



INCOSE  
Healthcare  
Systems  
Engineering  
Conference  
5th Annual Systems  
Engineering in Healthcare  
Conference  
May 1-2, 2019  
Minneapolis, MN

# Cultural Considerations for Systems Engineering in Healthcare Organizations

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How Systems Engineering Can Reduce Cost & Improve Quality | 1-2 May, 2019 | Twin Cities, Minnesota |  #hwgsec

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## Abstract

In many healthcare organizations, systems engineering represents a cultural shift from "the way things have always been done" to a fundamentally new way of thinking. This is similar to the cultural shift that mechanical-heritage organizations need to take place from a parts-based, manufacturing culture to a development-based, systems engineering culture.

This presentation will discuss the potential conflicts between two healthcare cultures and systems engineering:

- Science vs. Systems Engineering
- Compliance vs. Systems Engineering

First, the key elements of each culture will be examined. Then, these cultures will be contrasted with the cultural aspects of effective systems engineering. Suggestions to overcome these cultural issues will also be discussed.

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**Citation:**  
Walden, D., "Cultural Considerations for Systems Engineering in Healthcare Organizations." *Proceedings of the 5th Annual Conference on Systems Engineering in Healthcare (HWGSEC19)* (Bloomington, MN USA, May, 2019), The International Council on Systems Engineering (INCOSE), 2019.

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## Topics

- **Background on Systems Engineering and Culture**
- Important Cultures for Systems Engineering in Healthcare
- Wrap-up/Summary



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## Cultural Nature of Systems Engineering Change Management

- In many organizations, Systems Engineering represents a cultural shift to a fundamentally new way of thinking
- For mechanical-heritage organizations, the dominant cultural shift is from:
  - A parts-based, manufacturing culture to
  - A development-based, systems engineering culture
- For healthcare organizations, this does not appear to be the dominant cultural shift – others need to be considered



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## Nature of Culture

- Culture is acquired knowledge that people use to interpret experience and generate social behavior
- Key Characteristics
  - Learned
  - Shared
  - Transgenerational
  - Symbolic
  - Patterned
  - Adaptive



“The objective .. Is to help in dealing with the differences in thinking, feeling, and acting of people around the globe. It will show that although the variety in people's minds is enormous, there is a structure in this variety that can serve as a basis for mutual understanding.”

Geert Hofstede

Adapted from: (Hofstede and Hofstede, 2005)

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## Organizational Cultural

- An organization's culture builds up cumulatively, determined by factors like its leadership, products and services, relationships with competitors, and role in society
- Compared with one another, organizational cultures are not standardized because what works in one organization seldom works in another.
- Even so, strength in the following elements normally engenders a strong organizational culture:
  - corporate identity
  - leadership
  - morale and trust
  - teamwork and cooperation
  - job security
  - professional development and training
  - empowerment of individuals
  - confidence (for example, in quality and safety practices or in management communication and feedback)



Adapted from: (SEBoK, 2017)

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## Conflicts Between Development and Manufacturing Cultures

- Manufacturing “Culture”
  - 100% defined
  - Constants good
  - Variance bad
  - “Past referenced” const. baseline
  - Know what “done” is
  - Do it many times
  - Rigid processes
  - \$ = cost
  - Value = product out the door
  - **“Ideas are easy, the real work takes place in the factory.”**
- Development “Culture”
  - 0% defined
  - Variance good
  - Constants bad
  - “Future referenced” var. solution
  - Defining what “done” is
  - Do it a few times
  - Defined (but flexible) processes
  - \$ = investment
  - Value = net revenue @ end of LC
  - **“The real work is in the ideas, anybody can make things over and over.”**

Both are important – the key is balance and focus!



Adapted from: (Illif, 2010)

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## Cultural Nature of Systems Engineering Change Management

- In teaching and consulting in healthcare organizations, the manufacturing vs. development culture is illustrative, but does not appear to be dominant
- For healthcare organizations, other cultures need to be considered
- Several additional cultures have been identified
- For this presentation, we will focus on the two dominant cultures that repeatedly occur:
  - Science vs. Systems Engineering
  - Compliance vs. Systems Engineering



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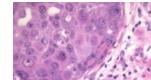


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## The “Scientific” Culture

- Most healthcare organizations are based upon some novel scientific principle
  - Electrical impulses for pacemakers
  - Dyes and staining for tissue diagnosis
  - Insulin for diabetic care
  - Dorsal root ganglia (DRG) stimulation for pain relief
  - etc.
- Many times, the founder(s) of the companies shaped the organization, and thus the culture, around these scientific principles
- The culture may in many ways resemble a “start-up mentality” (even beyond start-up)
- Systems engineering can be perceived as a threat to the existing organization culture built around these scientific principles



## Conflicts Between the Scientific and Systems Engineering Cultures

<ul style="list-style-type: none"> <li>• Scientific “Culture”           <ul style="list-style-type: none"> <li>• Embraces the Scientific Method               <ul style="list-style-type: none"> <li>• Hypothesis – Experiment – Verify – (Sometimes) Document</li> </ul> </li> <li>• Abstract</li> <li>• Targeted/specific</li> <li>• What can be done?</li> <li>• Isolate the variables</li> <li>• Does it work?</li> <li>• Won’t know what will work until it works</li> <li>• Cost is not a driving concern</li> <li>• Best</li> <li>• (Re)Invent</li> <li>• Individual</li> <li>• <b>“The money is in the science/chemistry. Engineering is a necessary evil.”</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Systems Engineering “Culture”           <ul style="list-style-type: none"> <li>• Embraces the SE Method (“Vee”)               <ul style="list-style-type: none"> <li>• Rqmts – Architect – Design – Integrate – Verification – Validation</li> </ul> </li> <li>• Concrete</li> <li>• Holistic/generalized</li> <li>• How &amp; when can it be done?</li> <li>• Interaction of the variables</li> <li>• How/why does it work?</li> <li>• Like to know what works early in the development effort</li> <li>• Cost conscious (including LCC)</li> <li>• Good enough</li> <li>• Make/Buy/Reuse</li> <li>• Team</li> <li>• <b>“The science is important, but it is useless if it doesn’t work.”</b></li> </ul> </li> </ul>
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## The “Compliance” Culture



- Compliance (FDA, EU, TuV, etc.) is critical in almost every healthcare organization
- If your system does not get through compliance, you won't be able to sell it
- Most healthcare organizations operate a compliance process rather than a development process

## Conflicts Between the Compliance and Systems Engineering Cultures

- Compliance “Culture”
  - Produce the documents and artifacts needed to get approval
  - Documentation is the product
  - Rigid process regardless of the nature of the system and team
  - The process is king
  - Low risk (of failing compliance)
  - Right the first time
  - Perfection
  - Compliance performance
  - **“The system is useless if we can’t get approval.”**
- Systems Engineering “Culture”
  - Produce all the artifacts needed to develop & deliver the system
  - The system is the product
  - Defined process, tailorable due to the nature of the system and team
  - The process enables the team
  - Balance of risk and opportunity
  - Iterations necessary
  - Adequate
  - Stakeholder satisfaction
  - **“There is a lot more needed to develop a system than the compliance documentation.”**



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## Wrap-up/Summary

- Organizational cultures can influence Systems Engineering in healthcare organizations
- The traditional “production vs. development” cultural differences may not be as relevant in healthcare
- This presentation explored two additional cultures to consider:
  - Science Culture
  - Compliance Culture
- Recognition and understanding of these cultural differences can improve the deployment and execution of Systems Engineering in healthcare organizations



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## Cultural Considerations for Systems Engineering in Healthcare Organizations

Comments?  
Questions?  
Other “Cultures” to consider?

**Thank you for attending!  
Share your experiences at #HWGSEC**



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