Tufts Security & Privacy Lab

Tufts UNIVERSITY

“There are rabbit holes I want to go down that I’m not allowed to go down”

An Investigation of Security Expert Threat Modeling Practices for Medical Devices

Ronald E. Thompson III
Tufts University

Madeline McLaughlin
Tufts University

Carson Powers
Tufts University

Daniel Votipka
Tufts University

USENIX Security 24

Vulnerabilities in medical devices are a continued issue

Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses

IEEE S&P

May. 2008

Insulin pumps are vulnerable to hacking, FDA warns amid recall

The Washington Post

Jun. 2019

Nine Vulnerabilities in Critical Infrastructure Used by 80% of Major Hospitals

ARMIS

Aug. 2021

Medical Device Regulators are pushing for “secure-by-design”

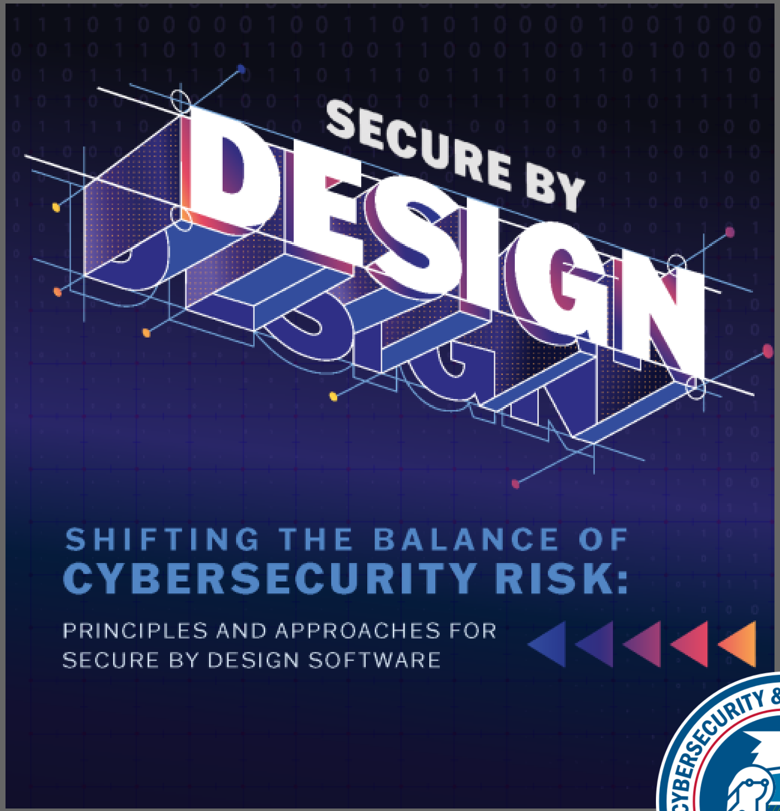
Threat modeling includes a **PROCESS FOR IDENTIFYING SECURITY OBJECTIVES, RISKS, AND VULNERABILITIES** across the system, and then **DEFINING COUNTERMEASURES TO PREVENT, OR MITIGATE THE EFFECTS OF, THREATS** to the system throughout its lifecycle.

FDA Pre-Market Cybersecurity Guidance [2023] FDA

Part of a larger trend by governments to use threat modeling

Use a tailored threat model during development to **PRIORITIZE THE MOST CRITICAL AND HIGH-IMPACT** products. Threat models consider a product’s specific use-case and enables development teams to fortify products.

Principles and Approaches for Secure by Design Software
Signed by 19 Different National Agencies



SECURE BY DESIGN

SHIFTING THE BALANCE OF CYBERSECURITY RISK:

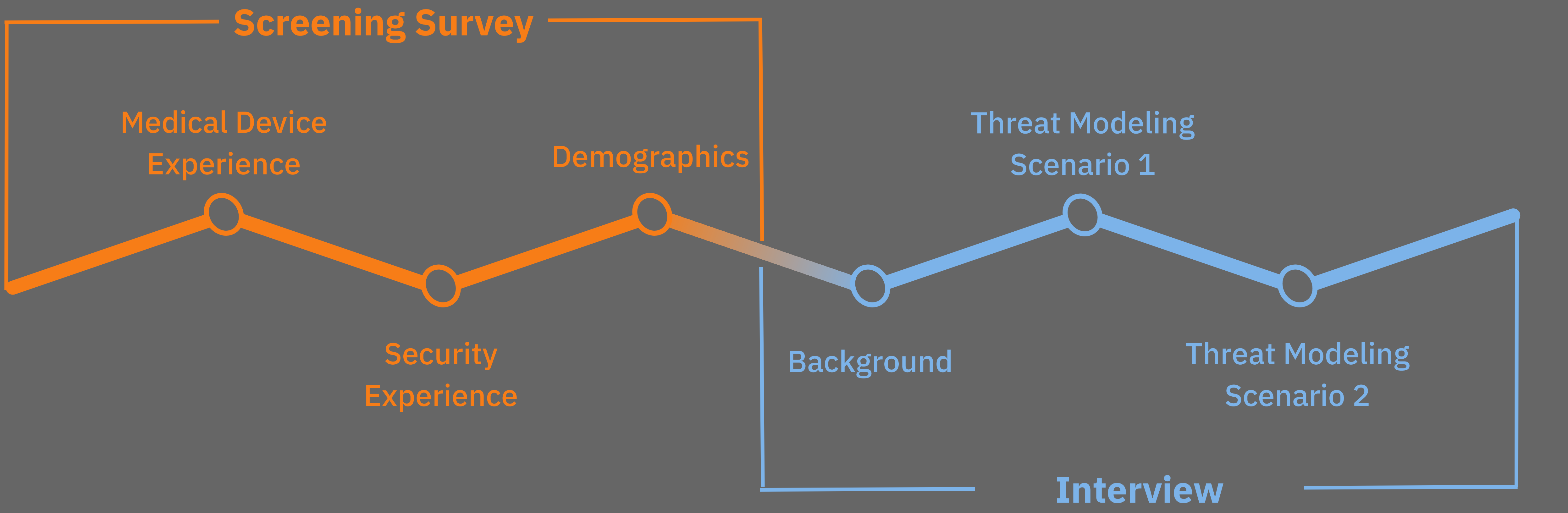
PRINCIPLES AND APPROACHES FOR SECURE BY DESIGN SOFTWARE

We wanted to understand how threat modeling is done in practice by medical device manufacturers (MDM) security experts

How do MDM Security Experts identify specific threats and mitigations?

What processes do MDM Security Experts follow when navigating a system's design to identify threats?

We screened participants and collected initial information before conducting 60 minute interviews


Screening Survey
Medical Device Experience
Demographics
Security Experience
Threat Modeling Scenario 1
Background
Threat Modeling Scenario 2
Interview

With the help of experts, we developed three realistic mock device scenarios spanning various harms and settings

Robotic Surgical System

Type: Surgical System
Setting: Hospital
Potential Harm: Patient Death
Classification: Class II

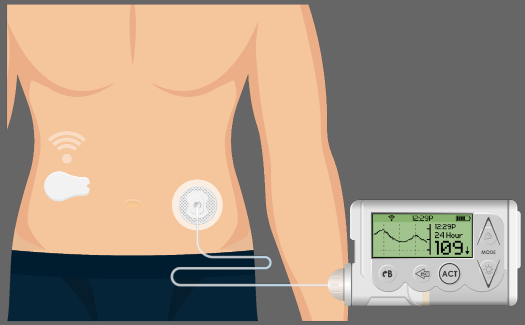
Next-Gen Sequencer

Type: Diagnostic Equipment
Setting: Laboratory
Potential Harm: Diagnostic Error
Classification: Class II/IIa

Artificial Pancreas

(Insulin Pump & Continuous Glucose Monitor)

Type: Implantable Medical Device
Setting: Implant
Potential Harm: Patient Death
Classification: Class III



All three scenarios are based on devices that are currently being used on the market today
Classifications are using FDA Guidance, EU MDR/IVDR, and Health Canada

Each scenario included a set of requirements, a high level context diagram, and a data flow diagram

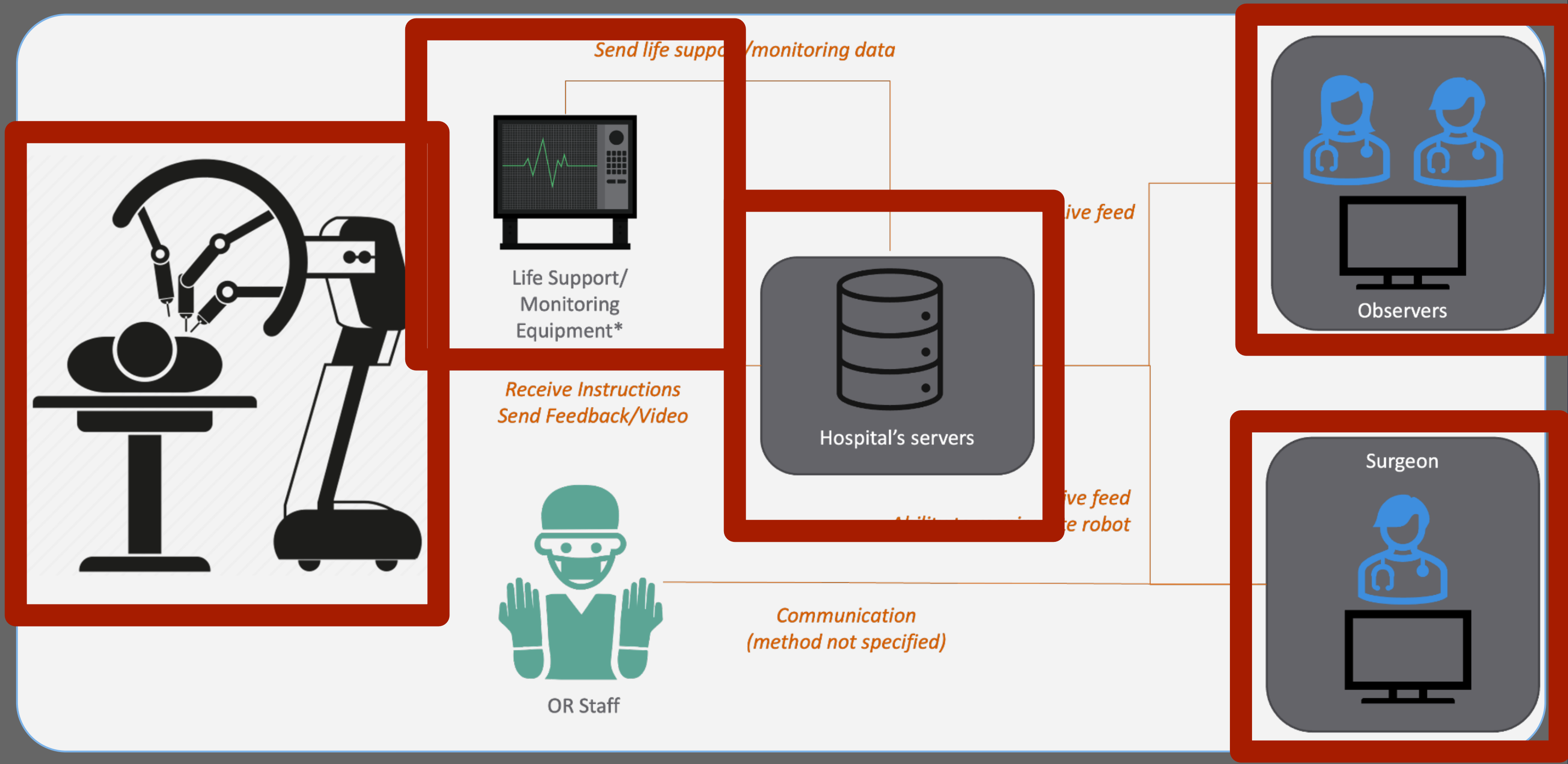
Robotic Surgical System

Allow for remote surgery

Store surgical reports on hospital server

Third-party monitoring equipment should send vitals to surgeon's console

Observers are able to watch the surgery (including the surgeon's viewpoi



Before recruiting, significant amount of time was invested in community engagement & building relationships

Health Sector Coordinating Council
Cybersecurity Working Group

ARCHIMEDES
Center for Healthcare and Device Security

BIOHACKING
VILLAGE

CYBERMED
SUMMIT

We interviewed 12 experts involved in securing medical devices

Participants started their careers in…	…medical devices (6) …security (6)
Participants hold roles in/as…	…large manufacturers (4) …specialized manufacturers (4) …consultants for manufacturers (4)
Participants had worked for…	…<5 years (2) …5-10 years (1) …10-20 years (2) …20-30 years (4) …30+ years (3)

75% >10 years { …10-20 years (2) …20-30 years (4) …30+ years (3)

Our results consisted of three major findings

Flexible process for brainstorming threats and controls

Safety considerations are critical, unclear how to integrate

} RQ1

Ad-hoc Navigation & Reliance on Use Cases for prioritization

RQ2

Our results consisted of three major findings

Flexible process for brainstorming threats and controls

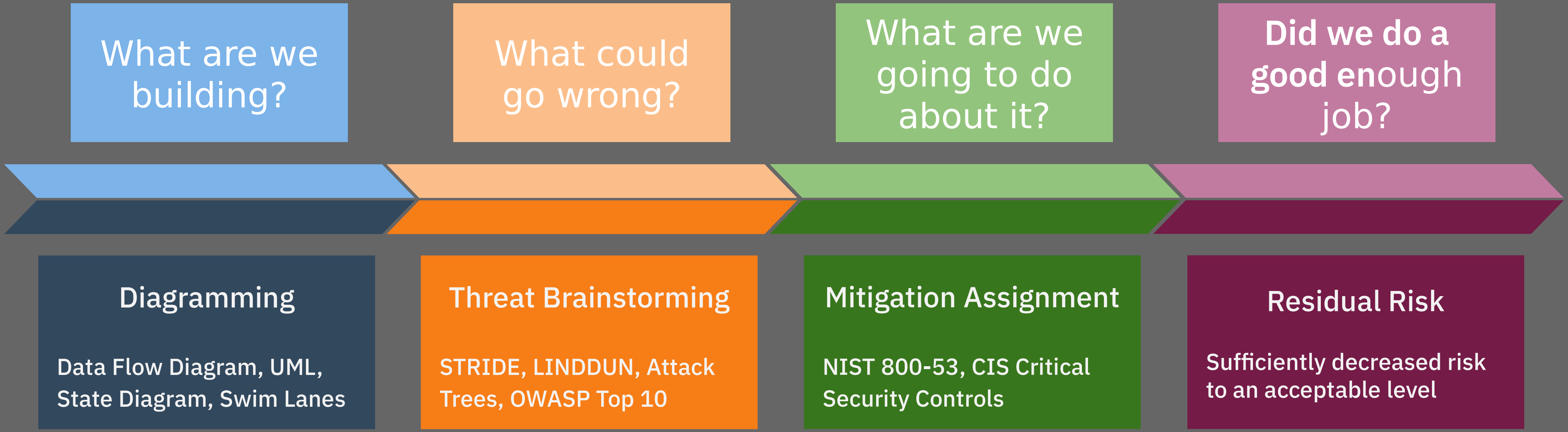
Safety considerations are critical, unclear how to integrate

RQ1

Ad-hoc Navigation & Reliance on Use Cases for prioritization

RQ2

We observed participants relying both explicitly and implicitly on Adam Shostack's Four Questions



What are we building?

What could go wrong?

What are we going to do about it?

Did we do a good enough job?

Diagramming

Data Flow Diagram, UML, State Diagram, Swim Lanes

Threat Brainstorming

STRIDE, LINDDUN, Attack Trees, OWASP Top 10

Mitigation Assignment

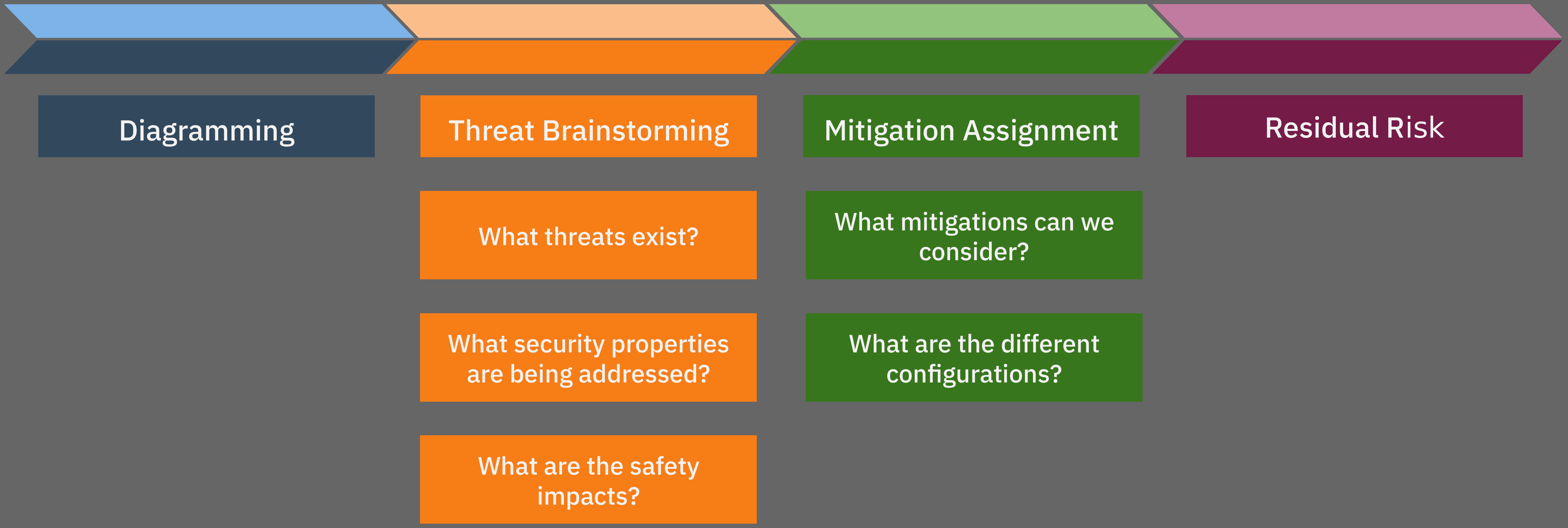
NIST 800-53, CIS Critical Security Controls

Residual Risk

Sufficiently decreased risk to an acceptable level

Flexible process for brainstorming threats and controls

We found that participants answered common implicit and explicit threat related questions



Diagramming

Threat Brainstorming

- What threats exist?
- What security properties are being addressed?
- What are the safety impacts?

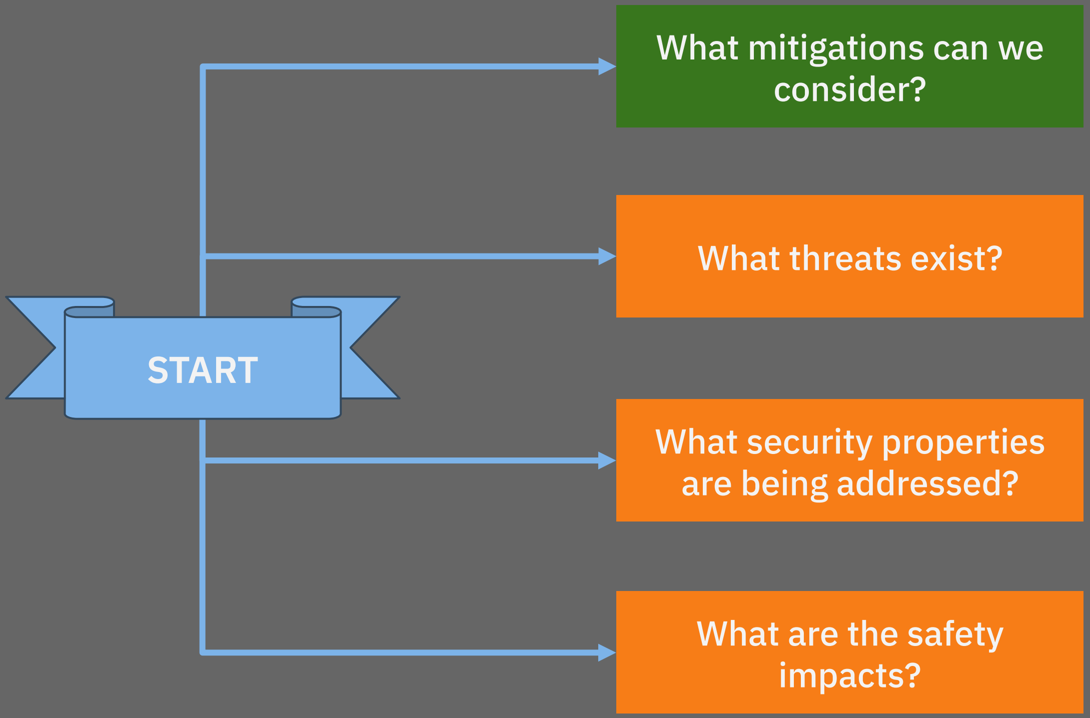
Mitigation Assignment

- What mitigations can we consider?
- What are the different configurations?

Residual Risk

Flexible process for brainstorming threats and controls

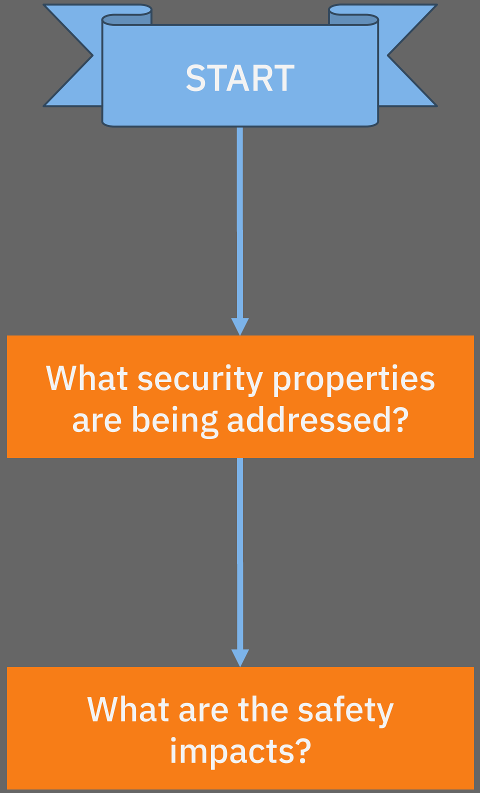
When looking at a particular component of the system, participants initially answered different questions


START
What mitigations can we consider?
What threats exist?
What security properties are being addressed?
What are the safety impacts?

Similar to the findings of prior work we found that these questions can be implicit assumptions *[Van Landuyt & Joosen, Softw Syst Model 21]*

Flexible process for brainstorming threats and controls

Evaluating the component would involve answering the initial question and linking it to another question



START

What security properties are being addressed?

What are the safety impacts?

> "**INTEGRITY** of the data that flows across the system as well as the **AVAILABILITY** of the data flow and both could result in **HARM TO THE PATIENT**."

Flexible process for brainstorming threats and controls

It might also involve thinking about additional answers to the same question

START
What mitigations can we consider?
What mitigations can we consider?

> “If the hospitals in charge of setting it up themselves, ideally I'd say put it on a **SEPARATE VLAN** and then have more **INDIVIDUAL ACCESS** for that. And then obviously the researchers and providers only a couple would've access to that for the people who would actually need it. So it'd be more **ROLE BASED ACCESS**.

Flexible process for brainstorming threats and controls

We developed a process model based on our results

Flexible process for brainstorming threats and controls

Safety considerations are critical, unclear how to integrate

RQ1

Ad-hoc Navigation & Reliance on Use Cases for prioritization

RQ2

Despite suggestions from various standards to separate the two, security must consider the impact on safety and clinical efficacy

> “We can’t just look at where data resides, **WE CAN’T JUST SAY, ‘HEY, HARDEN YOUR SERVERS,’** and things of that general statements. We have to really look at the function and what the data that’s flowing between each component to understand and wrench its **IMPACT TO AFFECTING THAT CLINICAL WORKFLOW**.”

Safety considerations are critical, unclear how to integrate

Participants expressed concern about how safety and security teams operate independently and use different language

> "The integration of this is very important, and we have **SEPARATE PROCESSES THAT HAVE SYNCHRONIZATION POINTS**, but without necessarily the two groups understanding each other, it **[POTENTIAL MISCOMMUNICATION] IS PRETTY DANGEROUS**."

-Study Participant [emphasis added]

We developed a process model based on our results

Flexible process for brainstorming threats and controls

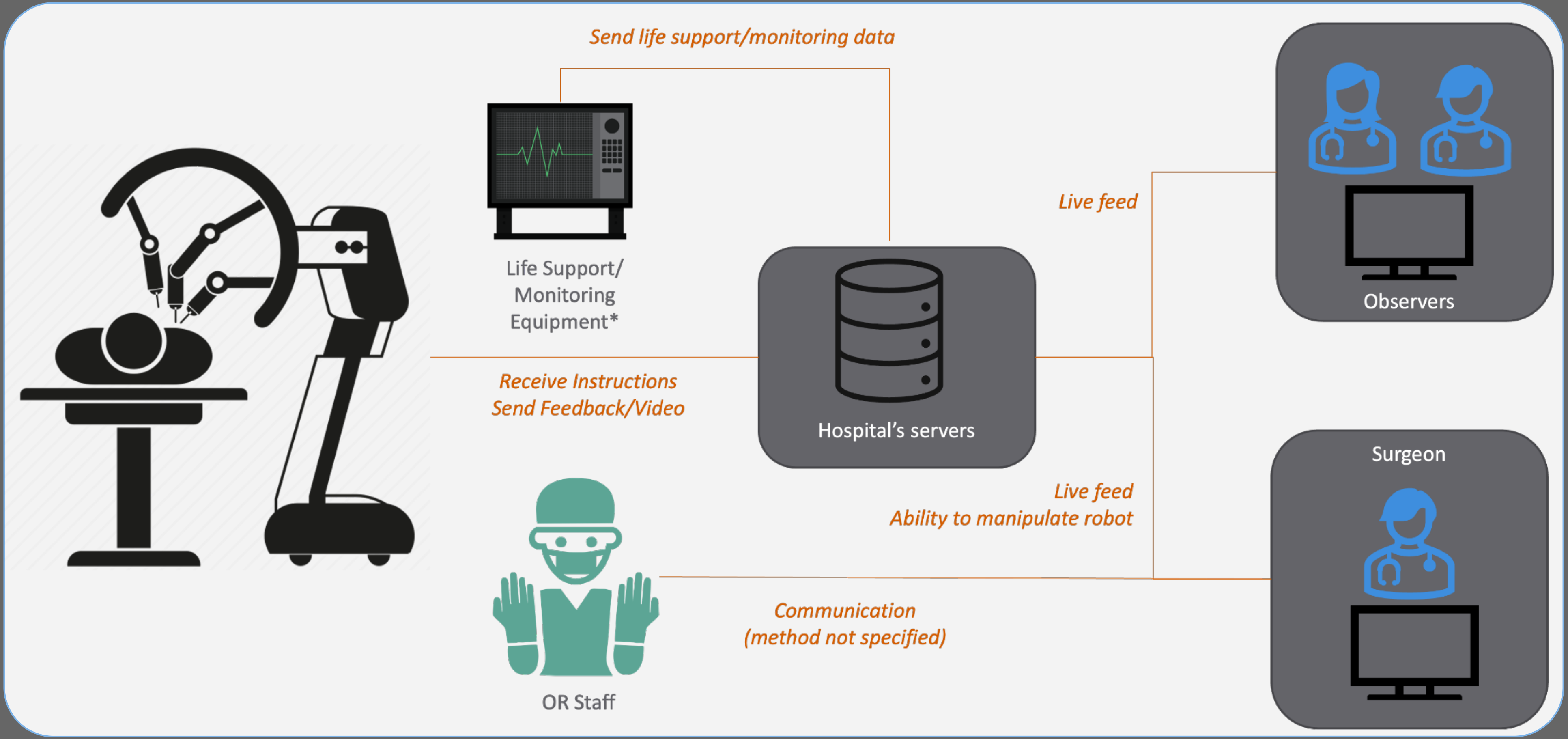
Safety considerations are critical, unclear how to integrate

} RQ1

Ad-hoc Navigation & Reliance on Use Cases for prioritization

RQ2

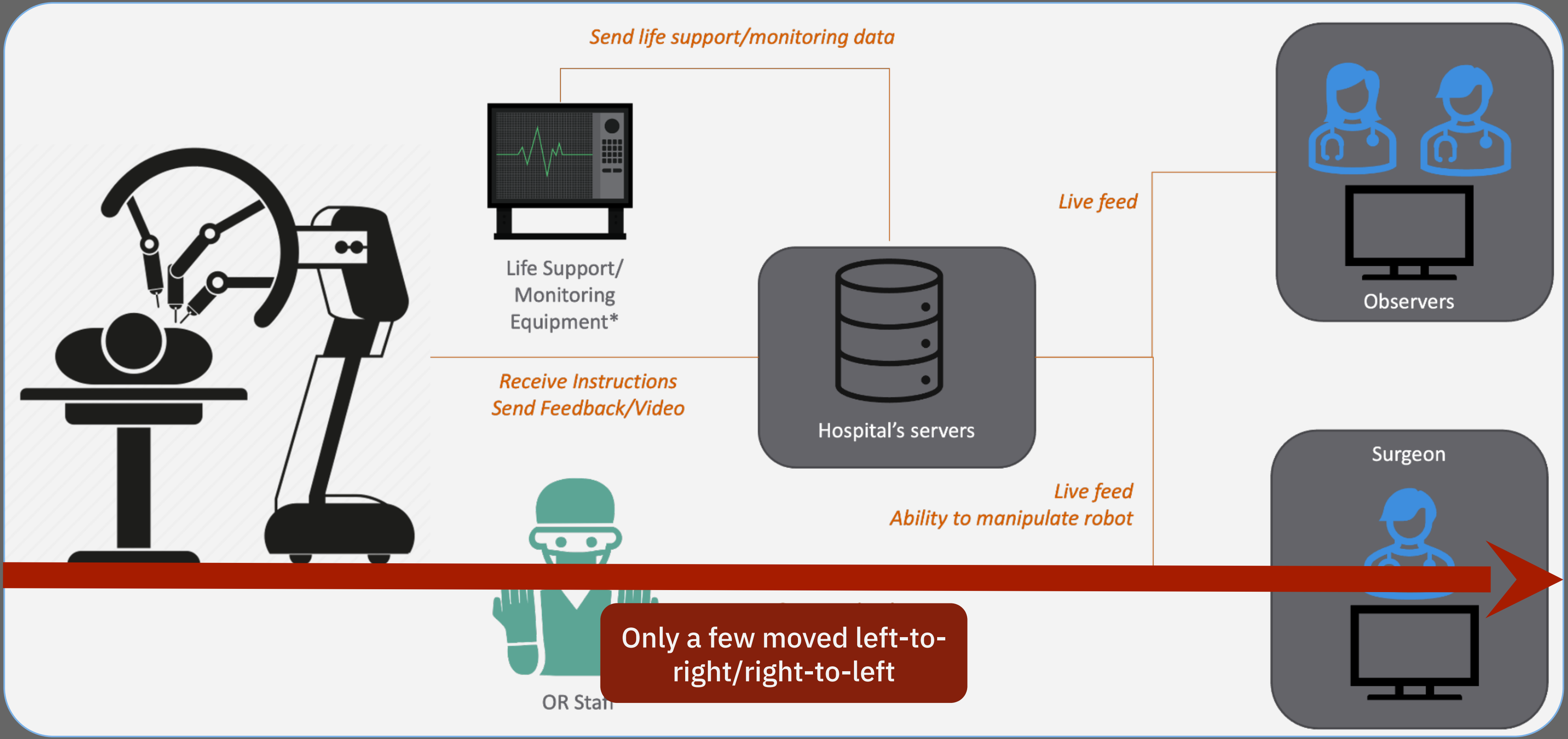
Participants would bounce between parts of the system based on what they previously thought about



Send life support/monitoring data
Life Support/ Monitoring Equipment*
Live feed
Observers
Receive Instructions
Send Feedback/Video
Hospital's servers
Surgeon
Live feed
Ability to manipulate robot
Communication (method not specified)
OR Staff

Ad-hoc Navigation & Reliance on Use Cases for prioritization

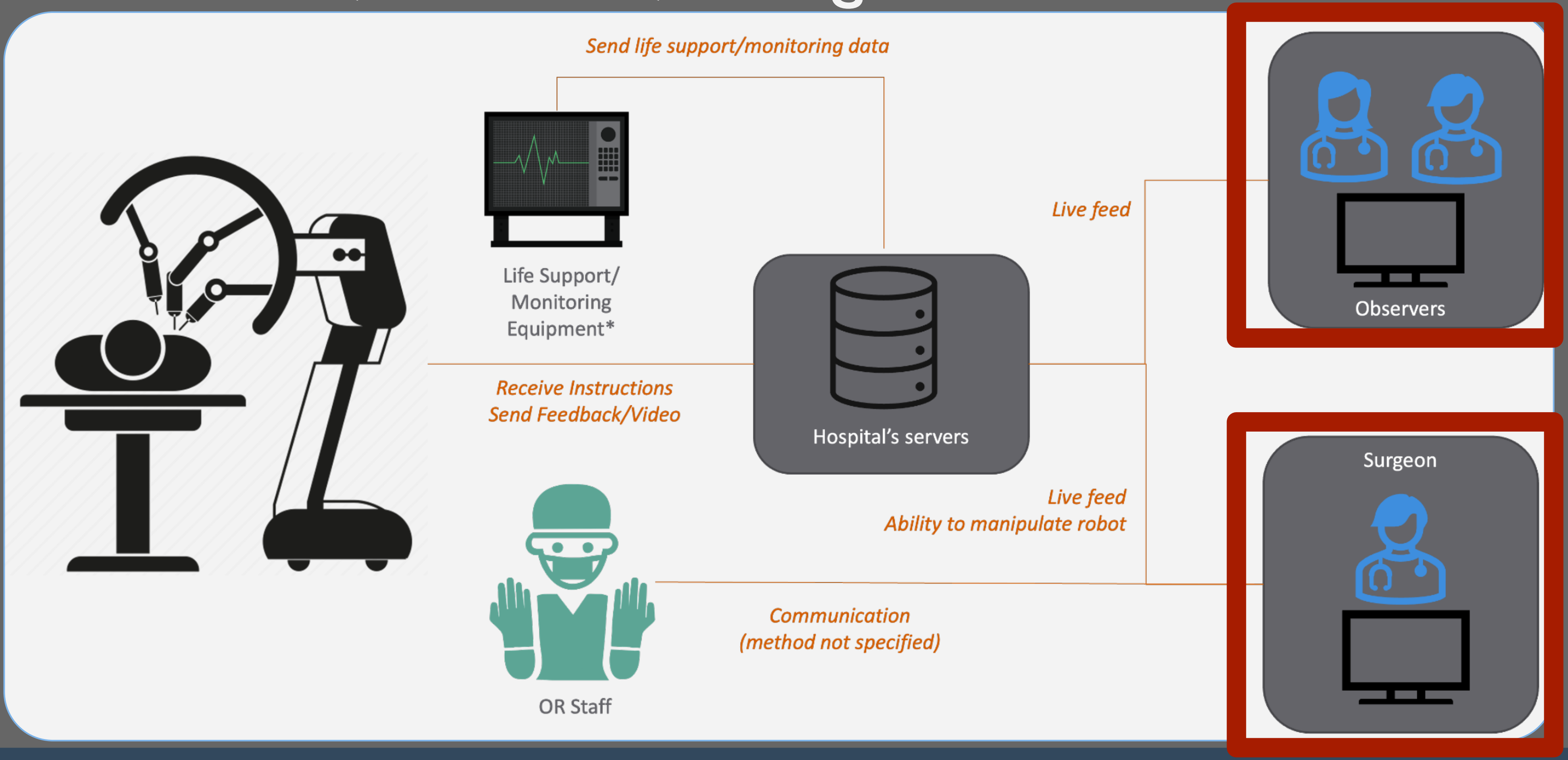
Participants would bounce between parts of the system based on what they previously thought about



Only a few moved left-to-right/right-to-left

Ad-hoc Navigation & Reliance on Use Cases for prioritization

Participants would bounce between parts of the system based on what they previously thought about

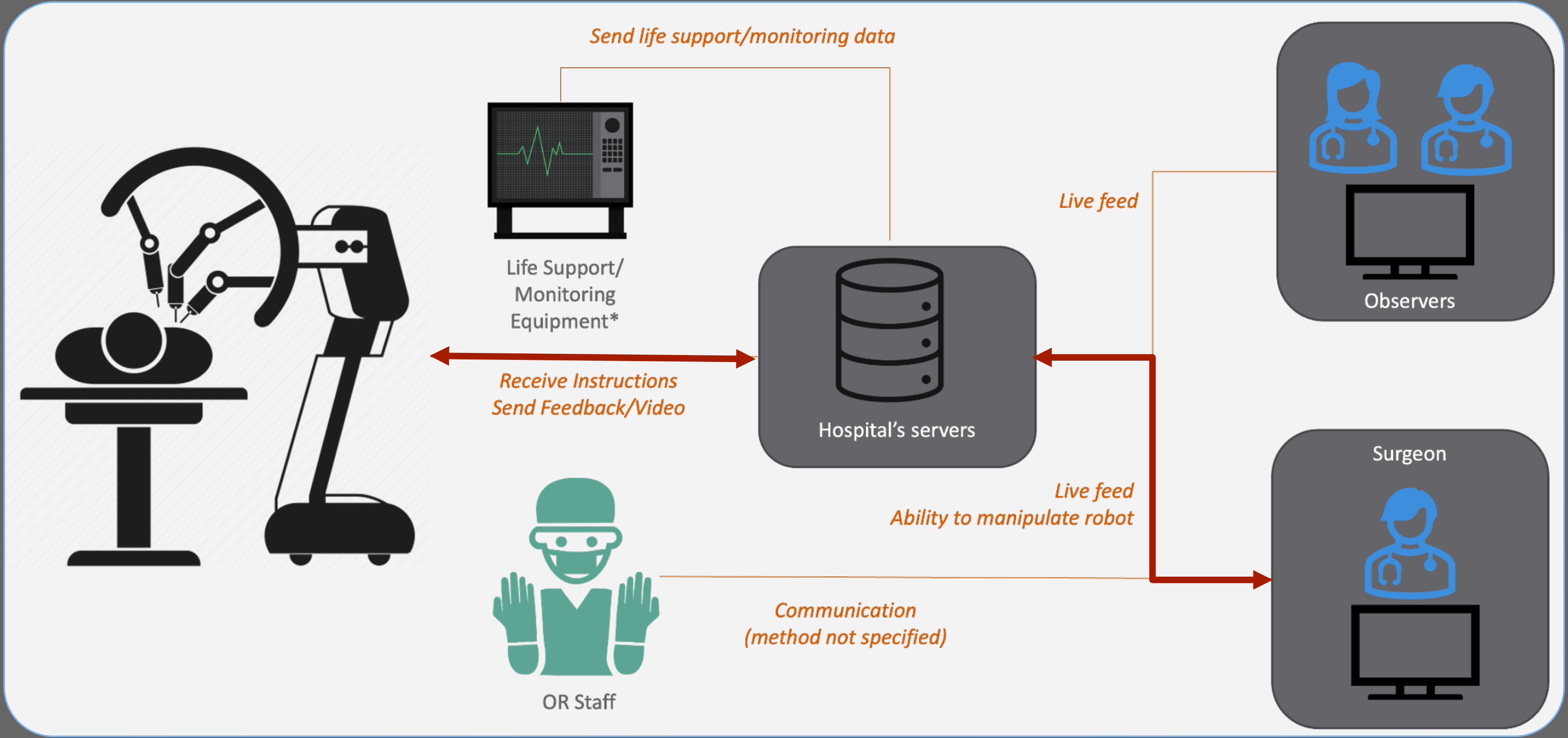

Send life support/monitoring data
Life Support/ Monitoring Equipment*
Live feed
Observers
Receive Instructions
Send Feedback/Video
Hospital's servers
Surgeon
Live feed
Ability to manipulate robot
Communication (method not specified)
OR Staff

Also add authentication for the observers

Add authentication for the surgeon

Ad-hoc Navigation & Reliance on Use Cases for prioritization

Participants rely on Use Cases to help them focus, but this is not accounted for in formalized threat modeling processes


Send life support/monitoring data
Life Support/ Monitoring Equipment*
Live feed
Observers
Receive Instructions
Send Feedback/Video
Hospital's servers
Surgeon
Live feed
Ability to manipulate robot
Communication (method not specified)
OR Staff

Adding more color to prior work that has found Data Flow Diagrams are not sufficient for threat modeling *[Sion et al, ICSEW 20]*

Ad-hoc Navigation & Reliance on Use Cases for prioritization

Our recommendations include accommodating this “natural” process in threat modeling tools

Automation & Tooling support the following:

Free-flowing process through interaction

Multiple configurations

Use-case views

Prompt for multi-patient harm

Integrate with safety risk processes

FDA & Other Regulators should ensure that manufacturers:

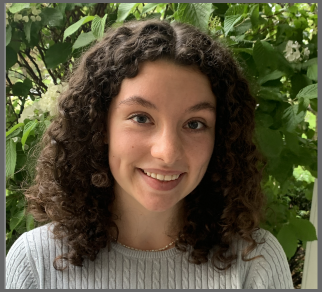
Delineate internal vs. external architecture & explain which configurations are essential to what aspects of security

Researchers are able to:

Build on top of the scenarios we developed to test frameworks and tools for medical device security & threat modeling

Research Team

Ronald Thompson
Tufts University


Madeline McLaughlin
Tufts University

Carson Powers
Tufts University

Dan Votipka, PhD
Tufts University

Acknowledgments

Shannon Lantzy, PhD
Independent Consultant

Rock Stevens, PhD
US Army

Peter Ney, PhD
University of Washington

Seth Carmody, PhD
MedCrypt

Naomi Schwartz
MedCrypt

Greg Garcia
HSCC

Funding

Medcrypt

cisco

Takeaways

Flexible process for brainstorming threats and controls

Safety considerations are critical, unclear how to integrate

Use Cases/Workflows are useful tools for prioritization

Supplemental Material

osf.io/p9xky

Includes scenarios, discussion on medical device regulations, codebook, and screening survey

Questions?

rthomp06@cs.tufts.edu

tsp.cs.tufts.edu

Funding Sponsors

cisco

Medcrypt