other notes | Error code     |
|---|----------|-------|-------------------------------|----------------|
| Wash hands with soap & water. Put on plastic apron.   |          |       |                               | N3             |
| Work in a clean aseptic field, e.g. a plastic tray cleaned with a detergent wipe, or soap and water, and allowed to dry |          |       |                               | N3             |
| Wash hands with soap & water or alcohol gel. Put on gloves  |          |       |                               | N3             |
| Remove seal from bathicillin vial & wipe septum with alcohol wipe. Allow to dry.  |          |       |                               | N1<br>N3       |
| Draw up reconstituting fluid:   |          |       |                               | N2             |
| • WFI or saline 0.9%  |          |       |                               | I1             |
| • Fluid has not expired   |          |       |                               | N4             |
| • Volume = 9.5 mL (8.6-10.5 mL)   |          |       |                               | I2             |
| Inject all the reconstituting fluid into the bathicillin vial:  |          |       |                               | I1<br>I2<br>N2 |
| • Use bathicillin 400mg vial  |          |       |                               | I3<br>N1       |
| • Bathicillin has not expired   |          |       |                               | N4             |
| Gently swirl until fully dissolved  |          |       |                               | I6<br>N2       |
| Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution  |          |       |                               | I3<br>N1<br>N2 |
| Inject 8.6-9.5 mL reconstituted bathicillin solution into infusion bag through centre of injection port                 |          |       |                               | I3<br>N1<br>N2 |

| Expected preparation/administration step   | No error | Error | Error description/other notes | Error code     |
|--|----------|-------|-------------------------------|----------------|
| • Infusion bag is <b>saline 0.9% or glucose 5%</b>   |          |       |                               | I4             |
| • Infusion bag volume is <b>100/250/500 mL</b>   |          |       |                               | I5             |
| • Infusion bag has not expired   |          |       |                               | N4             |
| Draw up <b>saline 0.9% or glucose 5% flush</b>   |          |       |                               | I8             |
| • Fluid has not expired  |          |       |                               | N4             |
| Clean hub of cannula with alcoholic chlorhexidine 2% wipe  |          |       |                               | N3             |
| Flush cannula with <b>saline 0.9% or glucose 5%</b> flush  |          |       |                               | I7<br>I8       |
| Administer infusion over 2-3 hours ( $\pm 10\%$ ):<br>• <b>59 mL = 0.30-0.55 mL/min = 6-10 drops/min = 17.9-32.8 mL/hour</b><br>• <b>109 mL = 0.55-1.01 mL/min = 11-20 drops/min = 33.0-60.6 mL/hour</b> |          |       | Rate of infusion:             | I7<br>I9<br>N2 |
| Use ANTT throughout, e.g:<br>• Don't touch syringe tips<br>• Don't touch needle<br>• Don't put down syringe with unsheathed needle   |          |       |                               | N3             |

**Trust 4 Observation recording form****Effects of User Testing Injectable Medicines Guidance – Phase 2**Department of  
Pharmacy &  
Pharmacology

Participant ID:

Participant randomisation code:

Date:

Time taken:

| Expected preparation/administration step  | No error | Error | Error description/other notes | Error code     |
|---|----------|-------|-------------------------------|----------------|
| Wash hands  |          |       |                               | N3             |
| Clean plastic tray with universal cleaning and disinfecting wipe. Allow to dry.                         |          |       |                               | N3             |
| Wash hands with soap & water or alcohol gel. Put on gloves & apron                                      |          |       |                               | N3             |
| Remove seal from bathicillin vial & clean septum  |          |       |                               | N1<br>N3       |
| Draw up reconstituting fluid:   |          |       |                               | N2             |
| • WFI or saline 0.9%  |          |       |                               | I1             |
| • Fluid has not expired   |          |       |                               | N4             |
| • Volume = 9.5 mL (8.6-10.5 mL)   |          |       |                               | I2             |
| Inject all the reconstituting fluid into the bathicillin vial:  |          |       |                               | I1<br>I2<br>N2 |
| • Use bathicillin 400mg vial  |          |       |                               | I3<br>N1       |
| • Bathicillin has not expired   |          |       |                               | N4             |
| Gently swirl until fully dissolved  |          |       |                               | I6<br>N2       |
| Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution  |          |       |                               | I3<br>N1<br>N2 |
| Inject 8.6-9.5 mL reconstituted bathicillin solution into infusion bag through centre of injection port |          |       |                               | I3<br>N1<br>N2 |



| Expected preparation/administration step   | No error | Error | Error description/other notes | Error code     |
|--|----------|-------|-------------------------------|----------------|
| • Infusion bag is <b>saline 0.9% or glucose 5%</b>   |          |       |                               | I4             |
| • Infusion bag volume is <b>100/250/500 mL</b>   |          |       |                               | I5             |
| • Infusion bag has not expired   |          |       |                               | N4             |
| Draw up <b>saline 0.9% flush</b>   |          |       |                               | I8             |
| • Flush volume is 5 mL   |          |       |                               | N5             |
| • Fluid has not expired  |          |       |                               | N4             |
| Remove gloves, clean hands with alcohol gel, put on new gloves   |          |       |                               | N3             |
| Clean hub of cannula with alcoholic chlorhexidine 2% wipe for 20 seconds and allow to dry completely   |          |       |                               | N3             |
| Flush cannula with 5ml <b>saline 0.9%</b> flush  |          |       |                               | I7<br>I8       |
| Administer infusion over 2-3 hours ( $\pm 10\%$ ):<br>• <b>59 mL = 0.30-0.55 mL/min = 6-10 drops/min = 17.9-32.8 mL/hour</b><br>• <b>109 mL = 0.55-1.01 mL/min = 11-20 drops/min = 33.0-60.6 mL/hour</b> |          |       | Rate of infusion:             | I7<br>I9<br>N2 |
| Use ANTT throughout, e.g:<br>• Don't touch syringe tips<br>• Don't touch needle<br>Don't put down syringe with unsheathed needle   |          |       |                               |                |

### Participant characteristics and feedback data collection form

Questions 13-20 on the final page make up the modified Provider Decision Process Assessment Instrument (mPDPAI) questionnaire. Questions 21 and 22 are the quality and satisfaction questions used to validate the mPDPAI. Question 22 is the guidelines preference question.

Department of  
Pharmacy &  
Pharmacology**Observation data collection form****Effects of User Testing Injectable Medicines Guidance – Phase 2***Completed by researcher:*

|  |        |        |        |        |
|--|--------|--------|--------|--------|
| <b>Hospital:</b>                       | Site 1 | Site 2 | Site 3 | Site 4 |
| <b>Participant randomisation code:</b> |        |        |        |        |

*Please answer the following questions (please circle one answer or fill in the box):*

|   |  |      |                   |  |
|---|--|------|-------------------|--|
| <b>Have you already taken part in this study on another day?</b>  | Yes  |      | No                |  |
| <b>What best describes your gender?</b>   | Female   | Male | Prefer not to say |  |
|   | Prefer to self-describe:                               |      |                   |  |
| <b>How many years old are you?</b>  |  |      |                   |  |
| <b>Is English your first language?</b>  | Yes  |      | No                |  |
| <b>Are you currently a qualified nurse or midwife registered with the Nursing and Midwifery Council</b>   | Yes  |      | No                |  |
| <b>For how long have you worked as a qualified nurse or midwife?</b>  |  |      |                   |  |
| <b>Are you currently authorised to prepare and administer IV medicines in this hospital?</b>  | Yes  |      | No                |  |
| <b>For how long have you been authorised to administer IV medicines?</b>  |  |      |                   |  |
| <b>Over the last six months (or since you were authorised), on approximately what percentage of your shifts have you prepared or administered an IV medicine?</b> | %  |      |                   |  |
| <b>Have you used the Medusa IV guide before?</b>  | I use it regularly at the moment                       |      |                   |  |
|   | I used it regularly in the past, but not at the moment |      |                   |  |
|   | I've seen it before, but not used it often             |      |                   |  |
|   | I haven't seen it before                               |      |                   |  |

*Please give this sheet back to the researcher*11<sup>th</sup> January, 2019

Version: 1.0

IRAS ID: 242505

Please answer the questions below to tell us about your experience of making and giving bathicillin (please circle one answer):

|    |  |                |       |                            |          |                   |
|----|--|----------------|-------|----------------------------|----------|-------------------|
| 13 | <b>It was hard to decide how to make and give bathicillin</b>  | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 14 | <b>I was unsure how to make and give bathicillin</b>   | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 15 | <b>It was clear how to make and give bathicillin</b>   | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 16 | <b>When deciding how to make and give bathicillin, I felt I did not know enough about the alternative ways of doing this</b> | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 17 | <b>I had trouble deciding how to make and give bathicillin because important information was not available</b>               | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 18 | <b>It was easy to identify all the information needed to make and give bathicillin</b>                                       | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 19 | <b>I am satisfied with how I made and gave bathicillin</b>   | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |
| 20 | <b>I am satisfied that the process used to decide how to make and give bathicillin was as good as it could be</b>            | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree |

|    |   |   |         |              |         |           |         |           |   |   |   |    |
|----|---|---|---------|--------------|---------|-----------|---------|-----------|---|---|---|----|
| 21 | <b>Please rate the quality of how you made and gave the dose of bathicillin</b>                               | 0   | 1       | 2            | 3       | 4         | 5       | 6         | 7 | 8 | 9 | 10 |
|    |   | Worst <span style="float: right;">▶ Best</span> |         |              |         |           |         |           |   |   |   |    |
| 22 | <b>How would you feel if you made every IV medicine for the rest of your career how you made bathicillin?</b> | Terrible  | Unhappy | Dissatisfied | Neutral | Satisfied | Pleased | Delighted |   |   |   |    |

Now ask the researcher to show you two IV guides (Guide X and Guide Y). You will have already used one of these guides - please do not tell the researcher which one this was! Please look at both guides and then answer the following question:

|    |                                   |                           |                  |                           |                                  |                           |                  |                           |
|----|-----------------------------------|---------------------------|------------------|---------------------------|----------------------------------|---------------------------|------------------|---------------------------|
| 23 | <b>Which guide do you prefer?</b> | I strongly prefer guide X | I prefer guide X | I somewhat prefer guide X | Same preference for guide X or Y | I somewhat prefer guide Y | I prefer guide Y | I strongly prefer guide Y |
|----|-----------------------------------|---------------------------|------------------|---------------------------|----------------------------------|---------------------------|------------------|---------------------------|

11<sup>th</sup> January, 2019

Version: 1.0

IRAS ID: 242505

### Images of simulated medicine

Participants selected a vial from a box that contained twenty-five identical placebo vials (Dummy-Ject Powder C, MockMeds, Houston, Texas). Twenty-three of these vials were labelled as the unexpired medicine required for the prescribed dose:

**For simulation research only**

Bathicillin for injection  
400 mg per vial  
Expiry: 31 Dec 2019

One of these vials was labelled as an alternative invented medicine name:

**For simulation research only**

Unimycin for injection  
400 mg per vial  
Expiry: 31 Dec 2019

The remaining one vial was labelled as the required medicine, but with an expiry date that had passed:

**For simulation research only**

Bathicillin for injection  
400 mg per vial  
Expiry: 31 Oct 2017

The labelled vials are shown below:

