28th Annual INCOSE international symposium
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Case Study: Application of DoD Architecture Framework to Characterizing a Hospital Emergency Department as the Intended Use Environment for Medical Devices

Context: Healthcare MBSE Challenge Team

- Healthcare Challenge Team Goals
  - Short term: develop MBSE examples medical device & healthcare problems
  - Long term: create MBSE best practices for medical device & healthcare problems
- Phase 1: Medical device MBSE [2011-2014]
  - Intent: develop a reference example of how MBSE can be used in the development of medical devices
  - Outcome: a non-proprietary MBSE model of an infusion pump
- Phase 2: Clinical operations MBSE [2014-2017]
  - Intent: understand what aspects of clinical operations would benefit from MBSE models
  - Outcome: three example models based on elicitations from clinical staff

This presentation addresses one of the three examples from Phase 2

Case Study Desired Outcomes

- The Challenge: Will conventional systems engineering tools and methods work for clinical operations?
  - Better understanding of challenges
    - Are clinical operations really so different that MBSE won't work?
    - Are clinical staff really so different that MBSE will not communicate?
  - Initial understanding of the utility
    - Lean methods and simulation applications have clearly demonstrated value
    - Does MBSE add anything? How does it compare to methods like SEIPS and HFMEA?
  - An initial demonstration of methodology and tools

These questions were the outcomes of three workshops with clinical staff

Enterprise Architecture Overall Approach

- Develop a draft high-level MBSE enterprise architecture
- Employ the MBSE architecture to address relevant problems
- Explore the potential to generalize the MBSE architecture

This work was focused on a hospital emergency department in order to control problem scope

Initial High-Level Architecture of a Hospital Emergency Department

High-Level Architecture: Emergency Department

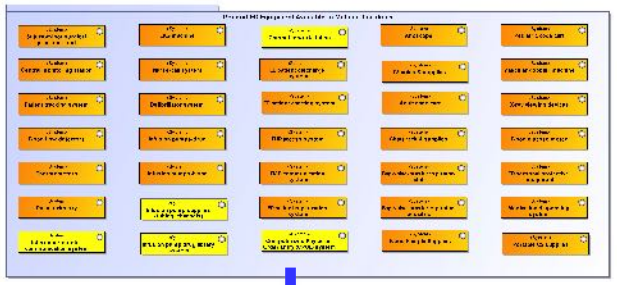
- Objective: proof of concept for MBSE & clinical operations

IW2015 Workshop

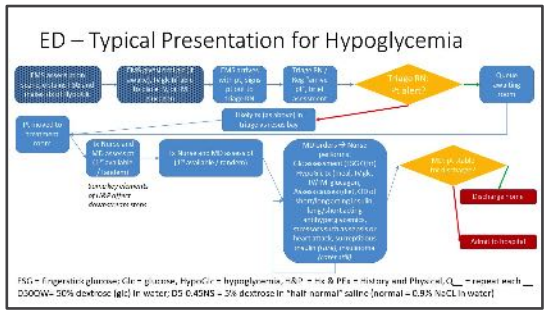
Standards & Guidelines


American College of Emergency Physicians
ADVANCING EMERGENCY CARE
POLICY STATEMENT
Approved April 2014
Emergency Department Planning and Resource Guidelines

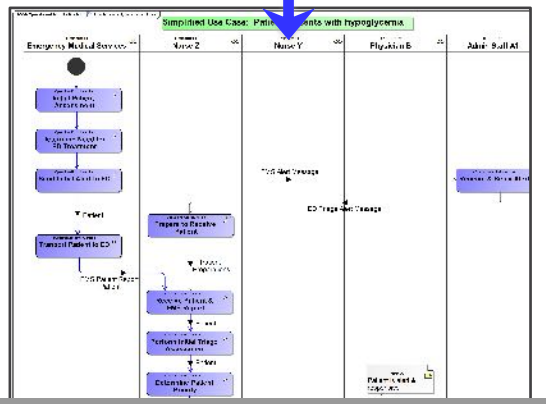
Entities for Constructing an Architecture

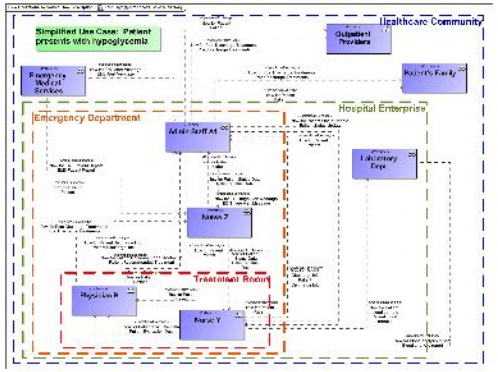


Clinician Elicitation



A Clinical Use Case

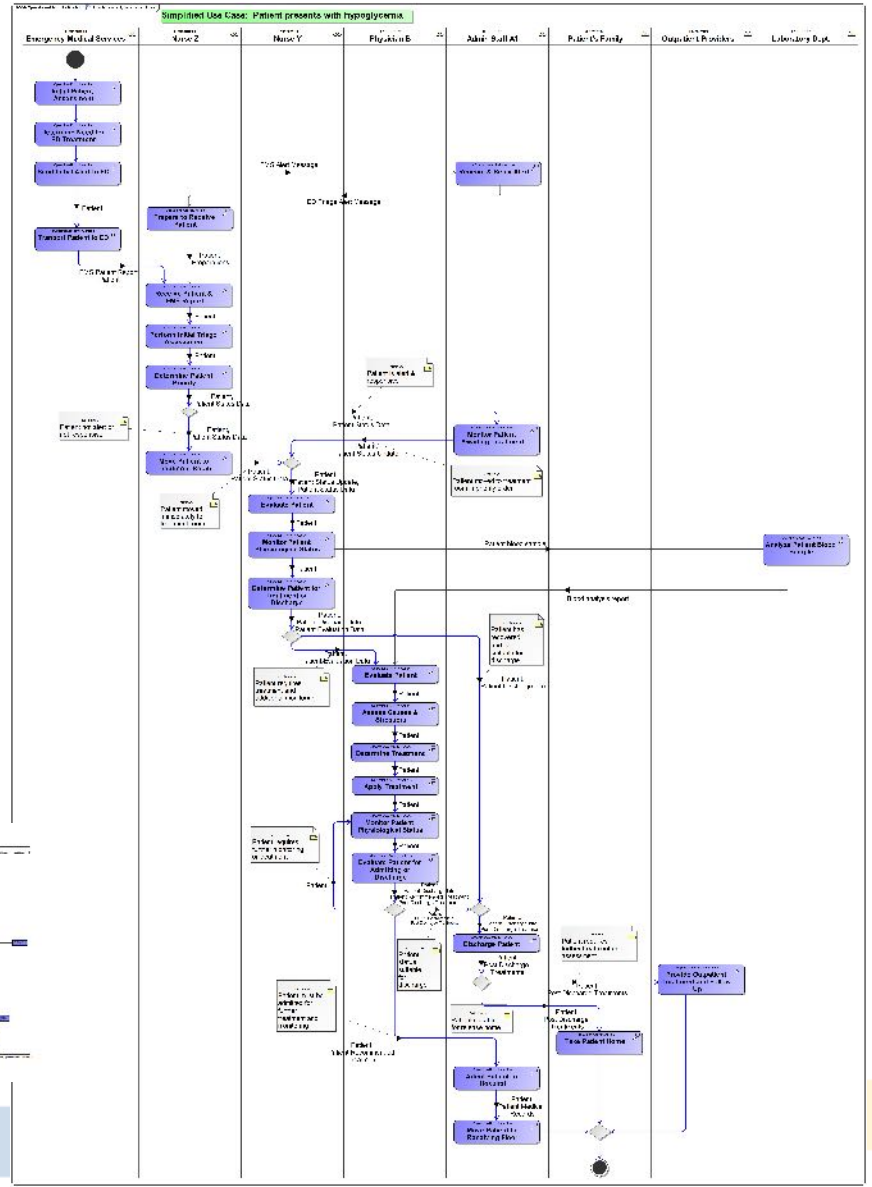




Draft High-level architecture

The process followed the standard “use cases to architecture” approach

ED Use Case: Hypoglycemia Treatment



Clinical roles

- Most identified during elicitation
- Remainder incorporated from standards & guidelines analyses

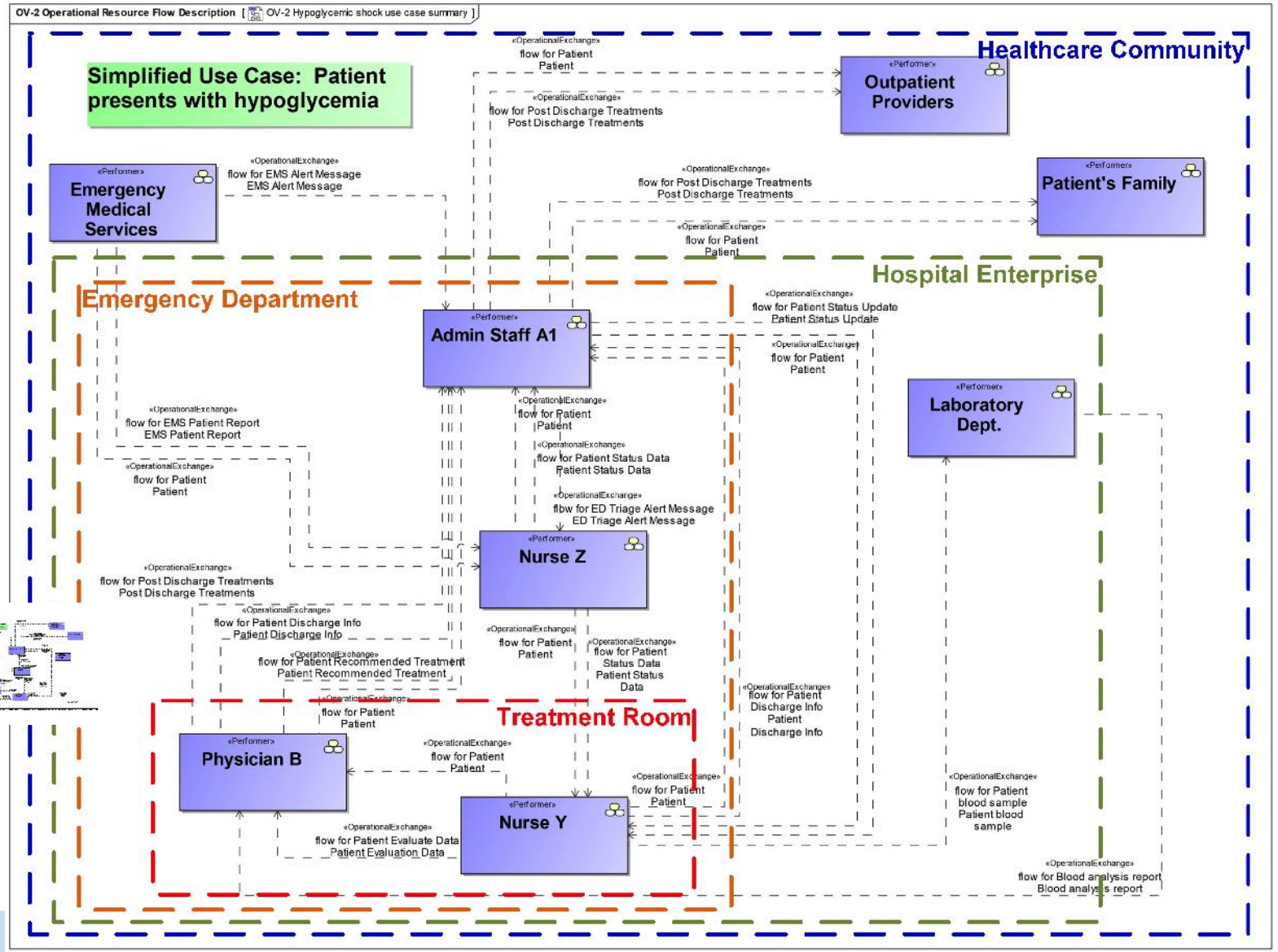
Clinical locations and equipment

- Primarily derived from standards & guidelines analyses
- Some obtained via literature review of ED modeling and simulation papers

Activity flow

- Derived from elicitation with Emergency Dept. physician

Formation of High-Level Architecture



The same information but a new view

- All interactions and relationships derived from the use case activity diagram
- Use MBSE tool to change perspectives

Shows the potential for further work analysis

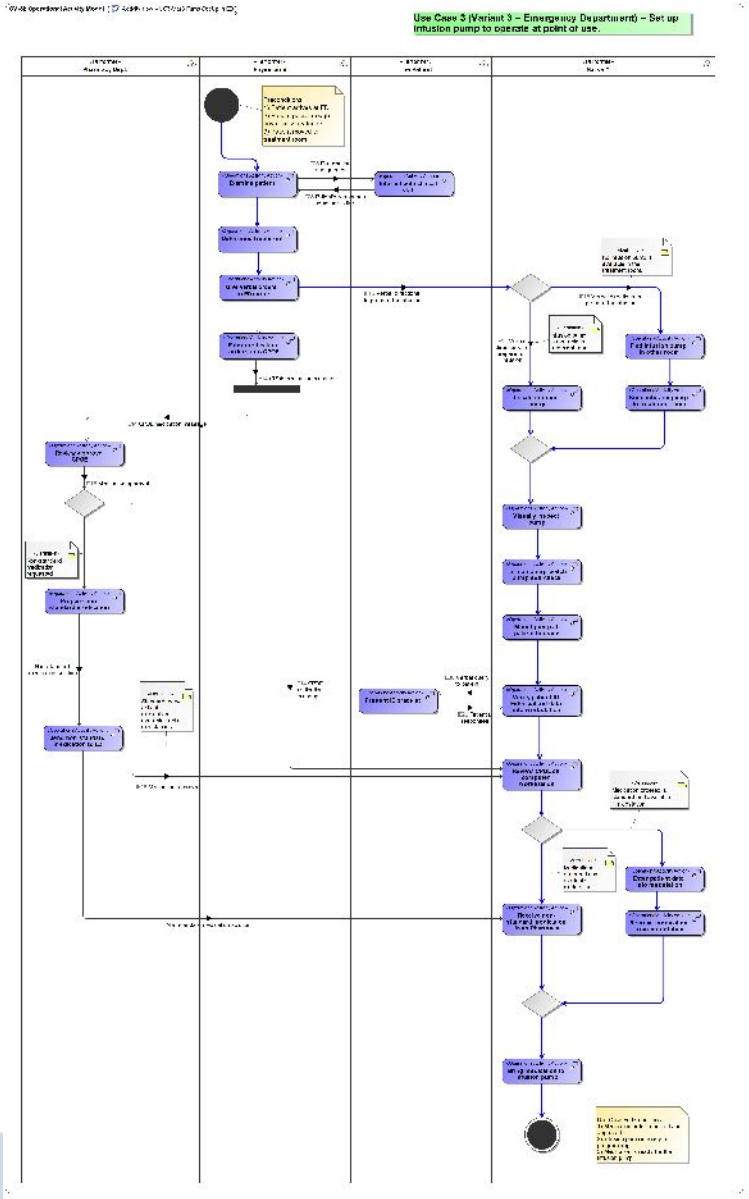
- MBSE is capable of capturing Emergency Dept. in context of entire hospital
- Suggests that MBSE tools could be suitable for analyzing clinical operations

Capturing the Emergency Department Clinical Environment for Device Developers

Capturing the ED Clinical Environment

- Objective: use the architecture to work problems
  - Assist device developers in understanding clinical environment factors
  - Improve patient safety by creating a feedback from clinicians to device engineers
- Approach
  - Elicitations with ED nurses of infusion pump work flow
  - Rendering workflow as a set of use cases within the high-level architecture
    - Link to locations
    - Link to equipment
  - Incorporate usability information affecting patient safety
  - Use the architecture to connect usability information to equipment
  - Use the architecture to produce requirements for device developers

ED Use Cases for Infusion Pumps



Identified nine use cases to span the infusion pump lifecycle from acquisition to disposal

Performed elicitations addressing three use cases

- UC 3: Set up pump to operate at the point of use
- UC 4: Program the infusion pump and connect it to the patient
- UC 5: Operate-monitor infusion pump during use

Integrated the use cases into the high-level architecture

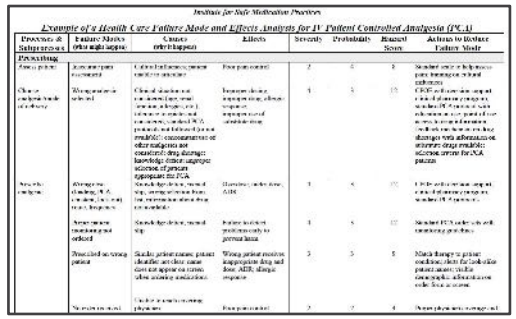
- Developed activity diagrams
- Linked to performers
- Mapped equipment to activities

Integrated patient safety data into the activity flow

- Patient safety data obtained from HFMEA published by the Institute for Safe Medication Practices

Incorporation of Patient Safety Information

Patient safety data from HFMEA



Process Failures/Risks
(things that could go wrong)

(description of failure/risk being prevented)

includes

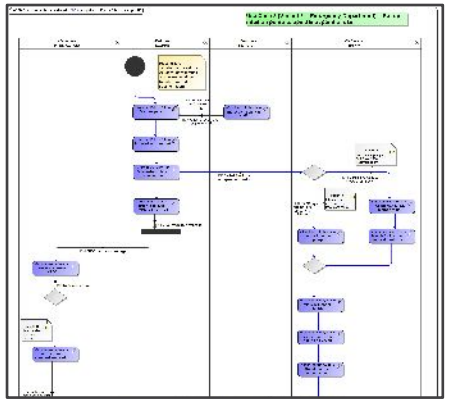
Operational constraints

(what must happen to prevent failure/risk)

allocated to

Usability Req't

applies to



Elicited Process Flow

Operational activity

uses

Device 1

Device 2

Device 3

allocated to

(recommended mitigation of failure/risk)

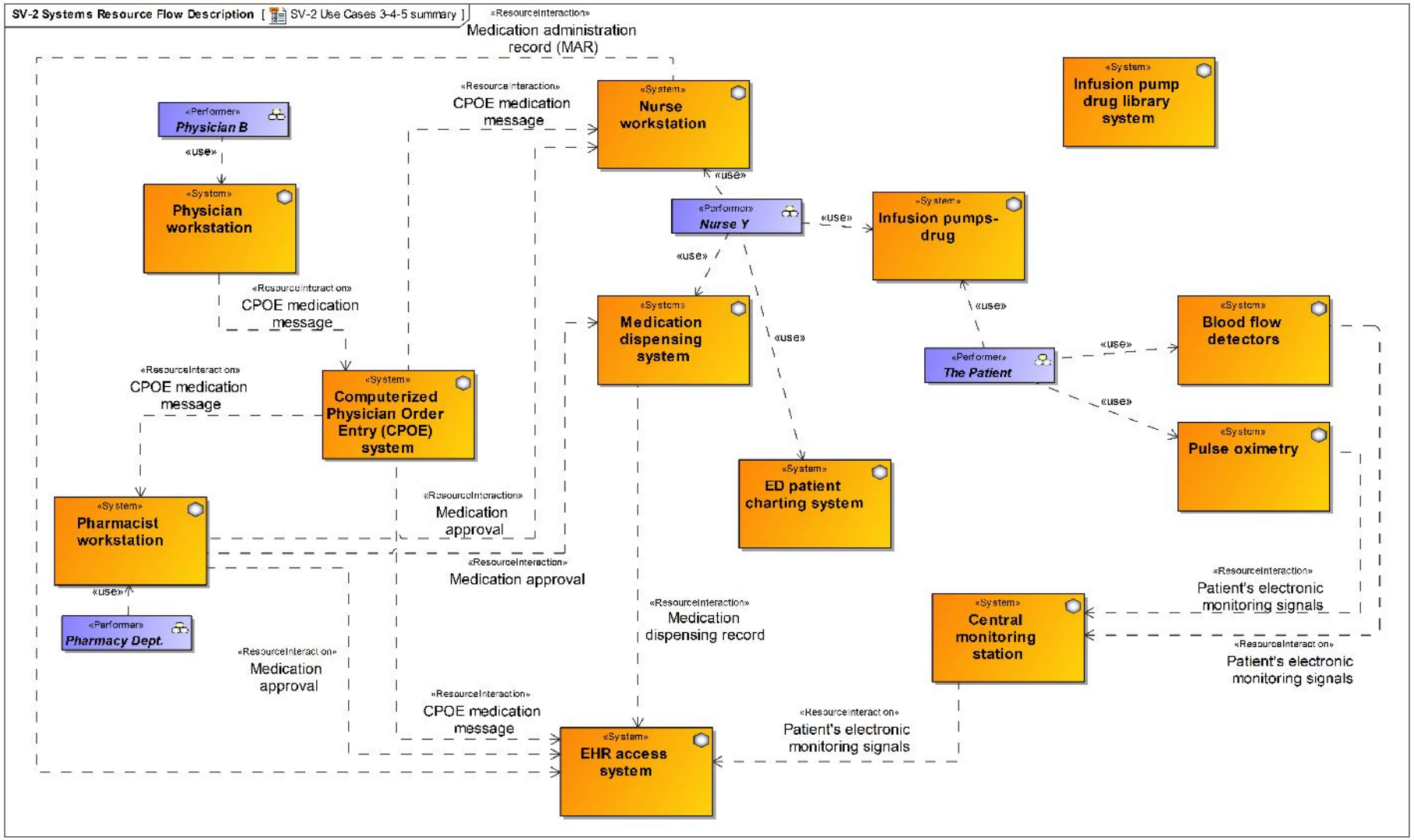
Requirements for Design Engineers

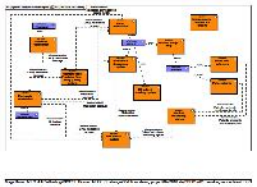
- Sort safety and requirements data by equipment item

#	Name	Allocated From	Requirement Origin	Activity Origin
1	Infusion pumps-drug	9 User interface must minimize units confusion	{0} Nurse must enter the medication flow rate and concentration correctly	Program CPOE ordered flowrates to each channel
		10 User interface must provide decision support	{0} Nurse must perform an accurate and effective check of pump programr	Review all programming data against CPOE
		11 User interface must accept patient ID electronically	{0} Nurse must enter the patient identification information correctly into inf	Verify programmed rates against drug library
		12 User interface must accept patient physical characteristics electronic	{0} Nurse must enter the patient physical characteristics correctly=Transcri	Enter patient physical information into pump
		13 Decision support system must guide selection of proper route and pı	{0} Nurse must connect the infusion pump to the patient to deliver the mec	Check tubing and pump channels against CPOE req'ts
		14 MAR must be automatically created once medication flow is started	{0} Nurse must document the medication accurately in the Medication Adm	Record medication delivery in patient record
2	Nurse workstation	12 User interface must accept patient physical characteristics electronic	{0} Nurse must enter the patient physical characteristics correctly=Transcri	Enter patient physical information into pump
		13 Decision support system must guide selection of proper route and pı	{0} Nurse must connect the infusion pump to the patient to deliver the mec	Check tubing and pump channels against CPOE req'ts
		14 MAR must be automatically created once medication flow is started	{0} Nurse must document the medication accurately in the Medication Adm	Record medication delivery in patient record
3	Computerized Physician Order Entry (CPOE) s	1 Alerts for look-alike patient names	{0} Physician must order the medication for the proper patient=Physician o	Enter medication orders into CPOE
		4 Medication ordering system decision support with access to drug infor	{0} Physician must select the proper medication given patient conditions an	Determine treatment
		6 Order flagging and receipt-documentation process	{0} Physician must select the proper dosage for patient characteristics and	Review-approve CPOE
			{0} Medication order must be received in a timely manner=Physician orders	
			{0} Medication order must be processed in a timely manner=Order receivin	
4	ED standard protocols and operating procedu	2 Standard scales and protocols to assess patient	{0} Physician must accurately evaluate patient conditions and treatment ne	Examine patient
		5 Standard monitoring protocols	{0} Physician must order the appropriate patient monitoring during medicat	Give verbal orders to ED nurse
		7 Ensure adequate staffing patterns	{0} Nurse must enter the patient identification information correctly=Wrong	Verify patient ID-Enter patient data into workstation
			{0} Nurse must perform an accurate and effective check of pump programr	Review all programming data against CPOE
				Verify programmed rates against drug library
5	ED training system -- cultural	3 Training on cultural influences	{0} Physician must accurately evaluate patient conditions and treatment ne	Examine patient
6	[redacted] -- medical	8 Ensure appropriate protocols are enforced	{0} Nurse must enter the patient identification information correctly=Wrong	Verify patient ID-Enter patient data into workstation

Future Directions: Clinical Communications and Data-Device Interoperabiliy

The Derived ED Data Environment





Summary

- Successfully addressed the challenge from IW2015 Workshop
  - Existing MBSE tools appear to represent clinical operations adequately
  - Existing SE methodologies appear to be suitable for capturing clinical operations
- Demonstrated an application of the resulting architecture
  - Translating clinician input on patient safety into requirements for equipment developers
  - Potentially could be a tool for Healthcare FMEA analysis
- Identified potential future applications in analyzing the hospital data architecture

Questions?

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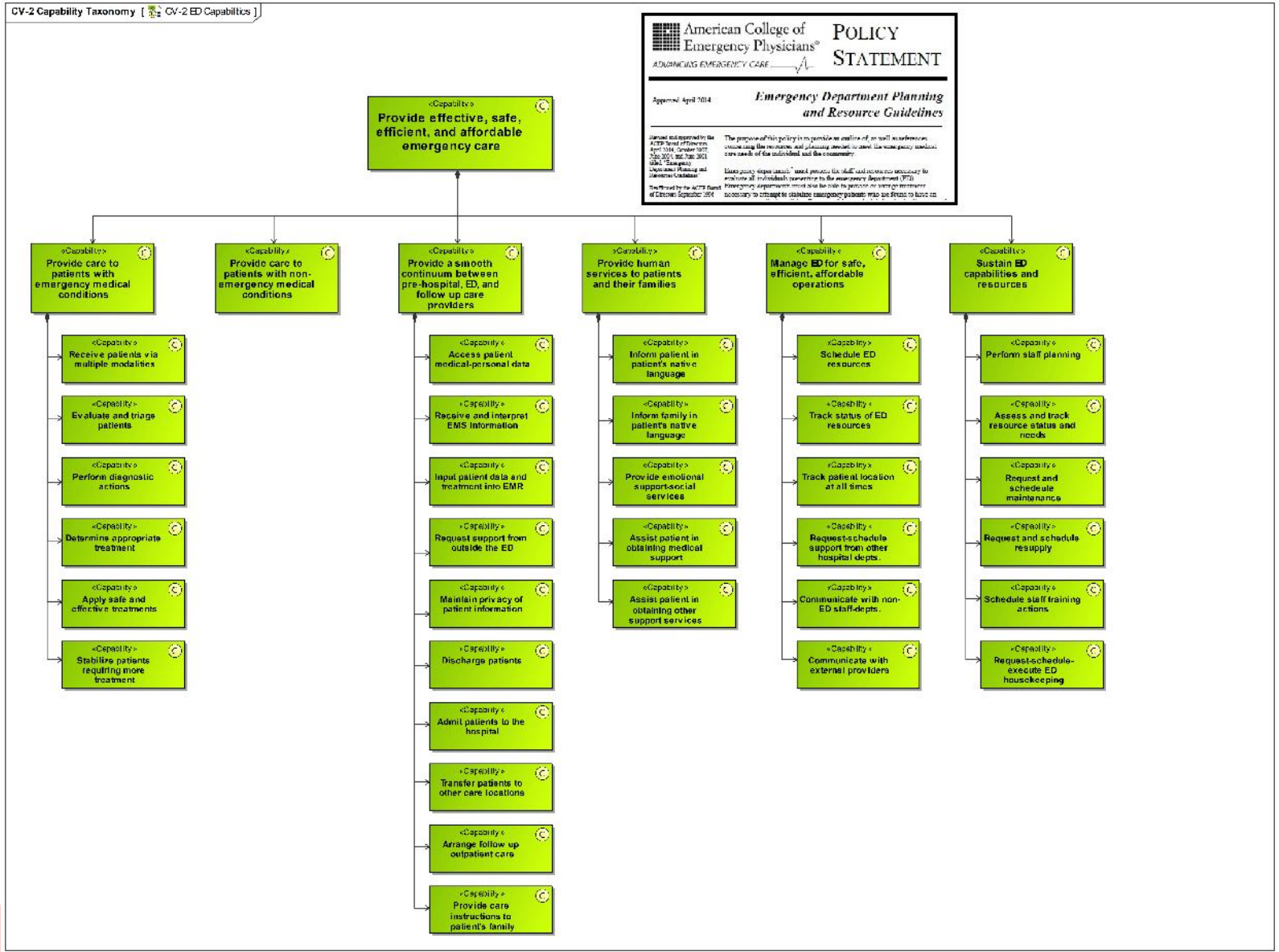
Analysis of ED Standards Documents



Infusion Pump Use Cases

- Nine use cases span the infusion pump lifecycle
  - UC 1: Infusion pump arrives and is “prepared” for use
  - UC 2: Pump is moved from supply to point of use
  - UC 3: Set up pump to operate at the point of use
  - UC 4: Program the infusion pump and connect it to the patient
  - UC 5: Operate-monitor infusion pump during use
  - UC 6: Move the infusion pump with the patient to new location
  - UC 7: Disconnect pump from patient and “restore” for next use
  - UC 8: Updates to software-library installed in the pump
  - UC 9: Perform preventive maintenance and calibration

Addressed during elicitations with ED nurses

FDA Human Factors Analysis Requirements

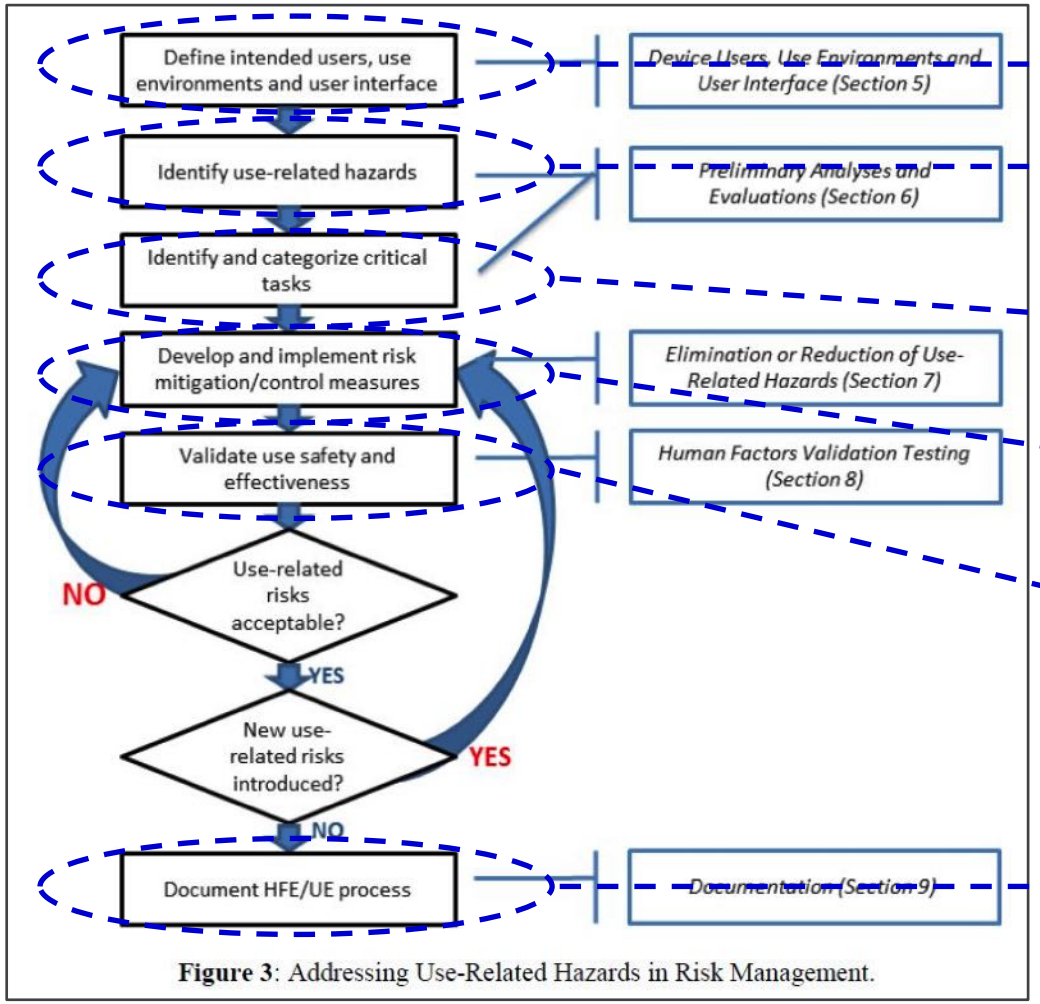


Figure 3: Addressing Use-Related Hazards in Risk Management.

Applying Human Factors and Usability Engineering to Medical Devices -- Guidance for Industry and Food and Drug Administration Staff

Mostly captured in the activity diagrams

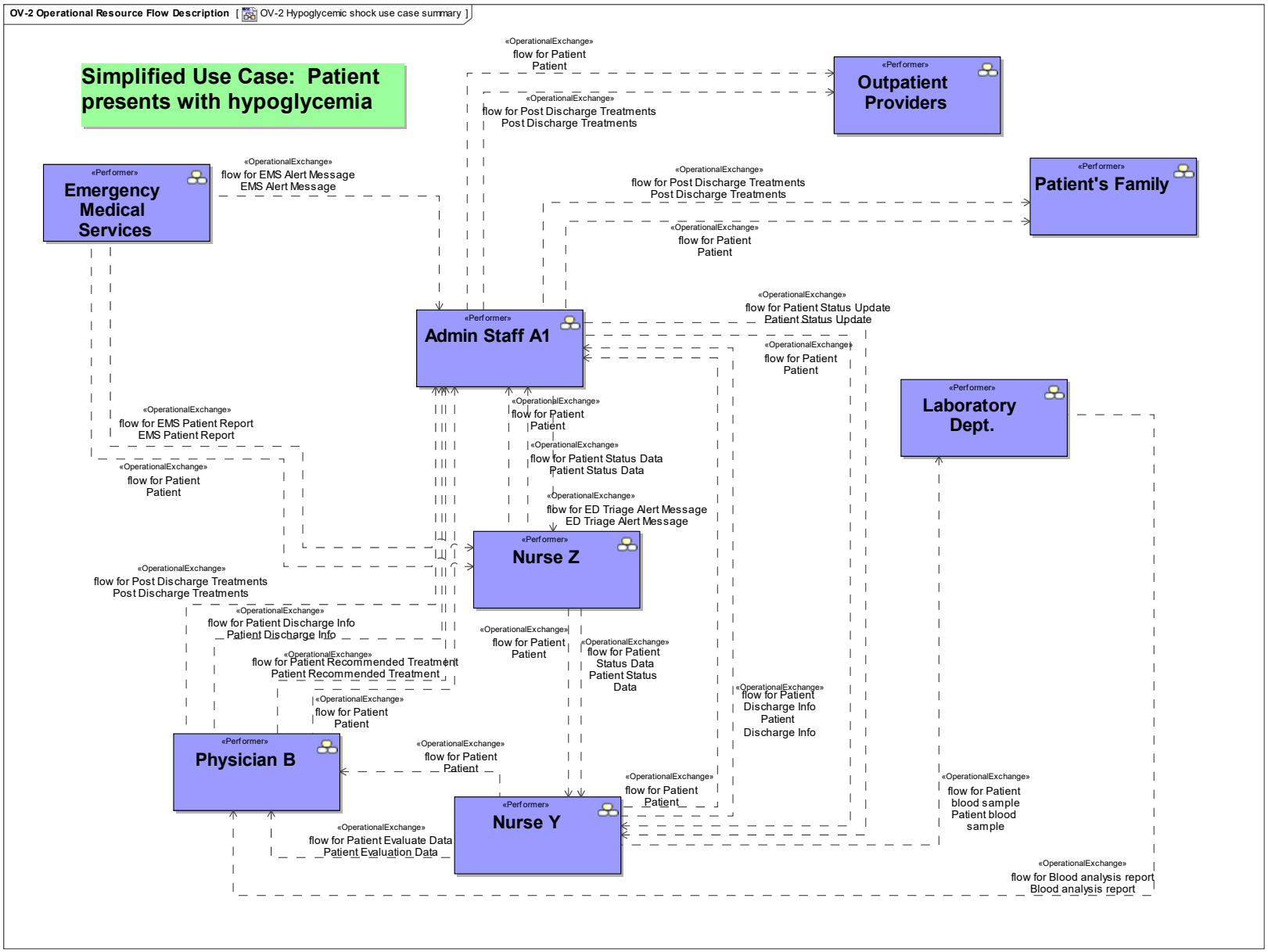
Taken from the existing HFMEA, but could be done directly in the model

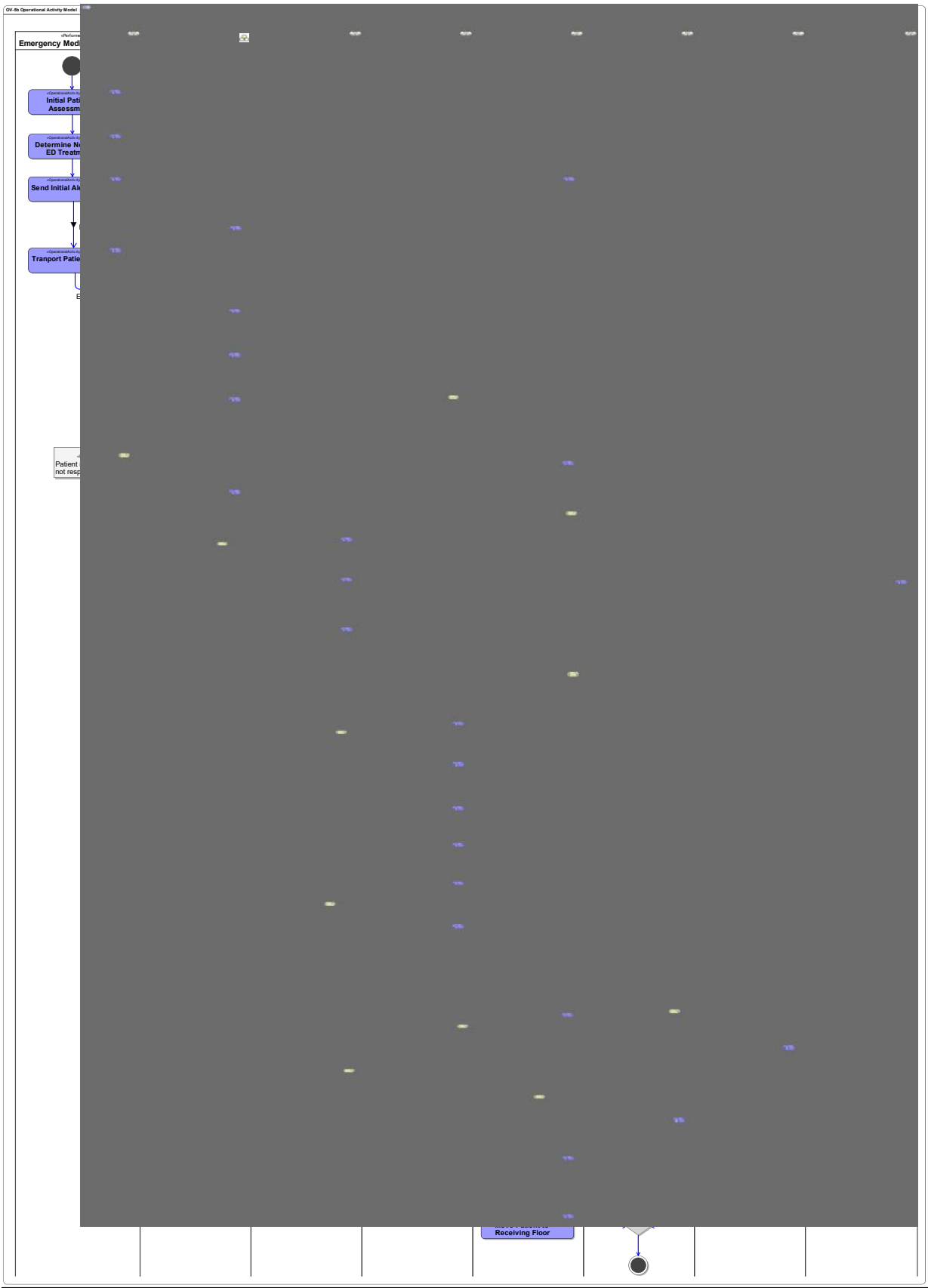
Not yet done – requires a plug-in to the tool that I don't have

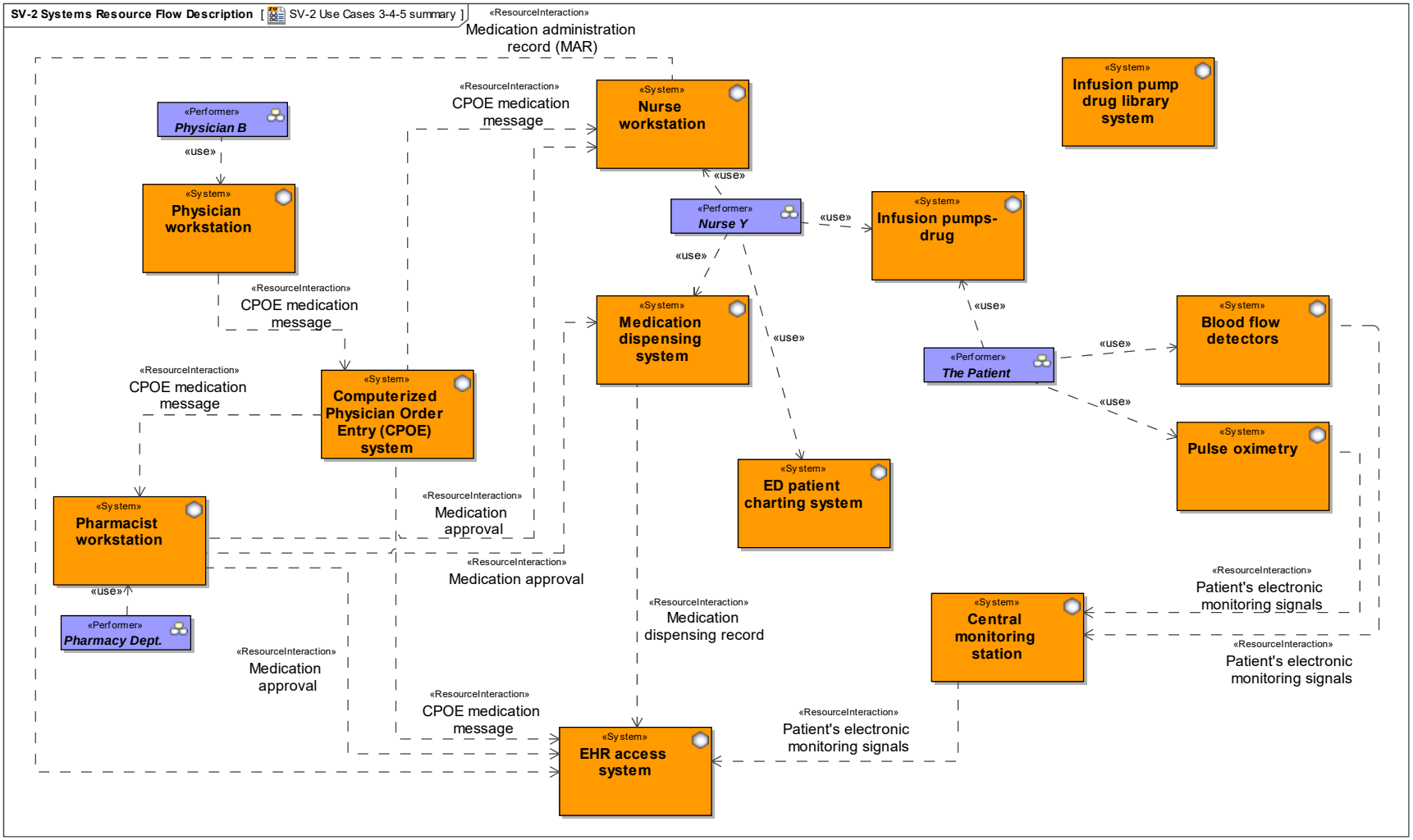
Taken from the existing HFMEA, but could be done directly in the model

Model provides req'ts to the developers/ owners of each system used in the process

Scripts can be built to export all model information into MS Office Suite documents


OV-2 Operational Resource Flow Description [OV-2 Hypoglycemic shock use case summary]
Simplified Use Case: Patient presents with hypoglycemia
Outpatient Providers
Emergency Medical Services
Patient's Family
Admin Staff A1
Laboratory Dept.
Nurse Z
Physician B
Nurse Y
«OperationalExchange» flow for Patient Patient
«OperationalExchange» flow for Post Discharge Treatments Post Discharge Treatments
«OperationalExchange» flow for EMS Alert Message EMS Alert Message
«OperationalExchange» flow for Patient Status Update Patient Status Update
«OperationalExchange» flow for EMS Patient Report EMS Patient Report
«OperationalExchange» flow for Patient Status Data Patient Status Data
«OperationalExchange» flow for ED Triage Alert Message ED Triage Alert Message
«OperationalExchange» flow for Patient Discharge Info Patient Discharge Info
«OperationalExchange» flow for Patient Recommended Treatment Patient Recommended Treatment
«OperationalExchange» flow for Patient Evaluate Data Patient Evaluation Data
«OperationalExchange» flow for Patient blood sample Patient blood sample
«OperationalExchange» flow for Blood analysis report Blood analysis report


OV-5b Operational Activity Model
Emergency Medi
Initial Pati
Assessm
Determine N
ED Treatm
Send Initial Al
Tranport Patie
Patient
not resp
Receiving Floor


SV-2 Systems Resource Flow Description [SV-2 Use Cases 3-4-5 summary]
«ResourceInteraction»
Medication administration record (MAR)
«Performer»
Physician B
«use»
«System»
Physician workstation
«ResourceInteraction»
CPOE medication message
«System»
Nurse workstation
«System»
Infusion pump drug library system
«use»
«Performer»
Nurse Y
«use»
«System»
Infusion pumps-drug
«use»
«System»
Medication dispensing system
«use»
«use»
«Performer»
The Patient
«use»
«System»
Blood flow detectors
«use»
«System»
Pulse oximetry
«ResourceInteraction»
CPOE medication message
«System»
Computerized Physician Order Entry (CPOE) system
«System»
ED patient charting system
«ResourceInteraction»
Medication approval
«System»
Pharmacist workstation
«ResourceInteraction»
Medication approval
«use»
«Performer»
Pharmacy Dept.
«ResourceInteraction»
Medication dispensing record
«System»
Central monitoring station
«ResourceInteraction»
Patient's electronic monitoring signals
«ResourceInteraction»
Patient's electronic monitoring signals
«ResourceInteraction»
Medication approval
«ResourceInteraction»
CPOE medication message
«ResourceInteraction»
Patient's electronic monitoring signals
«System»
EHR access system