HL7 Consumer Mobile Health Application Functional Framework (cMHAFF) Overview and Update

Mobile Health Workgroup
February 2020
HL7 Australia WGM
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
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?
Types of Ballot Comments

- Clarify ambiguous or confusing wording
- Consolidate similar criteria or moving to different section
- Recommend changes to conformance strength (e.g., SHOULD to SHALL or vice-versa)
- Recommend more specificity (e.g., data elements)
- Remove burdensome or un-actionable items
- Question about audience (developers vs consumers)
- Recommend more precise definition of app categories
Changes Since September’17

- Incorporation of remaining ballot comment dispositions
- Proposed Consumer Information Label
- Expanded Glossary
- Expanded and reorganized References
- U.K. PAS277 Guidelines (recommended in Sept’17 WGM)
- EU Regulatory Landscape Overview
- End-to-End Review
cMHAFF Exemplar Use Cases

A

App User

Health App

Smartphone

B

App User

Data Collection Device

Health App

PHR

C

App User

Data Collection Device

Health App

EHR

External Data Repository

<table>
<thead>
<tr>
<th></th>
<th>Simple</th>
<th>Device Integrated</th>
<th>EHR Integrated</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA App Categorization</td>
<td>wellness</td>
<td>wellness</td>
<td>medical</td>
</tr>
<tr>
<td>Device Data Collection</td>
<td>none</td>
<td>unregulated device</td>
<td>FDA regulated</td>
</tr>
<tr>
<td>PHI Data Storage</td>
<td>smartphone</td>
<td>smartphone/PHR</td>
<td>cloud/EHR</td>
</tr>
<tr>
<td>Data transmission by App</td>
<td>none</td>
<td>device-app-PHR</td>
<td>device-app-cloud-EHR</td>
</tr>
<tr>
<td>Importance of Data Integrity</td>
<td>low</td>
<td>mid</td>
<td>high</td>
</tr>
<tr>
<td>HIPAA covered?</td>
<td>no</td>
<td>no, but yes, if white-labeled</td>
<td>yes</td>
</tr>
</tbody>
</table>
cMHAFF Sections and App Life Cycle

**App Development and Support**
- Regulatory Considerations
- Risk Assessment and Mitigation
- Usability Assessment
- Customer Support

**Consumer Use of App**

1. **Product Information**
2. **Launch app, establish account**
3. **Authentication**
4. **Authorization/consent for data collection/use**

- **Data exchange/interop**
- **Data provenance/authenticity**
- **Security for data at rest & in transit**
- **Pairing or syncing with user devices**

5. **Notifications and Alerts**
6. **Product Upgrades**
7. **Audit**
8. **App and Data Removal**

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# Criteria Example: General Product Info

<table>
<thead>
<tr>
<th>No.</th>
<th>Strength</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1</td>
<td>SHALL</td>
<td>The description of an app includes the main functionality, the intended use, the intended (target) audience, and potential use of the user’s personal data by the app.</td>
</tr>
<tr>
<td>G2</td>
<td>SHALL</td>
<td>Screen shots of the app accurately depict the screens of the current version of the product.</td>
</tr>
<tr>
<td>G3</td>
<td>SHALL</td>
<td>Product information is provided before the app is used by the consumer, to help consumers decide whether the app is suitable.</td>
</tr>
<tr>
<td>G4</td>
<td>SHOULD</td>
<td>The app description clearly states the human languages the app supports.</td>
</tr>
<tr>
<td>G5</td>
<td>SHOULD</td>
<td>Provide information about accessibility characteristics in the app description and in contextual assistance sections of the app.</td>
</tr>
<tr>
<td>G6</td>
<td>SHOULD</td>
<td>Provide information about the app publisher (persons/organizations) and provide mechanisms to communicate with the publishers</td>
</tr>
<tr>
<td>G7</td>
<td>SHOULD</td>
<td>Provide disclosure about sources of funding and possible conflicts of interest for the app (e.g., app use could incent user to buy products or services from app publisher.</td>
</tr>
</tbody>
</table>
Informing Consumers

Disclosures
Evidence
Limitations
Contents
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
- German Mobile Health Assessment Criteria
- Andalusian App Recommendations
- U.K. PAS277 Quality Criteria
- Finland PHR Cert Criteria
- Other EU initiatives
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

- CMHAFF to Normative PSS Approved
- 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 connectathon
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

- Universitair Medisch Centrum Groningen
  - Pilot in progress
Children’s Hospital of Philadelphia

- 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.
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
GSD App evaluation: an application for the use of individual patients with hepatic GSD and their caregivers.

- The GSD App allows patients to support their dietary management provided by health care professionals, under normal circumstances and illness, by monitoring and sharing home site collected data with health care professionals.

Frank Ploeg, in cooperation with the lead developer/owner Bas te Boekhorst, went through the conformance statements published in the HL7_CMHAFF_R1_STU_2018JUN version of the cMHAFF standard.

- The conformance statements were extracted from STU cMHAFF standard document and published in a spreadsheet for purpose of assessing and scoring. See Assessment spreadsheet on confluence.
Quality & reliability for health and wellness apps

Why this is needed:

• Many **uncorroordinated 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
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

**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
CMHAFF Scoring Mechanism

Goal

- Need to be able to derive a method for determining the level of compliance/conformance/quality
- Need to identify which sections/measures carry greater weight than others
- Need to create a score that is rigorous, meaningful, reliable, and actionable
- Need to determine best practices for effectively scoring null values
Weighting per Domain

- How to effectively weight each domain per its impact/emphasis on scoring?
- How does security for data at rest compare to product information in terms of importance?
- Should specific conformance statements be weighed heavier than others?
Scoring per conformance level

- **Scoring SHALL**
  - Fully meets the criteria = 6
  - Partially meets the criteria = 3
  - Barely meets the criteria = 1
  - Does not meet the criteria = 0

- **Scoring SHOULD**
  - Fully meets the criteria = 2
  - Partially meets the criteria = 1
  - Barely meets the criteria = 0
  - Does not meet the criteria = 0

- **Scoring MAY**
  - Fully meets the criteria = 2
  - Partially meets the criteria = 0
  - Barely meets the criteria = 0
  - Does not meet the criteria = 0
The CMHAFF Web Guide is Live!

Check out our first draft of the CMHAFF web guide and pilot site at:
https://cmhaff.healtheservice.com
CMHAFF Web Guide Development

- Development of a web-based guide for accessing the CMHAFF standard.
- Increased transparency and visibility for the CMHAFF standard
- Provides ability to more easily cross-reference associated regulations and region-specific guidelines.
- Tooling for piloting of CMHAFF Standard
cMHAFF Invitation: Join us!

- It’s a major opportunity in an exploding space: get in on the ground floor!
- Action is under way around the world – people are ready!
- Passed STU ballot in January 2018: on its way to STU 2020!
- Help HL7 collaborate well with the public and private sectors
- Stay connected via HL7 Mobile Health listserv
Project and Contact Info

- cMHAFF meetings are Thursdays at 3pm Eastern
  - Project Leads: Nathan Botts, Frank Ploeg, Matthew Graham, Gora Datta

- **Join us** to publish and start using cMHAFF!