



L'importanza dei Pack Procedurali per l'inserzione e la gestione degli accessi venosi

Riccardo Carlino

Role of Human Factors Engineering in Infection Prevention: Gaps and Opportunities

Priyadarshini R. Pennathur, PhD^{1,}
Loreen A. Herwaldt, MD²*

- Utilizzare la conoscenza dei ***fattori umani*** per identificare i ***comportamenti non desiderabili***, ed esaminare e ***sviluppare*** Materiali, Strategie e Strumenti per:
- Aumentare Aderenza ai Protocolli
- Ridurre le «Performance Breackdown».

INTERVENTI EDUCATIVI

BUNDLE

CHECK-LIST

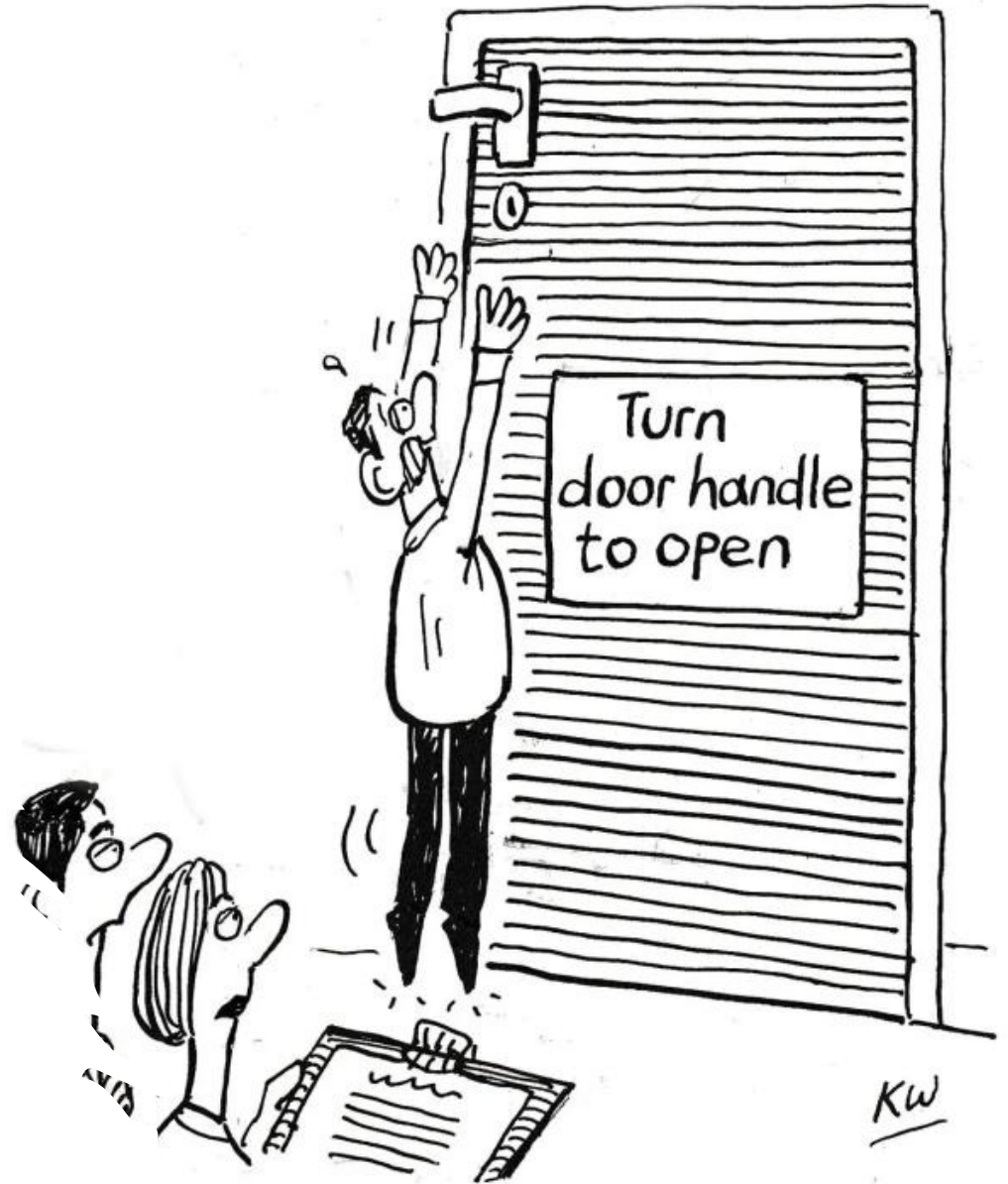
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- The diagram illustrates the interaction between three intervention types and a central set of barriers and context. Three boxes at the top—'INTERVENTI EDUCATIVI', 'BUNDLE', and 'CHECK-LIST'—have arrows pointing towards a large dark blue oval. Each box has a solid blue arrow pointing up and a dashed blue arrow pointing down into the oval. Inside the oval, a list of four items is presented: 'Barriere Culturali', 'Capacità/Limiti degli Operatori Sanitari', 'Condizioni Comportamentali/Ambientali', and 'Contesto Socio-Culturale'.
- **Barriere Culturali**
 - **Capacità/Limiti degli Operatori Sanitari**
 - **Condizioni Comportamentali/Ambientali**
 - **Contesto Socio-Culturale**

Migliore Performance Clinica

attraverso materiali
che implementano

HFE

(Human Factor Engineering)



Adherence Engineering: A New Approach to Increasing Adherence to Protocols

Semplificazione delle azioni che vogliamo siano perseguiti (aderenza al protocollo), riducendone il carico fisico-mentale al punto che non eseguirle in quel modo (NON aderenza al protocollo) sia più sconveniente con un carico fisico-mentale maggiore.

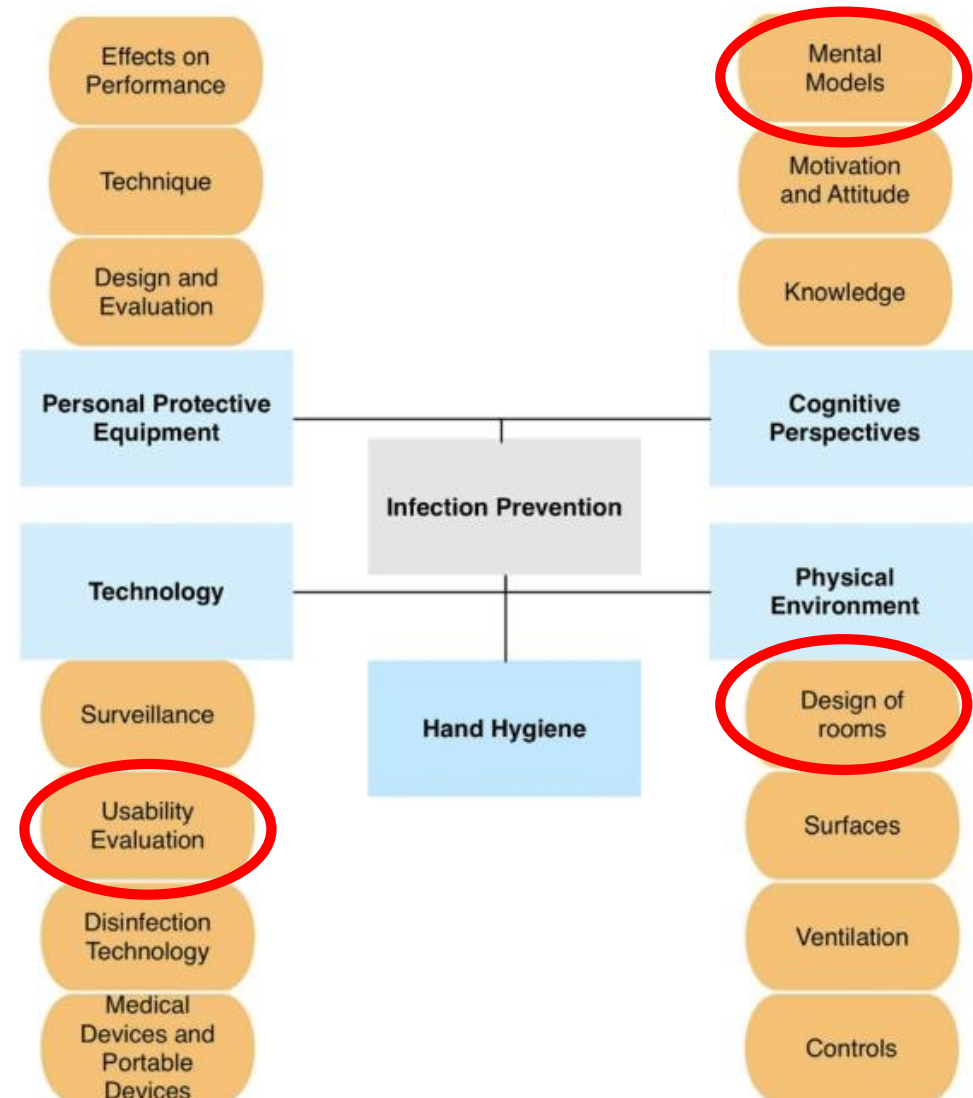
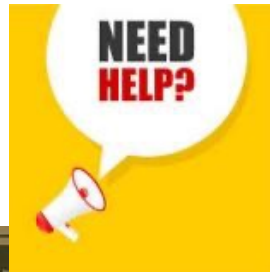


Fig. 2. Major themes in infection prevention and human factors engineering.

Human Factor Engineering Application

OBIETTIVO	ESEMPIO
Fornire una struttura della sequenza dei compiti	Ordine sequenziale degli oggetti nel pack
Sostenere l'aderenza suggerendo azioni auspicabili / escludendone altre	Posizionare il coprisonda sterile per incentivare Tip Location Ecografica Intraprocedurale
Aiutare a selezionare i materiali per lo svolgimento	Utilizzo di Membrane Trasparenti con MVTR, Misura e Design efficaci
Supportare l'esecuzione riducendo il carico cognitivo per eseguire l'attività	Icone ed etichette con sequenza strutturata delle azioni, Riduzione della pianificazione e omissione
Rendere conveniente l'aderenza	Non necessario camminare per prendere singolarmente gli oggetti





Quali Vantaggi ?

Quali Vantaggi ?

- Riducono l'incidenza di CABSI ?
- Migliorando la Performance ?
- Riducono i Tempi ?
- Sono Costo-Efficaci ?

Quali Vantaggi ?

- **Riducono l'incidenza di CABSI ?**
- Migliorando la Performance ?
- Riducono i Tempi ?
- Sono Costo-Efficaci ?

- Gestione -



Fig 2. Preparation phase contents of the central line maintenance kit.

- **STUDIO PRE – POST INTERVENTO**
- **Periodo di 18 mesi**
- 2,21 CLABSI x 1000 giorni/catetere (PRE)
- 0 CLABSI x 1000 giorni/catetere (POST)

Major Article

Improving central line maintenance to reduce central line-associated bloodstream infections

Frank A. Drews PhD ^{a,b,*}, Jonathan Z. Bakdash PhD ^a, Jeremy R. Gleed MS ^a

^a Salt Lake Informatics, Decision Enhancement, and Surveillance Center, VA Medical Center, Salt Lake City, UT

^b Department of Psychology, University of Utah, Salt Lake City, UT

- Impianto -

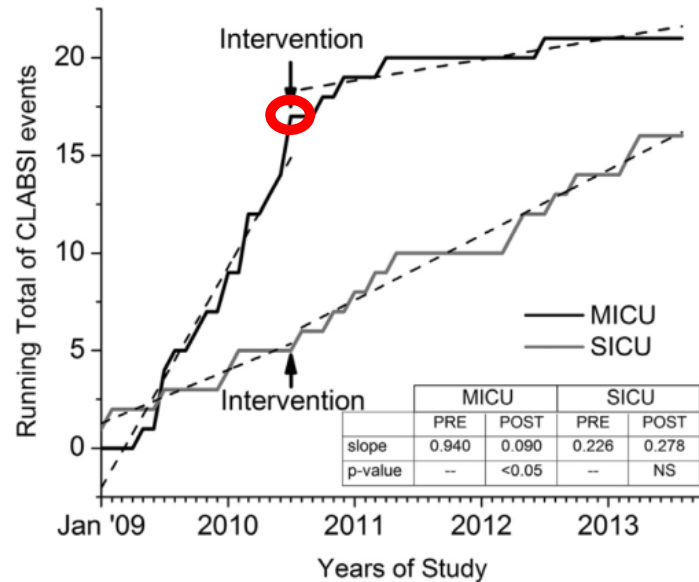


Fig 2. Cumulative running total of CLABSI events by month, over 56 months (19 months prior and 37 months following August 2010), in the MICU (thick black line) and the SICU (thick dark grey line), and linear fit slopes (dashed lines) to the portions of each curve up to and following July 2010. Arrows mark the time of the intervention on July 2010. The inset table shows that the slope of the curve changed significantly after the intervention ($P < .05$) for the MICU but not for the SICU.

Medical Intensive Care Unit

- 2,72 CLABSI x 1000 giorni/catetere (PRE)
- 0,4 CLABSI x 1000 giorni/catetere (POST)

A multitiered strategy of simulation training, kit consolidation, and electronic documentation is associated with a reduction in central line-associated bloodstream infections



Gilman B. Allen MD^{a,b,c,e}, Vincent Miller MD^{b,d}, Cate Nicholas MS, PA, EdD^{c,e}, Sally Hess CIC, MPH^f, Mari K. Cordes RN, VA-BC^g, John B. Fortune MD^{b,h}, Joan Blondin RRT, MBA^f, Takamaru Ashikaga PhDⁱ, Michael Ricci MD^{b,c,h,j}

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Quali Vantaggi ?

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- **Migliorando la Performance ?**

- Riducono i Tempi ?

- Sono Costo-Efficaci ?

- Gestione -

Table 4
Pre- and postintervention procedure step completion

Procedure step	Preintervention (completed/total observed = %)	Postintervention (completed/total observed = %)
Gathered equipment	80/86 = 93.02%	22/23 = 95.65%
→ Hands sanitized	66/128 = 51.56%	78/90 = 86.67%
Clinician masked/gloved	127/128 = 99.21%	86/86 = 100%
Patient masked	37/126 = 29.37%	62/86 = 72.09%
Catheters stabilized with tape	19/126 = 15.08%	45/86 = 52.33%
Old dressing/StatLock (Bard Medical, Covington, GA)* removed with alcohol	27/126 = 21.43%	39/85 = 45.88%
Clinician donned sterile gloves	121/126 = 96.03%	83/85 = 97.65%
Chlorhexidine scrub done	102/126 = 80.95%	80/85 = 94.12%
→ Skin prep for new StatLock†	35/83 = 42.17%	49/68 = 72.06%
Alcohol or chlorhexidine used to remove StatLock†	24/83 = 28.92%	43/70 = 61.43%
Antimicrobial dressing	114/126 = 90.48%	79/85 = 92.94%
Catheter clamped	69/124 = 55.65%	65/84 = 77.38%
Catheter hub kept sterile (no contact with nonsterile surface[s])	124/124 = 100%	79/84 = 94.05%
→ Disinfect catheter hub	26/124 = 20.97%	52/84 = 61.90%
→ Injection sites flushed	66/124 = 53.23%	63/84 = 75%
Injection sites kept sterile (no contact with nonsterile surface[s])	100/124 = 80.66%	66/84 = 78.57%
Transparent dressing dated	109/125 = 87.2%	78/83 = 93.98%
→ Antimicrobial caps	54/124 = 43.55%	63/82 = 76.83%

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- Items Omessi ridotti dal 41,4 % al 23.1 %
- Rapporto del tasso di completamente 1.32 (p<0.0001)

The use of procedural kits may reduce unscheduled central line dressing changes: A matched pre-post intervention study

Amit Bahl¹ , Nicholas Mielke² , Steven Matthew Gibson¹ and Julie George¹

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2024, Vol. 25(3): 73–81
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DOI: 10.1177/17571774241232063
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	N	Total number of unscheduled changes		Total number of eligible days	Rate of unscheduled changes (unadjusted)	Average number of days to unscheduled dressing change	Unscheduled rate ratio		p-Value
							Unadjusted	Adjusted	
Study cohort									
Pre-intervention (ref)	488	641		3059	0.21	4.7	1.00	1.00	<0.001
Post-intervention	488	379		3211	0.13	7.7	0.59	0.60	

- Riduzione del tasso di medicazioni NON-PROGRAMMATE

ANTT[®] standardisation facilitates new efficiencies with a novel partially-sterile Standard-ANTT PIVC Pack

Stephen Rowley and Simon Clare

- Impianto -

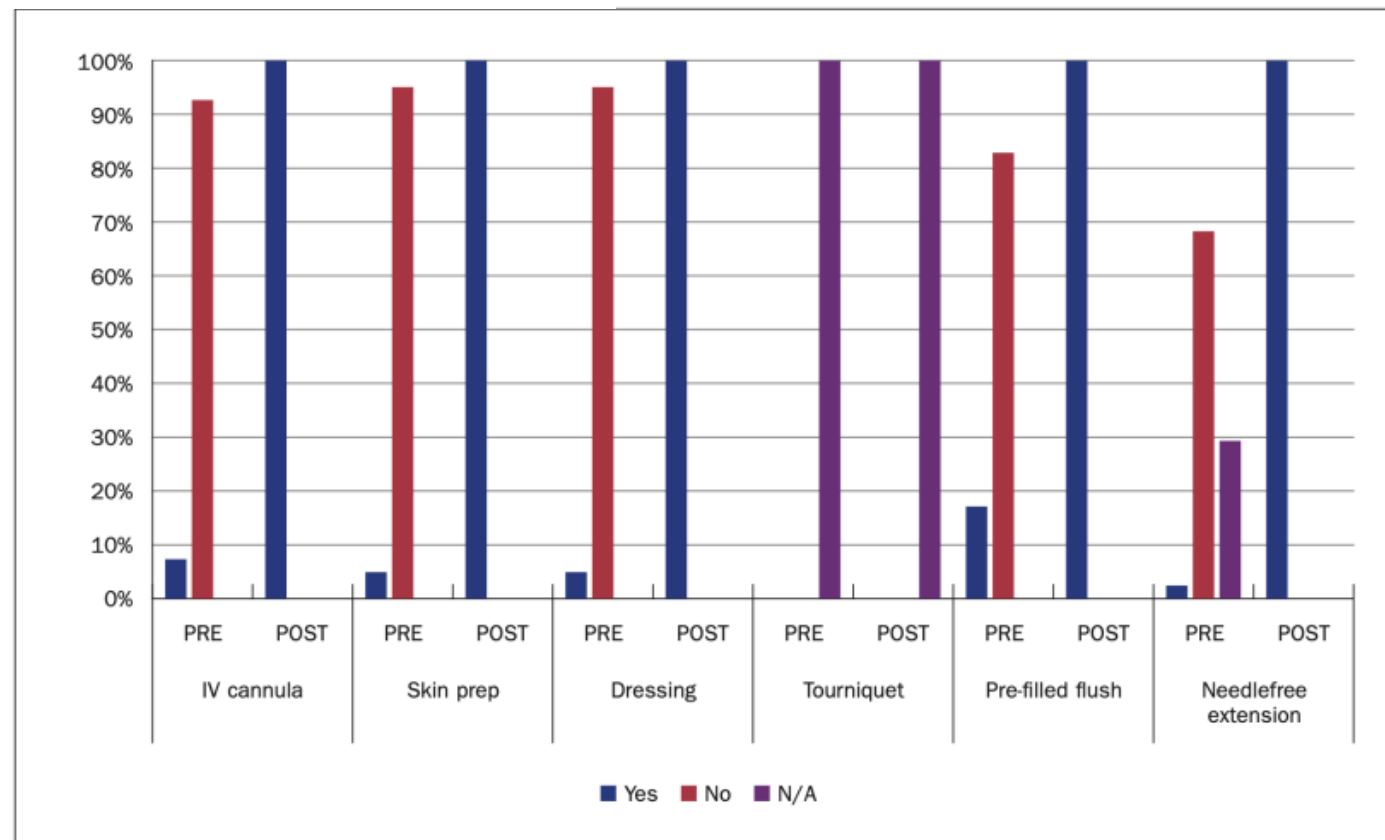
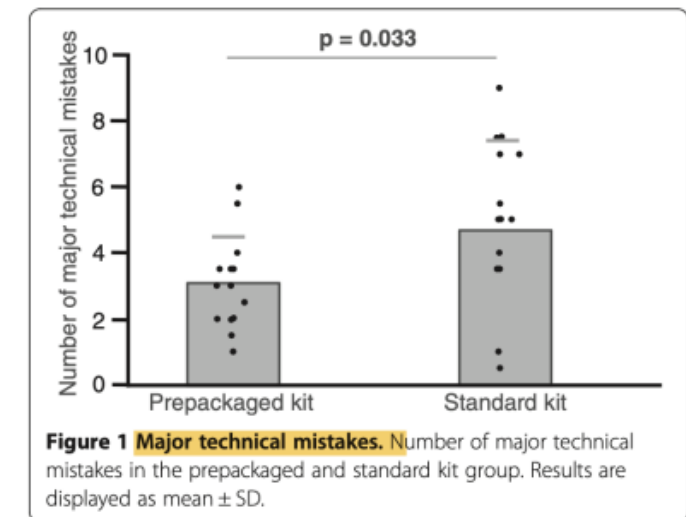
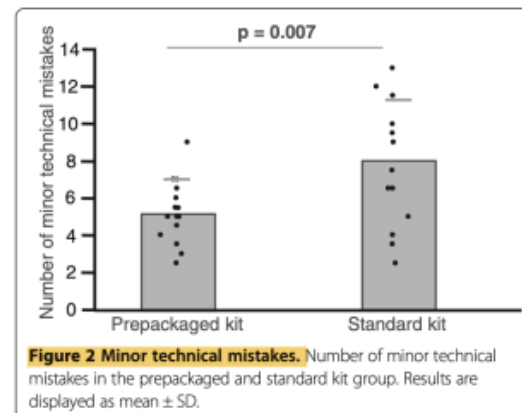
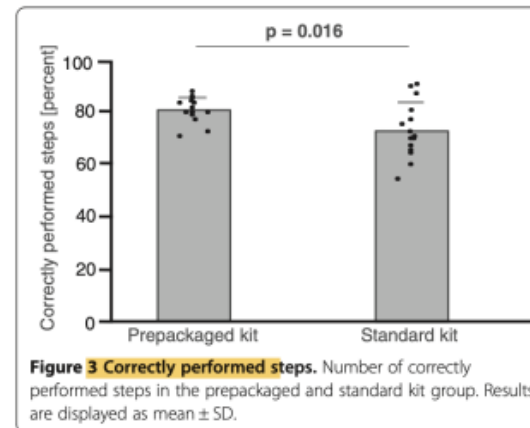


Figure 3. Equipment placed on General Aseptic Field individually protected with Micro Critical Aseptic Fields?

Prepackaged central line kits reduce procedural mistakes during central line insertion: a randomized controlled prospective trial

Yelena Fenik^{1†}, Nora Celebi^{2†}, Robert Wagner², Christoph Nikendei³, Frederike Lund³, Stephan Zipfel⁴, Reimer Riessen⁵ and Peter Weyrich²

- Personale Neoassunto e Inseperito



- Impianto -

Quali Vantaggi ?

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All-Inclusive Central Line Dressing Kits

A Lean Approach

Jason "Jake" Yaglowksi, BSN, RN

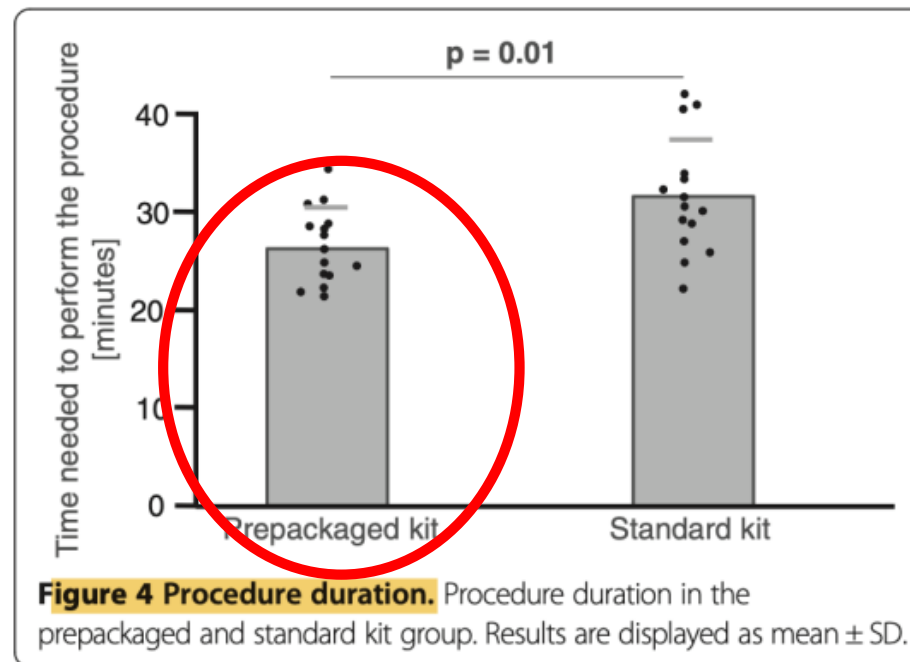
- **Gestione** -

	SINGOLI PRESIDI	PACK PROCEDURALE
Tempo Approvvisionamento	30s – 25min	1min
Tempo Medicazione	5min	4min

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- Impianto -



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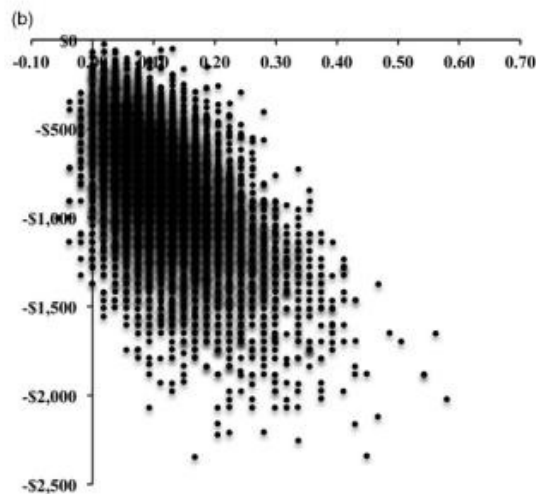
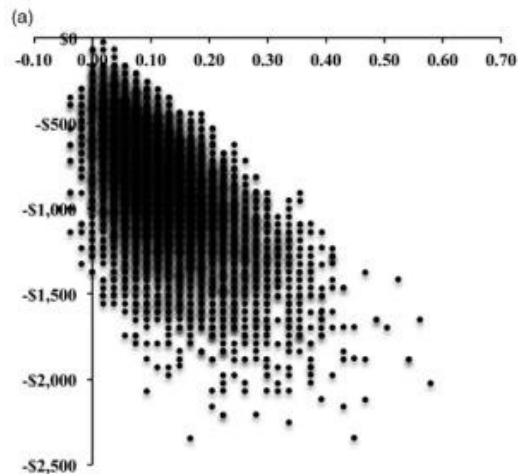


FIGURE 3. Scatterplots from probabilistic sensitivity analyses (10,000 2nd order Monte Carlo simulations) (a) Cost = calculated using total CLABSI cost Effectiveness-QALYs. (b) Cost = calculated using excess LOS Effectiveness = QALYs. Note: x-axis = difference in effectiveness between CLM kit and no CLM kit strategy; y-axis = difference in cost between CLM kit and no CLM kit strategy.

DATI DI PARTENZA :

- Costo Kit Procedurale 29.45 \$
- Costo Singoli Elementi 21,82 \$
- Costo CLABSI singolo evento 46.485 \$
- Allungamento degenza 6,9 giorni in ICU e 3,5 Degenza Ordinaria

• IPOTESI RIDUZIONE 50 % CLABSI con PACK Procedurale :

- 400 \$ meno costoso
- > 0.15 Life Years (LYs)
- > 0.13 Quality-adjusted life years (QALYs)

An Economic Analysis of Adherence Engineering to Improve Use of Best Practices During Central Line Maintenance Procedures

Richard E. Nelson, PhD;^{1,2} Aaron W. Angelovic, BSN, RN;¹ Scott D. Nelson, PharmD;^{1,3} Jeremy R. Gleed, BSN, RN;¹ Frank A. Drews, PhD⁴

A multitiered strategy of simulation training, kit consolidation, and electronic documentation is associated with a reduction in central line–associated bloodstream infections



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Risparmio di 1.669.000 \$
al netto delle spese per
formare 135 sanitari per 3
anni (39.000 \$)

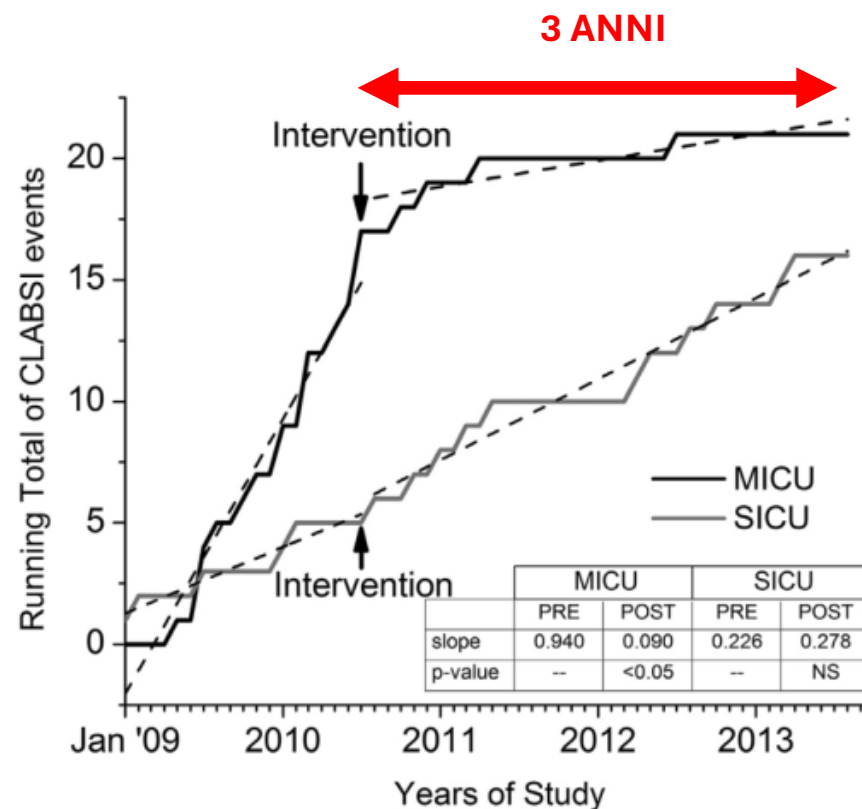


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**Come devono essere fatti
i PACK?**

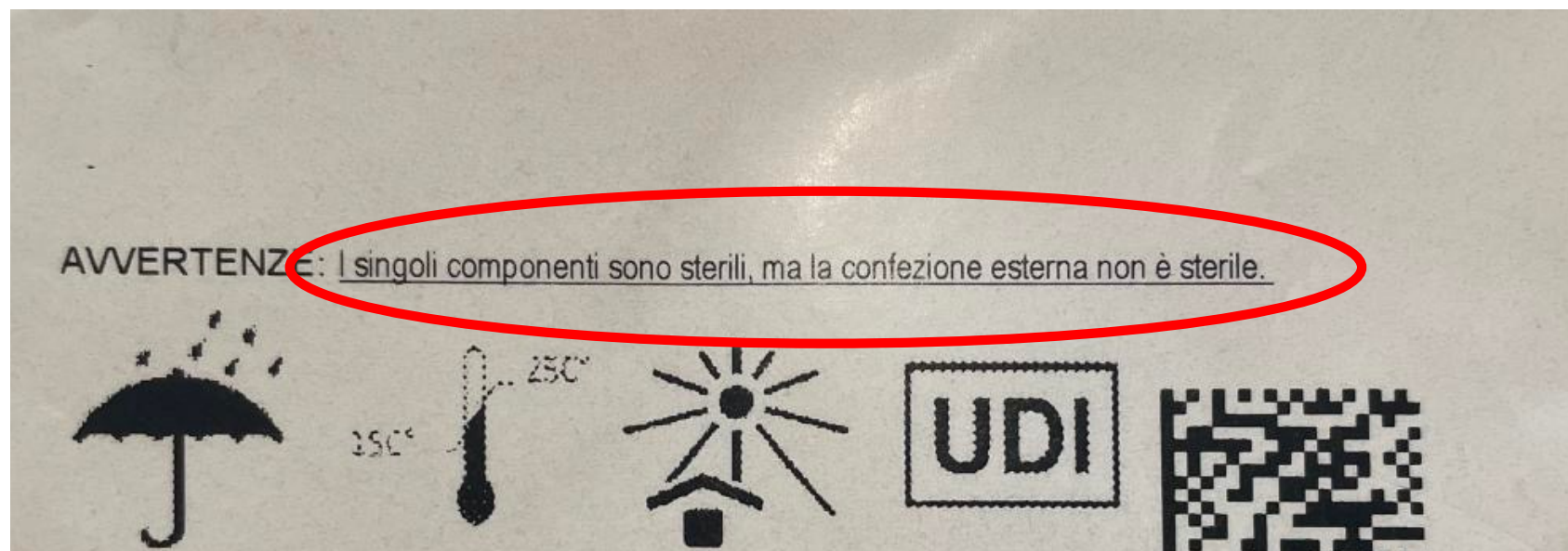
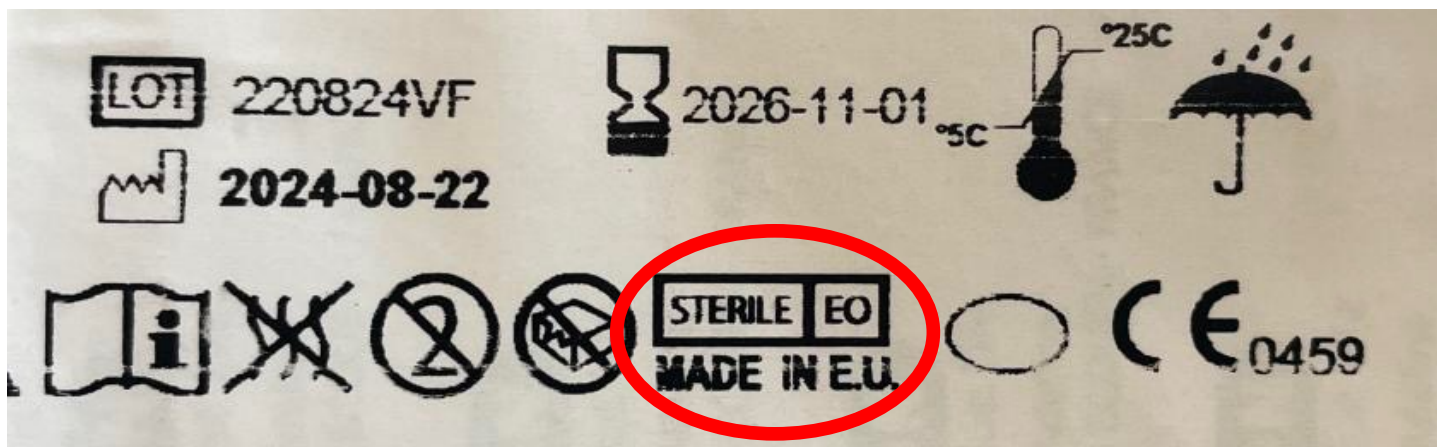


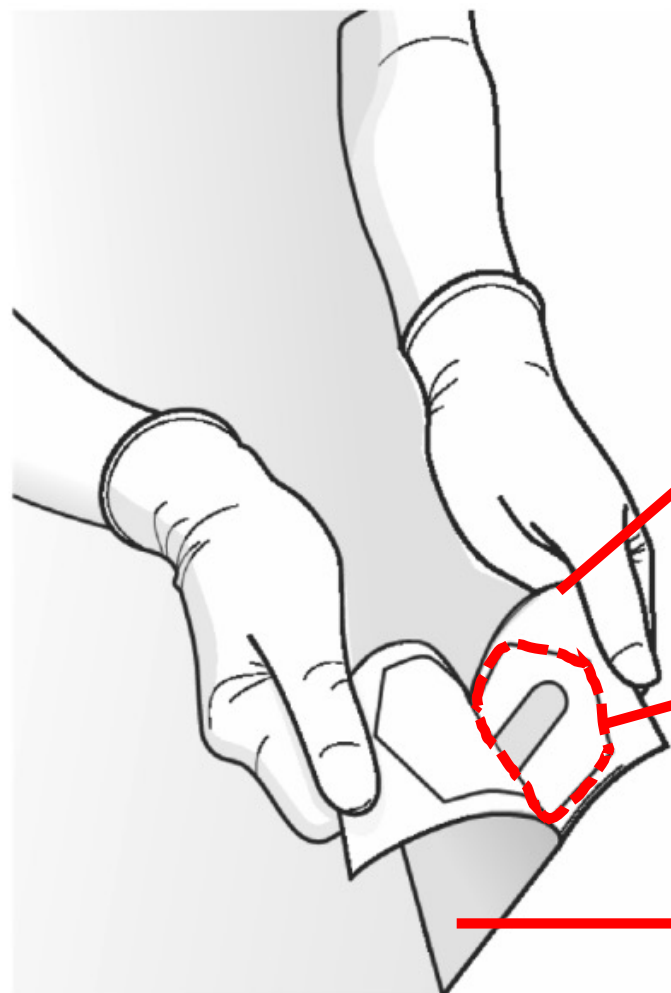
Regolamento UE 2017/745 Medical Device Regulation (26 Maggio 2021)

- ISO 11607-1 "Packaging for Terminally Sterilized Medical Device"

PARTE 1: "Requirements for materials, sterile barrier system and packaging system"

- a) "The ability to identify where to begin opening"
- b) "The ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents"
- c) "The ability to subsequently present the contents aseptically"





**Modalità di
Apertura**

**Dimensione del
Pack**

**Materiale di
Costruzione**

Come devono essere fatti i PACK ?

- Materiale di costruzione ?
- Modalità di Apertura ?
- Dimensione ?

Come devono essere fatti i PACK ?

- **Materiale di costruzione ?**

- Modalità di Apertura ?

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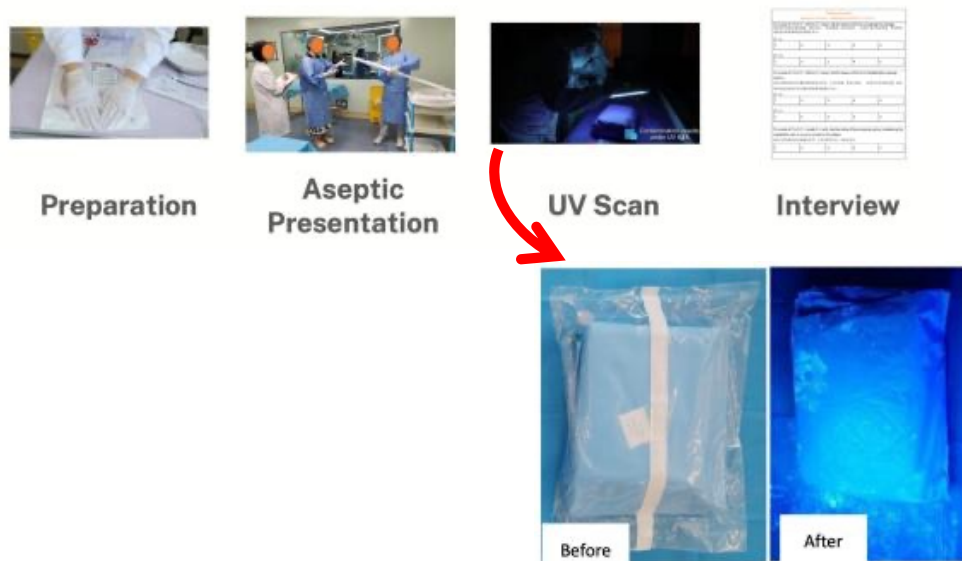
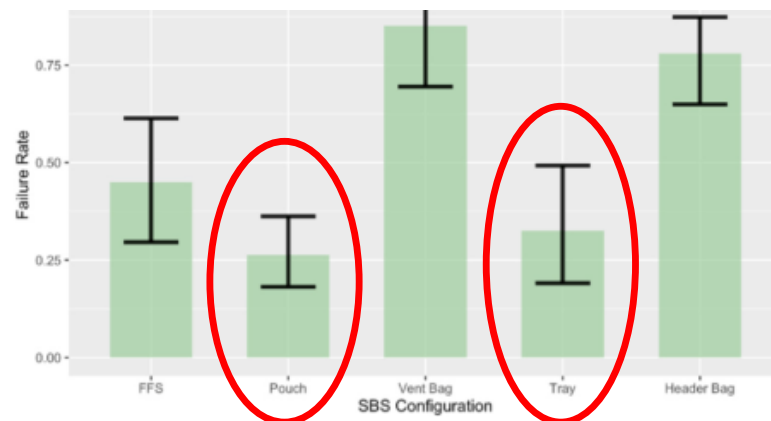


Figure 4. Failure rate for different sterile barrier system (SBS) configurations



Evaluating Aseptic Presentation of Different Medical Device Packaging Configurations

Selena Qin, Ran Li, Yong Yin, and Li Fang



Figure 2. Different medical device packaging configurations used in the study.

- a) Header Bag (1–3),
- b) Rigid Tray (4 e 5),**
- c) Vent Bag. (6 e 7),
- d) Pouch (8–12),**
- e) Form-fill Seal (13 e 14)

Come devono essere fatti i PACK ?

- Materiale di costruzione ?
- Modalità di Apertura ?
- Dimensione ?

Come devono essere fatti i PACK ?

- Materiale di costruzione ?

- **Modalità di Apertura ?**

- Dimensione ?

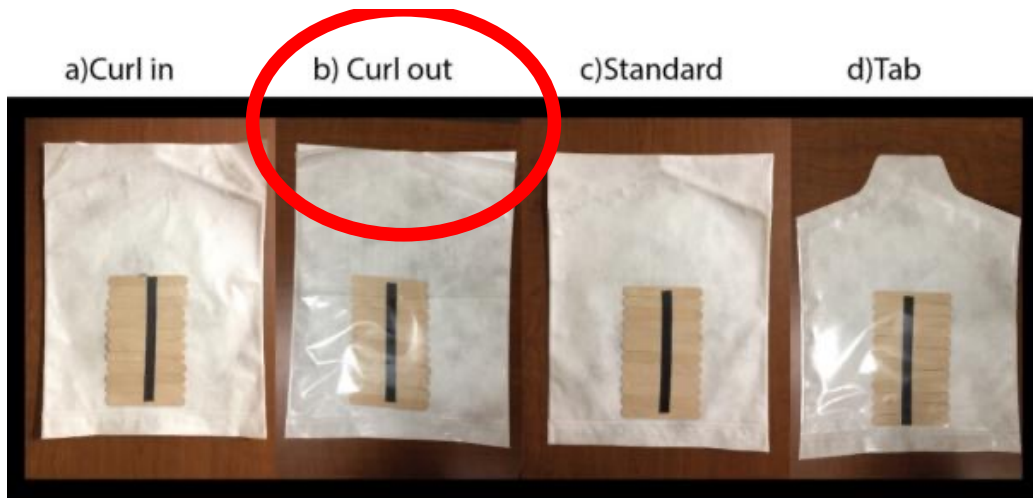
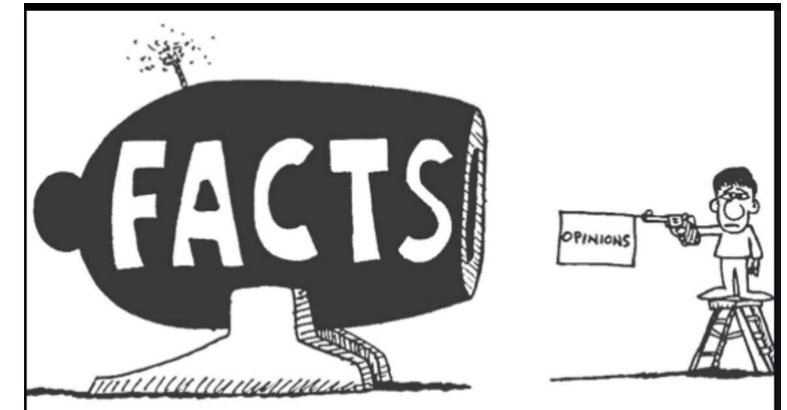


Fig 2. Pouch designs.

Reducing levels of medical device contamination through package redesign and opening technique

Paula Perez¹, Tamara Reid Bush², Hyokyoung G. Hong³, Wu Pan², Larissa Miller⁴, Laura Bix¹



$P < 0.001$

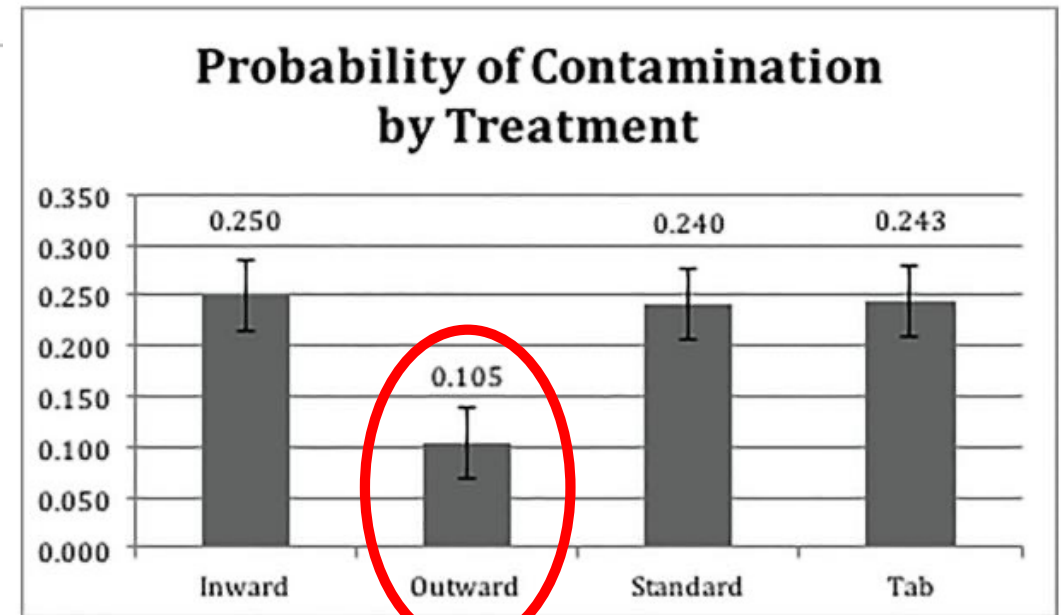


Fig 5. Probability of contamination by treatment.

Come devono essere fatti i PACK ?

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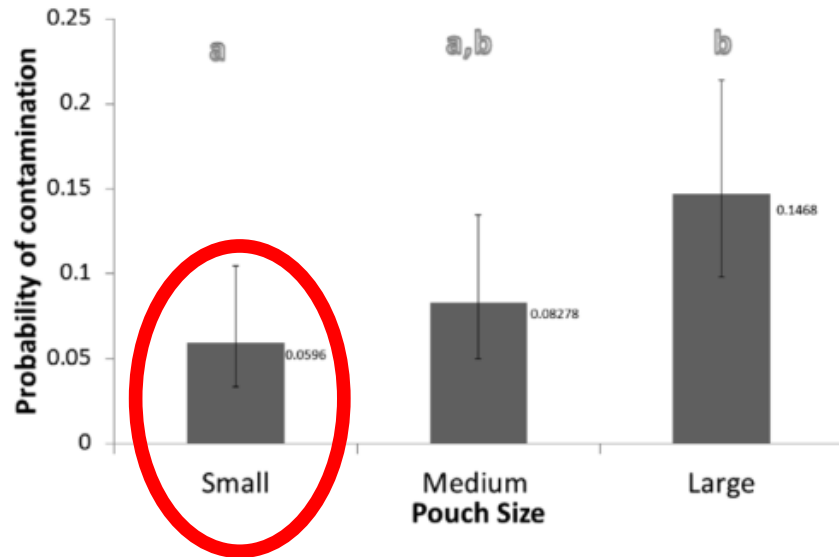


Figure 3. Estimated probability of contact of pouch contents presented to the simulated sterile field from small, medium and large pouches. Whiskers indicate 95% confidence intervals. (a,b) Letters indicate evidence for a significant difference between pouch sizes ($P < 0.05$) (e.g. the small significantly differs from the large but not the medium).

- Pack **più grandi** rispetto alle **dimensioni del contenuto** aumentano il **rischio di contaminazione** durante la presentazione

The Role of Packaging Size on Contamination Rates during Simulated Presentation to a Sterile Field

Tony Trier¹, Nora Bello², Tamara Reid Bush³, Laura Bix^{1*}

¹ School of Packaging, Michigan State University, East Lansing, Michigan, United States of America, ² Department of Statistics, Kansas State University, Manhattan, Kansas, United States of America, ³ Department of Mechanical Engineering, Michigan State University, East Lansing, Michigan, United States of America



Quindi per quale procedura
usiamo i PACK?

TUTTE!

PACK per :

- Impianto
- Medicazione
- Gestione della Linea Infusionale
- AUSPICABILE PER OGNI PROCEDURA!

La Nostra Realtà in TIN Gemelli

- **Pack Impianto : CVO/ECC & CICC/FICC**
- **Pack Medicazione : CICC/FICC & ECC**
- **Gestione Linea Infusionale : Tutti i VAD**

Fuori dal Pack : Anestetico Loc. / Clorexidina / SF / Catetere / SAS / Colla

- Impianto - CICC/FICC



- Impianto - CVO/ECC



- Medicazione -



Gestione - Linea Infusionale -



Le linee Guida

SHEA/IDSA/APIC Practice Recommendation

Strategies to prevent central line-associated bloodstream infections in acute-care hospitals: 2022 Update

Essential Practices

2. Perform hand hygiene prior to catheter insertion or manipulation (Quality of Evidence: MODERATE)^{1,3}
- ~~3. The subclavian site is preferred to reduce infectious complications when the cath~~
4. Use an all-inclusive catheter cart or kit (Quality of Evidence: MODERATE)^{1,3}
5. Use ultrasound guidance for catheter insertion (Quality of Evidence: HIGH)^{119,120}



39. VASCULAR ACCESS DEVICE POST-INSERTION CARE

- H. Use a dressing change kit to standardize the procedure and improve efficiency.^{1,18} (V)

32. VASCULAR ACCESS DEVICE INSERTION

2. Use a standardized supply cart or kit that contains all necessary components for the insertion of a CVAD.²⁶⁻²⁸ (IV)



I Protocolli Operativi

Table I. The seven steps of the SIECC protocol.

- | | |
|----|---|
| 1. | Pre-procedural evaluation of superficial veins (including the RaSuVA protocol) |
| 2. | Adoption of pre-assembled insertion kits |
| 3. | Appropriate aseptic technique (hand hygiene, maximal barrier precautions, skin antisepsis with 2% chlorhexidine in 70% isopropyl alcohol) |
| 4. | Intra-procedural assessment of tip navigation and tip location by ultrasound (adopting the Neo-ECHOTIP protocol) |
| 5. | Securement of the catheter and protection of the exit site |
| 6. | Post-procedural serial assessments of tip location by ultrasound |
| 7. | Removal of the device within 2 weeks |

Table I. The eight steps of the SIUVeC protocol.

- | |
|---|
| Pre-procedural evaluation (including US evaluation). |
| Adoption of pre-assembled insertion kits. |
| Appropriate aseptic technique (hand hygiene, maximal barrier precautions, skin antisepsis with 2% chlorhexidine in 70% isopropyl alcohol). |
| Vein cannulation using the smallest catheter that may meet the infusion requirements and choosing wisely between single versus double lumen UVC. |
| Real-time tip navigation and tip location by US (according to the NeoECHOTIP protocol). |
| Securement of the catheter and protection of the exit site (combining sutureless devices, cyanoacrylate glue, semipermeable transparent membranes). |
| Post-procedural serial assessment of tip location by US. |
| Early removal of the device (within 4–5 days). |

TAKE HOME MESSAGES

- PACK sono uno strumento per seguire **BUNDLE**
- Riducono la “**Performance Breackdown**”
- Aumentano **Compliance** alle Procedure
- Aiuta il personale **non-esperto / neo-assunto**
- Da affiancare sempre ad un **Training Adeguato**

