Mobile Health (MH) Working Group – Projects Update

HL7 January 2021 WGM
By Matthew Graham (Mayo Clinic)

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Mobile Health Work Group
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Mobile Health WGM Sessions

- Monday Q3 - EHR Mega Report Out
- Tuesday Q1 - EHR hosting MH
  - Mobile Health Projects Update
- Wednesday Q1 - State of Mobile Health
- Wednesday Q2 - Consumer Mobile Health Application Functional Framework (cMHAFF) Update
- Wednesday Q3 - School Health Information Framework leveraging Technology (SHIFT) Update
Mobile Health WGM Sessions

- Thursday Q1 – Mobile Health Application Data Exchange Update
- Thursday Q2 - DEV hosting MH
  - Remote Connected Care and Mobile Health Solutions (RCC-MH) Update
- Thursday Q3 – Unique Mobile Health App Identifier (UMHAI) Update
Mobile Health - Projects

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

Mobile Health
January 2021
HL7 Virtual WGM

cMHAFF Project (HL7 Confluence)
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

Non-Functional Requirements
- 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?
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 Next Steps

- Continued development of the CMHAFF Web Guide (https://cmhaff.healtheservice.com)
- Documentation of cMHAFF Piloting findings
- Participation with the Mobile Health Data Exchange project and connect-athon
- Create Notice of Intent to Ballot (NIB) STU2
HRSA HITEQ Children’s Health Fund

- Mapping cMHAFF recommendations to CHF health app decision tree
- Still piloting, but getting close
- Scoring and mLabel app under development
cMHAFF Pilots

- Children’s Hospital of Philadelphia
  - Pilot completed – April 2019
  - Debrief meeting with CHOP team - April 2019

- Children’s Health Fund – HRSA HITEQ
  - Pilot in progress

- CEN/ISO Health & Wellness Apps
CEN/ISO Health & Wellness Apps

Quality & reliability for health and wellness apps

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**:
  - DTS under approval to review to FDIS (final draft International standard)
  - Draft Technical Specification (DTS) published Feb 2021
- Used cMHAFF to test validation of the My CHOP patient navigation app
- Pilot conducted between March – April 2019
- CHOP Team found it valuable as a tool for reviewing their health app requirements and considering current maturity.
- Opened new considerations in understanding how to manage nulls, scoring across domains, and some statements that may be too prescriptive.
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
cMHAFF Web Guide!

The HL7 Consumer Mobile Health Application Web Guide

HL7 Consumer Mobile Health Application Functional Framework (CMHAFF)

The Consumer Mobile Health Application Functional Framework is an HL7 Standard for Trial Use (STU). The primary goals of the Consumer Mobile Health Functional Framework (cMHAFF) are to provide a standard against which a mobile app's foundational characteristics – including but not limited to security, privacy, data access, data export, and transparency/disclosure of conditions – can be assessed.

The framework is based on the lifecycle of an app, as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone. It is important to note that the framework does not speak directly to the specific health or clinical functionality of an app but can be extended to do so through the use of profiles (with constraints and/or extensions) developed on top of cMHAFF.

This site provides a visual overview of the HL7 CMHAFF STU and application for piloting CMHUFF use in testing and potential for certification of health apps.

Check out our first draft of the CMHAFF web guide and pilot site at: https://cmhaff.healtheservice.com
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
School Healthcare Information Framework utilizing Technology (SHIFT)

- New Mobile Health Project White Paper /PSS
- SHIFT Project (HL7 Confluence)
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.
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.
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

- Connectathon Update - Participation
  - Continua
  - AMA Self Measured Blood Pressure
  - Georgia Tech mFHIR

- Next Steps
  - Publish content from ballot reconciliation.
Meetings / Questions

- Mobile Health Fridays – Weekly Meeting
  - Every Friday at 11 am EST
- cMHAFF Project – Weekly Meeting
  - Every Thursday at 3 pm EST
- SHIFT Project – Weekly Meeting
  - Adhoc Daily
- Mobile Health App Data Exchange
- Unique Mobile Health Application Identifier