Accelerating Safe, Effective and Secure (SES) Remote Monitoring 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 & patient home care scenarios.***

Konstantinos Makrodimitris, Ph.D. (US FDA/DHHS liaison)

ISO/TC 215/WG 2 meeting, Systems and Device Interoperability

Monday, May 18, 2020

Disclaimer

Opinions expressed in this presentation are solely my own and do not express the views or opinions of my employer.

COVID-19 pandemic and need for remote monitoring and mobile health solutions

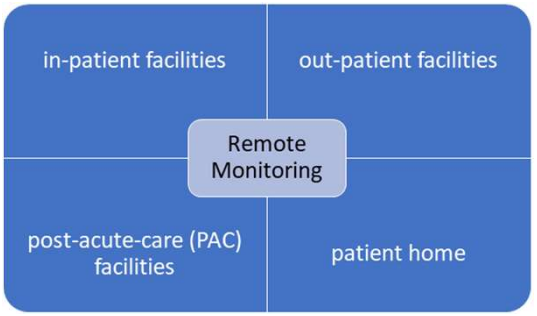
- Current COVID-19 pandemic created enormous need to allow patients and clinicians to communicate and report in a more flexible and virtual way
- Remote patient monitoring allows health providers to monitor disease and symptom progression remotely and interact with patients virtually
- Telehealth (telemedicine, teledentistry etc.) can be facilitated with remote patient monitoring and mobile health interoperable solutions

COVID-19 pandemic and need for remote monitoring and mobile health solutions

- Many government and agencies around the world encourage and provide guidance/policies to allow clinicians, dentists and patients to adopt telehealth virtual solutions and practices
- US FDA: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency For:
  - Non-Invasive Remote Monitoring Devices Used to Support Patient
  - Digital Health Devices For Treating Psychiatric Disorders
  - Remote Ophthalmic Assessment and Monitoring Devices
  - Non-Invasive Fetal and Maternal Monitoring Devices

Telehealth solutions: User Narratives and Use Cases

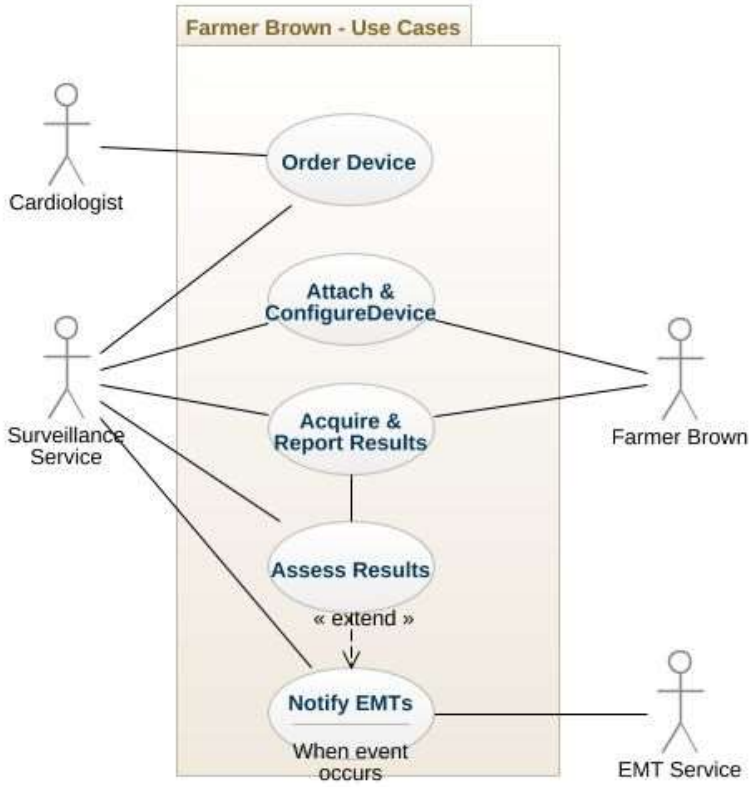
- **Need to identify a number of User Narratives decomposed into Use Cases for the purpose of extracting key interoperability requirements.**
- User Narratives will include:
  - Home based remote surveillance
    - Surveillance of a patient with a chronic disease
  - Home based remote clinician consult
    - Acquisition of vitals for remote consult
  - Long-term acute care monitoring
    - Acquisition of continuous patient vitals for remote consult and monitoring
  - In-Hospital patient monitoring
    - Integration of device data acquisition and control at the patient bedside



Courtesy Gora Datta

Telehealth solutions: User Narratives and Use Cases

- Example User Narrative – Remote Surveillance
  - Mr. Brown, a farmer in Nebraska, has a history of fainting with no specific diagnosis. After examination by his cardiologist he was prescribed a portable device which collects and transmits ECG (2-lead), blood pressure, and also detects falls. The solution communicates with a central command center which dispatches to the closest EMT.



Courtesy Ken Fuchs

Accelerating Safe, Effective and Secure Remote Monitoring and Mobile Health Interoperable Solutions (QUAD-chart)

- Title, team, partners
- Objective, Outcomes
- Aims
- Graph, Literature

PWI: ISO TC215 WG2/JWG7 MAY 2020

Title of the project:

Accelerating Safe, Effective and Secure (SES) Remote Monitoring 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 & patient home care scenarios.

Research area addressed: Standards development

- Length of the performance period: **1-2 years, 2020-2021**
- Initial SMEs in the project
  - KM: Kosta Makrodimitris
  - TC: Todd Cooper
  - SS: Stephan Schlichting
  - GD: Gora Datta
  - KF: Ken Fuchs
  - JR: John Rhoads
- Initial collaborative SDO partners/groups
  - ISO TC215: WG2 & JWG7
  - IHE-DEV
  - IEEE 11073
  - HL7 - Mobile Health, FHIR, DEV
- Government partners
  - FDA
  - CDC
  - CMS
  - ONC
  - EU, Asia health departments
- Healthcare providers partners
  - Hospital
  - PCP
  - PAC

Specific Aims

A. Publish White Paper: **Evaluate current interoperability standards** (HL7 FHIR/IEEE/ISO/IHE/HIMSS) applicability + maturity for **Remote Monitoring and Mobile Health Interoperability** of specific parameters (heart, respiration, temperature, mental health, imaging, compliance, sleep apnea, orthodontics, maternal-fetal etc.) for high risk patients affected in pandemic
  - Home use devices/patients
  - Patients in bedside in hospital env
  - "clinic" / primary care
  - post-acute-care

B. Define a possible **Minimum Set of Safe, Effective & Secure Medical Device and Mobile Health Interoperability** for rapid implementation in virtual settings. What SES principles and risks should be used to evaluate readiness for interoperable virtual settings, for Emergency Use Authorizations (EUA) by regulatory bodies and healthcare providers in pandemic.
4 KIPs: Connectivity, reporting, alerting & controlling
Leverage IHE SDPi + FHIR efforts, profiles to monitoring devices, Home setting to use protocols for 4 KIPs
(Key Interoperability Processes)

C. **Measure/Monitor conformance, adoption and implementation** to generate interoperable harmonized data from devices, reduce data delays, and ambiguity, improve the quality of care by making the right data available at the right time, at the right place to the right doctor and the right patient, and making interoperable Real World Data (RWD) available for analysis supporting Real-World Evidence (RWE) for clinical decision-making and innovation

D. **Initiate a Governance Body** & Public Private Partnership to oversee the implementation, adoption, cases, value for ROI of standards

Objective

Evaluate the needs/gaps and accelerate and simplify the implementation of interoperability standards in pandemic era to enhance remote monitoring

Expected Outcomes

A new project on MS-SES-MDI to ballot and create

1. **White paper (IHE/HL7/others)**
2. **TR: technical report (ISO TC215)**
3. **TS: technical specification (ISO TC215)**
4. **Governance: Monitor conformity/adoption/value**

Joint proposal: ISO TC215 JWG7/WG2

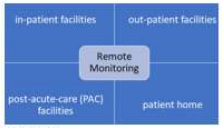
Goals/Vision

- How the project advances the ISO TC 215 standardization goals in pandemic era now and in the future.

To Present PWI:

May 18 (WG2/JWG7 virtual meeting 9-11am US ET)

GRAPH



Courtesy GD

Literature:

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https://www.healthcareitnews.com/news/guide-telehealth-vendors-use-covid-19
https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
https://www.smfm.org/covid-19-white-paper

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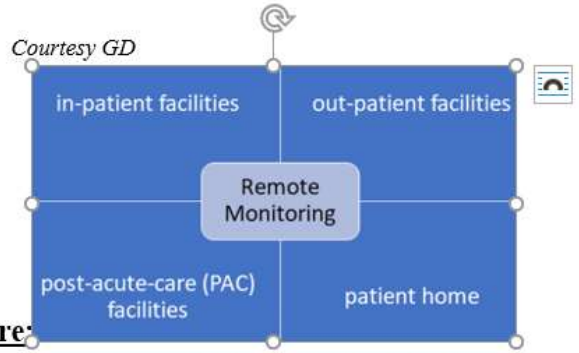

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https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
https://www.smfm.org/covid-19-white-paper

ISO/IEEE 11073 initiatives/standards

ISO/IEEE 11073 SDC – 15 Year Journey

2004

2004 — **BMBF Vision SOMIT FUSION / OrthoMIT**
Foundation for the idea of interoperability

2010 — **TekoMed**
Feasibility study to prove the SOA approach for medical devices

2011 — **Dienst-Orientierte OP Integration (DOOP)**
Networking project with various medical vendors to implement DPWS and demonstrate interoperability

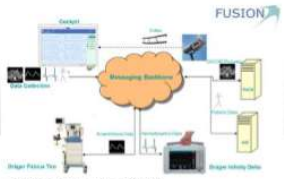
2013 — **BMBF-OR.NET**
A project funded by the German Ministry of Education and Research to consolidate all medical device interoperability research activities in Germany

2015 — **OR.NET Consortium** (OR.NET e.V.)
An association of different stakeholders in medical device interoperability

2016 — **IEEE 11073-20702**
Standard approved Medical Devices Communication Profile for Web Services

2017 — **IEEE 11073-10207**
Standard approved Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication

2018 — **IEEE 11073-20701**
Standard approved Service Oriented Medical Device Exchange Architecture Protocol Binding



Demonstrator, 2009

Demonstrator, 2011

OR.NET, Berlin, 15/04/2015


DOOP Demonstrator, Lübeck, 11/12/2013

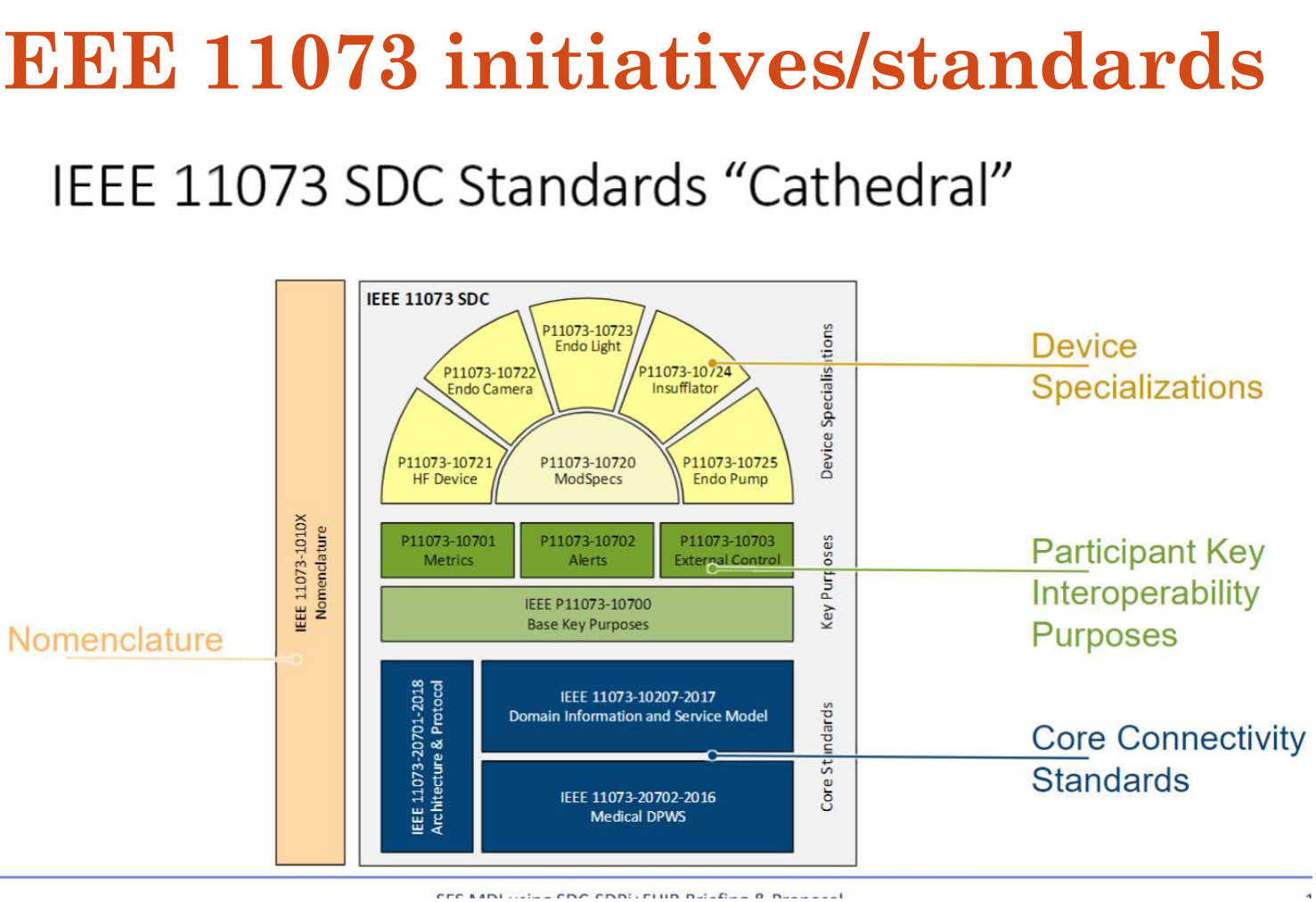
NOTE: This roughly parallels the timelines for IHE Devices Domain & HL7 Devices WG

SDC IEEE 11073 Series IEEE

SES MDI using SDC-SDPi+FHIR Briefing & Proposal

SDPi+FHIR Paper - SES MDI Created by Todd Cooper,

ISO/IEEE 11073 initiatives/standards



SDPi+FHIR Paper - SES MDI Created by Todd Cooper,

SDC

SERVICE-ORIENTED DEVICE CONNECTIVITY

The concept of a

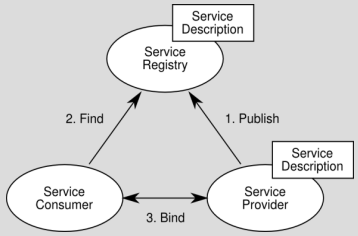
clinical workplace service-oriented medical device architecture

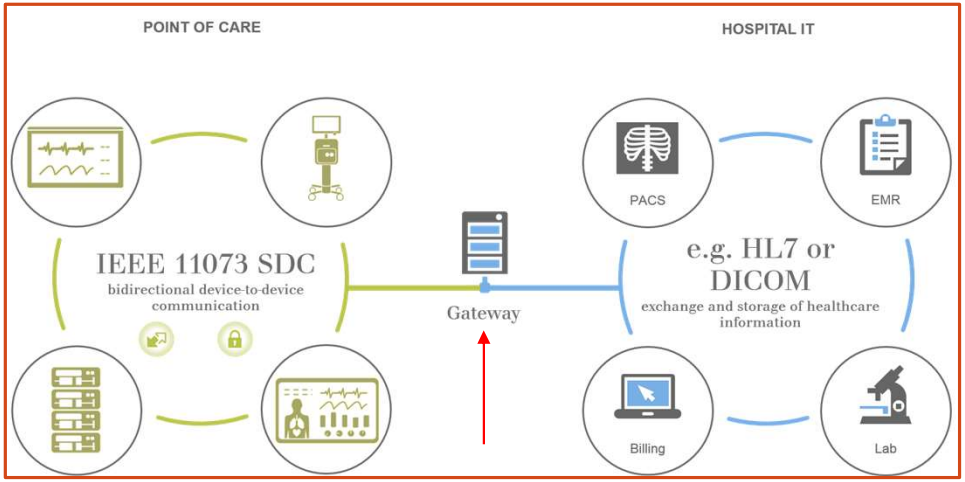
transfers the concept of a

service-oriented architecture

to the domain of

distributed system of medical devices for one clinical workplace.



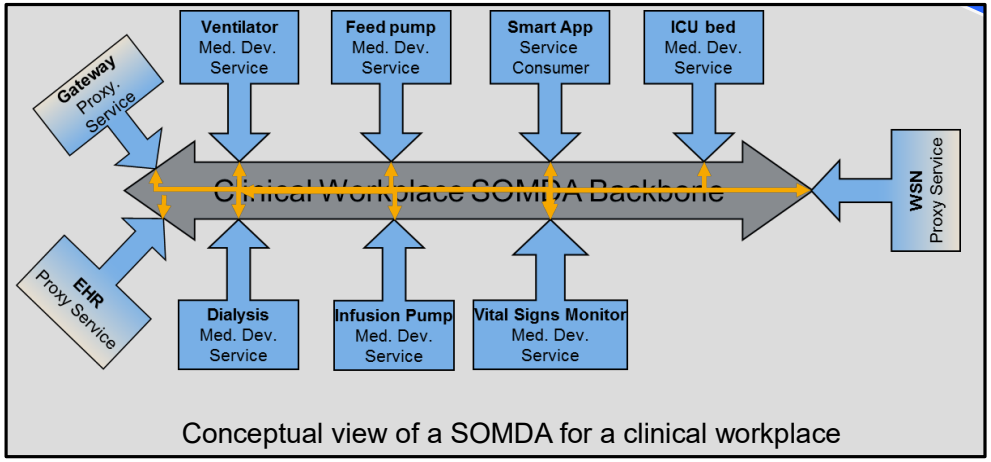


SDC Point-of-Care Context

HIT "Enterprise" Context

Device-to-Device Plug-and-Play for Reporting / Alerting & Controlling

(**PRAC***tical Interoperability*)



Conceptual view of a SOMDA for a clinical workplace

2020 Joint HL7-IHE Gemini Project

Full slide deck @ confluence.hl7.org "Device Interoperability using SDPi+FHIR" page

Gemini Project Deliverables & Governance

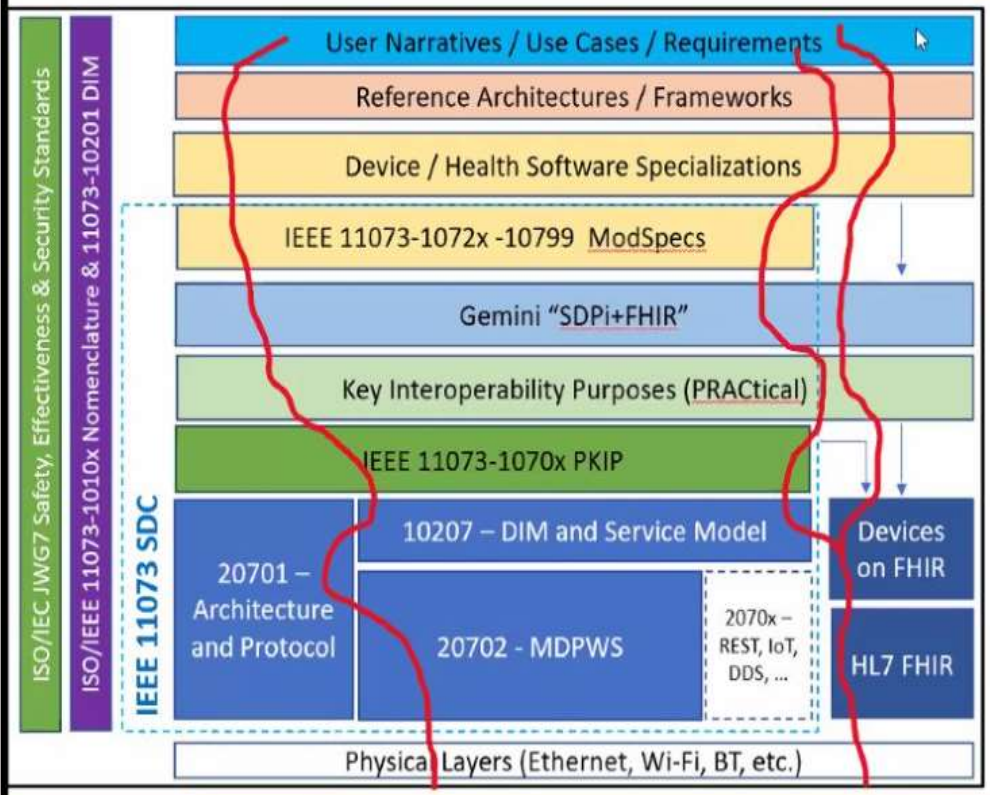
One set of cohesive, coordinated deliverables

1. **IHE SDPi Supplement** – published 2020 JUL, PAT/CAT testing Q3/4 '20
2. **HL7 DoF IG** supporting **SDC integration** & **Alerting** – ballot in 2020
   - ✓ DoF IG (proposed) for *Device Information Consumers* (title TBD)
3. Joint White Papers:
   - ✓ ***"What is a device?"*** - including AI/ML SAMD, across use context geographies
   - ✓ ***"Safe, Effective & Secure MDI Using SDC/SDPi + FHIR"*** – Quality / Regulatory / Legal Considerations
   - ✓ "***Accelerating Safe, Effective and Secure Remote Monitoring and Mobile Health Interoperable Solutions***" – How do you know that a rapid response to address crisis (e.g., pandemic) challenges is safe enough, effective enough, and secure enough to allow for implementation & use?

Governance based on HL7 or IHE project home organization processes

A Framework for *Trusted Interoperable Product Decoupling*

Addressing the SES MDI Ecosystem "Trust Gap" …



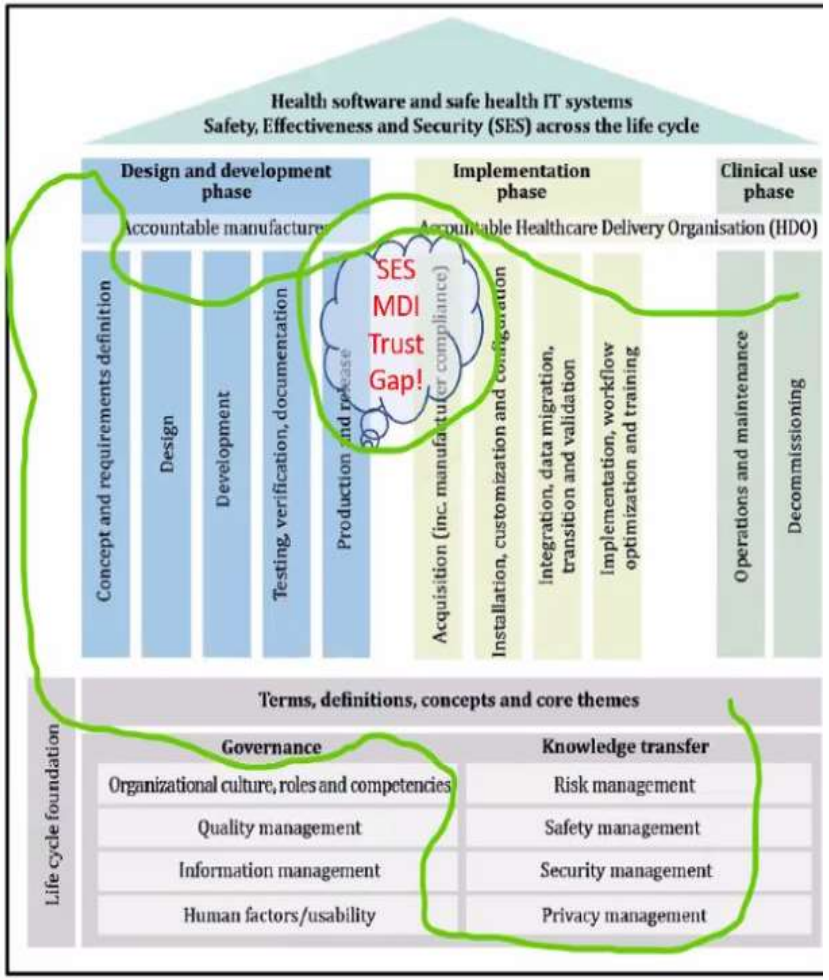


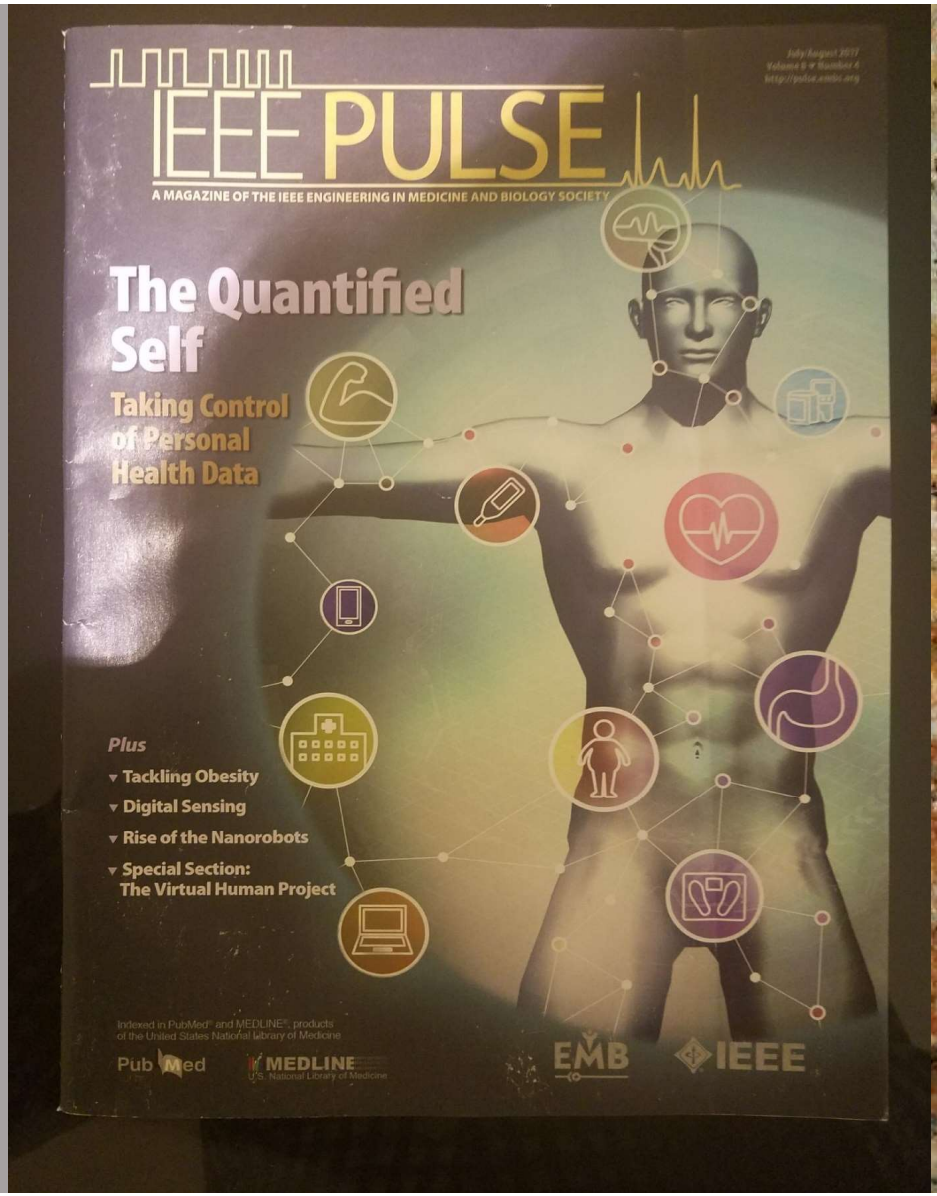
Diagram from 81001-1:2020 under Open Government License: see https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/

MOBILE HEALTH

Quality, efficacy, safety and security of mobile health apps

May 18, 2020

Gora DATTA, FHL7
LI: https://www.linkedin.com/in/goradatta/
TW: @goradatta


IEEE PULSE
A MAGAZINE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY
The Quantified Self
Taking Control of Personal Health Data
Plus
Tackling Obesity
Digital Sensing
Rise of the Nanorobots
Special Section: The Virtual Human Project
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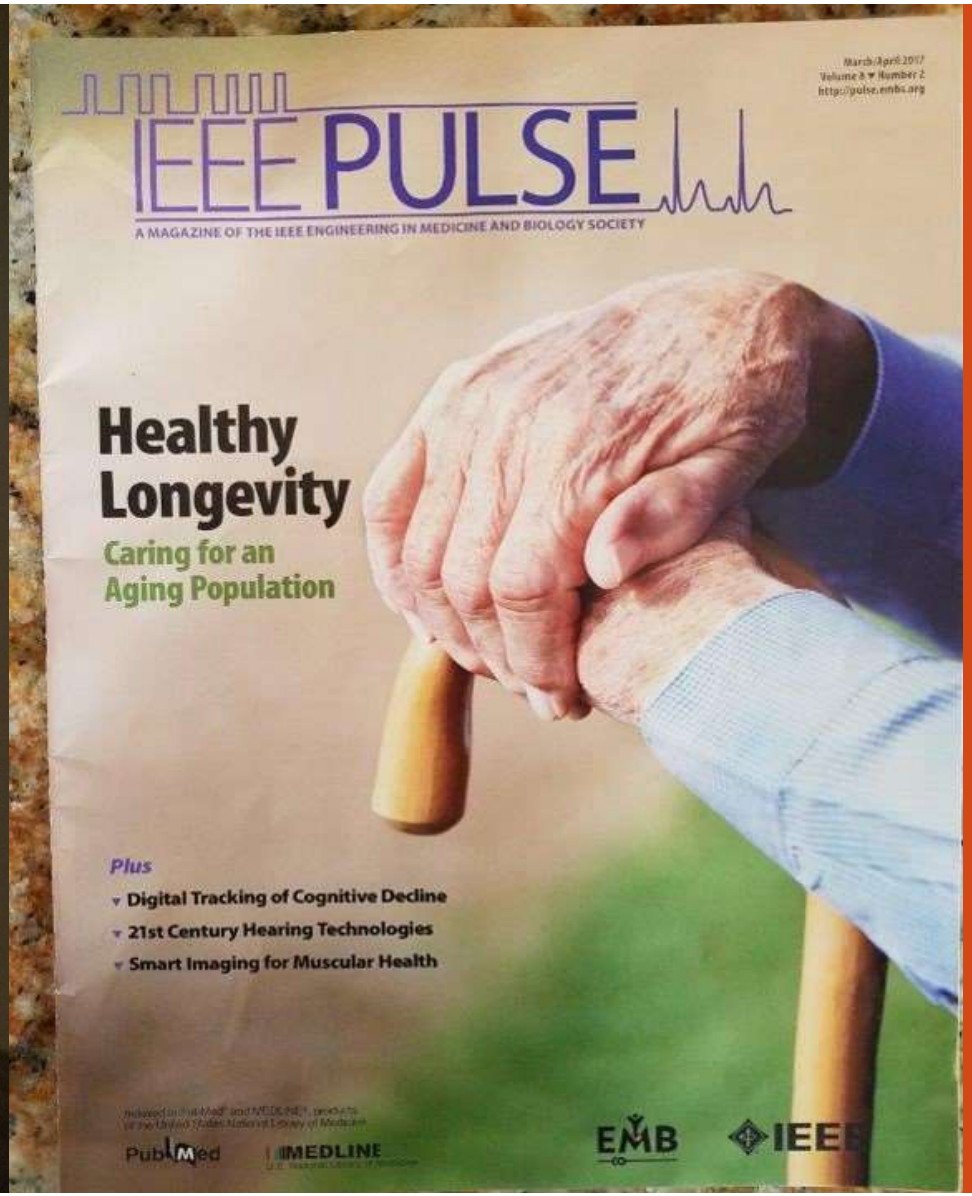
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21st Century Hearing Technologies
Smart Imaging for Muscular Health
PubMed
MEDLINE
EMB

Mobile Health – Integrated Innovation

Engagement

Security
Privacy

Trust

Fitness

EHRs

Healthcare

Medication

Wearables

Secure

Safety

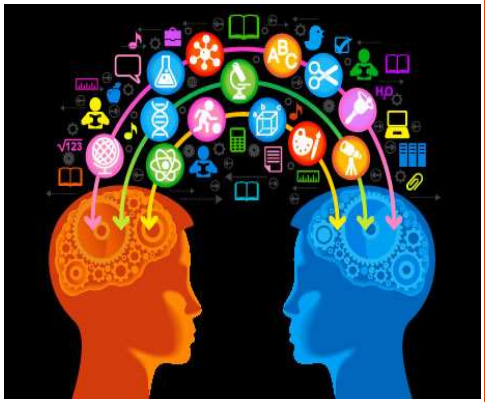
Patient Needs

Efficiency

Care Providers

Innovation

Guidelines
Best
Practices



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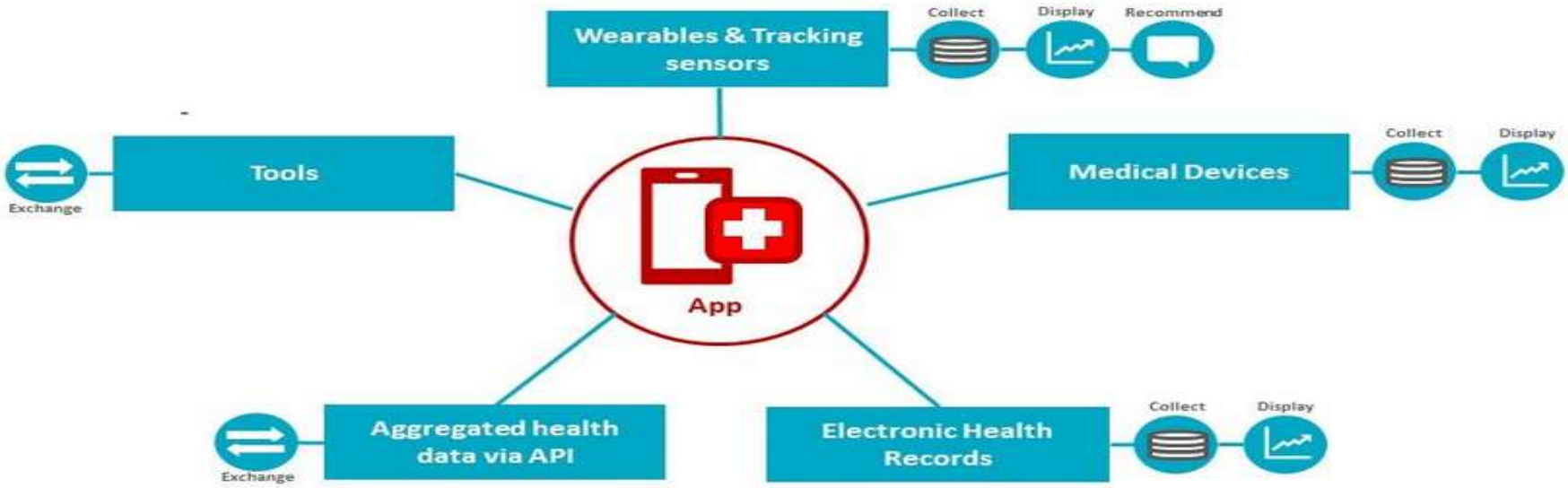
APP CENTRIC VIEW OF THE WORLD

TODAY DIGITAL HEALTH CONSISTS OF A COMPLEX CONNECTIVITY ECO-SYSTEM WITH THE APP IN ITS CENTER

Ways to connect digital health data and their respective main use cases



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REFLECTION TIME!

- There are between 400,000 to 500,000 health & fitness apps (Jan 2019)
- There are over 325,000 mobile health apps (Apr 2018)
- There are over 165,000 mobile health apps (2017)
- There are over 150,000 mobile health apps (2015-16)
- There are over 50,000 mobile health apps (2013-14)

What is driving this phenomenal growth?

- **KEY DRIVERS**
  - Increasing global population
  - Aging population (not only a Developed world issue)
  - Higher Life Expectancy (people living longer)
  - Increasing Chronic diseases*: e.g., diabetes, obesity, heart disease etc.
  - Technological advances
  - Emergence of Personalized medicine
  - Global reach of diseases

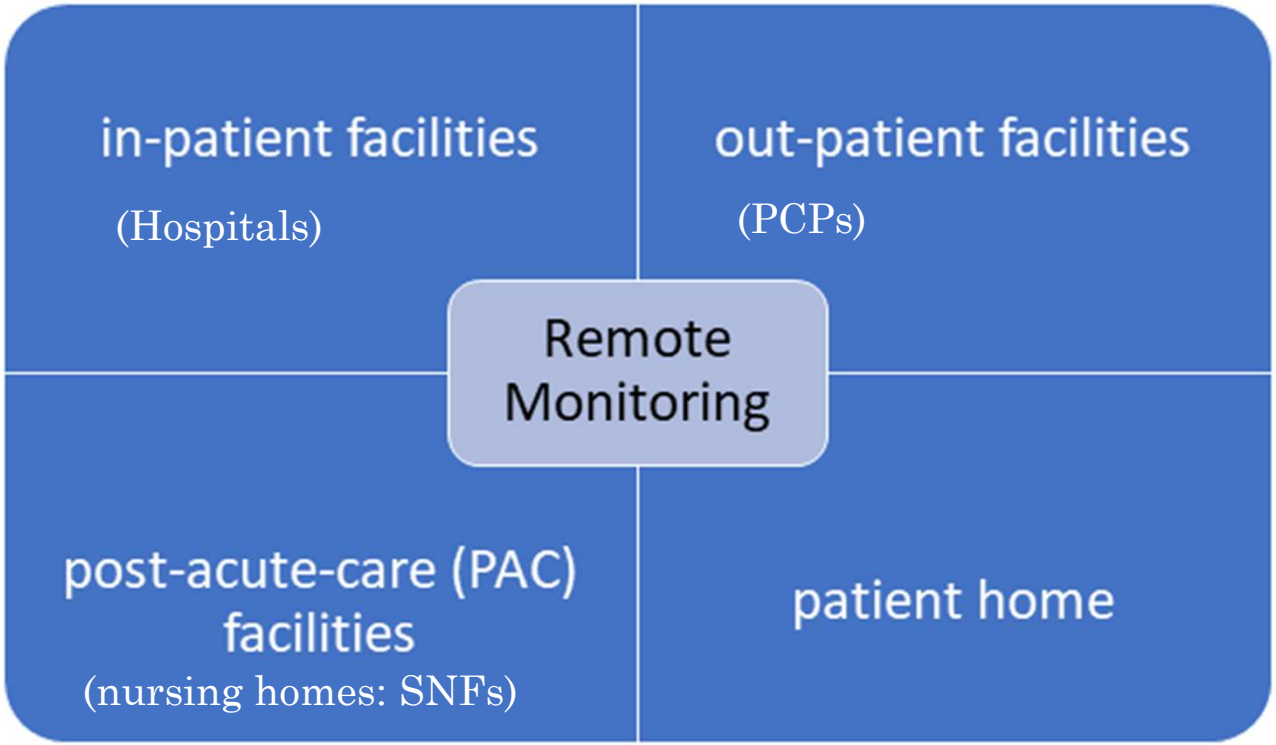
[Chronic Disease is a long-lasting condition that can be controlled but not cured]

© credit: Gora Datta

Mobile Health Scenarios

- Caregiver on the move
  - Hospitals, Clinics, Long term care, Hospice
- Patient empowerment
  - Patient involvement in care process across a wide range of lifestyles, including: support for long term conditions
- Independent living
  - Assisted living drawing on a range of mobile services
- Behavioral health
  - Behavioral health support anytime, anywhere
- Messaging (ranging from unsecure to secure)
  - Bridging the health divide
- Public/Population Health
  - Disaster Management to PH outreach

REMOTE MOBILE HEALTH



© credit: Gora Datta

COMING SOON-Mobile Health!

- Prescribing Mobile Health Apps
- **UHAI**: Unique Health App Identifier! (UDI for Mobile Health Apps)
- Mobile Health Apps Conformity Assessment, Certification Guidance

THANK YOU!