



INCOSE Healthcare Working Group Charter

1 PURPOSE

To improve healthcare delivery by bringing together systems engineers and systems thinkers in healthcare industry to identify, develop, and tailor best practices. We will achieve that by

- Articulating the value and application of systems engineering to healthcare through simple examples and easily deployable guidelines, and
- Providing a forum for developing and sharing best practices, meeting world class experts in Systems Engineering and Healthcare (and across other industries).

The creation of our group was driven by the fact that many if not most of the organizations in the biomedical and healthcare industries do not necessary recognize or understand the value of systems engineering and could thus benefit from the application of INCOSE principles.

2 GOAL

Our five year objectives are to:

- Increase the systems engineering and systems thinking capabilities of the healthcare delivery, medical devices manufacturers, and HCIT suppliers and users to enable improved healthcare outcomes
- Increase individual & corporate INCOSE membership from the healthcare industry
- Engage leaders in the healthcare industry seek to raise the use of systems engineering practices by engaging INCOSE support and services
- Publish impactful information on systems engineering in the healthcare industry and serve as the clearinghouse of healthcare needs and systems engineering best practices
- Accelerate the transformation of healthcare systems engineering to a model based discipline

To reach the five year strategic objectives, our theme for each year is

2016	Produce initial valuable work products	} Building the INCOSE brand in HC
2017	Pilot using those products	
'17	Education and Hospital Partnering	
'18	Device Developers and Government/Policy Thought leaders	
'18-19	Scale up application of HWG products	

5-year Vision

Applications of Systems Engineering to Healthcare: HWG is the recognized 'clearinghouse' for healthcare implementation best practices for systems engineering for healthcare delivery and device and services development

- Capturing and documenting systems engineering theory for the healthcare industry, as well as critical best practices (as captured in a Healthcare domain extension to SEBoK, among other places)
- Piloting of a best practice/solutions sharing community
- Capturing and documenting 'state of the art' Agile, Lean Startup, and Iterative Development practices in healthcare



INCOSE Healthcare Working Group Charter

- Healthcare specific guidance to ISO/IEC 29110 Systems and Software Engineering — Lifecycle Profiles for Very Small Entities (VSEs)

MBSE: HWG is the clearinghouse for systems engineering models and techniques for healthcare systems and healthcare product offerings

- Sponsor conferences for sharing state of the art in model based systems engineering
- Define the standard approach for hospital department systems engineering models
- Define the reference architecture method for integrated modeling of hospital departments
- Facilitate a repository of example healthcare reference architectures for community

Education: HWG is the recognized source for the definition of systems engineering competencies and methods in healthcare and the source for a suite of healthcare education products for use by the community

2016 Annual objectives

Application of SE Principles to Healthcare - Chris Unger

- Develop a strategy for a Healthcare SEBoK extension
- VSE Checklists customized to Healthcare: plan and initial delivery - Angela Robinson
- Develop practical Healthcare SE solution sharing forum – David Vickery
 - Develop a pilot healthcare solution sharing forum pilot; demonstrate basic feasibility
 - *Future: Develop a case study library*
- *Stretch: Develop healthcare SE user personas definition*
- *Stretch: Develop a strategy for a Healthcare SE competency model*
- *Stretch: Develop a collaboration with the UK NHS and the US VHA on Mobile Digital Health and sponsor a workshop at I.S. on “How systems approaches can keep people out of the hospital?”*

MBSE in Healthcare - Bob Malins, Michelle Lott

- Hold MBSE Workshop at IW2016 - Bob Malins
- Develop infusion pump reference model and user manual - Michelle Lott
- Plan for a hospital department model based systems engineering example – Bob Malins

Medical Device SE Deployment (Market Research) – Anil Prasad

- Survey the industry, develop initial needs assessment

Education Strategy - Nicole Hutchinson

- Develop an education outreach strategy and form team
- Hold an SE Education for Healthcare Summit - Rachel Leblanc, Chris Unger
- Develop a Healthcare SE education vision and strategy (*Stretch: including certification*)

Academic/Research Challenges - Open

- *Stretch: form a team, develop a strategy*

Working Group Operations - Bob Malins

- Hold bimonthly Healthcare Systems Engineering Webinars - Ammon Wright
- Drive Biomedical / Healthcare track at IS2016: papers and panel - Ammon Wright, Gary Smith



INCOSE Healthcare Working Group Charter

- Social Media: Grow Linked in membership, increase the threaded discussion participation +10% - Ammon Wright
- Grow the number of active members (members actively contributing to WG products) up 20% – Bob Malins
- *Stretch: Develop a publication/product summary (HC WG bibliography)*

HWG Marketing strategy / value proposition – Rachel Leblanc

- Define value statement of Systems Engineering in the healthcare space
 - Define the Value ‘themes’ for SE in healthcare
 - Define marketing material strategy (and begin developing materials)
- Develop a response to the PCAST report, joint with AAMI (Multi-year project)

Outreach Strategy - Steve Badelt

- Develop a useful HWG contact database
- Develop a strategy for conferences and partnership. Execute ~5 events. (Steve Badelt, et al.)
- Grow regional Healthcare WG participation (Mike Celentano/Midwest, Steve Badelt/West, Tina Srivastava/Northeast, Gary Robert Smith/Europe, Edmund Kienast/Australia, Alan Ravitz/Chesapeake, Angela Robinson/Northstar)
- Develop relationships with key partners: AAMI, ACCE, Veterans Administration, Society for Academic Emergency Medicine, Society for Simulation in Healthcare

3 WG SCOPE

The scope of our working group covers

- Manufacturers of devices and providers of services (Clinical and Research use only devices, in-vitro and in-vivo products, pharmaceuticals, and biologics),
- All points-of-care through the entire healthcare delivery life-cycle,
- Medical academic institutions,
- Regulatory agencies,
- Healthcare insurance providers, and
- Healthcare advocacy groups.

While these organizations may be served by other INCOSE working groups, it is believed that our working group will uniquely address the breadth of their needs.

4 SKILLS AND EXPERTISE REQUIRED

As an organization, this working group is expected to exhibit a broad range of expertise across the complete spectrum of the biomedical and healthcare industries. To support this goal, members should demonstrate one or more of the following skills:

- General systems engineering skills (ISO 15288, INCOSE SE Handbook, SDLC)
- Specific systems engineering skills (architecture, modeling, SysML, security, safety)
- Systems thinking ability (comprehensive understanding of basic to complex systems)
- Product or process development experience (e.g., medical devices, pharma, consulting)
- Regulatory or standards-based knowledge, including advocacy, training, or certification

- Active participatory skills (leading, mentoring, coaching, influencing)
- Good communication skills (writing, speaking, presenting)
- IT support for the problem/solution database

5 MEMBERS, ROLES AND RESPONSIBILITIES

INCOSE sponsors

- Tom Strandberg, Assistant Director of Industry Outreach Board
- Joe Marvin, Assistant Director for Industry

Overall WG Organizational Strategy

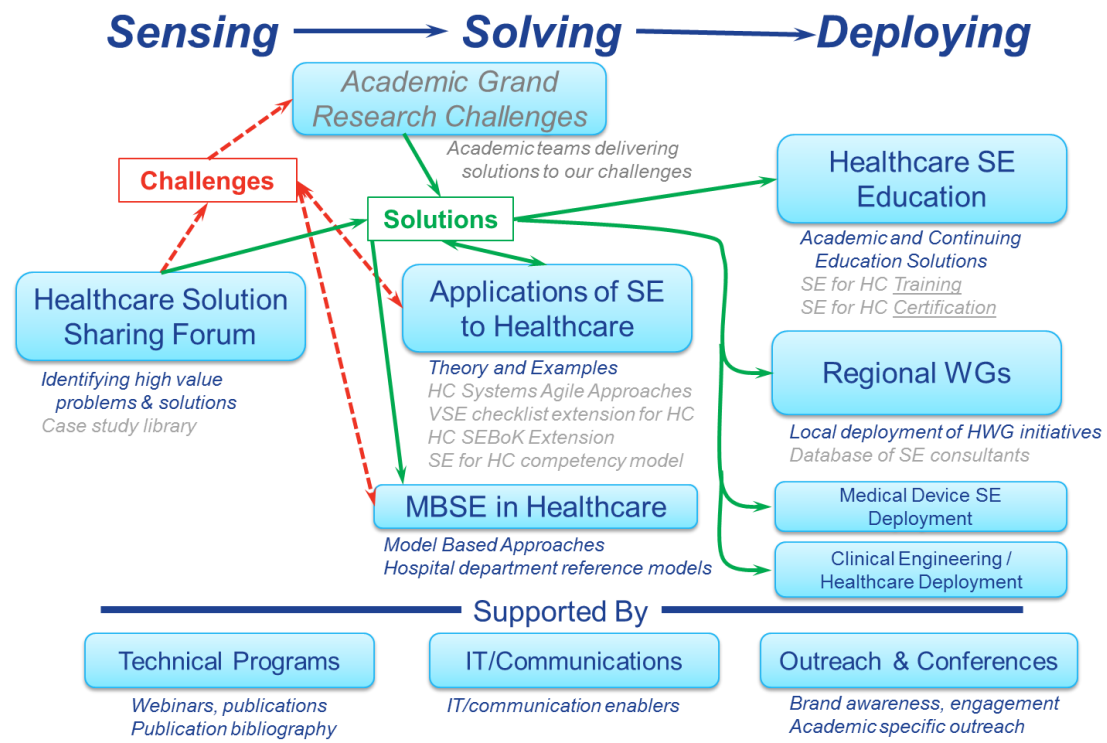


Figure 1: HWG Organization as a system

Working group leaders

Operations Leader: Bob Malins (WG Chair)

- Drive the WG execution to the roadmap, define and drive the WG metrics
- Run the WG operating mechanisms (team meetings, minutes, action item tracking)
- WG Member services (membership retention, increasing **active** participation)
- Manage the workstream execution and deploying the WG products
- Own the WG budget and checkbook

IT/Communications Leader: Bob Malins



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- Aggregate and publish working group materials on the INCOSE website
- Aggregate and publish relevant external information to working group members
- Curate and manage the INCOSE LinkedIn Group
- Manage the logistics of the webinars, including communications, meeting, posting materials, and facilitating a LinkedIn discussion thread after the meeting

Technical Program Leader: Ammon Wright

- Schedule knowledge exchange events on a bi-monthly basis (see Section 7 below)
- Organize cross-industry panels for the International Symposium

Chapter (Regional) WG Leaders: Steve Badelt (West), Mike Celentano (Midwest), Tina Srivastava (Northeast), Alan Ravitz (Chesapeake), Yves Theriault (San Diego), TBD (Los Angeles)

WG Architect: Chris Unger (WG Chair)

- Set the long term vision, Drive creation roadmap, WG priorities
- Own the technical content (Webinars, International Symposium, Publications)

Medical Device SE Deployment Leader: Anil Prasad

- Identify critical SE improvement needs in medical device companies
- Increase deployment of SE best practices, especially INCOSE products, in medical device companies

Outreach/Conferences Leader: Steve Badelt

- Develop and maintain a clear value proposition for the working group
- Develop and maintain collaborations with other professional organizations

Education Leader: Nicole Hutchinson

- Develop a clear value proposition for SE in healthcare and healthcare education
- Gain wider adoption of SE in Healthcare Education
- Partner with recognized organizations to build credibility for INCOSE
- Longer term – Develop a suite of healthcare education products for use by industry

Academic Grant/Grand Challenge, Research Leader: *Open*

- Transform HWG gaps into challenge statements academics could work on
- Recruit partners to execute those projects

Sector Leaders: Gary Robert Smith (Europe), Edmund Kienast (Australia)

Workstream Leaders

- Healthcare MBSE Challenge –B. Malins / M. Lott
- SE Applications to HC (including SEBoK domain extension) - C. Unger
- Healthcare solutions sharing forum – D. Vickery
- VSE Toolkits /Healthcare for Micro-Enterprises – A. Robinson

- **Succession plan:**

Red is a critical open position. Names in Blue are potential candidates, but either have not been contacted about their interest in the role or not have confirmed their intent.

Role

Person

Backfill



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Operations Leader (WG Chair)	Bob Malins	<i>TBD (outreach/member services)</i>
WG Architect (WG Chair)	Chris Unger	<i>TBD</i>
Outreach/Conferences Leader	Steve Badelt	<i>TBD</i>
<i>Europe</i>	<i>Gary Robert Smith</i>	<i>Brigitte Daniel Allegro (1 yr)</i>
<i>Australia</i>	<i>Edmund Kienast</i>	<i>TBD</i>
Technical Program Leader	Ammon Wright	<i>TBD</i>
IT/Communication Leader	Cary Bryczek	<i>Ammon Wright (1 year)</i>
Medical Device SE Deployment Leader	Anil Prasad	<i>TBD</i>
HC SE Education Leader	Nicole Hutchinson	<i>TBD</i>
Regional WG Coordination	<i>Open</i>	<i>TBD</i>
Academic Grant/Grand Challenge, Research Leader	<i>Open</i>	<i>TBD</i>
Workstream Leaders		
Applications of SE	Chris Unger	<i>TBD</i>
Healthcare Solutions Sharing Forum	David Vickery	<i>TBD</i>
MBSE in Healthcare	Bob Malins Michelle Lott	<i>TBD</i>
Lean in Healthcare	Bo Oppenheim	<i>TBD</i>
2016 Healthcare Industry Ambassadors	Gary Robert Smith Steve Badelt	<i>TBD</i>

6 OUTCOMES (PRODUCTS/SERVICES)

- Relevant information shared via regular (virtual) working group meetings (see Section 7 below)
- Relevant information shared via the INCOSE website
- Relevant presentations, panels, and roundtables at the International Symposium
- Specific work products (see Section 2 above)

7 APPROACH

- Regular communication meetings (virtual)
 - Working group meetings on a bi-monthly basis
 - Working group steering committee meetings on a bi-weekly or monthly basis
- Ad hoc meetings to discuss or work on specific working group activities (see Section 2 above)
- Annual attendance (in-person or virtual) at the International Symposium



INCOSE Healthcare Working Group Charter

- Annual attendance (in-person or virtual) at the International Workshop
- Participation or collaboration with other INCOSE working groups and professional partners

The working group intends for most working matters to be decided by the appropriate functional leader (see Section 5 above), without the need for a formal vote. However, for decisions that affect the operation of the group, a simple majority of the Steering Committee is required. For matters specific to a particular functional area, the majority vote must include the person responsible for that function. In cases where a majority vote is not possible (e.g., due to the unavailability of key members), both co-chairs must concur.

This approach will be revisited in the future as the working group matures.

8 MEASURES OF SUCCESS

- Active member participation in working group activities, defined as:
 - Stable, growing attendance at working group meetings
 - Stable, growing attendance at workshops and symposia
 - Growing active participation in developing WG products
 - Attendance levels greater than 10% of the working group roster
- A functioning website (see Section 9 below)

9 RESOURCE REQUIREMENTS

- See the WG checkbook for the 2016 Budget request details
- Normal WG resources (tele-/web conferencing , INCOSE website, meeting rooms at IW & IS)
- Help on the IT strategy for the Solution Sharing Forum from the INCOSE IT Director

10 DURATION

This charter will be reviewed annually at the INCOSE International Workshop.



INCOSE Healthcare Working Group Charter

11 SIGNATURES

Enter the signature block of the submitter Date

1st Level of Approval

Technical Director, INCOSE Date

2nd Level of Approval (Note this will be added by the INCOSE Technical Director when deemed appropriate.)

Chairman, INCOSE Board of Directors Date

Revision History

<u>Date</u>	<u>Revision</u>	<u>Description</u>	<u>Author</u>
April 2014	1.0	Initial draft	Tom Fairlie
September 2014	2.0	Updated with new roles, added backfill strategy	Chris Unger
January 2015	3.0	Updated for 2015...new roles (section 5), updated 105 deliverables (section 2)	Chris Unger
August 2015	3.1	Updated after International Symposium (changed "directors" to leaders", modified figure 1, added some leadership roles	Chris Unger Bob Malins
January 2016	3.2	Updated for the 2016 International Workshop	Chris Unger Bob Malins