



**TITLE: Sterile Pre-filled Saline Syringes for Acute Care Patients: A Review of Clinical Evidence, Cost-effectiveness, Evidence-based Guidelines, and Safety**

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**CONTEXT AND POLICY ISSUES**

Pre-filled syringes are routinely used to flush all types of vascular access devices.<sup>1</sup> As convenient, pre-labeled unit-of-use doses, pre-filled syringes reduce nursing time, and prevent cross contamination and infections common to reuse of multiple-dose vials or large volume saline bags.<sup>1</sup> While pre-filled syringes are intended to improve patient safety by facilitating catheter patency and preventing contact between incompatible medications, there is potential for misuse leading to medication errors and contamination.<sup>1</sup> The riskiest and most common misuse is that of adding medication to a pre-filled saline syringe for the reconstitution or dilution of medication.<sup>1</sup> Saline may be injected into a vial of medication and drawn back into the pre-filled syringe or a small amount of saline can be forced out of the syringe to allow a medication to be drawn into it.<sup>1</sup> Pre-filled syringes used for catheter flushing only have gradations at the half and full milliliter points making it impossible to accurately measure small doses of medication.<sup>1</sup> Pre-filled syringes are often used with high-alert medications that must be drawn within fractions of a milliliter that is not possible with pre-filled flush syringes.<sup>1</sup>

Using pre-filled saline syringes to dilute medications is considered to be an off-label use as manufacturers do not provide instructions for this so the nurse and employer would be legally liable for any adverse events.<sup>1</sup> Commercially available pre-filled flush syringes are prepared by aseptic processing that can introduce a risk of contamination so they are not sterile.<sup>1</sup> All pre-filled flush syringes are single-use devices that do not contain preservative, so there is a risk of contamination with excessive manipulation of the tip cap and syringe tip.<sup>1</sup> Proper labeling poses a problem when a medication has been added to a pre-filled syringe. The manufacturer's label is permanently affixed to the syringe barrel. Should a second medication be added, there is no adequate method to amend the manufacturer's label. A newly prepared syringe could easily be confused with one containing only saline flush.

This review evaluates the comparative clinical effectiveness, cost-effectiveness, guidelines and safety of sterile pre-filled saline syringes versus single dose saline vials for the dilution or reconstitution of medication.

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## RESEARCH QUESTIONS

1. What is the clinical evidence for the use of sterile pre-filled saline syringes versus single dose saline vials for the dilution or reconstitution of medication?
2. What is the cost-effectiveness of sterile pre-filled saline syringes versus single dose saline vials for the dilution or reconstitution of medication?
3. What are the evidence-based guidelines for the use of sterile pre-filled saline syringes and single dose saline vials for the dilution or reconstitution of medication?
4. What is the safety of sterile pre-filled saline syringes versus single dose saline vials for the dilution or reconstitution of medication?

## KEY MESSAGE

No evidence was found regarding the comparative clinical effectiveness, cost-effectiveness, guidelines or safety of pre-filled saline syringes versus single dose saline vials for diluting or reconstituting medications.

## METHODS

### Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, CINAHL, The Cochrane Library (2012, Issue 6), the University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. The search was limited to English language documents published between January 1, 2007 and June 21, 2012.

### Selection Criteria and Methods

One reviewer screened citations to identify health technology assessments, systematic reviews, meta-analyses, economic evaluations and guidelines on the use of sterile pre-filled saline syringes versus single dose saline vials for the dilution or reconstitution of medication. Potentially relevant articles were ordered based on titles and abstracts, where available. One reviewer considered full-text articles for inclusion according to the selection criteria listed in Table 1.

**Table 1: Selection Criteria**

<b>Population</b>	Adults, neonates or pediatric patients in acute care
<b>Intervention</b>	Sterile pre-filled saline syringes
<b>Comparator</b>	Single dose saline vials
<b>Outcomes</b>	Risk of infection, resource utilization (nurses, pharmacists, pharmacy technicians, physicians), treatment efficacy, dose accuracy, cost-effectiveness, recommendations
<b>Study Designs</b>	Health technology assessments, systematic reviews, meta-analyses, economic evaluations, guidelines

## **Exclusion Criteria**

Articles were excluded if they did not satisfy the selection criteria, if they had incomplete methods, were included in a selected systematic review, or were narrative reviews or case reports.

## **SUMMARY OF EVIDENCE**

### **Quantity of Research Available**

The literature search yielded 95 citations. Upon screening titles and abstracts, 11 potentially relevant articles were retrieved for full-text review. No additional potentially relevant reports were retrieved from grey literature or hand searching. Of the 11 potentially relevant reports, five contained an irrelevant intervention, and six cited unknown sources of saline diluent. No relevant publications were included in this review. The process of study selection is outlined in the PRISMA flowchart (Appendix 1).

### **Clinical Evidence, Cost-effectiveness, Guidelines, and Safety of Saline Syringes**

No evidence was found regarding the clinical effectiveness, cost-effectiveness, guidelines or safety of sterile pre-filled saline syringes versus single dose saline vials for the dilution or reconstitution of medication.

## **CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING**

No evidence was found regarding the comparative clinical or cost-effectiveness, guidelines or safety of pre-filled saline syringes versus single dose saline vials for diluting or reconstituting medications.

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## REFERENCES

1. Hadaway L. Misuse of prefilled flush syringes: implications for medication errors and contamination. Infection Control Resource [Internet]. 2008 [cited 2012 Jul 13];4(4):2-5. Available from: [http://www.infectioncontrolresource.org/Past\\_Issues/IC16.pdf](http://www.infectioncontrolresource.org/Past_Issues/IC16.pdf)

APPENDIX 1: Selection of Included Studies

