ISO PWI TR5615

Accelerating Safe, Effective and Secure Remote Connected Care and Mobile Health Interoperable Solutions

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

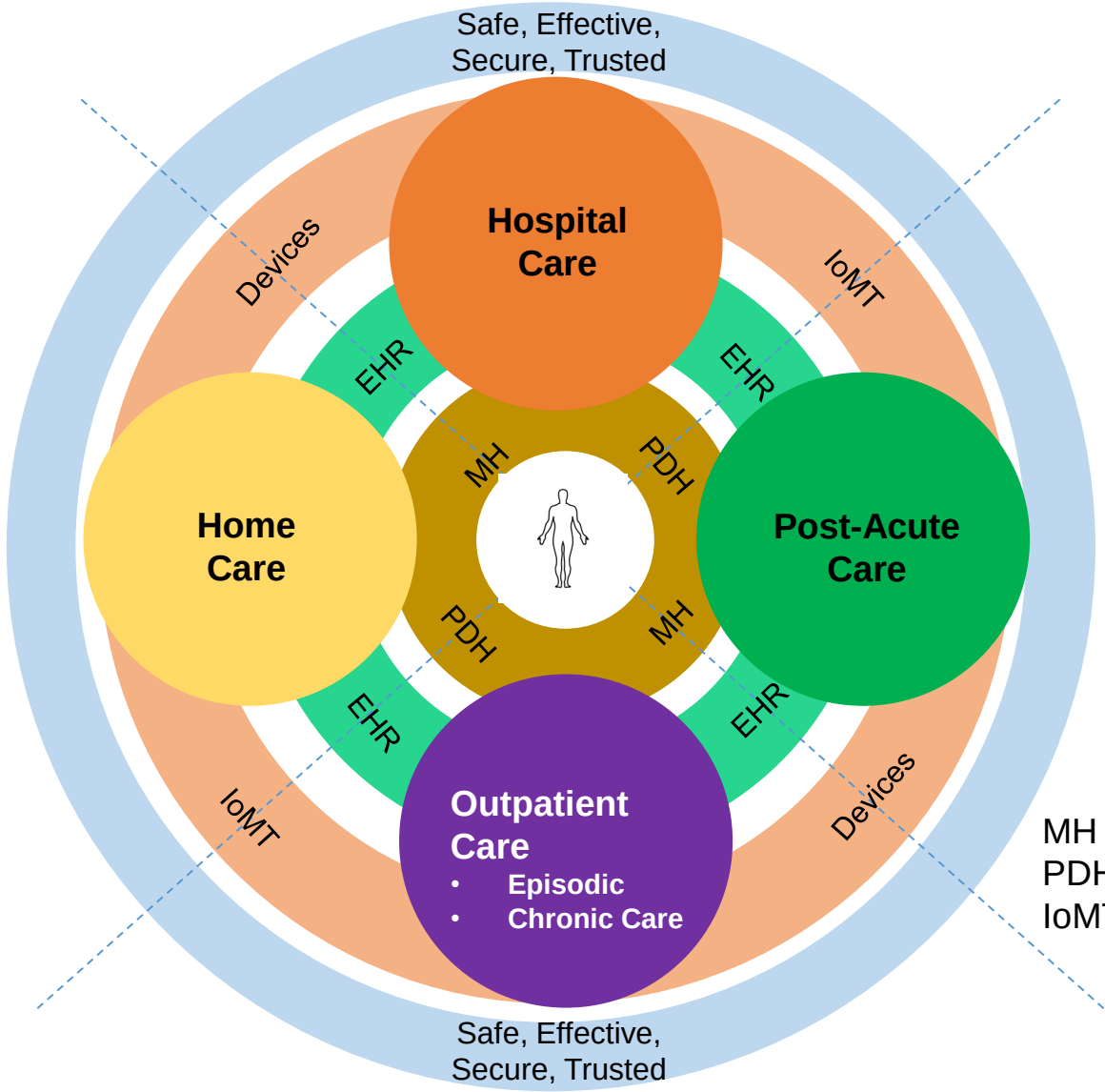
Update – ISO TC 215 WG2 – 7 October 2020

The Covid-19 pandemic: Accelerating 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 disease and symptom progression remotely and interact with patients virtually.
- Telehealth can be facilitated with RCC and MH interoperable solutions

Remote Connected Care and Mobile Health – Layers of Connectivity

- Our scope include the communication of:
  - Device data – including sensors, patient connected devices, lab and imaging devices
  - EHR and Health IT applications – as regards storage and availability of device data
  - Mobile Health apps – for both personal health and clinical use cases.



MH = Mobile Health
PDH = Personal Digital Health
IoMT = Internet of Medical Things

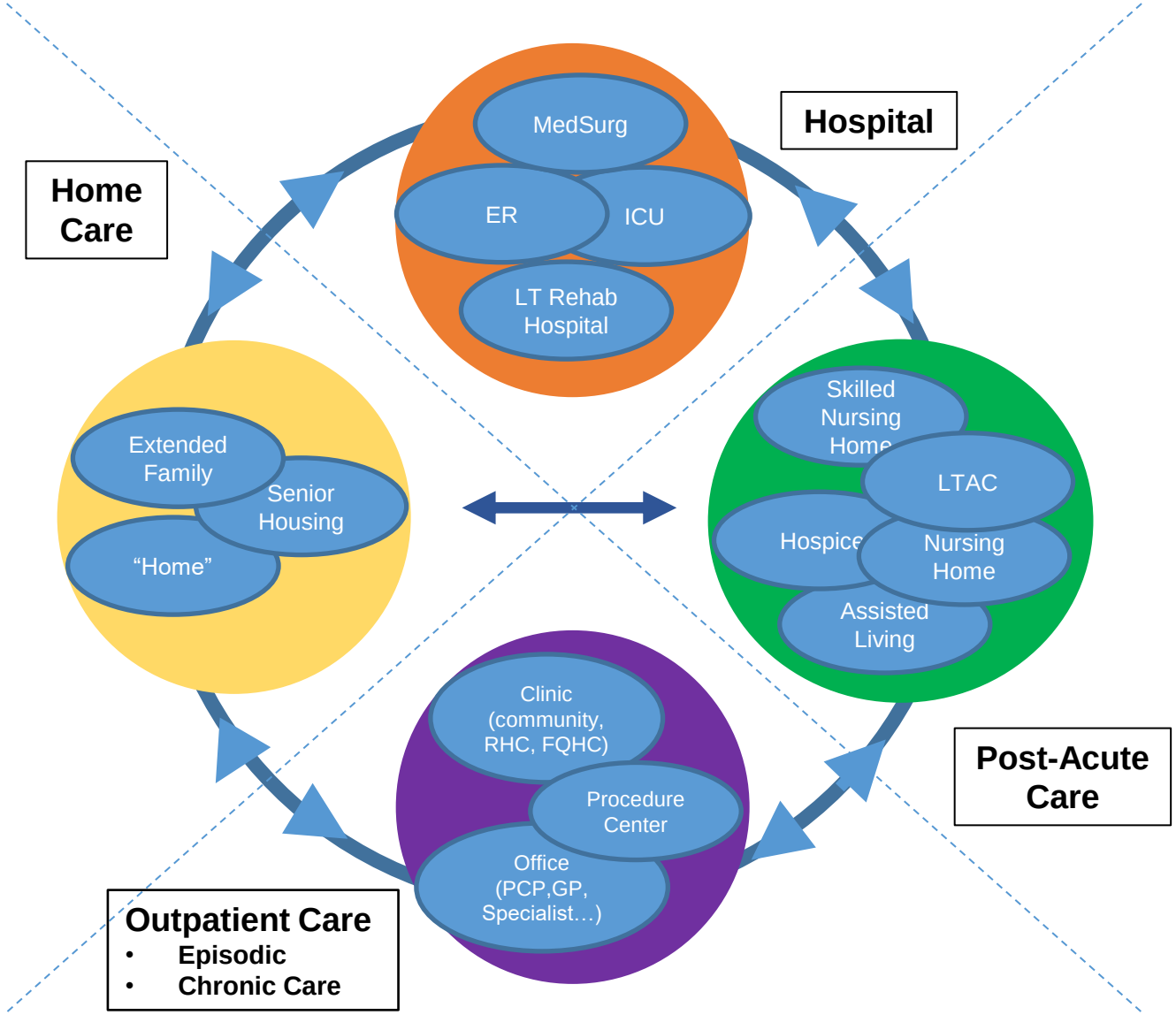
Remote Connected Care Services Part of the Picture

- Pharmacy
- Radiology
- Laboratory
- Surgery
- Infusion
- Wound Care
- Dialysis

- 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

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

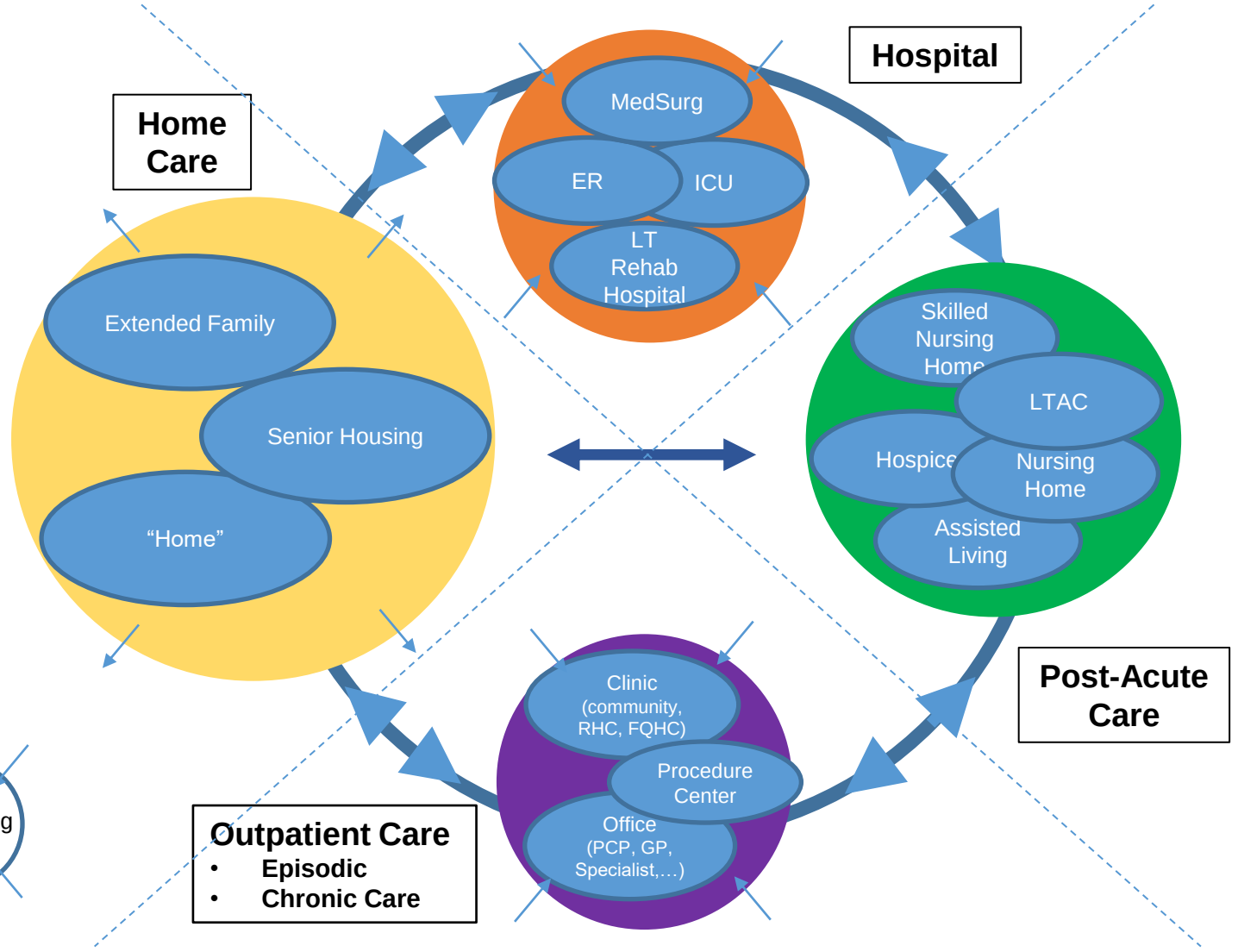


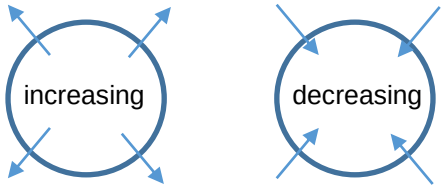
The Pandemic - accelerating RCC trends

- 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)

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

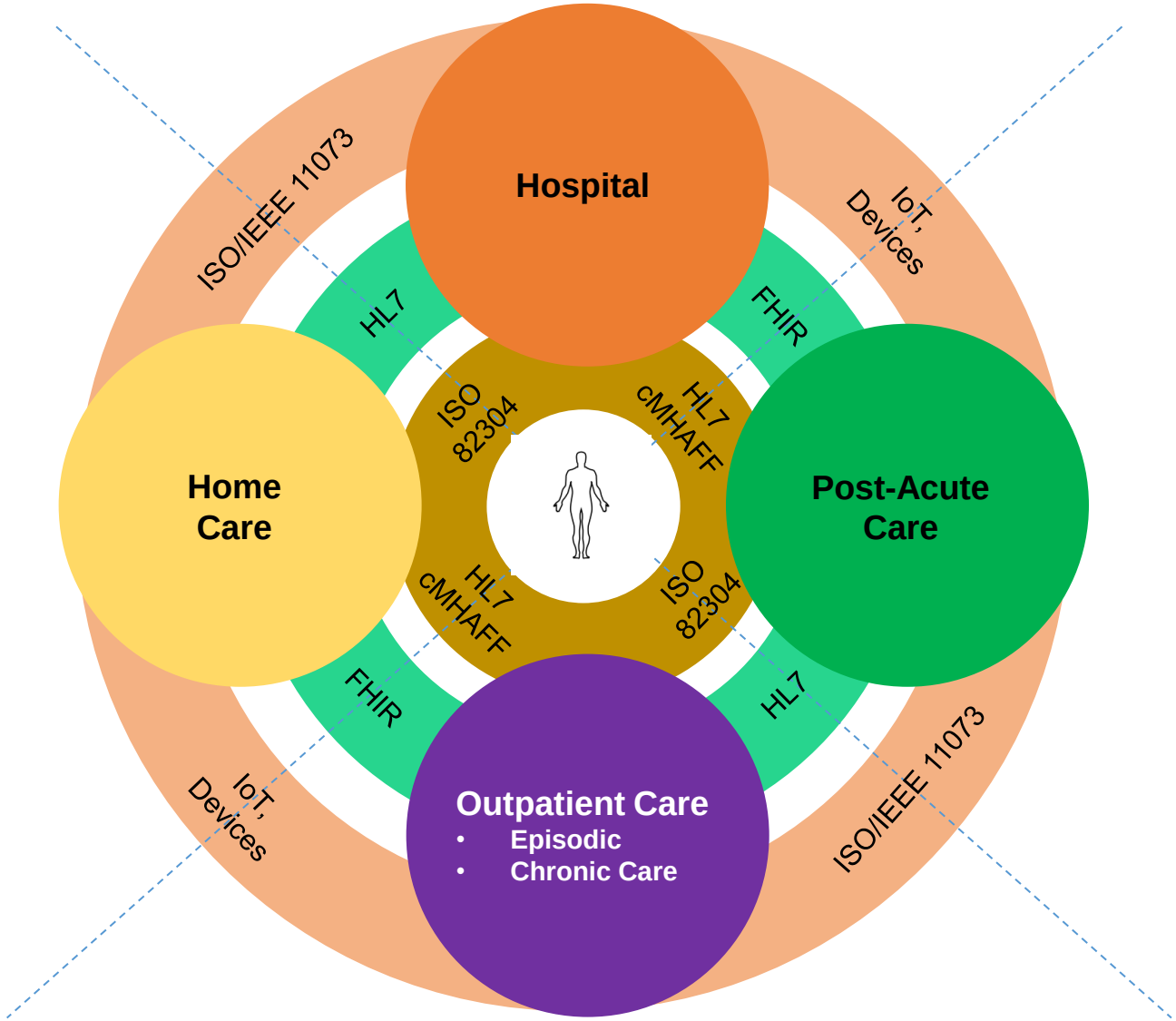
- We see increased use of RCC-MH due to:
  - Home based care increasing substantially
  - Outpatient care reduced
  - Hospital care reduced
  - Post-Acute care steady





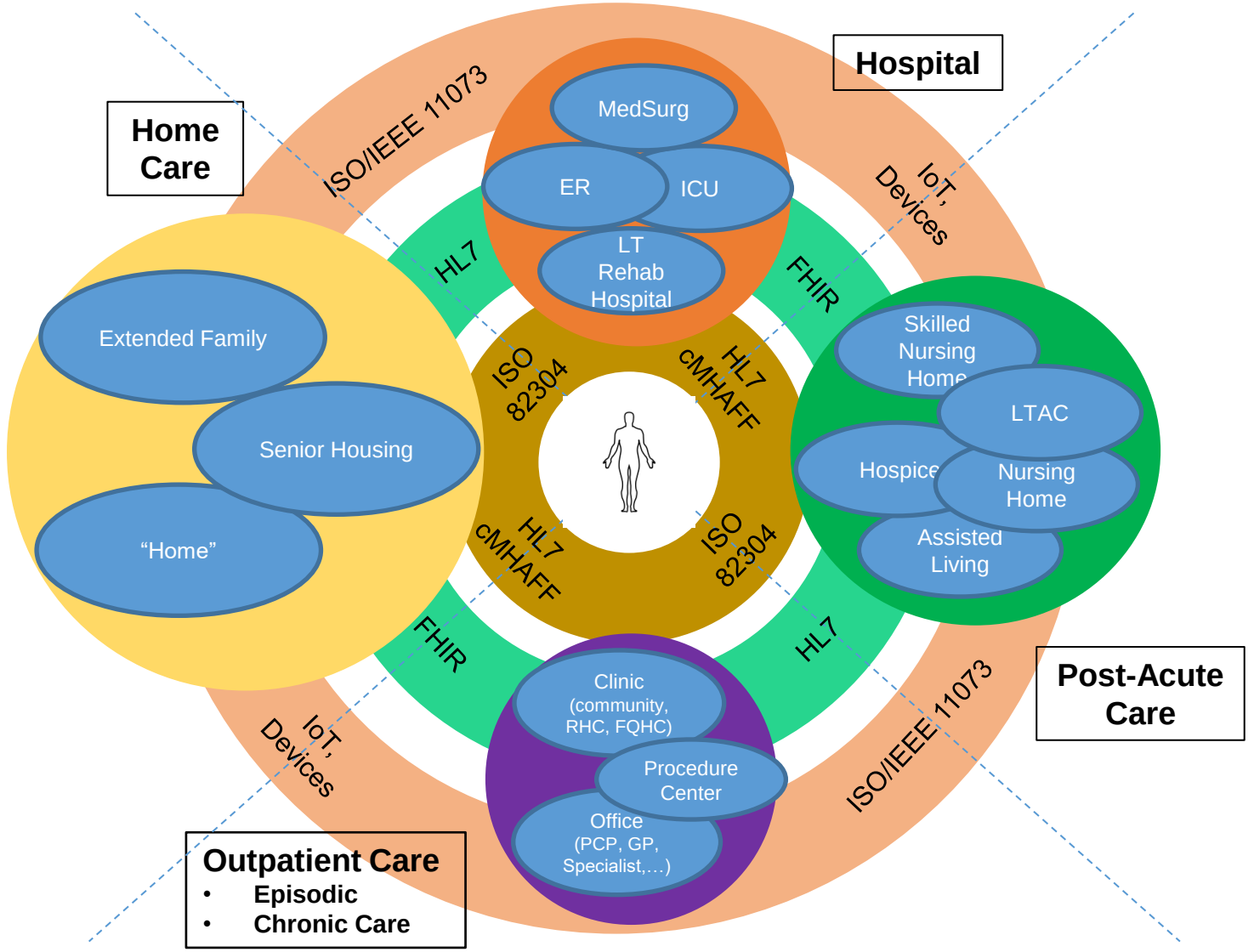
Remote Connected Care and Mobile Health – Potential Technical Approaches

- 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 EMR connectivity
  - MH apps and applications built to conform to ISO 82304

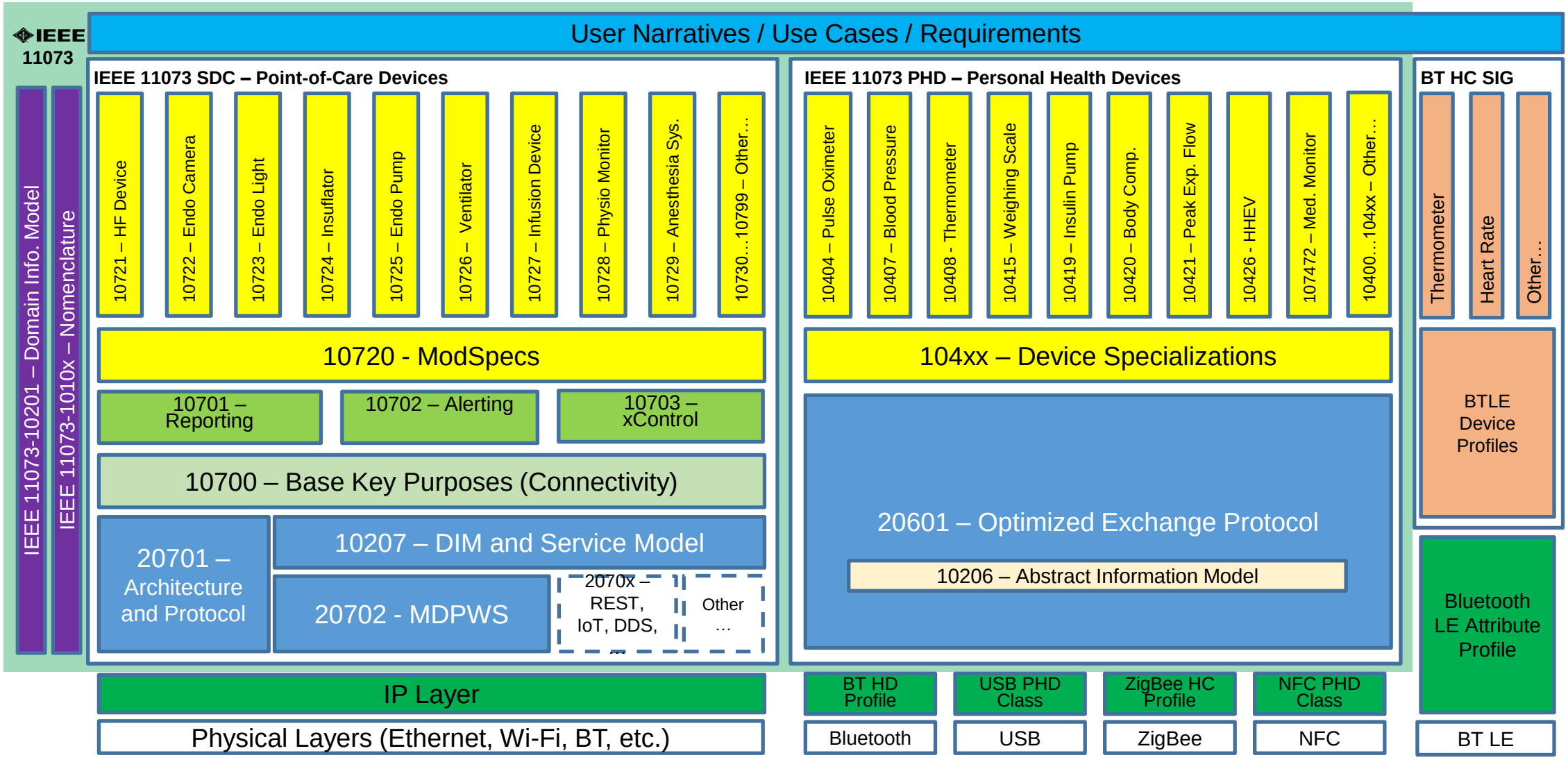


Remote Connected Care and Mobile Health – Potential Technical Approaches

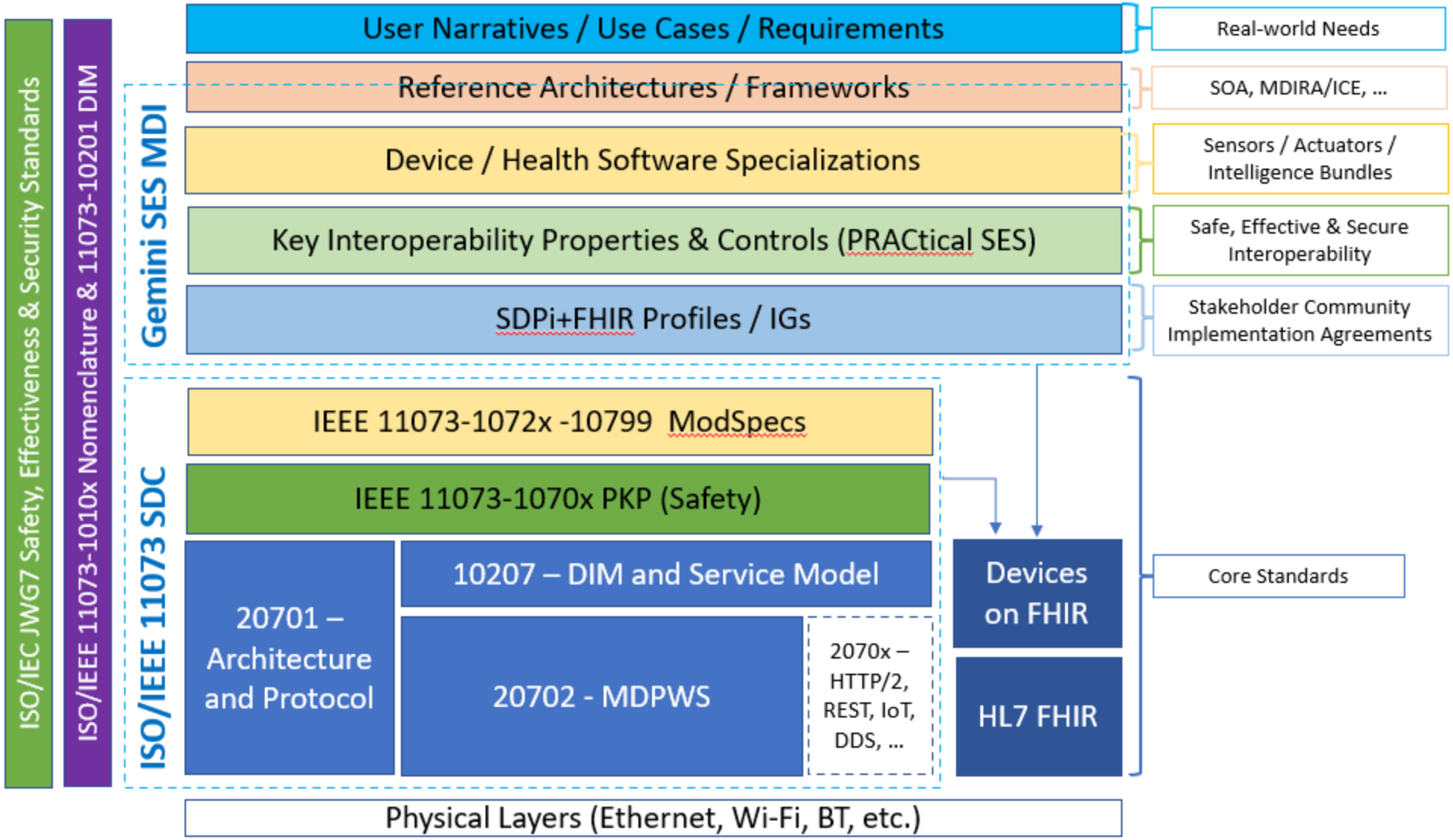
- With additional details…



11073 PoCD, PHD and BT Architectures



RCC-MH Architecture in Context



Activities

- We hold regular weekly meetings. Some of these meetings are dedicated to specific topics with expert speakers:
  - Edge Computing and Analytics
    - Gregory Pappas FDA
  - Security:
    - Brian Fitzgerald FDA
    - Axel Wirth MedCrypt
    - Christophe Fischer Roche Medical
    - Susan Wang NcCoe (NIST)
  - Provider Discussion:
    - ?
    - ?
    - ?

Activities

- Special Topics (cont'd):
  - Nomenclature Discussion:
    - Paul Schluter — Schluter Inc. – Editor of IEEE 11073 Nomenclature standards
  - Digital Medicine Discussion:
    - Pierre D'haese
    - Andrea Ruth Coravos — Elektra Labs - Co-Founder/CEO
    - Jennifer Goldsack — Digital Medicine (DiME) Society – Executive Director
  - Digital Health Discussion:
    - TBD — Members of the FDA Digital Health Center of Excellence

Proposed Table of Contents

- **Executive Overview**
- **Scope & Organization**
  - RCC MH pandemic
  - Levels: hospitals, home, nursing, states, federal, global
- **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

Proposed Table of Contents – cont'd.

- **RM/MH Architectural Perspectives**
  - <types of RCC ... 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, ...)
  - Considerations for pragmatically establishing an understanding of SES over RM/MH architectures
- **Recommendations for Further Standardization**
  - IHE-HL7? ISO/IEC JWG7? IEEE? DICOM? Etc.
- **BIBLIOGRAPHY**
- **Definitions / Glossary (annex)**
  - Remote connected care, Mobile Health, Interoperability (devices and interfaces: labs, meds, adm,), continuous/episodic

Thank You

- Key participants:
  - Konstantinos Makrodimitris — FDA
  - Gora Datta — Cal2Cal
  - Todd Cooper — Breakthrough Solutions Foundry
  - Ken Fuchs — Draeger Medical
- Contributing participants:
  - Axel Wirth — MedCrypt
  - Stefan Schlichting — Unity Consulting
  - John Rhoads — Philips Healthcare
  - Paul Schluter — Schluter, Inc.
  - Gregory Zeller
  - Gregory Pappas — FDA
  - John Garguilo — NIST
  - Christophe Fournier — Fresenius Medical
  - Michael Kirwan — DSheet
  - Raymond Krasinski — Philips Healthcare

Pandemic driven needs Emerging 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

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
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- For Health Consumers, Trust, Privacy & Good Experience Must be Baked into Digital Health Care
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  - 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=omeda%7C9875H9243956D8S&oly_enc_id=9875H9243956D8S