

Effects of user testing injectable medicines guidance – phase 2

SOP for *in situ* simulation

Equipment needed

- Clipboard
- Pens
- Laptop, charger and mouse
- Participant information sheet
- Consent form
- Observation form
- Data collection form
- Prescription
- Topic guide
- Monographs for comparison
- Mobile phone
- Manikin arm
- Placebo injections
- Stop watch
- Privacy filter
- Video camera
- Dictaphone
- ID badge

Procedure:

1. Set up manikin arm, box of placebo injections and laptop
2. Check participant has read PIS and if they have any questions
3. Complete consent form
4. Ask participant to complete Q1-10 on the data collection form
5. Confirm eligibility and randomise participant
6. Enter randomisation details into data collection form
7. Give participant prescription and point out box of placebo injections and manikin arm
8. Ask them to take other supplies from ward stock
9. Explain:
 - a. They need to prepare and give the dose following the prescription, the study IV guide and local policies, as they would for a real patient.
 - b. The simulation will stop at the point they would leave the patient's bedside and they should tell the researcher when they reach this point.
 - c. Assume the prescription is clinically appropriate – no need to check dose etc
 - d. Assume the information in the IV guide is all correct
 - e. No need for a second check of anything
 - f. We're testing the guide, not you
10. If needed, fit video camera to patient's forehead and start recording
11. Find the correct IV monograph with the participant's randomisation code on the laptop and highlight – DO NOT OPEN.
12. Place the privacy filter on the laptop screen and move so screen cannot be seen
13. Ask the participant to confirm the correct monograph has been selected and open it.
14. Ask the participant to confirm the correct monograph has opened.
15. Ask participant to begin preparing the dose as per previous instructions
16. Start the stop watch
17. Observe the preparation and complete the observation form
18. When the participant says they would leave the patient's bedside, stop the stop watch
19. Stop video recording
20. Ask participant to close the IV guide
21. Ask participant to complete Q13-22 on the data collection form
22. Whilst participant does this, tidy up the work area, disposing of sharps carefully into a sharps bin
23. Show participant print outs of both monographs then ask them to answer Q23 on the data collection form
24. If error observed, complete debrief interview