



---

# 6<sup>th</sup> Annual Systems Engineering in Healthcare Conference

Virtual Conference

Dates: 6<sup>th</sup>, 13<sup>th</sup> and 20<sup>th</sup> November 2020

Time: 1:00 pm to 4:30 pm EST

Attend: Free registration

<https://www.incose.org/hwg-conference>

The INCOSE Conference on Systems Engineering in Healthcare enables participants to share the best practices in the latest Systems Engineering topics as applied to both Medical Devices and Healthcare Delivery.

## Conference Program

The 6th Annual Systems Engineering in Healthcare Conference – originally scheduled for April 28-30 but cancelled due to the pandemic – has become a FREE virtual event. The event consists of three afternoon sessions on Nov 6, 13, and 20. Each session will run from 1:00-4:30 pm US Eastern Standard Time and will consist of a single track of 4 presentations.

Our conference goal is still the same: to share the best practices in the latest Systems Engineering topics as applied to both Medical Devices and Healthcare Delivery. Our conference theme remains as “**Advancing the Practice of Systems Engineering in the Healthcare Industry**”. We hope our virtual event will provide you as much value as our previous live events.

### Healthcare Delivery and Interoperability

06 November	Healthcare Delivery and Interoperability	
1:00 PM - 1:50 PM	Bo Oppenheim	Lean Healthcare Systems Engineering Process for Projects in Healthcare Delivery Operations
1:55 PM - 2:45 PM	Mike Pafford	Healthcare Systems Engineering: Resilient Hospital Reference Model (RHRM) MBSE Project
2:50 PM - 3:40 PM	George Grant	The Impact of Human Factors Engineering, Systems Engineering, and Information/Communications Technology in Healthcare
3:45 PM - 4:35 PM	Dan O’Neil	Medical Device Interoperability Reference Architecture (MDIRA)
4:35 PM - 4:45 PM	Summary/Poll	

### Model Based Approaches

13 November	Model Based Approaches	
1:00 PM - 1:50 PM	Stephane Lacrampe, Vijay Thukral	Healthcare Use Case - Application of MBSE in managing patient care in patients suffering from malnutrition
1:55 PM - 2:45 PM	David Hoadley, Rick Boldt, Kirthi Devleker	Bridging the System Engineering & Model-Based Design Gulf
2:50 PM - 3:40 PM	Mike Celentano, Sharath Gopal	An Approach to Integrating Systems & Engineering Models for Medical Devices
3:45 PM - 4:35 PM	David Quimby	Systematic Innovation in the Age of COVID
4:35 PM - 4:45 PM	Summary/Poll	

### Agile Methods, SE Process, Privacy, Engineering Software Skills

20 November	Agile Methods, SE Process, Privacy, Engineering Software Skills	
1:00 PM - 1:50 PM	Kelly Weyrauch	The Role of the Systems Engineer in Agile Development
1:55 PM - 2:45 PM	Brian Kram	Agile Product Development While Re-Architecting our Information Foundation
2:50 PM - 3:40 PM	Naeem Hashmi	Embedding “Privacy by Design” when Engineering AI/ML powered Digital Health Solutions
3:45 PM - 4:35 PM	Sean McCoy, Francesco Dazzi	Building Trust - A Systems Engineer’s Most Powerful Tool
4:35 PM - 4:45 PM	Summary/Poll	

- Conference will be free.
- We will be using the Zoom platform. Visit <https://www.incose.org/hwg-conference/home> for the live conference link.

- If you want to be reminded on the day of the INCOSE Healthcare Conference with conference connection detail please email:
 

Name                       Affiliation                       Email address

To: Kelly Weyrauch [Kelly@agilequalitysystems.com](mailto:Kelly@agilequalitysystems.com)

## Presentation

**Friday 6 November**

### Healthcare Delivery and Interoperability

<b>Authors</b>	Bo Oppenheim
<b>Title</b>	Lean Healthcare Systems Engineering Process for Projects in Healthcare Delivery Operations
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Healthcare Delivery and Interoperability <b>Time:</b> Friday November 06, 2020, 1:00 PM - 1:50 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p>The presentation will describe a new powerful generic process named <i>Lean Healthcare Systems Engineering Process</i> (LHSE). It integrates selected and simplified systems engineering steps and Lean in the context of healthcare delivery applications. Operational fragmentation is one of the biggest evils of healthcare operations, suffering from numerous imperfect interfaces between stakeholders. Systems engineering (SE) is the established body of knowledge for integrating fragmented elements across interfaces, but it suffers from inefficient and wasteful bureaucratic steps which prevent wide adoption in healthcare. Lean is a powerful methodology for identifying and removing waste from workflows, but is not effective in dealing with fragmentation. A combination of Lean and strongly simplified systems engineering has addressed the above deficiencies. LHSE is a logically rigorous but non-mathematical process that is easy to learn and practice and applies to any project in healthcare delivery operations in clinics, hospitals (including operating rooms and emergency departments), medical laboratories, and pharmacies. It has proven itself in several projects and met with praises from practitioners.</p>

<b>Authors</b>	Mike Pafford
<b>Title</b>	Healthcare Systems Engineering: Resilient Hospital Reference Model (RHRM) MBSE Project
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Healthcare Delivery and Interoperability <b>Time:</b> Friday November 06, 2020, 1:55 PM - 2:45 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p>This interactive presentation will walk attendees through an update to an ongoing healthcare MBSE project to design, develop, and deliver a Resilient Hospital Reference Model (RHRM). The presentation will include shared whiteboard and sticky notes, as well as QR Codes on slides, which attendees can scan and immediately retrieve information about the project. The purpose of the RHRM MBSE</p>

	<p>project is to offer hospitals decision aid system components they can use to enhance their analysis, planning, execution, recovery, assessment, and reporting before, during, and after extended power outages. The volunteer Resilient Hospital Systems Engineering Team (RHSET) is made up of MBSE practitioners from INCOSE, IEEE, and the FBI-sponsored InfraGard National Disaster Resilience Council (NDRC), working closely with key stakeholders from the healthcare community. In its Initial Project Planning (IPP), and now its Initial Project Execution (IPE) the RHSET has integrated into project work several best practices from the Lean Startup Method (LSM), as well as Agile Software Engineering, Systems Engineering, and Project Management.</p>
--	---

<b>Authors</b>	George Grant
<b>Title</b>	The Impact of Human Factors Engineering, Systems Engineering, and Information/Communications Technology in Healthcare
<b>Session</b>	<p><b>Type:</b> Virtual  <b>Theme:</b> Healthcare Delivery and Interoperability  <b>Time:</b> Friday November 06, 2020, 2:50 PM - 3:40 PM  <b>Room:</b> Virtual</p>
<b>Abstract</b>	<p>The United States (U.S.) healthcare delivery system lacks efficiency, quality, coordination, safety, is costly, and does not sufficiently support physicians, nurses, administration, patients, etc. (Fowler et al., 2011). For years, the focus has been towards the innovation of life sciences, physical sciences, and engineering of medical devices, instruments, and equipment treating patients (Reid et al., 2005). The advancements in healthcare have improved the quality of care, but also at a cost. Additionally, the lack of attention paid to the healthcare delivery system is one of the driving factors for increased costs (Reid et al., 2005). The purpose of this article is to discuss the impact of Human Factors Engineering (HFE), Systems Engineering (SE), and Information Technology (IT) associated with the healthcare delivery systems.</p>

<b>Authors</b>	Dan O'Neil
<b>Title</b>	Medical Device Interoperability Reference Architecture (MDIRA)
<b>Session</b>	<p><b>Type:</b> Virtual  <b>Theme:</b> Healthcare Delivery and Interoperability  <b>Time:</b> Friday November 06, 2020, 3:45 PM - 4:35 PM  <b>Room:</b> Virtual</p>
<b>Abstract</b>	<p>Objectives: The Medical Device Interoperability Reference Architecture is a collaborative framework that was developed to improve patient safety. Through technology standards, clinical practices, and government policies, MDIRA paves the path forward for autonomous /closed loop prototypes for military health care and civilian trauma/accidental injuries.</p>

	<p>Our presentation will elaborate the process and benefits of this move to interoperability. We intent to show how MDIRA:</p> <ul style="list-style-type: none"><li>• Specifies an environment into which medical devices can be quickly integrated to meet immediate trauma care needs.</li><li>• Provides a common terminology and taxonomy for physical and functional elements that enables an open-systems business model.</li><li>• Promotes synergy between designing systems for dual use in the military and civilian sectors that insures uncompromised safety in challenging, ever-changing conditions.</li></ul> <p>We will share our progress and look forward to short discussion together with attendees in hearing your ideas for promoting medical device interoperability.</p>
--	---

Friday 13 November

### Model Base Approaches

<b>Authors</b>	Stephane Lacrampe, Vijay Thukral
<b>Title</b>	Healthcare Use Case- Application of MBSE in managing patient care in patients suffering from malnutrition
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Model Based Approaches <b>Time:</b> Friday November 13, 2020, 1:00 PM - 1:50 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p>There are many MBSE tools providing powerful modeling capabilities. Graphical representation and management of various systems views, while essential, is secondary to the underlying need for rigorous application of SE principles to perform needs analysis, concept exploration, concept definition, to product design, integration and deployment.</p> <p>Patients with chronic disease processes are often malnourished on admission to hospital or health care facilities. As part of introduction to SE and system architecture we examined the needs for malnourished patient care that require short terms and/or long term enteral feeding intervention. Capella/Arcadia, is an open source readily available, powerful MBSE toolset. Capella provides practitioners of SE to do product development guided by SE principles. The tool served as a good introductory toolset for students starting to learn about SE principles and MBSE.</p> <p>The talk will focus on operational analysis to investigate the interaction between patient and various healthcare entities, define patient nutrition care objectives and conceptualize the functional analysis and logical architecture to manage nutritional care.</p>

<b>Authors</b>	David Hoadley, Rick Boldt, Kirthi Devleker
<b>Title</b>	Bridging the System Engineering & Model-Based Design Gulf
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Model Based Approaches <b>Time:</b> Friday November 13, 2020, 1:55 PM - 2:45 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p>Model-based system engineering and Model-Based Design have both shown great promise to improve the system development process by allowing a more rigorous and efficient analysis of system requirements through conceptual designs, detailed designs, implementation, and verification and validation. However, the current state of tools often leads to a gap between the abstract and detailed models used for implementation.</p> <p>Here, we present a workflow for system and software architectural modeling and analysis with a tight connection to Model-Based Design, using a medical device case study. Enabling this connection allows us to trace the digital thread from our system requirements through architectural and detailed design models, automatically-generated implementation code, and verification tests.</p>

<b>Authors</b>	Mike Celentano, Sharath Gopal
<b>Title</b>	An Approach to Integrating Systems & Engineering Models for Medical Devices
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Model Based Approaches <b>Time:</b> Friday November 13, 2020, 2:50 PM - 3:40 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p>Engineering computer aided design and engineering simulation have become a rather mature set of skills with a plethora of tools to support those skills in the medical device development domain. Model Based Systems Engineering (MBSE), by comparison, is a rather new skill for this domain. MBSE by itself has demonstrated value by providing more rigor to accounting for stakeholder needs, platform structures, user interactions, and system behaviors. However, even more value can come from MBSE if the engineering models are tied to the system models in order to ensure more thorough alignment between the design and requirements for a product.</p> <p>The authors will present a Generic Pre-Filled Syringe Model from two perspectives: a systems (or top-down) perspective and an engineering (or bottom-up perspective). Each model feeds off of each other and are integrated in a simple way to facilitate synchronized iterations of both. This generic model duet can be used by others as a framework if their organization is new to this approach. Also, the authors will have the audience compete against the models to solve a few problems. Lastly, the authors will welcome suggestions from other organizations that have more experience with this approach during the Q/A portion of the presentation.</p>

<b>Authors</b>	David Quimby
<b>Title</b>	Systematic Innovation in the Age of COVID
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Model Based Approaches <b>Time:</b> Friday November 13, 2020, 3:45 PM - 4:35 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p><i>Combining systems engineering and quantitative analysis to inform COVID-19 social intervention</i></p> <p>A sustainable approach to contact tracing is becoming a central factor in economic recovery. Concurrently preserving economic activity while containing the pandemic is a severe technical and social challenge. We applied systematic innovation and quantitative analysis in the context of this socio-technical system to predict / derive the Apple / Google initiative for a <u>non-intrusive</u> approach to contact tracing. Early in the history of the pandemic, we used systematic innovation to formulate a simulation that compared social interventions and corresponding biological outcomes in Italy and South Korea. Our analysis was ultimately published at ORMS Today - the journal of operations research / management science. It was</p>

published on the same day that the remarkable Apple / Google collaboration was announced. The Apple / Google solution, now widely known as "exposure notification", is gaining traction across the U.S. and internationally.

Systematic innovation is not only an effective instrument for identifying disruptive and long-term innovation; as we will illustrate, it also provides a foundation for reliable technology forecasting by identifying formidable challenges that are within reach of solution. Using COVID-19 social intervention and the Apple / Google solution as a case study, we will explore the process of identifying and solving contradictions. The process is scalable and repeatable -- it is broadly relevant to problem-solving in an increasingly complex world.



Friday 20 November

**Agile Methods, SE Process, Privacy, Engineering Software Skills**

<b>Authors</b>	Kelly Weyrauch
<b>Title</b>	The Role of the Systems Engineer in Agile Development
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Agile Methods, SE Process, Privacy, Engineering Software Skills <b>Time:</b> Friday November 20, 2020, 1:00 PM - 1:50 PM <b>Room:</b> Virtual
<b>Abstract</b>	What role does a System Engineer play in an organization that uses Agile methods? As is the case with many questions on how the Agile game is played, the answer is “It Depends”. Let’s explore what it depends on, and find the options of where the Agile game embraces the role of the SE.

<b>Authors</b>	Brian Kram
<b>Title</b>	Agile Product Development While Re-Architecting our Information Foundation
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Agile Methods, SE Process, Privacy, Engineering Software Skills <b>Time:</b> Friday November 20, 2020, 1:55 PM - 2:45 PM <b>Room:</b> Virtual
<b>Abstract</b>	<p>Ventana Medical Systems (a wholly owned subsidiary of Roche Diagnostics) is a storied medical device company, market leaders in the provision primarily of tissue-based clinical in vitro cancer diagnostic solutions comprising instruments, reagents, digital imaging, and interconnectivity software.</p> <p>Implementation of Scaled Agile has come with its typical transformation challenges as well as its payouts as more or less advertised per the commercial Agile training and testimonials. A convergent challenge we additionally and intentionally brought upon ourselves was to undertake no less than an overhaul of our information foundation and tool chain underpinning our product development processes (PDP). Was this necessary? Was this urgent? Was this wise? Was this disruptive? Was this justified? Is there precedent?</p> <p>Our story is presented as an exploratory case study intended to share our particular concerns and motivation from the perspective of the Scaled Agile Solution Architect for going beyond just reducing technical debt via teeing up Enablers for steady velocity gains. Through re-architecting the fine grain structure (scaling ‘down’) of key PDP information artifacts, a paradigm shift emerges in how product development work itself can be re-imagined. Our story is one of opportunity, serendipity, and risk taking that came about upon intentionally exploiting independent ongoing corporate level</p>

	initiatives: 1) early adopting and promoting a database migration initiative as our Trojan horse while 2) not disrupting nascent Scaled Agile transformation while 3) embracing an enterprise-wide quality improvement initiative (and the resources it had to offer).
--	--

<b>Authors</b>	Naeem Hashmi
<b>Title</b>	Embedding “Privacy by Design” when Engineering AI/ML powered Digital Health Solutions
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Agile Methods, SE Process, Privacy, Engineering Software Skills <b>Time:</b> Friday November 20, 2020, 2:50 PM - 3:40 PM <b>Room:</b> Virtual
<b>Abstract</b>	Digital Health solutions cover broad spectrum of ‘Health Systems’ ranging from wellness tracking and monitoring disease states, treatments and follow-ups through mobile apps and IoTs. Safeguarding personal and health information in healthcare systems is an enormous challenge. While many security models can be considered when engineering a digital health product, today, there are no working models that safeguard individual ‘privacy’. Recent enactment of EU General Data Protection Regulation (GDPR) has far reaching impact on system design approaches. Privacy by Design (PbD) principles needs to be considered when engineering Digital Health solution to ensure individual’s privacy.

<b>Authors</b>	Sean McCoy and Francesco Dazzi
<b>Title</b>	Building Trust - A Systems Engineer’s Most Powerful Tool
<b>Session</b>	<b>Type:</b> Virtual <b>Theme:</b> Agile Methods, SE Process, Privacy, Engineering Software Skills <b>Time:</b> Friday November 20, 2020, 3:45 PM - 4:35 PM <b>Room:</b> Virtual
<b>Abstract</b>	As a part of their normal work activity, systems engineers are called to develop both credibility and solid working relationships. Building trust is an important skill to help build credibility and working relationships. It is also a foundation for leading by influence. Influence is a critical ability for any systems engineer. Two pillars for building trust are honesty and integrity, or in other words: doing what is said, and saying what is done. It can be a struggle for engineers to understand what do to when honesty and integrity fall short and don’t establish trust, even when done exceptionally well. This presentation will dive into elements of trust that extend beyond basic honesty and integrity. Attendees will see other domains, and dynamics, related to trust and building trust. These include emotional trust, social trust, establishing these types of trust, correcting mistrust,

	<p>and avoiding things that erode trust. In the hands of a Systems Engineer, these tools can improve their effectiveness and smooth the execution of a project.</p> <p>The target audience for this presentation includes engineers, systems engineers, and engineering managers that look to expand their understanding and skills related to trust and building trust. Trust is noted in 5 of the 8 professional competency areas of the Systems Engineering Competency Framework - Communication, Ethics and Professionalism, Technical Leadership, Negotiation, and Team Dynamics.</p>
--	--

If you have questions, suggestions please free to contact the Healthcare  
Working Group Conference team members:

**Chairs**

Chris Unger [Christopher.Unger@med.ge.com](mailto:Christopher.Unger@med.ge.com)

Kelly Weyrauch [Kelly@AgileQualitySystems.com](mailto:Kelly@AgileQualitySystems.com)

**Technical Program Lead**

Kelly Weyrauch [Kelly@AgileQualitySystems.com](mailto:Kelly@AgileQualitySystems.com)

**Sponsor Contact**

Chris Unger [Christopher.Unger@med.ge.com](mailto:Christopher.Unger@med.ge.com)

**Local Site Logistics**

Phyllis Larson [mptbalarson@comcast.net](mailto:mptbalarson@comcast.net)

**Virtual & Media Communication**

Robert Malins [rjmalins@eaglesummittech.com](mailto:rjmalins@eaglesummittech.com)

Chris Unger [Christopher.Unger@med.ge.com](mailto:Christopher.Unger@med.ge.com)

Kelly Weyrauch [Kelly@AgileQualitySystems.com](mailto:Kelly@AgileQualitySystems.com)

Vijay Thukral [Vijay.Thukral@CientiveGroup.com](mailto:Vijay.Thukral@CientiveGroup.com)