Contingency Plan During Shortages of Water for Injection

Ministry of Health and Wellness
MAURITIUS

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Approval Form

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CONTINGENCY PLAN DURING SHORTAGES OF WATER FOR INJECTION			
	NAME	**SIGNATURE**	**DATE**
AUTHORIZED BY	Senior Chief Executive *Mrs. D. Seewooruthun*	✓	06/03/23
	Director General Health Services *Dr. B. Ori*	✓	01/03/23
APPROVED BY	National IPC Committee *Dr. A. Dinassing*	✓	03/03/23
PREPARED BY	IPC Writing Committee *Dr. D. Nuckchady*	✓	26/12/22

AUTHORS

Dr. K. Azmutally and Dr. D. Nuckchady. A draft of this document was vetted by the IPC Writing Committee.

PEER REVIEW

Mrs. S. Gopy-Burthia (Charge Nurse).

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Contingency Plan During Shortages of Water for Injection

Background

Sterile water for injection is used to dissolve or dilute medications. Due to recurrent shortages in the vials of water for injection (usually measuring 5ml to 100ml) in the public hospitals of Mauritius, our nurses often substitute sterile water with sterile 0.9% sodium chloride, which can be accepted as long as there are no interactions with the pharmaceutical product (e.g., resulting in hyperosmotic solutions that can cause infusion-site reactions or severe hypernatremia (sometimes fatal), or leading to crystallization due to an increase in the concentration of sodium salts).

Prefilled syringes with sterile 0.9% sodium chloride are already in use in some neonatal ICUs of the country, mostly for flushing lines.

Challenges faced

Often, for their own 'ease', nursing officers in Mauritius have been noted to prick 500ml normal saline bottles repeatedly to prepare medications, sometimes keeping the solution for days on the preparation table.

This practice is strictly prohibited since it can contaminate the medication – it constitutes medical negligence in view that after injection of the infected solution, patients can develop sepsis and die.

During several investigations in the hospitals of the country over the last 10 years, samples from such bottles have been found to be contaminated by different microbes (including multi-drug resistant organisms and *Burkholderia cepacia*) and the deaths of many patients are suspected to be linked to such malpractice.

Scope

Due to a global shortage in sterile water for injection, this document has been prepared to inform nurses about the alternative actions to take to safely prepare medications and reduce the risks to patient health.

This document does ***not*** give the green light to nurses to stop using vials of sterile water for injection whenever these are available – nurses should continue to request the procurement of such vials.

Recurrent manipulation of large volumes of water remains a source of contamination and under ***no*** circumstances should this standard operating procedure be considered an excuse to recurrently prick saline pints in an unhygienic manner when alternatives are present.

These vials should always be used if possible and the procedures outlined here apply only when there is a lack of said vials.

Steps

1. If feasible, consider ways to conserve sterile water for injection such as finding products that do not require reconstitution with sterile water for injection, including commercially available premixes. One can also identify medications suitable for reconstitution with an alternative to sterile water (like dextrose saline or lactated ringers).[1]

2. It is usually best for the pharmacy department to reconstitute unit doses of sterile water from large volumes using an aseptic technique in an area where engineering controls are used and strict sterile compounding regulations are followed; if it can be coordinated, it is preferred if pharmacists can prepare some of the commonly used medications under such stringent conditions.[2, 3]

3. Otherwise, during shortages, the use of 500ml to 1,000ml of sterile water or sterile 0.9% sodium chloride bottles or bags can be temporarily allowed. Wherever practical, it is best practice and preferred to use one bag for one patient.

4. Connect an infusion set to the bottle – do not prick the bottle or the bag. A closed system dispensing device is favored but is currently not available locally.

5. Label the bottle / bag with the time and date of first entry.

6. Depending on the quality of the product and the environmental conditions, the maximum time the contents of the bottle are considered sterile is 4 hours to 6 hours.[4, 5] In our local context, discard the contents after 6 hours of use.

    a. Medications should ideally be prepared in compliance with ISO 5 air quality (super-clean room; < 3,520 particles of size > 0.5 micron/m^3; ≥ 240 High-Efficiency Particulate Air filtration per hour or Ultra Low Penetration Air filtration; at most 10^5 particles per m^3). At the present time, this is not being practiced.

7. Despite the lack of evidence, when not in use, the open end of the infusion set should be closed with a dressing soaked in iodine; ensure that the patient on whom the fluid will be used is not allergic to iodine (if so, use alcohol instead). Do not allow the end of the line to touch bins, the floor or surrounding non-sterile areas.

References

1. National Home Infusion Association. Guidance for Addressing Shortages of Sterile Water for Injection and Sodium Chloride 0.9% for Injection for Compounding Sterile Preparations. 2020.
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4. American Society of Health-System Pharmacists. Sterile Water for Injection Shortage FAQ. 2022. Accessed at: https://www.ashp.org/drug-shortages/shortage-resources/sterile-water-for-injection-faq?loginreturnUrl=SSOCheckOnly
5. https://isocleanroom.co.uk/blog/iso-5-defining-cleanroom-classification-guidelines/