Mobile Health (MH) Working Group – Projects Update

HL7 September 2020 WGM
By Matthew Graham (Mayo Clinic)

September 23, 2020
Mobile Health Work Group
Co-Chairs

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Mobile Health WGM Sessions

- Monday 12 – 2 PM (US EST) EHR Mega Report Out
- Tuesday 12 – 2 PM (US EST) EHR hosting MH
- Wednesday 10 -11:30 AM (US EST) MH Session 1
- Wednesday 10 -11:30 PM (US EST) MH Session 2
- Thursday 11 AM – 12:30 PM (US EST) DEV hosting MH
Mobile Health - Projects

- Consumer Mobile Healthcare Application Functional Framework (cMHAFF)
- School Healthcare Information Framework utilizing Technology (SHIFT)
- Mobile Health App Data Exchange
Consumer Mobile Healthcare Application Functional Framework (cMHAFF)

Mobile Health
September 2020
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.
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
cMHAFF Next Steps

- Continued development of the CMHAFF Web Guide ([https://cmhaff.healtheservice.com](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
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
- Mapping cMHAFF recommendations to CHF health app decision tree
- Still piloting, but getting close
- Scoring and mLabel app under development
### HITEQ Health App Decision Tree

- A sustainable decision tree workflow that allows for creating new decision forks and guidance as new safety and cybersecurity needs are identified
- Provides ability for scoring and grading health apps across key categories of assessment (e.g., privacy, security, quality, etc.)
- Provides direct links to associated standards for each area of guidance
- Tracks answers specific to each question so that opportunities for aggregation across devices and function-types are easy to report out on.

#### Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Maybe</th>
<th>Category</th>
<th>Inappropriate Answer</th>
<th>Yes Mention</th>
<th>No Mention</th>
<th>Maybe Mention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the app selling a product or therapy?</td>
<td>3.00</td>
<td>10.00</td>
<td>5.00</td>
<td>Organizational Policy</td>
<td>Yes</td>
<td></td>
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<tr>
<td>2. Is there specific and clearly outlined information about the pricing and terms of agreements associated with the app?</td>
<td>10.00</td>
<td>3.00</td>
<td>5.00</td>
<td>Organizational Policy</td>
<td>Yes</td>
<td></td>
<td></td>
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<tr>
<td>3. Does the app promote a social or political agenda?</td>
<td>0.00</td>
<td>10.00</td>
<td>5.00</td>
<td>Organizational Policy</td>
<td>Yes</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4. Does the app provide clear information about the publisher/vendor?</td>
<td>10.00</td>
<td>5.00</td>
<td>5.00</td>
<td>Organizational Policy</td>
<td>No</td>
<td></td>
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</tbody>
</table>
HITEQ Health App Analyzer Key Functionalities

- Allows health centers to conduct multiple assessments of different health apps they are considering for use
- Is mobile oriented so that it can be effectively used on smartphones and tablets
- Can be embedded in health center/HCCN/PCA websites for use across a range of users
- Provides users with an assessment report for each one completed that can be printed out, sent by email or maintained in the database
- Provides health centers with a dashboard that can be used to track assessments and filter across categories
- Completed submissions are provided with a HITEQ Health App Analyzer badge to encourage participation
- Provides a Public Assessment report for non-private assessments
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 QualityInterventions
- **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
TS: ISO 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:**
- Working Draft 2 published, WD 3 internal may – June
- 30 November submission for publication
- 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
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
- German Mobile Health Assessment Criteria
- Andalusian App Recommendations
- U.K. PAS277 Quality Criteria
- 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.
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.
Visualization

Precision Medicine Data Funnel

Consumer Health Devices/Apps
(~$4B/122M Units Global)

Mobile Platforms
Android
(88% Global/42% US)

iOS
(12% Global/57% US)

HealthKit

Medical Devices/DME
(~$4B/50K Units Global)

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Mobile Health App Data Exchange Project

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

- Next Steps
  - Define opportunities for collaboration HL7 WG, Vitals Project, etc.
  - Incorporate ballot content on after reconciliation STU.

- Weekly Meetings - TBD
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
  - Adhoc