

Introduction

The parenteral nutrition unit prepares syringes of vitamin-lipid emulsion : Smoflipide®-Vitalipide® (**SV**) for the neonatology and neonatal and pediatric intensive care units.

A stock solution of SMOF-VITA is prepared and then dispensed into syringes using a Baxa Repeater® peristaltic pump.



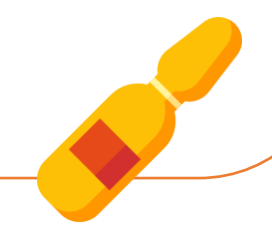
Challenge

Vitalipide® pediatric ampoules → Manual opening and dispensing

→ Repetitive, time-consuming tasks

→ May cause musculoskeletal disorders (MSDs)

Purchase of an ampoule opener



Primary Objective

Evaluation of the ampoule opener in routine practice when preparing SV syringes + evaluation of the experience of hospital pharmacy technicians (HPTs)

Secondary Objective

To demonstrate that the **Vitalipide® emulsion** remains unchanged after 5 µm filtration.

Equipment

- ZETA potential and particle size: Zetasizer Nano ZS
- Baxa Repeater® peristaltic pump
- Ampoule opener + 16G sampling needle + 5 µm filter (to trap any glass particles)



Ampoule Opener

- ✓ Allows for the simultaneous opening of 20 ampoules
- ✓ Time-saving
- ✓ Easy to use → reduces MSDs

Method

Study over **5 Month** – December 2024 to April 2025

Evaluation and Comparison of preparation time before and after the introduction of the ampoule opener

- ❖ Total time required to prepare syringes (= start time and end time of preparation)
- ❖ Time required for administration (= opening + withdrawal) of Vitalipide® ampoules into the master bag



Stability study of the Vitalipide® emulsion after use of the ampoule opener + 16G withdrawal needle + 5µm filter

3 bags containing 60 ampoules per bag + 1 unfiltered Vitalipide® ampoule (control)

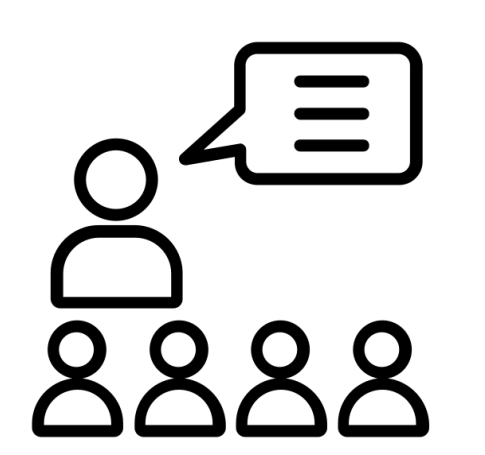
→ Analyses: 3 samples per bag—over **1 day**

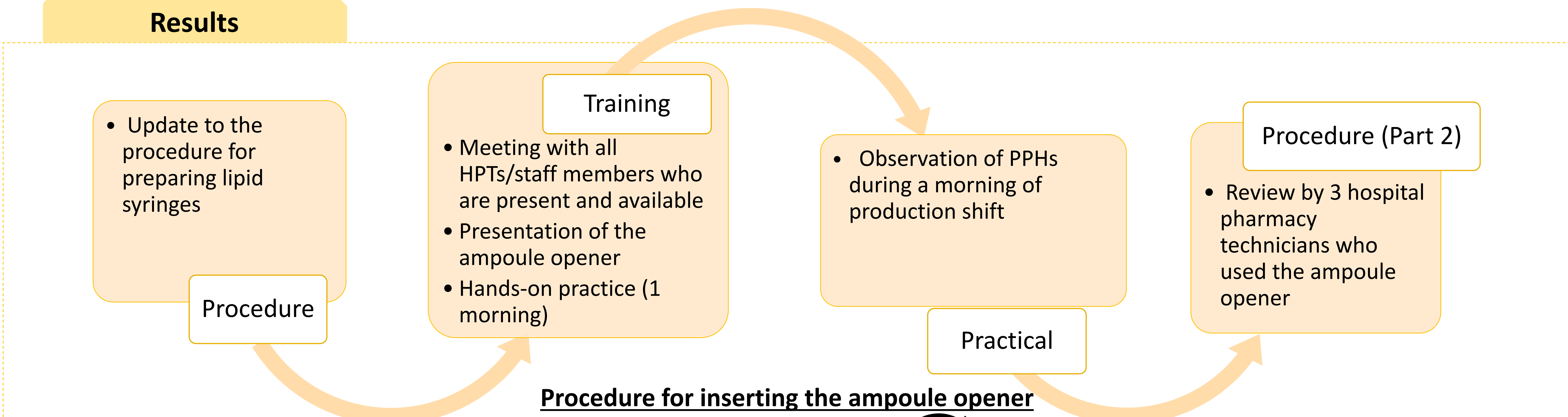
- Microscopic analysis
- Analysis of the average particle diameter
- Zeta potential measurement



Training for HPTs and agents + Development of a questionnaire for HPTs

- ✓ 9 questions
- ✓ 3 categories: device evaluation, syringe preparation, musculoskeletal disorders
- ✓ Submitted to 3 HPTs







Total time required to prepare SV syringes

Time (in minutes)	Before*	After**
Average number of syringes	72	64
Average, Standard Deviation	78,25 ± 21,6	60 ± 14,7
Min, Max	[58;108]	[44 ; 73]
Median	73,5	63

Time required to open and withdraw Vitalipide® ampoules from the master bag

Average number of ampoules	60	53
Time (in minutes)	Before*	After**
Average, Standard Deviation	32 ± 7,5	10,3 ± 1,2
Min, Max	[21 ; 38]	[9 ; 11]
Median	34,5	11

*Before: Opening the ampoules and withdrawing the contents manually, one by one

**After: Opening with the ampoule opener and withdrawing the contents using the withdrawal needle

FORMULATION STABILITY

Parameters	Vitalipide® ampoule (control)	3 bags containing 60 Vitalipide® ampoules
Macroscopic appearance	None creaming, precipitation, or coalescence	
Average diameter of lipid globules	226 nm	224 nm
Zeta potential	-47 mV	-53 mV



100 % of HPTs find :

- The device **easy** to use
- The training (meeting + hands-on practice): **adequate**
- No difficulty** in operating it under the hood

Satisfaction survey: 3 HPTs (100%) completed the survey

100% of HPTs note :

- easier-to-open ampoules, which **save time**

100% of HPTs have experienced pain while preparing medication without an ampoule opener, including (2) cases of moderate pain and (1) case of mild pain.

Since **using the ampoule opener** :

100% report a **↓** in symptoms and a reduction in **pain level to 0**.

- A decrease in the repetitiveness of movements.

Conclusion

The ampoule opener made it possible to :

- optimize the preparation of SVs by reducing the time required to open and withdraw Vitalipide® ampoules from the master bag
- improve working conditions
- improve the comfort of HPTs

Vitalipide® emulsion remains unchanged after using the ampoule opener and a 5 µm filter.

