2018 Annual INCOSE
Great Lakes Regional Conference
SYSTEMS AT THE CROSSROADS
17 - 20 October 2018 | Indianapolis, Indiana

David A. Flanigan, Ph.D.
The Johns Hopkins University Applied Physics Laboratory

Systems Engineering in Healthcare Course Development

Objective

- The Johns Hopkins University Engineering for Professionals (JHU EP) program provides a masters level degree in numerous majors, to include Systems Engineering
- Recently, a new program to tailor systems engineering to the healthcare industry is under development
- This program is aimed at physicians, nurses, and engineers that work in the health care industry as potential students
- A description of the program is provided, discussing the similarities and differences between the Systems Engineering and Healthcare Systems Engineering programs
- We will also describe the challenges of converting a program that primarily focused on the aerospace and defense industry, while still retaining the core systems engineering fundamentals, into a program to serve the health care industry

JHU EP Background

- JHU EP offers online and part-time master's degrees and certificates in 20 program areas from within engineering and applied sciences

JHU SE Program Overview

- The Systems Engineering Program take real-world activities and use these as topics within the curriculum

CORE COURSES FOR MASTER'S DEGREES

(The first six courses are required for the Graduate Certificate.)

645.662 - Introduction to Systems Engineering

645.667 - Management of Systems Projects

645.764 - Software Systems Engineering

645.767 - System Conceptual Design

645.768 - System Design and Integration

645.769 - System Test and Evaluation

645.800 - Systems Engineering Master's Project or

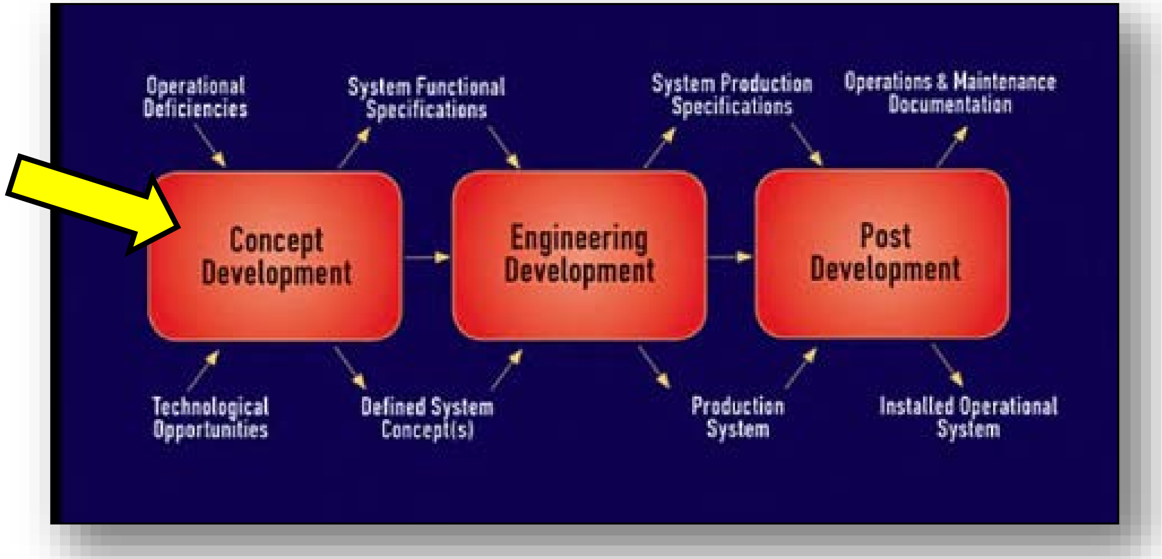
645.801 - Systems Engineering Master's Thesis and

645.802 - Systems Engineering Master's Thesis

Motivation for Creating HSE Program

- A new program was created to serve a different student population for healthcare professionals
- Includes: physicians, nurses, and engineers
- This may also emulate INCOSE’s diversity in domains beyond the aerospace and defense, similar to the GLRC agendas

Class Outline



- Divided into 8 modules
- 1-2 weeks in duration
- Focuses on specific elements / capabilities during the initial conceptual design phase

Module	Topics
Module 1	Introduction, Systems Engineering Processes
Module 2	Operational & System Requirements
Module 3	Objectives & Functional Analysis
Module 4	Systems Architecting
Module 5	Operations Analysis
Module 6	Risk Management
Module 7	Conceptual Modeling
Module 8	Additional Conceptual Design Concepts & Team Project Report

Approach for Development

- Initial course development reviews each of the modules
- Updates topics where needed
- Replace (where applicable) the defense / aerospace references with healthcare materials and examples
- Research and insert additional HSE materials
- In some cases, there were areas that necessitated defense topics remain

Challenges to Determine Proper Scope

- Some healthcare stakeholders can include:
  - Patient
  - Provider
  - Hospital / Clinic
  - Regulator
  - Payer
  - Healthcare Delivery
  - Physicians
  - Nursing Homes
  - Pharmaceuticals

- The introduction to HSE course focused on a single system
- This course focused on a hospital and associated activities
- Expect other courses to modify the scope to adjust to their specific activities (e.g. design, integration, testing)

N. Wickramasinghe, S. Chalasani, R. V. Boppana and A. M. Madni, "Healthcare System of Systems," 2007 IEEE International Conference on System of Systems Engineering, San Antonio, TX, 2007, pp. 1-6.

Challenges During Development - Acquisition

- No existing acquisition frameworks were found that equally applied to healthcare systems
- Health and Human Services (HHS) had an example acquisition process that was used in the class
- Existing acquisition sources (DoD, DHS, NASA) were retained for reference

Challenges During Development - Requirements

- No existing requirements framework applied equally to the healthcare domain, but focused on
  - System / equipment application
  - Process
  - Personnel / HMI

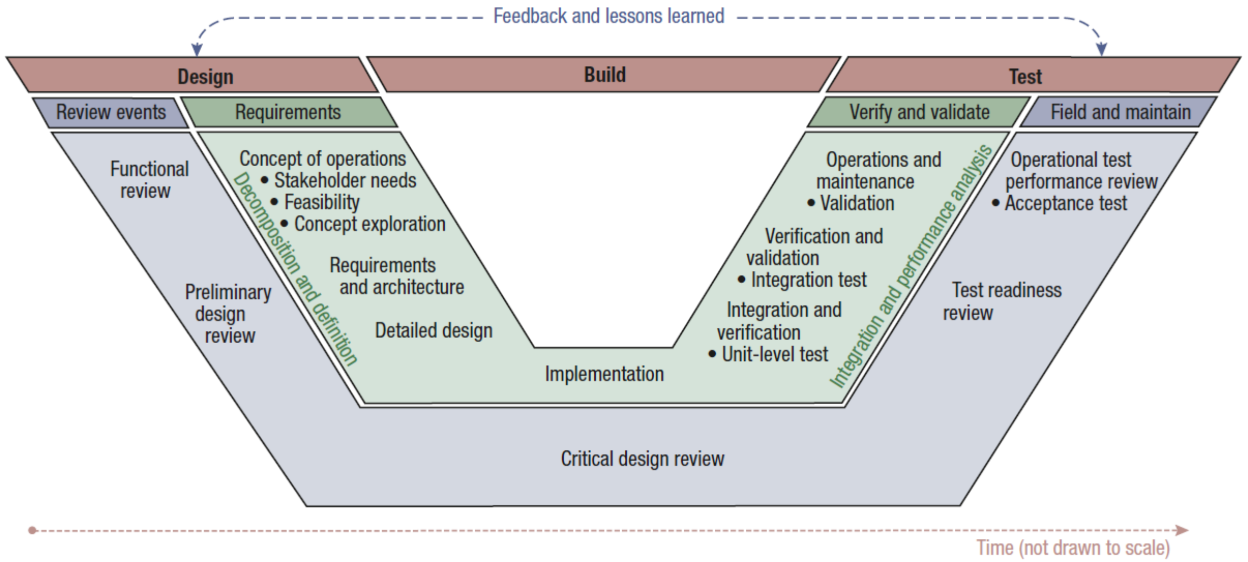


Figure 1. System development life cycle.

Ravitz et al., "Systems Approach and Systems Engineering Applied to Health Care: Improving Patient Safety and Health Care Delivery", http://www.jhuapl.edu/techdigest/TD/td3104/31_04-Ravitz.pdf

Requirements Format Examples

<u>DHS Operational Requirements Document Template</u>

1 General Description of Operational Capability
2 Threat
3 Existing System Shortfalls
4 Capabilities Required
5 System Support
6 Force Structure
7 Schedule
8 System Affordability
9 Signatures
10 Appendixes
11 Glossary

<u>DoD Capability Development Document (CDD)</u>

1.Operational Context
2.Threat Summary
3.Capability Discussion
4.Program Summary
5.Development KPPs, KSAs, and APAs
6.Other System Attributes
7.Spectrum Requirements
8.Intelligence Supportability
9.Weapon Safety Assurance
10.Technology Readiness Assessment
11.DOTmLPF-P Considerations
12.Program Affordability

<u>NASA Operational Requirements Document</u>

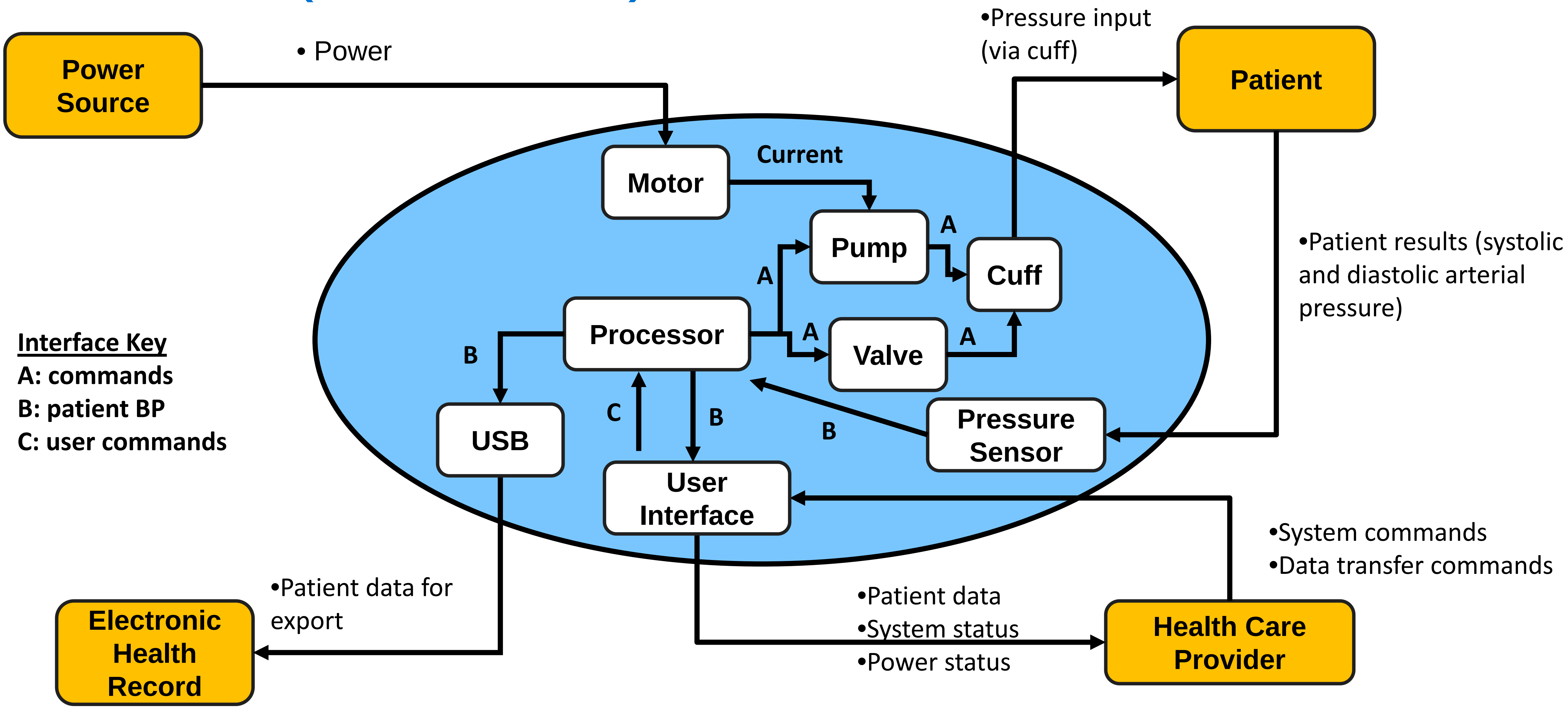
1 General Description of Operational Capability
2 Threat
3 Shortcomings of Existing Systems
4 Capabilities Required
5 Integrated Logistics Support (ILS)
6 Infrastructure Support and Interoperability
7 Force Structure
8 Schedule Considerations

<u>Infusion Pump Example</u>

1. System Overview
2. System Assumptions
3. Environment Description
4. System Hardware and Software
5. Input variables
6. Infusion configuration
7. Patient data validation
8. Drug data validation
9. Infusion monitoring
10. Drug reservoir
11. Drug monitoring
12. Self test
13. Power
14. Access control

DHS: https://www.dhs.gov/xlibrary/assets/Developing_Operational_Requirements_Guides.pdf
DoD JCIDS Manual: http://www.acqnotes.com/acqnote/acquisitions/jcids-manual-operations
NASA National Polar-Orbiting Operational Environmental Satellite System (NPOESS) : https://solidearth.jpl.nasa.gov/insar/documents/IORD.pdf
Infusion Pump Requirements, http://www.greggay.com/courses/fall17csce740/Documents/InfusionRequirements.pdf

Context Diagram Example: Blood Pressure Monitor (White Box)



Challenges During Development - Scope

- Scope is wide and varied!
- Many areas to select for healthcare
- Hospitals were selected for the initial scope of activities for this class
- Could also expand in future areas – austere operations, home healthcare, consortiums of facilities / services, financial aspect

Class Modifications – Operations Research

- Other techniques could be applied to addressing the issues commonly found in hospitals, some of which include:
  - Queuing
  - Processing
  - Resource allocation (people / equipment)
  - Scheduling
  - Throughput

OR Example: Linear Programming (Assignment Problem)

- Problem: we have 10 functions that need to be satisfied
- We are given 3 systems that have a single use (e.g. satisfies one function), that are lower cost
- We have 3 systems that have multiple uses (satisfied more than one function), that are more expensive
- Find which systems to use that covers all the functions and minimizes the total cost
- This could be applicable to high cost, infrequently used equipment that can be transferred between operating rooms, as an example
- Extra: we identify some functions that are done by multiple systems, so we have a duplication threshold for our solution set (e.g. we desire to minimize the number of systems that will duplicate certain functions)

Assignment Problem Setup

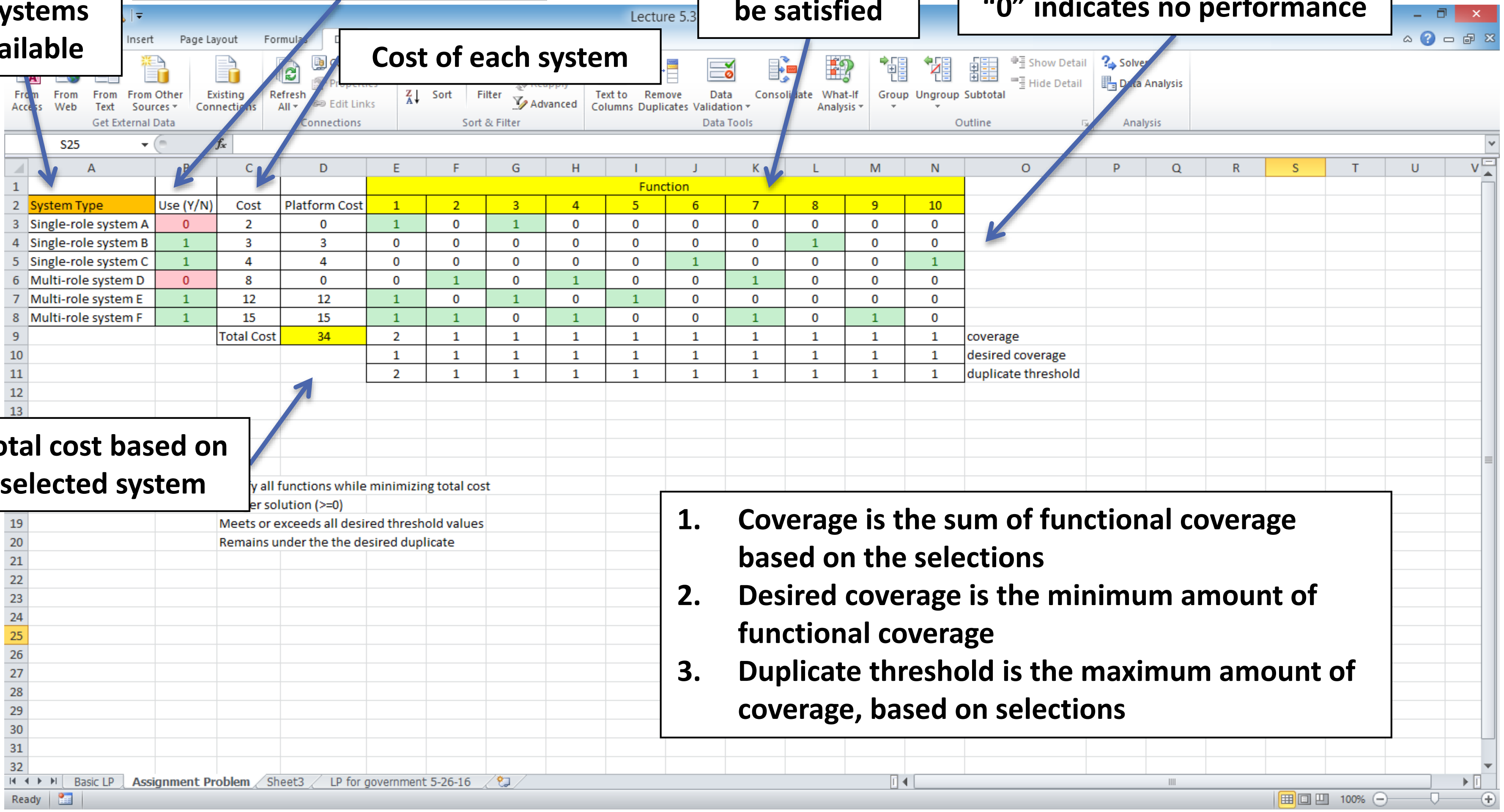
6 systems available

Whether we use the system or not

Cost of each system

10 functions that need to be satisfied

"1" indicates the system can perform the function, while "0" indicates no performance



				Function										
System Type	Use (Y/N)	Cost	Platform Cost	1	2	3	4	5	6	7	8	9	10	
Single-role system A	0	2	0	1	0	1	0	0	0	0	0	0	0	
Single-role system B	1	3	3	0	0	0	0	0	0	0	1	0	0	
Single-role system C	1	4	4	0	0	0	0	0	1	0	0	0	1	
Multi-role system D	0	8	0	0	1	0	1	0	0	1	0	0	0	
Multi-role system E	1	12	12	1	0	1	0	1	0	0	0	0	0	
Multi-role system F	1	15	15	1	1	0	1	0	0	1	0	1	0	
		Total Cost	34	2	1	1	1	1	1	1	1	1	1	coverage
				1	1	1	1	1	1	1	1	1	1	desired coverage
				2	1	1	1	1	1	1	1	1	1	duplicate threshold

...y all functions while minimizing total cost

...er solution (>=0)

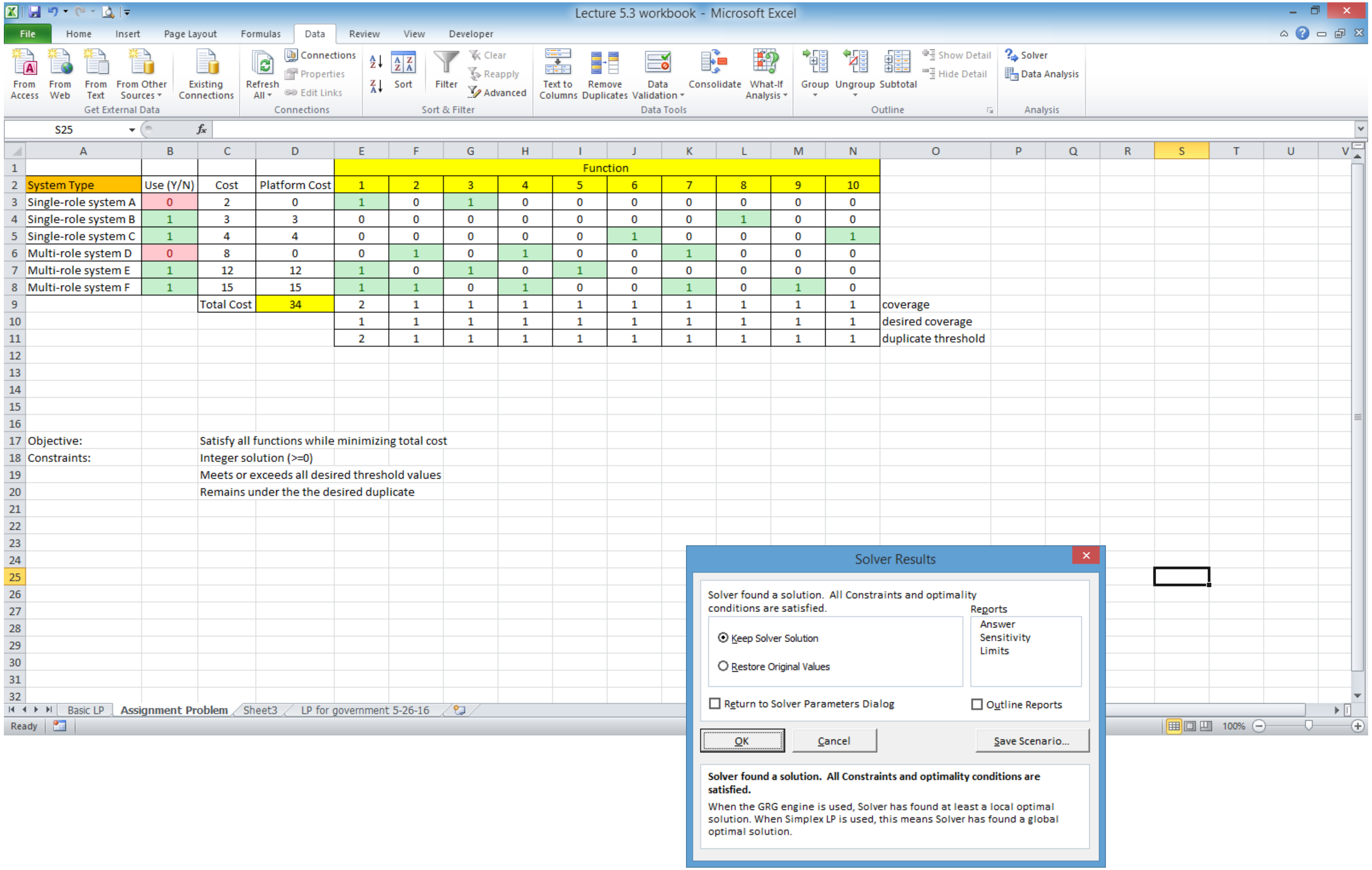
Meets or exceeds all desired threshold values

Remains under the the desired duplicate

Total cost based on selected system

1. Coverage is the sum of functional coverage based on the selections
2. Desired coverage is the minimum amount of functional coverage
3. Duplicate threshold is the maximum amount of coverage, based on selections

Assignment Problem Solution



System Type	Use (Y/N)	Cost	Platform Cost	1	2	3	4	5	6	7	8	9	10	
Single-role system A	0	2	0	1	0	1	0	0	0	0	0	0	0	
Single-role system B	1	3	3	0	0	0	0	0	0	0	1	0	0	
Single-role system C	1	4	4	0	0	0	0	0	1	0	0	0	1	
Multi-role system D	0	8	0	0	1	0	1	0	0	1	0	0	0	
Multi-role system E	1	12	12	1	0	1	0	1	0	0	0	0	0	
Multi-role system F	1	15	15	1	1	0	1	0	0	1	0	1	0	
		Total Cost	34	2	1	1	1	1	1	1	1	1	1	coverage
				1	1	1	1	1	1	1	1	1	1	desired coverage
				2	1	1	1	1	1	1	1	1	1	duplicate threshold

Objective: Satisfy all functions while minimizing total cost

Constraints: Integer solution (>=0)

Meets or exceeds all desired threshold values

Remains under the the desired duplicate

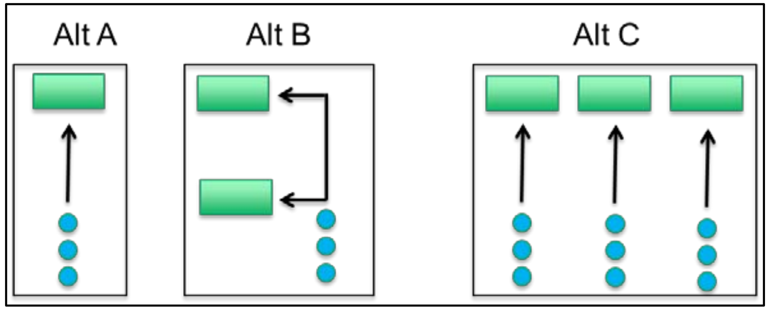
- Based on our LP setup, we find that selecting:
    - Single-role system B and C
    - Multiple-role system E and F
- Provides the full coverage of functions and minimizes total cost

Class Modifications – Trade Studies

- Use of decision analysis to capture the best selection
- Multi-attribute Utility Theory
- Analytical Hierarchy Process

Class Modifications – Trade Studies

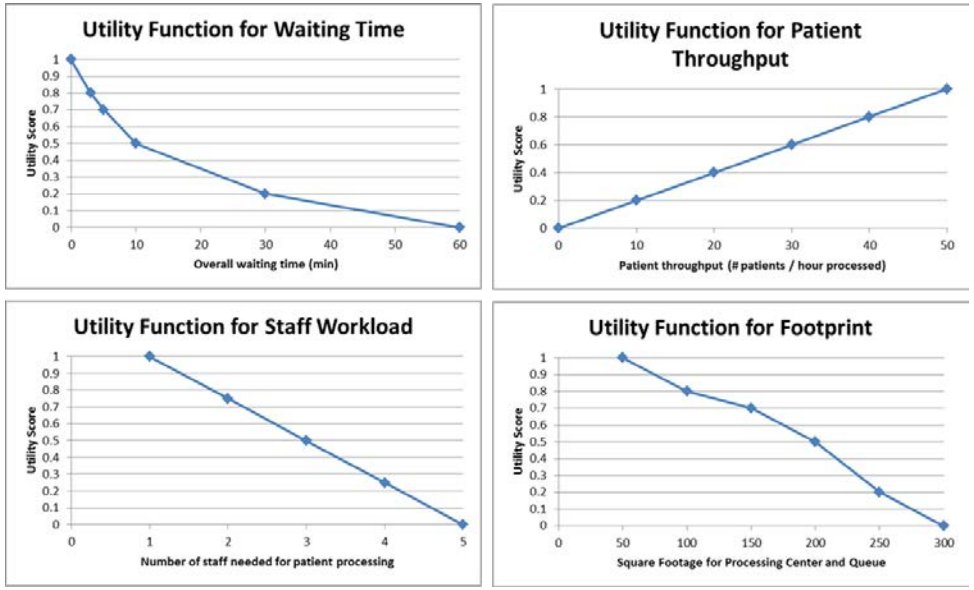
- Problem: the existing hospital has a shortfall with the in-processing of patients that arrive, causing large delays, overwork for the processing system, and delay of patients being seen
- A trade study is proposed to evaluate different processing concepts in order to facilitate greater processing throughput
- The technical criteria considered is: waiting time, patient throughput, staff workload, patient processing footprint
- Other criteria (not considered): cost, data security, patient privacy
- The alternatives considered are:
  - Alt A: Single queue, single processing station
  - Alt B: Single queue, multiple processing stations
  - Alt C: Multiple queues, multiple processing stations



Class Modifications – Trade Studies

	Waiting time	Patient throughput	Staff workload	Footprint	Sum	Weight
Waiting time	1.00	3.00	3.00	5.00	12.00	0.46
Patient throughput	0.33	1.00	0.33	3.00	4.67	0.18
Staff workload	0.33	3.00	1.00	3.00	7.33	0.28
Footprint	0.20	0.33	0.33	1.00	1.87	0.07
					25.87	

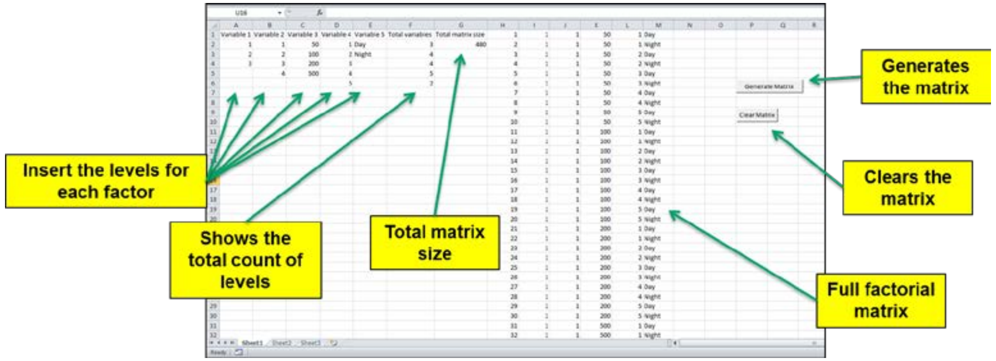
Criteria A	Criteria B	Score	Rationale
Waiting time	Patient throughput	1	Waiting time is more important than throughput
Waiting time	Staff workload	3	Waiting time is more important than workload
Waiting time	Footprint	5	Waiting time is much more important than footprint
Patient throughput	Staff workload	0.33	Workload is more important than throughput
Patient throughput	Footprint	3	Throughput is more important than footprint
Staff workload	Footprint	3	Worklad is more important than footprint



Criteria weighting

Utility Functions

Class Modifications – Design of Experiments



Full Factorial Development

Modification of DOE full factorial with infeasible combinations

Original Matrix (54)

Number	Queue size	# of stations	Sq footage	# of staff
1	1 queue	1 station	50	1 staff
2	1 queue	1 station	50	3 staff
3	1 queue	1 station	50	5 staff
4	1 queue	1 station	100	1 staff
5	1 queue	1 station	100	3 staff
6	1 queue	1 station	100	5 staff
7	1 queue	1 station	200	1 staff
8	1 queue	1 station	200	3 staff
9	1 queue	1 station	200	5 staff
10	1 queue	2 stations	50	1 staff
11	1 queue	2 stations	50	3 staff
12	1 queue	2 stations	50	5 staff
13	1 queue	2 stations	100	1 staff
14	1 queue	2 stations	100	3 staff
15	1 queue	2 stations	100	5 staff
16	1 queue	2 stations	200	1 staff
17	1 queue	2 stations	200	3 staff
18	1 queue	2 stations	200	5 staff

Number	Queue size	# of stations	Sq footage	# of staff
19	1 queue	3 stations	50	1 staff
20	1 queue	3 stations	50	3 staff
21	1 queue	3 stations	50	5 staff
22	1 queue	3 stations	100	1 staff
23	1 queue	3 stations	100	3 staff
24	1 queue	3 stations	100	5 staff
25	1 queue	3 stations	200	1 staff
26	1 queue	3 stations	200	3 staff
27	1 queue	3 stations	200	5 staff
28	2 queue	1 station	50	1 staff
29	2 queue	1 station	50	3 staff
30	2 queue	1 station	50	5 staff
31	2 queue	1 station	100	1 staff
32	2 queue	1 station	100	3 staff
33	2 queue	1 station	100	5 staff
34	2 queue	1 station	200	1 staff
35	2 queue	1 station	200	3 staff
36	2 queue	1 station	200	5 staff

Number	Queue size	# of stations	Sq footage	# of staff
37	2 queue	2 stations	50	1 staff
38	2 queue	2 stations	50	3 staff
39	2 queue	2 stations	50	5 staff
40	2 queue	2 stations	100	1 staff
41	2 queue	2 stations	100	3 staff
42	2 queue	2 stations	100	5 staff
43	2 queue	2 stations	200	1 staff
44	2 queue	2 stations	200	3 staff
45	2 queue	2 stations	200	5 staff
46	2 queue	3 stations	50	1 staff
47	2 queue	3 stations	50	3 staff
48	2 queue	3 stations	50	5 staff
49	2 queue	3 stations	100	1 staff
50	2 queue	3 stations	100	3 staff
51	2 queue	3 stations	100	5 staff
52	2 queue	3 stations	200	1 staff
53	2 queue	3 stations	200	3 staff
54	2 queue	3 stations	200	5 staff

Revised Matrix: 12 remain, after a manual review of the infeasible combinations (highlighted in yellow, blue, and green)

Number	Queue size	# of stations	Sq footage	# of staff
1	1 queue	1 station	50	1 staff
2	1 queue	1 station	50	3 staff
3	1 queue	1 station	50	5 staff
4	1 queue	1 station	100	1 staff
5	1 queue	1 station	100	3 staff
6	1 queue	1 station	100	5 staff
7	1 queue	1 station	200	1 staff
8	1 queue	1 station	200	3 staff
9	1 queue	1 station	200	5 staff
10	1 queue	2 stations	50	1 staff
11	1 queue	2 stations	50	3 staff
12	1 queue	2 stations	50	5 staff
13	1 queue	2 stations	100	1 staff
14	1 queue	2 stations	100	3 staff
15	1 queue	2 stations	100	5 staff
16	1 queue	2 stations	200	1 staff
17	1 queue	2 stations	200	3 staff
18	1 queue	2 stations	200	5 staff

Number	Queue size	# of stations	Sq footage	# of staff
19	1 queue	3 stations	50	1 staff
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21	1 queue	3 stations	50	5 staff
22	1 queue	3 stations	100	1 staff
23	1 queue	3 stations	100	3 staff
24	1 queue	3 stations	100	5 staff
25	1 queue	3 stations	200	1 staff
26	1 queue	3 stations	200	3 staff
27	1 queue	3 stations	200	5 staff
28	2 queue	1 station	50	1 staff
29	2 queue	1 station	50	3 staff
30	2 queue	1 station	50	5 staff
31	2 queue	1 station	100	1 staff
32	2 queue	1 station	100	3 staff
33	2 queue	1 station	100	5 staff
34	2 queue	1 station	200	1 staff
35	2 queue	1 station	200	3 staff
36	2 queue	1 station	200	5 staff

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37	2 queue	2 stations	50	1 staff
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40	2 queue	2 stations	100	1 staff
41	2 queue	2 stations	100	3 staff
42	2 queue	2 stations	100	5 staff
43	2 queue	2 stations	200	1 staff
44	2 queue	2 stations	200	3 staff
45	2 queue	2 stations	200	5 staff
46	2 queue	3 stations	50	1 staff
47	2 queue	3 stations	50	3 staff
48	2 queue	3 stations	50	5 staff
49	2 queue	3 stations	100	1 staff
50	2 queue	3 stations	100	3 staff
51	2 queue	3 stations	100	5 staff
52	2 queue	3 stations	200	1 staff
53	2 queue	3 stations	200	3 staff
54	2 queue	3 stations	200	5 staff

Class Modifications – System of Systems (SoS)

SoS Characteristic	Global Transportation (Air, ground, and maritime)	Healthcare
Operational Independence	Transportation systems are operated independently and can achieve their respective goals independent of the others.	Operational dependencies exist between healthcare entities in terms of continuity of patient care, exchange of data, insurance claim processing, payment, and regulations, etc. It is difficult to consider this degree of interdependence operational independence.
Managerial Independence	Transportation systems (e.g. aviation, rail, etc.) are each managed by respective entities, each for its own purpose rather than for the purposes of the global transportation SoS. Management entities establish agreements (standards, policies, procedures) to allow aircraft, ships, etc. as well as people, goods, or services flow between jurisdictions or modes of transportation.	Each healthcare entity has its own management structure where each is managed for its own purpose rather than for the purpose of the overall SoS. Arguably, this lack of cross-dependency adversely impacts the ability of the healthcare SoS to achieve desirable safety, outcomes, and value.
Geographic Separation	Generally, transportation systems occupy different locations in space. At a granular level within a transportation system, the separation may shrink. For example, at-grade-level rail and automobile intersections can occupy the same geographic location highlighting the need to pay attention to the interfaces between systems.	A matter of context: At the macro-level, there is little impact to the overall healthcare SoS that, e.g., regulators are not co-located with other entities. At a more granular level, i.e. at the point of care, various devices, personnel, etc. may be co-located with a room or may be distributed within a unit, office, building, or in the case of information technology, even in the Cloud.
Emergent Behavior	Transportation platforms can be combined to, for example, ship a package from a specific location in Beijing to a specific address in Boston – an accomplishment that none of these could achieve alone.	Hospitals, emergency medical services etc. are examples of the ability of diverse subsystems coming together to achieve an end result that any single subsystem could not achieve alone.
Evolutionary Development	Advancements are familiar to passenger automobile drivers - new models include developments that improve safety, comfort, or value.	Technical advancements clearly impact healthcare but so do developments in policy (e.g. US Affordable Care Act [11]; Turkey's Health Transformation Program [12]), regulation, and care provisioning models and all evolve independently and on their respective timelines through independent funding mechanisms.

Ravitz, Alan D., et al. "The Future of Healthcare through a Systems Approach." System of Systems Engineering Conference (SoSE), 2018 13th. IEEE, 2018.

Class Modifications - System of Systems in Healthcare

- Healthcare (like other SoS) has numerous stakeholders
- Patients, physicians, nurses, hospitals, healthcare organizations, pharmacies, government regulatory agencies, funding agencies
- Healthcare may experience more evolutionary development from most SoS, due to the change in:
  - Government regulations
  - Advances in medical technology
  - Advances in pharmaceutical products
  - Events requiring attention (e.g. natural disasters)

Wickramasinghe et al., "Lean Thinking for Healthcare, Healthcare Delivery in the Information Age"

Next Steps and Future Interactions

- Healthcare SE program expected to launch in spring 2019 semester
- Good to be able to apply the SE framework to a different domain
- Some areas / topics are not readily available with materials
- Should think about applying this in the INCOSE HWG to a broader scope beyond individual systems / devices
  - Bob Malin's INCOSE IS 2018 paper starts to identify some of these areas
    - "Case Study: Application of DoD Architecture Framework to Characterizing a Hospital Emergency Department as the Intended Use Environment for Medical Devices"
  - FDA 21CFR820.30 has some device/drug-specific development regulations, which can be used when considering system scope selection

INCOSE

GLRC 2018

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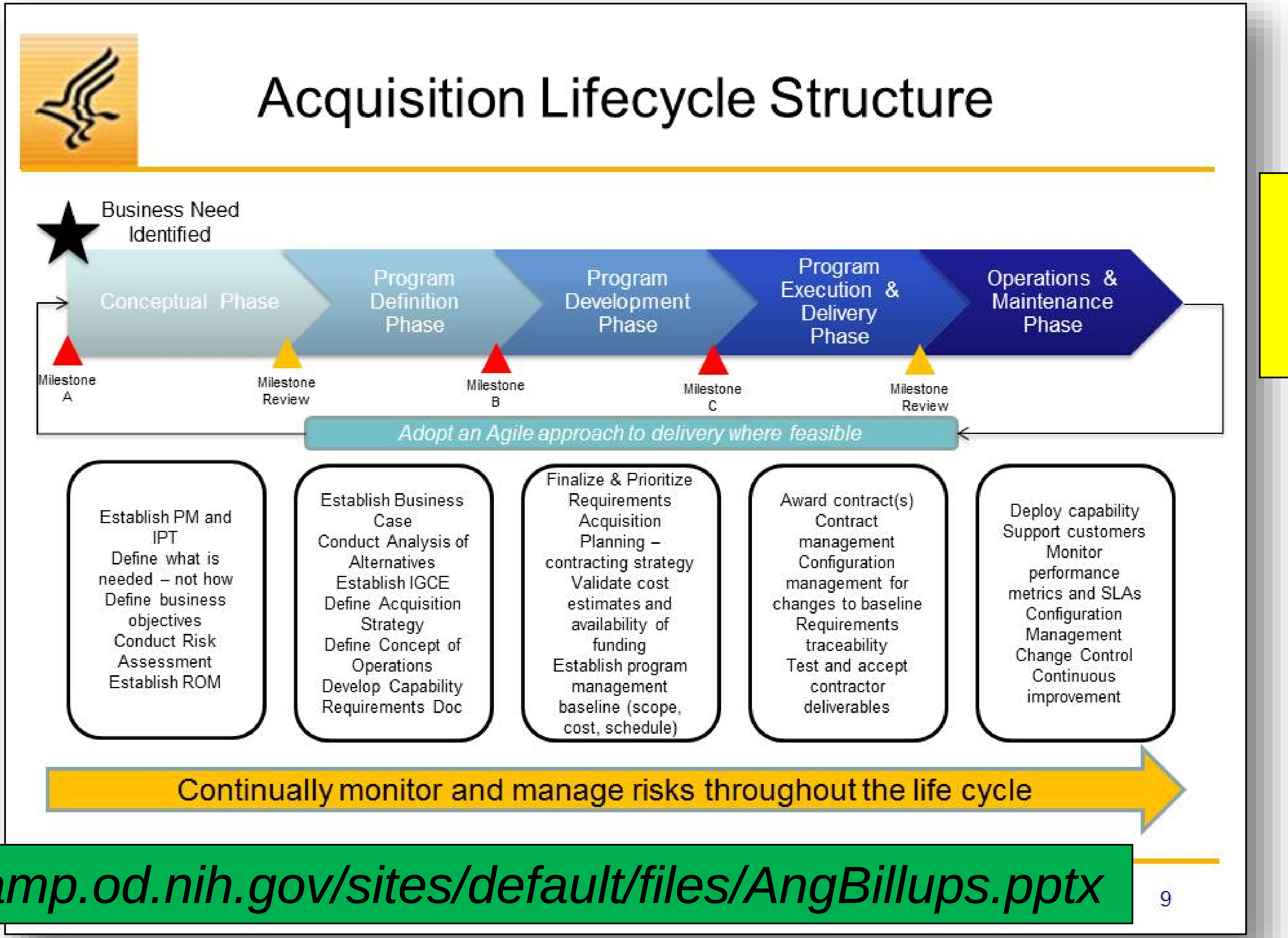
David A. Flanigan, Ph.D.

- Dr. Flanigan is from the Johns Hopkins University Applied Physics Laboratory (JHU/APL) and works with government, industry, and academia to plan and execute analytical studies in support of advanced concepts and integrated acquisition strategies. Before arriving at JHU/APL, he was a Naval officer and retired from the US Naval Reserve. Dr. Flanigan is the vice-chair of the Systems Engineering program for Johns Hopkins University, and is a member of INCOSE, INFORMS, and MORS.

System Acquisition Process (HHS)



Similar to generalized lifecycle

https://oamp.od.nih.gov/sites/default/files/AngBillups.pptx

Some Operations Research Publications Related to Healthcare

- ScienceDirect, "Operations Research for Health Care"
  - https://www.sciencedirect.com/journal/operations-research-for-health-care
- Springer, "Operations Research Applications in Health Care Management"
  - https://www.springer.com/us/book/9783319654539
- Sainfort et al., "Operations Research for Health Care Delivery Systems"
  - http://www.wtec.org/or/report/OR-report.pdf
- IIE Transactions on Healthcare Systems Engineering, "Operations research applications in hospital operations: Part I"
  - https://www.tandfonline.com/doi/full/10.1080/19488300.2015.1134727
- IIE Transactions on Healthcare Systems Engineering, "Operations research applications in hospital operations: Part II"
  - https://www.tandfonline.com/doi/full/10.1080/19488300.2016.1162880