Accelerating Standards Development for Remote Connected Care and Mobile Health (RCC-MH)

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Remote Connected Care – Mobile Health (RCC-MH)

- The Pandemic – Accelerating RCC-MH Adoption
- Use Cases and Scope
- Our Process
- Security and Interoperability
- Gap Analysis
- Acceleration via Preparedness
- Recommendations
- Roadmap
- Contacts
The Pandemic
Accelerating RCC-MH Adoption

♦ The Pandemic demanded Remote Connected Care and Mobile Health (RCC-MH) Solutions. Unfortunately the world found that we were not ready. As a result we received support from a number of SDOs (Standards Development Organizations) to investigate and publish a Technical Report (TR) on:

– Accelerating Safe, Effective and Secure Remote Connected Care and Mobile Health (RCC-MH) Interoperable Solutions in Pandemics
The Pandemic
Accelerating RCC-MH Adoption

♦ Our objective is to assess the current ability of RCC-MH related standards, regulations and solutions to address the challenges brought on by the Pandemic and recommend approaches to accelerate identified gaps and future needs.
  – The TR focuses on the challenges of monitoring and treating patients ‘remotely’ with a focus on device communication and evolving mobile app solutions while taking into account various care locations and use cases.

♦ This TR is being developed initially under the auspices of the joint HL7/IHE Gemini project. It will then be advanced to ISO/TC 215 WG2 (where it has already been accepted as a PWI (Preliminary Work Item)) for additional international participation, review and subsequent publication.
Public Health Emergency Declaration

♦ WHO declared the COVID-19 outbreak to be a Public Health Emergency of International Concern (PHEIC) on Jan 30, 2020

♦ In the USA, on Jan 31st 2020, the Secretary of Health and Human Services, pursuant to the authority under section 319 of the Public Health Service Act, declared a nationwide Public Health Emergency.
US Governmental Responses to the Pandemic

♦ FDA
  – Impact of FDA’s Emergency Use Authorization – Feb. 4th
    • One impact was the ability for device manufacturers to clear their devices for remote monitoring and therapy control for Covid-19 related applications w/o needing a 510k under specific changes and conditions.

♦ CMS
  – COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers
  – Telehealth: Delivering Care Safely During COVID-19
  – Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge

♦ ONC
  – Tools and Resources for the Health IT and Clinical Community

♦ CDC
  – Responses to Covid-19
RCC-MH Scope

♦ Our scope includes the communication, structure and quality of:
  – Medical Device data – including sensors, patient connected devices, lab and imaging devices
  – EHR and Health IT data – such as storage and availability of device data
  – Mobile Health apps data – for both personal health and clinical use cases.

MH = Mobile Health
PDH = Personal Digital Health
IoMT = Internet of Medical Things
PGHD = Patient Generated Health Data
SDOH = Social Determinants of Health
RCC-MH Use Cases

♦ The pandemic has been a catalyst for accelerating existing shifts in patient care, and the need to address these challenges in a safe, effective and secure manner.

♦ Use Cases considered in this work include:
  - Hospital Care:
    • Adoption of new device technology “overnight”
    • Remote access and control of devices to reduce patient contact and risk of infection
  - Post-Acute Care (PAC)
    • Skilled Nursing Facility (SNF)/Long-term Acute Care (LTAC)/Hospice
  - Home Care
    • Shift to remote continuous monitoring and care – “hospital at home”
    • Increased adoption of Mobile Health tools and advent of Public Health related deployments
  - Outpatient Care
    • Exponential adoption of mobile (health) apps for acute and chronic care
      - PCP/GP to Home and and PAC patients
      - Specialist to PCP/GP (and patient)
      - Specialist to hospital (and patient)
    • Integration of person generated health data into the health eco-system
  - Virtual clinical trials (VCTs)
    • Accommodating the special requirements for VCTs
  - Patient Engagement
    • Patient Generated Health Data
    • Social Determinants of Health
Remote Connected Care enables large shifts in where care is delivered.

- From hospitals and outpatient centers to the Home and Physician offices
Key Areas Addressed

♦ Care Locations
♦ Use Cases and Gap Analysis
♦ Socio-Technical Challenges
♦ Standards Landscape for:
  – Safety
  – Effectiveness
  – Security
  – Interoperability Processes, Communications and Architectures
♦ Regulatory Landscape
♦ Legal Landscape
♦ Patient Impact
Engaging the Stakeholders

♦ Meetings were held dedicated to specific topics with domain experts:
  – Scientific Computing, Analytics, Real World Evidence (RWE)
  – Security
  – Provider Discussions
  – Nomenclature Discussions
  – Industry/Digital Medicine/Trials
  – Digital health Policy / Interoperability
  – Digital health and Pre-Natal Cardiac Care
  – Discussion of the Securing Telehealth and Telemedicine White Paper
Engaging Standards Experts

• HL7 USA and Europe
• IHE DEV(ices) Domain
• IEEE
  • IEEE 11073 (Healthcare Informatics – Medical Device Interop.)
  • IEEE P2933 (Clinical IoT and TIPPSS)
  • IEEE P1752 (Open Mobile Health)
• ISO/TC 215
  • WG2 – Systems and Device Interoperability
  • WG4 – Security, Safety and Privacy
  • WG11 – Personalized Digital Health
Key Concepts

♦ Safety
♦ Effectiveness
♦ Security
♦ Interoperability
♦ Remote Connected Care
♦ Mobile Health
Safety And Effectiveness

“Items that medical device manufacturers should consider to provide a reasonable assurance of safety and effectiveness of their interoperable medical devices: 1) designing systems with interoperability as an objective; 2) conducting appropriate verification, validation and risk management activities; and 3) specifying the relevant functional, performance, and interface characteristics in a user available manner such as labeling.”

https://www.fda.gov/media/95636/download
## Cybersecurity Aspects of Safety

### 1. Protect the Device

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>HDO</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hardened design</td>
<td>• Secure networking</td>
</tr>
<tr>
<td>• HIDS/HIPS (whitelisting)</td>
<td>• Integration and deployment best practices</td>
</tr>
</tbody>
</table>
| • Key/Certificate-based:  
  • Encryption  
  • Code signing  
  • Secure boot  
  • Hardware certificates | • Cyber-Hygiene:  
  • Secure handling  
  • Media use (esp. USB) |

### 2. Protect the Ecosystem

<table>
<thead>
<tr>
<th>Manufacturer</th>
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</tr>
</thead>
<tbody>
<tr>
<td>• Secure remote access</td>
<td>• Network architecture</td>
</tr>
<tr>
<td>• Strong password / 2FA</td>
<td>• Anomaly detection</td>
</tr>
<tr>
<td>• Security best practices documentation</td>
<td>• Event monitoring</td>
</tr>
<tr>
<td>• Enablement &amp; Training</td>
<td>• Firewalls / Gateways</td>
</tr>
</tbody>
</table>

### 3. Manage Devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
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</tr>
</thead>
<tbody>
<tr>
<td>• Secure lifecycle mgmt.</td>
<td>• Procurement &amp; contracting</td>
</tr>
<tr>
<td>• V&amp;V incl. security</td>
<td>• Asset management</td>
</tr>
<tr>
<td>• Vulnerability disclosure</td>
<td>• Dependency mgmt.</td>
</tr>
<tr>
<td>• Security documentation (e.g., SBoM)</td>
<td>• Risk Management and Mitigation</td>
</tr>
<tr>
<td>• Supply chain management</td>
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### 4. Respond to Incidents

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>HDO</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Threat &amp; Vulnerability monitoring and management</td>
<td>• Detect, Respond, Recover</td>
</tr>
<tr>
<td>• Incident detection</td>
<td>• Impact Analysis, Forensics</td>
</tr>
<tr>
<td>• Regulatory reporting</td>
<td>• Communication &amp; Decision making</td>
</tr>
<tr>
<td></td>
<td>• Reporting as needed</td>
</tr>
</tbody>
</table>
Interoperability and RCC-MH

♦ Interoperability is a complex topic
  – A device can be interoperable because it support Wi-Fi or Ethernet or Bluetooth and use a totally proprietary communications language or dialect.
    • Unfortunately most health devices today are built this way.
    • This results in time consuming, expensive projects to integrate those devices into a Health IT Infrastructure.

♦ Besides physical (Wi-Fi, USB) and transport layer (TCP, UDP) interoperability there are more layers…
# Levels of Interoperability –
## Diagram adapted from ISO 23903:2021

<table>
<thead>
<tr>
<th>Interoperability Levels</th>
<th>Information Defined</th>
<th>Contents clearly defined</th>
<th>RCC-MH related Examples</th>
<th>RCC-MH Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Technical</td>
<td>Technical PnP, signal &amp; protocol compatibility</td>
<td>• Light-weight interactions</td>
<td>WiFi, Bluetooth</td>
<td>Integratable</td>
</tr>
<tr>
<td>2 Structural</td>
<td>Simple EDI, envelopes</td>
<td>• Data sharing</td>
<td>CDA, Files</td>
<td></td>
</tr>
<tr>
<td>3 Syntactic</td>
<td>Messages and clinical documents w/agreed vocabulary</td>
<td>• Information sharing</td>
<td>HL7 v2, LOINC, 11073 Nomen. ASN.1</td>
<td></td>
</tr>
<tr>
<td>4 Semantic</td>
<td>Advanced messaging with common information models and terminologies</td>
<td>• Knowledge sharing at IT concept level in computer-parsable form • Coordination</td>
<td>HL7 RIM, 11073 DIM</td>
<td>Interoperable</td>
</tr>
<tr>
<td>5 Organization / Service</td>
<td>Common business process</td>
<td>• Knowledge sharing at business concept level • Agreed service function level cooperation</td>
<td>HL7 IGs, IHE Profiles, 11073 Specializations</td>
<td></td>
</tr>
<tr>
<td>6 Knowledge Based</td>
<td>Multi-domain processes</td>
<td>• Knowledge sharing at domain level • Cross-domain cooperation</td>
<td>Domain Profiles</td>
<td></td>
</tr>
<tr>
<td>7 Skills based</td>
<td>Individual engagement in multiple domains</td>
<td>• Knowledge sharing in individual context</td>
<td>Individual Profiles</td>
<td></td>
</tr>
</tbody>
</table>

Increasing Interoperability

[https://www.iso.org/standard/77337.html](https://www.iso.org/standard/77337.html)
US FDA Guidance on Interoperability

- **Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices** (Sept. 6, 2017)

  “Medical device manufacturers must manage risks including those associated with an electronic interface that is incorporated into the medical device. The following considerations should be appropriately tailored to the selected interface technology, and the intended use and use environments for the medical device.”

  1. Purpose of the Electronic Interface
  2. The Anticipated Users
  3. Risk Management
  4. Verification and Validation
  5. Labeling Considerations
  6. **Use of Consensus Standards**

- Also see [https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability](https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability)
RCC-MH Services/Data Types:
Interoperability spectrum and applications

♦ Pharmacy
♦ Radiology
♦ Laboratory
♦ Surgery
♦ Cardiovascular
♦ Neurology/Mental health
♦ Infusion
♦ Dialysis

♦ Clinical trials
♦ Adverse event reports
♦ PT, OT, RT (Respiratory Therapy)
♦ Visiting Nursing
♦ PCA (Patient Care Assistant)
♦ DME logistics
♦ Telehealth Centers
RCC-MH Services/Data Types:
Emerging Technologies

♦ Mobile Health Apps Stores
   – Wellness, Health, SaMD, SiMD
♦ “Visiting” Physician – remote consult
♦ Drone logistics/supply-chain
♦ AI/ML
♦ AR/VR/MR/XR
♦ IoT/IoH
♦ 3D-Printing
♦ Drone: Observation, Intervention, Remote Care
♦ Robots @ Home
♦ Blockchain/DLT
♦ ...
# Gap Analysis

*Use Cases were analyzed to uncover potential Gaps/Needs in standards coverage*

*Example Gap Analysis (3 out of 35)*

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Pre-Pandemic (Current State)</th>
<th>Post-Pandemic (Desired State)</th>
<th>Gap/Need</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimize contact with infectious patients for device reading and adjustment.</td>
<td>Caregivers must enter the patient room to obtain readings and adjust settings on devices. This usually requires a change of PPE for each instance.</td>
<td>Remotely obtain readings and adjust settings on devices. Caregivers have reduced patient contact and do not need to change PPE if they don’t enter the room.</td>
<td>Devices that can be monitored and adjusted remotely.</td>
</tr>
<tr>
<td>Track device usage, status for recall or infection control purposes.</td>
<td>Most devices are tracked by association with other devices at a location. When they are moved that information is lost.</td>
<td>Devices can also be tracked via a globally unique ID which can help trace the device as well as understand its provenance.</td>
<td>While there are UDI schemes there are no requirements for electronic reporting of the UDI and it is not very secure.</td>
</tr>
<tr>
<td>Physicians need to track compliance of a patient with a device usage regimen.</td>
<td>If the health device is not connected and the data is entered manually there is no way of telling if the entry time or physiological measurement value is accurate.</td>
<td>Data is collected from connected devices which can report the time of acquisition and the physiological measurement reported by the health device.</td>
<td>Connected health devices must be easy to use so that they are used as prescribed by patients.</td>
</tr>
</tbody>
</table>
Gap/Needs Analysis

♦ Example Gaps include:
  – Various available health device connectivity open standards need to be reviewed from a provisioning and remote maintenance perspective to assess the level of sophistication and training required to deploy systems based on these standards.
  – Many medical device vendors do provide remote servicing (including remote SW/FW update) capabilities. However these are all proprietary and separate from each other. Standards are not available.
  – While there are UDI schemes there are no requirements for electronic reporting of the UDI.
  – The current UDI schemes are not secure and can be used by rogue devices.
  – While standards which support seamless interoperability are available, adoption is very sparse leading to integration time and cost. Adoption needs to be encouraged.
  – There are no interoperability standards for technical error logs.
  – There are no interoperability standards for device user logs.
  – Mobile health apps currently exist in a ‘buyer be aware’ environment.
  – Special requirements for Virtual Clinical Trials need to be accommodated.
Some of the Relevant Standards…#1

- **Device Interoperability relevant Standards including:**
  - IEEE 11073 (Patient connected devices)
  - IHE DEV Profiles, HL7 v2
  - IEEE P2933 (Clinical IoT and TIPPSS)
  - DICOM (Imaging devices)
  - AAMI 2700-1 (Integrated Clinical Environment Architecture)

- **Security relevant Standards including:**
  - NIST Guidance and NcCOE Use Cases
  - ISO 80001-2-2, ISO 80001-2-8
  - UL 2900-1, UL 2900-2-1
Some of the Relevant Standards…#2

• Mobile Health relevant Standards including:
  • IEEE P1752 (Open Mobile Health)
  • HL7 FHIR (Device Gateways, Cloud architectures)
  • HL7 CMHAFF (Mobile Health App Functional Framework)
  • HL7 UMHAI (Unique Mobile Health App Identifier)
  • ISO TS 82304-2 (Quality Criteria for Health and Wellness Apps)
  • ISO/TC215 WG11 - Personalized Digital Health
Acceleration via Preparedness

♦ Acceleration via preparedness
  – Recommendation for minimal set of standards to ease implementation
  – Regulatory requirements can be pre-established for emergency situations
    • Returning to ‘normal’ can be an issue
  – Manufacturer preparedness through compliance with established standards
    • Conformity assessment - Certified solutions
  – Patient preparedness
    • Solutions that work for people with low digital literacy
  – Healthcare provider preparedness
    • Remote connected care
  – Public health agency preparedness
From Gaps/Needs to **Recommendations**

∗ Some example recommendations:

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Gap/Need</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devices are always at the latest software release and patch levels with the intention of improving their safety and security.</td>
<td>In some cases, vendors support remote SW updates but it is all done via proprietary protocols and approaches.</td>
<td>Standards are required that support the post-release phase of the device life cycle. One aspect of these standards should specify an industry wide approach to safe and secure remote software and firmware updates</td>
</tr>
<tr>
<td>Elimination of inter- and intra-system dependencies that prevent SW/FW updates or break integration when updated.</td>
<td>Deploying SW and FW updates are complicated by the fact that incompatibilities may occur between different devices running incompatible interoperability protocols. This can result in patient safety issues.</td>
<td>An industry-wide standards based approach needs to be developed to identify SW and FW release levels and to manage updates so that they do not disrupt operations or impact patient safety.</td>
</tr>
<tr>
<td>Track device usage, status for recall or infection control purposes.</td>
<td>While there are UDI schemes there are no requirements for electronic reporting of the UDI and it is not very secure.</td>
<td>Each device must be uniquely identified. UDI is a good start but is not very secure. IHE should consider a project to assess the use cases, requirements and potential technical solutions for device tracking.</td>
</tr>
</tbody>
</table>
From Gaps/Needs to Recommendations

♦ Additional example recommendations:
  • Standards should be developed and adopted for:
    – Secure reporting of Device Identity
      » Electronic UDI
      » Software Bill of Materials (SBOM)
      » Firmware Bill of Materials (FBOM)
    – Secure interoperable software and firmware updates
    – Remote management of health devices
  • Governments need to encourage adoption of open standards-based interoperable solutions
    – FDA is engaged, but cannot mandate specific solutions
    – EU MDR has some specific language concerning interoperability
What’s Next

♦ IHE/HL7 Process
  – IHE Review v1
  – HL7 Review v1

♦ ISO/TC215 Process
  – Engage ISO/TC 215 Experts
  – Draft TR v2
  – ISO/TC 215 Review

♦ Balloting Process
  – HL7 / IHE / ISO Ballot
  – HL7 / IHE / ISO Publication
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  Family medicine physician – rural location
  Internal medicine physician – suburban location
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  FDA – CBER (via written questionnaire)

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Accelerating Standards Development for Remote Connected Care and Mobile Health

Thank you for attending our session
Thank You for Attending the AAMI eXchange