

Accelerating Remote Connected Care and Mobile Health Solutions

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SPEAKERS



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Conflict of Interest

Konstantinos Makrodimitris, MSc, PhD

Has no real or apparent conflicts of interest to report.

Gora Datta, FHL7, VS, MS, BE

Has no real or apparent conflicts of interest to report.

Agenda

- Learning Objectives
- The Global Health Informatics Standards Community
- The Pandemic – Accelerating RCC-MH Adoption
- Scope of the Technical Report
- Gap Analysis
- Recommendations
- Roadmap
- Leaders and Participants

Learning Objectives

- Choose appropriate informatics interoperability standards when developing remote connected care & mobile health solutions
- Judge which safety, effectiveness & security (SES) standards should be leveraged to balance solution options with risk-based public good assessments
- Describe how application of open interoperability standards can accelerate deployments especially in crisis situations where resources and time are highly constrained

When the going gets tough... The Community gets going!

- STANDARDS COMMUNITY COLLABORATION
 - Experts from ISO/TC215, HL7, IEEE, IHE came together in April-May 2020
 - Group meets once a week...for the past 16 months and still continuing
 - Focusing on: “RCC-MH: Remote Connected Care & Mobile Health Solutions”



Making
Healthcare
Interoperable

- FAST FORWARD to JUNE 4, 2021
 - [G7 Health Ministers' Communique*](#)
 - #34...the ability for digital healthcare systems to work together seamlessly using common and open **standards is critical to the safe, effective and efficient** use of technology in health and care.
 - #35...We support the **development of and the building** upon existing open **health data standards**
 - #37: ...facilitating and promoting the use of open standards for international health data to encourage the **widest possible adoption of standards** and greater interoperability.

Reacting to the Pandemic via Standards

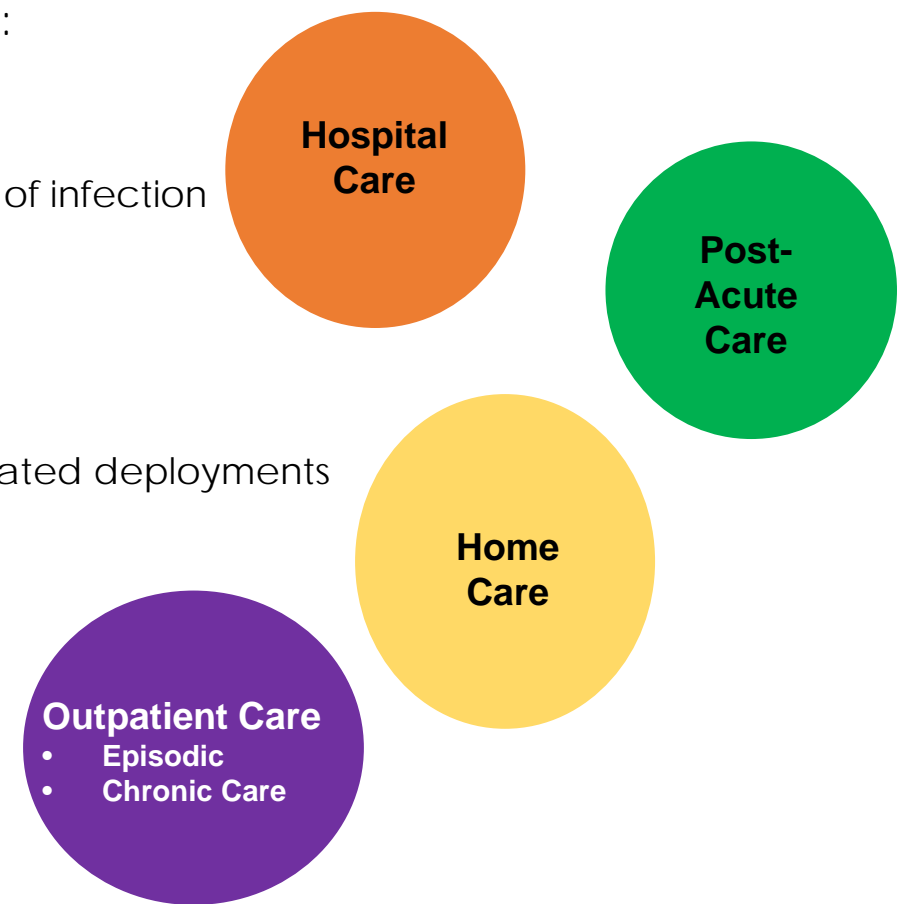
- The world was not ready to deploy Remote Connected Care and Mobile Health Solutions. As a result, we received support to investigate and publish a Technical Report (TR) as an ISO TC215 project(PWI) in June 2020 on:

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

- Our objective is to assesses 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 mitigating 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 a joint HL7/IHE Gemini project. It will then be advanced to ISO/TC 215 WG2 (where it has already been accepted as a PWI, 2020) for additional international participation, review and subsequent publication

The Pandemic - Accelerating RCC-MH Adoption

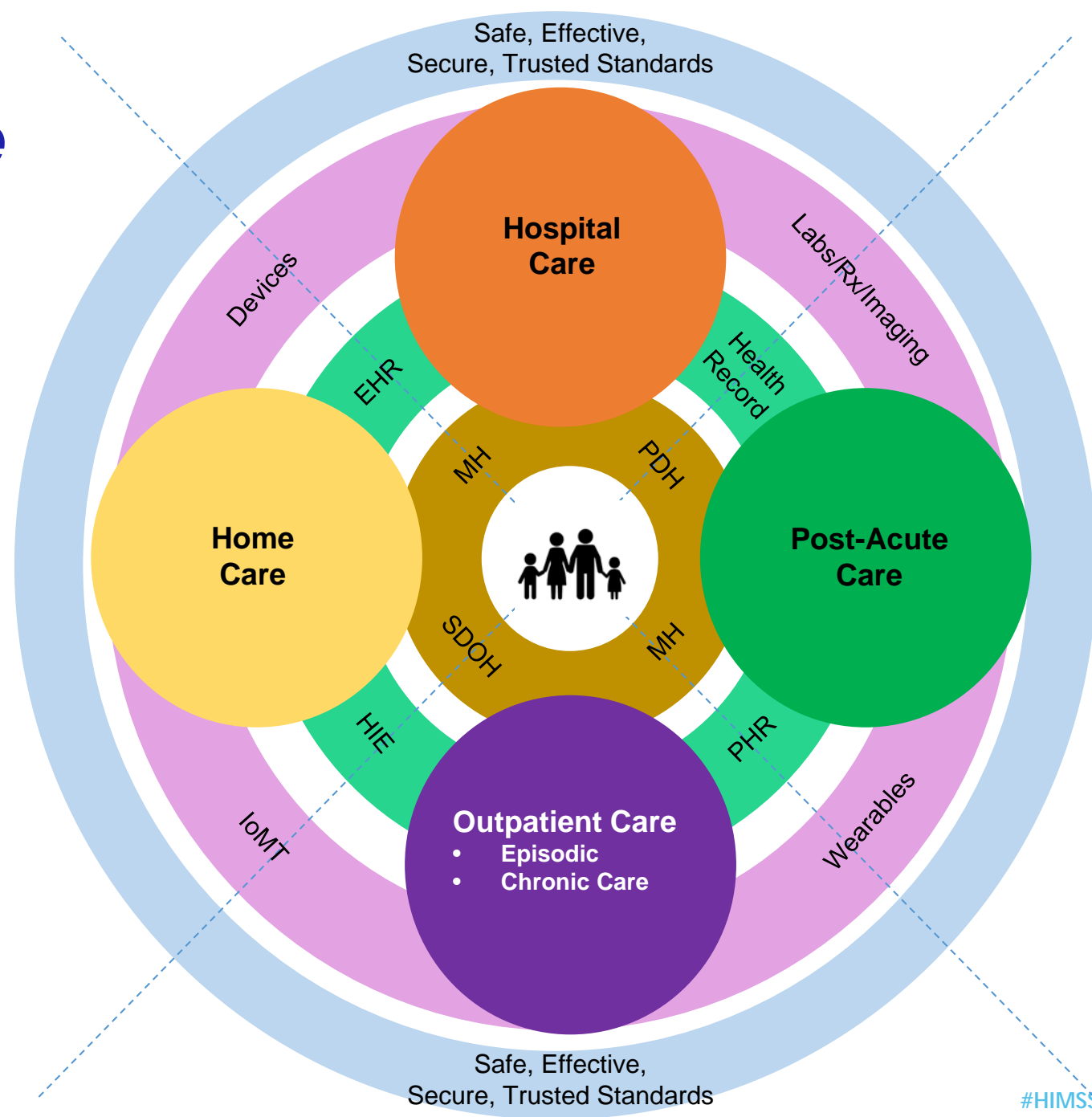
- The pandemic has been a catalyst for accelerating existing shifts in patient care, and the need to address these challenges in a safe, effective and secure manner:
 - **Hospital Care:**
 - Adoption of new device technology “overnight”
 - Remote access and control of devices to reduce patient contact and risk of infection
 - **Post-Acute Care (PAC)**
 - SNF/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
 - **Clinical trials for device innovation and changes**
 - Virtual settings (home)
 - Safety of devices/subjects/clinicians



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
SDOH = Social Determinants of Health

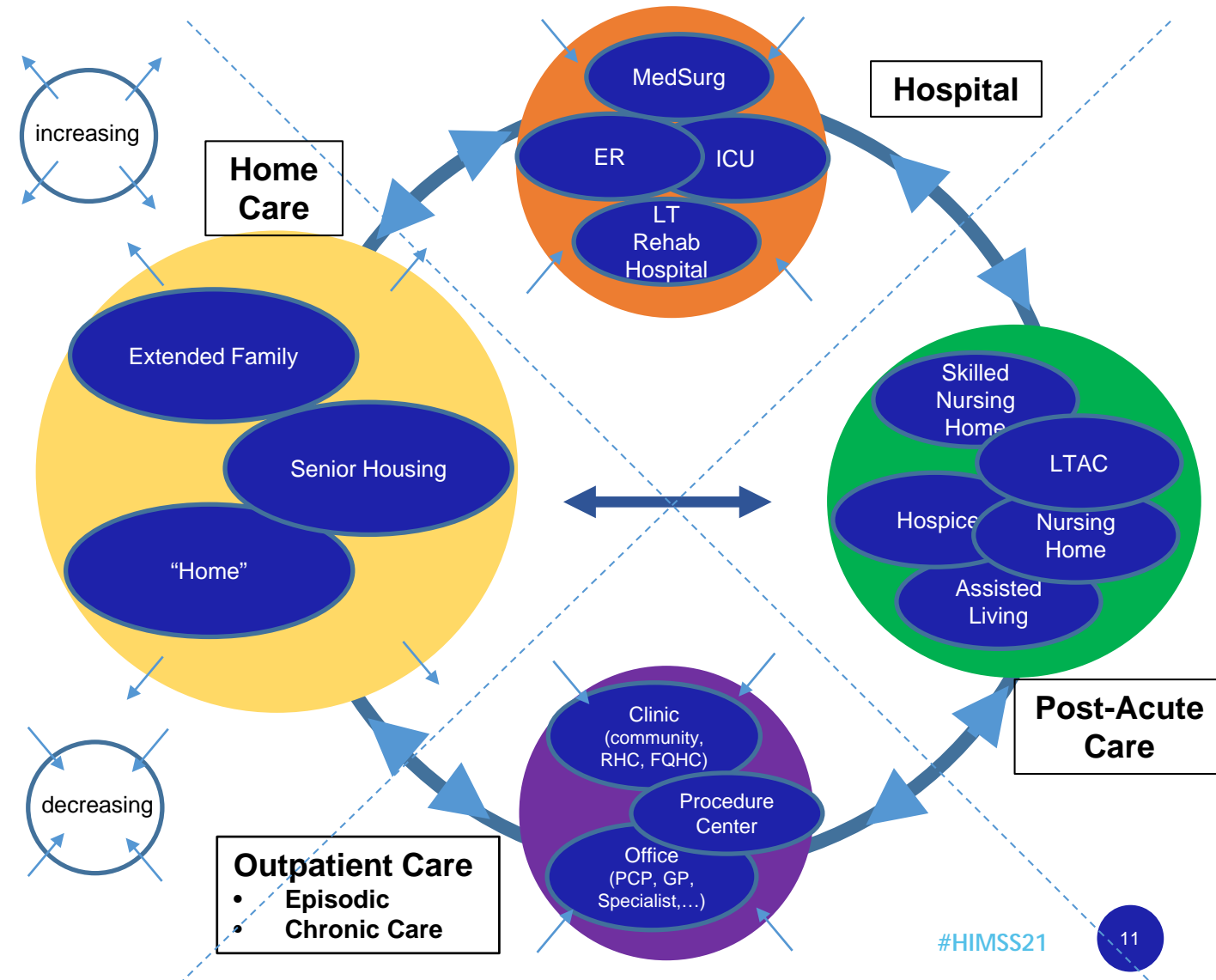


Key Concepts

- Safety
- Effectiveness
- Security
- Remote Connected Care
- Mobile Health
- Interoperability

Key Areas to be Addressed

- Care Locations
- Gap Analysis
- Socio-Technical Challenges
- Safety, Effectiveness and Security
- Architectural Perspectives
- Standards Landscape
- Regulatory Landscape
- Legal Landscape
- Patient Impact




A Team of Experts in Interoperability Standards

- Focus on Safe, Effective and Secure Interoperability:
 - Confluence of HL7, IHE, IEEE, and ISO SDOs
 - Confluence of government, industry, academia, national, international
 - Confluence of key stakeholders: clinicians, rural practitioners, hospital based practitioners
- Interoperability relevant Standards including:
 - IEEE 11073 (Patient connected devices)
 - IHE DEV Profiles, HL7 v2 and HL7 FHIR (Device Gateways, MH)
 - IEEE P2933 (Clinical IoT) and P1752 (Open MH)
 - 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

Gap Analysis

“ Addressing the immediate and future needs and gaps exposed by the Pandemic focusing on: in-patient, outpatient, post-acute-care and patient home care scenarios”

- Example Gap Analysis

Objective	Current State	Desired State	Gap	Recommendation
1.Minimize contact with infectious patients for device reading and adjustment.	Caregivers must enter the patient room to obtain readings and adjust settings on devices. This usually requires a change of PPE for each instance.	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.	Devices that can be monitored and adjusted remotely.	In process 

Gap Analysis

- Example Gaps (there are over 20) include:
 - Many vendors support remote SW update but it is all done via proprietary protocols and approaches. Ideally an industry-wide standards-based interoperable approach can be developed and adopted.
 - Currently all devices require an integration project since very few support open interoperability standards.
 - Although the UDI is supported by most contemporary communication protocols, there are no enforceable requirements for electronic communication and reporting of the UDI by devices, apps and/or applications.
 - Various available standards such as the 11073 series, IHE profiles, etc. need to be reviewed from a provisioning and DevOps 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 capabilities. However these are all proprietary and separate from each other. Standards are not available. Ideally an industry-wide standards-based interoperable approach can be developed and adopted.
 - An industry-wide standards-based interoperable approach to acquire and format device technical error and user logs.

Recommendation – Unified Data Nomenclature is Essential!

- Unified semantic representation of measurements and other observations is essential for medical device and system interoperability
- IEEE 11073-10101 Medical Device Nomenclature
 - Acute care Point-of-Care (ICU, CCU, OR, ER, implanted cardiac devices, hemodialysis, ...)
 - Telemedicine and personal health IEEE Personal Health Devices (PHD) and specializations
- LOINC
 - Laboratory and other observation identifiers (not already covered by IEEE 11073)
- SNOMED
 - Additional enumerated value sets (not already covered by IEEE 11073 or LOINC)
- Nomenclature is available at no cost on repositories such as the NIST RTMMS, with device and application specific co-constraints and data (containment) models.
- Testable using openly available tools such as the NIST Test Tools, ideally at public test venues such as IHE Connectathons with multiple test partners, ultimately leading to full device and system interoperability certification.

Recommendation – Addressing the Cybersecurity Aspects of Safety

1. Protect the Device	
Manufacturer	HDO
<ul style="list-style-type: none"> • Hardened design • HIDS/HIPS (whitelisting) • Key/Certificate-based: <ul style="list-style-type: none"> • Encryption • Code signing • Secure boot • Hardware certificates 	<ul style="list-style-type: none"> • Secure networking • Integration and deployment best practices • Cyber-Hygiene: <ul style="list-style-type: none"> • Secure handling • Media use (esp. USB)

3. Manage Devices	
Manufacturer	HDO
<ul style="list-style-type: none"> • Secure lifecycle mgmt. • V&V incl. security • Vulnerability disclosure • Security documentation (e.g., SBoM) • Supply chain management 	<ul style="list-style-type: none"> • Procurement & contracting • Asset management • Dependency mgmt. • Risk Management and Mitigation

2. Protect the Ecosystem	
Manufacturer	HDO
<ul style="list-style-type: none"> • Secure remote access • Strong password / 2FA • Security best practices documentation • Enablement & Training 	<ul style="list-style-type: none"> • Network architecture • Anomaly detection • Event monitoring • Firewalls / Gateways • Enablement & Training

4. Respond to Incidents	
Manufacturer	HDO
<ul style="list-style-type: none"> • Threat & Vulnerability monitoring and management • Incident detection • Regulatory reporting 	<ul style="list-style-type: none"> • Detect, Respond, Recover • Impact Analysis, Forensics • Communication & Decision making • Reporting as needed

Additional Recommendations...

- 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
- The work on recommendations continues...

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 (Physical/Occupational/Respiratory Therapy)
- Visiting Nursing
- PCA (Patient Care Assistant)
- DME: Durable Medical Equipment logistics

Emerging Areas



- Mobile Health Apps, Wellness Apps, SaMD, SiMD
- “Visiting” Physician – remote consult
- AI, ML: Machine Learning, Artificial Intelligence
- Digital Twin: Virtual/Augmented/Mixed/Xtended Reality
- IoT (Internet of Things), Cloud, 3D-Printing, 5G/6G
- Drone: Delivery/Logistics, Observation
- Blockchain/DLT (Distributed Ledger Technology)

Roadmap/What's Next

- Internal Process
 - Complete Draft TR Sep. 2021
 - Internal Review Oct. 2021
- IHE/HL7 Process
 - IHE Review Nov. 2021
 - HL7 Review Nov. 2021
- ISO/TC215 Process
 - Engage ISO/TC 215 Experts Sep. 2021
 - ISO/TC 215 Review Dec. 2021
- Balloting Process
 - HL7 / IHE / ISO Ballot Feb. 2022
 - HL7 / IHE / ISO Publication Mar. 2022

Recent Activities

- Meetings are held dedicated to specific topics with domain experts:
 - Scientific Computing, Analytics, Real World Evidence
 - Security
 - Provider Discussion
 - Nomenclature Discussion
 - Industry/Digital Medicine/Trials
 - Digital health Policy/Interop/RWE
 - Digital health and Pre-Natal Cardiac Care
 - Coordination with IEEE P1752
 - Discussion with HSCC JCWG on Telemedicine Cybersecurity paper
- We hold regular weekly meetings: Tuesday @ 4pm ET-US
 - See [RCC & MH Confluence Page](#)* for documents and minutes.

* <https://confluence.hl7.org/display/GP/Paper%3A+++SES+Remote+Connected+Care+and+Mobile+Health>

Project Lead/Editors

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| • Axel Wirth | MedCrypt | • Andrea Coravos | Digital Health Pvt Sector |
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| • Christophe Fischer | Roche Medical | • Maria Isabel Tejero | FDA |
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| • Martin Rosner | Phillips | • Greg Garcia | HCCS |
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| • Dana Wolff-Hughes | NCI: National Cancer Institute | | |

**REAL WORLD EVIDENCE (RWE):
Practicing Physicians -
Hospitalists**



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- Bryanna Schwartz Children's National Hospital

OTHER CONTRIBUTORS...

RWE: Practicing Primary
Care Physician



- Provider Discussion:

- | | |
|-------------------------------|--|
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| • Dr. Jessica Basa | Family medicine physician – rural location |
| • Dr. Ratul Chatterjee | Internal medicine physician – suburban location |
| • Dr. Mahadevappa Hunasikatti | FDA – CDRH/FDA, FCCP (via written questionnaire) |
| • Dr. Jonatan Reich | FDA – CBER/FDA, Pediatrics (via written questionnaire) |
| • Dr. Greg Pappas | FDA – CBER/FDA (via written questionnaire) |

- Digital Medicine Discussion:

- | | |
|-----------------------|---|
| • Pierre D’Haese | |
| • Andrea Ruth Coravos | Elektra Labs - Co-Founder/CEO |
| • Jennifer Goldsack | Digital Medicine (DiME) Society – Executive Dir |

- Digital Health Discussion:

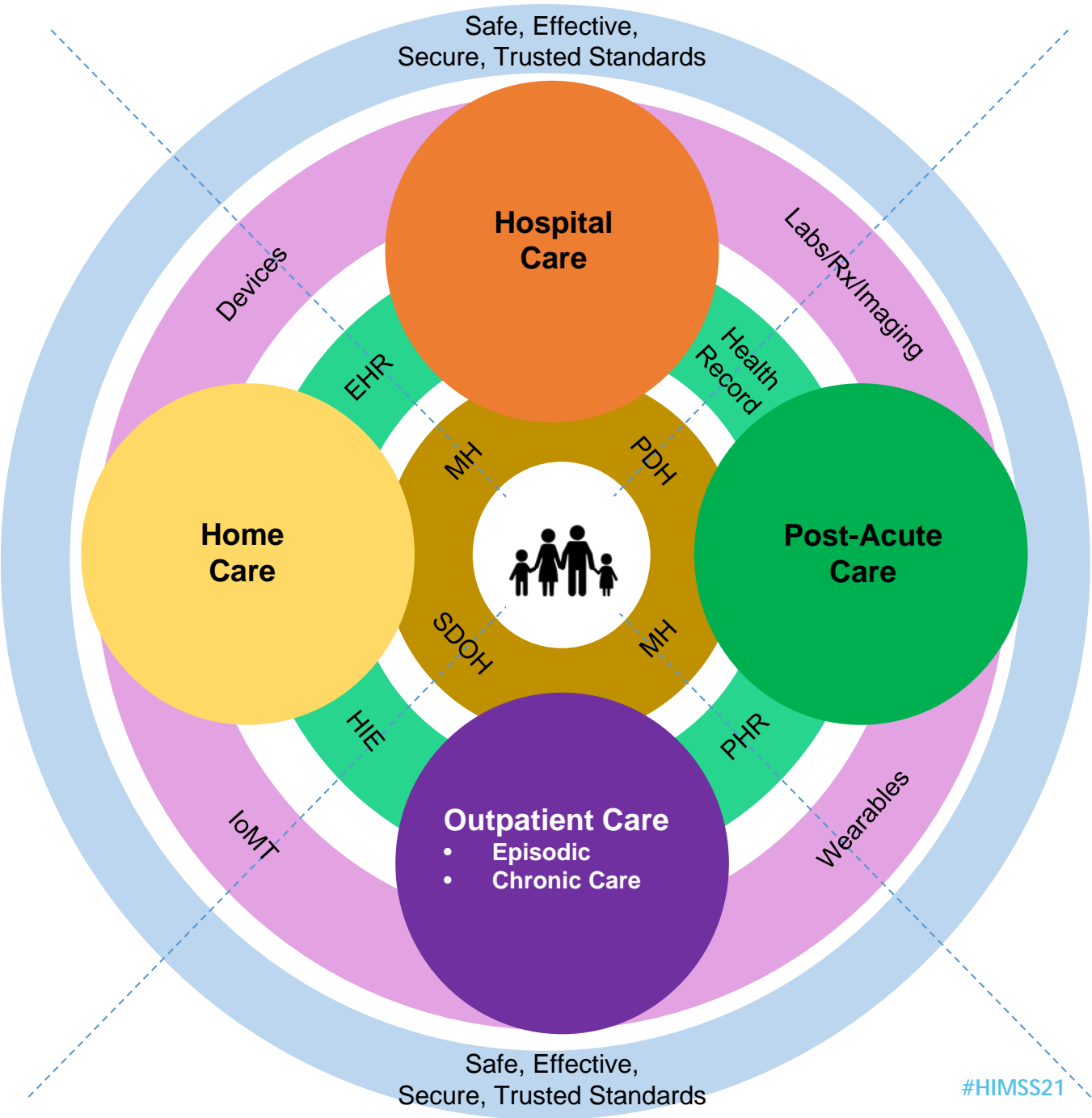
- Members of the FDA Digital Health Center of Excellence, FDA (Vinay Pai, PhD)

- European Perspective:

- | | |
|----------------------|-------------|
| • Catherine Chronaki | Greece |
| • Frank Ploeg | Netherlands |

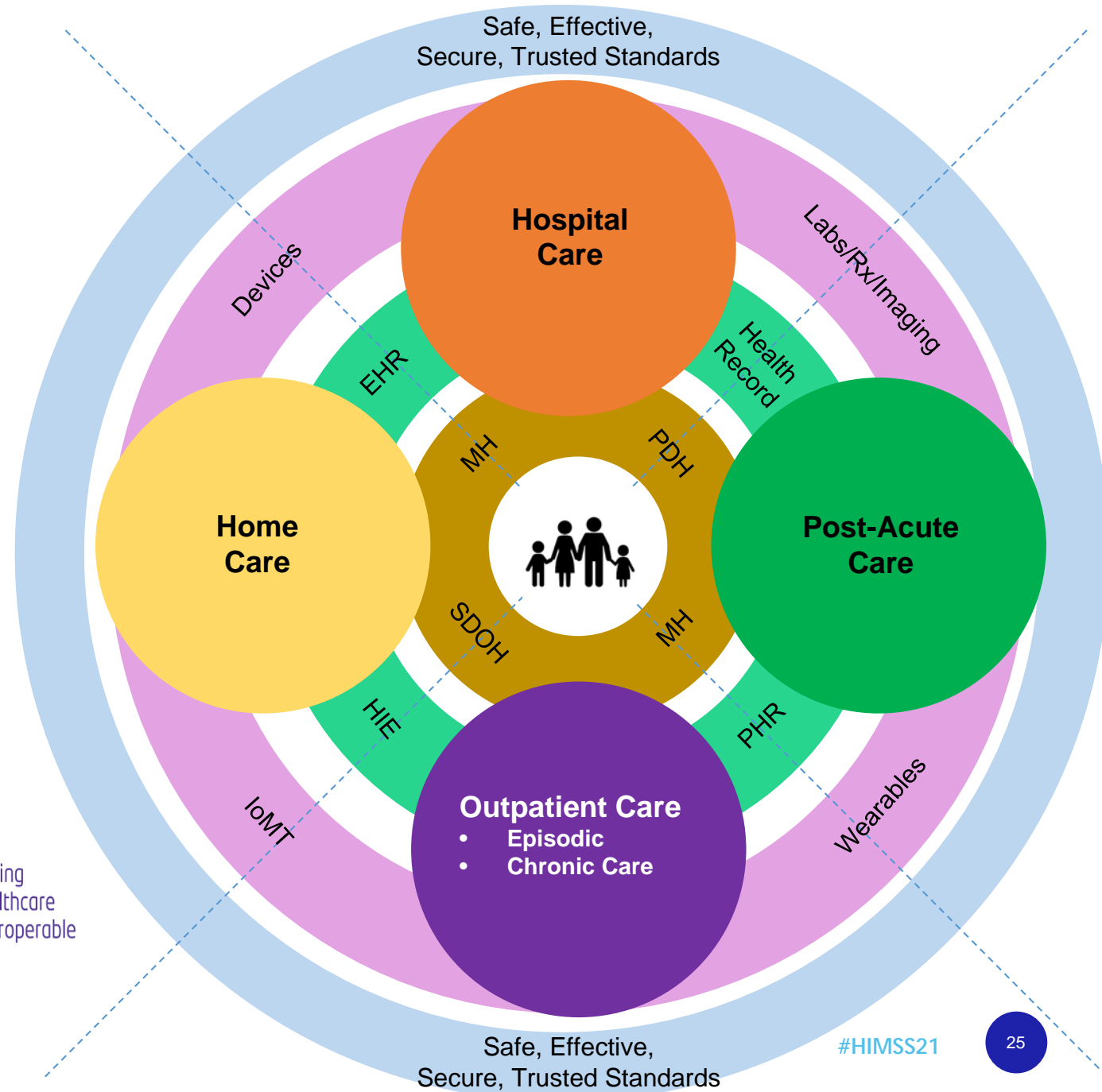
Questions

- RCC-MH: Accelerating Remote Connected Care and Mobile Health solutions



Thank you!

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