



Secure My Intravenous Line Effectively – (The SMILE Trial).

Innovative Peripheral Intravenous (PIV)
Dressing Techniques to Reduce PIV Failure

### **INSERT SESSION NAME HERE**

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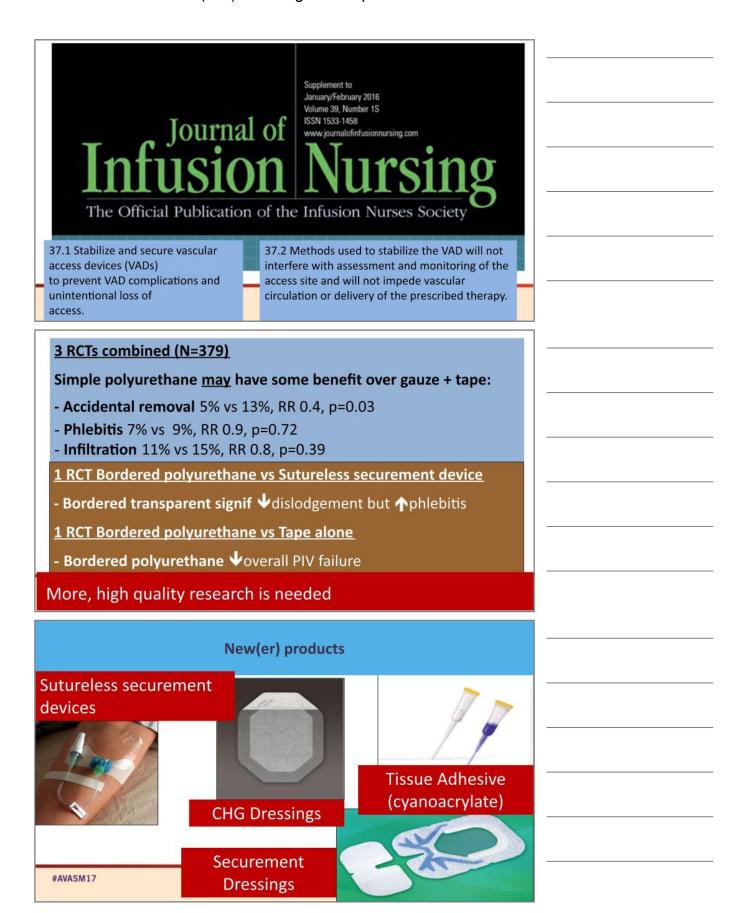
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### **Objective**

- · Test the feasibility of an randomized trial
- Identify clinical and cost-effective methods to prevent failure
- To compare usual care dressings with novel methods
- Evaluate the acceptability of these devices to patients and health professionals
- · Study adverse effect profiles

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### **Adults - PIVs**



Standard Care

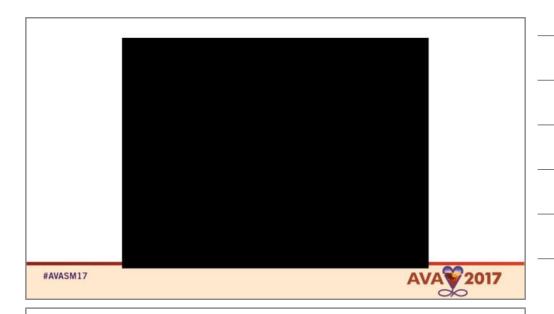


**Integrated Securement Dressing** 



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### **Inclusion Criteria**

- >/16 yrs
- PVC expected >24 hours
- Will remain in hospital for at least 24 hours
- Written informed consent

### **Exclusion Criteria**

- Known, current bloodstream infection (within 48 hours)
- Non English speaking with no interpreter
- PIV inserted through burned or scarred skin
- Current skin tear/high risk of skin tears
- Previous allergy to study products
- Previous enrolment in the study

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### Sample size

- As a Pilot RCT sample size of 150 per group was chosen to primarily test feasibility
- Not designed to prove statistical differences

### Sample recruitment

- Research Nurses visited medical/surgical wards
- · Explanation of study and request for consent



### **Data collection**

### At time of PVC insertion

Patient & PVC information

### Daily PVC check

- Protocol adherence
- Dressing appearance
- Infusates
- Pain and tenderness (0=no pain; 10= worst possible)
- Redness and swelling (in cms from insertion site)
- Palpable cord (in cms from insertion site)
- Number of dressings used
- Leakage (yes/no)

### **PVC** removal

- Time insitu
- Inspect for phlebitis/skin complications
- · Document reason for removal
- Patient satisfaction (0=completely dissatisfied; 10 = completely satisfied)

### •48 hours post removal

- •\_Infection endpoints (BSI or positive tip/swab)
- Serious adverse event (including

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mortality)



### **Patient factors**



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Characteristics	Control N (%)	Integrated dressing N (%)
Average age (mean)	60 years	62 years
Males	88 (59)	98 (65)
Surgical patients	108 (72)	107 (72)
Co-morbidities ≥2	106 (71)	124 (82)
Obese (BMI>30)	69 (46)	71 (49)
Poor skin integrity	14 (9)	13 (9)
Infection at baseline	37 (25)	43 (29)
Wound at baseline	72 (48)	80 (53)

### **PIV factors**

PIV Characteristics	Control N (%)	Intervention N (%)
Device Size 20 g	86 (57)	80 (53)
Placement in forearm	95 (76)	106 (71)
Multiple insertion attempts	19 (13)	25 (17)
Difficult insertion	56 (37)	56 (37)
Site clipped	82 (55)	79 (53)
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### **Dressing factors**

Control N (%)	Integrated dressing N (%)
156	152
99 (66)	124 (83)
26 (17)	27 (18)
11 (7)	15 (10)
	N (%) 156 99 (66) 26 (17)

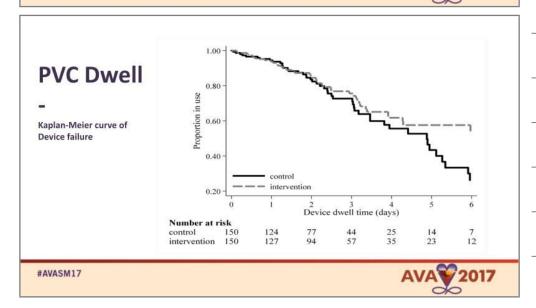
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### **Results**



	Control N	Integrated dressing N
Device failure	46 (31%)	44 (29%)
Dwell time in hours	57.9	68.8

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	Comp	lications	at removal
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Complication	Control	Integrated dressing
	N (%)	N (%)
Occlusion	7 (5)	3 (2)
Infiltration/extravasation	17 (11)	17 (12)
To painful to tolerate	8 (5)	7 (5)
Leaking	9 (6)	12 (8)
Phlebitis (clinical definition)	3 (2)	1 (1)
Partial/complete dislodgement	8 (5)	7 (5)
Unknown	5 (3%)	6 (4%)

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### Cox regression: risk factors for failure

- Significant predictors (<0.05) in bivariate model
  - Fair/poor skin quality
  - 22/24g device
  - Accessory cephalic/medial antebrachial vein
  - Lack of elasticised bandage
- · Significant predictors in final multivariate model
  - 22/24g device
  - lack of elasticised bandage
- Integrated dressing adjusted hazard ratio 0.77 (95% CI 0.51-1.17)

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### Skin reactions

There were 12 skin reactions to study products observed in this study (4%)

	Control	Integrated dressing
Mild itching	3	4
Severe itching	2	0
Rash	1	0
Blister	0	1
Skin tear	0	1



### **Feasibility outcomes**

- 91% of screened patients were eligible for participation
- 5 (1.5%) patients refused participation
- · 2 protocol violations
- · 0 withdrew from study
- 0 missing primary outcome

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### **Adults – Arterial Catheters**





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### The Princess Alexandra Hospital

Standard Care



Integrated securement device



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### The Prince Charles Hospital

Standard Care



Integrated securement device



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# PIVC in Pediatrics



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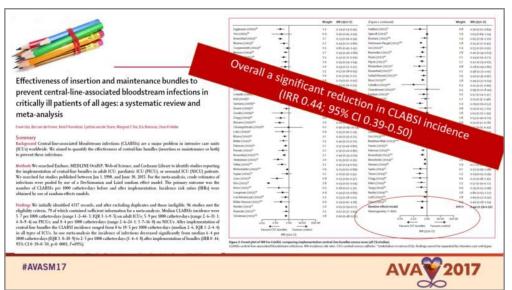
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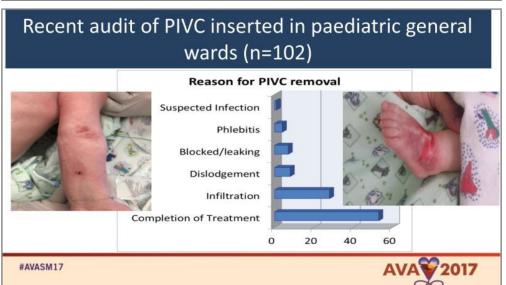
# Pressure Area Phlebitis Extravasation #AVASM17

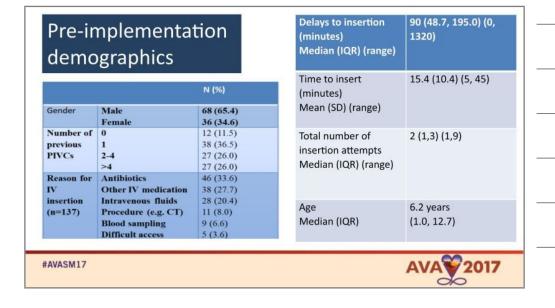




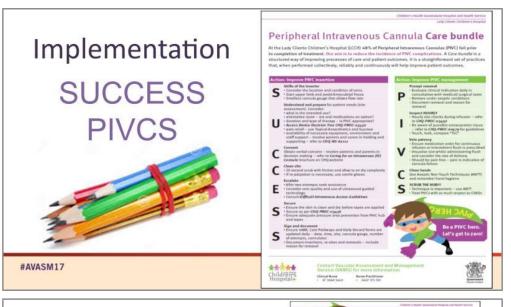


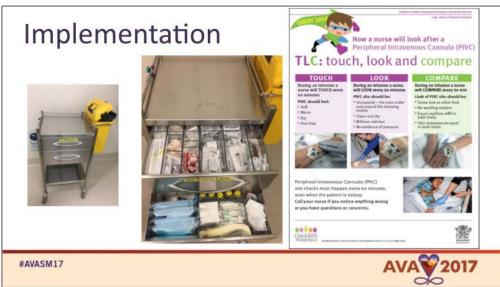


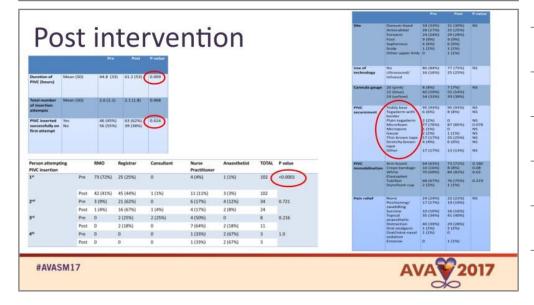


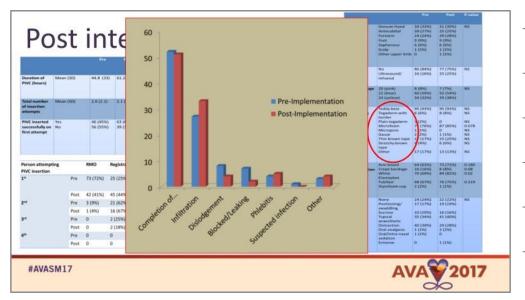












### SMILE – Pediatrics





- · Feasibility study
- · Randomised controlled trial
- Lady Cilento Children's Hospital
   Large tertiary pediatric hospital
- · 330 patients
  - 100 patients to 3 trial arms
  - 10% attrition
- Medical and surgical inpatient wards

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### **SMILE**





Standard Care



Integrated Securement Dressing



Tissue Adhesive

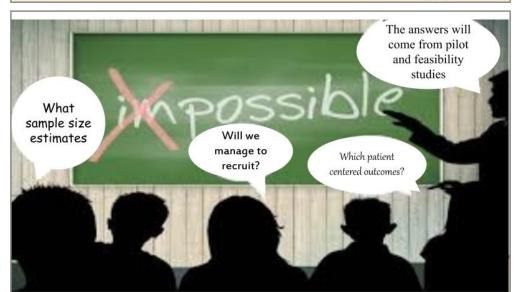
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Inclusion Criteria	Exclusion Criteria
0-18 years	Previous participation on current study
PIVC expected dwell >24 hours	Non-English speakers without an interpreter
Inpatient > 24 hours	Known/current bloodstream infection (previous 48 hours)
Written informed consent	Other types of vascular access devices insitu
	Previous allergy to any study product
	Current skin tears/ burnt/scarred skin

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<u>Patient</u>	Characteristics	Standard Care	Integrated Dressing
factors	Age (average)	N (%) 4.8 (4.3)	N (%) 5.8 (4.3)
	Age (average)	4.0 (4.3)	3.6 (4.3)
	Female	17 (49)	16 (44)
	Medical	18 (51)	15 (42)
	Poor skin integrity	1 (3)	0 (0)
AD .	Co-morbidities >2	8 (23)	4 (11)
	Infection at baseline	17 (49)	16 (44)
66	Wound at baseline	14 (40)	13 (36)
	Wt. appearance (Excessive)	23 (66)	21 (58)

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Tissue

**Adhesive** 

N (%)

5.6 (4.5)

22 (58)

17 (45)

3 (8)

7 (18)

20 (53)

15 (39)

15 (39)

PIVC factors				
PIVC Characteristics	Standard Care	Integrated Securement	Tissue Adhesive	
	N (%)	Dressing N (%)	N (%)	
Difficult insertion	14 (41)	15 (43)	22 (58)	
Multiple insertion attempts	13 (38)	15 (43)	18 (47)	
Size/ 22 gauge	28 (85)	28 (80)	25 (66)	
Placement in forearm	21 (60)	24 (63)	27 (71)	
Placement by VA team	20 (61)	26 (74)	75 (71)	
Continuous IV infusion	47%	35%	38%	
No obvious use	4 (15%)	8 (29%)	4 (13%)	
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<b>Dressing</b>	factors

Dressing Characteristics	Control N (%)	Integrated securement dressing N (%)	Tissue Adhesive N (%)
Number of dressings used	36 (1.09)	37 (1.06)	40 (1.05)
Life of first dressing (hours)	49.0 (25.2-97.5)	47.7 (26.5-71.1)	66.5 (34.8-95.9)
Reason for dressing change:			
- dressing lifting	3	1	1
- sweating	1	0	0
- other	1	1	1
Protocol deviations	0 (0%)	1 (4%)	3 (10%)
			1.75.1

## **Dressing factors**

Dressing Characteristics	Control N (%)	Integrated securement dressing N (%)	Tissue Adhesive N (%)
Additional tubular elasticised bandage or bandage	53%	55%	61%
Armboard	19%	16%	10%

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### **Dressing factors**

Additional dressing devices:	Standard Care	Integrated Securement Dressing	TA + IV Tegaderm
- none	65%	89%	84%
- sterile tape at hub	0%	1%	0%
- microfoam	13%	0%	4%
- non-sterile tape	24%	6%	5%
- Hyperfix	2%	3%	1%

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### **Results**



	Standard Care N=	Integrated Securement Dressing N=	Tissue Adhesive N=
Device failure	19 (54%)	10 (28%)	13 (34%)
Dwell time (hours)	74.0 (53.7)	55.3 (37.8)	78.1 (48.8)

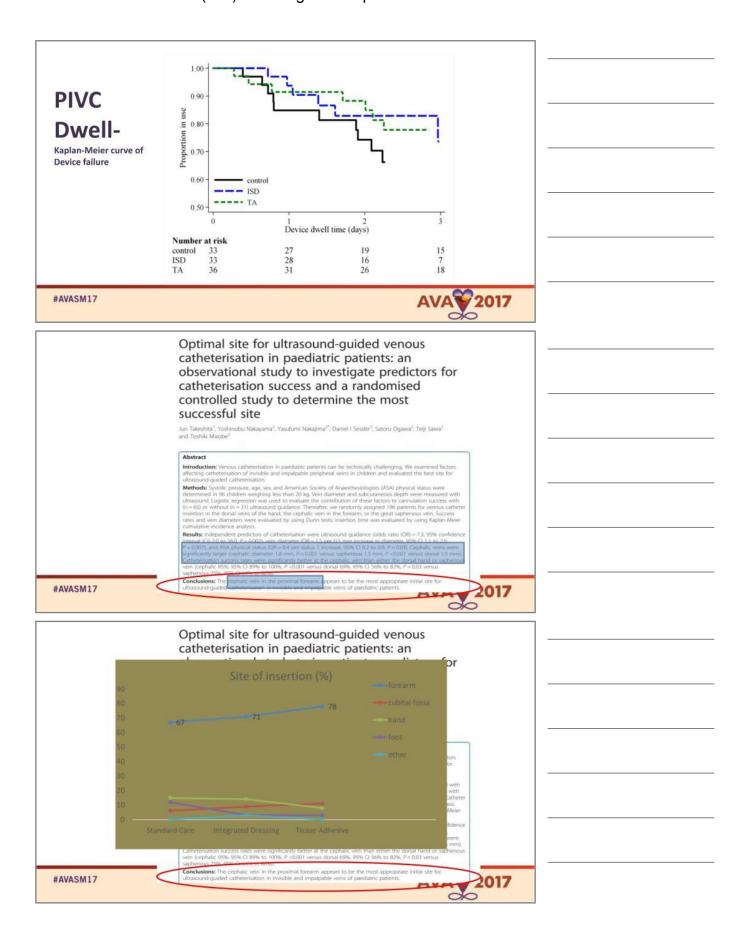
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## **Complications at removal**

Complication at	Standard Care	Integrated securement	Tissue Adhesive
removal	N (%)	dressing N (%)	N (%)
occlusion	9 (26)	3 (8)	7 (18)
infiltration or extravasation	5 (14)	6 (17)	4 (11)
too painful to tolerate	3 (9)	1 (3)	3 (8)
device leaking	4 (11)	2 (6)	1 (3)
phlebitis (clinical definition)	1 (3)	1 (3)	2 (5)
accidental removal	3 (9)	0 (0)	1 (3)





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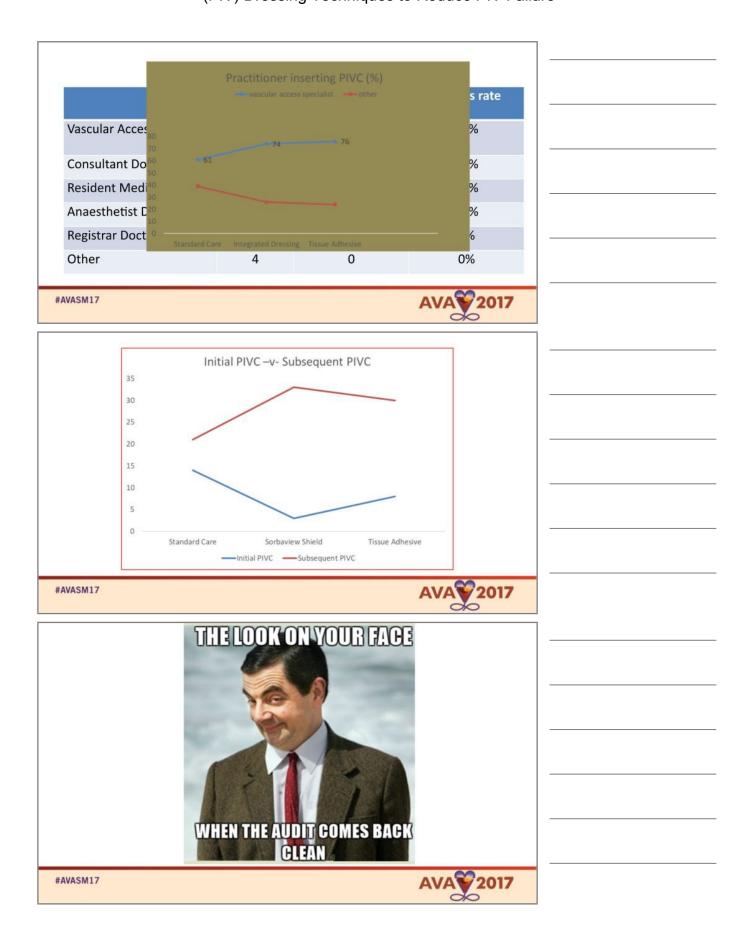
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# Ultrasound guidance allows faster peripheral IV cannulation in children under 3 years of age with difficult ven Mehdi Muriel (00) 1 Opport 2 Depart 80 79 14 Lore of 0 1-1 Lore of 0 1-1

	Number of attempts	Number of successes	Success rate
Vascular Access Specialist	80	75	94%
Consultant Doctor	6	2	33%
Resident Medical Officer	91	15	16%
Anaesthetist Doctor	36	5	14%
Registrar Doctor	98	9	9%
Other	4	0	0%





	will require that the neral IV catheter as an rable tool be discarded."  (Helm RE et al. Accepted but unacceptable: peripheral IV catheter failure. Journal of Infusion Nursing. 2015;38(3):189-203	
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