Medical Device Interoperability – A Brief History & Current Initiatives

for

IEEE Tech Talk: Health Electronics ~ Seattle

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FHIR is a trademark of Health Level 7, International.
SDC is a registered trademark of OR.NET
Medical Device Interoperability – A Brief History + Current Initiatives

MDI – Why is it so hard?

Current Standards-based Programs

SES+MDI – Plug-and-Trust for Acute Care

Personalized Health Navigation – The future?

Q & A
Medical Device Interoperability – A Brief History
40+ Year Promise of Medical Device Interoperability:

As we ponder the NEXT 40 ...

*Why do we think it will be any different?!*
Does it have to be this hard?

*Life-critical MedTech is HARD!*

Is it a technology problem?

*Not in the last 40 years!*

Why such a challenge?

#1 *Misaligned Business Drivers*

#2 *Incomplete Standards Solutions*
Acute Care MDI – A Brief History

MDI: A 40 Year Wander!

IEEE “1073” started early 1980’s ...

1980’s Technical solution ... Vendors choked life out of it
1990’s Technical & Business solution ... $$$$ & no user demand
2000’s Global Standards & IHE Collaboration ... no user demand
2010’s U.S. “C4MI” Created to Focus user demand ... remains TBD
2020’s Is there hope? Yes!!! ... maybe ...

NEXT REST AREA
40 YEARS
Acute Care MDI – *Today’s Reality!*

**The Value of MDI?**

**THE VALUE OF MEDICAL DEVICE INTEROPERABILITY:**

Improving patient care with more than $30 billion in annual healthcare savings

© westhealth institute

@westhealth | #interoperability westhealth.org
Updated Value of MDI Study

**USE CASES**

<table>
<thead>
<tr>
<th>Healthcare</th>
<th>Overall NPS</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolation Room</td>
<td>65%</td>
<td>1</td>
</tr>
<tr>
<td>Digital Charting</td>
<td>47%</td>
<td>2</td>
</tr>
<tr>
<td>Ward Round Pol</td>
<td>44%</td>
<td>3</td>
</tr>
<tr>
<td>Quiet ICU Ward</td>
<td>41%</td>
<td>4</td>
</tr>
<tr>
<td>Integrated UI</td>
<td>41%</td>
<td>5</td>
</tr>
<tr>
<td>Surgical Display</td>
<td>31%</td>
<td>6</td>
</tr>
<tr>
<td>Spotcheck Monitoring</td>
<td>27%</td>
<td>7</td>
</tr>
<tr>
<td>Automated OR Setup</td>
<td>22%</td>
<td>8</td>
</tr>
<tr>
<td>Service – Predictive Maintenance</td>
<td>16%</td>
<td>9</td>
</tr>
</tbody>
</table>

- Physiological Closed Loop Control: 17% (RANK 10)
- Central Patient Watch: 13% (RANK 11)
- Intra Hospital Transport Monitor: 12% (RANK 12)
- Service – Biomed Notification: 9% (RANK 13)
- Treatment Recommendation: 6% (RANK 14)
- Augmented Surgical Display: 3% (RANK 15)
- Personal Health Integration: 0% (RANK 16)
- Safety Interlock: 4% (RANK 17)
- Dual Bedside Display & Control: -1% (RANK 18)
- Benchmark Therapy: -18% (RANK 19)

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**THE REAL VALUE OF MEDICAL DEVICE INTEROPERABILITY IN HOSPITALS**

Medical Device Interoperability (MDI) is one of the most relevant technology trends in the development of medical devices. As the result of a study conducted with more than 230 participants from the main areas of patient care in hospitals, we summarize which MDI use cases are valued most by both medical technology manufacturers and especially the previously neglected perspective of healthcare professionals. We also provide valuable recommendations for the future direction of MDI development.
Medical Device Interoperability – Current Standards-based Programs
## Device Interoperability Standards Landscape

<table>
<thead>
<tr>
<th>Program</th>
<th>IHE PCD</th>
<th>IEEE PHD / Continua</th>
<th>IEEE SDC / IHE SDPi</th>
<th>HL7 Devices on FHIR</th>
<th>IEEE / EMBS Mobile Health Data (P1752)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Use Context</td>
<td>Healthcare Enterprise</td>
<td>Home / Mobile</td>
<td>High Acuity (OR/ICU/ED)</td>
<td>Enterprise / Mobile / Home</td>
<td>Mobile (wearables)</td>
</tr>
<tr>
<td>Technical Base</td>
<td>HL7 V2.6 ¹</td>
<td>IEEE 11073</td>
<td>WS*</td>
<td>REST / HTTP</td>
<td>Open mHealth / JSON</td>
</tr>
<tr>
<td>Maturity / Production Systems</td>
<td>Dozens of commercially available products</td>
<td>100’s of Certified PnP Products</td>
<td>Prototyped; First devices placed into patient use; tools &amp; open source</td>
<td>PoCD &amp; PHD IGs; FHIR Connectathons; Continua FHIR Guidelines &amp; Source</td>
<td>Early stages of development – TBD sync w/ FHIR</td>
</tr>
<tr>
<td>Semantics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>IEEE 11073 Terminology &amp; Model</strong> ²</td>
</tr>
</tbody>
</table>

¹ + 2.7, 2.8.x    ² Core 11073 terms mapped to LOINC
2019 IHE PCD Domain => DEV Domain

3 Device Use Contexts …
One consolidated IHE Technical Framework

Download @ www.pchalliance.org/continua-design-guidelines
Use Case: Transient, but clinically significant (suboptimal) drops in systemic blood pressure that correlate with each metoprolol administration

- Open standards-based API’s (e.g., HL7 FHIR & CDS)
- Systems developed independent of use case
- Who is risk managing @ implementation & use?!
  (note 80001-1 revision)
What devices are we talking about?

- Wearables + IoT + Cloud + ...
- Spans home to hospital contexts
- Mostly simple ... but Billions of them!
- Physio parameters + environmental + patient generated + ...
- Personal & Professional Users
Medical Device Interoperability –
\textit{SES+MDI} –
\textit{Plug-and-Trust for Acute Care}
Standards for device-to-device interoperability at Point-of-Care?
SDC & Silent ICU Use Case Narrative ...

SILENT ICU BY ALARM SIGNAL DELEGATION

Today

Tomorrow

Reduction of alarms

Alarm Distribution

~ 80 - 95 % clinically irrelevant

up to 40 min. to alarm confirmation

50 % are not noticed

~ 40 different sounds in one ICU

road to

1

alarming device per patient

Gemini SES MDI – IHE Catalyst Study Project
1. The alarm producer has to make **all information available** that are necessary for the remote alarm notifiers, like alert condition presence, alert manifestation, etc. **Interoperability** and semantical interpretability have to be ensured.

2. The system has to be suitable for **multiple alarm producers** and **several remote alarm notifying devices**.

3. The alarm producer has to be able to determine whether other devices are **ready to generate the alarm notification**.

4. The alarm producer has to be able to observe that the **alert is generated correctly**.

*Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC“, Kasparick et al.*
SDC – Security is a Core Capability

SDC Communication

- Standard based encryption of communication: TLS 1.2+
- Each endpoint has a certificate.
- Authentication at both endpoints
- No communication if no trust chain can be established

- Certificates are used to secure communication
- Authorization and Authentication
- Certificates carry roles of participants
- Each device can decide if remote control is OK based on certificate roles and certifying organization

SDC = Enables Trusted Interoperable Product Decoupling
SDC Basics ...

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)

Conceptual view of a SOMDA for a clinical workplace

SDC Point-of-Care Context

HIT “Enterprise” Context

IEEE 11073 SDC bidirectional device-to-device communication

Gateway

e.g. HL7 or DICOM exchange and storage of healthcare information

Billing

Lab

PACS

EMR
What is SDC?

Service-oriented Device Connectivity

A family of international standards for interoperable exchange of real-time information between medical devices and external systems in dynamic IP networks.
There has been “hallway” discussion about considering an additional messaging protocol / transport as an option to MDPWS …

1. Use of gRPC with protobufs is now being seriously considered!
2. Informal prototyping in 2020 & 2021 was very encouraging
3. PAT #5 2021-12 included a gRPC/protobuf test track …
   ✓ Complete success within a few hours
   ✓ “Blazingly fast” results!!!
4. gRPC/protobuf option being added to the SDPi-P profile + added to the 3-Year Roadmap

But even more seriously ... check out protoSDC.org
JWG7 SES “Temple” Diagram

Model developed over last 10 years in response to better manage the interrelations ...
✓ Across Stakeholders ...
✓ Across Product Lifecycles ...
✓ Across Subject Areas
✓ Across Multiple Standards

Problem: SES+MDI “Trust Gap” recognized but no practical real-world solutions – too resource & labor intensive

Source: ISO/IEC 81001-1:2021
ISO/IEEE 11073 SDC MDI “Cathedral” Model

The SDC Standards Family

“Cathedral” Model
Gemini SES+MDI “Hanging Gardens” Framework

User Narratives / Use Cases / Requirements
Reference Architectures / Frameworks
Device / Health Software Specializations
Key Interoperability Properties & Controls (PRActical SES)

SDPi+FHIR Profiles / IGs

IEEE 11073-1072x -10799 ModSpecs

IEEE 11073-1070x PKP (Safety)

20701 - Architecture and Protocol

10207 – DIM and Service Model

20702 - MDPWS

2070x – HTTP/2, REST, IoT, DDS, ...

Devices on FHIR

HL7 FHIR

Physical Layers (Ethernet, Wi-Fi, BT, etc.)

SES+MDI Plug-n-Trust Interface

(More @ https://confluence.hl7.org/x/4ijxB)
**Problem?** Ecosystem Pathway group will leverage the SES+MDI “Hanging Gardens” Framework ... to address the pesky “Trust Gap” product ecosystem challenges!
Medical Device Interoperability – Personalized Health Navigation ...
The future?
What should healthcare look like in 10 years?
THT: What do people want ... In 10 years!

To create a digital health legacy for Southern California, we asked people for their opinions:

- **#1: Access & Affordability**
- **It is about ME ... I am in control of all info & care**
- **Focus: Health & Wellness**
- **Healthcare** when & where I need it to return to health & wellness ... optimally (time & therapy)
- **Available to everyone ... EVERYONE**
- **Use latest best technology & knowledge**
One September in San Diego …
✓ Hives? Maybe
✓ Go to Ready Care? No!
✓ Call “ÜberDoc”!
✓ MD + Assistant …
✓ in my home …
✓ < 90 minutes …
✓ $99 flat fee

They spent 45 minutes with me!
(in the U.S., that’s unheard of …)
The First Wave of the Internet was all about building the infrastructure and foundation for an online world.

The Second Wave was about building on top of the Internet. Search engines like Google made it easier to explore the sheer volume of information available on the web. Amazon and eBay turned their corner of the Internet into a one-stop shop. It was during the Second Wave that social networking came of age...

The Third Wave is characterized by:

- Ubiquitous communication (IoT)
- Unlimited computing power (cloud)
- Data-/Knowledge-Driven (Big Data)
- AI & ML + VR & MR
- Personalized
Future of Individualized Medicine

March 14-15, 2019 | La Jolla, California

* Online registration has closed. Walk-in registration will be available onsite. *

After 11 annual conferences exploring genomic medicine, we’re broadening our scope.

In 2019, the newly renamed Future of Individualized Medicine (formerly Future of Genomic Medicine) conference will expand to include additional perspectives on how to tailor medicine to the individual. Individualized medicine takes into account a person’s genes—and genomics will remain a core topic for exploration and discussion—but it also considers the full spectrum of a person’s uniqueness from their biologic, physiologic, anatomic, lifestyle and environmental information. The Future of Individualized Medicine conference will thus incorporate perspectives from the emerging fields of digital medicine, artificial intelligence and machine learning, behavioral science and others. This is truly a multidisciplinary forum.
Opinion

The A.I. Diet

Forget government-issued food pyramids. Let an algorithm tell you how to eat.

By Eric Topol
Dr. Topol is a cardiologist.

March 2, 2019

Some months ago, I participated in a two-week experiment that involved using a smartphone app to track every morsel of food I ate, every beverage I drank and every medication I took, as well as how much I slept and exercised. I wore a sensor that monitored my blood-

For now, it’s striking that it took big data and A.I. to reboot our perceptions about something as fundamental as what we eat. We’re still a ways away from “You Paleo, me Keto,” but at least we’re finally making progress, learning that there is no such thing as a universal diet.

NEURAL INTELLIGENCE SOLUTION for PRECISION HEALTHCARE

Preventing ED & Hospital Visits Due to Asthma and COPD, Using Deep Learning Technology and Real-Time Data
NEURAL INTELLIGENCE SYSTEMS
REAL-TIME DATA + PERSONALIZED ANALYTICS + TIMELY ALERTS
A Navigational Approach to Health: Actionable Guidance for Improved Quality of Life

Nitish Nag and Ramesh Jain, University of California, Irvine

Health and well-being are shaped by how lifestyle and the environment interact with biological machines. A navigational paradigm can help users reach a specific health goal by using constantly captured measurements to estimate how their health is continuously changing and provide actionable guidance.
Consider: Personal Health “Navigator”

❖ What if an app could guide you to better health, similar to how GPS navigation directs you to your desired destination? Think: Apple / Alibaba / ... "maps"

❖ What if the app could use real-time information to redirect you around a disease, just as you’re rerouted to avoid traffic? Think: Waze

❖ What if the app could provide step-by-step directions to get you to your optimal health state, whether you’re a young professional athlete or an old retired school teacher? Think: Google walking “directions”

(Source: Dr. Ramesh Jain / UCI Institute for Future Health; https://arxiv.org/abs/1805.05402)
Leverage AI / ML / Cybersystems…in daily life!

Cybernetics: Feedback revolutionizes system design

Modern control theory and AI came from Cybernetics.

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)
Consider modern car (and foot!) navigation

Magic Happened: Can you drive without a navigation system?

Maps
Points of Interest

Current State: GPS
Current Traffic: Waze

Destination

Navigation system

Cybernetic loop

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)
What everyone wants: Perpetual Health!

Perpetual Health Guidance

Measure
Collect all data

Estimate
(Health State)

Influence and
Compliance

Inspiration:
Navigation Systems.

Guidance

How do we close the loop?

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)
Navigational Health (Dr. Ramesh Jain / UCI)

Lifestyle and environment are more important for human health than medicine

Health is not just about medical care. Changing your lifestyle will make larger impact on your health. So tracking lifestyle data makes sense.

(Source: Dr. Ramesh Jain / UCI Institute for Future Health; https://www.slideshare.net/jain49/jain-socal-himss-keynote-1805018)
The Problem: What is Right? vs. What is Easy?

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)
Navigational Health: A New Perspective

Focus on:
- Personal Models
- Cybernetics

Enter ...
- Social Care Informatics
- Social Determinates of Health
- Traditional Medicines
- “Lifestyle” Informatics

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)
Personal Health “Navigator”

Science Fusion!

Quantified Daily Activities

Precision Medicine

(Source: Dr. Ramesh Jain / UCI Institute for Future Health; https://arxiv.org/abs/1805.05402)
Personal Health "Navigator": Diabetes

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)
Dr. Ed Hammond –
Father of American Health Informatics @ Duke

In 10 years, healthcare will be increasingly delivered by robots, drones & avatars

Sophia – Ed’s #1 Choice!

www.MedicalDrones.org
Home Automation @ Ageing in Home

※ Source: Gartner
Technology & Services @ Ageing -
Questions & Answers
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