Mobile Health (MH) Working Group – Projects Update

HL7 January 2022 WGM
By Matthew Graham

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Mobile Health Work Group
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Mobile Health WGM Sessions

- **Tuesday**
  - Q1 - EHR hosting MH - Mobile Health Projects Update

- **Wednesday**
  - Q1 – State of Mobile Health (SoMH) Address
  - Q2 – cMHAFF: consumer Mobile Health Application Functional Framework Update
  - Q3 – Patient Engagement - Self Measured Blood Pressures – PGHD
  - Q4 – UMHAI: Unique Mobile Health App Identifier Update

- **Thursday**
  - Q1 – SHIFT: School Health Innovation Framework leveraging Technology Update
  - Q2 – Joint Devices and MH
Mobile Health - Projects

- Consumer Mobile Healthcare Application Functional Framework (cMHAFF)
- Mobile Health App Data Exchange (MH-ADE)
- School Healthcare Information Framework utilizing Technology (SHIFT)
- Unique Mobile Health App Identifier (UMHAI)
cMHAFF Scope and Goals

- Provide a framework for assessment of the **common foundations** of mobile health apps
  - Product Information (disclosures/transparency)
  - Security
  - Privacy/consent/authorization
  - Risk assessment/analysis
  - Data access privileges
  - Data exchange/sharing
  - Usability & Accessibility

- Assessment could include attestation, endorsement, testing, voluntary or regulatory-driven certification

- Out of scope: specific clinical content or functionality

- Includes functions, requirements, and IG specifications
CMHAFF Domains

**Functional Requirements**
- Usability & Accessibility
- Download & Installation Considerations
- App Launch & Registration
- App Use & Operation
- Consent for Data Collection
- Account Synchronization
- Security for Data at Rest
- Security for Data in Transit
- Data Authenticity, Provenance, and Associated Metadata

**Non-Functional Requirements**
- Data Exchange and Interoperability
- Product Upgrades
- Audit
- App and Data Removal
- Permitted Uses of Data Post Account Closure

**Product Risk Assessment & Mitigation**
- Regulatory Considerations
- Product Information
- Conditions and Agreements
Why cMHAFF? What’s the Need?

- Target Audience: **mobile health app developers** needing guidance on building apps
- Beneficiaries: consumers, providers, caregivers
- Consumers need protection, transparency and assurance regarding mobile apps. Some examples:
  - What does the app **do**? What **evidence** supports it?
  - What **security** protections exist behind that “cloud?”
  - Who can the app **share** data with?
  - What does the app **know** about me (location, microphone, camera, contacts, etc.), and what can it **do** on my device?
  - Can I **access** my app data like I can under HIPAA?
Why this is needed:

- Many **uncoordinated national initiatives** for App Quality Frameworks
- **Thousands of Apps in the wild already** – unknown quality / safety
- Apps are developed on **App Platforms**, and are distributed through **App Stores** – distinctive opportunities for Quality Interventions
- **Software as a Medical Device** – Not the whole answer
- Apps are developed by **Very Small Entities** – need focused documents targeted at their needs.
- Apps developers are **Disruptive** – new community not part of the healthcare IT tradition
CEN/ISO – additional info/timeline

- **TS: IEC 82304-2**: Health Software — Part 2: Quality and reliability criteria for health and wellness apps
  - **IEC 82304-1**: Health software – part 1: general requirements for product safety
  - **IEC 62304**: Medical device software – Software life cycle processes

- **Timeline:**
  - Draft Technical Specification (DTS) open for review until end of May 2021
Sample of U.S. Policies & Guidelines Assessed

- Health Insurance Portability and Accountability Act
- FDA Playbook on Medical Device Cybersecurity
- NIST Special Publication: 1800-1
- FTC Cross-Device Tracking Considerations
- FTC Guidance for mHealth Developers
Sample of European Guidelines Assessed

- French mHealth Good Practice Guidelines (2016)
- German Mobile Health Assessment Criteria (2016)
- Andalusian App Recommendations
- Finland PHR Cert Criteria
- Other EU initiatives
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  - **IEC 62304**: Medical device software – Software life cycle processes

- **Timeline:**
  - Published August 2021: [https://www.iso.org/standard/78182.html](https://www.iso.org/standard/78182.html)
European Innovation and Knowledge mHealth Hub

- To operationalise an mHealth Innovation Hub for integration into the national health systems in Europe.
- To serve as a focal point for expertise on mHealth in the WHO European Region.
- To assist countries in implementing mHealth strategies.
- To act as facilitator of innovation in mHealth.
- To act as an accelerator for the EU Digital Single Market.
- To produce Knowledge Tools for health systems and services on NCDs.
- To provide a code of ethics for mHealth data.
Work Areas:
- mHealth assessment frameworks, Evidence-based mHealth solutions on NCDs, Integration of mHealth into health systems, Support for large-scale implementation of mHealth programmes, Contribution to policy frameworks on mHealth topics, Ethics

European project with involvement of HL7 Europe:
- Catherine Chronaki, Giorgio Cangioli, Gora Datta, Frank Ploeg

Project timeline: 01/2020 – 06/2022

Publications so far
- Health Apps Assessment Framework
- Policy & Innovation papers on Italy, Austria, Portugal
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cMHAFF Policy Guidance & Collaborations

- Review of GDPR constraints
- Submission of CMHAFF related comments to the ONC Interoperability Standards Advisory
- Meeting with the University of Arkansas Medical Sciences
- Meeting with the All of Us research project ONC/NIH
- Gap analysis between cMHAFF and CEN/ISO
cMHAFF Recent Updates

- CMHAFF STU1 (2018) to STU2 (2021) – Approved!
  - Affirmative=36 (27 required for approval)
  - Negative=9
  - Abstained =59
  - Quorum= 78.79%

- Ballot under reconciliation– goal to complete in Q1 2022
- Further alignment with EHR-FM format
- Push toward normative
The initial scope of this project is to analyze variation in FHIR data exchanged from mobile health apps and devices for personal health information. Because mobile health apps and devices can convey a wide variety of data including hundreds of different kinds of measurements, this project will first look at a limited scope of data, including vital signs, physical activity, sleep and blood sugar.
Mobile Health App Data Exchange Project

- Project Lead: Keith Boone
- Project was balloted in May 2020
- Ballot reconciliation completed September 2020
- Ballot content and FHIR Implementation Guide final review and publishing in May 2022
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Next Steps

- Ballot has past and notification has occurred
- Publication Readiness Checklist
- Publication Request has been completed Keith W. Boone
- FHIR Management Checklist for FHIR IGs
- Push latest build out and make sure all QA is complete
- Review HTA issues
- WG/ FMG and TSC approval needed
SHIFT – Goal, Purpose and Vision

- **Goal**: Improve the health of students in order to improve the student’s academic outcomes.
- **Purpose**: Improve the health of school students via enhancements to school health–based technology and services.
- **Vision**: Continually improving school health technology and health care services.

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The scope of the SHIFT Project is to create a Framework that addresses the needs of various stakeholders who are involved in the health and well-being of students to facilitate learning and activities in the school environment. The White Paper envisions the set of healthcare standards that will support the Framework.
School Healthcare Information Framework utilizing Technology (SHIFT)

- Project Leads: John Ritter and Gora Datta
- Developed Executive Summary February 2022
- Finish content and publish technical report June 2022
Unique Mobile Health App Identifier (UMHAI)

- New Mobile Project **PSS-1867** ready for review September 2021
- Project Leads: Gora Datta / Matthew Graham
- Project Scope PSS-1867 reviewed by TSC and Mobile Health WG
- Project Confluence page:
  [https://confluence.hl7.org/display/MH/Unique+Mobile+Health+Application+Identifier+%28UMHAI%29+Project](https://confluence.hl7.org/display/MH/Unique+Mobile+Health+Application+Identifier+%28UMHAI%29+Project)
USCDI UMHAII Proposal

- United States Core Data for Interoperability (USCDI)
- Draft USCDI V2
  - Level 2
  - Level 1
  - Comment
    - Medical Device or Equipment
      - Unique Mobile Health Application Identifier (UMHAI)

This project will develop an Unique Mobile Health Application Identifier (UMHAI) which uniquely identifies a mobile health application instance as installed on a mobile device and used by a specific person. The UMHAI enables identification of application instance to provide precision therapy and facilitate recall, maintenance, transparency and traceability.

The project will consider data elements which may be used to create, or incorporated in, a UMHAI. Potential data elements may include Application name, App Builder, version, build number, hosting device, and unique identifier(s) for the person.

This effort will be aligned with existing work in HL7 standards (e.g., CDA, FHIR, V2) on UDI.
Unique Mobile Health App Identifier (UMHAI)

- Use Cases:
  - Consumer use of Mobile Health Apps for Health and Fitness Tracking
  - Prescription of Mobile Health Apps for Care Management
  - Digital Therapeutics
  - Patient Safety and Data Privacy
  - Data Interoperability Compliance
Use Case: Consumer use of Mobile Health Apps for Health and Fitness Tracking

Mobile Health Apps are used on mobile devices to collect and aggregate Patient Generated Health Data (PGHD). Mobile Health Apps can utilize mobile device components (GPS, accelerometers, audio data, visual data) to improve health and support independent living. Integration with Wearable and Smart Devices facilitate remote monitor and track longitudinal data trends to improve patient health or quality of life.
Use Case: Prescription of Mobile Health Apps for Care Management

Mobile Health Apps and wearable device are moving toward prescribe healthcare solutions. It is becoming increasingly important to understand the context and provenance of the mobile health app and devices used to acquire and manage PGHD/PRO/PRE/SDOH and meta data collected by these apps and devices. Also, for safety and privacy it will be beneficial to track Apps and the context of their deployment to facilitate timely updates and possible recall of defect in implementation and deployment.
Use Case: Digital Therapeutics

In the emerging field of Digital Therapeutics, the need to uniquely identify the software that is providing the therapeutics is critical and therefore an standardized unique identifier is essential for support.
Use Case: Patient Safety and Data Privacy

Safety and Data Privacy concerns are factors driving the need for tracking of Unique Mobile Health Application Identifier (UMHAI), many nations are looking to provide safeguards and guidance to Mobile Health App Developers to ensure patient safety and consumer privacy measures comply to local or national standards. How will Mobile Health App assert conformance? If a defect is discovered in App Build affecting safety or privacy how will the user receive update build or disable App usage?
Use Case: Data Interoperability Compliance

What standards for data interoperability are support for a given application instance by the mobile health app.
Benefits

- Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem mobile health apps can be identified and corrected more quickly.

- Enhancing analysis of mobile health apps on the market by providing a standard and clear way to document mobile health apps use in clinical information systems. A more robust post-market surveillance system can also be leveraged to support pre-market approval or clearance of new mobile health apps and new uses of currently marketed mobile health apps.

- Providing a standardized identifier that will allow App Developers and Stores and healthcare facilities to more effectively manage medical mobile health apps recalls.

- Leading to the development of a medical mobile health apps identification system that is recognized around the world.
Project Meetings / Questions

- Mobile Health Fridays – Weekly Meeting
  - Every Friday at 11 am EST

- cMHAFF Project – Weekly Meeting
  - Every Thursday at 2 pm EST

- SHIFT Project – Weekly Meeting
  - Every Monday at 11 pm EST

- Unique Mobile Health Application Identifier
  - Every other Wednesday at 10 am EST and 11 pm EST