From Operating Room to "Hospital at Home" –

**Emerging “SES MDI” Medical Device Standards Ready to Address Persistent Clinical Engineering Challenges**

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40+ Year *Promise* of Medical Device Interoperability:

Question ...
Clinical Engineers are at the “end of the line” for realizing MDI:

Question ...
Does it have to be this hard?
CE’s persistent challenges …
✓ Ensure “Safe, Effective & Secure” (SES) …
✓ Ensure “Medical Device Interoperability” (MDI) …
✓ Ensure risk managed networks of medical technology …

but
✓ Increasing technology complexity …
✓ Limited help from “standards based” solutions …
✓ Limited resources, time, budget …

**Question:** Why would the promises of a better future be different from the failed promises of the past?
Clinical engineers have played a key role in advancing open standards-based device integration by leading the creation of IHE patient care devices (PCD) work group starting in 2001 ...
Over last 15+ years, IHE PCD has become the ONLY successful standards-based initiative for the seamless exchange of device-sourced content!
BEFORE IHE PCD ...
➢ Connectathon testing was I.T. centric

AFTER IHE PCD ...
➢ Connectathon testing now included real-world medical devices!
➢ ACCE provided “independent test monitors”
HIMSS Interoperability Showcase Transformation...

Paul Sherman continued the ACCE / “Manny Style” leadership in IHE devices ...

Looks like healthcare!
(vs. a bunch of HIT terminals)
Clinical Engineers &
The “SES” Risk Management Journey

Since the 2010 publication of ISO/IEC 80001-1 for risk management of Medical I.T. networks that integrate medical devices and health software ... AAMI and clinical engineers have helped their learn and implement the standard...

How’s THAT working out for everyone?
ISO/IEC 80001-1:2010
Arrived with great anticipation ...

APPLICATION OF RISK MANAGEMENT FOR IT-NETWORKS
INCORPORATING MEDICAL DEVICES –

Part 1: Roles, responsibilities and activities

“SES”

1 Scope
Recognizing that MEDICAL DEVICES are incorporated into IT-NETWORKS to achieve desirable benefits (for example, INTEROPERABILITY), this international standard defines the roles, responsibilities and activities that are necessary for RISK MANAGEMENT of IT-NETWORKS incorporating MEDICAL DEVICES to address SAFETY, EFFECTIVENESS and DATA AND SYSTEM SECURITY (the KEY PROPERTIES). This international standard does not specify acceptable RISK levels.

NOTE 1 The RISK MANAGEMENT activities described in this standard are derived from those in ISO 14971 [4]. The relationship between ISO 14971 and this standard is described in Annex A.

This standard applies after a MEDICAL DEVICE has been acquired by a RESPONSIBLE ORGANIZATION and is a candidate for incorporation into an IT-NETWORK.

NOTE 2 This standard does not cover pre-market RISK MANAGEMENT.

This standard applies throughout the life cycle of IT-NETWORKS incorporating MEDICAL DEVICES.

NOTE 3 The life cycle management activities described in this standard are very similar to those of ISO/IEC 20000-2 [10]. The relationship between ISO/IEC 20000-2 and this standard is described in Annex D.
But did it deliver on the promise?

Consider over the last 10+ years …
✓ Webinars, conferences, publications … *impact?*
✓ Application guidance documents (80001-2-1 to 9) … *impact?*
✓ Pilot projects like @
  ❑ Scripps Healthcare in San Diego … *impact?*
    ▪ Actually **YES!** Changed some aspects of biz-as-usual … but …
    ▪ Today? How broad?
  ❑ *U.K. NHS 15+ year health technology risk management program* still sets a high bar!
  ❑ *German hospitals* recently requiring MedTech products to support 80001-1:2010!
✓ Technology sea change last 3+ years … *continued relevance?*

What to do? *Original challenges have only increased!*

*Revise 80001-1 & write more standards … !????*
New Standard: **81001-1**

Content includes ...

- Foundations for the broad context of *real-world MedTech SES management in hospitals*
- Integrates Canadian & U.K. care providers experience
- Defines a lifecycle-based “Temple” Model ...

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**CE’s work here ...**

*“SES”*
But are we there yet?!  

After 40 years of pursuing medical device interoperability, and seeing incremental gains at the enterprise level, are we done? Is device integration around the acute point-of-care ... "as good as it gets"?!
Is there hope?!  

As we ponder the NEXT 40 ...
Missing ingredient: \textit{SES+MDI}

The communities advancing “Safe, Effective & Secure” \textit{quality-focused} solutions and those advancing Medical Device Interoperability \textit{technology-focused} solutions ... exist in parallel universes ... \textit{Why}?!
Problem: Medical device interoperability (MDI) standards & Medical Technology Safety, Effectiveness & Security (SES) standards exist in parallel universes BUT products allowed for patient use must meet both the informatics interoperability technology requirements + quality, regulatory, and legal requirements.

Question: Can a framework be created to enable Trusted Interoperable Product Decoupling

Using

- ISO/IEEE 11073 SDC, IHE SDPi & HL7 FHIR Interoperability Standards
- + ISO/IEC JWG7 Safety, Effectiveness & Security Standards?
“Beauty is in the eyes of the beholder” … in this case, Standards guys!

… the Gardens help “make sense” of specific standards from different SDOs … in a pragmatic real-world product context …

… all with a combined technical & process “SES MDI” community subject focus

But does this truly help or just add to the confusion?!
A Framework for **Trusted Interoperable Product Decoupling**

Addressing the SES MDI Ecosystem “Trust Gap” ...

Gemini SDC/SDPi+FHIR ... Laying the foundation for Plug-n-Trust

Closing the “SES MDI Trust Gap” ... that implementation space between MedTech Product Developers & Clinical Users ... can be realized utilizing the ISO/IEEE 11073 SDC / IHE SDPi+FHIR specifications to engineer systems of products that offload the CE burden of 80001-based risk management by integrating resilience into the MDI infrastructure!
Yes! There is hope ... the *Gemini SES MDI Project*!

**IHE-HL7 Gemini MDI SDPi+FHIR – Project Update**

**for**

**Joint IEEE / HL7 / IHE Working Group Meetings**

2021.01.27 (Finalized 2021.02.19)

[See more details](https://confluence.hl7.org/x/Xzf9Aw)
The concept of a clinical workplace service-oriented medical device architecture transfers the concept of a service-oriented architecture to the domain of distributed system of medical devices for one clinical workplace.

Device-to-Device Plug-and-Play for Reporting / Alerting & Controlling

(PRACtical Interoperability)
Coming Attractions: MDIRA / ICE

Advancing research from Johns Hopkins University / Applied Physics Lab (JHU/APL) defining a Medical Device Interoperability Reference Architecture (MDIRA) that leverages Integrated Clinical Environment (ICE) framework components supporting intelligent autonomous medical technologies...
JHU/APL MDIRA focus:

“... applied research for technical architectures to support autonomous medical systems for prolonged care in austere environments and hospitals of the future”
Advancing an IHE DEV “MDIRA Profile”

✓ MDIRA directly targets safety and autonomous MedTech deployed in acute SES MDI environments

✓ In March, IHE Devices approved development of a MDIRA-based specification leveraging the IEEE SDC / IHE SDPi SES MDI specifications

MDIRA System Components Model

IHE MDIRA profile provides “SES MDI” standards solutions needed for the emerging “Hospital@Home”

See also IHE-HL7 Gemini MDIRA Confluence page @ https://confluence.hl7.org/x/GA7xB
Is there hope? Yes!

Are we there yet? No ... but ...

Clinical engineers have helped guide & trail blaze to this point in the journey ... and that leadership is need now more than ever!
Next Step ... continue to let your CE voice be heard!

✓ Participate in ...

www.globalcea.org/
ced.ifmbe.org/

✓ Advance CE voice in the “SES MDI” standards community

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