



ISO PWI TR5615

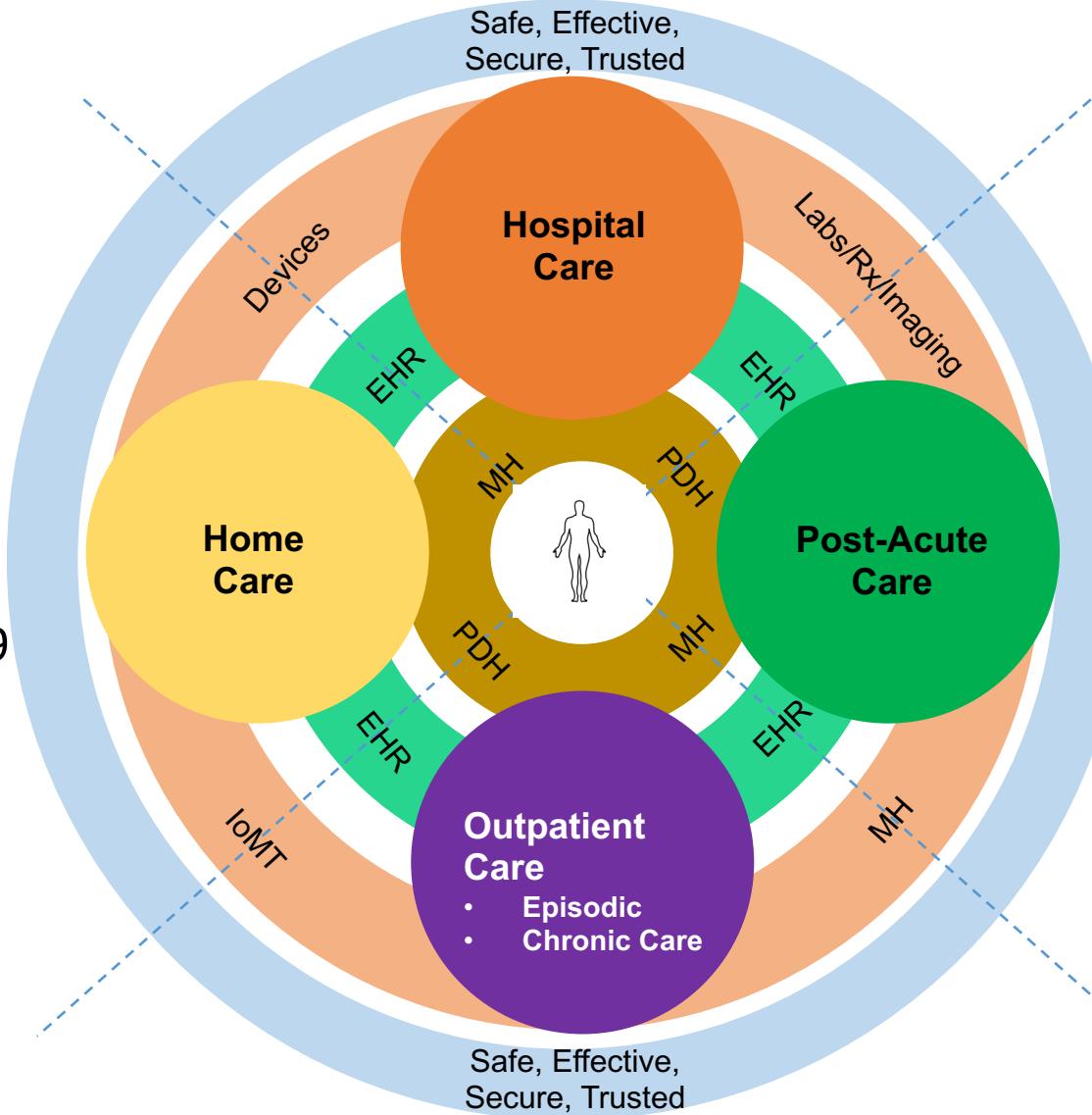
Accelerating Safe, Effective and Secure Remote Connected Care and Mobile Health (RCC-MH) Interoperable Solutions in Pandemics

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

Update – ISO TC 215 WG2 – 7 October 2020

OUTLINE: ISO PWI TR5615

- ❑ Background
- ❑ Recent activities
- ❑ Technical Report structure/TOC
- ❑ RCC-MH Layers of Connectivity
- ❑ RCC-MH Services/Types/Data
- ❑ Pandemic - accelerating RCC trends
- ❑ RCC MH interoperability: gaps & issues evaluation
- ❑ RCC MH Patient Flow and Care Locations Pre-post Covid19
- ❑ RCC MH Potential Technical Approaches
- ❑ Cybersecurity
- ❑ Emerging Interoperability Use Cases...
- ❑ Acknowledgement



BACKGROUND

The Covid-19 pandemic: Accelerating the need for Remote Connected Care (RCC) and Mobile Health (MH) Solutions

- ❖ The current Covid-19 pandemic has created an enormous need to allow patients and clinicians to communicate and report in a more flexible and virtual way.
- ❖ Remote Connected Care allows health providers to monitor/diagnose disease remotely and interact with patients virtually.
- ❖ Telehealth can be facilitated with RCC and MH interoperable solutions
- ❖ RCC MH interoperability solutions can have great effect/benefit in the design, of virtual and safer trials and surveillance/Real World Evidence data for medical product needs

Note:

- This TR is being developed initially under the auspices of the joint HL7/IHE Gemini project. It will then be advanced to WG2 for additional review and input.
- Title was adjusted from Monitoring (PWI TR5615) to Connected Care after group consensus for better coverage of current cases

Recent Activities

- We hold regular weekly meetings: Tuesday @ 3pm EST-US
 - See [RCC & MH Confluence Page](#)* for documents and minutes.
- Some of these meetings are dedicated to specific topics with expert speakers:
 - Scientific Computing, Analytics, Real World Evidence
 - Gregory Pappas FDA
 - Konstantinos Makrodimitris FDA
 - Security:
 - Brian Fitzgerald FDA
 - Axel Wirth MedCrypt
 - Axel Wirth MedCrypt
 - Christophe Fischer Roche Medical
 - Provider Discussion:
 - Dr. Michael Baluyut Family medicine – suburban (video call)
 - Dr. Jessica Basa Family medicine – rural (video call)
 - Dr. Ratul Chatterjee Internal medicine – suburban (video call)
 - Dr. Mahadevappa Hunasikatti FDA – FCCP (written response)
 - Dr. Jonathan Reich FDA – Pediatrics (written response)
 - Dr. Greg Pappas FDA – CBER (written response)
 - Nomenclature Discussion:
 - Paul Schluter Paul Schluter Computing – Editor IEEE 11073 Nomenclature standards
 - IEEE 11073 PHD/POCD experts
 - Industry/Digital Medicine/Trials:
 - Andy Coravos ElectraLabs CEO
 - Jen Goldsack Exec DigiMedicine
 - Pierre D'haese Neurotargeting CEO
 - Digital health Policy/Interop/RWE:
 - Lawrence Callahan FDA
 - Charles Ho FDA
 - Vinay Pai FDA
 - Orlando Lopez NIH
 - Renee Rookwood MITRE (representing ONC)
 - Catherine Chronaki HL7 Europe

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

Technical Report structure: Proposed Table of Contents

- **Executive Overview**
- **Scope & Organization**
 - RCC MH pandemic
 - Levels: hospitals, home, nursing, states, federal, global
 - Contributors
- **Introduction**
 - <.... sections...>
 - RCC – MH definitions, interop levels
 - MH vs. SaMD vs. wearables; AR, VR, AI
 - Stakeholders
 - infrastructure,
 - legacy systems,
- **Safe Effective & Secure**
 - <what do we mean by SES>
 - <standards & framework to be leveraged>
 - Cases/clinical
- **RCC-MH Architectural Perspectives**
 - <types of RCC-MH ... scenarios ...>
 - diagnosis / treatment / monitoring
 - Data types for interop--- aggregated, analytics, patient, waveforms, images
- **Accelerating SES in a Rapid Response to Crisis**
 - Perspectives (clinic, hospital, state, federal , patients, trials)
 - Considerations for pragmatically establishing an understanding of SES over RM/MH architectures
 - Define a possible Minimum Set of Safe, Effective & Secure Medical Device practices/report/standard
- **Expert (multiple) Sessions**
 - Nomenclature, Providers, Digital Health, Industry, Policy
- **Recommendations for Standardization/Adoption/Governance**
 - IHE-HL7? ISO/IEC JWG7? IEEE? DICOM? Etc.
 - Measure/Monitor adoption to generate interoperable harmonized quality structured data
 - Initiate/Establish Governance body/Taskforce pandemics
- **BIBLIOGRAPHY**
- **Definitions / Glossary (annex)**
 - Remote connected care, Mobile Health, Interoperability (devices and interfaces: labs, meds, admin.) continuous/episodic

RCC-MH Services/Data Types: Interoperability spectrum and applications

- Pharmacy
- Radiology
- Laboratory
- Surgery
- Cardiovascular
- Neurology/Mental health
- Infusion
- Wound Care
- Dialysis
- Clinical trials
- Adverse event reports
- PT, OT, RT (Resp Therapy)
- Visiting Nursing
- PCA (Patient Care Assistant)
- DME logistics
 - (wheelchairs, beds, walkers, etc.)
- Mobile Health Apps
- “Visiting” Physician – remote consult
- Drone logistics
- AR, VR, MR, XR

The Pandemic - accelerating RCC trends

- The pandemic has been a catalyst for accelerating already existing shifts in patient care:
 - Hospital Care:
 - Adoption of new device technology “overnight”
 - Remote access and control of devices to reduce patient contact
 - Home Care and Post-Acute Care (PAC):
 - 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 telehealth for acute and chronic care
 - PCP to Home and and PAC patients
 - Specialist to PCP (and patient)
 - Specialist to hospital (and patient)
 - Clinical trials for device innovation and changes
 - Virtual settings (home)
 - Safety of devices/subjects/clinicians

Pandemic driven needs Emerging Interoperability Use Cases...

The pandemic has exposed numerous weaknesses that interoperability can help mitigate

- Hospitals receive donated equipment or equipment from the strategic stockpile – how do they integrate this equipment? Was the equipment secure, not tampered or hacked?
- Hospitals have a need to reduce personnel contact with infectious patients
- Due to capacity and resource issues the “hospital at home” concept is gaining momentum
- Clinical trials are driven in pandemic to be virtual remote and safer (devices, subjects)
- Clinics and Providers are not always aware about the current medical device innovation & available MH apps and technologies
- Data integrity and quality from EHRs, trials and other RWD is important to assess the interoperable solutions in pandemics and accelerate the monitoring/diagnosis of patients.

***** We really appreciate the input of healthcare providers and medical officers from private sector and public health/Questionnaire!**

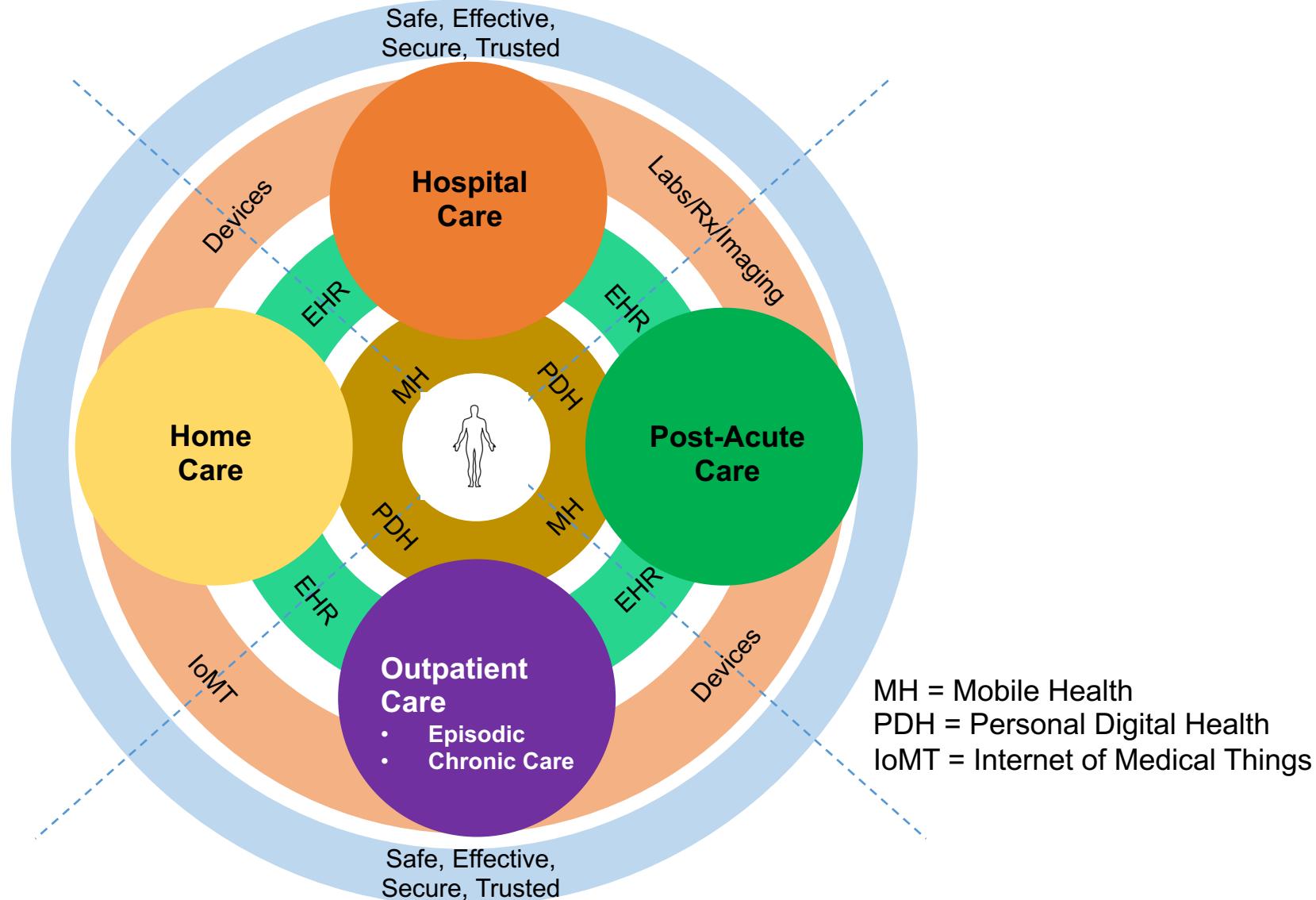
RCC MH interoperability: gaps & issues evaluation

- ❑ Terminology expansion/specialization needs more support and adoption/harmonization is slow (IEEE 11073 terminology groups work diligently under limited resources)
- ❑ Cybersecurity best minimum practices complied for different remote settings eg home
- ❑ Different communication platforms and
- ❑ Legacy old interoperable standards still in place
- ❑ Unstructured data
- ❑ Data integrity and quality lacks for analytics and statistics
- ❑ Adoption of new standards (eg IEEE/ISO 11073 SDC) is not universal (value of standards)
- ❑ Agencies and stakeholders in US and worldwide not in the same page(Governance PPP needed)

*****This evaluation of gaps is part of our goals to layout in the Technical Report as we promised for this ISO project. Will help us to recommend accelerating solutions and start projects asap in 2021**

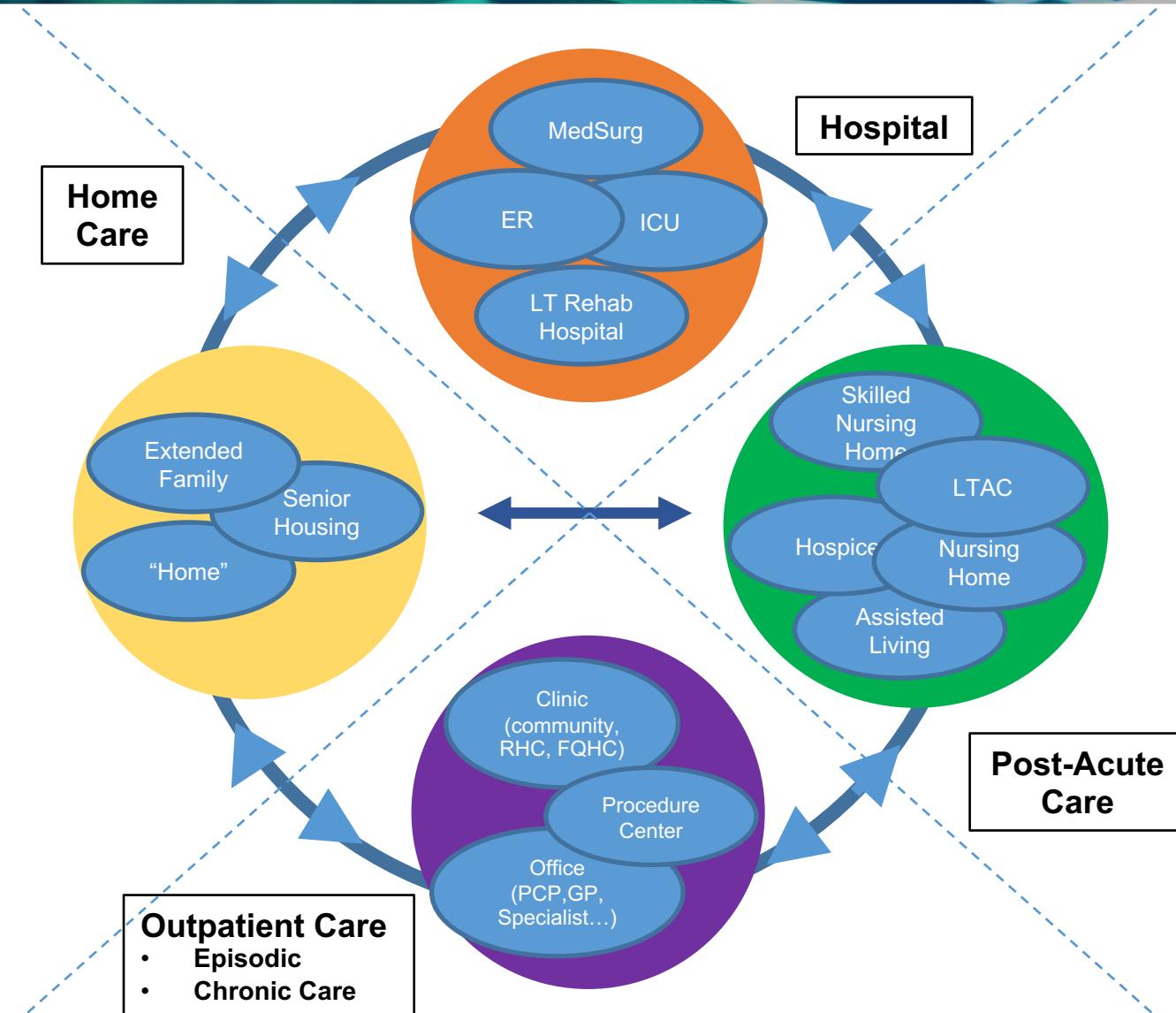
Remote Connected Care and Mobile Health – Layers of Connectivity

- Our scope include 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.



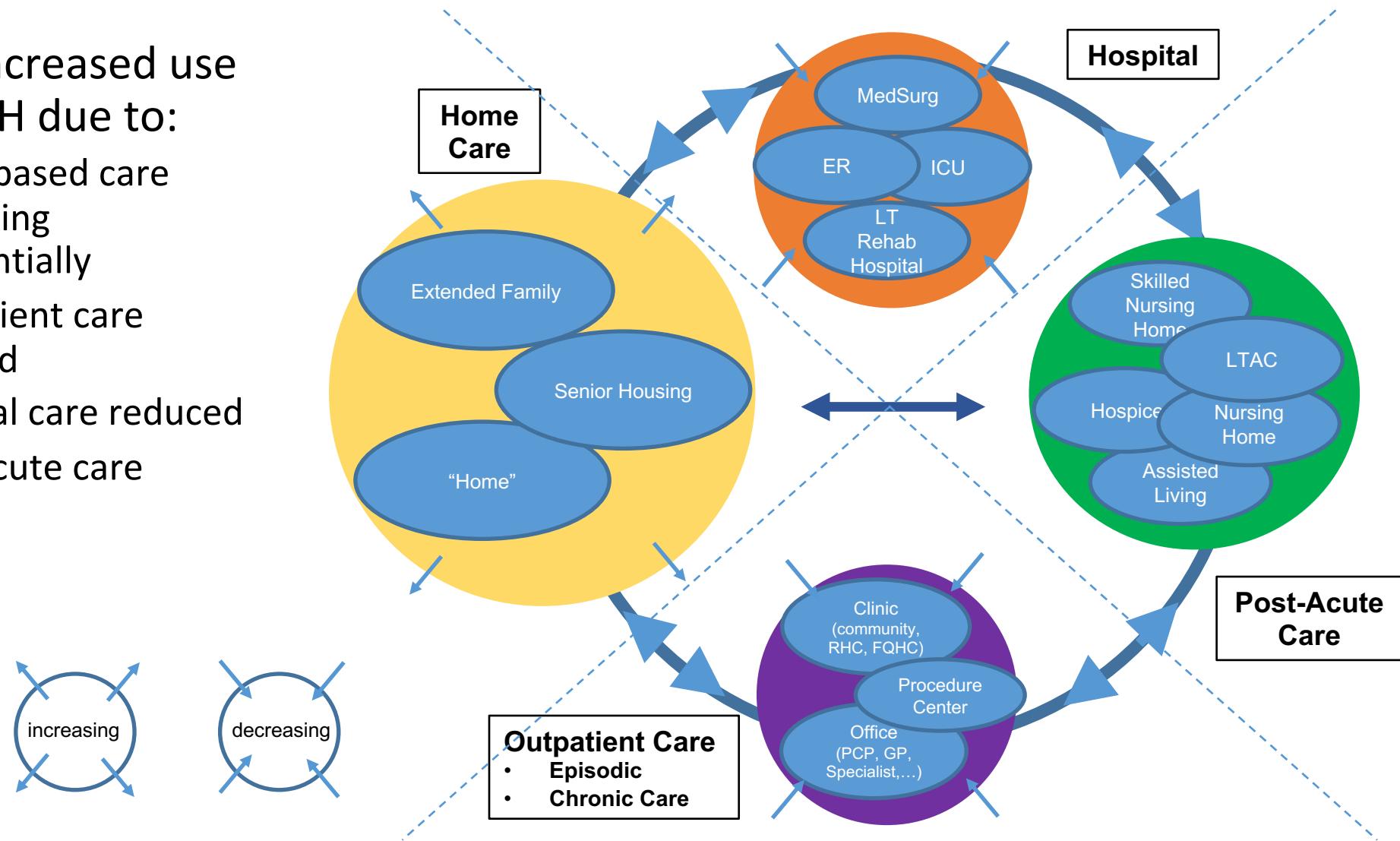
Remote Connected Care and Mobile Health – Patient Flow and Care Locations – Pre-Covid

- These are some of the key patient care locations and flows as experienced during the pre-Covid era.
 - Not to scale



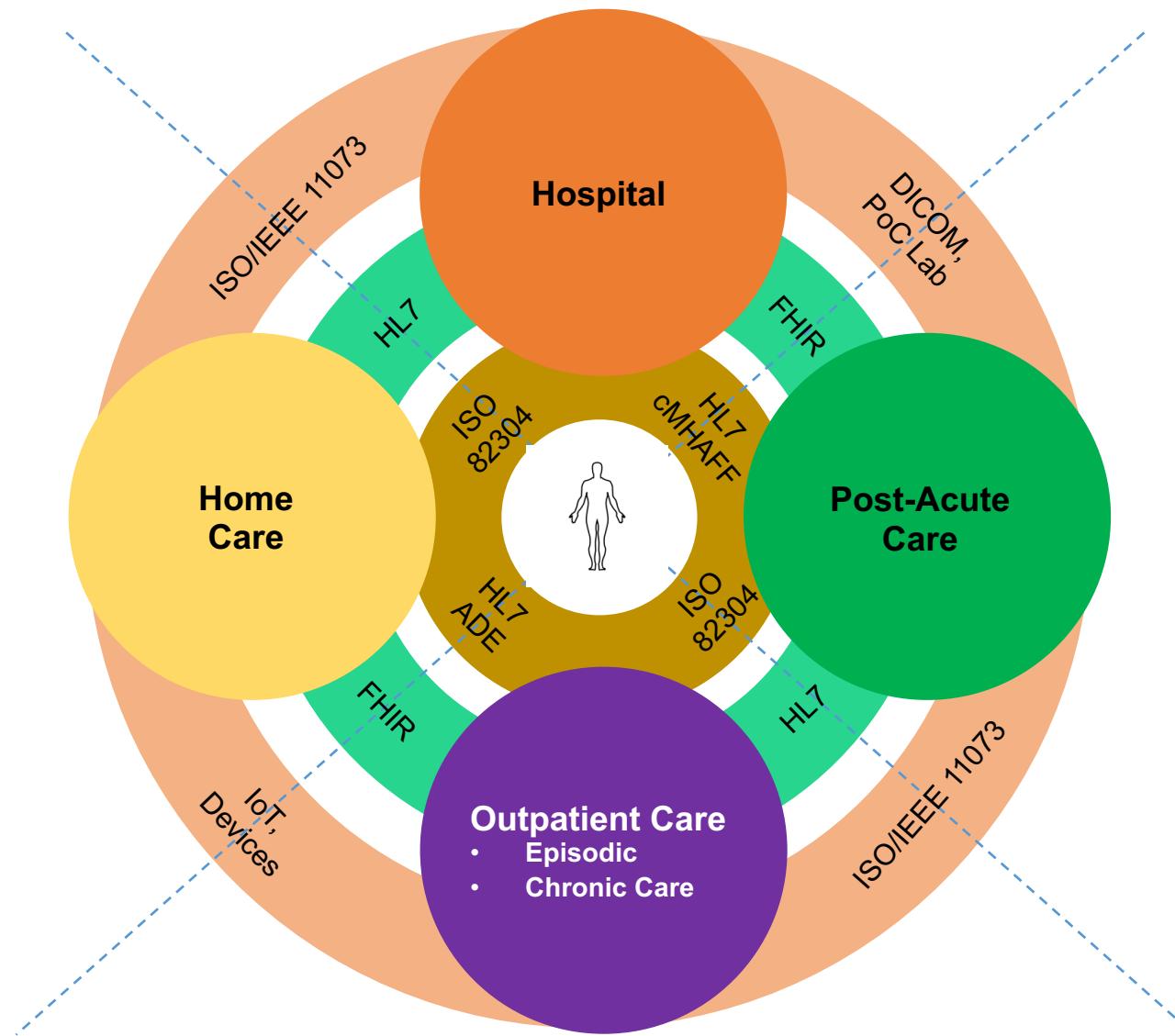
Remote Connected Care and Mobile Health – Patient Flow and Care Locations – Covid & Post Covid

- We see increased use of RCC-MH due to:
 - Home based care increasing substantially
 - Outpatient care reduced
 - Hospital care reduced
 - Post-Acute care steady



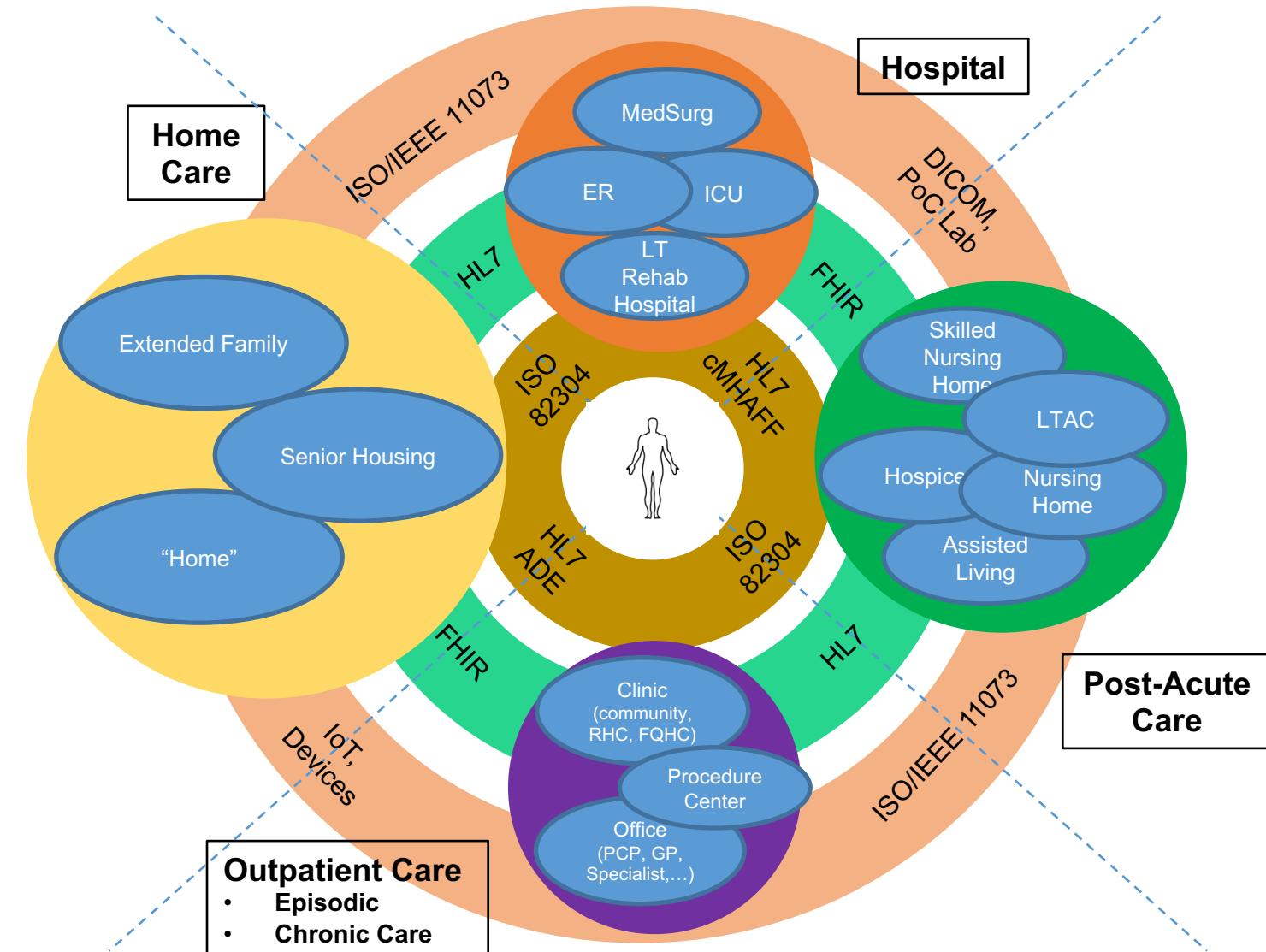
Remote Connected Care and Mobile Health – Potential Technical Approaches

- Potential technical solutions to enable RCC and MH.
 - ISO/IEEE 11073 for IoT and Device connectivity.
 - 11073 PHD for Home and Outpatient Care
 - 11073 SDC for Hospital and Post-Acute Care
 - HL7 v2 and/or HL7 FHIR for device to EHR connectivity
 - MH apps and applications built to conform to HL7 cMHAFF & ISO 82304

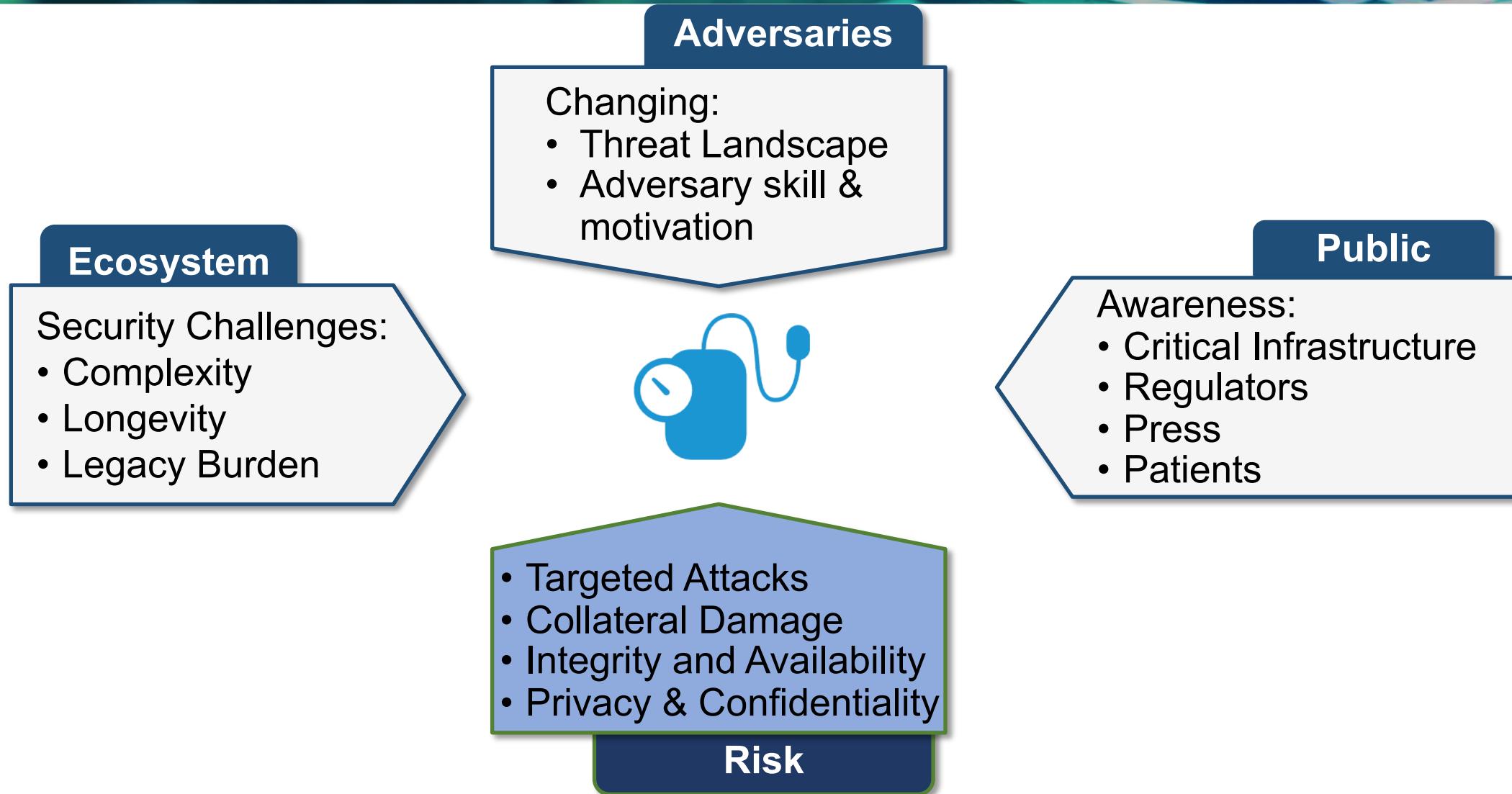


Remote Connected Care and Mobile Health – Potential Technical Approaches

- With additional details...



Medical Devices under (Security) Pressure



Thank You

- Key participants:
 - **Konstantinos Makrodimitris**
 - Gora Datta
 - Todd Cooper
 - Ken Fuchs
 - Contributing participants:
 - Axel Wirth
 - Stefan Schlichting
 - John Rhoads
 - Paul Schluter
 - Gregory Zeller
 - Gregory Pappas
 - John Garguilo
 - Christophe Fournier
 - Michael Kirwan
 - Raymond Krasinski
- FDA
CAL2CAL
Breakthrough Solutions Foundry
Draeger Medical
- MedCrypt
Unity Consulting
Philips Healthcare
Schluter, Inc.
- ADA
FDA
NIST
Fresenius Medical
DSheet
Philips Healthcare

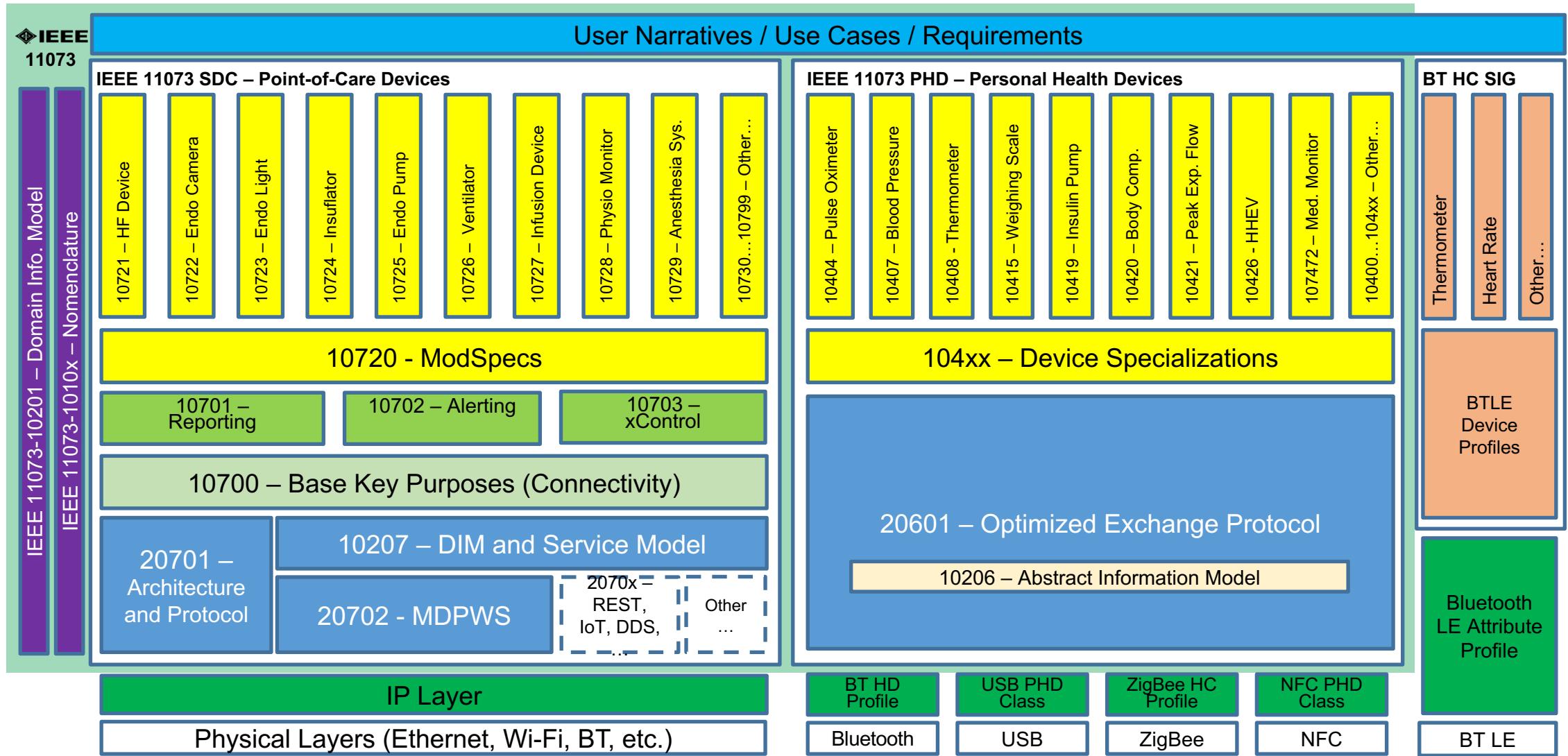


APPENDIX

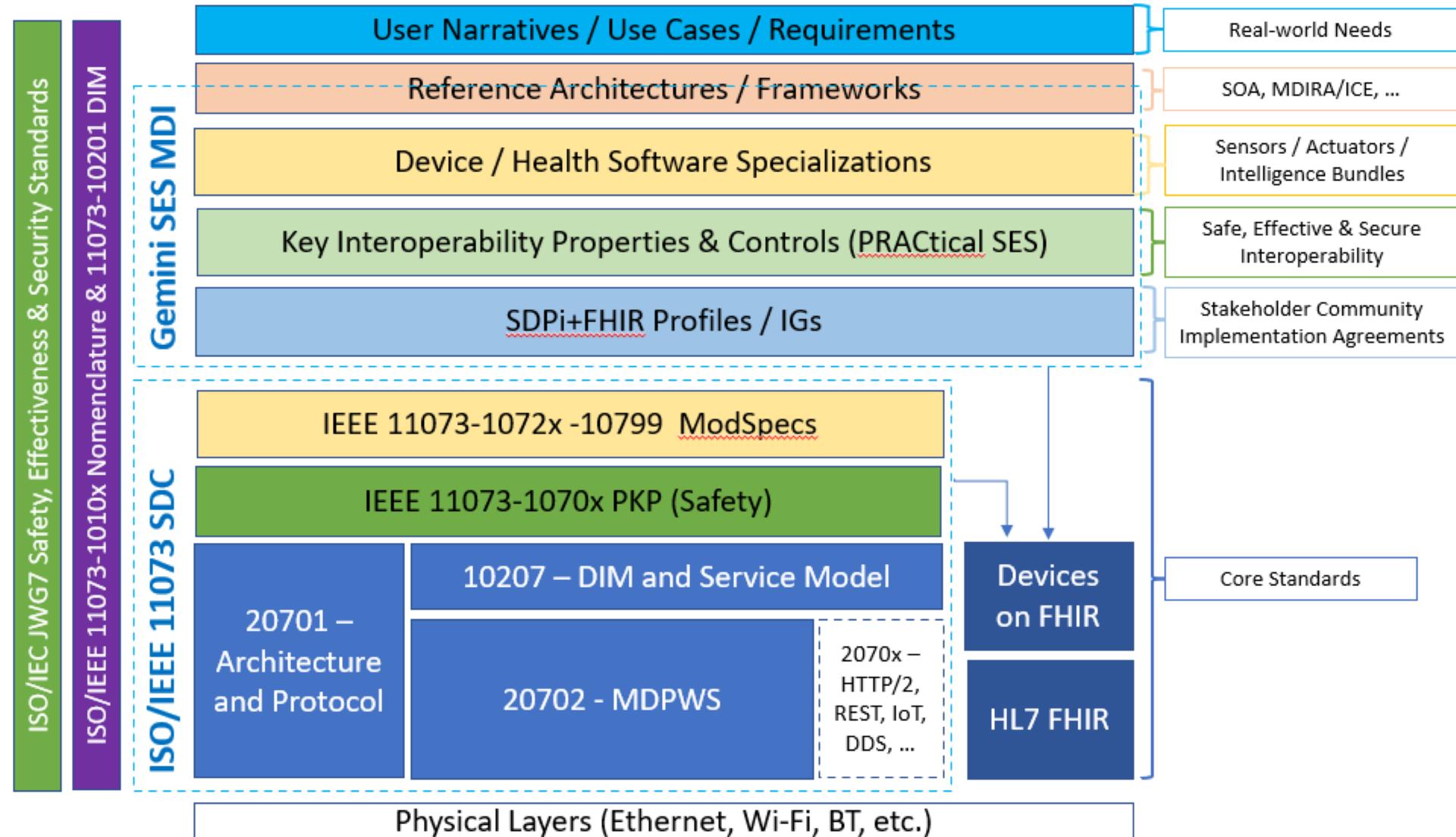
Medical Device Cybersecurity - The 4 Cybersecurity Tenets

1. Protect the Device		3. Manage Devices	
Manufacturer	HDO	Manufacturer	HDO
<ul style="list-style-type: none">• Hardened design• HIDS/HIPS (whitelisting)• Key/Certificate-based:<ul style="list-style-type: none">• Encryption• Signing• Authentication• Updates	<ul style="list-style-type: none">• Secure use and handling• Media use, esp. USB• Integration best practices• Secure networking	<ul style="list-style-type: none">• Secure Development Lifecycle• V&V incl. security• SBoM• Vulnerability disclosure and management• Supply Chain mgmt.	<ul style="list-style-type: none">• Procurement & Contracting• Replacement planning• Asset management• Dependency mgmt.• Risk Management and Mitigation• Security maintenance
2. Protect the Ecosystem		4. Respond to Incidents	
Manufacturer	HDO	Manufacturer	HDO
<ul style="list-style-type: none">• Secure remote access• Strong password / 2FA• Cloud security• Security documentation• Enablement & Training	<ul style="list-style-type: none">• Network architecture• Anomaly detection• Event monitoring• Firewalls / Gateways• Enablement & Training	<ul style="list-style-type: none">• Threat & Vulnerability monitoring, mgmt.• Incident preparedness• Regulatory reporting	<ul style="list-style-type: none">• Detect, Respond, Recover• Impact Analysis, Forensics• Decision making / triage• Communication• Report as needed

11073 PoCD, PHD and BT Architectures



RCC-MH Architecture in Context



Pandemic driven needs Emerging Interoperability Use Cases...

The pandemic has exposed numerous weaknesses that interoperability can help mitigate

- Hospitals receive donated equipment or equipment from the strategic stockpile – how do they integrate this equipment?
 - Normal cycles for integration of new equipment can take months including negotiations with your integration provider
 - Standards compliant SES interoperable (certified) devices would allow “immediate” integration
 - Need to make sure the device is up to date especially from a security standpoint
- Hospitals have a need to reduce personnel contact with infectious patients
 - This is primarily due to a desire to reduce the possibility of infections as well as to reduce the need to put on and take off PPE which takes considerable time.
 - Leads to a need for remote control of in-room devices, especially therapy devices
 - SES Interoperable devices that support remote control would support this requirement
- Due to capacity and resource issues the “hospital at home” concept is gaining momentum
 - Hospitals need to build their own solutions around single vendor offerings
 - Required devices may not be available
 - FDA is interested in reducing barriers to entry for devices to qualify for remote home monitoring.
 - IT integration is challenging due to proprietary interfaces
 - Standards compliant SES interoperable devices and interoperable IT interfaces would support accelerated implementation of RCC
- Clinical trials are driven in pandemic to be virtual remote and safer (devices, subjects)
- Clinics and Providers are not always aware about the current medical device innovation MHapps available
- Data integrity and quality from EHRs, trials and other RWD is important to assess the interoperable solutions in pandemics and accelerate the monitoring and diagnosis of high risk patients.

*** We really appreciate the input of healthcare providers and medical officers from private sector and public health/Questionairie!

Use Cases to capture these RCC situations

- Remote monitoring and integration of new device (from strategic reserve) in hospital ICU
 - Ventilator
- Control cockpit outside isolation room
 - Monitor and control devices inside room
- Remote monitoring of patient at home using mix of devices and manufacturers
- Remote PCP visit
 - Review of vitals and glucose measurement trends
- Remote PCP and Specialist
 - Specialist consulting real-time with PCP and Patient (remote or in-person)

Some References to Telehealth Articles

- Rapid Telehealth-Centered Response to COVID-19 Outbreaks in Postacute and Long-Term Care Facilities
 - Harris, D. et al
 - <https://www.liebertpub.com/doi/10.1089/tmj.2020.0236>
- COVID-19 Collaborative Model for an Academic Hospital and Long-Term Care Facilities
 - Archbald-Pannone, L.R. et al
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- For Health Consumers, Trust, Privacy & Good Experience Must be Baked into Digital Health Care
 - <https://www.healthpopuli.com/2020/08/24/for-health-consumers-trust-privacy-good-experience-must-be-baked-into-digital-health-care/>
- Will the Digital Health Surge During Covid-19 Last?
 - https://www.hcinnovationgroup.com/population-health-management/consumerism/news/21151941/will-the-digital-health-surge-during-covid19-last?utm_source=HI+Daily+NL&utm_medium=email&utm_campaign=CPS200827068&o_eid=9875H9243956D8S&rdx.ident%5Bpull%5D=omedab%7C9875H9243956D8S&oly_enc_id=9875H9243956D8S