
Evaluating Systems with Multiple Processes Using STPA

A Case Study in a Medical Intensive Care Unit

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Why does patient safety matter?

Leape et al. in 1991 found that 98,000 patients die every year from medical errors in the US [1]

That's the equivalent of crashing a jumbo jet every day

Why does patient safety matter?

- ❑ Using a more rigorous updated methodology, James in 2013 found that the number is actually closer to 210,000 – 440,000 patients every year in the US [2]
- ❑ Leading causes of death in the US?
- ❑ 1- Heart Disease
- ❑ 2- Cancer
- ❑ 3- Medical errors

Intensive Care Units (ICU)

- They care for the sickest patients
 - Sick patients have little “physiologic reserve” so there is little room for error
 - Sick patients require more complex care involving more opportunities for error
- As a result, these tend to be the most safety conscious areas of the hospital

Patient Safety Approaches

- FMEA has been applied very frequently in ICU settings because clinicians recognize that it is one of the highest risk areas of the hospital
- Examples:
 - Implementation of Smart IV Pumps [3]
 - Drawing blood and sending samples to the laboratory [4]
 - Ordering and administering chemotherapy [5]

Limitations of FMEA

- There are several weaknesses we typically consider [6]:
 - Based on a linear chain of events accident causation model
 - Cannot analyze interactions between components; limited to analyzing component failures
- In healthcare, we need to consider one more:
 - Cannot analyze interactions between processes

Multiple Processes In Healthcare

- Healthcare at the top level can be seen as the process of delivering care to the patient
 - Which is composed of many processes, like drawing lab specimens and giving medications
- FMEA is a bottom up approach
 - It therefore requires a much more detailed process than the top level “delivering care”

Hypothesis

- If we model the entire process of delivering care in an ICU with STPA we can see interactions between these more detailed processes that we miss with FMEA

Methods

- Use STPA at a higher level to simultaneously analyze multiple processes involved in delivering patient care
 - Typically in healthcare have limited ourselves to single processes, such as delivery of radiation therapy [7]
- Compare resultant recommendations to FMEA from an ICU

System

- ☐ Studied an eight bed medical ICU in a 635 bed hospital in Boston, MA, USA
 - ☐ Average staffing:
 - 6 nurses
 - 6 physicians
 - ☐ 2 interns
 - ☐ 2 residents
 - ☐ 1 fellow
 - ☐ 1 attending
 - 2 nurse aides
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Accidents and Hazards

Hazards

[H-1] Patient's condition not appropriately treated

[H-1.1] Over-treatment

[H-1.2] Under-treatment

[H-1.3] Mistreatment

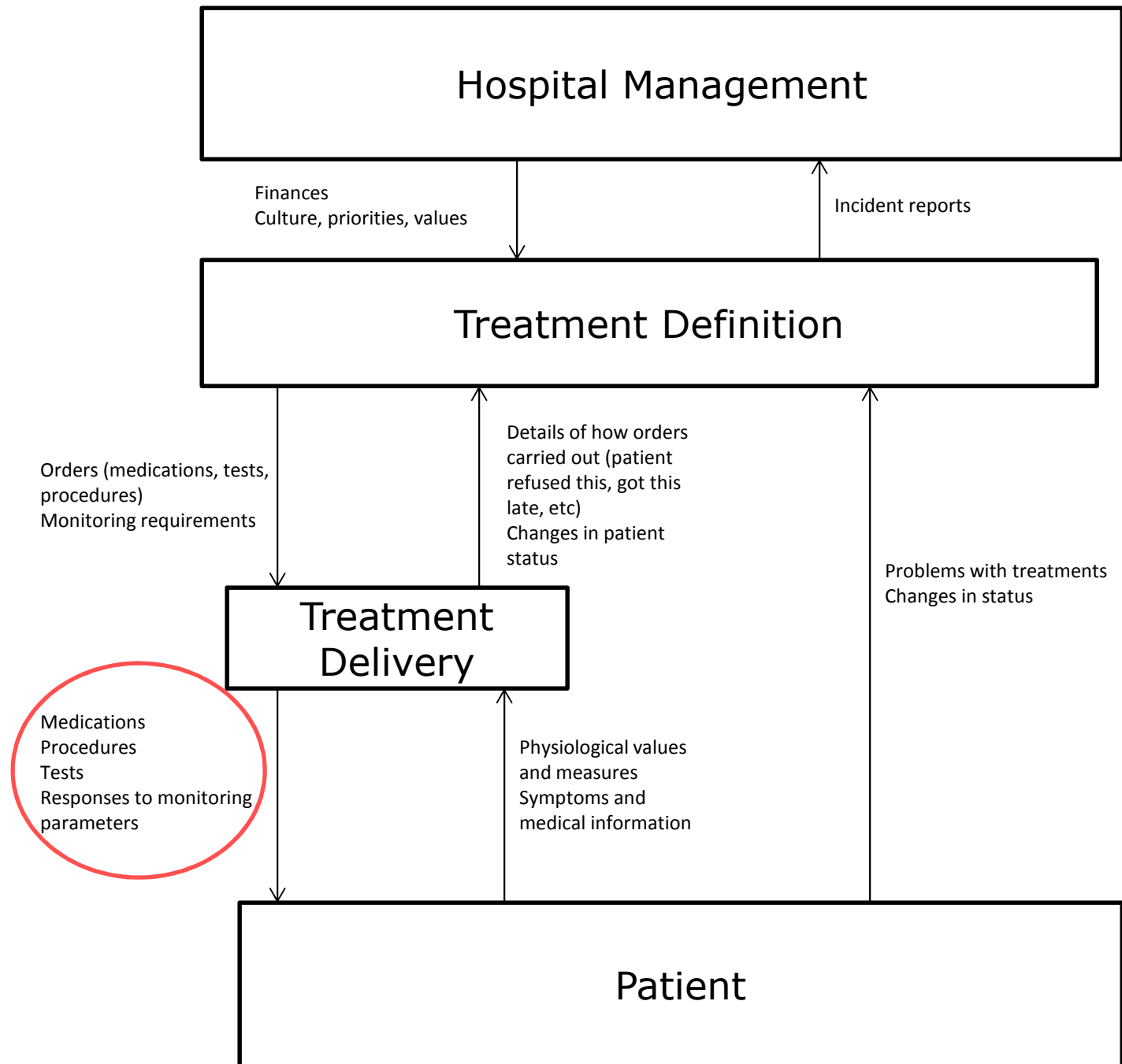
[H-2] Patient given a condition not present on admission (iatrogenic harm)

Accidents

[A-1] Patient dies or is seriously injured by medical action or inaction

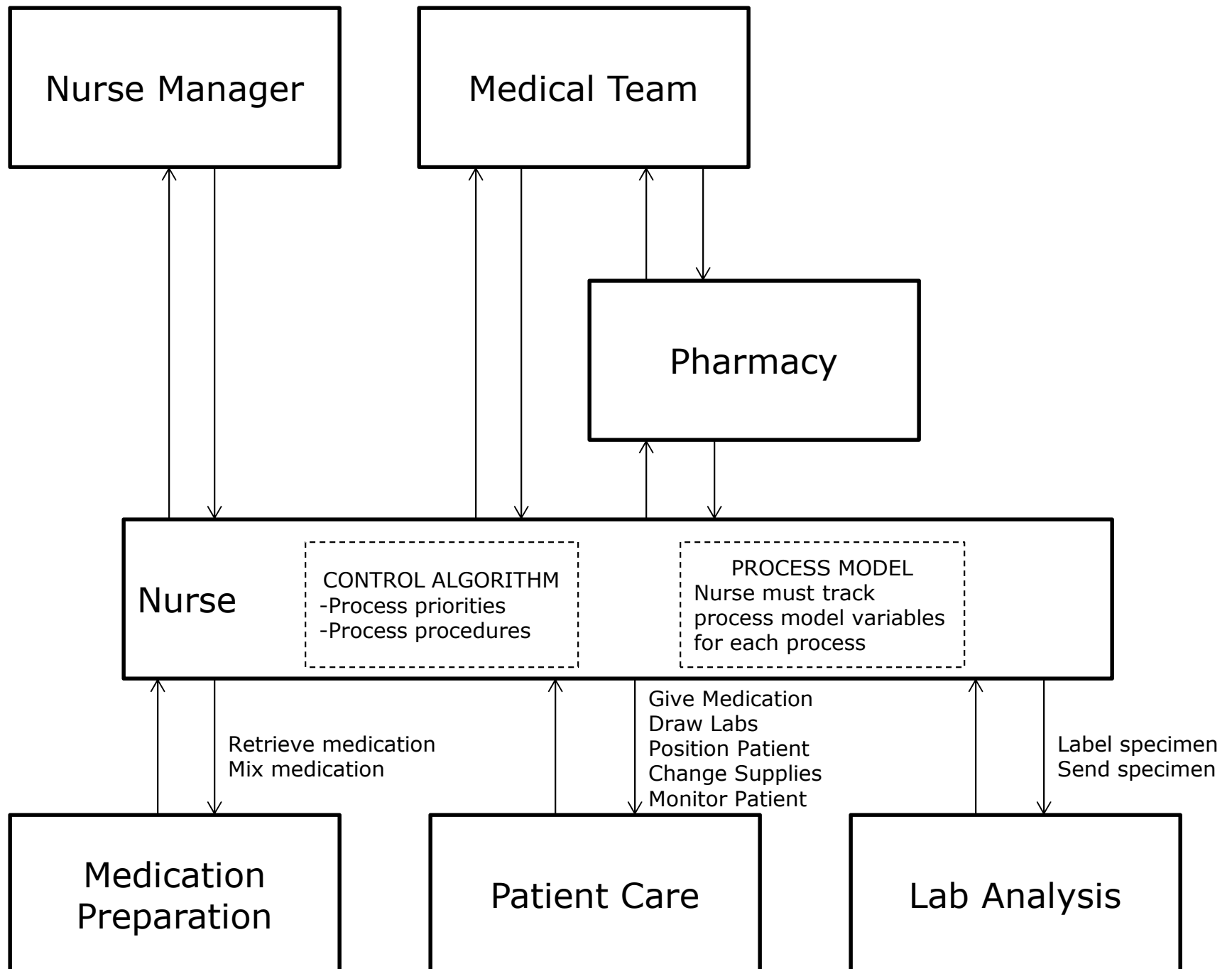
High Level Control Structure

- ❑ Adapted from the proton therapy STPA [7]
- ❑ Side note:
 - Healthcare delivery tends to follow a similar pattern
 - We can treat this model as a reusable template for control structures



More Detailed Control Structure

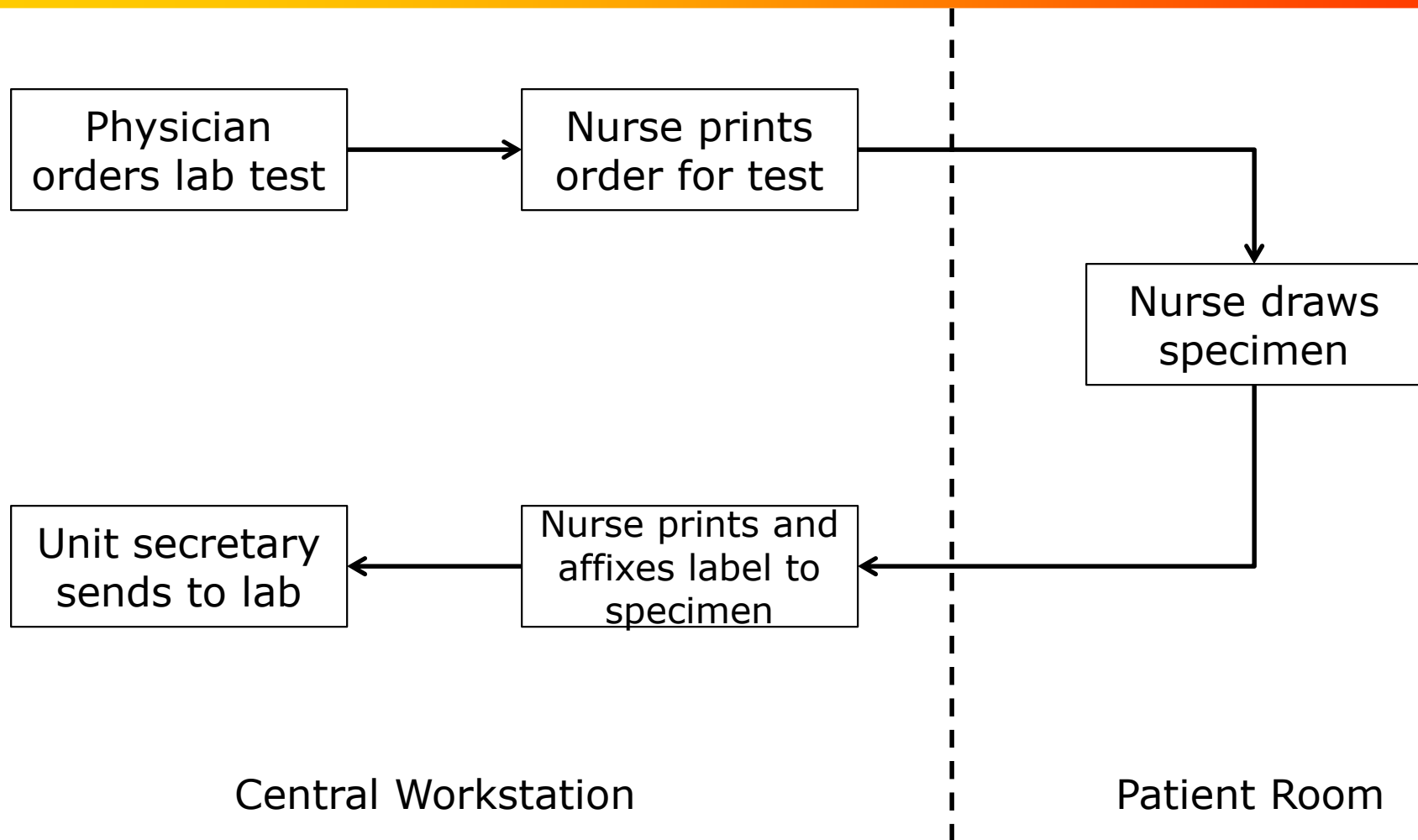
- We will zoom in on the control structure to get more detail beyond the functional boxes



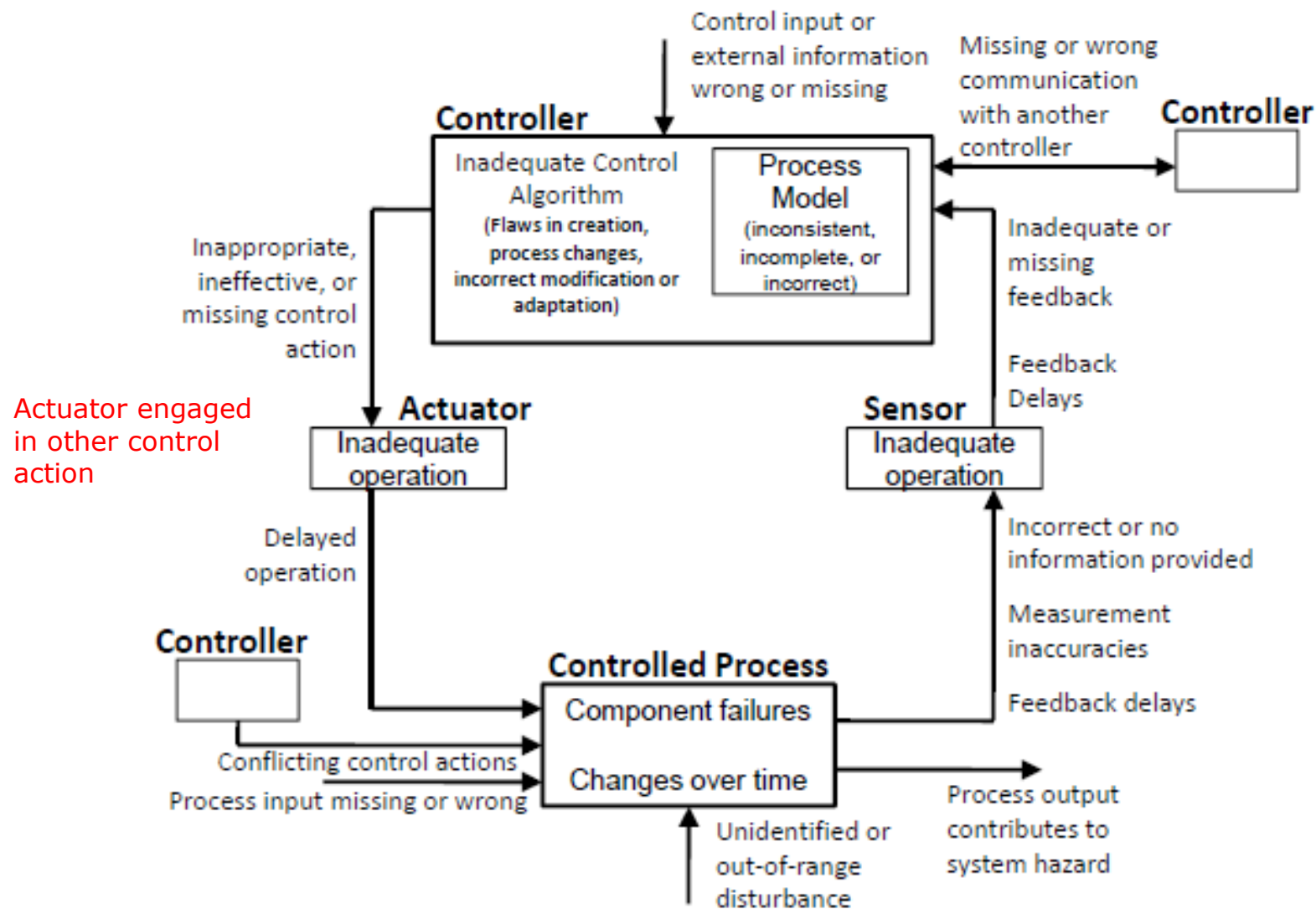
Step 1

- ❑ 9 control actions for the nurse were analyzed using classic Step 1 tables
- ❑ Identified 25 Unsafe Control Actions
- ❑ Example:
 - The nurse does not label lab specimen after drawing it
 - ❑ This makes it impossible to link the results of the lab test back to the patient

Procedure for Drawing Labs



Step 2



Step 2 – Causal Scenario

- ❑ UCA: Nurse not labeling lab specimen
- ❑ Can we imagine a scenario where the specimen was labeled with incorrect or incomplete patient identifiers because the actuator was involved in carrying out another control action?

Causal Scenario

- ❑ Nurse is drawing a “drug trough” level
- ❑ Draws lab and sets aside
- ❑ Gives medication
- ❑ Exits room leaving behind unlabeled lab specimen
 - When the nurse would have been labeling the specimen, he was otherwise engaged in giving the medication

Recommended Controls

- ❑ Change the process to print labels for specimens before drawing them
 - Removes the clash of needing to give medication and print labels simultaneously
- ❑ Assign two nurses to draw drug troughs
 - One to manage the specimen and one to manage the medication

Comparison to FMEA

FMEA Results [4]

Failure Mode:

Incomplete labeling
of lab specimen

Recommendations: Re-
train nurses in how to
label lab specimens

STPA Results

UCA: The nurse did not
label the lab specimen

Recommendations:

Change the process to
print labels before
drawing lab.

Change the process to
have two nurses in the
room for drawing drug
troughs

Conclusions

- ❑ STPA can analyze multiple processes occurring within one control structure
 - Very common occurrence in healthcare systems
- ❑ Analyzing these processes together yields important insights into “process interactions”
- ❑ This ability is another strength of STPA compared to FMEA

References

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- [7] Antoine, B.: *Systems Theoretic Hazard Analysis (STPA) Applied to the Risk Review of Complex Systems: An Example from the Medical Device Industry*, MIT PhD Thesis, 2012.

See associated abstract:

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