

WOCOVA
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16-18 OCTOBER MEGARON
2022 ATHENS
GREECE

T-EDTA 4%: Lock solution

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Speaker Info and Disclosures

- Clinical Nurse Specialist, Advanced Practice Nurse: St. Paul's Hospital, Providence Health Care, Vancouver BC Canada
 - Portfolio: Vascular Access, IV Therapy, Home Infusion and Chemotherapy.
- Current Presidential Advisor/past president for AVA (2022)
- Past President for CVAA
- Consultant for/honouraria from:
 - Adhezion Biomedical
 - Angiodynamics
 - BD Medical
 - Interrad Medical
 - NIPRO
 - Smiths Medical
 - Sterile Care - *some content in this presentation was adapted from SterileCare, Inc. with permission.
 - Teleflex Medical

Objectives

1. Review the importance of CVADs in healthcare delivery and the need to prevent complications.
2. Describe the benefits and use of T-EDTA 4% as a CVAD lock solution, using current experience in Canada as successful examples.
3. Compare T-EDTA 4% to other lock solutions and describe why T-EDTA 4% is the best option to prevent CVAD complications.

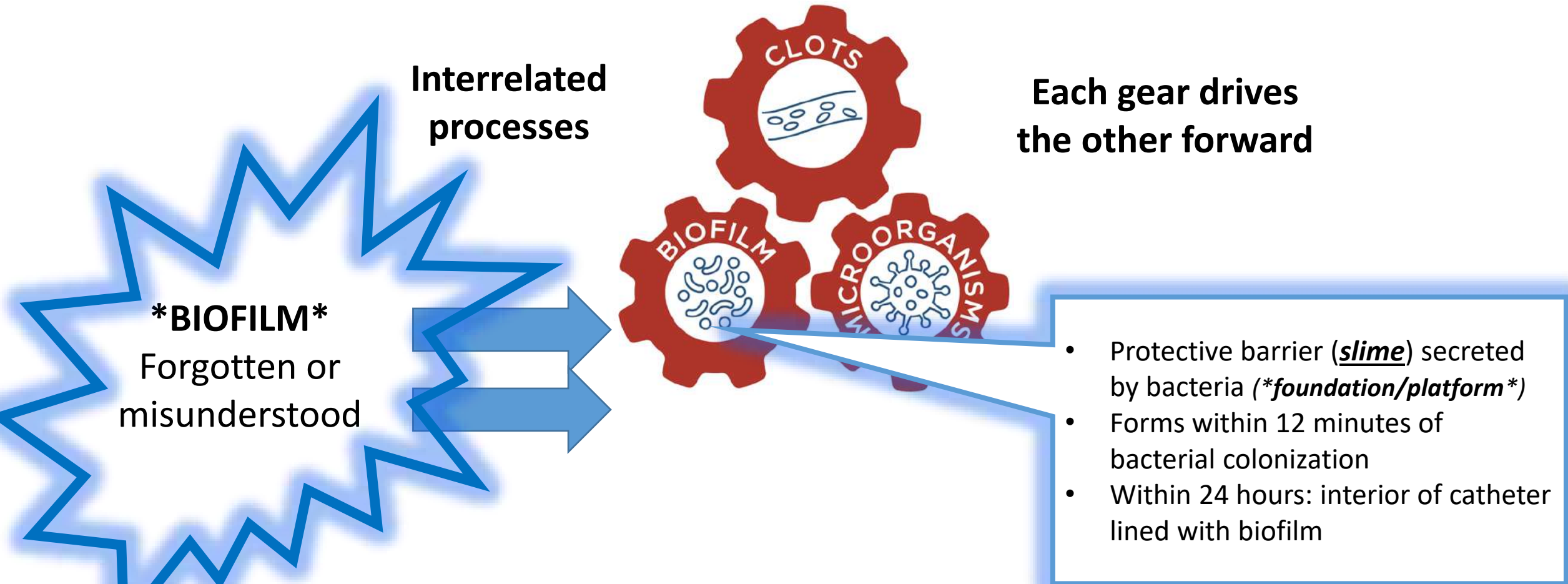
CVADs – Vital device in healthcare

Lifelines.

- IV hydration
- Trauma / resuscitation
- Medications – antibiotics, anti-emetics, analgesics, cardiac support, kidney support, anesthesia, thrombolytics, anticoagulants
- Chemotherapy
- Blood products
- Parenteral nutrition
- Blood sampling



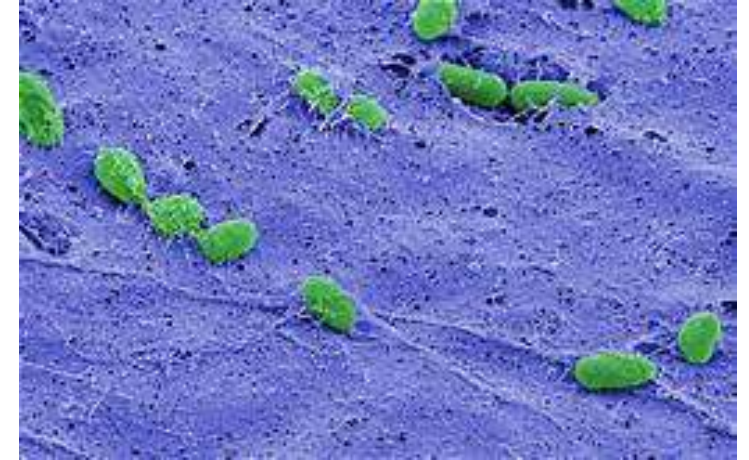
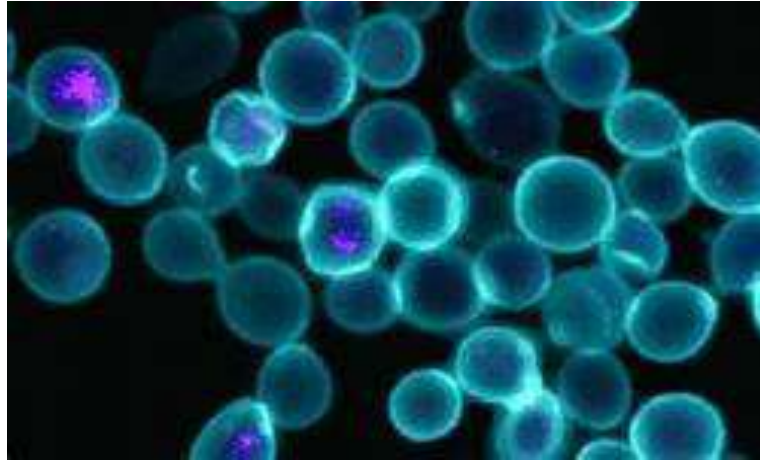
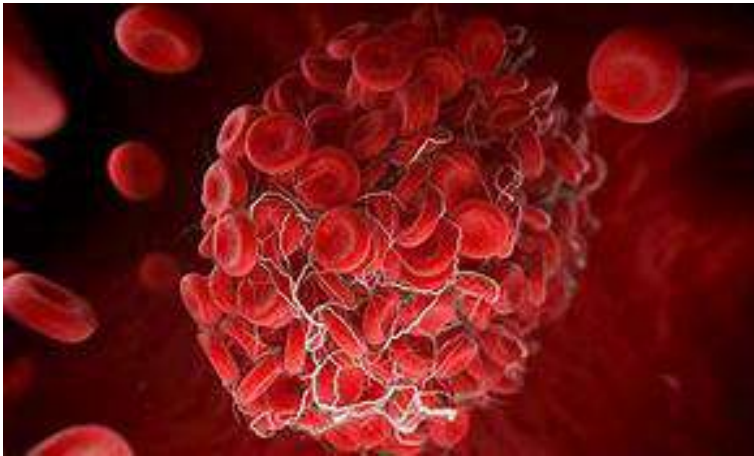
Three threats = Lead to Complications



Need to stop all three processes to reduce complications

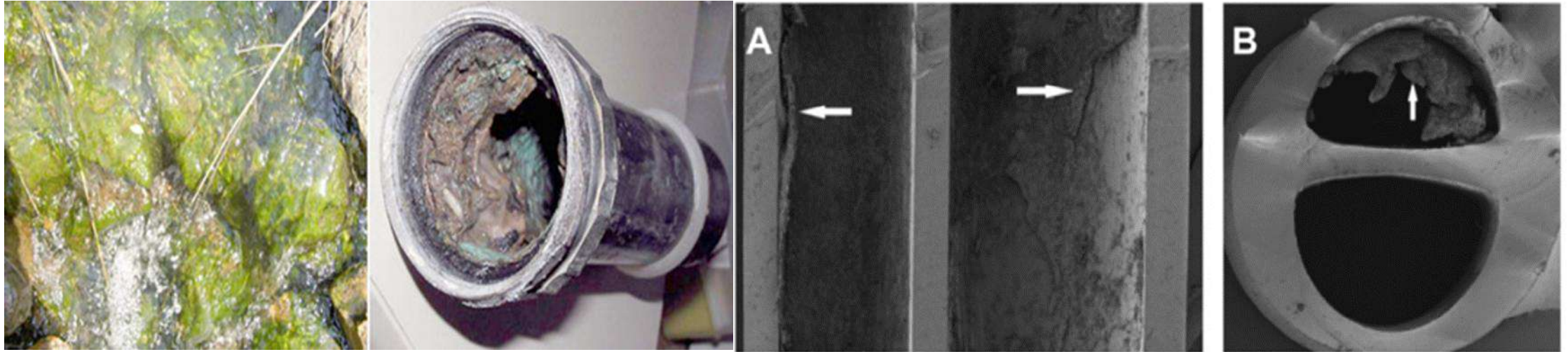
NOTE: Biofilm associated with multi-drug resistant bacteria

CVADs: Infection and Occlusion Complications



- CLABSI numbers have come down over the years however we are facing higher risks.
- Occlusion rates not tracked accurately
- 12-25% death rate related to infections
- 1 in 6 infections are related to antibiotic resistant bacteria (super bugs)
- 22-40% with patency complications
- 63% increase in CLABSI during COVID19 pandemic

Threat: Infections/Occlusions related to Biofilm



Biofilm can block our water lines >>>>>

How do we not consider it a factor in CVAD patency and infection?

Patient impact

- Blocked CVAD = need for thrombolytic therapy
- Infected CVAD = need for antibiotic therapy
- Suboptimal, sub therapeutic dosing of medication and therapy
- Interruption and delay of therapy, medication, nutrition, procedure requiring vascular access
- Stress, anxiety, pain, worsening of disease, no relief of symptoms
- Disruption of healing process
- CLINICAL/HEALTHCARE IMPACT?

The solution

- Stop the cycle of threats
- Stop the threats
- Get to the root / foundation of the problem = BIOFILM

*tetrasodium
ethylene-diamine-tetra-acetic acid*

Tetrasodium EDTA 4%

- Chelator
 - Strong binding affinity for calcium
 - Inhibits coagulation cascade
 - Kills planktonic/sessile bacteria
 - Penetrates and dismantles biofilm matrix

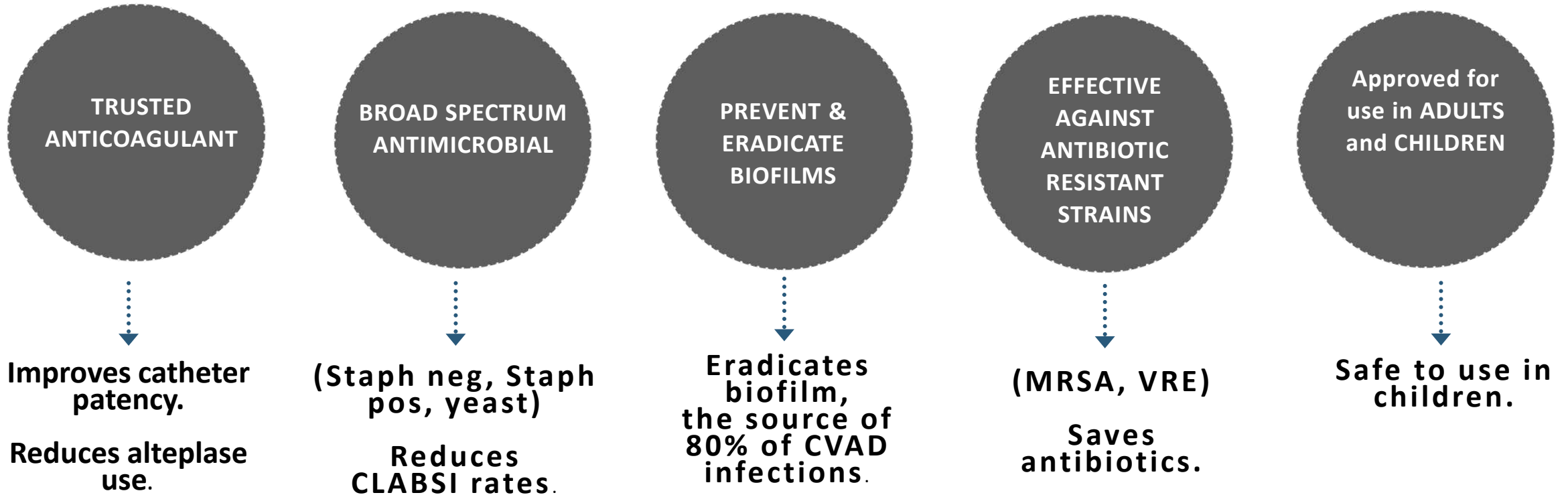


Disodium EDTA

Anticoagulant	√	Trusted anticoagulant (intraluminal only; not systemic) 10 times stronger than citrate
Antimicrobial	√	Effective against gram positive, gram negative and yeast
Antibiofilm	√	Prevents and eradicates biofilm (MIC/MBC/MBEC) All bacterial and fungi strains (including super bugs)

- Regulatory approved for use in children (Health Canada, CE Mark, TGA (Australia))
- T-EDTA 2%: human-use clinical data not yet available

THE SOLUTION



In the literature from



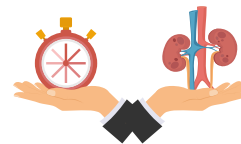
Landmark article 2018:

American Society for Microbiology

Liu F, Hansra S, Crockford G, Köster W, Allan BJ, Blondeau JM, Lainesse C, White AP. Tetrasodium EDTA is effective at eradicating biofilms formed by clinically relevant microorganisms from patients' central venous catheters. *MSphere*. 2018 Nov 28;3(6):e00525-18.

- Microbiological Analysis of 300 CVAD tips
- tEDTA effectiveness against biofilms
- Microbiology of Dialysis Catheters: DNA Sequencing

SickKids®



Clinical Efficacy In Adults on HPN

- 71% reduction in CLABSI ($p = 0.04$)
- 100% reduction in occlusions
- 63% reduction in healthcare cost

Reduction of Central Line Complications in Pediatrics

- 100% reduction in infections ($p = 0.002$)
- 50% reduction in occlusions ($p = 0.018$)
- Markov Model proves financial efficacy of KiteLock™ compared to standard of care, heparin

Canadian Dialysis Units

- Up to 70% reduction in occlusions and alteplase use (costly clot busting drug)
- Data presented at the World Congress of Nephrology April 2021

CanHealth Network Projects



Hamilton Health Sciences (Cancer Center)

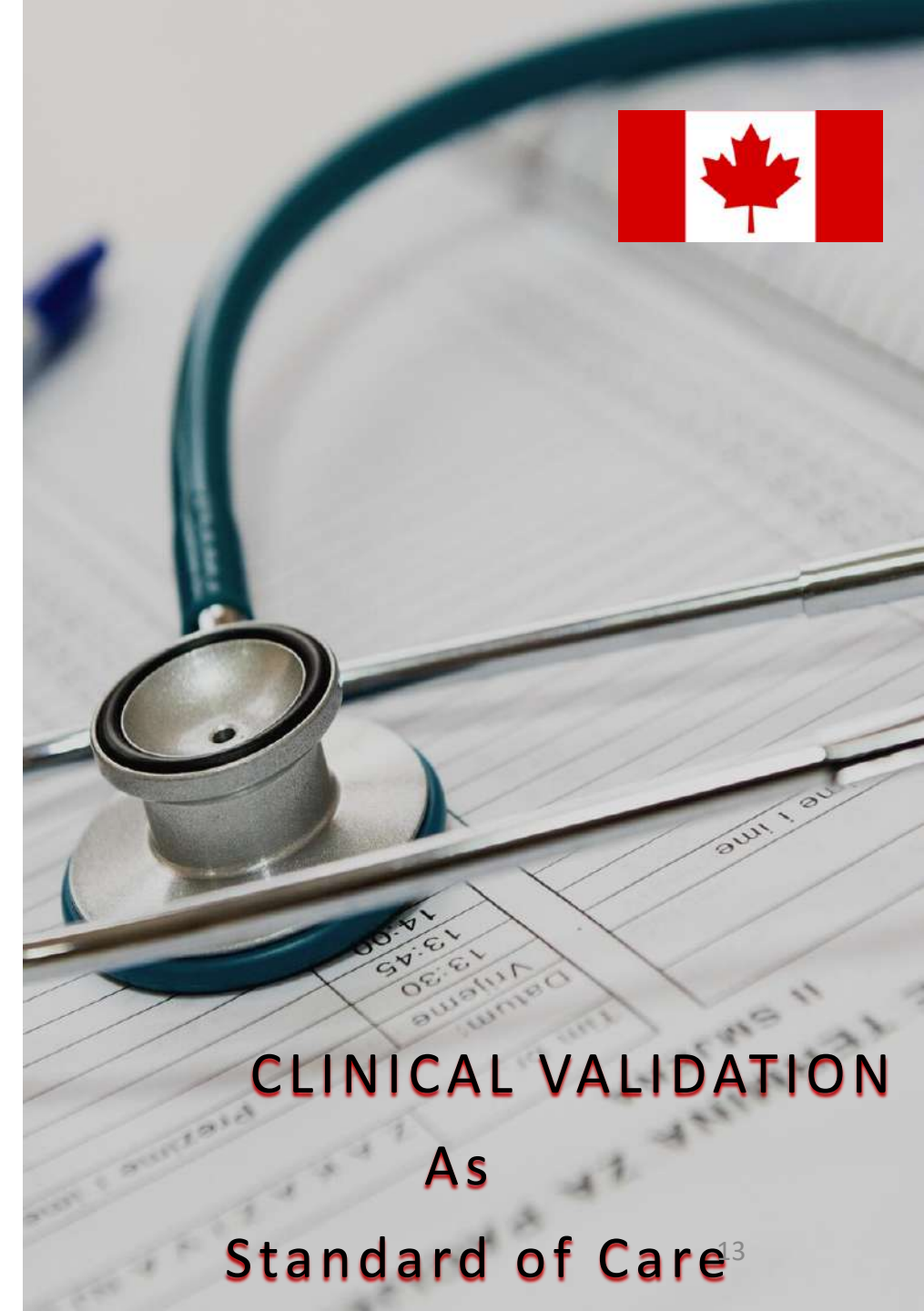
- Hospital wide conversion to KiteLock™ from Oct '21 to April '22 (during the 6th COVID wave)
- Hematology and oncology patients
- Results showed a significant difference of 60% reduction ($p=0.046$) in CLABSI

CLiCK Study

- Pre-Observation Study: 20% of CVADs are locked
- CLiCK Trial (Control of Line Complications with KiteLock™)
- Multi-Centre, cluster randomized, double blinded; crossover study
- **5 Canadian Sites**; 3600 patients
- Decrease in CVAD complications: CLABSI, occlusions (alteplase use)

UHN Dialysis

- Quality Improvement Project to determine:
 - Decrease in occlusions (alteplase use)
 - Decrease in infections
 - Financial Impact



CLINICAL VALIDATION
As
Standard of Care

CLOCK Trial - Australia



\$2 million boost to improve treatment for children with cancer - Faculty of Medicine - University of Queensland

The Accelerating Collaborative Cancer Research (ACCR) grant provides funding of \$2,000,000 over four years, comprising \$350,000 per annum from Cancer Council Queensland and a contribution of \$150,000 per annum from UQ.

medicine.uq.edu.au

Preventing adverse events during pediatric cancer treatment:

- multi-site hybrid RCT of catheter lock solutions
- 756 patients
- Australia (Queensland, Victoria, New South Wales and New Zealand)
- Type-1 Hybrid effectiveness-implementation three-arm, superiority, effectiveness RCT (funding by Cancer Council Queensland)

GOAL: Level One Evidence to Change Clinical Practice Guidelines.

Product	Anticoagulant	Antimicrobial	Antibiofilm (prevent) MIC/MBC	Antibiofilm (eradicate) MBEC	Comments
Saline	X	X	X	X	Lock/flush
Heparin	√	X	X	X	Stimulates biofilm; HIT
Citrate 4%	√	√	√	X	Need for thrombolytic treatment
Citrate 46.7%	√	√	√	X	Reduced antimicrobial effect
Citrate 4% +/-30% Ethanol	√	√	√	X	Protein precipitation; need for thrombolytic treatment
Ethanol 70%	X	√	√	X	Stimulates biofilm; need for thrombolytic tx; CVC damage
Antibiotic cocktail	X	√	√	X	Antibiotic resistance risk; not efficient against biofilm
Taurolidine ± heparin, ± 4% citrate, ± urokinase	√	√	√	X	G+ limitations; need for thrombolytic treatment
rtPA/urokinase	X	X	X	X	Most likely to be associated with undesired effects or hemorrhagic complications; costly
4% T-EDTA	√	√	√	√	MBEC ≤ 4% for G+, G-, yeast including MDR microorganisms

T-EDTA 4% – hits the mark for the Triple Threat

- Decrease in alteplase use for occlusion management.
- Decrease in infection leading to decrease use of antibiotics and therefore also minimizes antibiotic resistance.
- Prevents formation and eradicates biofilm.

USE AS STANDARD OF CARE FOR
CVAD LOCK SOLUTION



In addition...T-EDTA 4%:

- Labelled and approved as a medical device, not as a drug.
- Approved for use in children.
- Compatible with common catheter material such as polyurethane and silicone – will not interact or interfere with catheters that are coated or impregnated.
- Documented safety profile if unable to aspirate (no documented complications related to serum calcium levels or growth).

Summary

- The CVAD is a lifeline for our patients.
- Goals to preserve and protect the CVAD are paramount.
- The Triple Threat will impact CVADs and patients – Biofilm is the underappreciated, foundational threat.
- 4% T-EDTA is the lock solution that will best preserve and protect the CVAD.
- Global expansion of use and continues to be studied and proven.

Conclusion

- ❖ Focus on the key properties of a lock solution
 - Anticoagulant
 - Antimicrobial
 - Antibiofilm = **prevent AND eradicate**



- ❖ ***Don't take biofilm for granted.***

It is the foundation of all threats and the lock solution must tackle it in order to be fully effective to fight complications.

- ❖ T-EDTA 4% is the lock solution that will tackle all 3 threats as a ***non-antibiotic, antimicrobial solution.***
- ❖ Final word: ***Patients.***
 - Let them focus on their treatment, not complications related to their CVAD

Patient Testimonials

Since Kiera started on KiteLock™ 4% four years ago, she has Not been to the hospital once for a line blockage - it's been life-changing for all of us!



KEIRA

I have never felt so confident that I can get on with life and travel without concern about a sepsis incident since beginning to use KiteLock™ 4%.



LAURIE

Thank you

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2023 CVAA & WOCOVA SPECIAL EVENT

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Global Vascular Access Network

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World Congress Vascular Access

48th Annual CVAA Conference

April 26-28, 2023

Toronto, ON



WoCoVA GloVANet
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