HERSTON INFECTIOUS DISEASES INSTITUTE

DART 3: A pragmatic stepped wedge cluster randomised trial of ultrasound guidance to reducing multiple PIVC insertions in hospitalised patients

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on behalf of the larger investigator team:

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RBWH Foundation

The University Of Queensland AUSTRALIA | CREATE CHANGE

Metro North Hospital and Health Service

Queensland Government

Acknowledgment of **Country**

We acknowledge the Traditional Owners and their custodianship of the lands on which we meet.

We pay our respects to their Ancestors and their descendants, who continue cultural and spiritual connections to Country.

We recognise their valuable contributions to Australian and global society.

No conflicts of interest to declare


“PIVC insertion is one of the most practiced clinical procedures in hospitals, yet carries the greatest risk of failure of any medical device”
Dr Evan Alexandrou

Difficult IntraVenous Access (DIVA)

Characterised by: Limited suitable veins

Evident in: Half of hospitalised patients; one-third of ED presentations

Defined by: So many ways…

Table 3. Multivariate regression analyses.

Factor	ß	SE	*p* Value	Odds Ratio	95% CI
History of a difficult intravenous cannulation	0.976	0.180	<0.001	2.7	1.6 to 4.4
Practitioner's expectation of a difficult intravenous access	0.936	0.191	<0.001	2.6	1.6 to 4.0
No palpable vein after tourniquet placement	1.670	0.187	<0.001	4.8	2.5 to 8.1
No visible vein after tourniquet placement	1.879	0.192	<0.001	5.9	2.5 to 10.1
Diameter of the vein less than 3 millimeters after tourniquet placement	1.247	0.094	<0.001	3.5	2.7 to 4.4

Constant ß 8.950, SE 0.543, $p < 0.001$. SE = Standard Error. CI = Confidence Interval.

Carr et al JHM 2017

Scoping RV of 13 DIVA tools, rules and algorithms

Vein characteristics most common:

- Number/Quality/Size/Location/ Visibility/Palpability

Risks:

- Chronic disease (Diabetes OR 2.1, SCD OR 3.5, IVDU OR 2.4)
- Obesity or emaciated
- Smaller gauge OR 6.4
- History of DIVA

Success:

- Visible veins OR 0.79-5.05
- ↑ procedural volume OR 4.4
- Certification
- Predicted success OR 1.06

van Loon et al. The Modified A-DIVA Scale as a Predictive Tool for Prospective Identification of Adult Patients at Risk of DIVA: A Multicenter Validation Study. J Clin Med 2019.

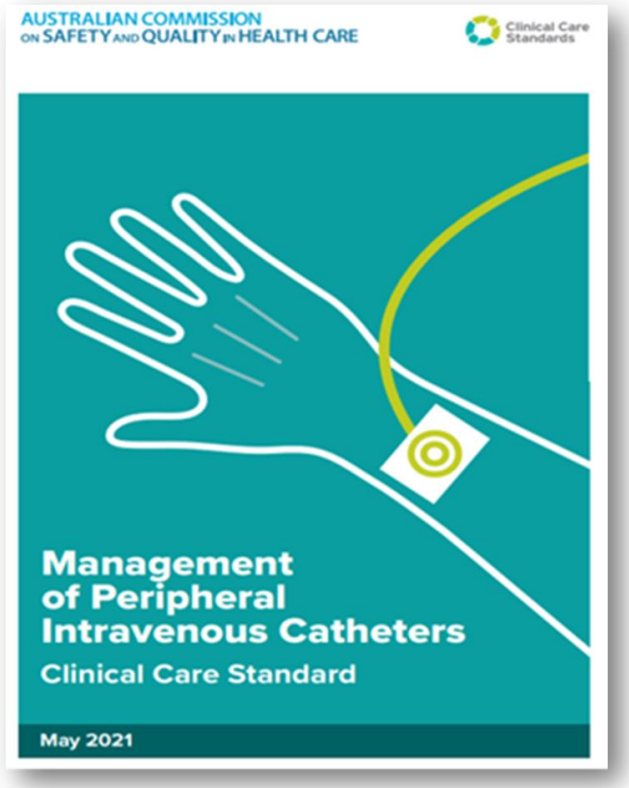
Consumer experience of DIVA

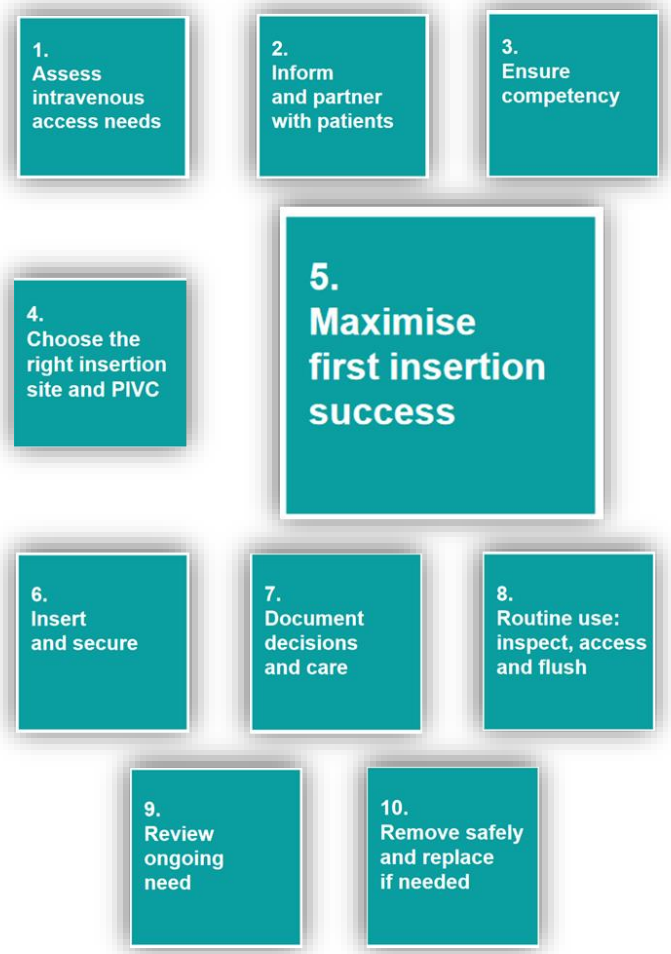
- 1st time success 44-58% inpatients, 77%-86% ED
- 25% had multiple inserters
- Some patients 10 attempts
- 28% had procedure abandoned or a CVAD inserted

Kleidon et al, JPCH 2019
Farrell et al, Canc Nurs Prac 2017
Marsh et al, JHM 2018
Rippey EMA 2016
Marsh et al, Trials 2018

Consumer survey (Cooke PLoS One 2018)

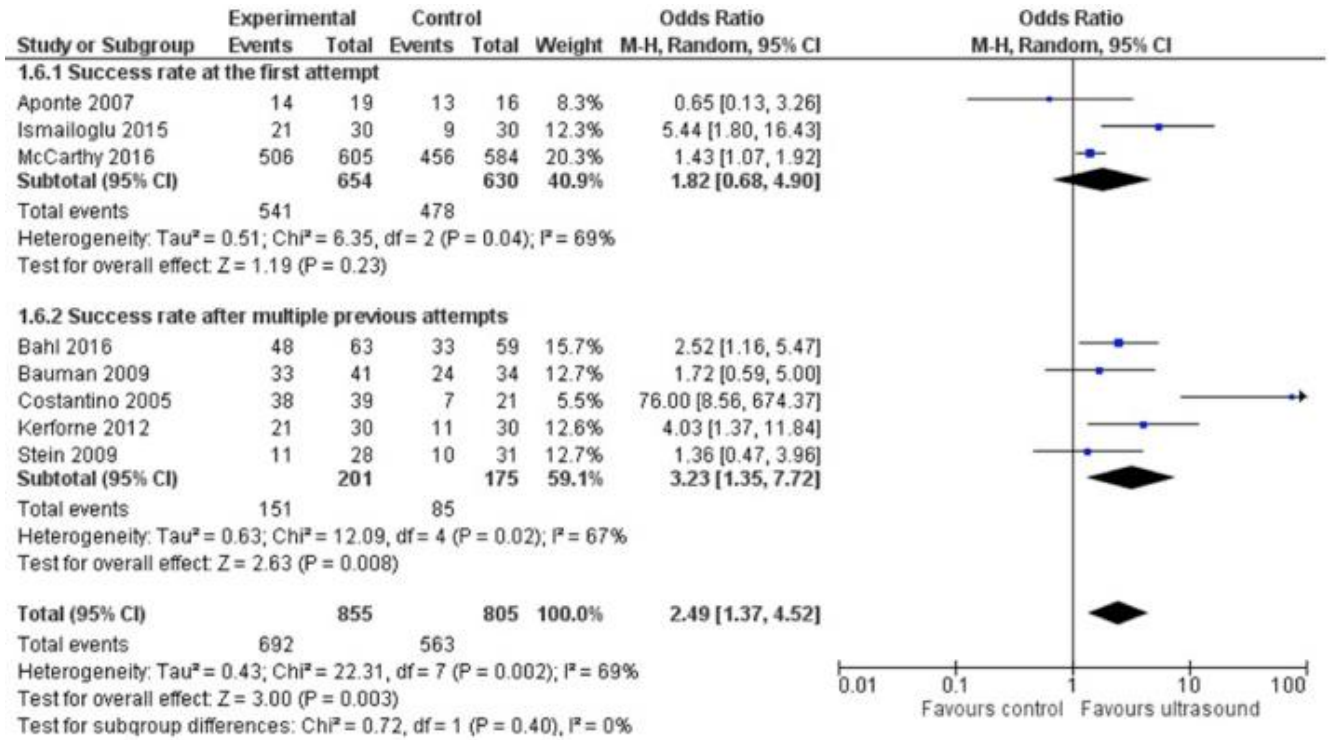
Questions	Adult Survey	n (%)	Paediatric Survey	n (%)	p value
	Responses		Responses		
	n = 570		n = 142		
Last time you/your child needed an IV, how painful or stressful was the experience? ᶜ	**Median (IQR)**	4 (2, 7)		7 (5, 9)	*<0.001^*
1 = no pain/distress;	Minimal pain/distress (≤ 3)	268 (47.5)		25 (18)	
10 = extreme pain/distress	Moderate (4–7)	197 (34.9)		45 (32.4)	
	Severe pain/distress (≥ 8)	99 (17.5)		69 (49.6)	


AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE
Clinical Care Standards
Management of Peripheral Intravenous Catheters
Clinical Care Standard
May 2021


1. Assess intravenous access needs
2. Inform and partner with patients
3. Ensure competency
4. Choose the right insertion site and PIVC
5. Maximise first insertion success
6. Insert and secure
7. Document decisions and care
8. Routine use: inspect, access and flush
9. Review ongoing need
10. Remove safely and replace if needed

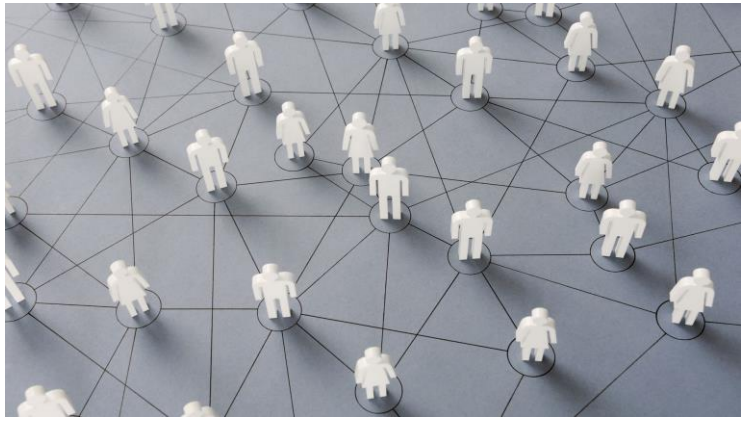
SCAN ME

Ultrasound: Maximising first attempt success



(Van Loon et al. Brit J Anaesth 2018)

Workforce issues



DART3 - DIFFICULT ACCESS REQUIRES THOUGHT, TRAINING AND TECHNOLOGY

Co-developing an ultrasound pathway for patients with difficult intravenous access

Phase n° 1

Stakeholder and consumer interviews

Literature reviews of DIVA tools

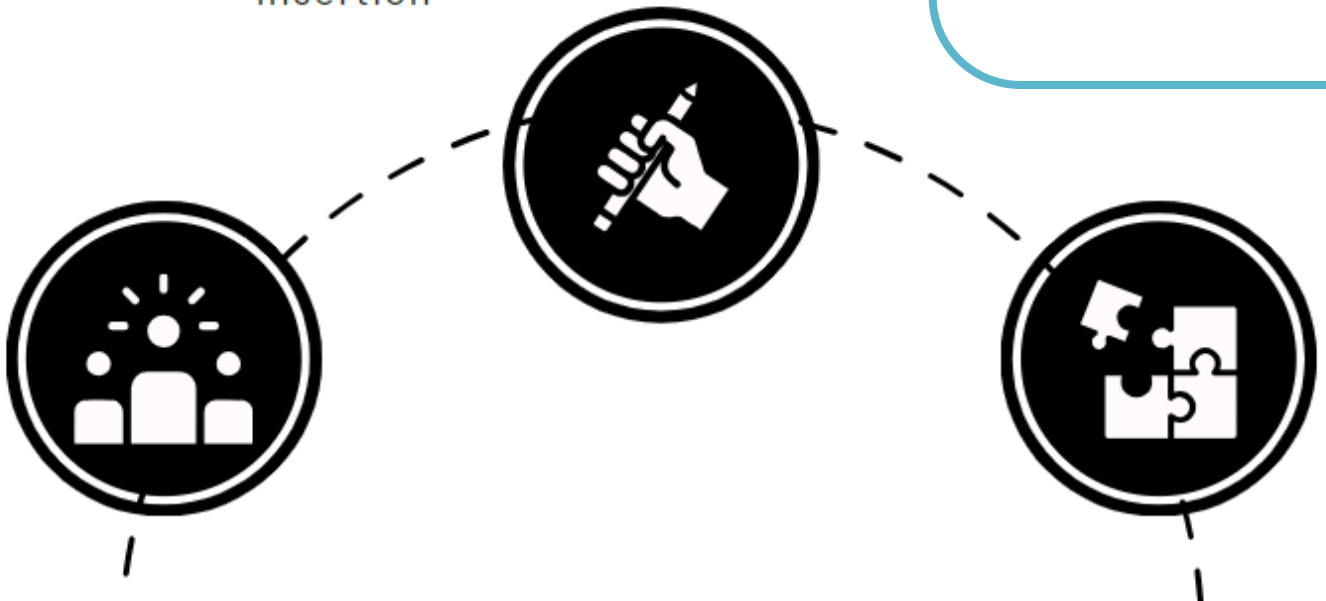
Phase n° 2

Co-development and pilot test DIVA tools + implementation strategies

Evaluation of funding for PIVC insertion

Phase n° 3

Implement and evaluate the DIVA identification and escalation pathway effect on clinical and implementation outcomes



Australian Government
National Health and Medical Research Council

NHMRC

Schults et al. BMC Health Services Research (2023) 23:587
https://doi.org/10.1186/s12913-023-09499-0

BMC Health Services Research

Phase 3. Clinical trial

STUDY PROTOCOL Open Access

Improving difficult peripheral intravenous access requires thought, training and technology (DART^3): a stepped-wedge, cluster randomised controlled trial protocol

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Abstract

Background Peripheral intravenous catheters (PIVCs) are the most used invasive medical device in healthc around half of insertion attempts are unsuccessful leading to delayed medical treatments and patient disco harm. Ultrasound-guided PIVC (USGPIVC) insertion is an evidence-based intervention shown to improve in success especially in patients with Difficult IntraVenous Access (BMC Health Serv Res 22:220, 2022), however the implementation in some healthcare settings remains suboptimal. This study aims to co-design interventions that optimise ultrasound guided PIVC insertion in patients with DIVA, implement and evaluate these initiatives and develop scale up activities.

Methods A stepped-wedge cluster randomized controlled trial will be conducted in three hospitals (two adult, one paediatric) in Queensland, Australia. The intervention will be rolled out across 12 distinct clusters (four per hospital). Intervention development will be guided by Michie's Behavior Change Wheel with the aim to increase local staff capability, opportunity, and motivation for appropriate, sustainable adoption of USGPIVC insertion. Eligible clusters include all wards or departments where > 10 PIVCs/week are typically inserted. All clusters will commence in the control (baseline) phase, then, one cluster per hospital will step up every two months, as feasible, to the implementation phase, where the intervention will be rolled out. Implementation strategies are tailored for each hospital by local investigators and advisory groups, through context assessments, staff surveys, and stakeholder interviews and informed by extensive consumer interviews and consultation. Outcome measures align with the RE-AIM framework including clinical-effectiveness outcomes (e.g., first-time PIVC insertion success for DIVA patients [primary outcome], number of insertion attempts); implementation outcomes (e.g., intervention fidelity, readiness assessment) and cost effectiveness outcomes. The Consolidated Framework for Implementation Research framework

BUILDING A HEALTHY AUSTRALIA

Trial registration ACTRN12621001497897

DART 3
Difficult Access Requires: Thought, Training and Technology

Set the study sites: 3 metropolitan hospitals in Brisbane QLD (2 adult hospital and 1 paediatric hospital)

Primary concept building

- Establish a DIVA advisory group
- Co-development of DIVA tool and Implementation strategies
- Pilot testing draft DIVA tool

Stepped-Wedge Randomised Control Trial

Purposive sampling for 12 identified clusters (4 clusters from each hospital, covering emergency, general medical/surgical and critical care)

Baseline Assessment

1) Clinical and economic data collection of PIVC insertion practice
2) Implementation data (site readiness surveys, research nurse questionnaires, action table, field notes)

Randomisation:

One cluster per hospital is randomly allocated to step up each timepoint with allocation concealment until study commencement.

	Cluster 1	Cluster 2	Cluster 3	Cluster 4
Step 1: Month 1 & 2	Baseline	Baseline	Baseline	Baseline
Step 2: Month 3 & 4	Implementation	Baseline	Baseline	Baseline
Step 3: Month 5 & 6	Implementation	Implementation	Baseline	Baseline
Step 4: Month 7 & 8	Implementation	Implementation	Implementation	Baseline
Step 5: Month 9 & 10	Implementation	Implementation	Implementation	Implementation
Step 6: Month 11 to 13	Sustainability	Sustainability	Sustainability	Sustainability
Step 7: Month 14 to 16	Sustainability	Sustainability	Sustainability	Sustainability

Baseline: standard of care

Implementation: implementation of DIVA escalation tool and pathway.

Sustainability: Evaluation of sustained effect of intervention on clinical and economic measures.

600 baseline observations; 600 implementation observations; 480 sustainability observations

Outcome measures

1. Implementation outcome;
2. Clinical outcomes;
3. Process evaluation

Public, university affiliated paediatric hospital

Public, university affiliated adult hospitals x 2

Hospital and location	Setting	Inpatient Beds	Cluster wards
Gold Coast University Hospital; Gold Coast, QLD	Metropolitan	750	• Emergency/Medical Decision Unit • Cancer and Blood Disorders • Vascular • Trauma and Orthopaedics
Queensland Children's Hospital; Brisbane, QLD	Metropolitan	359	• Paediatric Intensive Care • Inpatient Surgical • Inpatient Medical • Infants including neonates
Royal Brisbane and Women's Hospital; Brisbane, QLD	Metropolitan	929	• General Surgical • General Surgical and Colorectal • Coronary Care Unit • Emergency and Trauma Centre

Participants

Eligible clusters:

Emergency departments, inpatient wards, or day procedure units where >10 PIVCs/week are typically inserted.

* We excluded operating theatres, radiology, rehabilitation, or psychiatric units. Clinician emergencies where IO access was used were also excluded.

Included PIVC: Any patient (DIVA or non-DIVA) of any age requiring a PIVC

Sample size: Target 1680 observations

20 PIVC insertions per ward, per two-month step was expected, plus a further 20 PIVC insertion during each of the sustainability phases

Outcomes

Table 1 DART[3] outcomes. Outcomes, definitions, and data collection organised by RE-AIM domains

Outcomes	Information	Data source
Patient and service level outcomes		
Primary		
First attempt insertion success in patients identified as DIVA	One needle puncture, by one inserter, to achieve successful insertion of a functional (can be aspirated/flushed) PIVC [2]	Hospital-based assessments
Secondary		
First attempt insertion success for all patients (regardless of DIVA status)	One needle puncture, by one inserter, to achieve successful of a functional (can be aspirated/flushed) PIVC [2]	Hospital-based assessments
Number of attempts	Number of skin punctures to attempt PIVC insertion [3]	Hospital-based assessments
Procedure outcome:	Successful PIVC insertion; time from PIVC referral to PIVC insertion (censored at 48 h); alternate device; alternate route (e.g., oral) [4]	Hospital-based assessments
PIVC failure	Composite measure of local infection, primary bloodstream infection (BSI), occlusion, infiltration/extravasation, dislodgement (includes leaking), thrombosis and/or phlebitis [6 7]	Hospital-based assessments
Insertion/post-insertion complications	Bruising, haematoma, nerve injury, arterial puncture, or skin injury as well as the individual components of PIVC failure (above) [6 8]	Hospital-based assessments
PIVC dwell time	Time from PIVC insertion to PIVC removal (in hours) [6]	Hospital-based assessments
PIVC necessity	PIVC used for fluids or medications within 24 h (excluding patients who require a prophylactic PIVC in situ as part of their treatment e.g., status epilepticus) [5]	Hospital-based assessments
Incidence of blood stream infection	Cluster level routinely-collected rates of primary BSI and S. Aureus BSI [9]	Hospital-based assessments
Economic outcomes		
Cost-effectiveness	Direct and indirect healthcare costs to the health system, patients/carers: (time to insertion/therapy, cost of products, number of staff, staff time, costs of responding to failed insertion including cancelled appointments)	Hospital-based assessments

DART^3 Intervention

co-designed

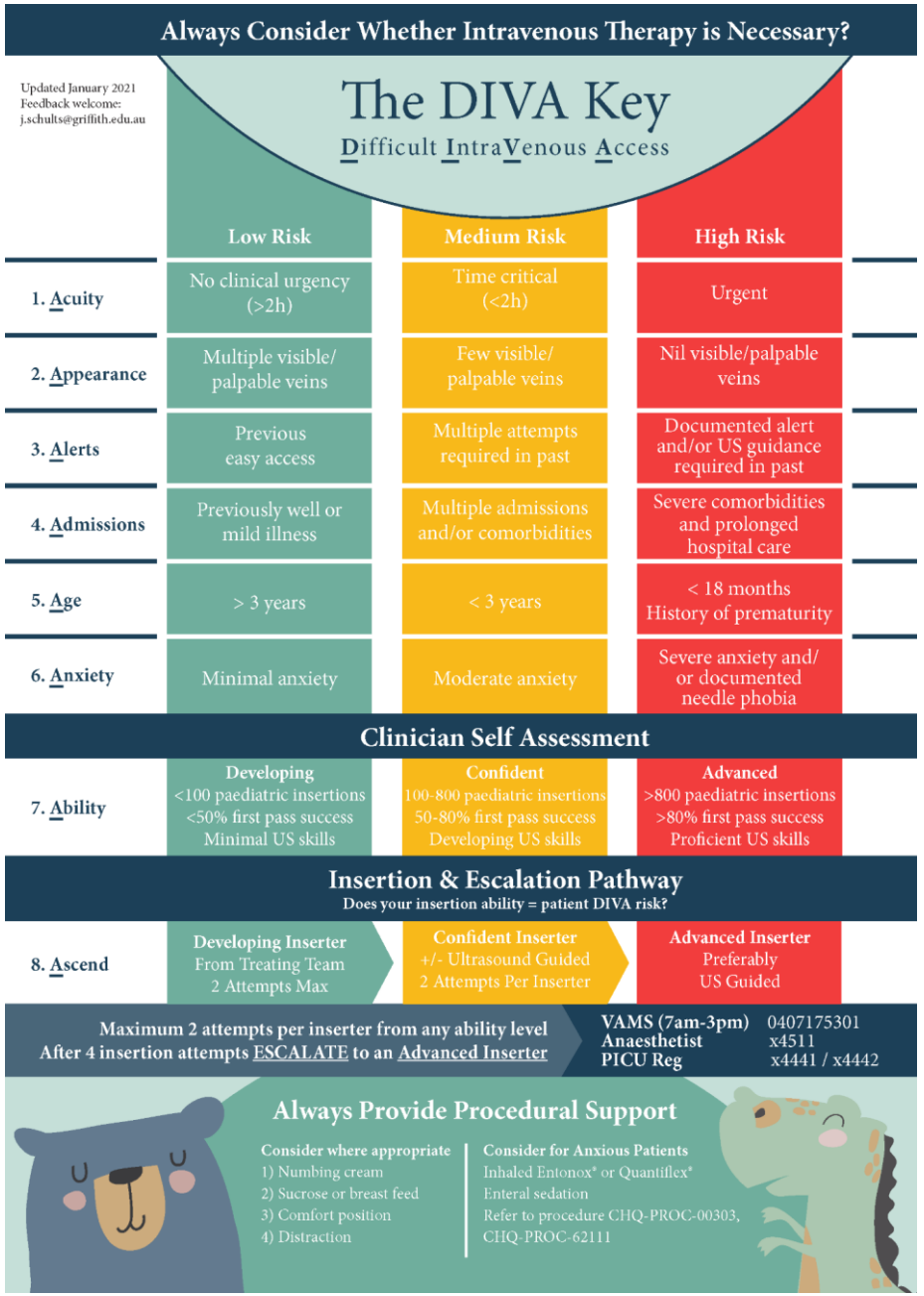
1. Vein assessment tool
2. Escalation pathway +/- USG
3. Implementation strategies, including

- Education on the use of the DIVA tool and escalation pathway
- Training in ultrasound guided PIVC insertion
- Support for trained staff (nurses and doctors) to become competent ultrasound guided PIVC inserters.

DIVA classification

Classified as non-DIVA, potential DIVA or DIVA by site DIVA assessment tool

- *N.B. In baseline, vein assessment was by the inserter.*



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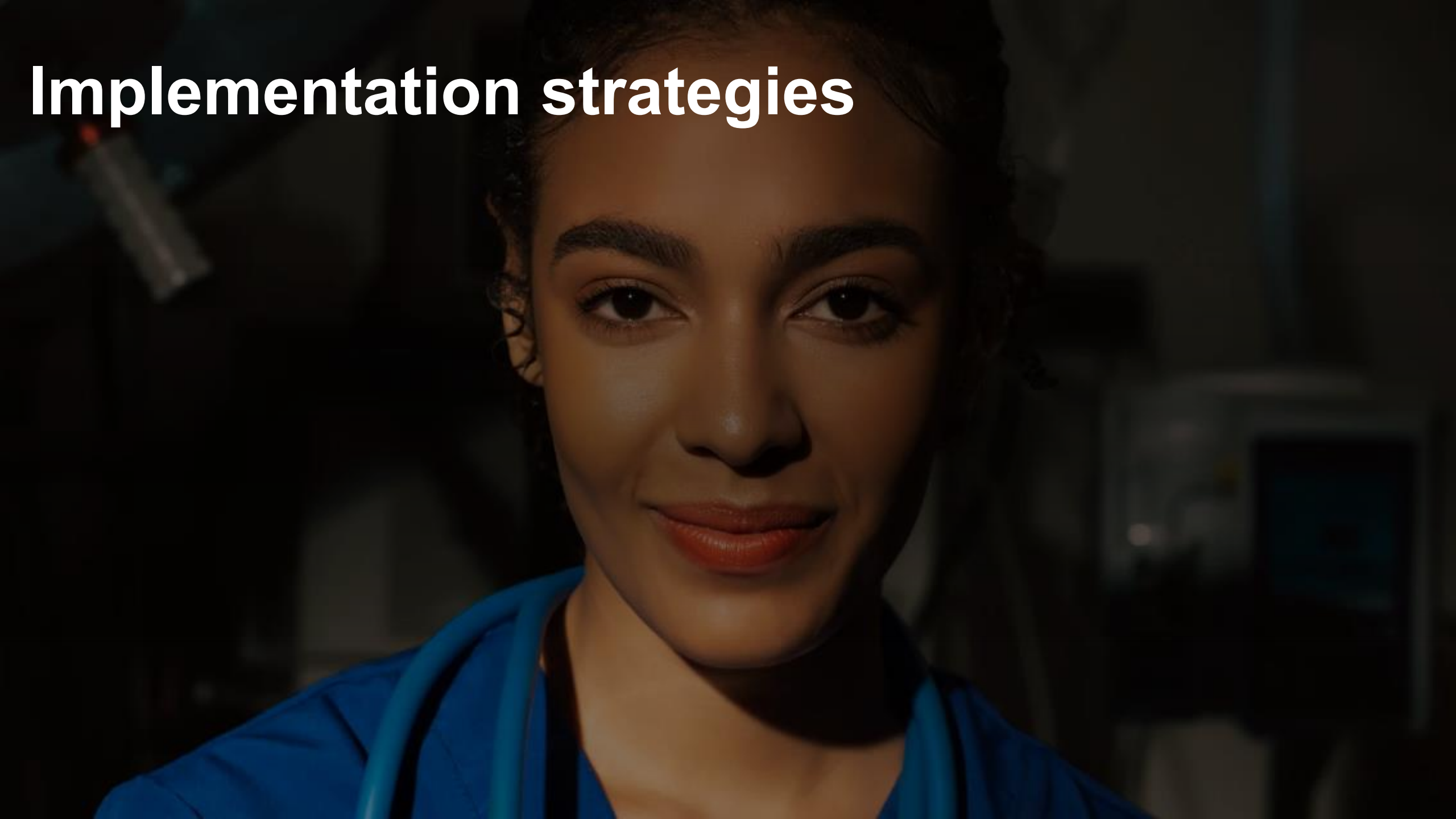
Implementation strategies




Get pills
Take pills
Feel better

CFIR components

Intervention characteristics
- Co-designed intervention
- Flexible escalation
- Multidisciplinary and collaborative approach

Inner setting
- Cultural belief ultrasound is for medical staff
- Staff shortages influencing escalation processes and choice of intervention
- Staff shortages influenced training availability

Outer setting
- Staffing shortages
- Changes to cluster composition
- COVID-19 impacts

Characteristics of individuals
- Clinical staff fatigued
- Heavy workloads
- Staff supportive of change
- Staff believe in the effectiveness of identifying DIVA early

Process
- Co-designed implementation toolkit

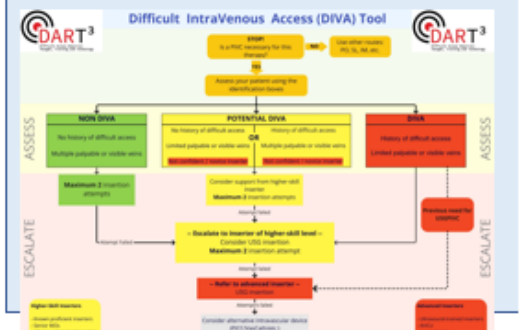
pointed as
aders

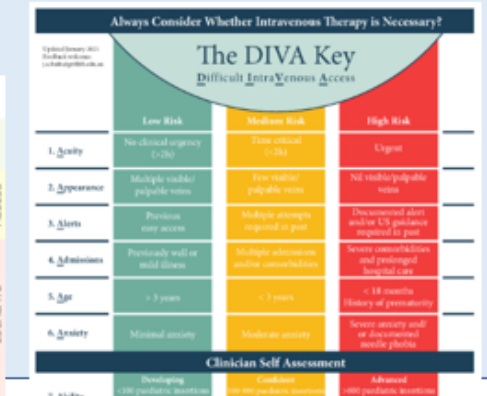
Implementation Research Logic Model: How DART3 is envisaged to work

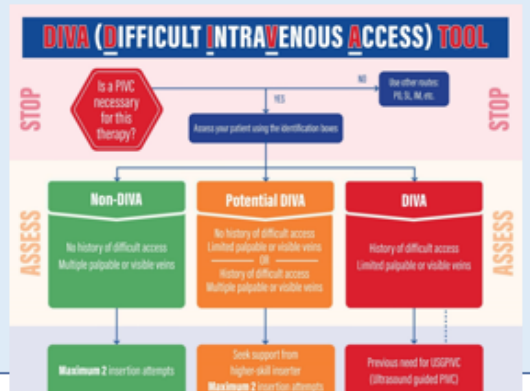
Implementation strategies
- Customised DIVA tool and escalation pathway established at each site and adapted for Emergency and ICU departments (for in-house escalation)
- Lanyards with escalation pathway for ward nursing staff.
- Badges and magnets to identify Ultrasound competent PIVC inserters
- Ultrasound machines sourced for each participating ward.
- Training, USGPIVC workshops, hospital wide and ward specific as well as bedside education and support by research nurses.
- Mentoring / shadowing for USGPIVC trained nurses with vascular experts / teams
- Identification and upskilling of change champions for each participating ward
- Regular (per step) feedback for each site and ward with recruitment numbers, first attempt insertion success and upcoming news, such as workshops.
- Development and local endorsement of clinical skill assessment tool for ultrasound guided PIVC insertion competency achievement in nursing staff.
- Coffee vouchers and doughnuts rewards for wards with biggest recruitment

Mechanisms
- Promotes multidisciplinary involvement
- Intervention flexible with cluster needs

Intervention



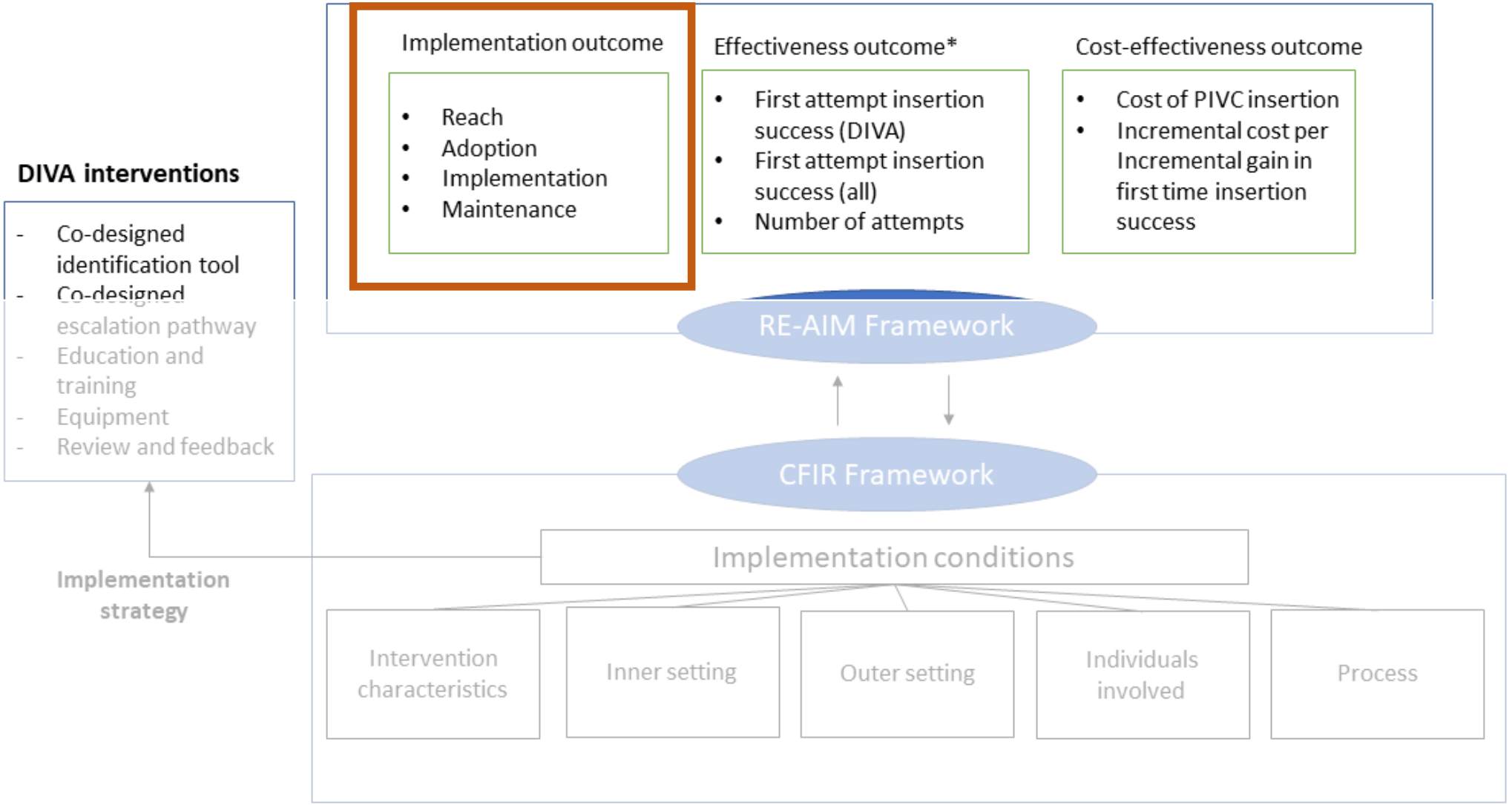




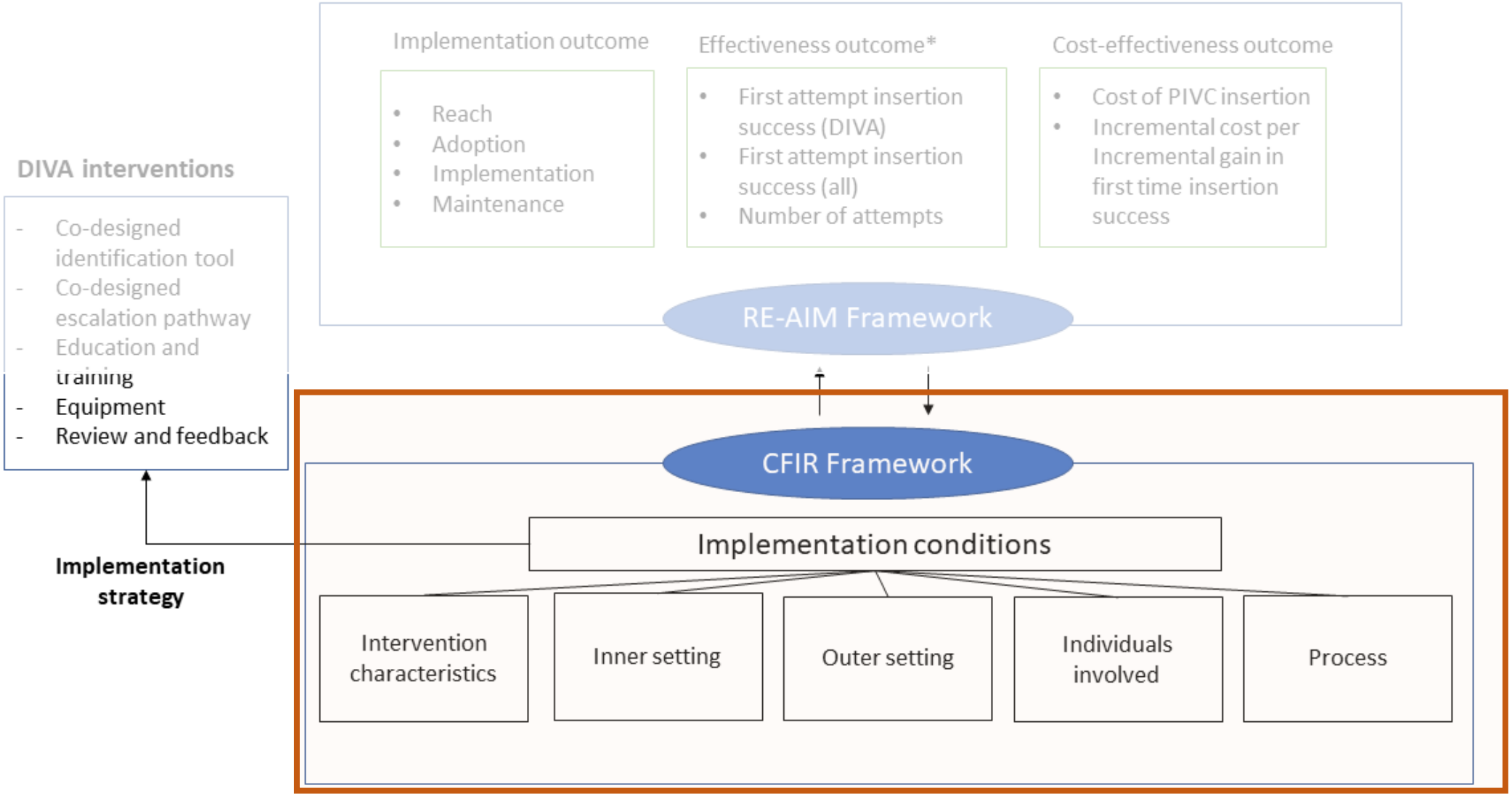
Reduce:
- Number of attempts
- PIVC failure
- Insertion/post-insertion complications
- BSI infection

Cost outcomes
- Cost of PIVC insertion
- Incremental cost per incremental gain in first time insertion success

Implementation outcomes
- Implementation
- Reach
- Adoption
- Maintenance & sustainability



1.Glasgow RE, Vogt TM, Boles SM. **Evaluating the public health impact of health promotion interventions: the RE-AIM framework**. Am J Public Health. 1999;89(9):1322-7.
2.Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. **RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review**. Front Public Health. 2019;7:64.
3.Keith RE, Crosson JC, O'Malley AS, Cromp D, Taylor EF. **Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation**. Implement Sci. 2017;12(1):15.



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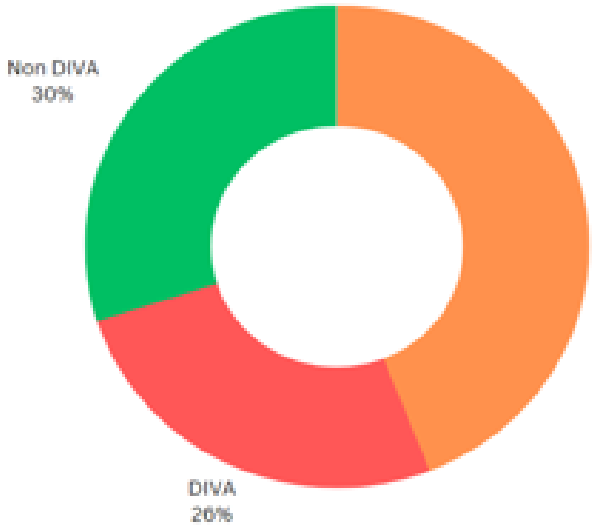
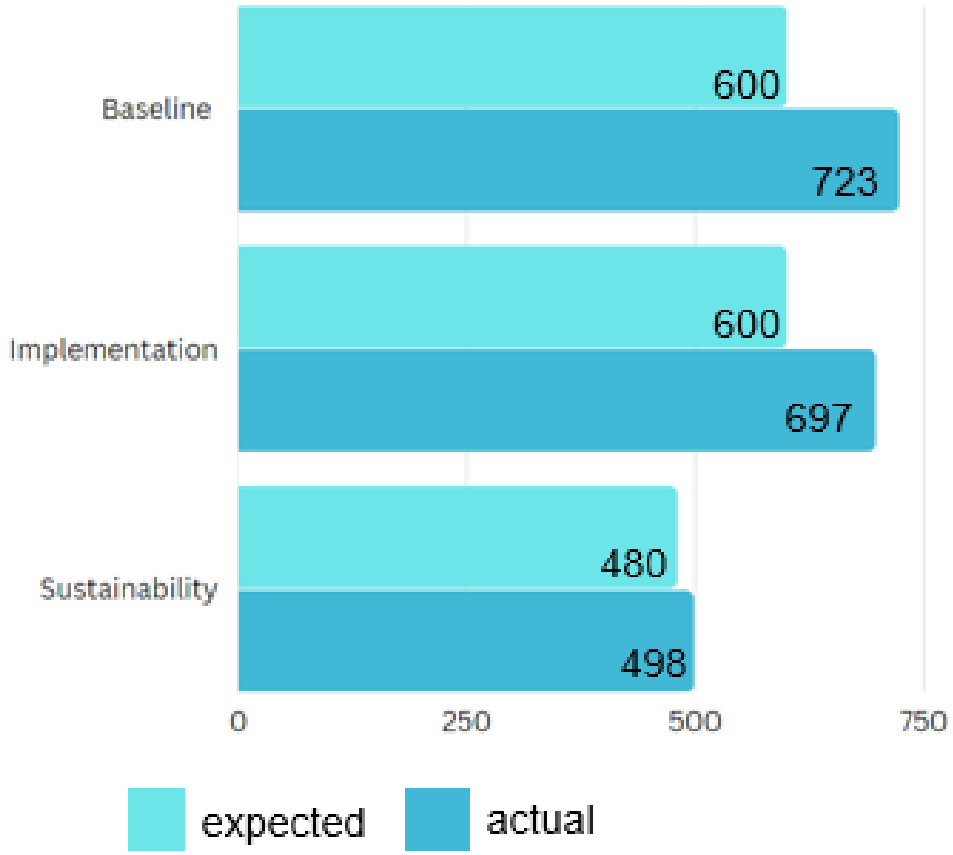
Results

Recruitment





Participant Demographics

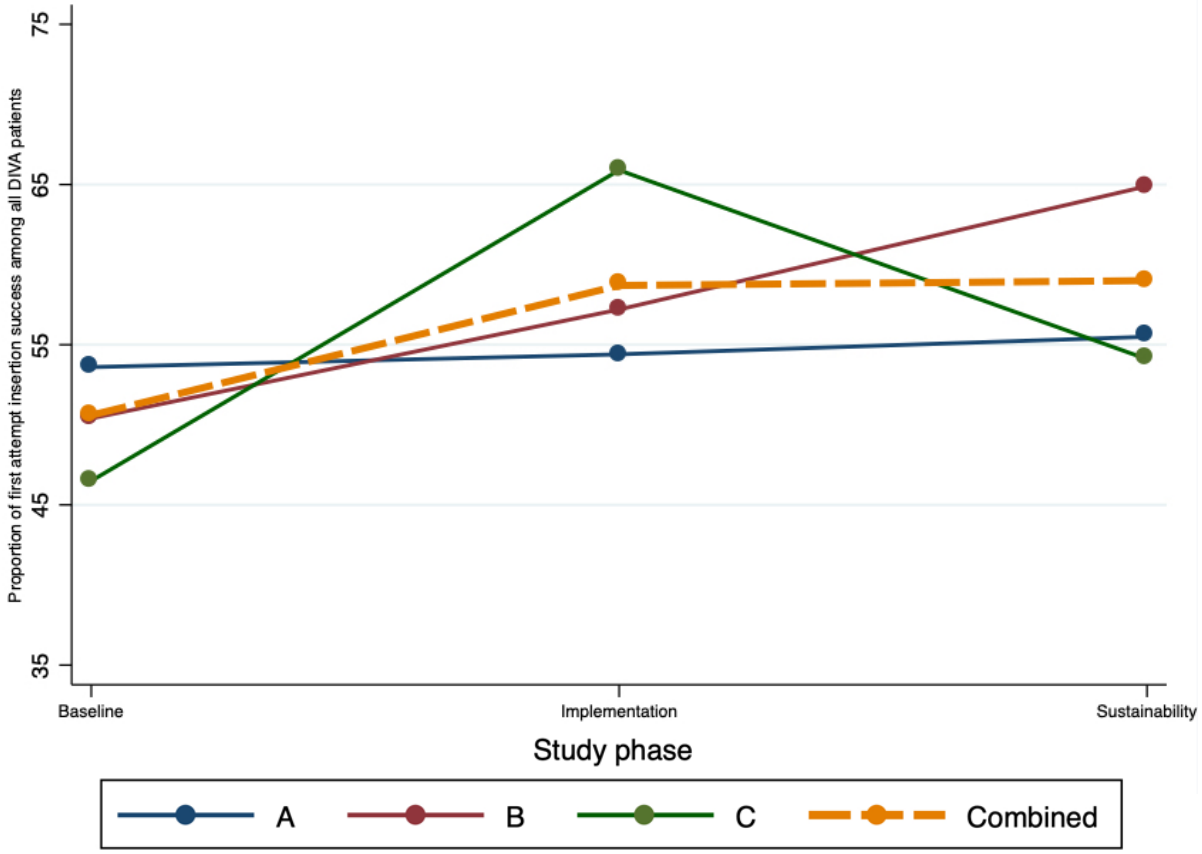
Characteristics	Baseline Frequency (%) or Median (IQR) N=673	Implementation Frequency (%) or Median (IQR) N=685	3-mo sustainability Frequency (%) or Median (IQR) N=237	6-mo sustainability Frequency (%) or Median (IQR) N=235
DIVA tool outcome				
Potential DIVA	285 (43%)	300 (44%)	120 (51%)	89 (38%)
Definite DIVA	192 (28%)	162 (24%)	51 (21%)	76 (32%)
Non-DIVA	196 (29%)	223 (32%)	66 (28%)	70 (30%)
Sex				
Male	386 (53%)	388 (57%)	141 (56%)	145 (59%)
Age in years				
Children (<18 yrs)	2 (0.2 to 8)	2 (0.3 to 11)	1 (0.3 to 7)	3 (0.2 to 10)
Adults (>18 yrs)	64 (47 to 76)	65 (51 to 75)	64.6 (48 to 75)	67.2 (51 to 76)

Primary outcome: First attempt insertion success

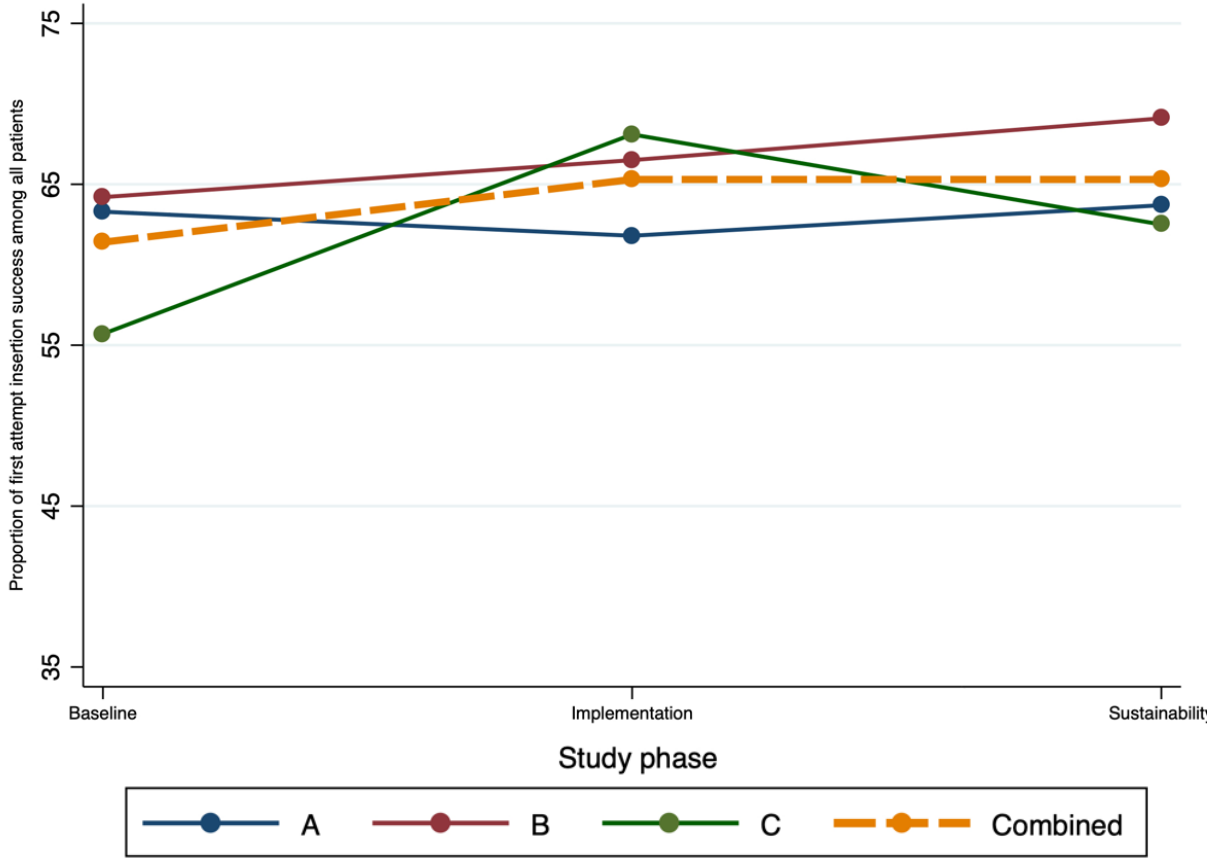
		Baseline	Implementation	Sustainability
DIVA pts	First attempt success among DEFINITE DIVA patients	80/192 (42%)	89/162 (55%)	67/127 (53%)
	First attempt success among POTENTIAL DIVA patients	161/284 (57%)	182/300 (61%)	131/209 (63%)
	First attempt success among ALL DIVA patients	241/476 (51%)	271/462 (59%)	198/336 (59%) **1.5 (1.1 to 2.2)** [1]
All pts	First attempt success among all patients	434/707 (61%)	452/692 (65%)	318/487 (65%)

Predictability of study phase on study outcomes (adjusted for trial step)
Effect estimate (95% CI), [1]Odds ratio

Proportion of first attempt insertion success



All DIVA



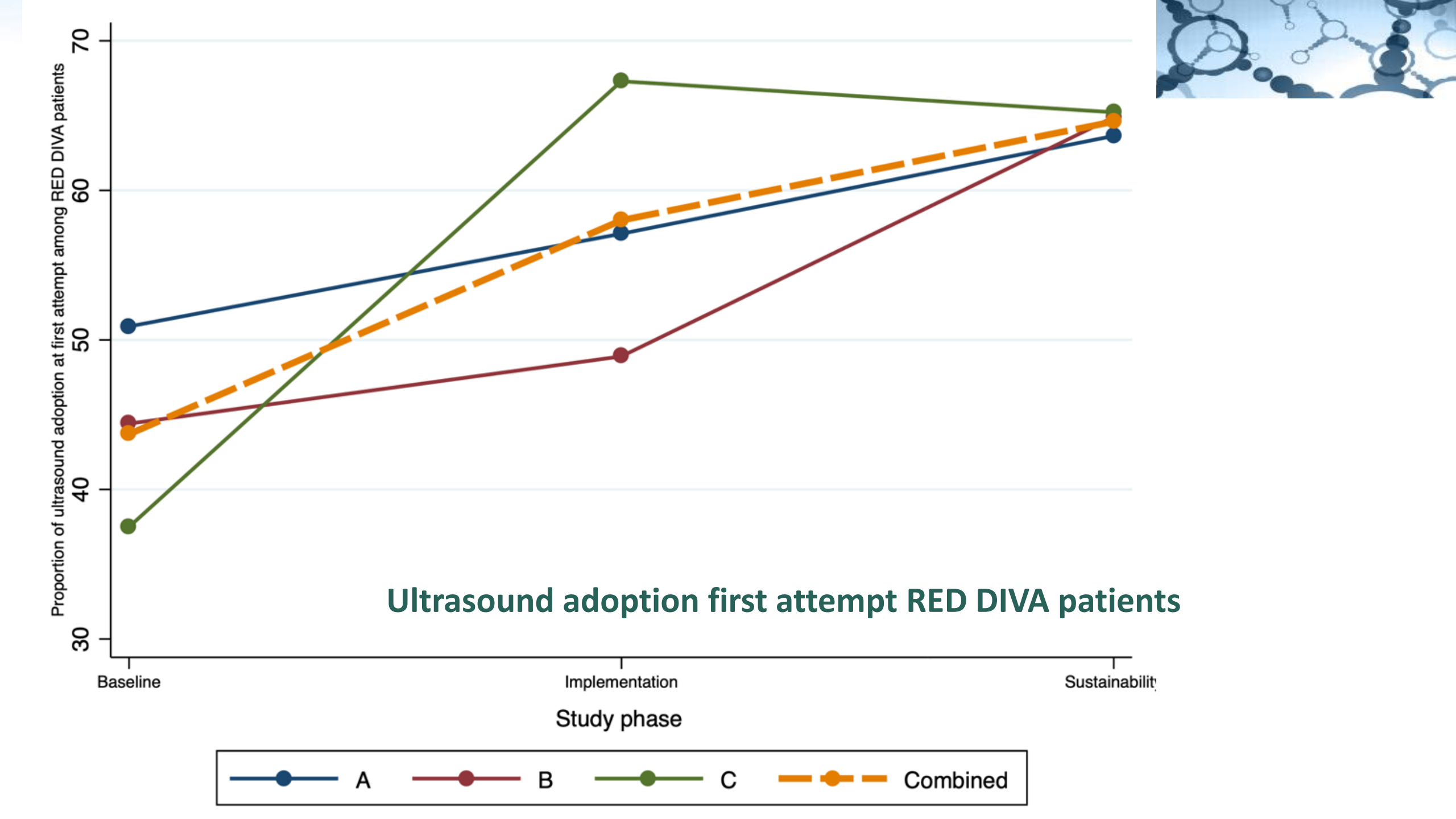
All patients

Ultrasound adoption

	Baseline	Implementation	Sustainability
First attempt among DEFINITE DIVA patients	69/158 (44%)	80/138 (58%)	53/82 (65%) ➡ **3.4 (1.9 to 6.8)**
First attempt among POTENTIAL DIVA patients	71/227 (31%)	62/259 (24%)	35/151 (23%)
First attempt among ALL DIVA patients	140/385 (36%)	142/397 (36%)	88/233 (38%) **1.6 (1.1 to 2.5)**
Any attempt among DEFINITE DIVA patients	129/190 (68%)	125/161 (77%)	95/125 (76%) ➡ **1.9 (1.1 to 3.6)**
Any attempt among POTENTIAL DIVA patients	127/280 (45%)	109/295 (37%)	65/206 (32%)
Any attempt among ALL DIVA patients	256/470 (55%)	234/456 (51%)	160/331 (48%)

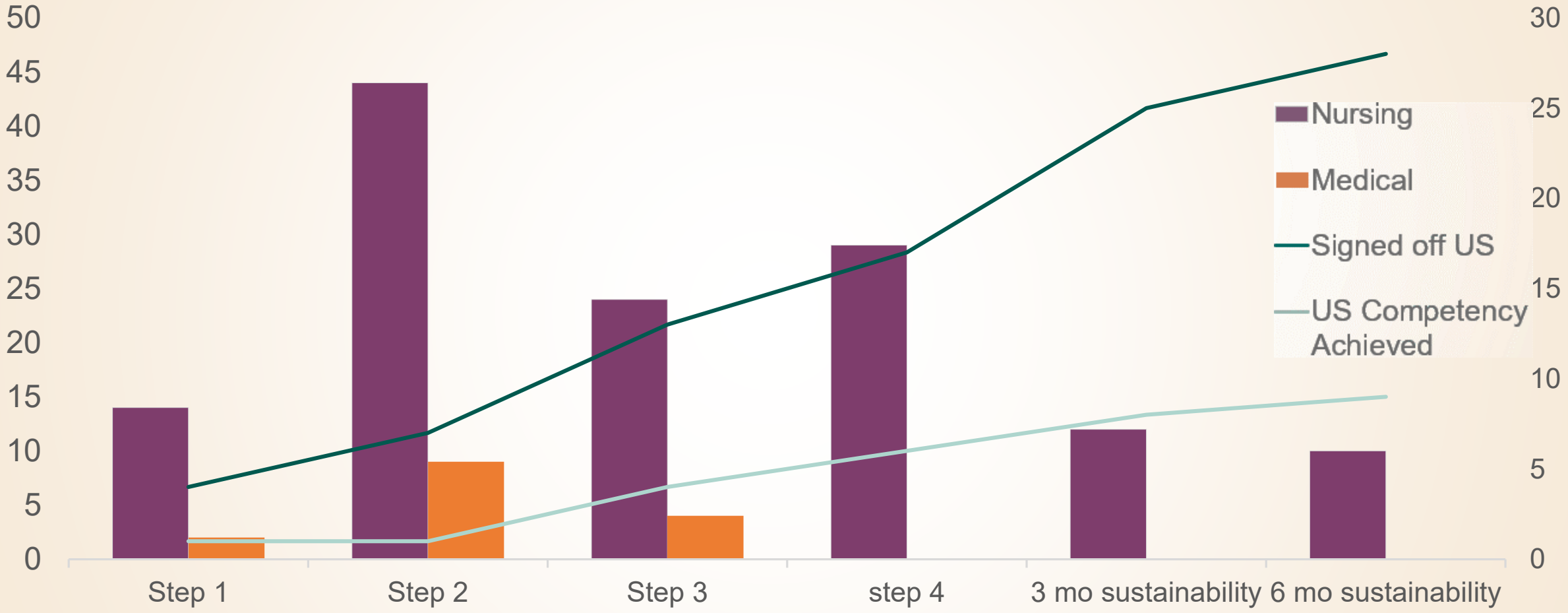
Predictability of study phase on study outcomes (adjusted for trial step)
Effect estimate (95% CI), [1]Odds ratio

Implementation outcomes



Ultrasound adoption first attempt RED DIVA patients

Reach: Ultrasound accreditation



*Example of conversion to ultrasound guided PIVC insertion competence at one site; Sign off and competency numbers are cumulative

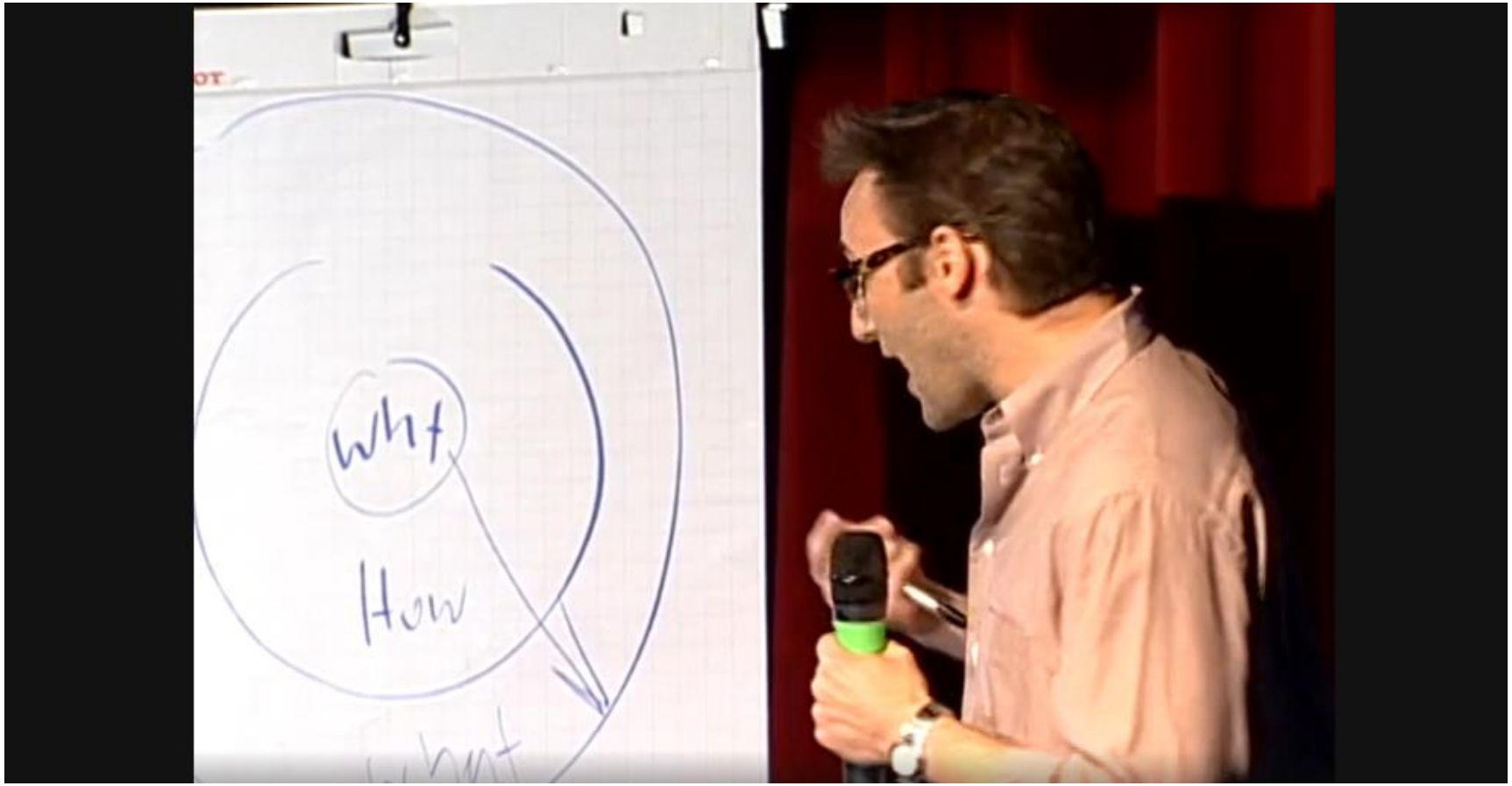
Patient/carer/inserter satisfaction and pain with insertion procedure

	Baseline	Implementation	Sustainability
Patient/carer satisfaction with insertion procedure	9.0 (7.0 to 10.0)	9.0 (8.0 to 10.0)	10.0 (8.0 to 10.0)
Patient/carer pain with insertion procedure	3.0 (1.0 to 5.0)	3.0 (1.0 to 5.0)	2.0 (1.0 to 4.0)
Staff satisfaction with insertion procedure	8.0 (6.0 to 10.0)	9.0 (8.0 to 10.0)	9.0 (8.0 to 10.0)

Scale 0 -10 numerical rating
Predictability of study phase on study outcomes (adjusted for trial step)
Effect estimate (95% CI), [2]correlation coefficient

Global health-service change is hard

Start with a golden circle and the question: "Why?"



TED Ideas worth spreading

Simon Sinek
Leadership expert

Ultrasound accreditation

Journal of Diagnostic Medical Sonography
Volume 35, Issue 5, September/October 2019, Pages 401-411

https://doi.org/10.1177/8756479319838234

SAGE journals

Literature Reviews

Accreditation,
Diagnostic Me

Kimberly Sorrentino,

Abstract

There are few regulati
medical sonography (D
based by the operator.
accreditation, credential
papers and 42 editorials
sonography specialty
correlations between accreditation and improved quality and also a positive correlation between credentialing and improved image quality. The survey studies revealed overwhelming support for accreditation and credentialing. Many articles raised concerns about the unknown quality of sonograms performed in nonaccredited facilities or by uncredentialed sonographers. If facility accreditation and/or individual credentialing could be implemented nationwide in DMS, it may lead to increased quality within the field.

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Bridging the logistical gap between ultrasound enthusiasm and accreditation

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The benefit of a vascular access specialist placing a peripheral intravenous catheter: a narrative review of the literature

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Table 1. Characteristics of included studies

Author (year)	State/Country	Setting	VAS team (label)	Comparison	Outcome measure
Bosma (2002)	British Columbia, Canada	Single centre; non-critical medical and surgical wards	'Infusion nurses'	*Not applicable*	Number of consultations; successful PIVC insertion
Carr (2010)	Galway, Ireland	Single centre; hospital wide	IV 'Cannulation 'Team	Pre–post commencement of IV Cannulation Team	First-time insertion success
Da Silva (2010)	Sau Paulo, Brazil	Single centre; medical, surgery, haematology and oncology units	'IV Team'	Pre–post commencement of IV Team	First-time insertion success; number of PIVCs; phlebitis
Hunter (2003)	Wisconsin, USA	Single centre (Phase 2); medical and surgical wards	'Vascular Access Team'	*Unclear*	PIVC-related complication; number of insertion attempts
Palefski (2001)	Unknown, USA	Multi-centre; hospital wide, 'infusion centre'; and patients' homes	'Infusion nurse'	Generalist nurse	PIVC-related complications
Meier (1998)	Iowa, USA	Single centre; acute and critical care wards	'Specialised IV Team'	House staff, medical students, and ward nurses	Primary BSIs
Miller (1996)	Pennsylvania USA	Single centre; medical and surgical wards	'IV Therapy Team'	House staff and nursing personnel	PIVC-related infections
Scalley (1992)	Colorado, USA	Single centre; hospital wide	'IV Team'	'Non-IVT'	Phlebitis
Soifer (1998)	Illinois, USA	Single centre; medical inpatient service	'IV team'	Medical house staff	PIVC-related complications
Tomford (1984)	Ohio, USA	Single centre; general medical firms (inpatient and outpatient units)	'IV team'	Medical house staff	PIVC-related complications

Thank you

- Patients involved in the study
- DART3 project team
- DART3 investigators
- Hospitals and health service partners
- Policy and government partners
- National Health and Medical Research Council
- University affiliates

Let's talk

Get In *Touch*

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““The secret to being good at anything is to approach it like a curious idiot, rather than a know-it-all genius.”
~ Mike Monteiro