2-2021

CONEXO

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Jefferson
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conexo

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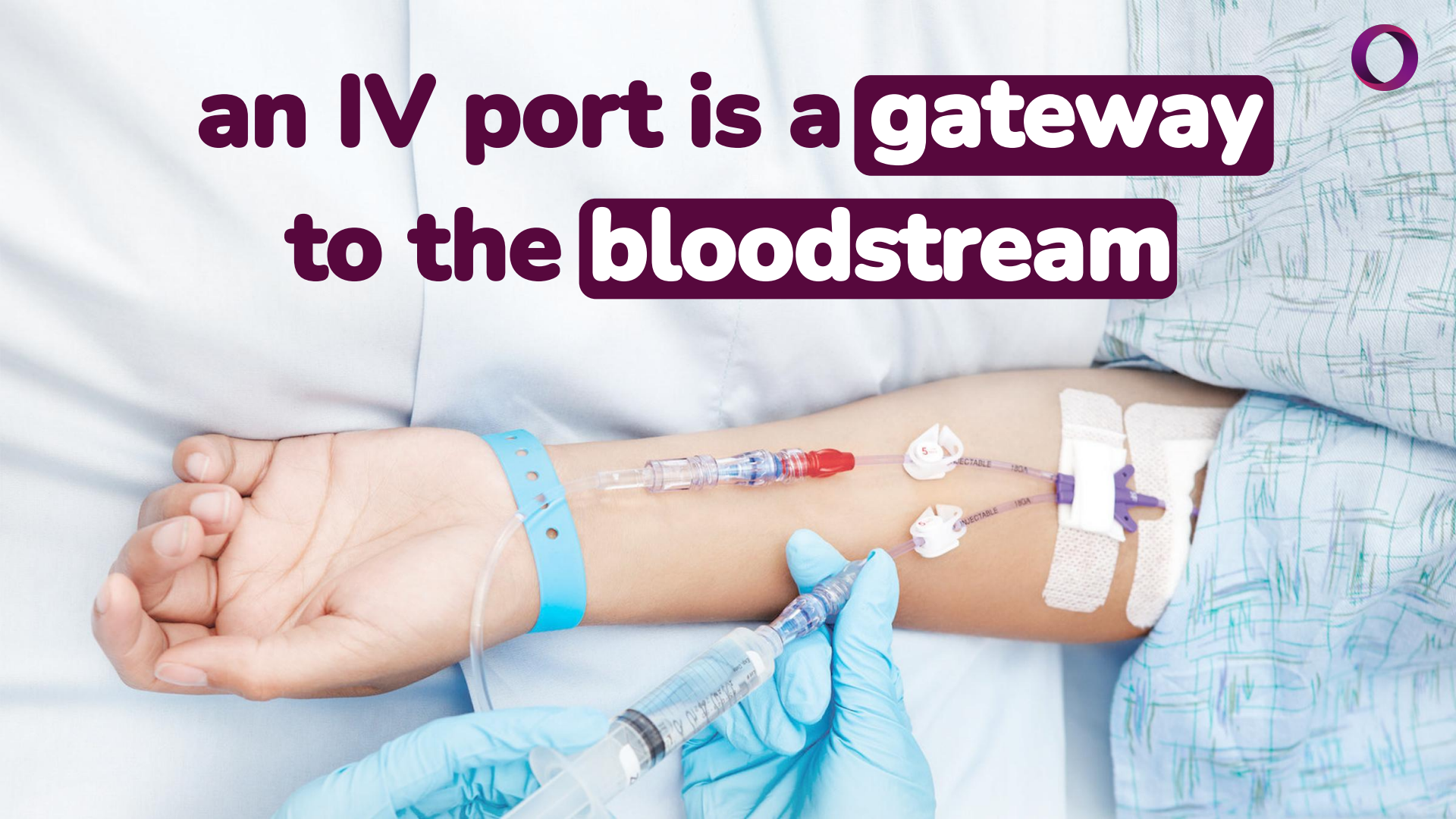
Gigi Geary
Lauren Huggler
Stephanie Szymanski
Dr. Matthew Fields*

(*) Indicates primary advisor
(**) Indicates another student who is also declaring the same project as primary for SI

intro


an IV port is a gateway
to the bloodstream

30,000 CLABSI cases

annually in US ICUs

up to

25%

mortality rate

7,500

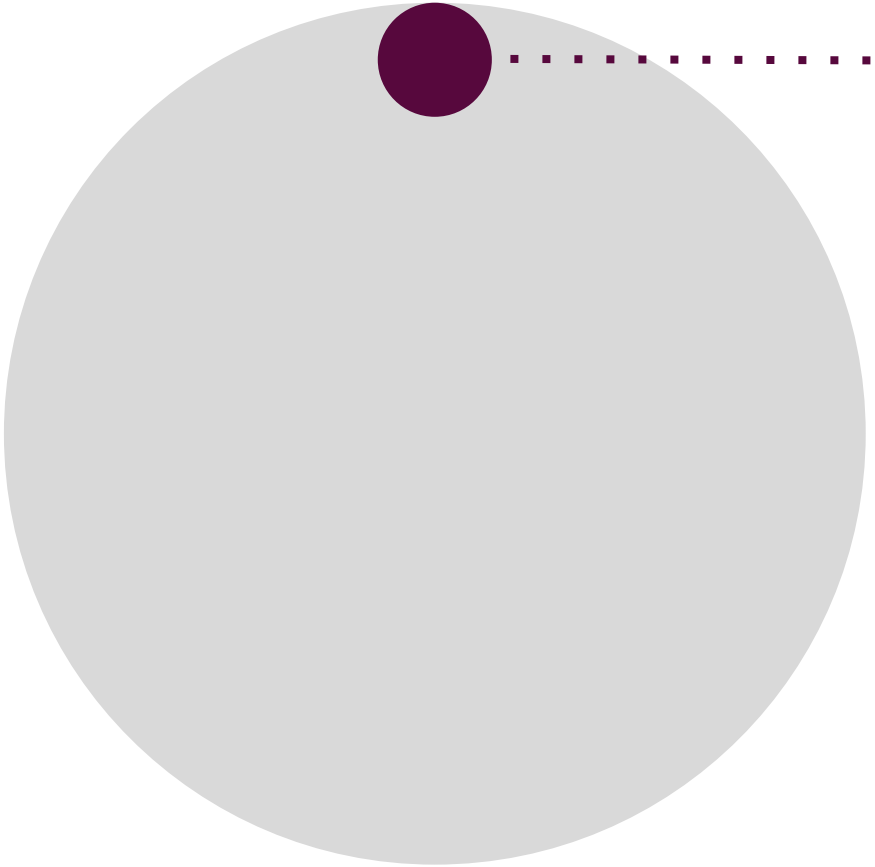
deaths per year

5-20 day

extension of hospital stay

$45,000

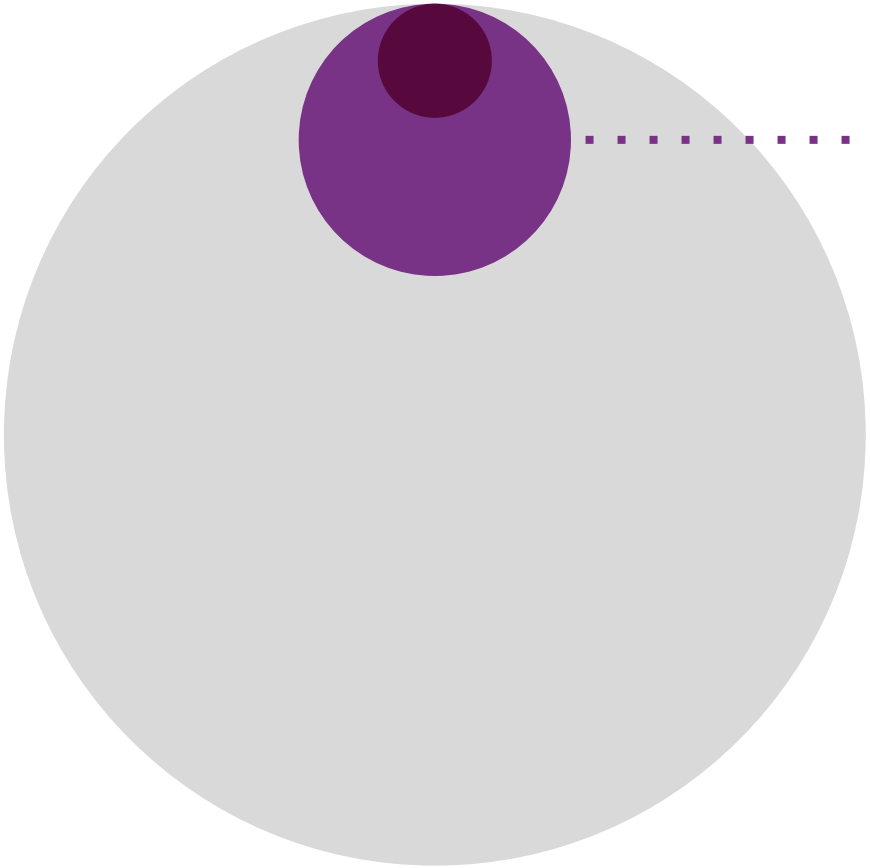
avg. additional patient cost



CLABSI in ICUs*

30,000 cases

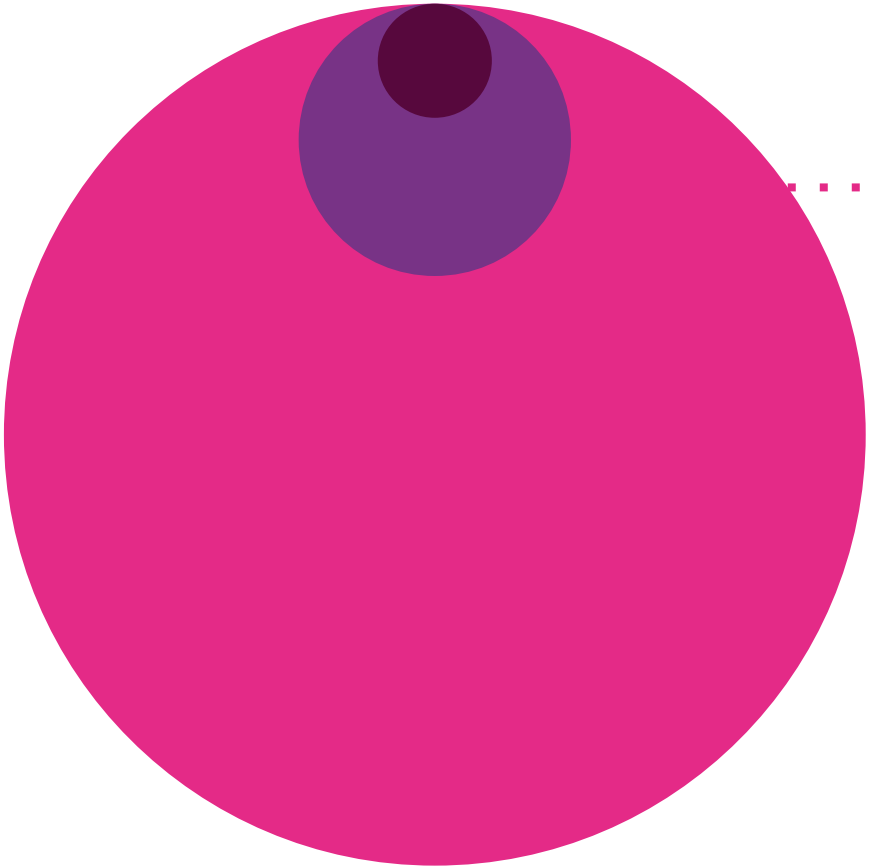
**annually in the United States*
CLABSI: Central Line-associated Bloodstream Infections



CRBSI in ICU*

80,000 cases

**annually in the United States*
CRBSI: Catheter-related Bloodstream Infections



CRBSI in hospitals*

250,000 cases

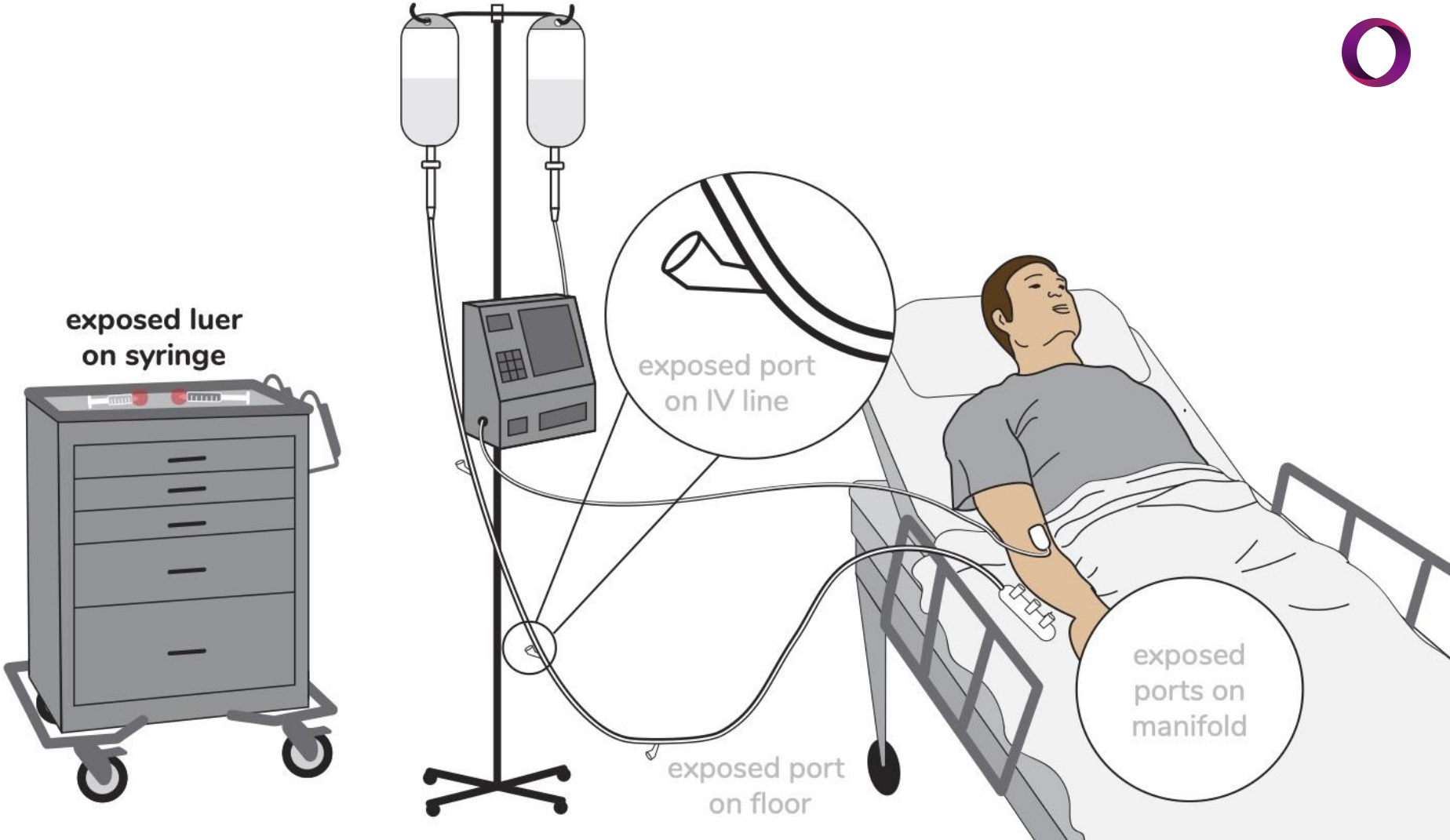
**annually in the United States*
CRBSI: Catheter-related Bloodstream Infections

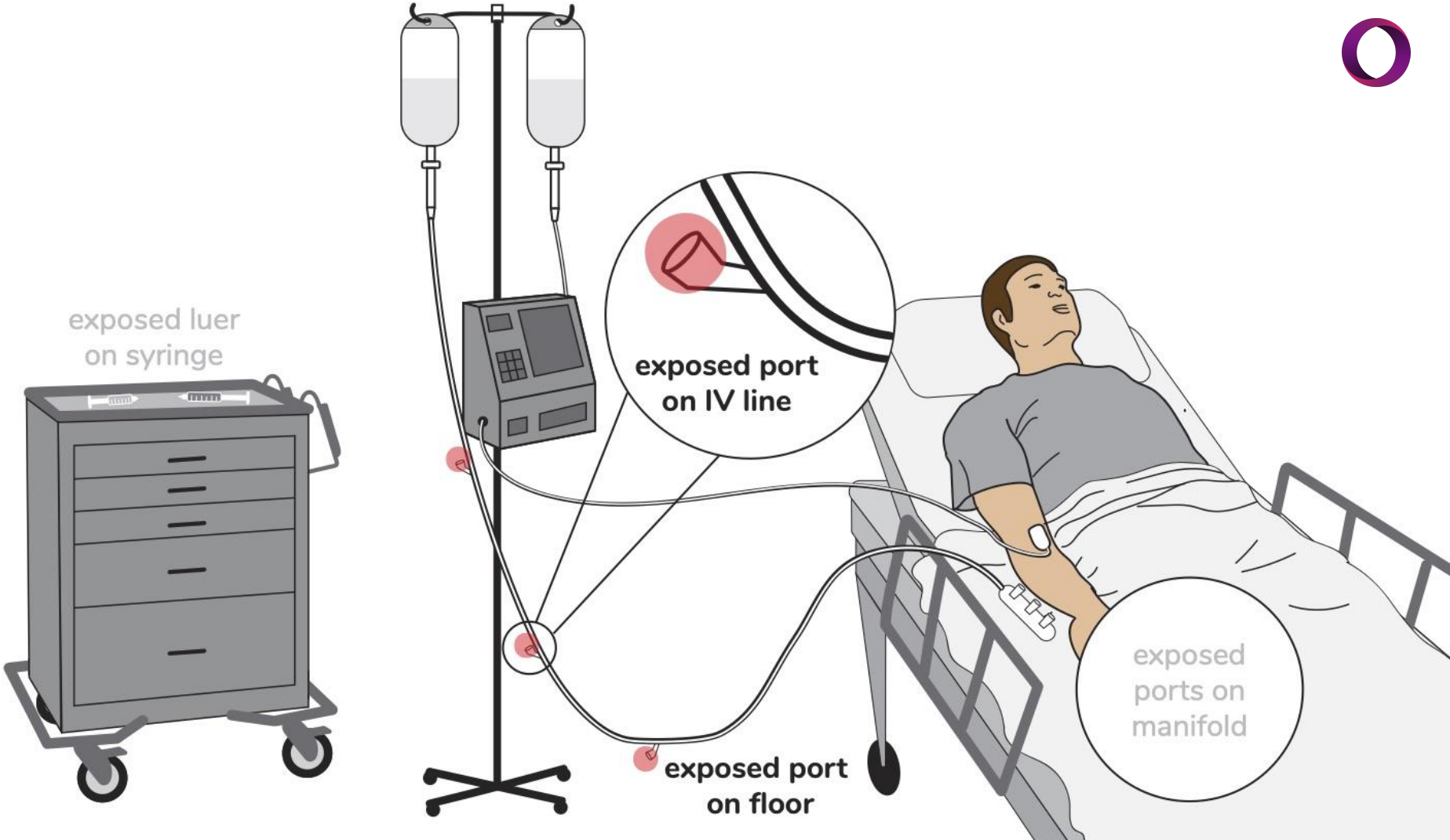
Catheter-related bloodstream infections (CRBSI) are **preventable**.

continuous exposure

incidental contact

misalignment


exposed luer
on syringe
exposed port
on IV line
exposed port
on floor
exposed
ports on
manifold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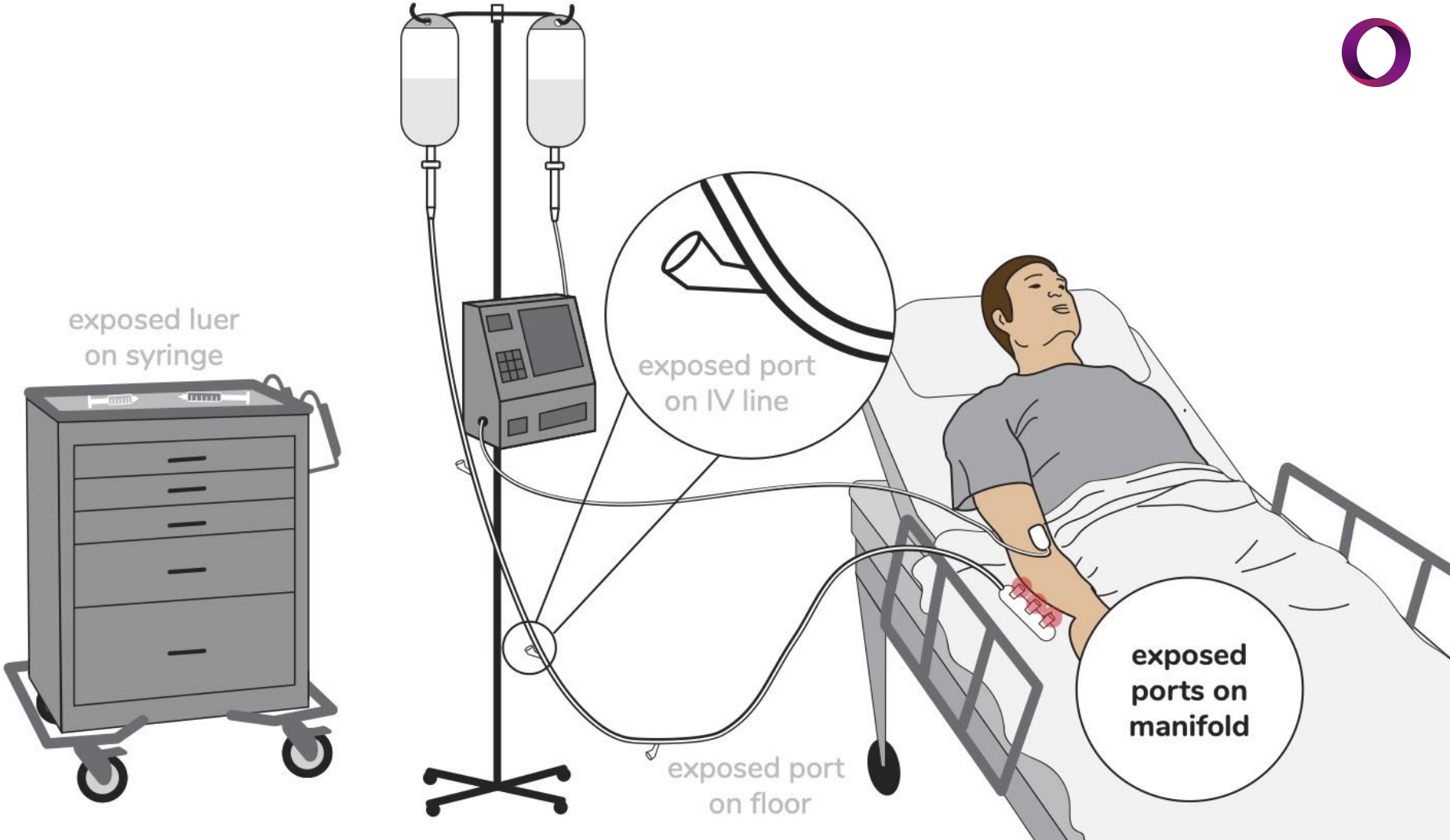

exposed luer
on syringe
exposed port
on IV line
exposed port
on floor
exposed
ports on
manifold

How might we help

healthcare workers

keep IV lines clean

in order to

reduce **preventable**

bloodstream infections?

background

how to prevent central line associated bloodstream infections

> Am J Infect Control. 2020 Feb;48(2):216-218. doi: 10.1016/j.ajic.2019.08.010. Epub

Assessing burden of central line-associated bloodstream infections present on hospital admission

Hannah Leeman [1], Sara E Cosgrove [2], Deborah Williams [3], Sara C Keller [4]

Affiliations + expand

PMID: 31515099 PMCID: PMC6980992 DOI: 10.1016/j.ajic.2019.08.010

Free PMC article

Achieving Zero Catheter Related Blood Stream Infections: 15 Months Success in a Community Based Medical Center

Sophie A. Harnage, BSN, RN

CLABSI–Related Morbidity, Mortality, and Costs

It has been estimated that 80,000 CLABSIs occur in ICUs in the United States each year[46]; however, if patients outside ICUs are also included, the estimate increases to 250,000 cases of CLABSI each year.[3] CLABSIs are serious but often preventable infections when evidence-based guidelines are followed for the insertion and maintenance of central lines. This preventability is even more acutely apparent in developing countries, where use of these devices may occur in the absence of the most basic infection prevention and control practices and limited availability of supplies.[38,40]

Incidence of Intravenous Medication Errors in a Chinese Hospital

Qian Ding, PhD[1,], Kenneth N. Barker, PhD[2], Elizabeth A. Flynn, PhD[3], Salisa C. Westrick, PhD[2], Ming Chang, MS[4], Robert E. Thomas, PhD[5], Kimberly Braxton-Lloyd, PhD[6], Richard Sesek, PhD[6]*

[1]*Department of Pharmaceutical Sciences, Ferris State University, Big Rapids, MI, USA;* [2]*Department of Health Outcomes Research and Policy, Auburn University, Auburn, AL, USA;* [3]*Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida, Gainesville, FL, USA;* [4]*China Resources Purenhong Pharmaceutical Co., Ltd., Beijing, China;* [5]*Department of Industrial and Systems Engineering, Auburn University, Auburn, AL, USA;* [6]*Department of Pharmacy Practice, Auburn University, Auburn, AL, USA*

ABSTRACT

Objectives: The purpose of this study was to explore intravenous (IV) medication errors in a Chinese hospital. The specific objectives were to 1) explore and measure the frequency of IV medication errors by direct observation and identify clues to their causes in Chinese hospital inpatient wards and 2) identify the clinical importance of the errors

as prepared and administered to the patients wa
3, 2010, to August 13, 2010. The overall error rat
ward was 12.8%. The most frequent errors by ca
(5.4%), wrong time (3.7%), omission (2.7%), unor
extra dose (0.3%). Excluding wrong time errors,
Non-TPN medications had significantly higher e

ESTIMATE HOW MANY LINE INTERACTIONS HAPPEN DAILY

15M CVC days in the ICUs in the US/year

5M CVC insertions in the US/year

Need to be flushed every 12 hours with either saline or heparin

CLABSI rate in intensive care units (ICU) is estimated to be 0.8/1000 central line days

55% of ICU patients and 24% of non-ICU patients had central lines. 70% of hospitalized patients with central venous catheters were outside the ICU

The mean number of infusion pumps was 4.8 ± 2.6

Does this mean we can just take ICU numbers and multiply it by this ratio????

Only if the infection rates are same in the ICU and out of the ICU

The rates of CLABSI associated with PICCs are statistically similar to the conventional central venous catheters (CVCs) in the hospital setting[8]. In a multi-center study of 27,289 patients, CLABSI outcomes between the PICCs placed in ICU compared to the general medical ward were similar. However, the study was limited, with an overall low number of events

So this says infection rates are same in the general ward of the hospital and ICU, but what about outside of the hospital??

4 hr/shift
4.5 pt/shift
47.05 infusions/shift

2.61 infusions per patient per hour

62.64 infusions per patient per day

62.64 infusions per CVC Day

939.6M infusions per year in US ICUs

Not including infusions within ER, OR, or outpatient environments

The cumulative incidence of CRBSIs for PICCs is 1.1 per 1000 PICC-days. However, it is found to be higher in the inpatient setting (2.1 per 1000 PICC-days). This could be because patients managed on an outpatient basis are healthier in general, and their catheter is accessed less frequently. There is still question whether PICCS or centrally inserted venous catheters (CICCs) have lower infection rates. Though past studies have argued for lower infection rates with PICCS among critically ill patients, recent publications, in including a 2016 study comparing 200 PICCs and 200 CICCs, have shown no difference.

CVC vs PICC

Can CVCs be used in the ER?

# of interactions different between hospital/ non hospital use

COST ESTIMATES

Globally, length of stay increases between 5-20 days

Many hospitals now have "PICC nurses" teams or IV teams dedicated just to placing lines - this has decreased complications but I'm sure it adds to the cost

Hospitals employing QA teams specific for CLABSI have shown decreased infection rates at no additional cost when compared to "non-program" hospitals...

$1.85B spent annually treating CLABSI

CLABSI most expensive HAI to treat; adds an average of $45,814 to patients' hospital bills

CLABSI – The Data

~30,000 CLABSI Events annually

- ~46% Reduction
- Mortality Rate 12-25%
- Cost ~ $70,696

	CLABSIs Prevented*	Deaths Prevented		Excess Costs Averted*
		Mortality Rate 12%	Mortality Rate 25%	
Reported	2,187	262	547	$36,194,850
Estimated	2,419	290	605	$40,034,450

Estimates of infections and deaths prevented and excess costs averted among participating adult ICUs using all data ("reported") and data after missing value imputation ("estimated") using CDC estimates

Health Research and Education Trust.(October 2012), Eliminating CLABSI, A National Patient Safety Imperative – AHRQ. Retrieved from https://www.ahrq.gov/sites/default/files/publications/file/clabsicompanion.pdf

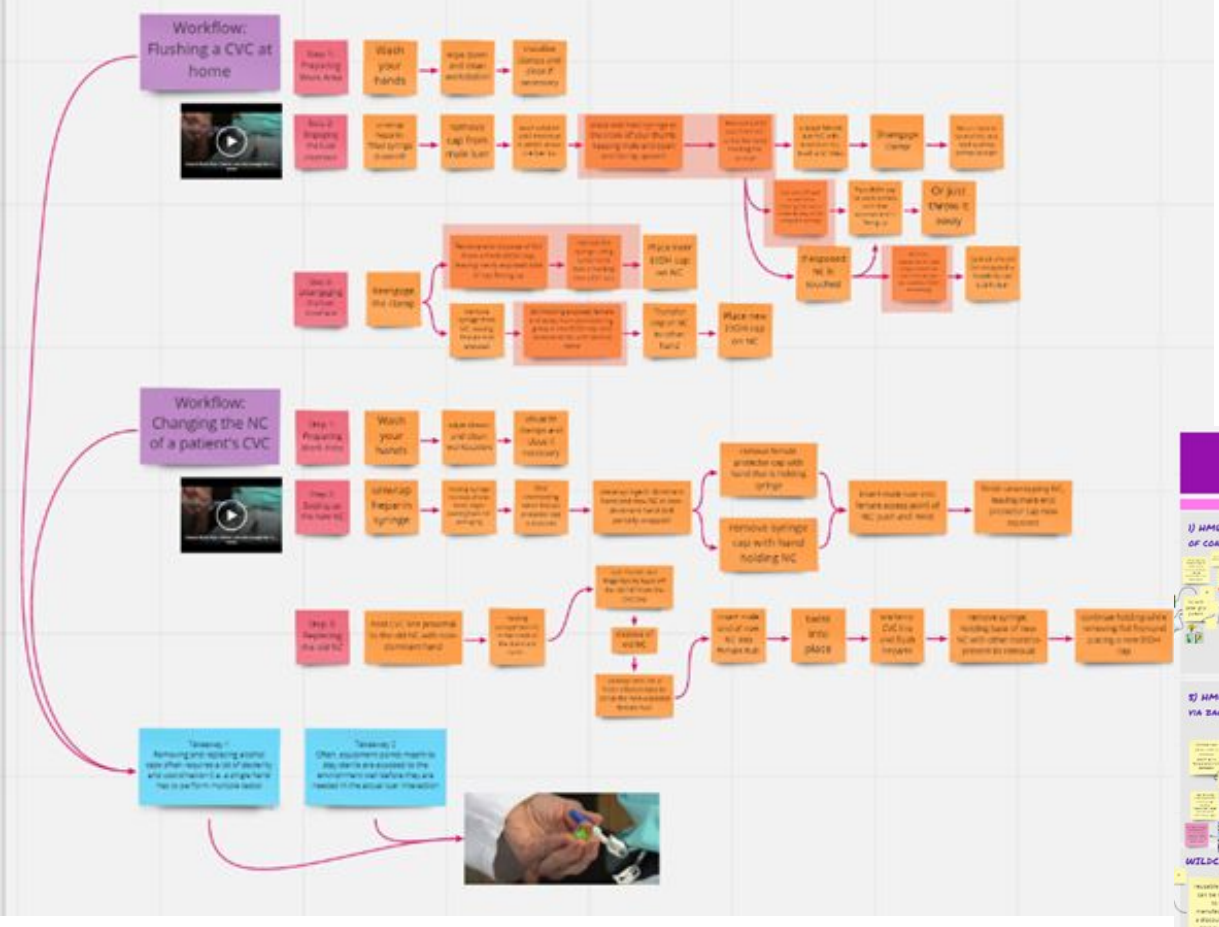
30,000 CLABSI cases/year

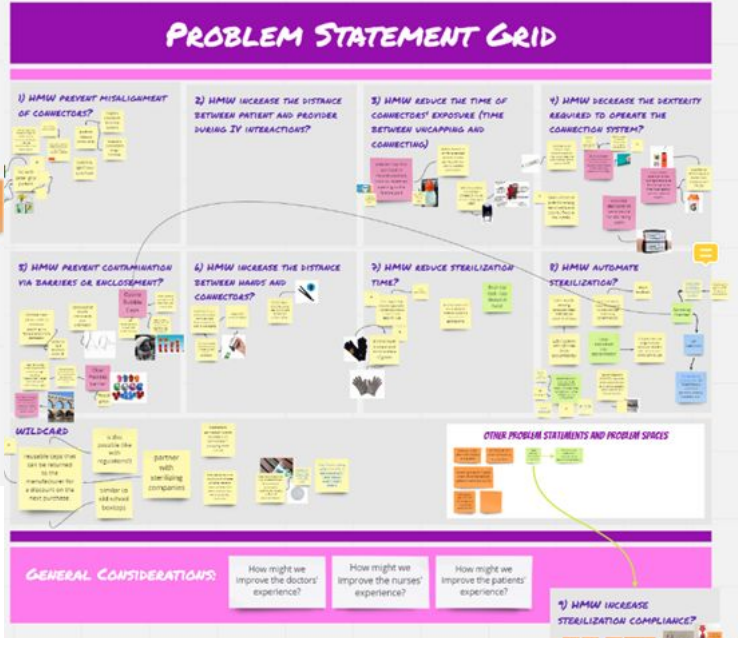
Average cost $70,696

Increases hospital bills by average of $45K

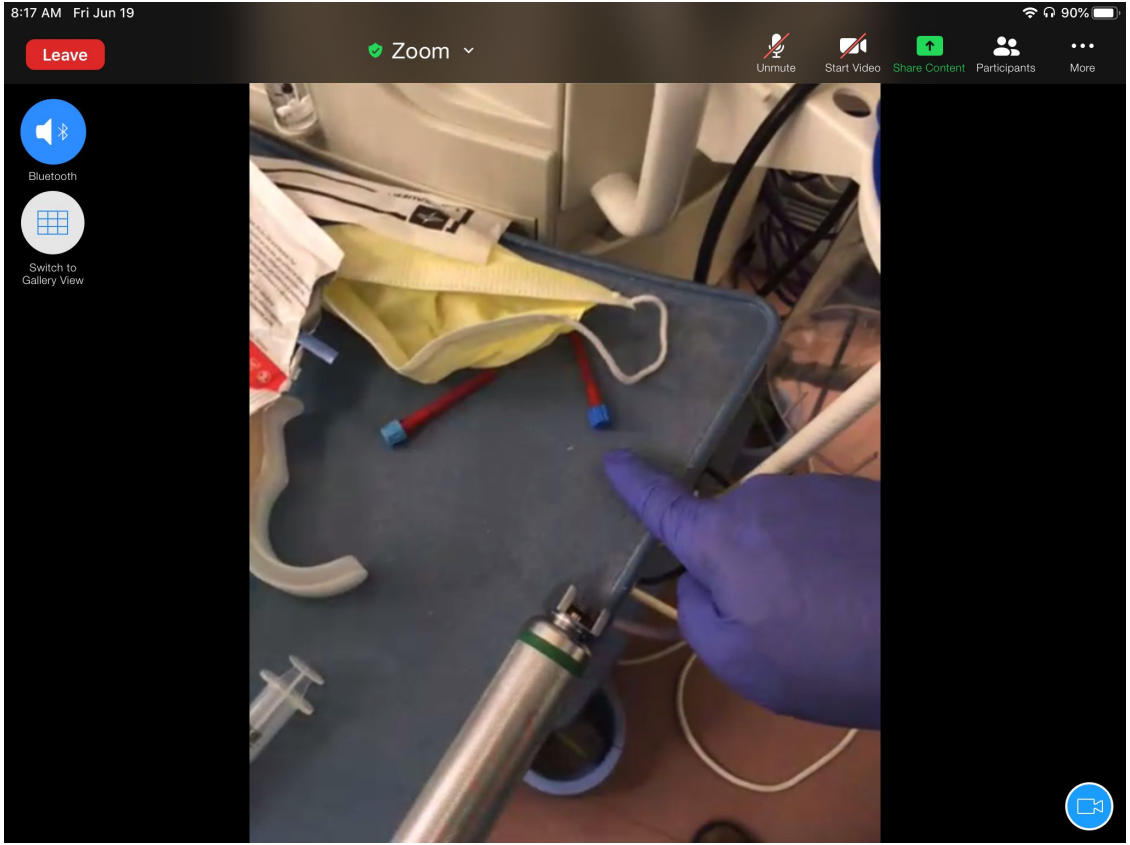
Mortality rate 25%

Average of 7500 deaths per year


Workflow: Flushing a CVC at home
Wash your hands
Or just throw it away
Workflow: Changing the NC of a patient's CVC
Wash your hands
Remove female protector cap with hand that is holding syringe
Remove syringe cap with hand holding NC
Place new SWAB cap on NC
Takeaway 1
Takeaway 2


PROBLEM STATEMENT GRID
1) HMW PREVENT MISALIGNMENT OF CONNECTORS?
2) HMW INCREASE THE DISTANCE BETWEEN PATIENT AND PROVIDER DURING IV INTERACTIONS?
3) HMW REDUCE THE TIME OF CONNECTORS' EXPOSURE (TIME BETWEEN UNCAPPING AND CONNECTING)
4) HMW DECREASE THE DEXTERITY REQUIRED TO OPERATE THE CONNECTION SYSTEM?
5) HMW PREVENT CONTAMINATION VIA BARRIERS OR ENCLOSEMENT?
6) HMW INCREASE THE DISTANCE BETWEEN HANDS AND CONNECTORS?
7) HMW REDUCE STERILIZATION TIME?
8) HMW AUTOMATE STERILIZATION?
WILDCARD
OTHER PROBLEM STATEMENTS AND PROBLEM SPACES
GENERAL CONSIDERATIONS:
How might we improve the doctors' experience?
How might we improve the nurses' experience?
How might we improve the patients' experience?
9) HMW INCREASE STERILIZATION COMPLIANCE?

OR Shadowing with Dr. Gravenstein, Jefferson Anesthesia



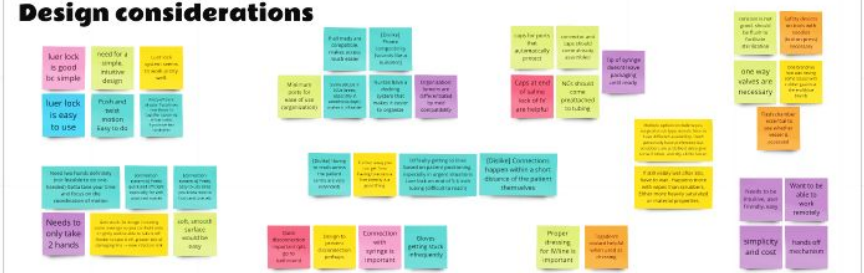
Sterilization

Misc. Problems

Solutions

Education

Design considerations



Cause of infection

Time

Access

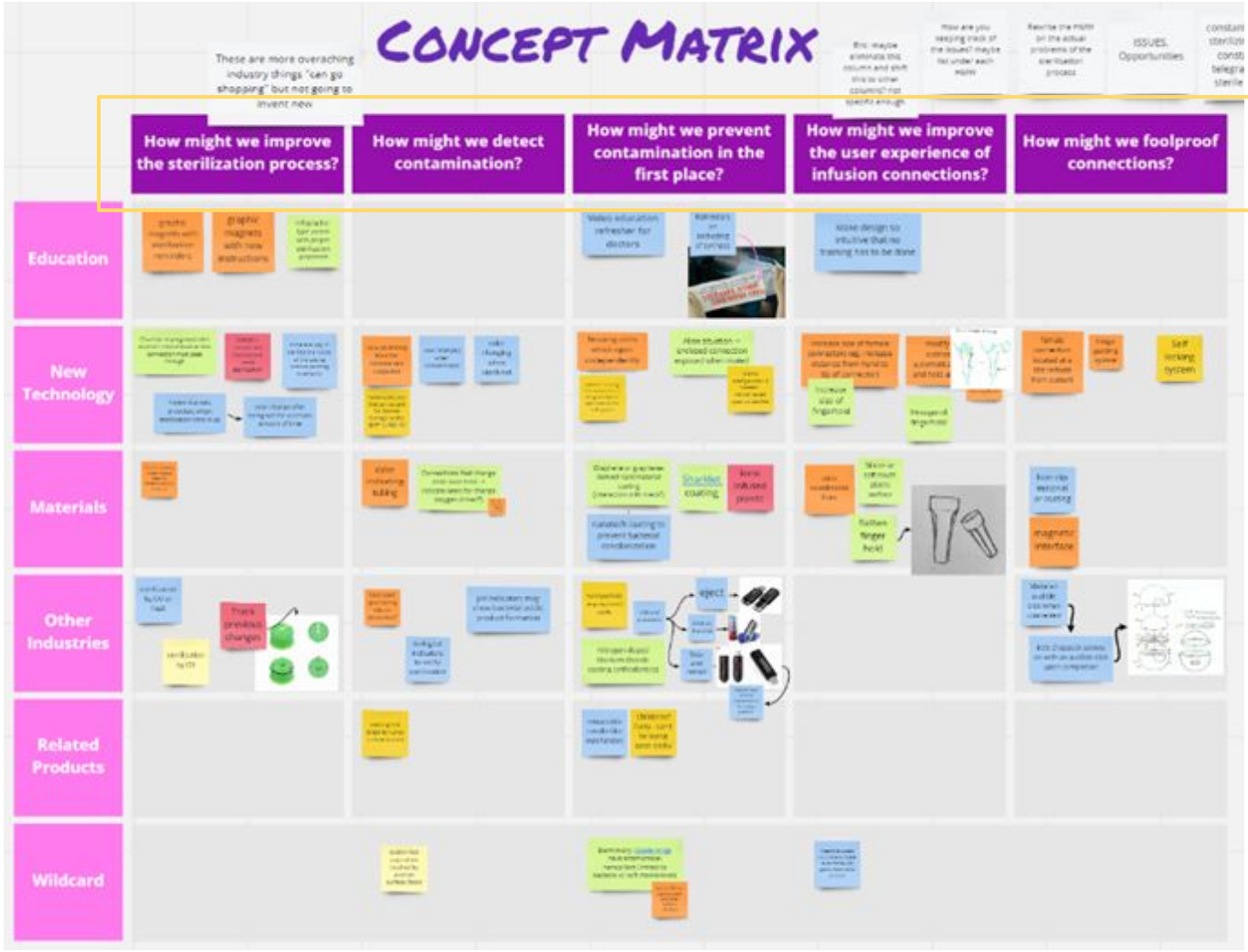
Misc.

Interview Key 01 02 03 04 05 06 07 08

Concept Matrix

These are more overaching industry things "can go shopping" but not going to invent new

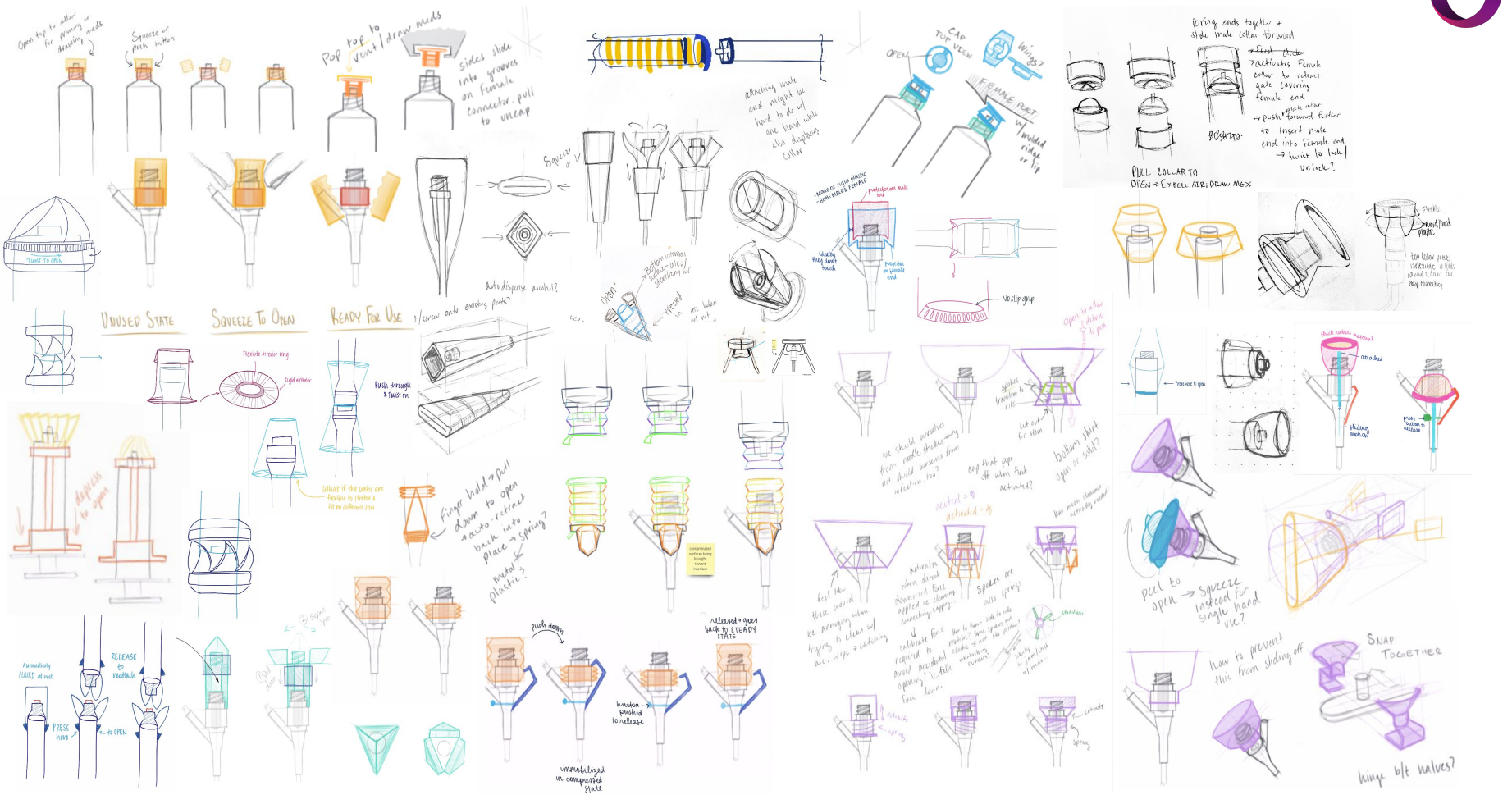
	How might we improve the sterilization process?	How might we detect contamination?	How might we prevent contamination in the first place?	How might we improve the user experience of infusion connections?	How might we foolproof connections?
Education					
New Technology					
Materials					
Other Industries					
Related Products					
Wildcard					



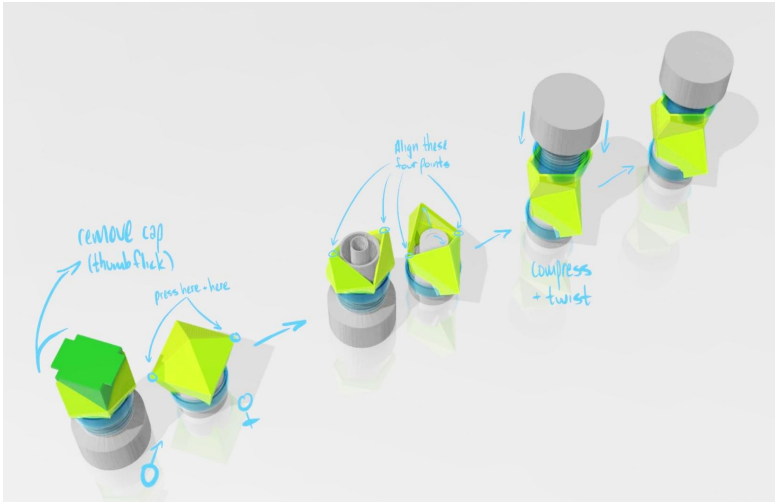
CONCEPT GENERATION: ROUND 1

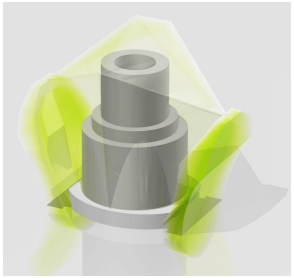
methods

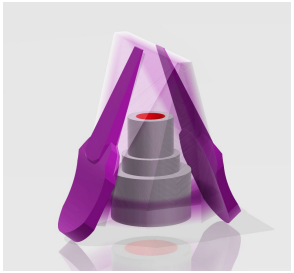
Concept Generation

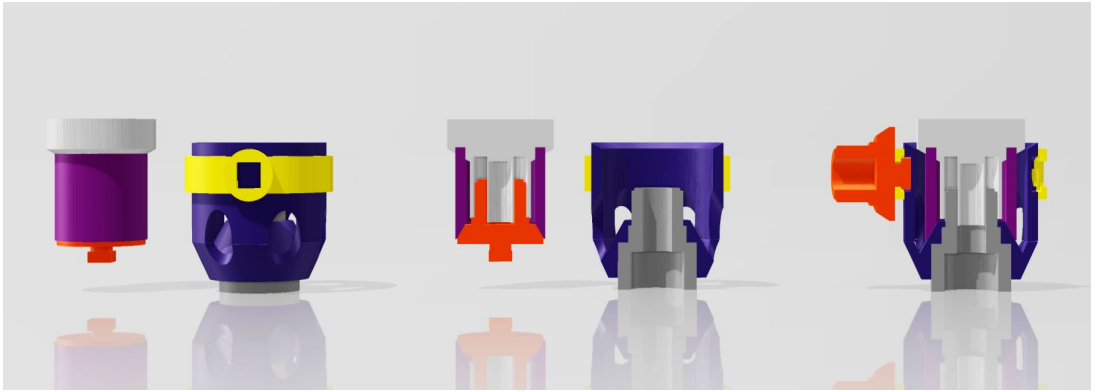


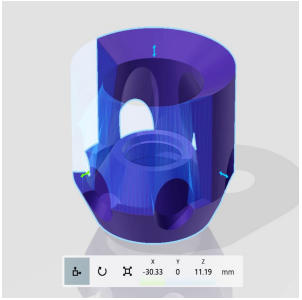
Concept Generation

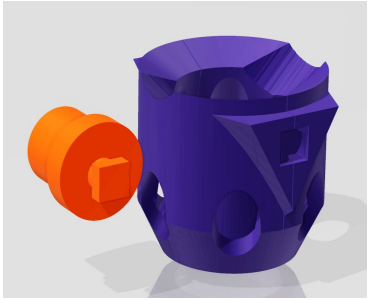








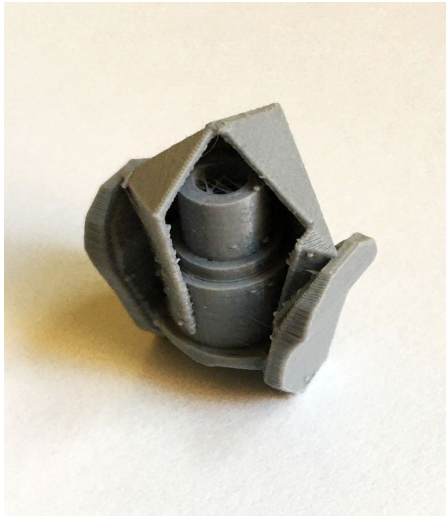




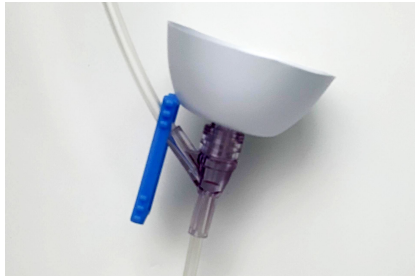
Prototyping

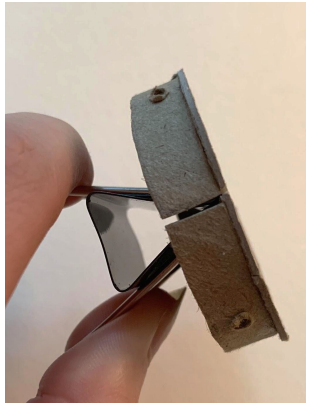
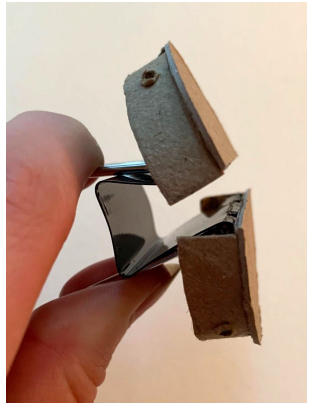
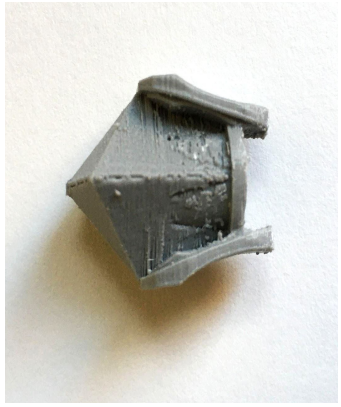


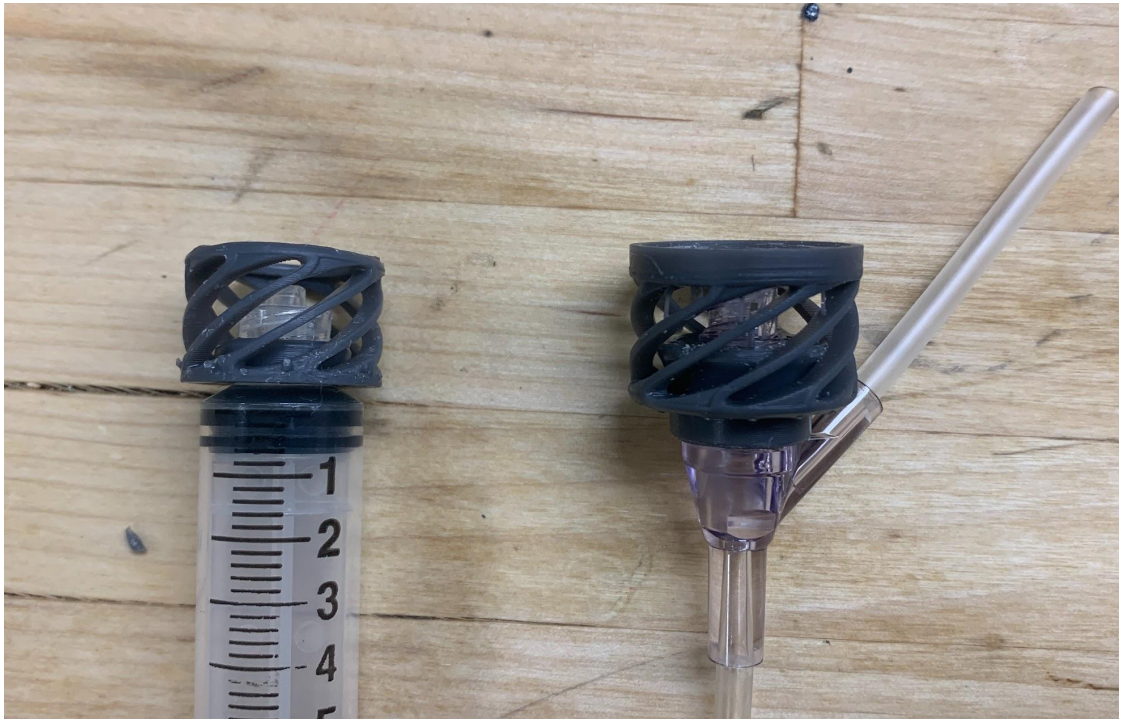









1
2
3
4

results

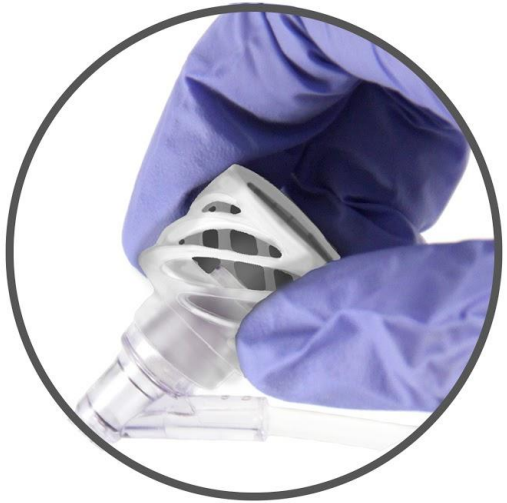
conexo

the guard system for your IV line

receiving guard

inserting guard

minimal
exposure



discourages
incidental contact

guided
alignment

syringe guard alone

both guards together

line guard alone

conexo is made from a **flexible** yet **durable** thermoplastic
(Methyl Methacrylate Acrylonitrile Butadiene Styrene or MABS)
that is resistant to wear and tear and easy to clean

protects **inactive** and **active** connections

conexo

single use

continuous use

DualCap system

Swabcap + Swabflush

ClearGuard HD

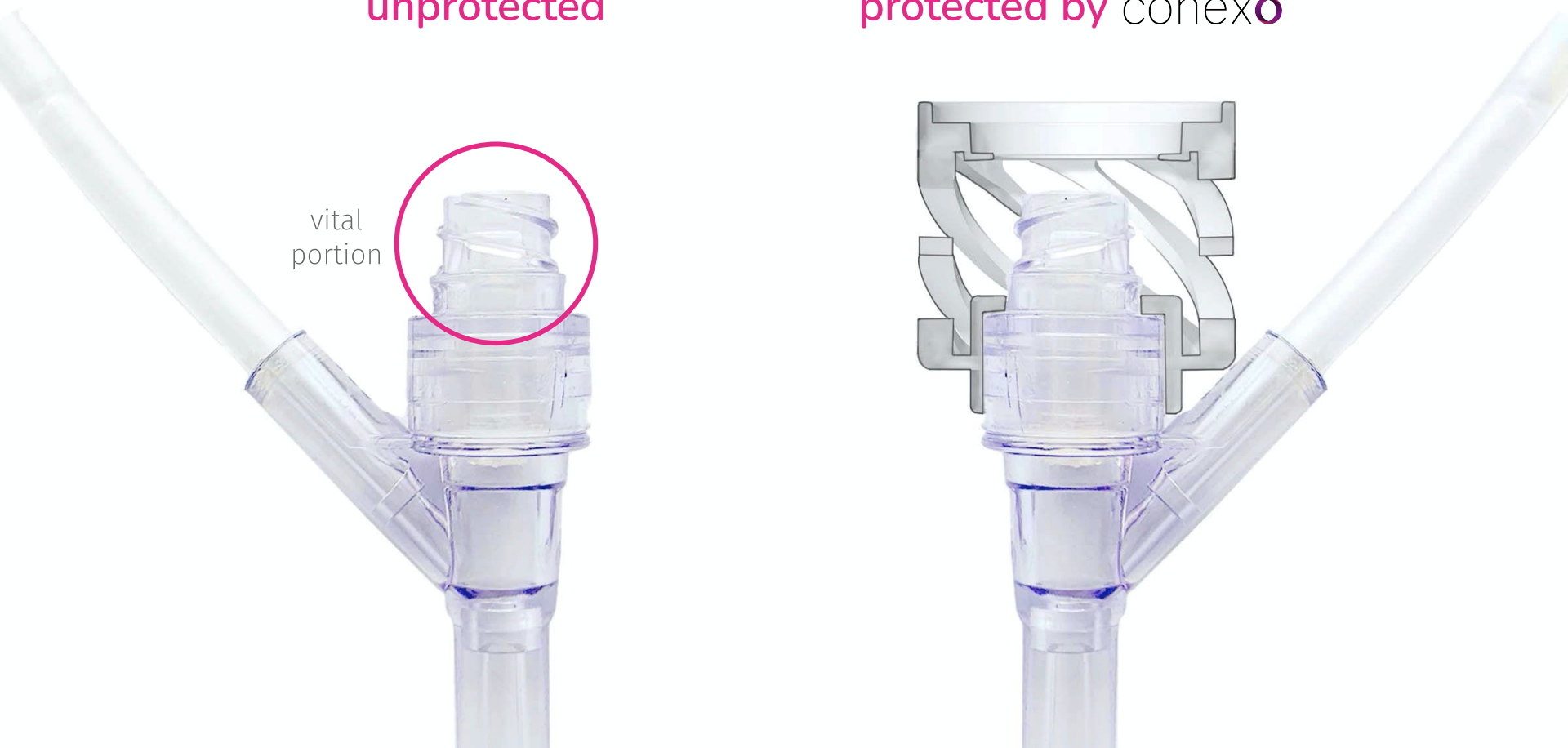
DOCit + HubSCRUB

Curos caps

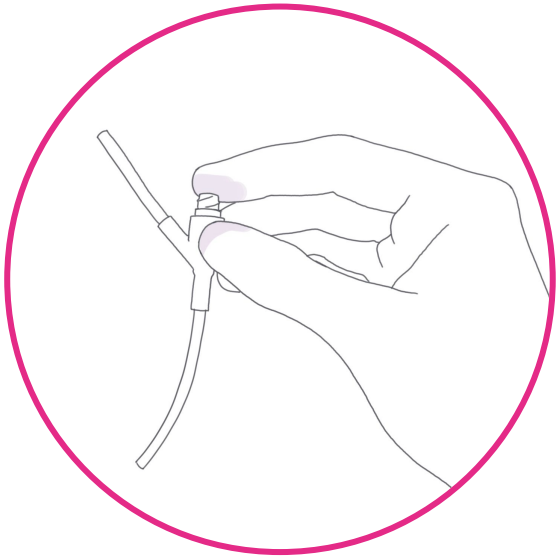
disinfects inactive connections only

unprotected

protected by conexo



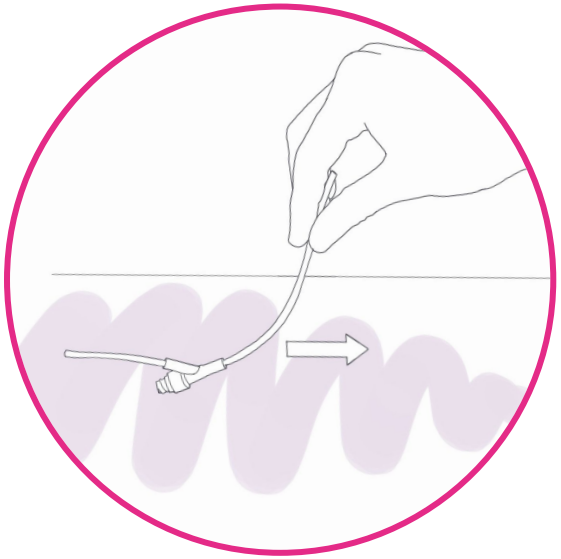
contact test



unprotected

protected by conexo

drag test



unprotected

protected by conexo

our team

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Former recovery worker
The Wedge

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Gigi Geary

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Jefferson

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Engineering, and Commerce

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Former translational research assistant
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Stephanie Szymanski

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special thanks...

Jefferson
Philadelphia University + Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

BRESSLERGROUP

HEALTH DESIGN LAB

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Dr. Mary Herman

Dr. Michael Mahla

Dr. J. Matthew Fields

Dr. Robert Pugliese

Dr. Bon Ku

Dr. Mark Tykocinski

Tod Corlett

Eric Schneider

Kurt Dammermann

Questions?

visit **www.conexoguard.com** or email
conexoguard@gmail.com for more information

APPENDIX

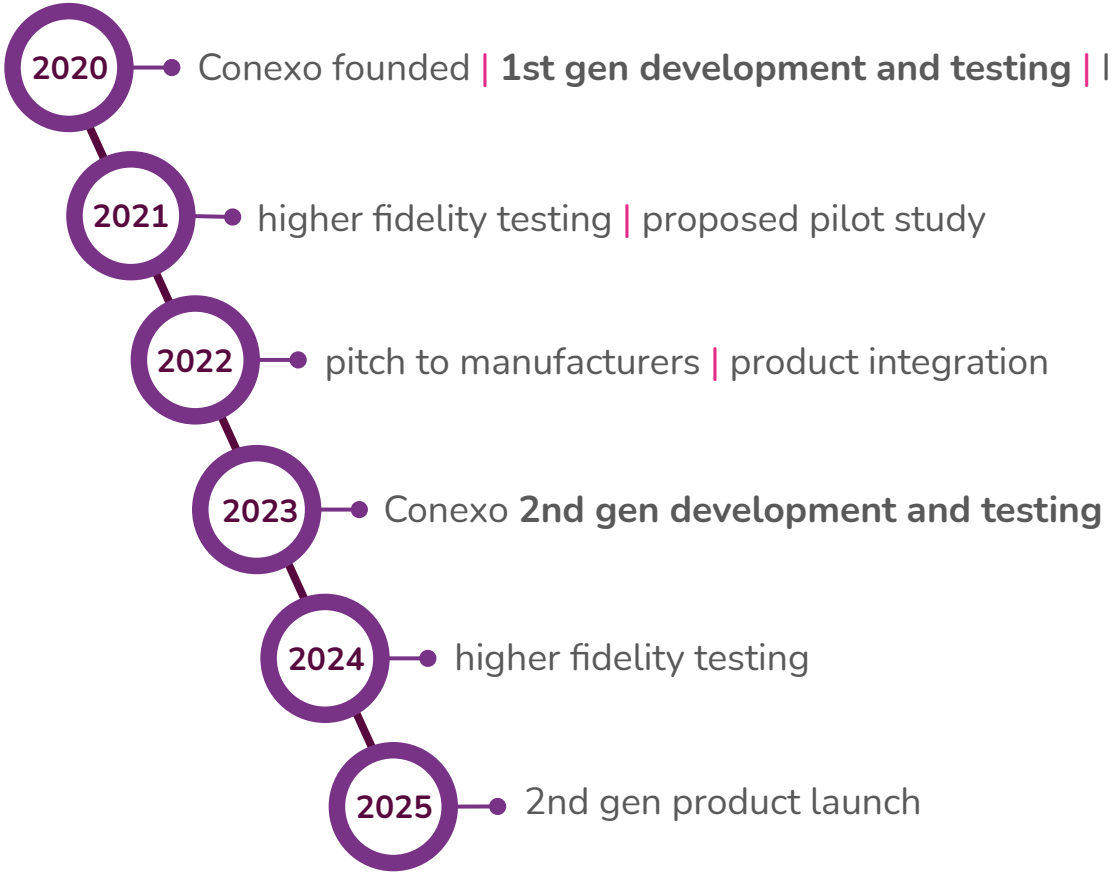

Steph Szymanski
Anjali Patel
Joey
Gigi Geary
Heli Patel
Lauren Huggler

1st Generation

Conexo used as an adapter to current line sets.

2nd Generation

Conexo incorporated into manufactured infusion sets.


2020
Conexo founded | 1st gen development and testing | IP Submission | initial pitch
2021
higher fidelity testing | proposed pilot study
2022
pitch to manufacturers | product integration
2023
Conexo 2nd gen development and testing
2024
higher fidelity testing
2025
2nd gen product launch

growing market
for needleless connectors

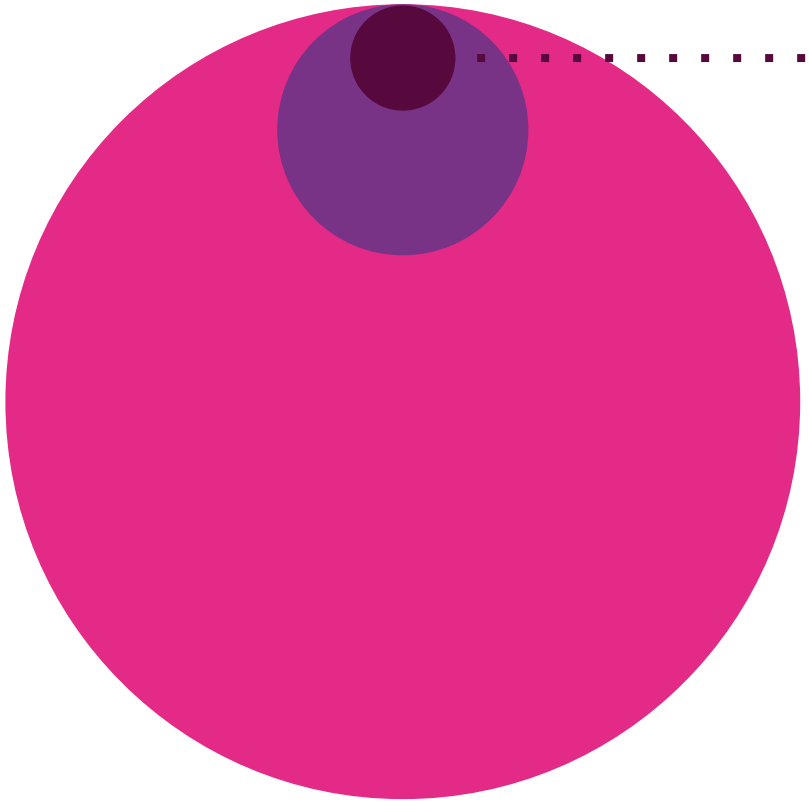
CAGR +10% during forecast period 2020-2027

growing need
for infection prevention

no direct competition
for our product

CONEXO is a novel solution that works in conjunction with current infection prevention products

CAGR: Compound annual growth rate
Source: www.medgadget.com



CLABSI in ICUs

30,000 CLABSI in ICUs*

$70,696 avg. cost per case

$1.85 billion

national expenditures on CLABSI treatment

**annually in the United States*
CLABSI: Central Line-associated Bloodstream Infections

$2.7 million

HAC Reduction Penalty to Jefferson University Hospital, Inc.
partially due to increased CLABSI rate

Source: Clinical Quality and Reporting at Thomas Jefferson University Hospital


conexo

Jefferson
Philadelphia University + Thomas Jefferson University

Project Title

Student Name, Co-author#1, Co-author#2**, Co-author#3* etc.

(*) Indicates primary advisor

(**) Indicates another student who is also declaring the same project as primary for SI

JeffMD: SI Design Track - Oral Presentation of Group Project

Criteria	Outstanding (3 Points)	Satisfactory (2 Points)	Unsatisfactory (0 Points)
Introduction and Objectives (10%). Connects subject and background to project's purpose, using a structured and organized framework. States inquiry question ("how might we").	Describes and connects the subject and background to the project's purpose, in an organized, specific, and concise manner. Rationale is logical for the project question/purpose. Clear inquiry question or hypothesis stated.	Reasonable organization of the project's purpose but lacks specifics at times. Attempts to connect to prior work. Rationale is present for the project's main question or purpose. Inquiry question or hypothesis stated but is unclear.	Lacks organization and specific details. Tenuous or no connection to prior work. Project's purpose is unclear or without rationale. No inquiry question or hypothesis.
Background (10%). Background research has been performed and displayed (abstracts, articles, landscape research)	Background research is provided and easy to follow; the underlying design challenge is unambiguous and very compelling.	Background research is provided, though limited in scope. The design challenge is understandable and somewhat compelling.	Little to no background research provided; design challenge is difficult to understand. The issue is neither desirable nor compelling.
Problem Definition / Goals (10%). What is this project? (POV statement, HMW, goals)	The presentation includes a clear point-of-view statement and coherently states the design problem in the HMW format. Project goals are easy to understand and link back to the defined problem.	The overall problem is defined. However the presentation lacks or has serious deficiencies in **one** of the following: - POV, - HMW, or - project goals.	The problem is not clearly defined, or the presentation lacks or has serious deficiencies in **two or more** of the following: - POV, - HMW, or - project goals.
Methods (10%). Describes the methods used and their applicability to the presented work.	Describes methods applicable to presented work. Description is organized, specific, and concise.	Describes methods applicable to presented work, but description is disorganized or incomplete or lacking specifics.	Methods included are unclear and/or have no evident applicability to presented work. Lacks specific details.
Results (10%). Summarizes main results as they pertain to the project's objectives: what was collected, accomplished, discovered, or produced.	Summarizes main results in an organized, specific, and concise manner.	Summarizes main results in fairly clear manner, although they may not always be concise or easily understood.	Does not provide concrete results (without explanation), or results that are presented are unclear or irrelevant to project's objectives.

Presentation Style and Delivery (15%). Clarity and coherence of oral presentation, and engagement with audience.	Presentation is engaging, with effective transitions, and within time limits. Speaker(s) uses a clear audible voice and maintains eye contact consistently with their audience.	**One** of the following is present: - Transitions are not always smooth, or - Audience engagement declines at times, or - Presentation is too long or short. - Speaker(s) is difficult to understand, with little to no eye contact, and speech interrupted by reliance upon notes.	**Two or more** of the following are present: - Transitions are not always smooth, or - Audience engagement declines at times, or - Presentation is too long or short. - Speaker(s) is difficult to understand, with little to no eye contact, and speech interrupted by reliance upon notes.
Slides (15%). Effectiveness and visual appeal of slides (formatting, content, organization,	Well-organized and visually compelling slide presentation that connects to the project's main purpose. Text is readable, clear, and of	Organization of slides and presentation of information in a logical sequence. **One** of the following is present:	Slides have no clear organization, or **two or more** of the following are present:
pictures/tables/graphs, artifacts). Disclosures & acknowledgements.	appropriate length. Included pictures, tables, or graphs are relevant and instructive. Exceptional slide design. Lists title, all authors, and indicates advisor. Disclosures/acknowledgments present.	- Text is often unreadable, unclear, or too long. - Slides have no visual appeal. - Pictures, tables, or graphs are not relevant or instructive. - Listing of title, authors & advisor is incomplete or missing. - No disclosures/acknowledgments.	- Text is often unreadable, unclear, or too long. - Slides have no visual appeal. - Pictures, tables, or graphs are not relevant or instructive. - Listing of title, authors & advisor is incomplete or missing. - No disclosures/acknowledgments.
Design Solution (20%). The presentation describes a solution to the defined problem.	The proposed solution is clearly displayed, easily understandable, has desirability, viability, and novelty.	The proposed solution is displayed but **one** of the following is present: - is difficult to understand, - lacks desirability, - is not novel, or - lacks viability.	The proposed solution is not displayed or, if displayed, **two or more** of the following are present: - is difficult to understand, - lacks desirability, - is not novel, - lacks viability.