



Seven Reasons to Promote CIVAS-assembled Point-Of-Care Activated Systems for Infusion of Labile Drugs instead of On-Ward Traditional Methods

Jacques Douchamps, Amélie Bury, Caroline Sneessens, Michel Courtois
Pharmacy department, Centre Hospitalier Universitaire de Charleroi (Hôpital André Vésale),
Montigny-le-Tilleul, Belgium

Background

Point-Of-Care Activated Systems (POCAS) use an isolation technology that separates the drug and diluent until administration¹.

- It comprises the glass vial of freeze-dried active powder, the infusion bag and a connecting device between both (assembled in a clean room or an isolator)
- When needed, the nurse activates the system at the patient bedside

POCAS is particularly recommended for labile drugs like co-amoxiclav². However in Europe nurses are generally ignorant of the POCAS concept and use syringe&needle (SYRNE) or transfer-set (TRASE) methods to deliver i.v. drugs, although such methods are at high risk of patient infection and manipulator harm^{3,4}.

Objectives

To promote the replacement of traditional methods by POCAS.

Materials and Methods

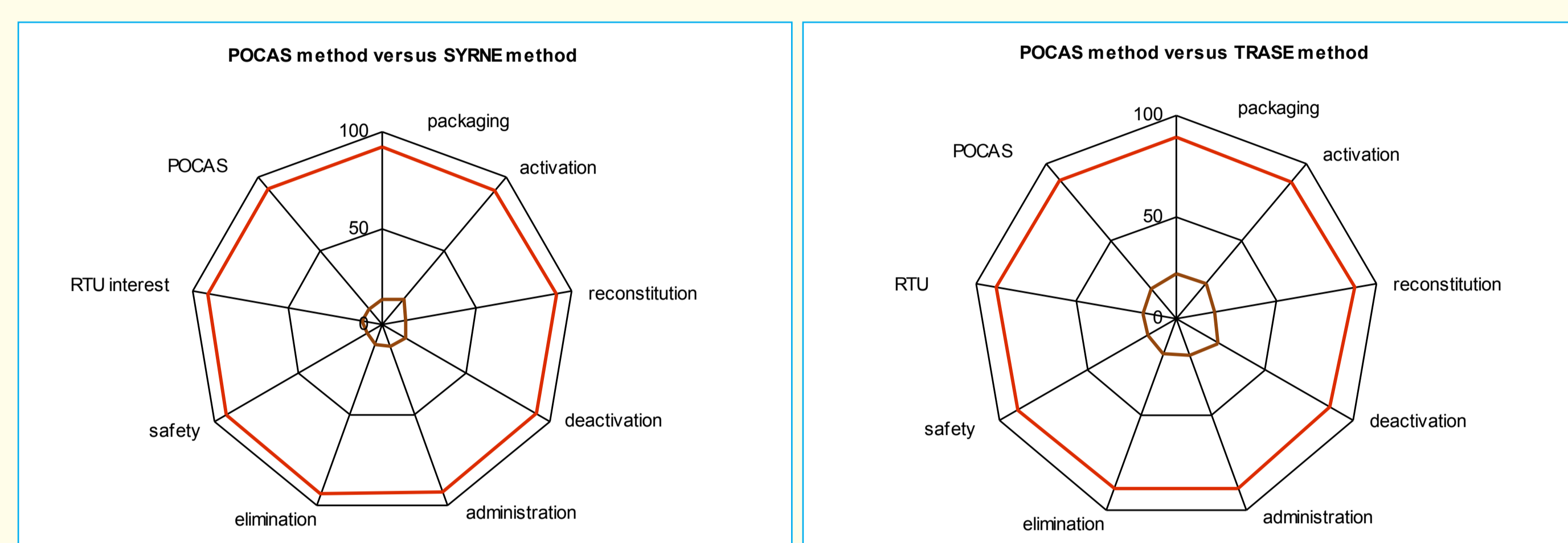
Within the last 6 years, our CIVAS routinely produced 95,000 POCAS of co-amoxiclav or meropenem for our hospital internal use without any complaint for contamination.

In parallel, in order to compare traditional versus POCAS methods, we carried out 4 different studies in 4 unrelated hospitals where nurses were naive to POCAS.^{5,6,7,8}

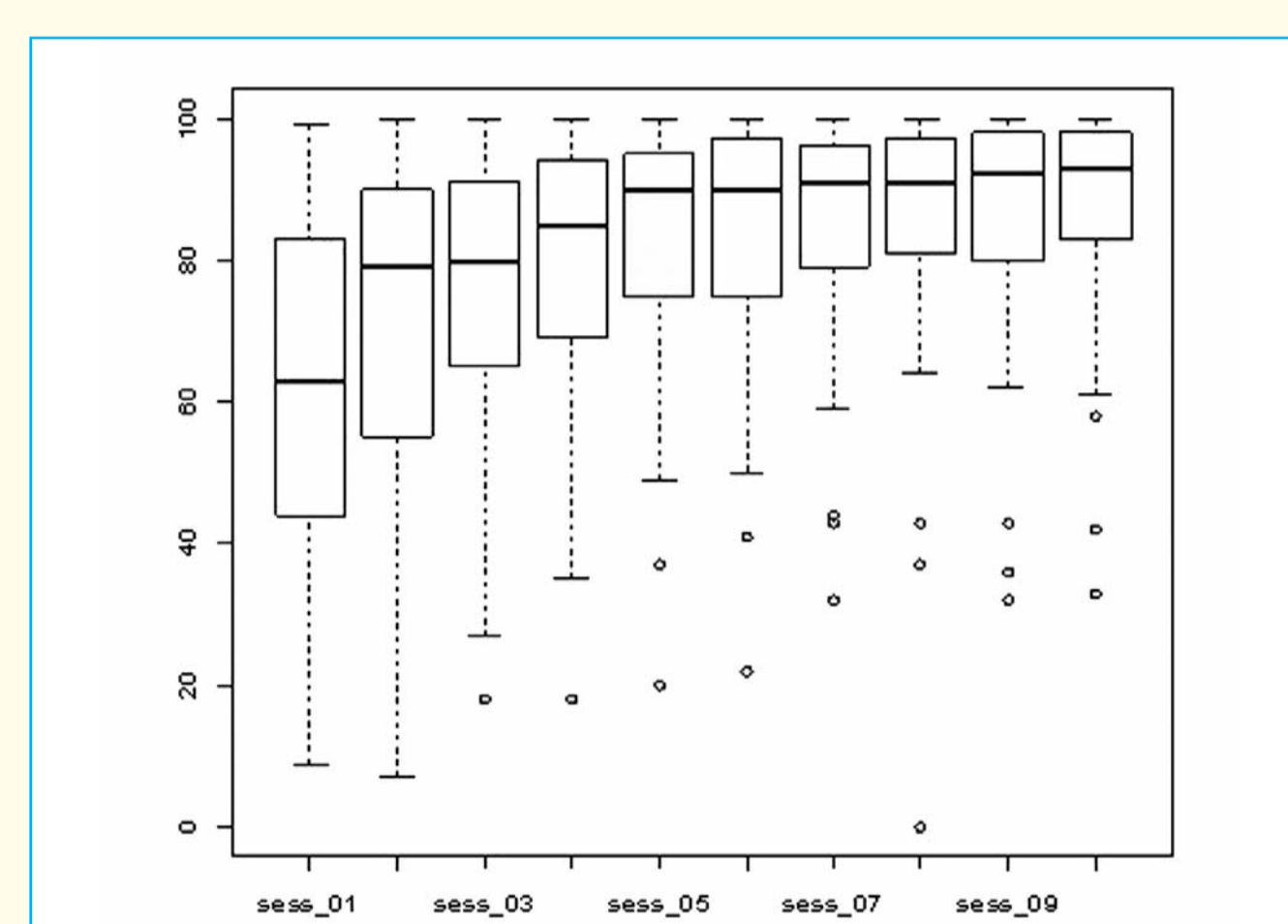
- POCAS: Augmentin[®]-1g vial + 50-mL saline Viaflo[®] bag + EuroVialMate[®] connector
- 96 nurses performed 984 reconstitutions/administrations
- They rated 9-criterion visual analogue scales (440 assessments)
 - ◊ Medians (centration) and interquartile intervals (dispersion) for each hospital
 - ◊ Overall median comparisons and learning effects assessed by non-parametric tests

For comparison purpose, POCAS results were adjusted on 100% excellence scales where the SYRNE method (or TRASE method) served as reference (50% score).

Comparisons of the 9 criteria evaluated by the nurses for the POCAS method versus either the SYRNE (left) or the TRASE (right) traditional methods (50% line).
Medians and interquartile intervals; all comparisons reached statistical significance ($p < 0.05$)



Satisfaction for the activation manoeuvre (42 naive nurses; first 10 infusions)
Medians and interquartile intervals



Results

1. Nurse Safety

Nurses' pricks occur mainly during reconstitution and administration (26%), manipulation (37%) and waste elimination (25%), i.e. 38 % at bedside⁹.

POCAS safety was judged excellent: 94% full scale vs both SYRNE & TRASE methods due to :

- No needle prick risk
- In line with EC directive requiring a safe method and a safe device¹⁰
- No contact with allergizing drugs when manipulating¹¹

2. Intuitive Training and Ease of Use

Quick training of naive nurses is capital to ensure POCAS rapid adoption in hospitals on a large country scale:

- POCAS obtained 90% of full scale versus the SYRNE method (89% vs TRASE)
- The activation manoeuvre required training (see habituation graph for activation)
- The most cost-effective training consisted in a 10-min group course followed by a 10-min personal teaching with practice of 3 activation-deactivation manoeuvres

3. Patient Safety

POCAS was judged very safe with 94% of full excellence scale when SYRNE or TRASE (50% of full scale) because of :

- No risk of bacterial contamination (closed system)
- Correct drug, dosage, diluent and volume
- Correct labelling and excellent traceability

4. Product Quality

92% of full excellence scale versus SYRNE (89% vs TRASE) due to :

- Isolator compounding with high quality control process
- Semi-automatic production (300-unit batches)
- Individual packaging for 6-month storage at room temperature

5. Outsourcing Opportunity

- For small hospitals deprived of PICs-compliant facilities
- As encouraged by Belgian health authorities (royal decree/29th January 2007)

6. Ecological Impact

91% versus SYRNE (89% vs TRASE):

- No dioxin rejected in the air during incineration

7. Cost containment

Because of late unexpected events which might occur between reconstitution and bedside administration, wastage of labile drugs rises up to 15% with SYRNE method¹²:

- Identical unitary costs for POCAS and SYRNE (or TRASE) method were obtained when considering a 14%-waste for co-amoxiclav (see below the simulation table) or 4%-waste for meropenem (NB: wastage cost varies with molecule prices)
- POCAS semi-automated production induced a 40%-time gain over manual assembly
- Considering the nurse's infusion delivery time, a 44%-time gain over SYRNE was obtained with POCAS (54 versus 109 seconds)
- With POCAS, there is a complete suppression of labile drug wastage because of just-in-time bedside reconstitution

Unitary costs (€)	POCAS	SYRNE +0%	SYRNE +5%	SYRNE +14%
Materials	1.1700	0.3014	0.3014	0.3014
Workload	0.7156	0.9203	0.9203	0.9203
Unit cost	1.8856	1.2217	1.4587	1.8856
POCAS gain		-0.6639	-0.4269	0.0000

Conclusions

- **POCAS is a closed-system method much safer for the patient and the nurse than the on-ward SYRNE or TRASE traditional methods of reconstitution and administration of i.v. drugs infusion**
- **After a 20-min training, nurses ignorant of the POCAS concept readily adopt it because it is felt safer, easier and quicker than traditional methods**
- **Activity-based cost calculations taking into account materials, pharmacy and nursing workloads as well as possible wastage show that POCAS is equivalent to a SYRNE method entailed of a 14%-wastage for co-amoxiclav or 4%-wastage for meropenem**
- **We recommend that campaigns of the European Union to secure i.v. infusion promote the POCAS method, especially for labile drugs.**

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Conflict of Interest

None, the four studies being totally supported by the Research Funds of the Charleroi University Hospital

