IHE USA’s Path to Production Digital Series
Phase 3 – Defining the Business Case | June 22nd & 23rd, 2022

Integrating Devices from Hospital to Home
Agenda

✓ “Got devices?” – IHE Devices is here for you!
✓ From Preeclampsia during Pregnancy to Silent ICU
✓ PCD for Healthcare Enterprise Integration
✓ PCH for Home & Mobile Integration
✓ DPI for Acute Bed Device-to-Device Integration
“Got devices?” – They’re everywhere!

✓ IHE Devices Domain:
  ▪ Founded in 2005 as PCD – Reorganized as “Devices” in 2019
  ▪ Acute Care & Personal Health devices ~ From hospital to clinic to home
  ▪ Profile specifications integrating standards from ISO / IEEE, HL7 (V2 & FHIR)
  ▪ One IHE Devices Technical Framework greatly simplifies product implementation

✓ Most successful – arguably ONLY – open standards-based device integration solution suite available today, anywhere!
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 health care savings

westhealth® institute
## 2021 Updated Value of MDI Study

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<tr>
<th>Use Case</th>
<th>HDO Rank</th>
<th>MDM Rank</th>
<th>ICU Rank</th>
<th>OR Rank</th>
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### USE CASES

1. Isolation Room
2. Digital Charting
3. Ward Round Pol
4. Quiet ICU Ward
5. Integrated UI
6. Surgical Display
7. Spotcheck Monitoring
8. Automated OR Setup
9. Service – Predictive Maintenance
10. Physiological Closed Loop Control
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12. Intra-Hospital Transport Monitor
13. Service – Biometric Notification
14. Treatment Recommendation
15. Augmented Surgical Display
16. Personal Health Integration
17. Safety Interlock
18. Dust Bedside Display & Control
19. Benchmark Therapy

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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 220 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.
Consider: Preeclampsia During Pregnancy

Use Case: Supporting preeclampsia maternal care from home to clinic to hospital back to home …

- PHD & PoCD
- HL7 V2 & FHIR
- IEEE Semantics
Consider: Silent ICU

Today

Tomorrow

~ 80 - 95% clinically irrelevant

up to 40 min. to alarm confirmation

50% are not noticed

~ 40 different sounds in one ICU

Reduction of alarms

Alarm Distribution

road to 1 alarming device per patient

SILENT ICU BY ALARM SIGNAL DELEGATION
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**.

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Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC“, Kasparick et al.
What’s in a name: “Device”

15+ Years ago it was easy: Medical Device or Personal Health Device?

Today? Not so much …

- **Use Cases** - both that are distinct to a specific use context and that involve two or three and require cross-context coordination
- **Use Contexts** - are the (3) suggested appropriate or should there be a further breakdown? Architectures?
- **Ecosystem** – Intra & Inter Context Providers / Consumers (e.g., EHR consumers of PoC device content)
- **Risk => Criticality => Regulatedness**: Clearly this is involved in all three use contexts, but at different levels?
- **Quality** – including process requirements (e.g., ISO 13485, 82304-1 & -2, 62304, etc.)
- **User** - professional clinician to personal grandpa or family caregiver
- **Technology** - esp. with the advent of Medical IoT, mobile FHIR-based, AI/ML MD ... EMBS SC initiatives? Etc.
  - Consider **RWD** needs of FDA and others @ AI-enabled MDs … melding a few of the above aspects
- **Example**: **Digital Therapeutics** – SaMD? SiMD? Both?!
3 Device Use Contexts ...

One consolidated IHE DEV Technical Framework

❖ Semantic interoperability across all contexts! (via IHE DEV “Rosetta” Terminology Mapping & Device Specialization Value Sets)
PCD: Patient Care Devices Program

Integration Context Focus: Healthcare Enterprise

- **Problem:** Integration of device data to EHRs & other enterprise systems
  - **Solution:** *Device to Enterprise Communication (DEC) Profile*

- **Problem:** Integration of infusion pump programing info (5 Rights Checking)
  - **Solution:** *Point-of-care Infusion Verification (PIV) Profile*

- **Problem:** Integration of infusion pump operational / event information
  - **Solution:** *Infusion Pump Event Communication (IPEC) Profile*

- **Problem:** Distribution of device alerts to the right clinician
  - **Solution:** *Alert Communication Management (ACM) Profile*

- **Problem:** Ensuring that devices & their data are associated with the right patient
  - **Solution:** *Point-of-Care Identity Management (PCIM) Profile*

Note: PCD Profile Connectathon Testing @ www.iheusa.org/ihe-na-connectathon
PCH: Personal Connected Health Program

Integration Context Focus: Home & Mobile

Problem: Uploading of home-based personal health device data using FHIR
Solution: Personal Health Device Observation Upload (POU) Profile

Note: Additional PHD profiles under development as well

Note: PCH Profile Connectathon Testing @ www.iheusa.org/ihe-na-connectathon
DPI: Device Point-of-Care Interoperability Program

Integration Context Focus: Highest Acuity Point-of-Care (OR, ICU, ER, …)

Problem: Device-to-device Plug-n-Trust Interoperability around the bedside

Solution: **Service-oriented Device Point-of-care Interoperability (SDPi) Profile**

Notes: This is a joint “Gemini” development program between IHE DEV and HL7 DEV, including the Devices on FHIR community

Pathway to Production for SDPi-enabled products?
Requires parallel & convergent ...

“We” Quality / Risk Management / Regulatory Affairs Pathway
+ “MDI” Technical Pathway

See “Pathway to an Ecosystem of Plug-and-Trust Products” for more information
Joint IHE-HL7 Gemini SES+MDI Program

Service-oriented
Device Point-of-care
Interoperability (SDPi)

✓ Four profile specifications:
  • SDPi-P for Plug-and-Trust Interoperability
  • SDPi-R for Reporting Medical Information
  • SDPi-A for Alerting
  • SDPi-xC for External Controlling

✓ Three IHE DEV TF Volumes:
  • TF-1 Profiles / use cases / actors / ...
  • TF-2 Transactions / MDPWS messaging
  • TF-3 BICEPS content modules / device specializations
IHE Devices – Get involved!

✓ Join IHE International today!

✓ Contact Sarah, John or Todd (below) about where and how to engage in the different program activities

✓ Review the IHE Devices Technical Specifications @ profiles.ihe.net/DEV/

✓ IHE USA Connectathon Information @ www.iheusa.org/ihe-na-connectathon (September 12-16, 2022 ~ joint IHE EU & IHE North America)

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