



BC Cancer Agency

CARE + RESEARCH

An agency of the Provincial Health Services Authority

Closed Drug Transfer System Usability Study

Co-Investigators:

Joan Fabbro, Chemotherapy Certification Pharmacist

Michelle Koberinski, Chemotherapy Certification Pharmacy Assistant

Crystal Amos, Pharmacy Professional Practice Leader, ACC

Consultants:

Rachel White, Human Factors Specialist, University Health Network

Allison Filewich, Clinical Nurse Leader, Systemic Therapy, CSI

December 3, 2011

Disclosures

- Michelle, Joan and Crystal attended a multi-disciplinary advisory board meeting sponsored by Carmel Pharma
- Carmel Pharma, ICU Medical and B Braun each supplied their closed system components that were required for the Usability Study free of charge

Outline

- Background
- Objectives
- Systems
- Methodology
- Results
- Discussion and Observations
- Summary

Background

What is a usability study?

- Formal method of observation
- Target users; real tasks
- Measurable criteria

Background

Why consider a CSDTD for the BCCA?

- Occupational exposure still occurs despite current protective measures
- Further minimize occupational exposure for healthcare workers
- Designed to enable a leak-free drug transfer
- Effective when used as the manufacturer intended

Why do a usability study?

- Identify safety concerns
- Assess how well system is adapted to the tasks
- Reduce potential negative outcomes

Objectives

- Assess the intuitiveness of three closed-drug transfer systems ***without training***

Why no training?

Philosophy: Mimic the worst case scenario

- Some people will forget what they learned, especially under pressure or casual staff; people learn differently; some trainers are better than others
 - If you make the study task as easy as it can be by providing teaching, then you might miss things that you would see in the real world
 - You can't simulate what actually happens in the real world, therefore, simulate the worst-case scenario!
- Identify usability problems with the user interface
 - Navigation errors
 - Presentation errors
 - Present data to the BCCA Closed System Transfer Device Steering Group

Systems

PhaSeal® (Carmel Pharma)



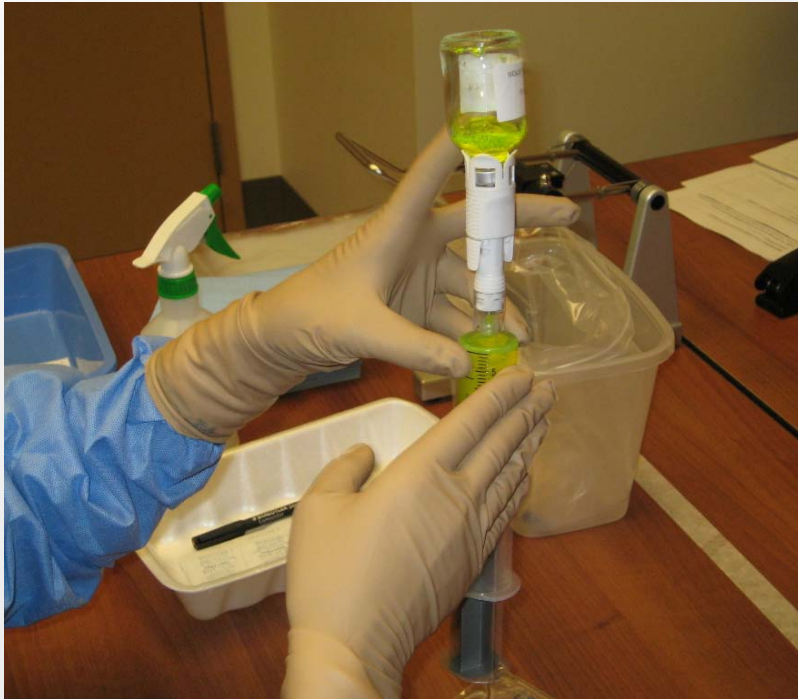
Systems

ChemoCLAVE™ (ICU Medical)



Systems

OnGuard™ (B. Braun)



Methodology

Purpose & background info

Pharmacy Assistants (12 participants) – Withdraw fluorescein dye solution ('chemo' drug) from vial and inject into the infusion bag; provided with labels and the necessary components to complete the task

Nurses (12 participants)- Administer two different 'chemo' drugs (fluorescein) to an imaginary patient; provided with primed primary line and the necessary components to complete the task

No training/instruction provided

Allowed to ask for help

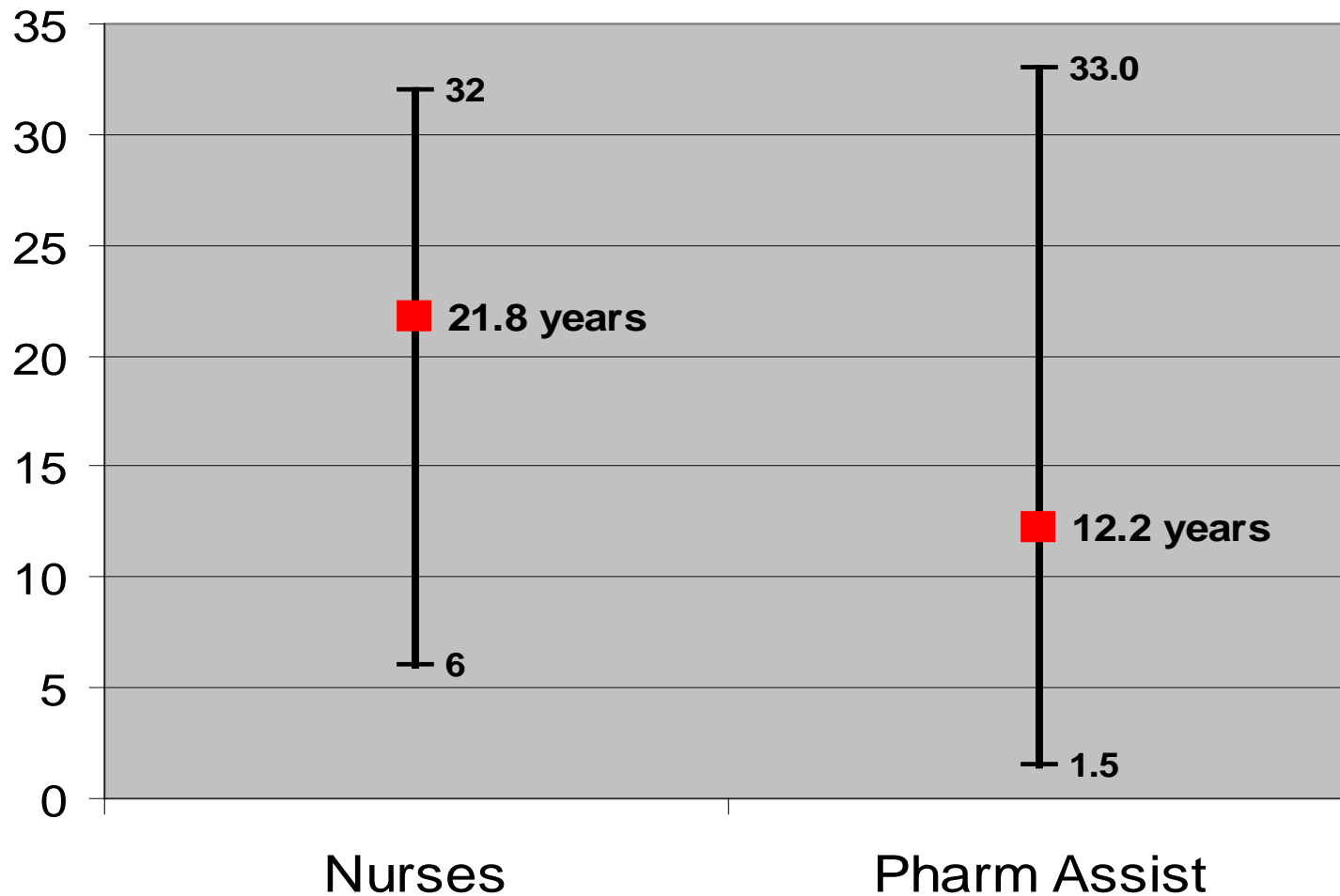
Tested devices for evidence of fluorescein with UV light

Question set asked after completion of task

Qualitative and quantitative data collection

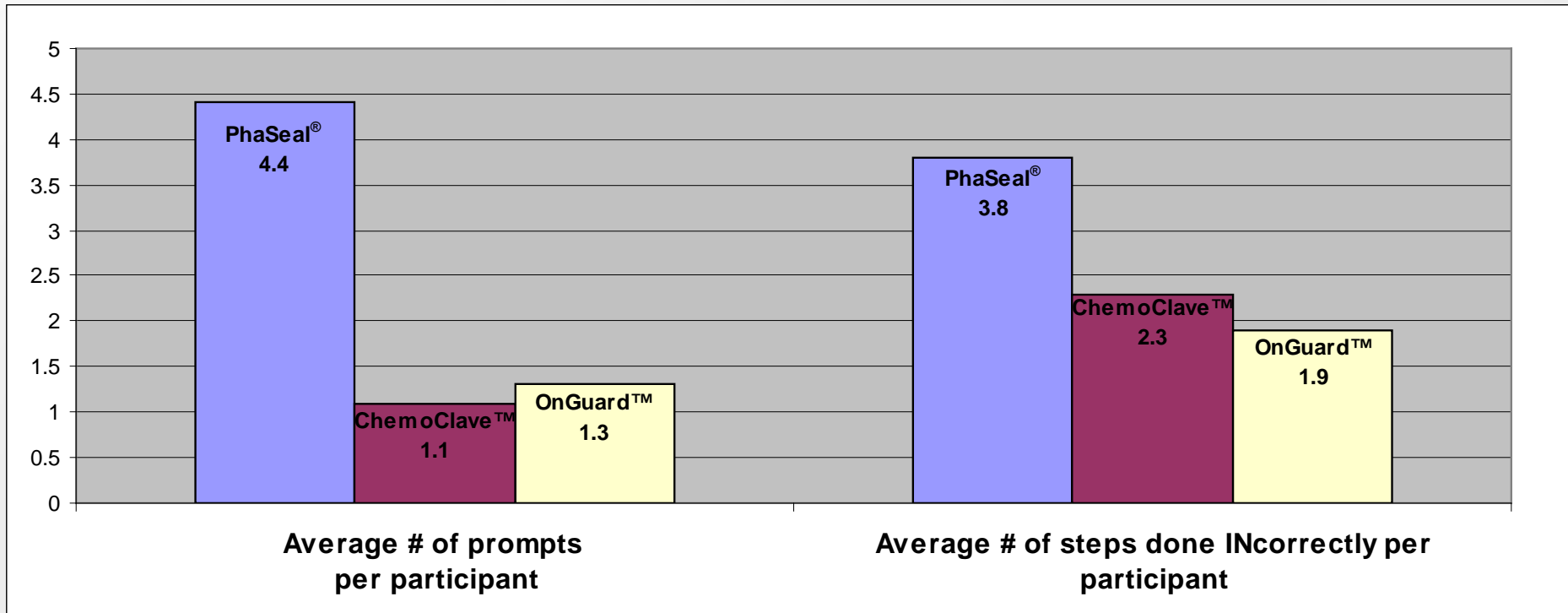
Results (Demographics)

Years of Work Experience



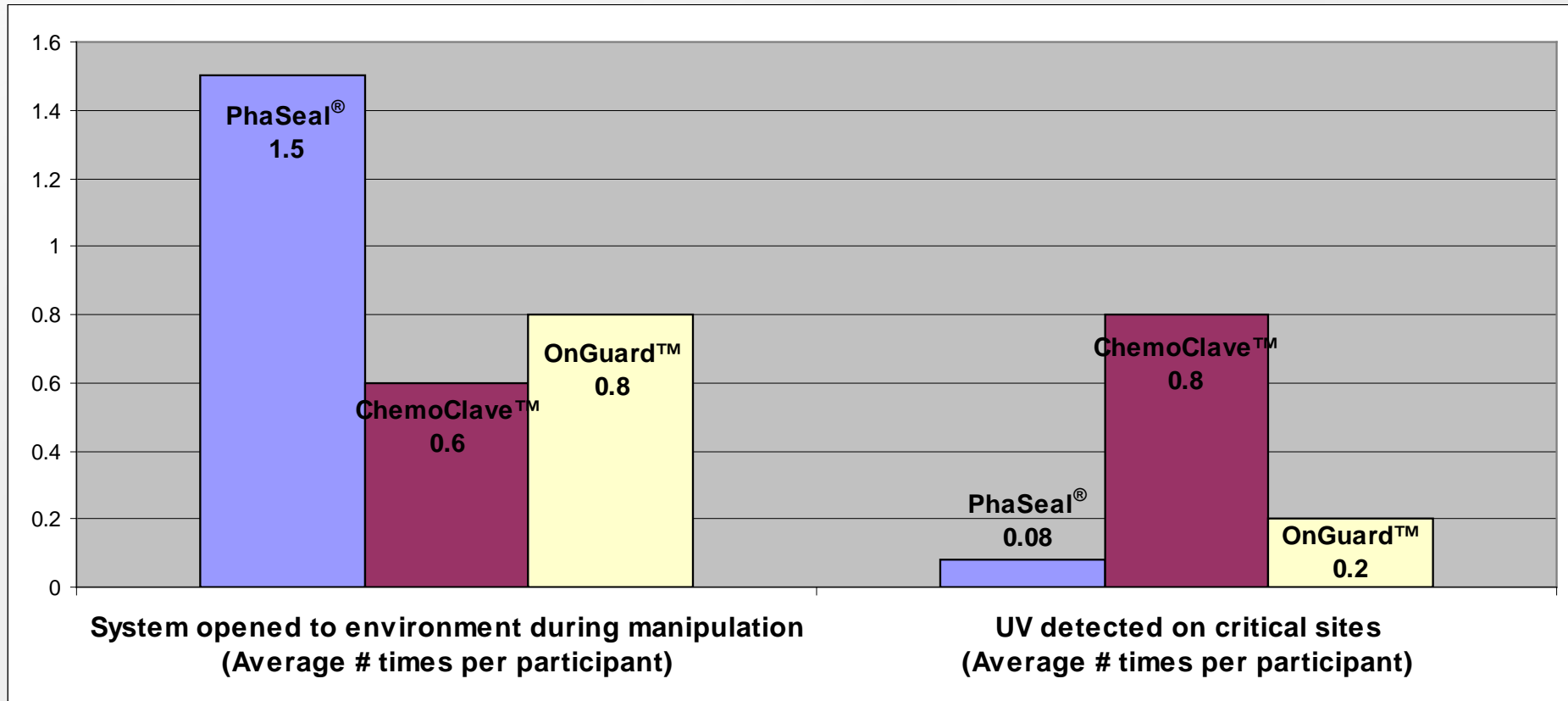
Results (Checklist)

Pharmacy Assistants



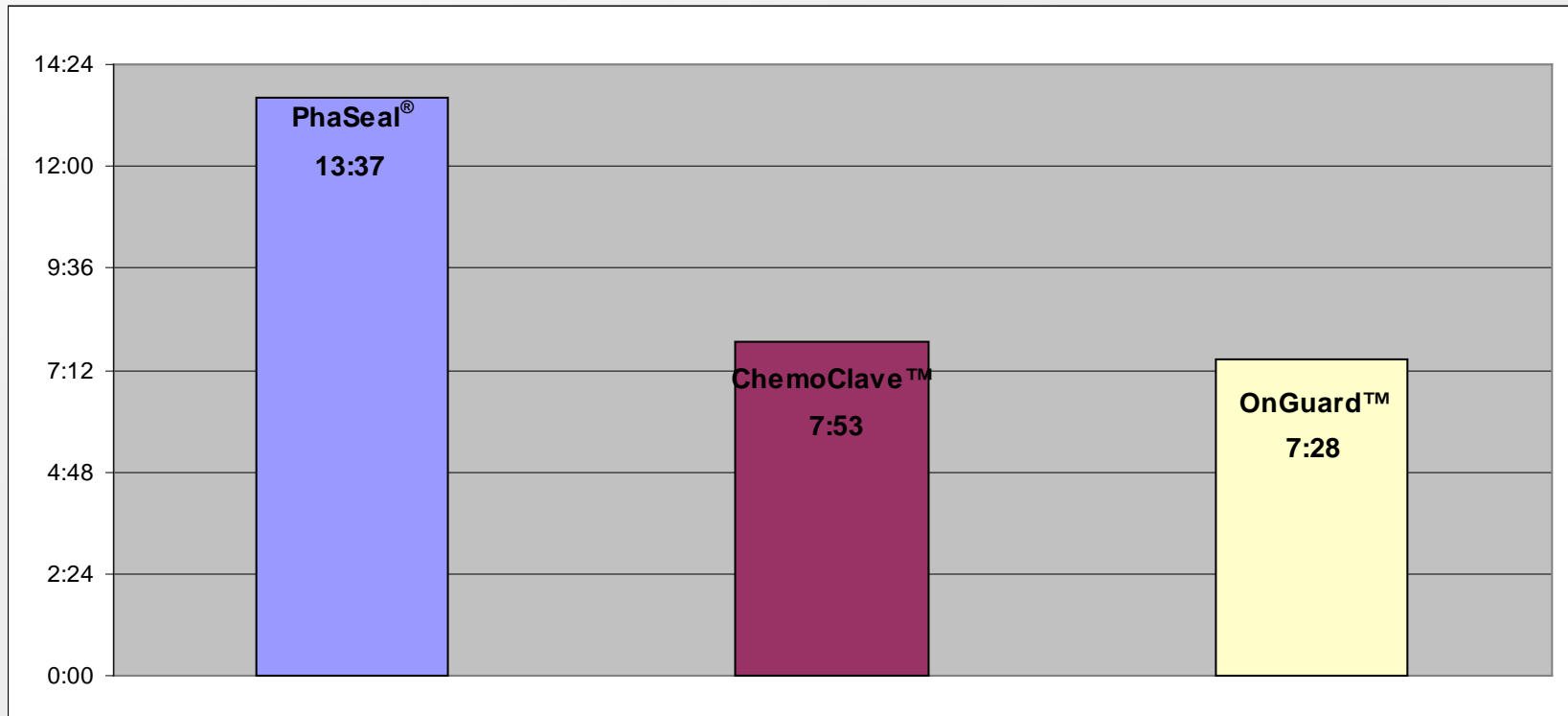
Results (Checklist)

Pharmacy Assistants



Results (Checklist)

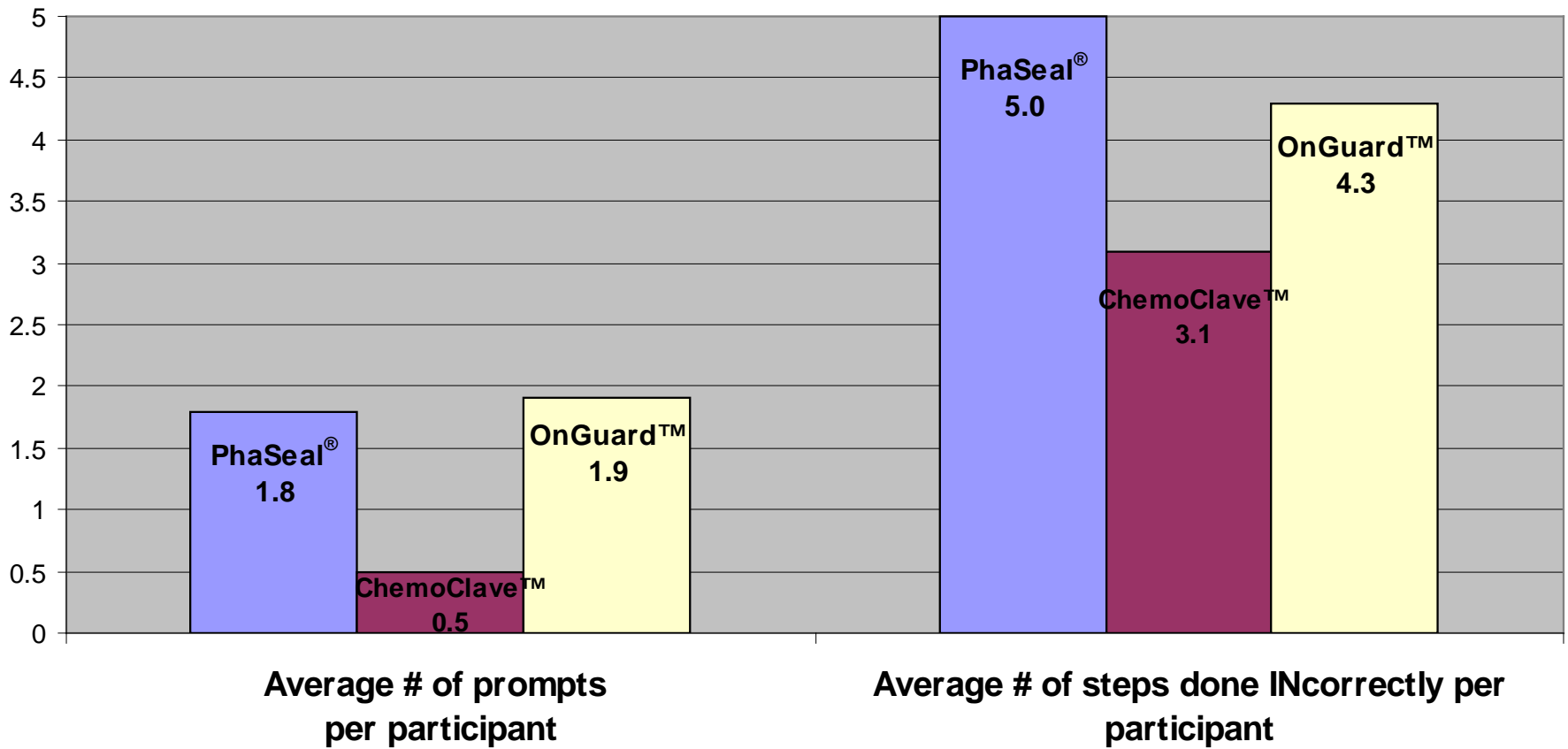
Pharmacy Assistants



Average time to complete the entire task

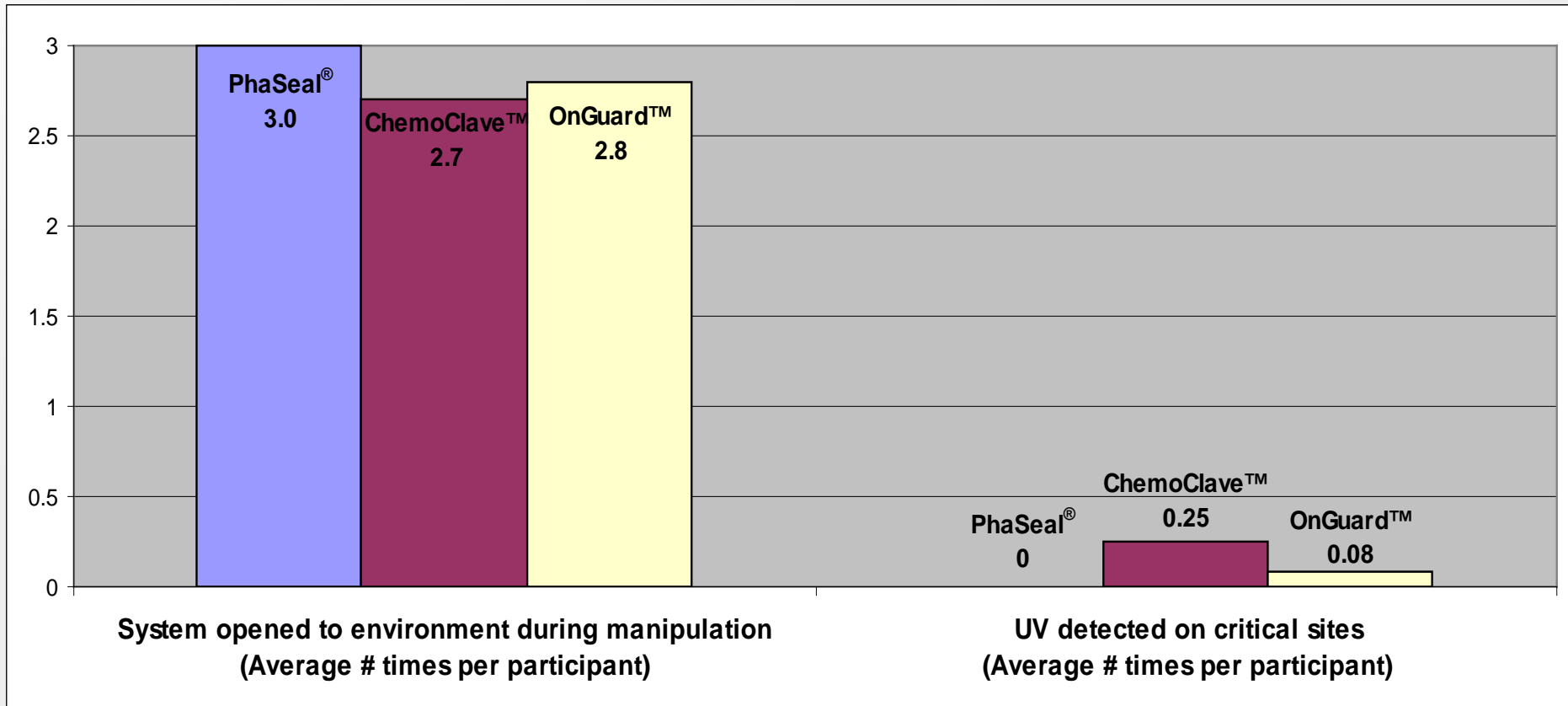
Results (Checklist)

Nurses



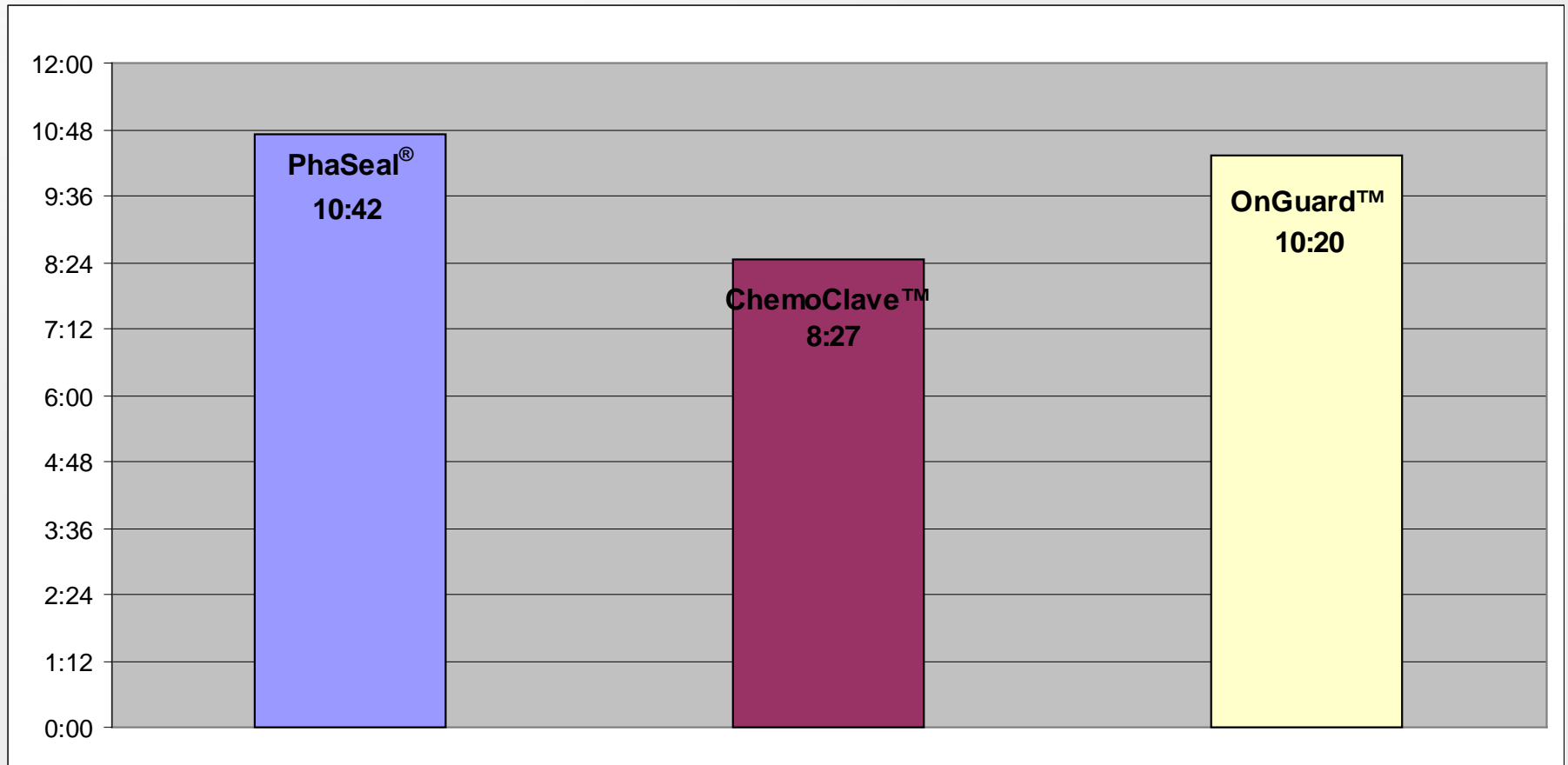
Results (Checklist)

Nurses



Results (Checklist)

Nurses



Average time to complete the entire task

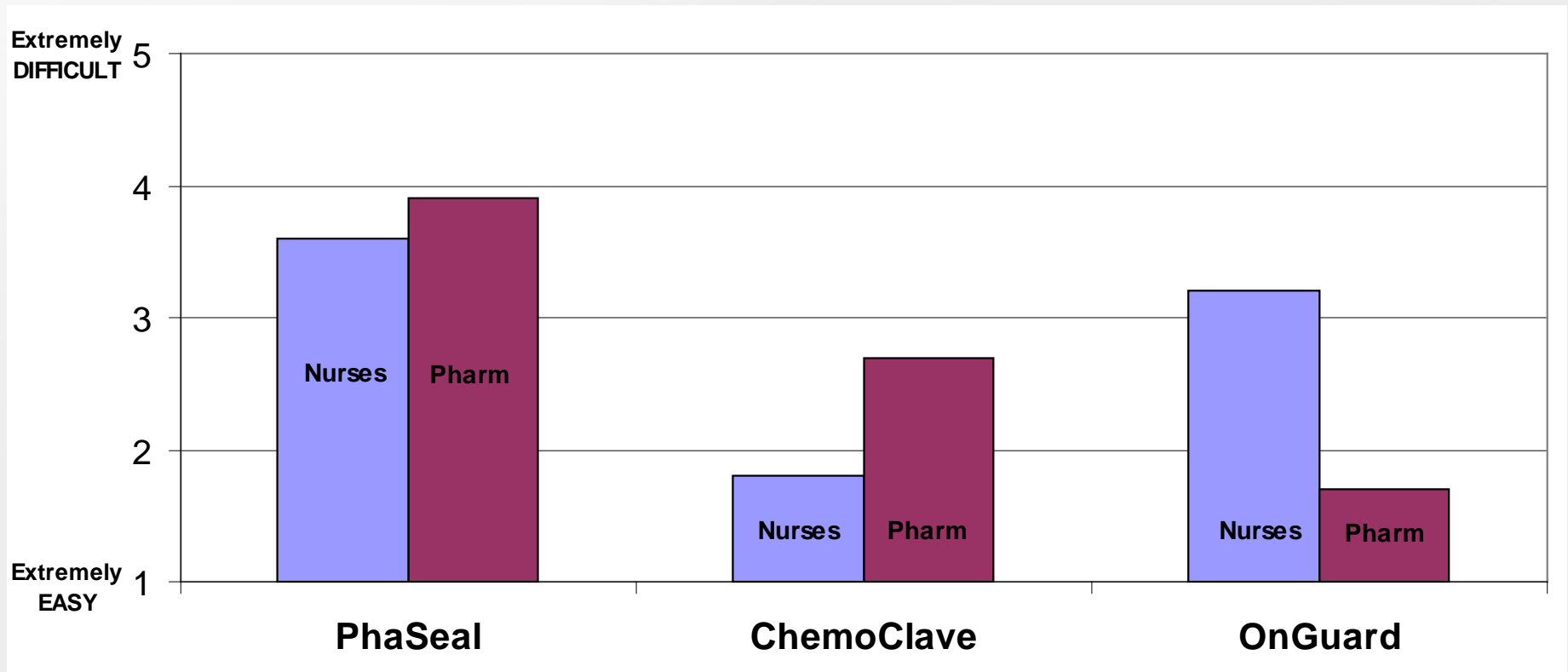
Results (Checklist Summary)

	PhaSeal®		ChemoCLAVE™		OnGuard™	
	Pharmacy	Nursing	Pharmacy	Nursing	Pharmacy	Nursing
Performance Data						
# prompts needed	High	Medium	Medium	Low	Medium	Medium
# steps done incorrectly	Medium	High	Low	Medium	Low	High
Time to complete task	High	High	Medium	Medium	Medium	High
System opened to environment	Medium	High	Low	High	Low	High
Result of Fluorescein Testing	Low	Medium	High	Low	Low	Low

Results (Questionnaire)

Question 1:

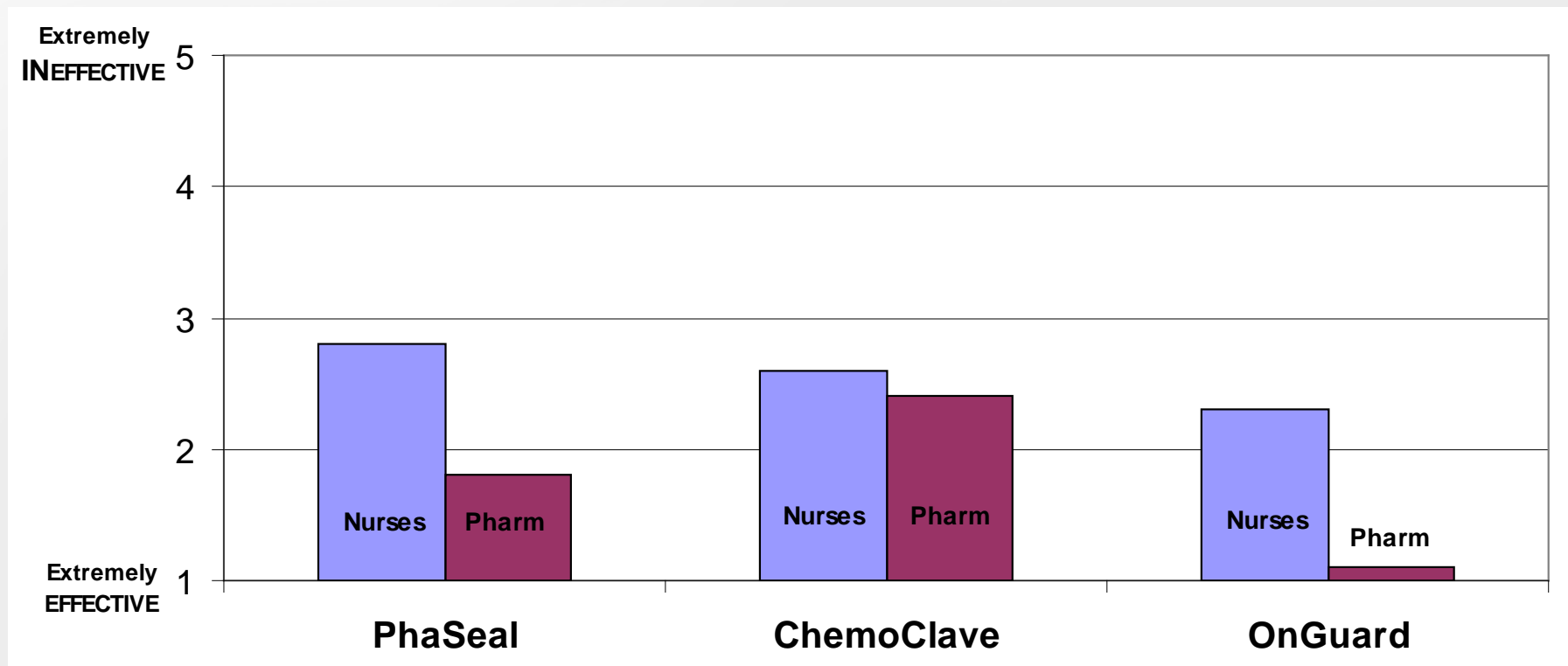
How easy was it to use the system on a scale of 1 to 5?



Results (Questionnaire)

Question 2:

In your opinion, how effective was the system at containing the medication within the system on a scale of 1 to 5?



Results (Questionnaire)

Question 3:

In your opinion, what are the **BEST features** of each system?

Best features of PhaSeal®:

Pharmacy Assistants

- No drug spillage/appears safe (5)
- Spike easy to put into bag (2)
- Easy to puncture into vial with vial assembly (2)
- Nothing! (2)
- Easy to push drug into bag (1)

Nurses

- Appears to contain everything (3)
- Likes the locking mechanism (3)
- Likes the bag adaptor port (3)
- Nothing! (2)
- Likes the size of the parts (easier to manipulate with hands) (1)

Results (Questionnaire)

Question 3:

In your opinion, what are the **BEST** features of each system?

Best features of ChemoCLAVE™

Pharmacy Assistants

- Very easy to use (2)
- No needle (2)
- Easy for spike to go in vial (2)
- Appears safe/No spillage (2)
- Nothing! (2)
- Not as bulky (1)

Nurses

- Spiros / connection easy (9)
- Not a lot of parts (2)
- More intuitive (1)

Results (Questionnaire)

Question 3:

In your opinion, what are the **BEST features** of each system?

Best features of OnGuard™

Pharmacy Assistants

- Instinctive and easy to use (5)
- No exposure / safe (3)
- Didn't have to use force (2)
- The way it clicks (1)
- Transferring into bag easy (1)

Nurses

- Connections appear secure (4)
- Easy to use (4)
- Nothing! (3)
- Likes extra clamp on bag adaptor (3)

Results (Questionnaire)

Question 4:

In your opinion, what are the **WORST** features of each system?

Worst features of PhaSeal®

Pharmacy Assistants

- Twist and click awkward (5)
- Doesn't like vial assembly in hood – too bulky (5)
- Very hard to use (3)
- Requires air to withdraw drug (1)
- Finicky and not intuitive (1)
- Hurts wrists (1)

Nurses

- More complicated (4)
- Not intuitive / difficult (3)
- Unclear how to swab connections (2)
- Nothing (2)
- Worried about wrist injuries (1)
- Didn't like infusion bag adaptor

Results (Questionnaire)

Question 4:

In your opinion, what are the **WORST** features of each system?

Worst features of ChemoCLAVE™

Pharmacy Assistants

- Drug sucks back / pressure when pulling back on syringe (3)
- Spiros doesn't feel like it's screwed on correctly (3)
- Not intuitive (2)
- Balloon was weird (1)
- Bag spike is long (1)
- Cumbersome (1)

Nurses

- Difficult to spike bag adaptor (9)
- Nothing (2)
- Difficult to pull tab off end of bag adaptor (1)

Results (Questionnaire)

Question 4:

In your opinion, what are the **WORST** features of each system?

Worst features of OnGuard™

Pharmacy Assistants

- Nothing (4)
- A lot of parts / pieces (2)
- Vial adaptor feels wobbly when withdrawing (1)
- Doesn't like clamp on bag adaptor (1)
- Hard on hands (1)

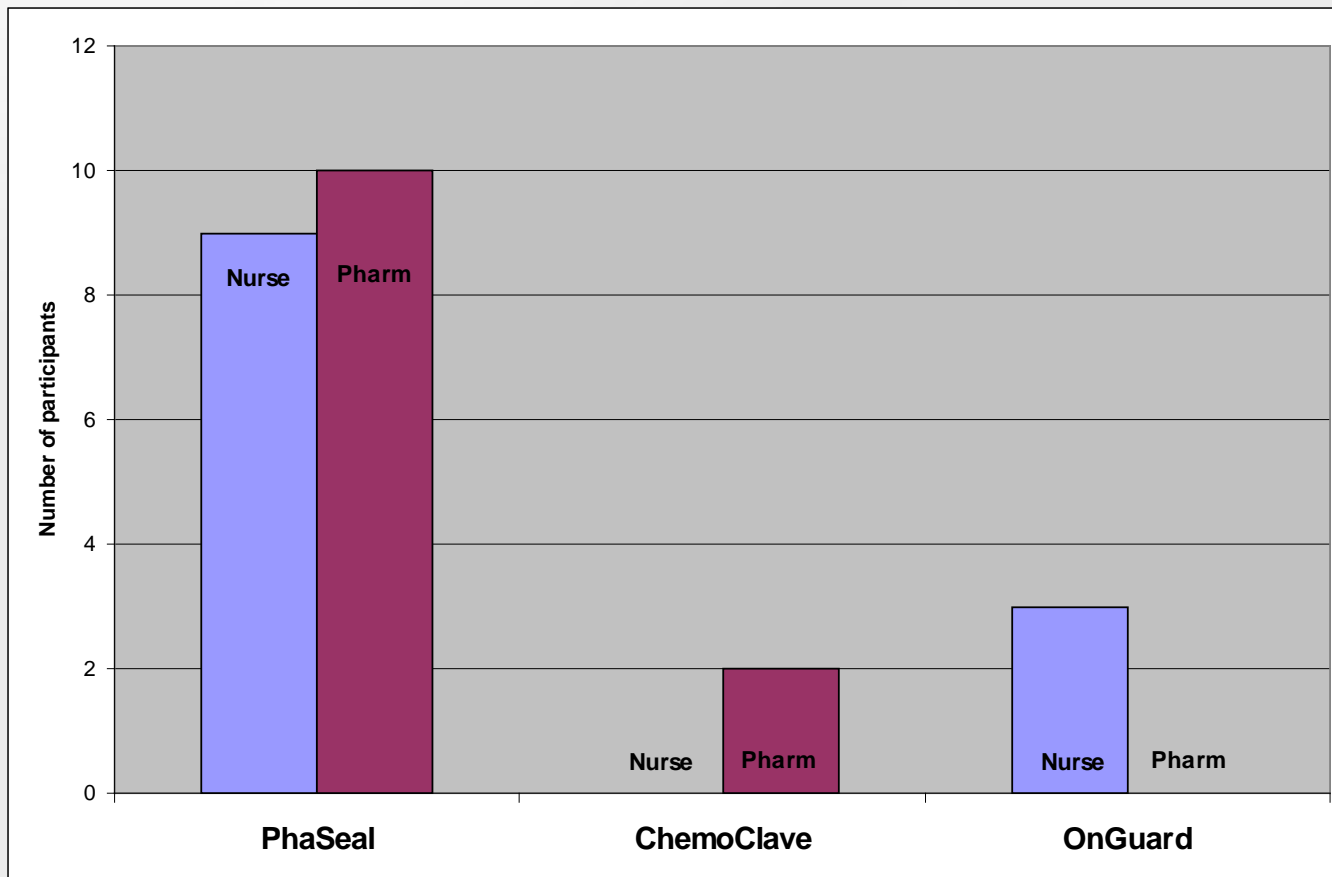
Nurses

- Too many pieces (6)
- Don't like snap off piece on bag adaptor (2)
- Difficult to attach (1)
- Nothing (1)

Results (Questionnaire)

Question 5:

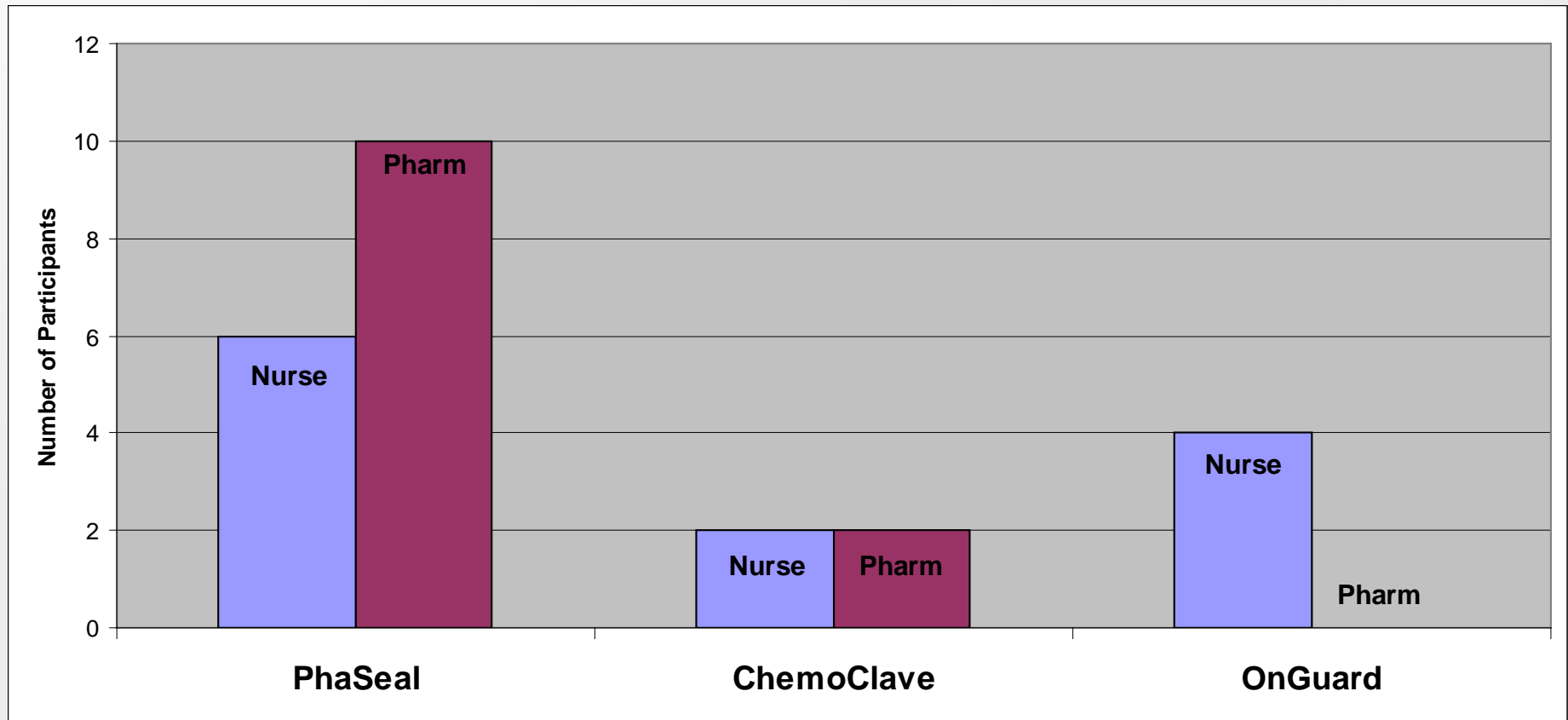
In your opinion, which system would be the HARDEST to train someone how to use?



Results (Questionnaire)

Question 6:

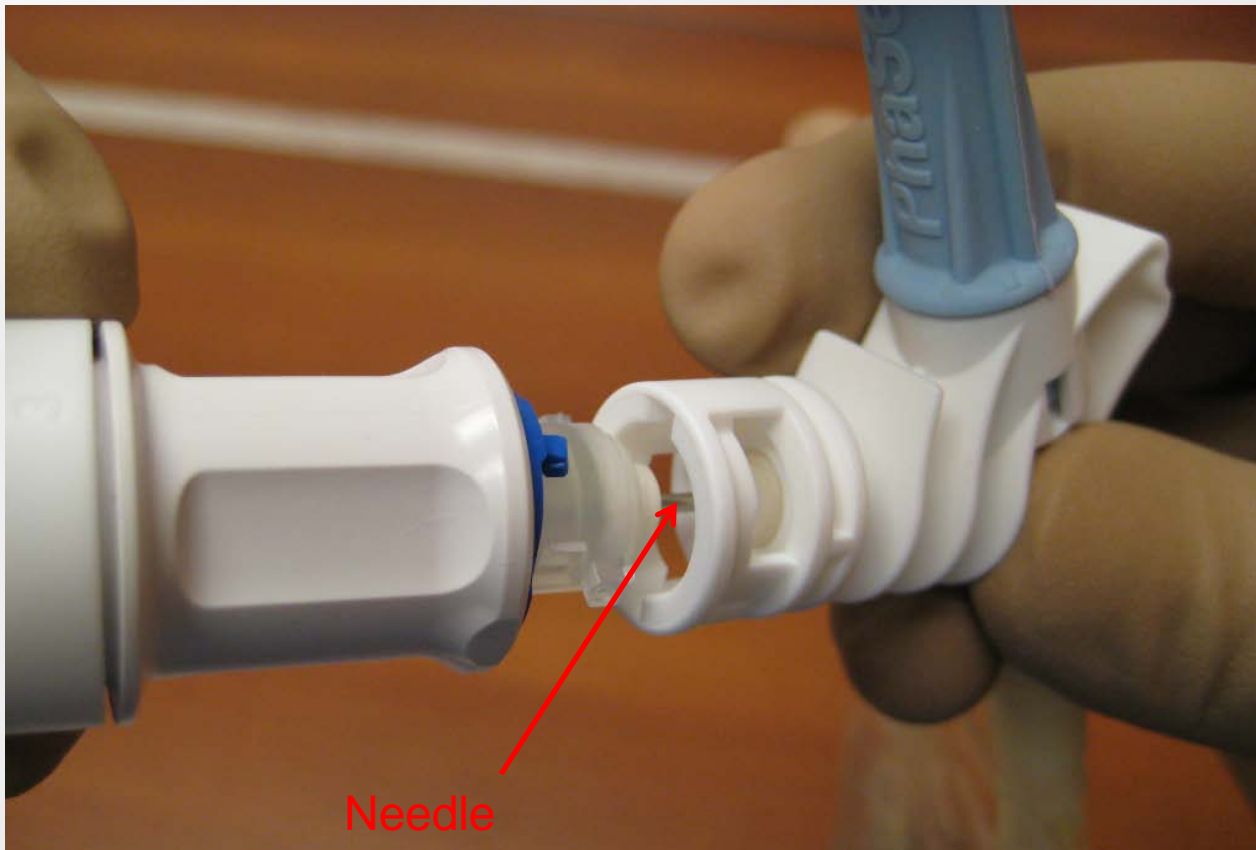
Which system do you LEAST prefer?



Discussion and Observations

PhaSeal®

Needle exposure occurred twice



Discussion and Observations

PhaSeal®

Drug in Vial Adapter bubble:



'Drug'

Discussion and Observations

Potential workarounds:

PhaSeal®

Not using vial assembly
(attached vial adaptor directly
to vial)



All three systems

Attach secondary line without
without using closed system



Discussion and Observations

Potential workarounds (cont'd):

ChemoCLAVE™

Syringe attached directly to vial adaptor (spinning spiros [inset] not used and therefore open system upon removal of syringe)

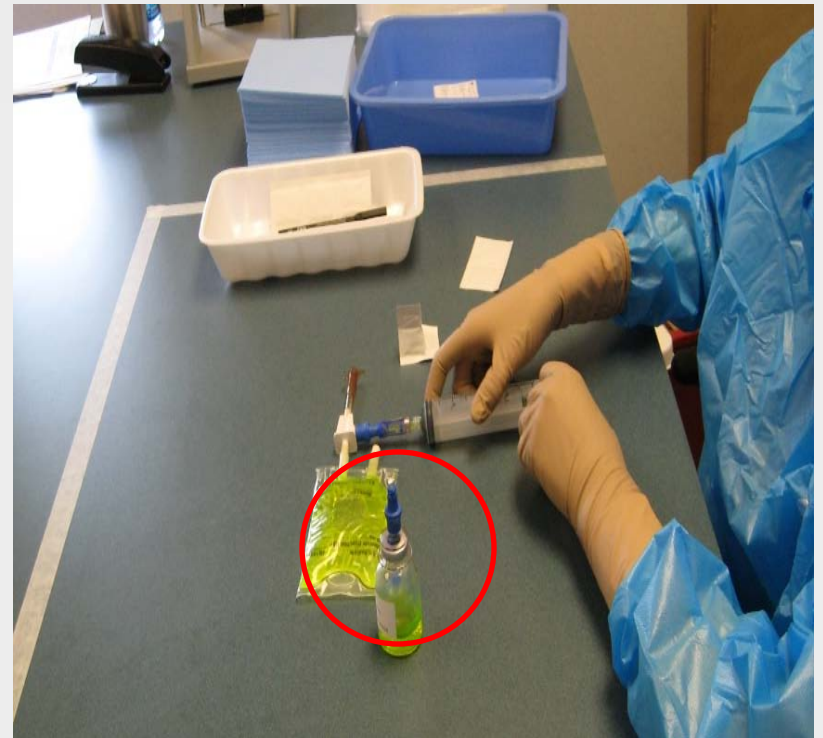
(can't do this with PhaSeal® or OnGuard™)



Discussion and Observations

ChemoCLAVE™

Pressure pullback → Incorrect volume withdrawn



Discussion and Observations

ChemoCLAVE™ bag port adaptor

Administration line spike bent upon attempted insertion



Discussion and Observations

Spills:

ChemoCLAVE™

Spiking the infusion bag adaptor



All three systems

Attaching both adaptor and connector to primed line opened the system



Discussion and Observations

ChemoCLAVE™ - Spinning Spiros

Safety feature **or** potential hazard?

“There’s no Click” or “You can’t feel it tighten”



Summary

	PhaSeal®		ChemoCLAVE™		OnGuard™	
	Pharmacy	Nursing	Pharmacy	Nursing	Pharmacy	Nursing
Qualitative Data						
Ease of Use	Hard	Hard	Medium	Easy	Easy	Hard
Locking Mechanism	Twist/push	Twist/push	Twist	Twist	Click	Click
Storage	Bulky	Bulky	Excellent	Excellent	Good	Bulky
Disposal Management	Safety Needle	Safety Needle	Needleless	Needleless	Safety Needle	Safety Needle
Potential for repetitive injury	Twisting and pushing	Twisting and pushing	Twisting	Twisting and pushing (bag spike)	Squeezing	Squeezing
Number of parts/pieces	Too many	Too many	Excellent	Excellent	Too many	Too many
Ease of Training	Hard to train	Hard to train	Medium to train	Easy to train	Easy to train	Medium to train
Staff Preference	Least prefer	Least prefer	Medium	Most prefer	Most prefer	Medium

Conclusions

- No system is perfect: All three systems showed varying degrees of usability challenges.
- PhaSeal[®] and OnGuard[™] showed comparable effectiveness, however PhaSeal[®] generally scored lower on user preference and user comments about ease of training.
- ChemoCLAVE[™] required the least amount of time to complete the tasks, however it appeared to be the least effective.

Conclusions (Cont'd)

- Each system will require proper staff training
- Specific usability challenges have been identified and must be addressed during training and implementation.
- User intuitiveness can not be relied on for appropriate use.
- These systems do not replace the use of protective equipment, protective clothing and best practice safety measures while handling hazardous drugs.

