Anti-microbial or hydrophobic materials vs conventional peripherally inserted central catheters (PICNIC):

A multicentre, randomised controlled trial

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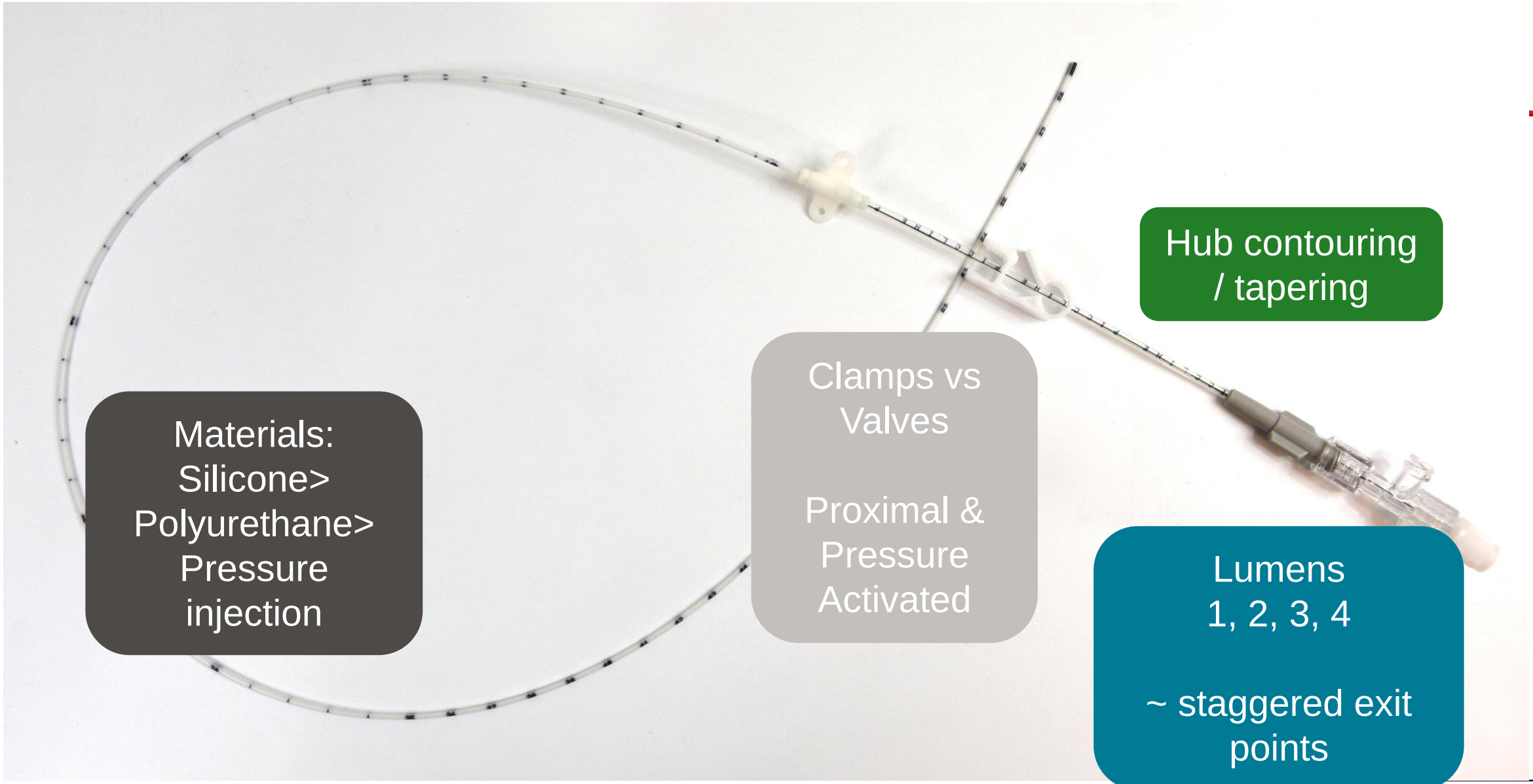
This study was funded by the Australian Government (the National Health and Medical Research Council APP1157178).

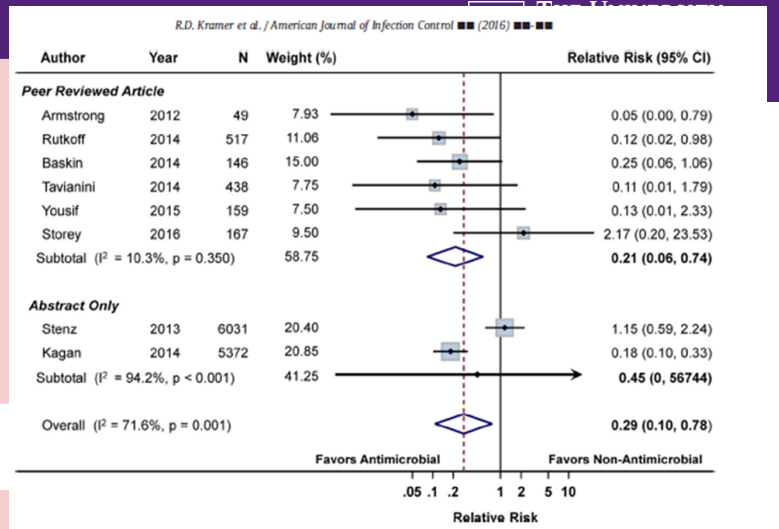
No commercial entity had any role in the conception, design or funding of this study, or is the preparation of this manuscript.

AJUs former and current employers have received unrestricted research and educational grants to support her research (unrelated from the current project) from 3M, Becton Dickinson, Medline and Biolife. DAs former and current employer has received consultancy payments for educational lectures based on her research and clinical expertise from 3M and Navi Medical Technologies. TKs former and current employer has received unrestricted research and educational grants from 3M, Becton Dickinson, and Medical Specialties Australasia. RMWs employer has received unrestricted research and educational grants to support her research (unrelated to current project) from Becton Dickinson. NMs former employer has received unrestricted research and educational grants to support her research (unrelated from the current project) from 3M, Becton Dickinson, Biolife and Cardinal Health. Griffith University (ACBs employer) has received educational and research grants from Angiodynamics, ICUMedical and 3M on behalf of the AVATAR group, in addition to consultancy payments from Becton Dickinson and investigator initiated research grant funding from B.Braun (unrelated to the current project). Griffith University (JB's employer) has received unrestricted research and educational grants to support her research (unrelated to current project) from Becton Dickinson, and Navi Technologies. PM is a member of Myeloma Advisory Boards for Celgene, Janssen, Amgen, Takeda, and Amyloidosis Advisory Boards for Pfizer and Caelum. No personal fees have been received for these services. PM's has received a research grant from Janssen for a clinical trial. PM has accommodation and registration provided by Amgen for attendance at the International Myeloma Workshop in 2019. CMRs current and prior employers have received unrestricted research and educational grants to support her research (unrelated to the current project) from 3M, Becton Dickinson and Cardinal Health.


CLABSI
Occlusion
Thrombosis


Materials:
Silicone>
Polyurethane>
Pressure
injection
Clamps vs
Valves
Proximal &
Pressure
Activated
Hub contouring
/ tapering
Lumens
1, 2, 3, 4
~ staggered exit
points

Observational study metanalysis

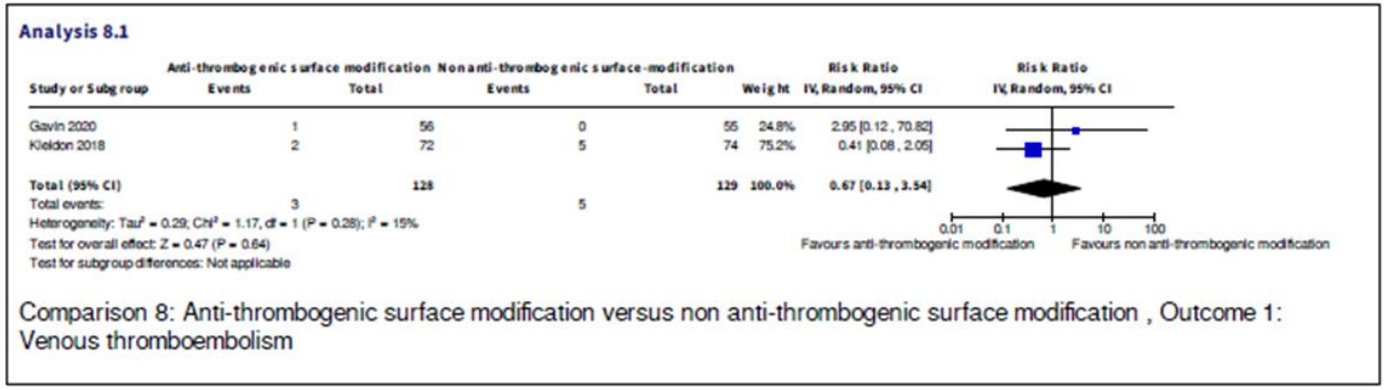


Observational study

Table 2. Multivariate Cox Model for CLABSI

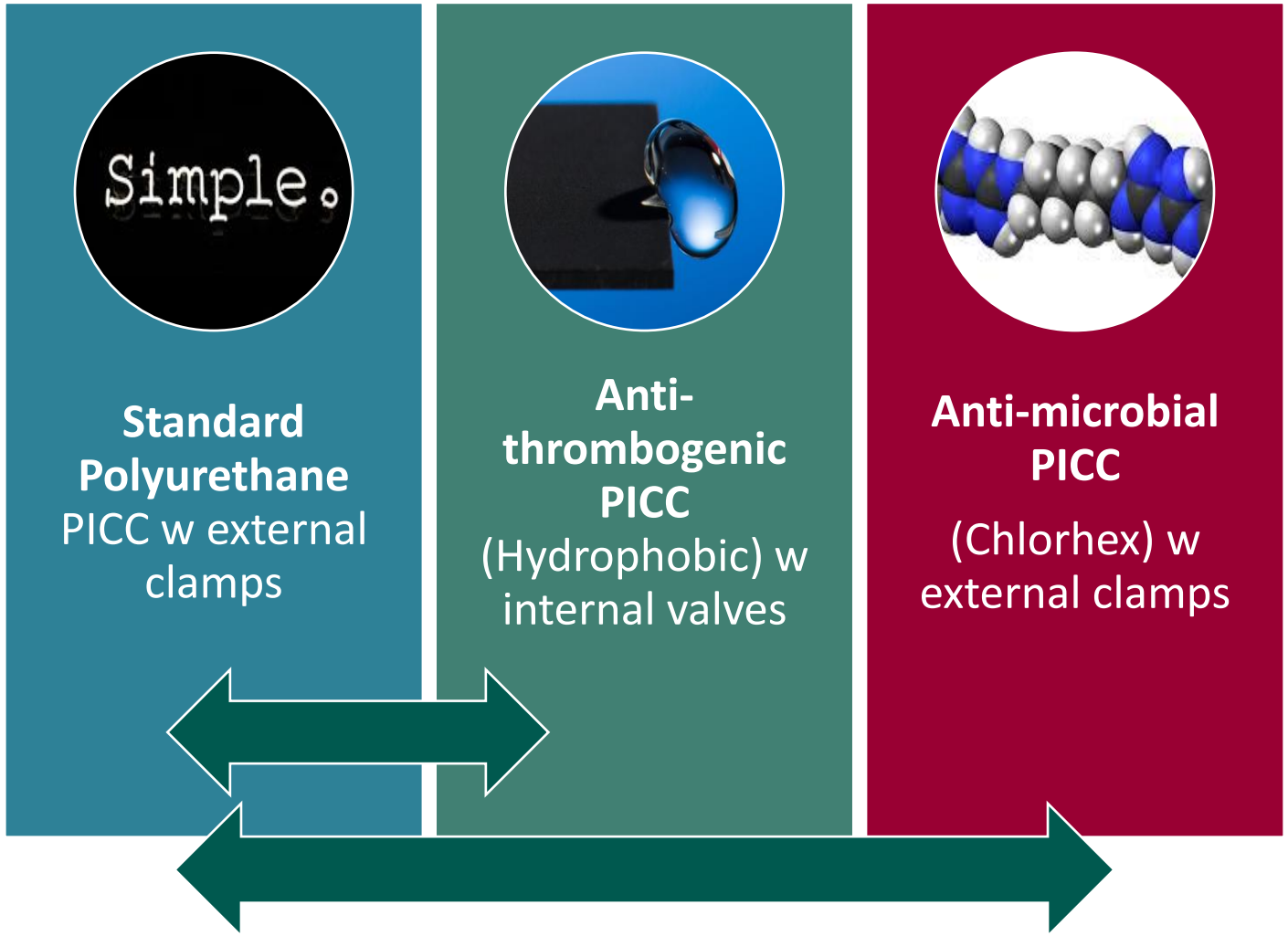
Variable	All PICCs (n=42,562) HR (95% CI)	*P* Value	Non-ICU/Nononcology (n=28,111) HR (95% CI)	*P* Value	ICU (n=12,078) HR (95% CI)	*P* Value	Oncology (n=1,407) HR (95% CI)	*P* Value
Antimicrobial coating[a]	1.16 (0.82–1.64)	.3997	1.22 (0.75–1.98)	.4254	1.10 (0.60–1.99)	.7655	2.14 (0.61–7.53)	.234

Cochrane review



Comparison 8: Anti-thrombogenic surface modification versus non anti-thrombogenic surface modification , Outcome 1: Venous thromboembolism

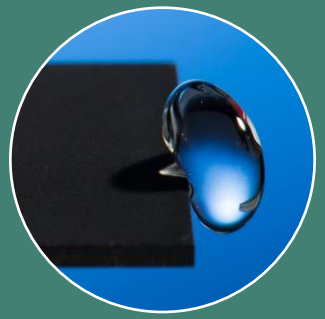
PICNIC: Multi-centre, investigator-initiated, parallel group, open-label, **superiority**, randomized controlled trial (RCT)



BMJ Open

PICNIC: Multi-centre, investigator-initiated, parallel group, open-label, **superiority**, randomized controlled trial (RCT)

Standard Polyurethane
PICC w external clamps



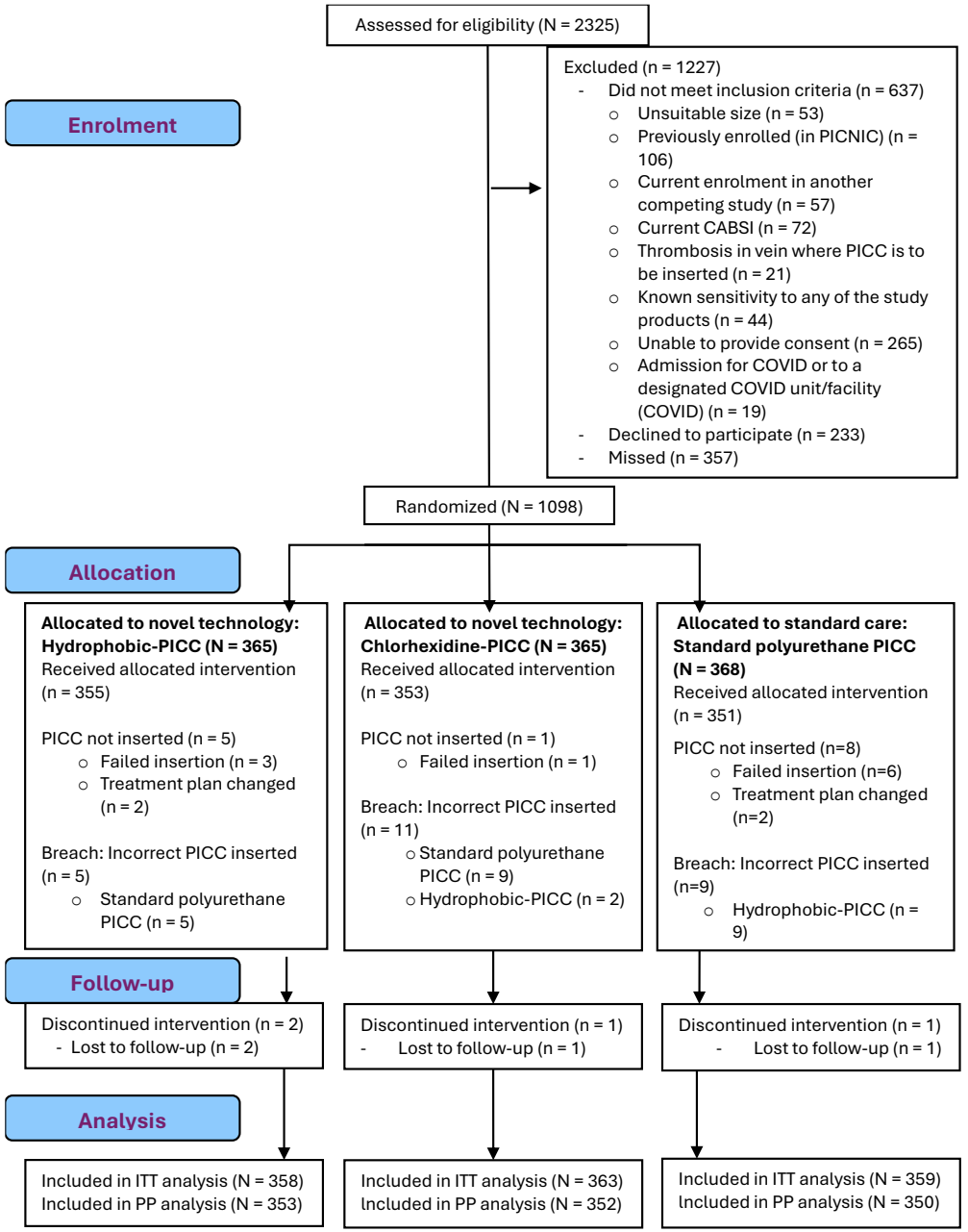
Anti-thrombogenic PICC
(Hydrophobic) w internal valves

Anti-microbial PICC
(Chlorhex) w external clamps

3 Large Tertiary, Metropolitan Hospitals in Queensland
2 Adult, 1 Paediatric
1,098 patients: September 2019 to December 2022

BMJ Open

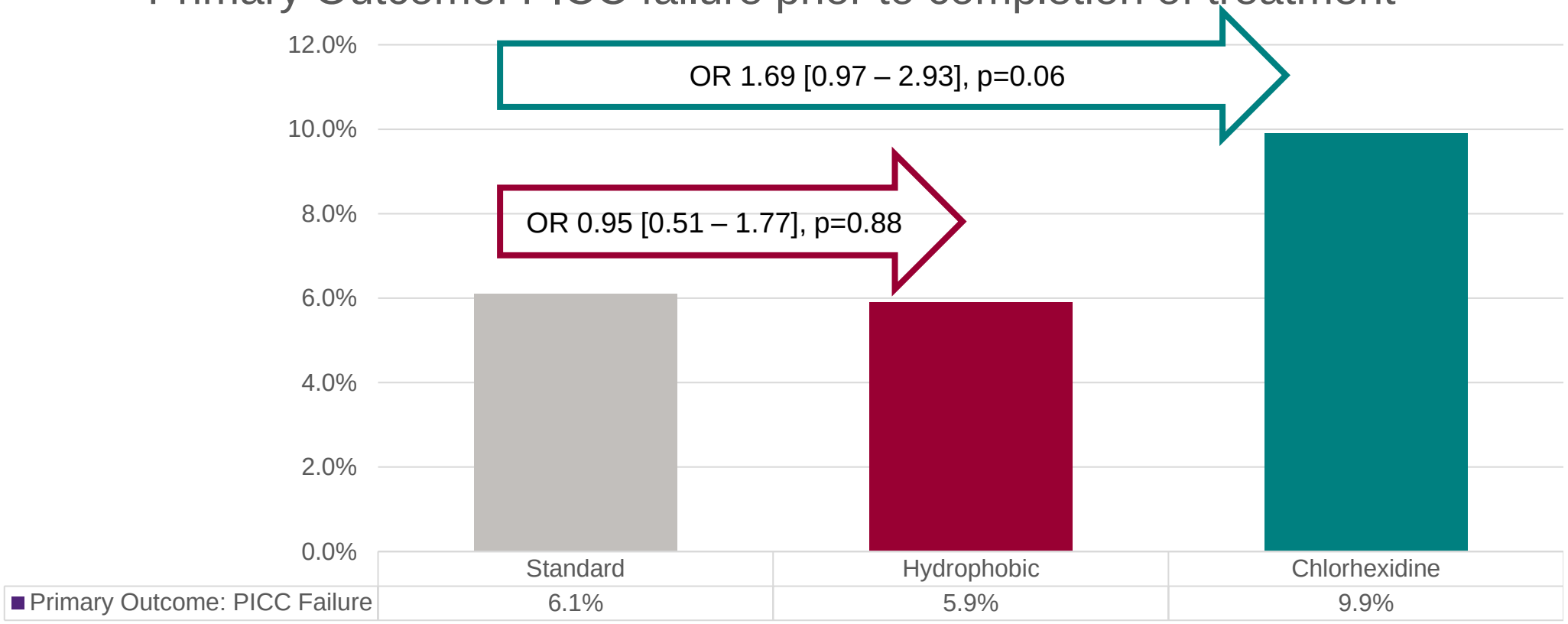
PICC failure	• Composite of thrombotic & infective complications severe enough to cause **cessation of PICC function** prior to therapy completion.
All-cause PICC complications	• Any thrombotic or infection complications **during dwell & at removal**
Non-infectious complications	• VTE: Symptomatic, image confirmed • Breakage: Split with leakage or scan • Occlusion: Partial & complete (CINAS)
Infectious complications	• PICC associated bloodstream infections (CLABSI NHSN) • Local infections (VASC, NHSN)
Secondary outcomes	• Individual complication types • Adverse events, Dwell, Patient/parent satisfaction • Costs


Assessed for eligibility (N = 2325)
Enrolment
Excluded (n = 1227)
- Did not meet inclusion criteria (n = 637)
  - Unsuitable size (n = 53)
  - Previously enrolled (in PICNIC) (n = 106)
  - Current enrolment in another competing study (n = 57)
  - Current CABSI (n = 72)
  - Thrombosis in vein where PICC is to be inserted (n = 21)
  - Known sensitivity to any of the study products (n = 44)
  - Unable to provide consent (n = 265)
  - Admission for COVID or to a designated COVID unit/facility (COVID) (n = 19)
- Declined to participate (n = 233)
- Missed (n = 357)
Randomized (N = 1098)
Allocation
Allocated to novel technology: Hydrophobic-PICC (N = 365)
Received allocated intervention (n = 355)
PICC not inserted (n = 5)
Failed insertion (n = 3)
Treatment plan changed (n = 2)
Breach: Incorrect PICC inserted (n = 5)
Standard polyurethane PICC (n = 5)
Allocated to novel technology: Chlorhexidine-PICC (N = 365)
Received allocated intervention (n = 353)
PICC not inserted (n = 1)
Failed insertion (n = 1)
Breach: Incorrect PICC inserted (n = 11)
Standard polyurethane PICC (n = 9)
Hydrophobic-PICC (n = 2)
Allocated to standard care: Standard polyurethane PICC (N = 368)
Received allocated intervention (n = 351)
PICC not inserted (n=8)
Failed insertion (n=6)
Treatment plan changed (n=2)
Breach: Incorrect PICC inserted (n=9)
Hydrophobic-PICC (n = 9)
Follow-up
Discontinued intervention (n = 2)
- Lost to follow-up (n = 2)
Discontinued intervention (n = 1)
- Lost to follow-up (n = 1)
Discontinued intervention (n = 1)
- Lost to follow-up (n = 1)
Analysis
Included in ITT analysis (N = 358)
Included in PP analysis (N = 353)
Included in ITT analysis (N = 363)
Included in PP analysis (N = 352)
Included in ITT analysis (N = 359)
Included in PP analysis (N = 350)

Characteristic	Standard polyurethane (N = 368) n (%)	Hydrophobic (N = 365) n (%)	Chlorhexidine (N = 365) n (%)
Age (in years)	49.7 (SD 21.7)	50.7 (SD 22.3)	50.4 (SD 21.7)
Gender (Female)	149 (40.5)	144 (39.5)	146 (40.0)
Number of co-morbidities 1	65 (17.7)	65 (17.8)	67 (18.4)
2	52 (14.1)	63 (17.3)	61 (16.7)
3	32 (8.7)	21 (5.8)	27 (7.4)
>3	179 (48.6)	171 (46.9)	161 (44.1)
Diagnostic group Surgical	118 (32.1)	129 (35.3)	120 (32.9)
Oncology	91 (24.7)	82 (22.5)	82 (22.5)
Hematology	52 (14.1)	54 (14.8)	54 (14.8)
Respiratory	25 (6.8)	29 (8.0)	23 (6.3)
Gastroenterology	33 (9.0)	26 (7.1)	27 (7.4)
Medical	40 (10.9)	28 (7.7)	27 (7.4)
Cardiac	8 (2.2)	20 (5.5)	27 (7.4)
Infectious diseases	12 (3.3)	11 (3.0)	15 (4.1)
Initial CVAD across life span of participant	212 (57.6)	214 (58.9)	216 (59.2)
High Michigan Risk Scores (Adults)	200 (64.9)	200 (65.6)	203 (66.1)

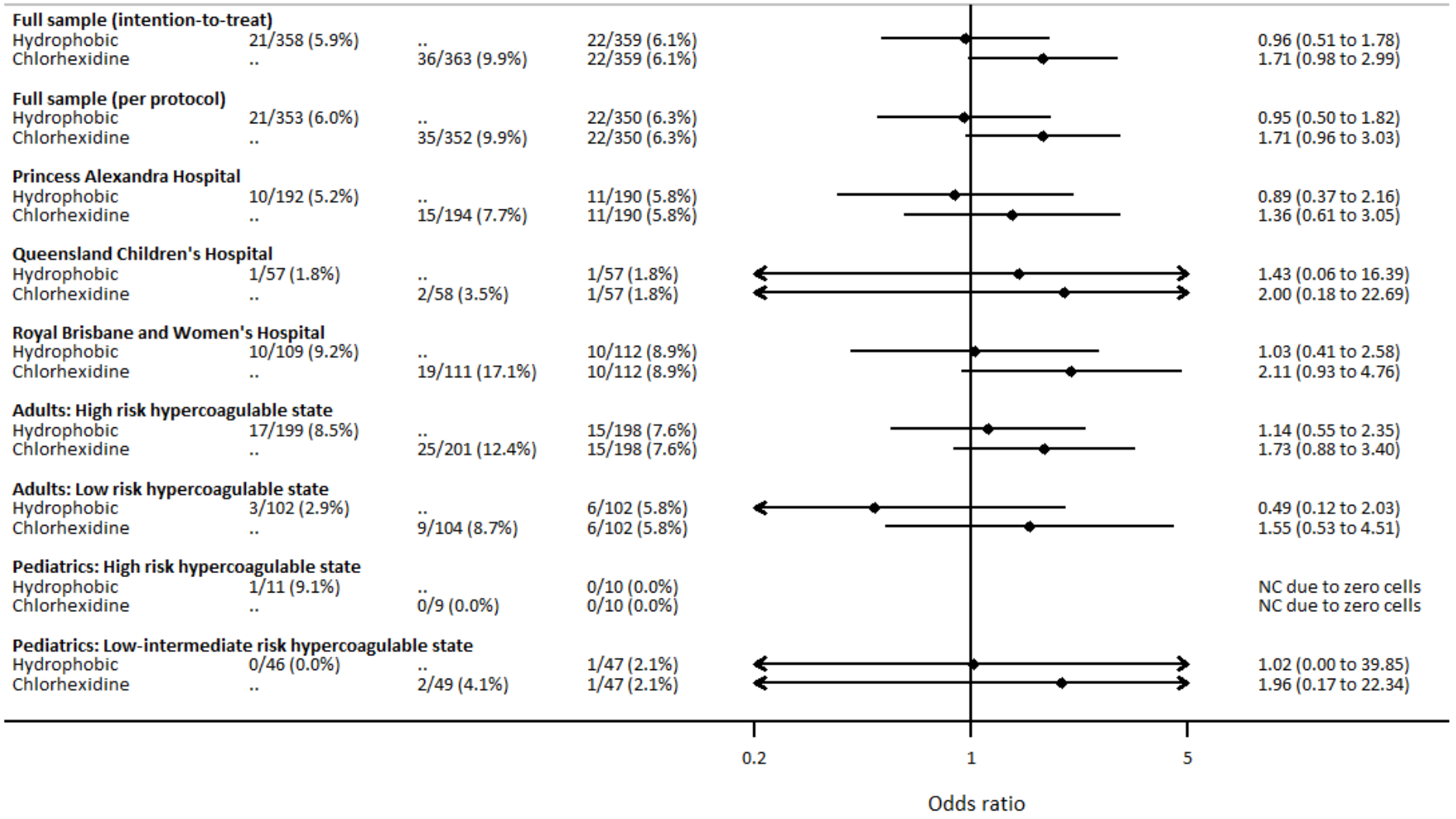
Characteristic	Standard polyurethane (N = 368) n (%)	Hydrophobic (N = 365) n (%)	Chlorhexidine (N = 365) n (%)
PICC lumens 1	48 (13.3)	46 (12.8)	50 (13.7)
2	311 (86.4)	310 (86.1)	307 (84.3)
3	1 (0.3)	4 (1.1)	7 (1.9)
PICC placement Basilic	305 (84.7)	322 (89.4)	306 (84.1)
Brachial	44 (12.2)	32 (8.9)	54 (14.8)
Department of insertion Radiology	327 (90.1)	324 (89.8)	338 (92.9)
Operating theatre	36 (9.9)	37 (10.3)	26 (7.1)
Multiple attempts required	50 (13.8)	51 (14.1)	46 (12.6)
Number of times inserter has used product First time	12 (3.3)	28 (7.8)	59 (16.2)
2-10	30 (8.3)	111 (30.8)	107 (29.4)
11-20	25 (6.9)	75 (20.8)	73 (20.1)
>20	289 (79.6)	144 (39.9)	121 (33.2)

Primary Outcome: PICC failure prior to completion of treatment



Confirmation of null hypothesis: No evidence of superiority of interventions on primary outcome

Sample	Hydrophobic	Chlorhexidine	Standard polyurethane	Odds ratio (95% CI)
Full sample (intention-to-treat)				
Hydrophobic	21/358 (5.9%)	..	22/359 (6.1%)	0.96 (0.51 to 1.78)
Chlorhexidine	..	36/363 (9.9%)	22/359 (6.1%)	1.71 (0.98 to 2.99)
Full sample (per protocol)				
Hydrophobic	21/353 (6.0%)	..	22/350 (6.3%)	0.95 (0.50 to 1.82)
Chlorhexidine	..	35/352 (9.9%)	22/350 (6.3%)	1.71 (0.96 to 3.03)
Princess Alexandra Hospital				
Hydrophobic	10/192 (5.2%)	..	11/190 (5.8%)	0.89 (0.37 to 2.16)
Chlorhexidine	..	15/194 (7.7%)	11/190 (5.8%)	1.36 (0.61 to 3.05)
Queensland Children's Hospital				
Hydrophobic	1/57 (1.8%)	..	1/57 (1.8%)	1.43 (0.06 to 16.39)
Chlorhexidine	..	2/58 (3.5%)	1/57 (1.8%)	2.00 (0.18 to 22.69)
Royal Brisbane and Women's Hospital				
Hydrophobic	10/109 (9.2%)	..	10/112 (8.9%)	1.03 (0.41 to 2.58)
Chlorhexidine	..	19/111 (17.1%)	10/112 (8.9%)	2.11 (0.93 to 4.76)
Adults: High risk hypercoagulable state				
Hydrophobic	17/199 (8.5%)	..	15/198 (7.6%)	1.14 (0.55 to 2.35)
Chlorhexidine	..	25/201 (12.4%)	15/198 (7.6%)	1.73 (0.88 to 3.40)
Adults: Low risk hypercoagulable state				
Hydrophobic	3/102 (2.9%)	..	6/102 (5.8%)	0.49 (0.12 to 2.03)
Chlorhexidine	..	9/104 (8.7%)	6/102 (5.8%)	1.55 (0.53 to 4.51)
Pediatrics: High risk hypercoagulable state				
Hydrophobic	1/11 (9.1%)	..	0/10 (0.0%)	NC due to zero cells
Chlorhexidine	..	0/9 (0.0%)	0/10 (0.0%)	NC due to zero cells
Pediatrics: Low-intermediate risk hypercoagulable state				
Hydrophobic	0/46 (0.0%)	..	1/47 (2.1%)	1.02 (0.00 to 39.85)
Chlorhexidine	..	2/49 (4.1%)	1/47 (2.1%)	1.96 (0.17 to 22.34)



Secondary outcomes	Standard polyurethane (N = 359)	Hydrophobic (N = 358)	OR (95% CI)	Chlorhex (N = 363)	OR (95% CI)
All-cause complications (ever): occurring during PICC dwell or at or near treatment completion, with or without associated failure	78 (21.7)	77 (21.5)	0.99 (0.69 to 1.41)	140 (38.6)	2.26 (1.63 to 3.14)
Non-infectious complication (ever)	70 (19.5)	71 (19.8)	1.02 (0.71 to 1.48)	132 (36.4)	2.36 (1.68 to 3.31)
Venous thrombosis	23 (6.4)	11 (3.1)	0.46 (0.22 to 0.96)	12 (3.3)	0.50 (0.24 to 1.02)
Breakage	2 (0.6)	3 (0.8)	1.51 (0.25 to 9.08)	0 (0.0)	NC to due zero cells
Occlusion	51 (14.2)	61 (17.0)	1.24 (0.83 to 1.86)	122 (33.6)	3.06 (2.12 to 4.42)
Complete occlusion	18 (5.0)	32 (8.9)	1.86 (1.02 to 3.38)	87 (24.0)	5.97 (3.51 to 10.16)
Partial occlusion	37 (10.3)	41 (11.5)	1.13 (0.71 to 1.81)	82 (22.7)	2.56 (1.68 to 3.89)
Infective complication (ever)	14 (3.9)	12 (3.4)	0.85 (0.39 to 1.87)	16 (4.4)	1.14 (0.55 to 2.36)
PICC-associated BSI	7 (2.0)	5 (1.4)	0.71 (0.22 to 2.27)	6 (1.7)	0.85 (0.28 to 2.54)
Local Infection	8 (2.2)	7 (2.0)	0.88 (0.31 to 2.44)	10 (2.8)	1.24 (0.48 to 3.19)

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Secondary outcomes	Standard polyurethane (N = 359)	Hydrophobic (N = 358)	Effect Estimates (95% CI)	Chlorhex (N = 363)	Effect Estimates (95% CI)
Adverse events (n (%))	1 (0.3)	0 (0.0)	OR = NC due to zero cells	0 (0.0)	OR = NC due to zero cells
PICC dwell, days (mean (SD))	28.8 (18.9)	26.1 (18.1)	MD = -2.6 (-5.3 to 0.1)	27.5 (18.0)	MD = -1.2 (-3.9 to 1.4)
Satisfaction (NRS 0 to 100), median (IQR)					
Staff (at insertion), ease of PICC insertion	100 (90 to 100)	90 (70 to 100)	MedD = -10 (-12 to -8)	100 (90 to 100)	MedD = 0 (-2 to 2)
Staff (at insertion), satisfaction with insertion kit	100 (100 to 100)	80 (50 to 100)	MedD = -20 (-22 to -19)	100 (90 to 100)	MedD = 0 (-1 to 1)
Patient/parent (at removal), overall experience	96 (70 to 100)	98 (77 to 100)	MedD = 2 (-3 to 7)	88 (59 to 100)	MedD = -8 (-13 to -3)

The PICNIC trial team

Thank you!!!













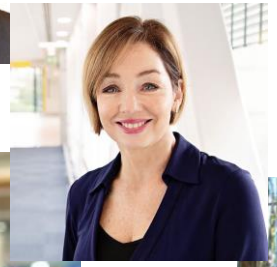



Not pictured: Joanne Leema, Cathy Biles, Katrina Southam, Nimco Habbad, Haiyang Tian, Michelle Bauer, Cat O'Brien, Stephanie Hall

- What's causing all those occlusions?
- Is Chlorhexidine Acetate that different from CHG?
- De-implementation process in the US?
- If its not catheter materials – what will work across all 3 complications? Is this possible?
- Future projects should target high risk populations only

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA
CREATE CHANGE

Thank you

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CRICOS code 00025B