



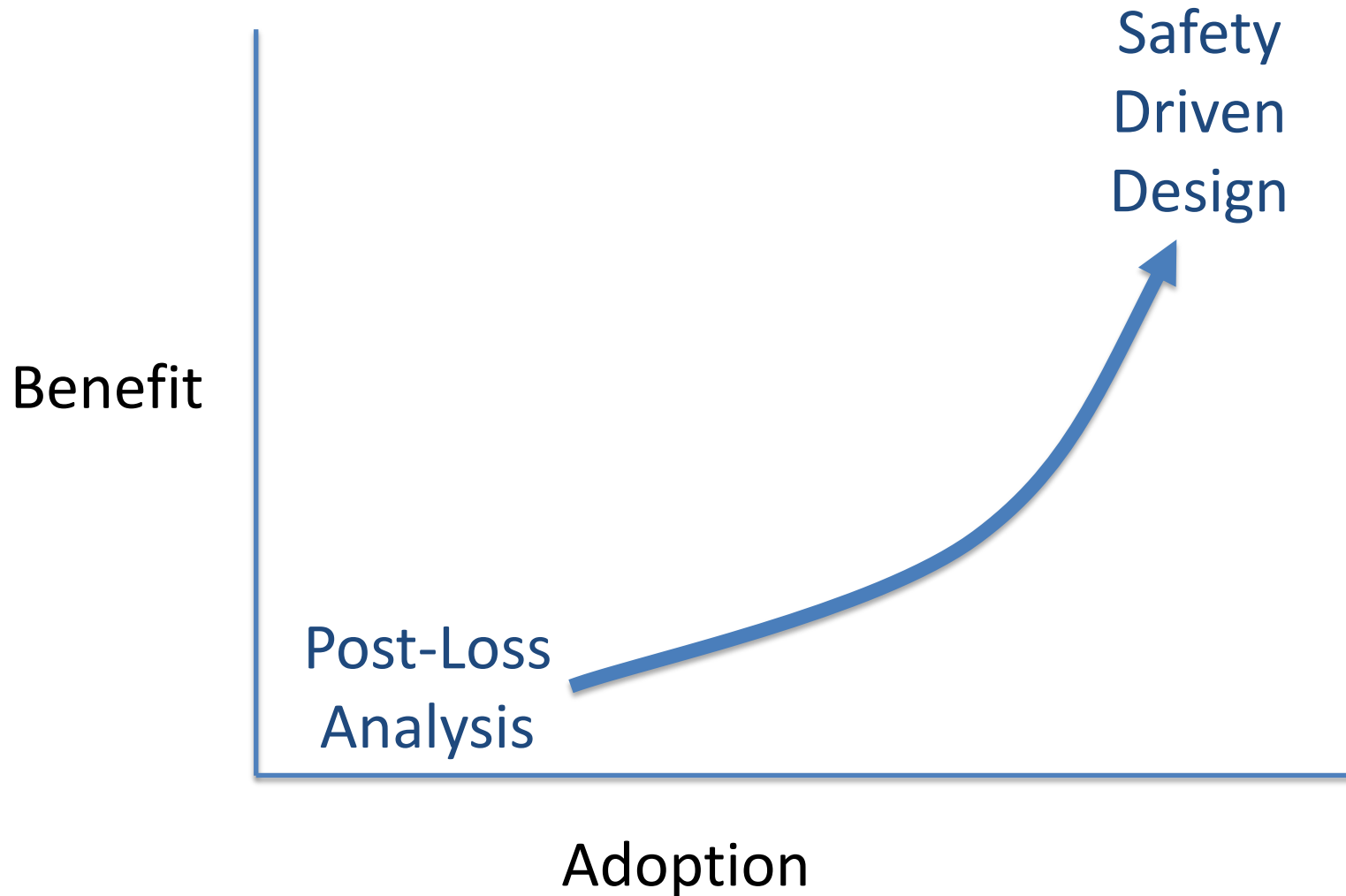
STAMP applied to Healthcare

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This presentation reflects my personal work and views and not of my employer

Adoption of System Safety



VA Collaboration - Case Study

- CAST applied to a Sample Accident (used for RC training)

Pneumothorax Case and Instructors Guide

NOTE: This teaching case has elements from many real case studies, but many details were manufactured to provide enough information to accomplish the RCA Team exercise

Team Members

- 1) Radiology resident (not involved in this case)
- 2) Radiology physician (not involved in this case)
- 3) Nurse
- 4) Department

Event has occurred before

Corrective action
on service; check
within 2 hrs, u

Summary of the Event

A.B. is a 55-year old male with a history of chronic obstructive pulmonary disease (COPD) and a 10mm nodule in the upper lobe of his right lung. He was subsequently seen by a pulmonary medicine consultant who advised a CT scan guided fine needle biopsy of the lung nodule. The clinic physician and nurse both informed the patient there was likely to be minor discomfort after the procedure and it would not be necessary to stay overnight.

A.B. was admitted to the short stay hospital unit (SSU) on the morning of 11/1/99 to have a CT scan guided fine needle biopsy of the lung nodule. After he was mildly sedated, the patient was transported to the radiology department. The patient also had an IV catheter inserted and cardiac rhythm and blood pressure monitors attached. The interventional radiologist was assisted by a radiology resident. The role of the resident was to learn the technique by assisting with the procedure and monitoring the patient. The CT scan image was used to locate the lesion. The radiologist inserted a needle through the chest wall into the nodule and aspirated tissue for the specimen. After the needle was withdrawn both clinicians noticed a small (~10%) pneumothorax (air inside the chest cavity but outside the Right lung), a common complication. The partially sedated patient had no complaints and denied any shortness of breath or pleuritic chest pain.

After a 15-minute delay in transport, the patient was taken back to SSU, and monitors were re-attached. In the next 30 minutes, no staff had directly checked on the patient. During that time, the pulse oximeter alarmed "low oxygen" repeatedly, but the patient began to silence the alarm as he previously had learned to do. The patient was surprised that he had right-sided chest pain with inspiration but he did not inform his nurse. He had rationalized this pain as a transient problem that would soon disappear.

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Introduction to System Safety Analysis

Root Cause

- Based on chain of events model
- Identifies a limited number of “root causes”
- Recommended by Joint Commission based on NASA engineering approach
- Basis of Incident Reporting Tools used by the FDA, Joint Commission, Patient Safety Organizations

Traditional RC approach became mainstream after “To Err is Human”

CAST

- Based on System Engineering
- Design for complex systems (Recognizes emergent properties)
- Identifies a larger set of causes
- Hardware component failures, component interactions, human and software interactions, systemic accidents (i.e. mode confusion) etc.
- Treats safety as a dynamic control problem

Necessary for complex systems

Accident Overview

*Solitary Pulmonary nodule
in upper lobe of right lung*

Diagnosis



*CT scan guided fine needle
biopsy of the lung nodule*

Biopsy
Procedure

10% Pneumothorax



*1 day Observation in
Short Stay Unit (SSU)*

Post Procedure
Recovery

*50% Pneumothorax
Chest Tube Placed
4 day recovery*

VA Root Cause Analysis

Contributing Factors:

- The complication was not disclosed to the patient or treatment team
- No hand-off of the patient from Radiology to the SSU
- Delay in patient assessment
- Patient is managing his own alarm- alarm safety issues
- This nurse is practicing out of her scope of practice if she is an RN. She should have called the Resident/physician responsible for the care of this patient.

Root Causes: There was a lack of communication to the patient and treatment team regarding the complication which occurred in Radiology. This combined with the delay in patient assessment post procedure and the patient silencing his own alarm eliminated the opportunity to detect the pneumothorax in a timely manner.

Strongest Actions Proposed

- Lock out pulse oximeter so patient cannot manage controls
- Face to face hand offs with check lists
- Practice Issues
 - Addressed by peer review and addressed by supervisor

Accident Description

Accident:

(General) Patient harmed as a result of hospital care

(Specific) Patient's lung is harmed while in the hospital for a procedure to biopsy a lung nodule

System Hazards (related to this accident):

H1 Procedure damages sensitive tissue

H2 Patient is unable to fully recover from procedure

The System Safety Constraints (related to this accident):

- Lung nodule must be biopsied without harming the patient
- The patient must be monitored and treated appropriately while recovering from the procedure

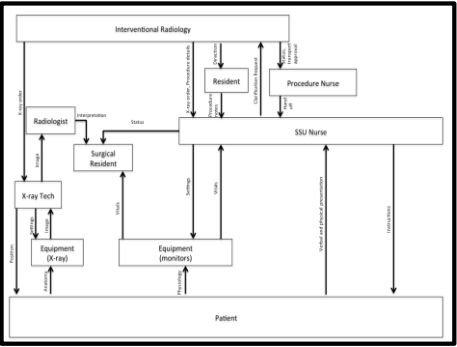
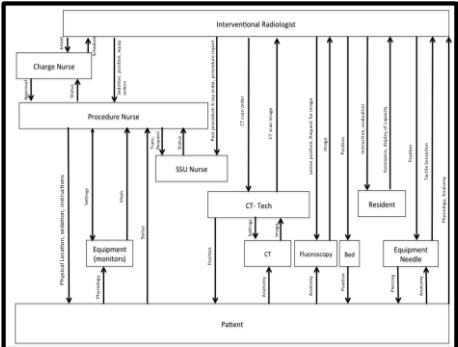
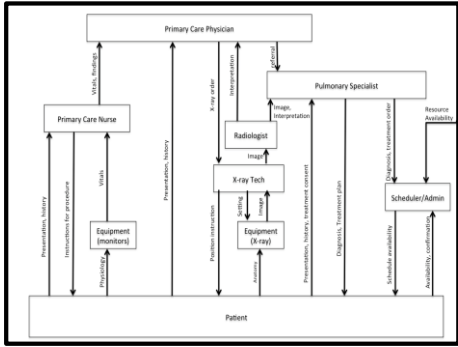
Control Structure Creation

Diagnosis

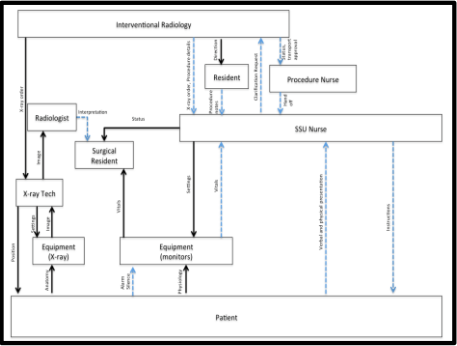
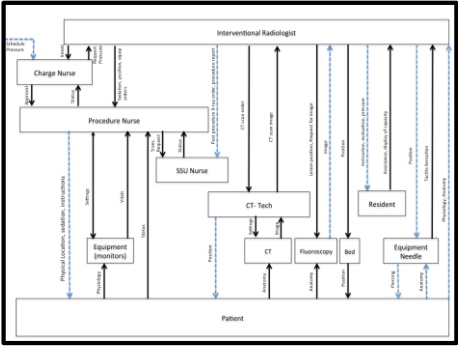
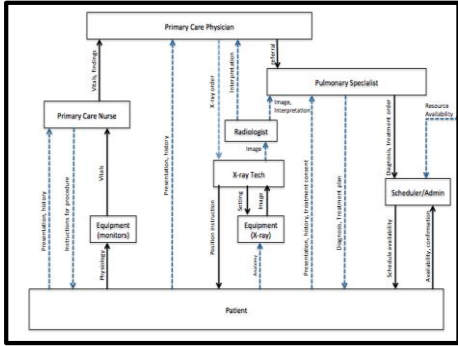
Biopsy Procedure

Recovery

Designed



Actual



Control Diagram created for each phase displayed in appendix
As Designed and Actual

CAST Analysis

Physical System (partial results)

CT/Fluoroscopy Guided Biopsy



Safety Requirements/ Constraints Violated

- Provide imaging to aid in maintaining a safe pathway to nodule
- Obtain sample without harming patient

Failures and Inadequate Controls

- 10% Pneumothorax resulted from biopsy procedure
- Non quantitative method for assessing extent of pneumothorax
- Patient movement is not prevented or monitored

Physical Contextual Factors

- Inadequate imaging provides only intermittent partial views of the safe pathway, need to minimize harm from continuous imaging
- Post CT scan is used to view complications, X-ray used in follow-up

Patient Record



Safety Requirements/Constraints Violated

- Communicate patient status, actions performed, and procedure complications to all healthcare providers involved in patient's care

Failures and Inadequate Controls

- Illegible writing in physical chart could result in lack of procedure details and complications available to SSU nurse and surgical resident
- Delay in transcriptions available in EMR

Physical Contextual Factors

- Physical Patient Files used are populated real time by hand believed to be fastest form of communication. EMR used as long term record, billing
- Staffing/time pressures as well as stress can affect the quality and readability of the information in the chart

Short Stay Unit (SSU)



Safety Requirements/ Constraints Violated

- Provide continuous monitoring of patient status post procedure

Failures and Inadequate Controls

- Did not provide awareness of patient distress

Physical Contextual Factors

- Multiple patients are assigned to each nurse in the SSU
- Close proximity and open floor plan assumes nurses will be aware of patients in distress or worsening condition and gives patients the impression that they are continuously monitored
- Newly opened facility
- Patient was silencing the oximeter alarm

Controller Analysis (partial results)

Patient

Safety Related Responsibility

- Provide accurate and complete information (physical and verbal clinical presentation)
- Provide consent and acknowledge understanding of the diagnosis, treatment plan as well as instructions for the procedure

- **Follow instructions provided by Health Care Professionals**

Unsafe Decisions and Control Action

- *Patient may not have conveyed all relevant information to providers regarding pneumothorax risk factors*
- *Patient may not have remained still during the procedure*
- **Patient silenced the alarming oximeter during recovery in the SSU**
- *Patient may have been coughing or attempted to get out of bed while in the SSU*

Process Model Flaw

- **The patient most likely did not know what information was relevant for pneumothorax risk factors**
- *The patient may not have known he was at a high risk of pneumothorax*
- *The patient may not have understood the diagnosis or what pneumothorax was*
- *The patient may not have understood the requirements for the biopsy procedure*
- **The patient thought the pain he was experiencing was normal and not due to a complication**
- **The patient did not realize that he was in need of immediate medical attention**

Context

- *The patient likely had strong emotions at the time of this diagnosis (having just been told about the potential for lung cancer), which may have affected the patient's ability to comprehend the procedure and its implications*
- *There may have been co-morbidities present which created a high risk of pneumothorax*
- *The patient may have had additional questions that he did not ask due to time pressure, embarrassment, or expectation that he should have known the answer*
- *The patient may have received previous treatment and therefore did not perceive a risk this time*
- *The information may have been given to the patient only verbally, making it difficult to remember and impossible to review after leaving the office*
- **The patient expected that he was being monitored**

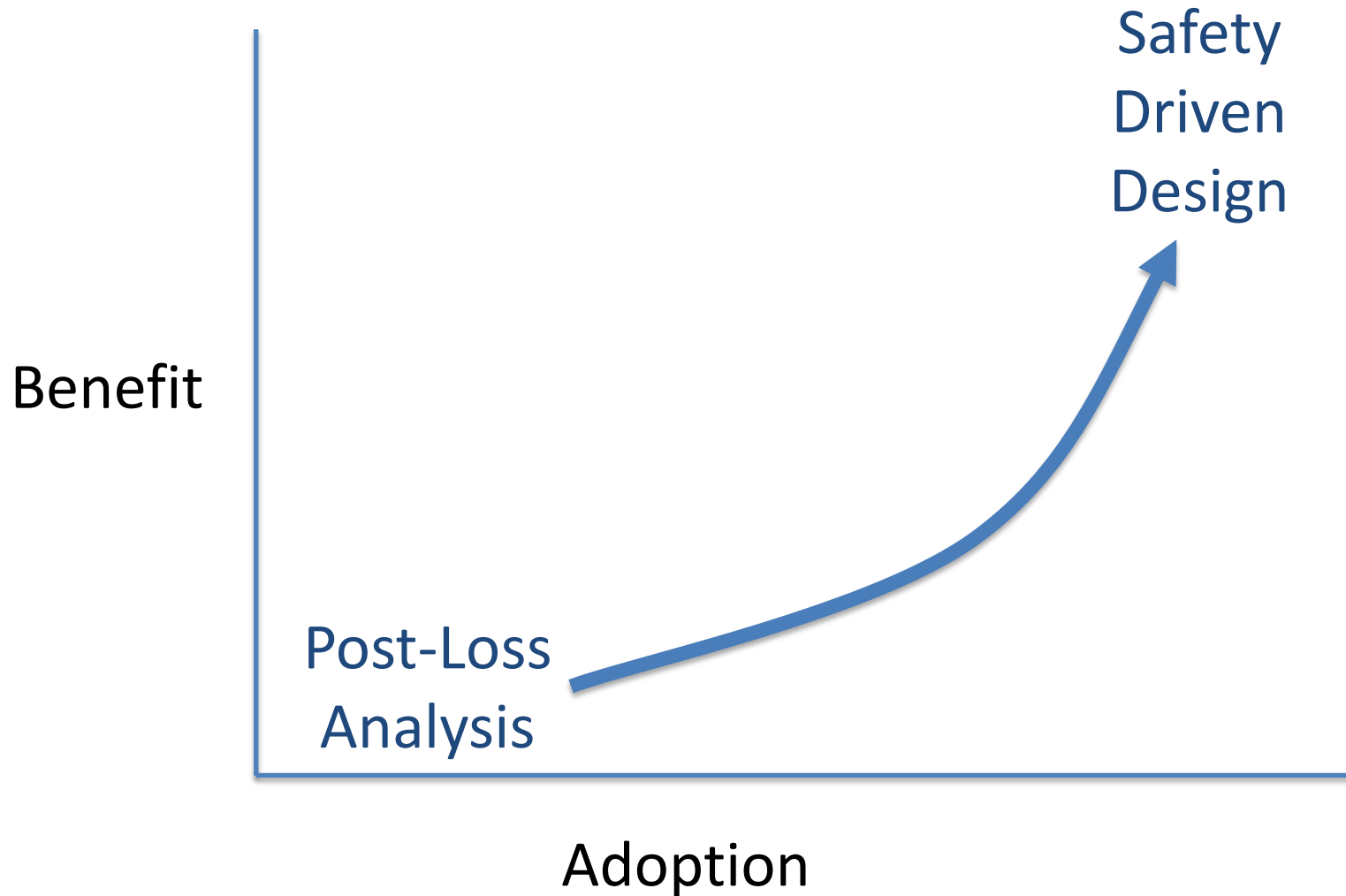
CAST results (partial)

- A number of violated constraints should be addressed both for the physical system and the controllers
- Feedback throughout the system is lacking
 - Ensure a safe pathway to eliminate harm
 - Ensure communication is complete and understood
 - Adequately monitor condition for change
 - Improve the proactive measures to prevent decline

CAST Summary

- CAST provides a number of questions that can aid the patient safety officer investigating incidents
- Analysis uncovers more causal factors than the standard root cause analysis
- CAST allows for the identification of systemic hazards

Adoption of System Safety





Applying STAMP to
Infection Prevention



1:25 hospitalized patients acquire an HAI

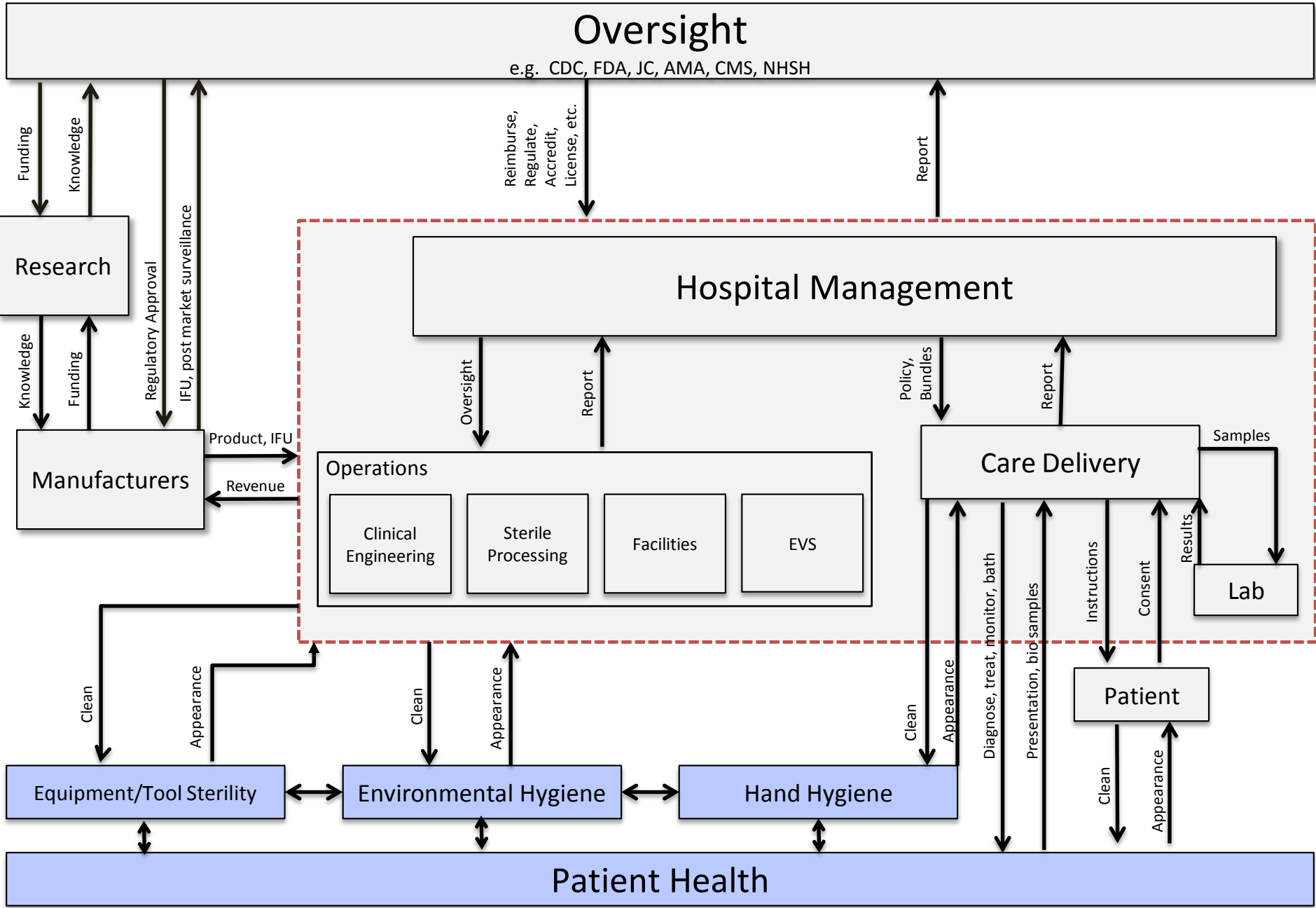
1.7 Million HAI's occurred in 2012

99,000 Patients died of HAI

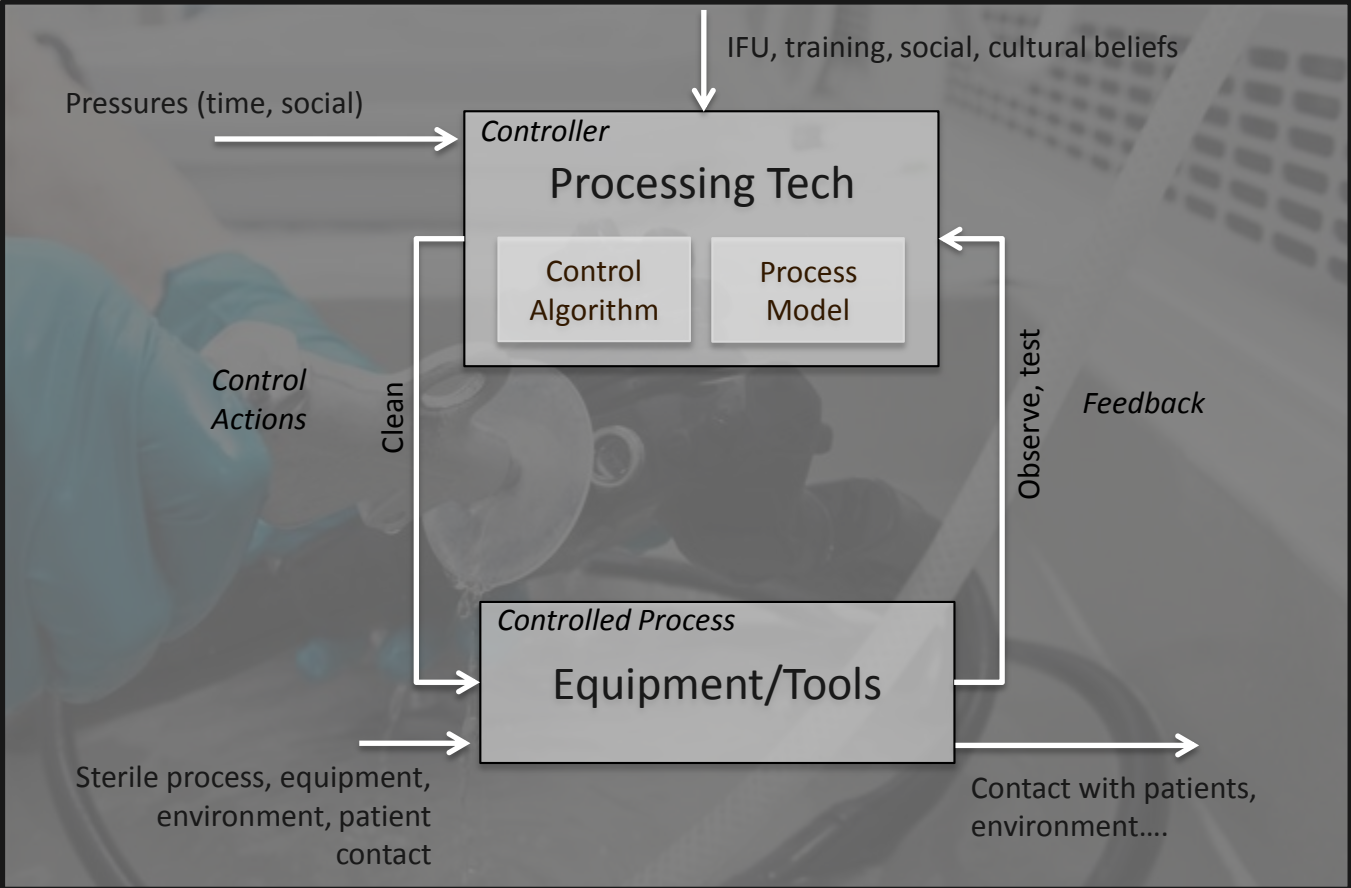
Source: 2011, CDC <http://www.cdc.gov/hai/surveillance/>

Providing care that doesn't result in HAI's

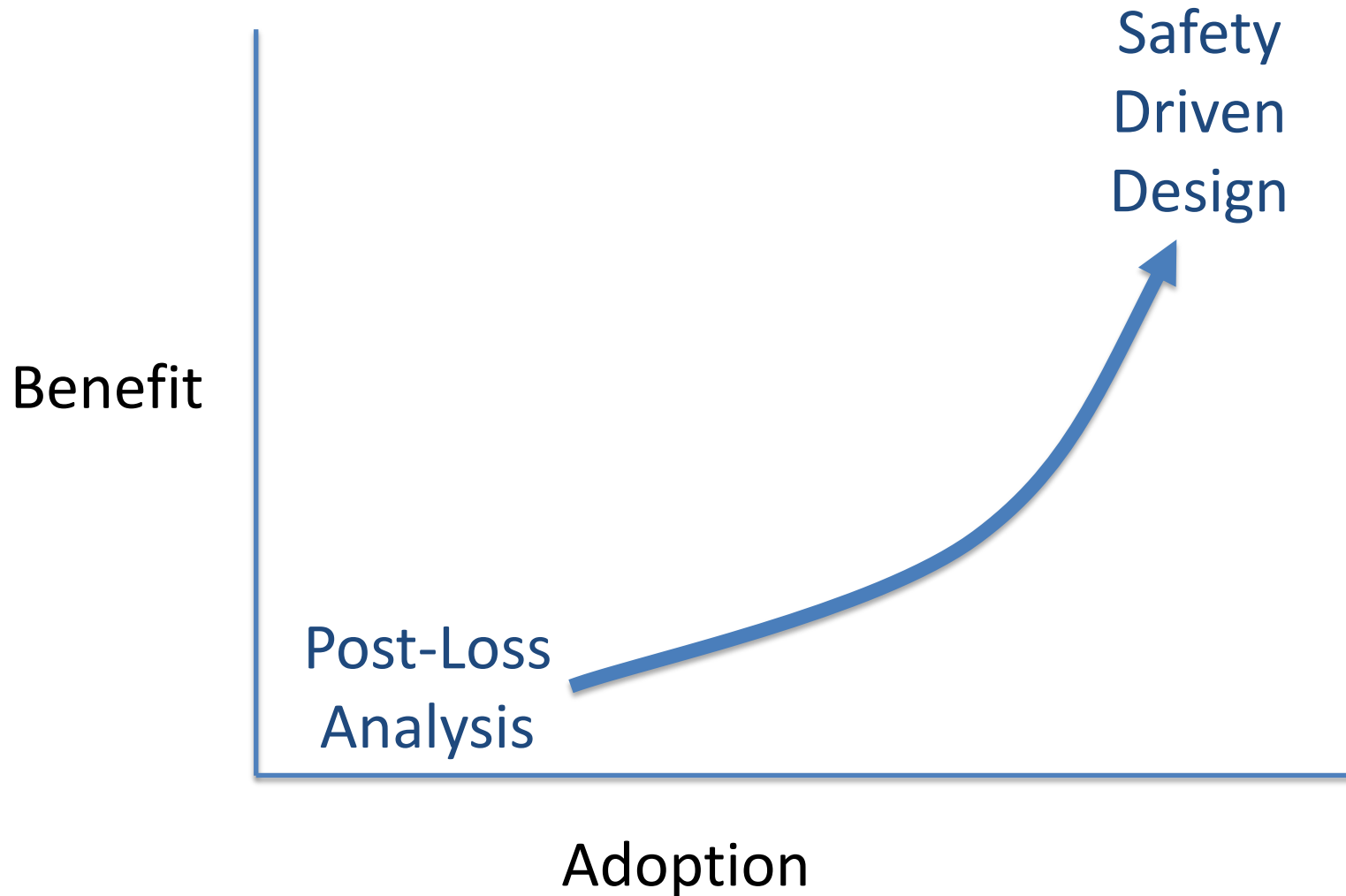
High-level Hierarchical Control Structure



Sterilizing Re-usable Tools

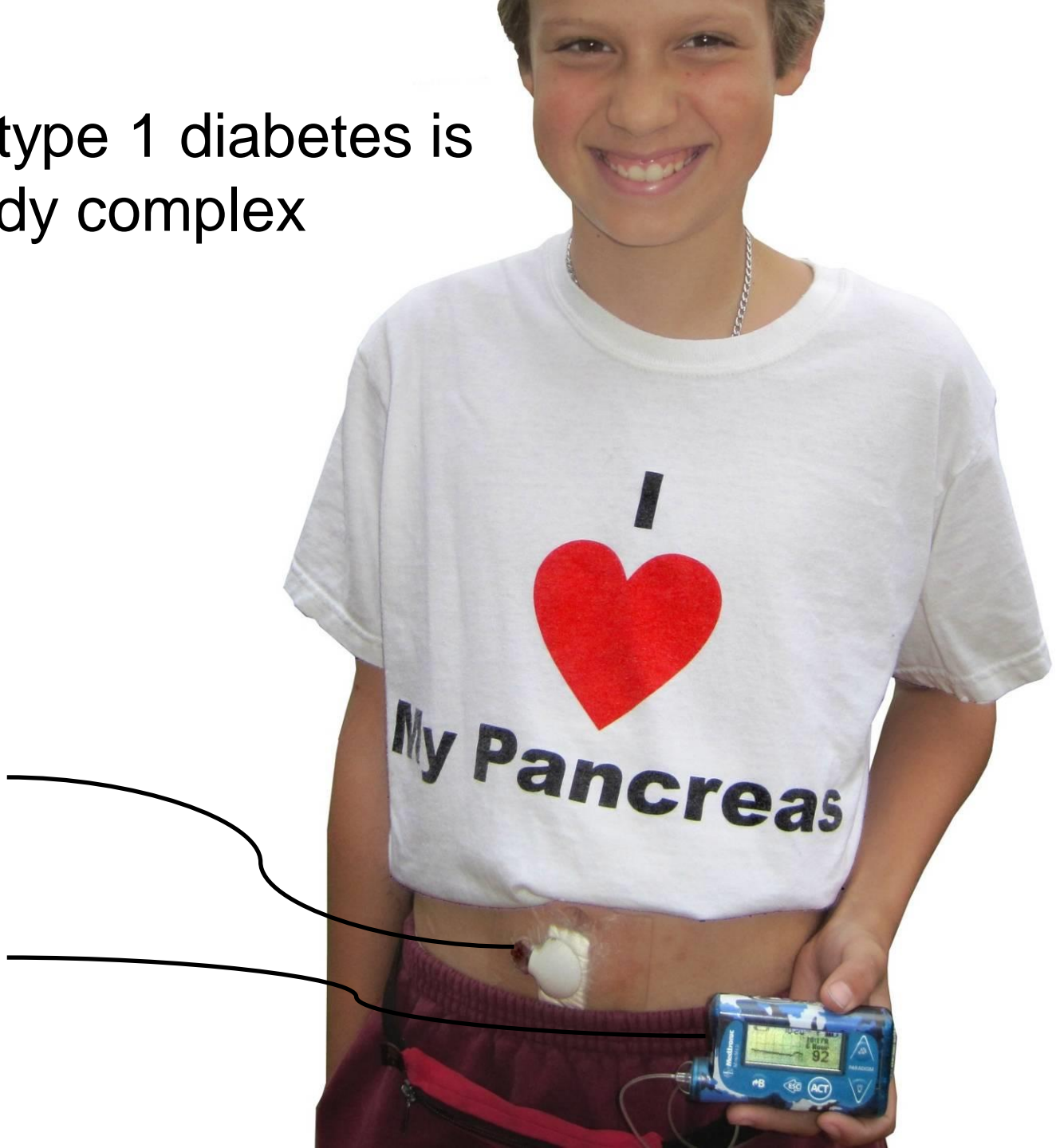


Adoption of System Safety

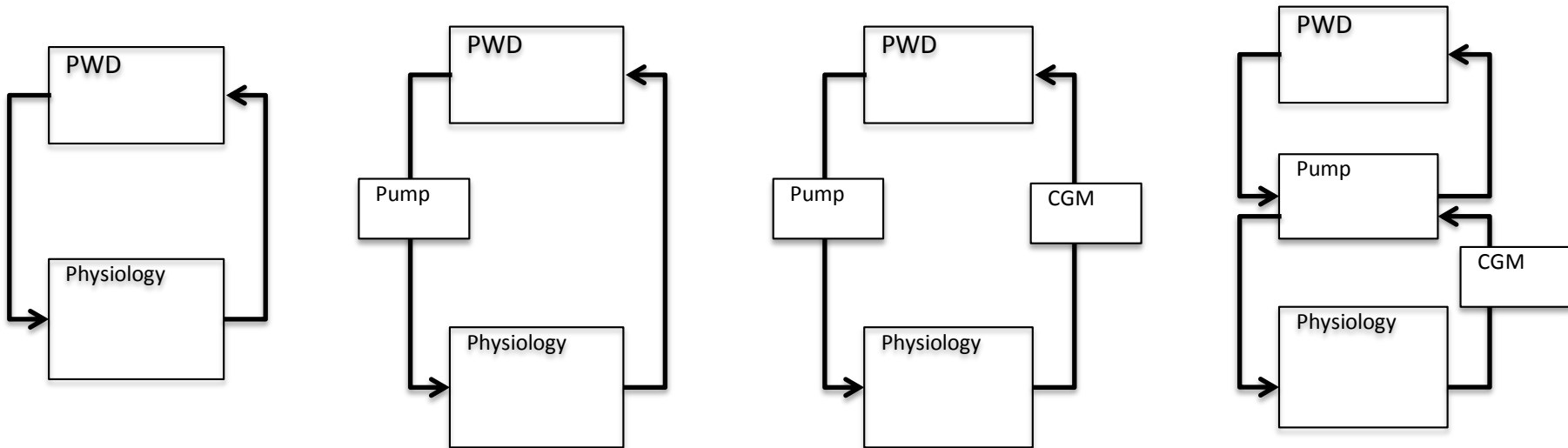


Living with type 1 diabetes is
already complex

glucose
sensor
insulin
pump



Variation in Control Structures



Lessons Learned & Observations

Need

Trade Study

General Concepts

General Control Structure

STAMP Training

Challenges/Opportunities

Design Iterations



STPA Iterations

There is significant value in the process of performing STPA iteratively throughout the design process

Thank you

