

Effects of user testing existing guidelines on the safety of intravenous medicines administration: a randomised *in-situ* simulation study

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

Participant ID:

Participant randomisation code:

Date:

Time taken:

Department of
Pharmacy &
Pharmacology



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 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 I2 N2
• Use bathicillin 400mg vial				I3 N1
• Bathicillin has not expired				N4
With syringe in place, gently swirl until fully dissolved				I6 N2
Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution				I3 N1 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 N1 N2
• Infusion bag is saline 0.9% or glucose 5%				I4

Expected preparation/administration step	No error	Error	Error description/other notes	Error code
• Infusion bag volume is 100/250/500 mL				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 saline 0.9% or glucose 5% flush				I8
• Fluid has not expired				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 saline 0.9% or glucose 5% flush				I7 I8
Attach giving set to cannula. Open roller clamp/start pump & set infusion rate to give infusion over 2-3 hours ($\pm 10\%$): • 59 mL = 0.30-0.55 mL/min = 6-10 drops/min = 17.9-32.8 mL/hour • 109 mL = 0.55-1.01 mL/min = 11-20 drops/min = 33.0-60.6 mL/hour			Rate of infusion:	I7 I9 N2
Use ANTT throughout, e.g: • Don't touch syringe tips • Don't touch needle • Don't put down syringe with unsheathed needle				N3

Trust 2 Observation recording form

Effects of User Testing Injectable Medicines Guidance – Phase 2

Participant ID:

Participant randomisation code:

Date:

Time taken:

Department of
Pharmacy &
Pharmacology



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"> • Don't touch syringe tips or needle • Don't put down syringe with unsheathed needle 				N3
Remove seal from bathicillin vial & wipe septum with 2% chlorhexidine/70% alcohol wipe. Allow to dry for 30 secs				N1 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
Change needle on syringe				N2
Inject all the reconstituting fluid into the bathicillin vial:				I1 I2 N2
• Use bathicillin 400mg vial				I3 N1
• Bathicillin has not expired				N4
With syringe in place, gently swirl until fully dissolved				I6 N2
Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution				I3 N1 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 8.6-9.5 mL reconstituted bathicillin solution into infusion bag through centre of injection port				I3 N1 N2
• Infusion bag is saline 0.9% or glucose 5%				I4
• Infusion bag volume is 100/250/500 mL				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 saline 0.9% or glucose 5% flush				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 saline 0.9% or glucose 5% flush				I7 I8
Attach giving set to cannula. Open roller clamp/start pump & set infusion rate to give infusion over 2-3 hours ($\pm 10\%$): • 59 mL = 0.30-0.55 mL/min = 6-10 drops/min = 17.9-32.8 mL/hour • 109 mL = 0.55-1.01 mL/min = 11-20 drops/min = 33.0-60.6 mL/hour			Rate of infusion:	I7 I9 N2

Trust 3 Observation recording form

Effects of User Testing Injectable Medicines Guidance – Phase 2

Participant ID:

Participant randomisation code:

Date:

Time taken:

Department of
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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 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 I2 N2
• Use bathicillin 400mg vial				I3 N1
• Bathicillin has not expired				N4
Gently swirl until fully dissolved				I6 N2
Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution				I3 N1 N2
Inject 8.6-9.5 mL reconstituted bathicillin solution into infusion bag through centre of injection port				I3 N1 N2

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

Trust 4 Observation recording form

Effects of User Testing Injectable Medicines Guidance – Phase 2

Participant ID:

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Date:

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Department of
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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 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 I2 N2
• Use bathicillin 400mg vial				I3 N1
• Bathicillin has not expired				N4
Gently swirl until fully dissolved				I6 N2
Draw up 9mL (8.6-9.5 mL) of reconstituted bathicillin solution				I3 N1 N2
Inject 8.6-9.5 mL reconstituted bathicillin solution into infusion bag through centre of injection port				I3 N1 N2

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