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

Mobile Health
May 2018
HL7 Cologne, Germany 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?”
  - Can I **comprehend**, or even find, privacy policy and terms of use?
  - 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?
  - What happens to my **data** if I delete an app?
cMHAFF January’18 Ballot Results

- Passed!
  - 48 Affirmative (30 needed to pass)
  - 0 Negative
  - 57 Abstain

- 79 specific comments
  - 3 NEG (UPDATE: All withdrawn)
  - 76 A-S, A-Q, or A-C
  - **All** comments RESOLVED
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

<table>
<thead>
<tr>
<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>
</tr>
<tr>
<td>Device Data Collection</td>
<td>none</td>
<td>unregulated device</td>
</tr>
<tr>
<td>PHI Data Storage</td>
<td>smartphone</td>
<td>smartphone/PHR</td>
</tr>
<tr>
<td>Data transmission by App</td>
<td>none</td>
<td>device-app-PHR</td>
</tr>
<tr>
<td>Importance of Data Integrity</td>
<td>low</td>
<td>mid</td>
</tr>
<tr>
<td>HIPAA covered?</td>
<td>no</td>
<td>no, but yes, if white-labeled</td>
</tr>
</tbody>
</table>
EHR-Integrated Use Case “C”

A diabetes management app allows a consumer to collect blood sugar readings through a Bluetooth-enabled glucometer. A healthcare provider offers the app to enable the patient’s blood sugar to be captured through devices, rather than relying on manual entry by the patient, and to electronically transmit the readings to the patient’s physician, rather than using paper or FAX. Activity data are collected through an activity tracker, and a consumer can open the app to record meals and snacks to enable estimates of caloric consumption. Collected data is automatically “pushed” to a third-party cloud-based platform. The patient is aware of the cloud, though not familiar in detail with how data are protected in transit or storage. When a consumer views information in the app, which shows daily glucometer readings and related information, this information is “pulled” in but does not persist on the smartphone when the app is closed. It is also possible for the consumer to directly enter blood sugar readings (e.g., if Bluetooth connection is not working). From the cloud platform, consumer information is “pushed” to a provider’s Electronic Health Record (EHR), where it is accepted as Patient Generated Health Data (PGHD), according to the preferences of the patient and the policies of the provider. From the EHR, a physician can define logic to assess blood sugar readings such that the consumer is alerted through the app when a measurement is out of range, or when a set number of high or low readings are noted within a prescribed period of time.
cMHAFF Sections and App Life Cycle

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

Consumer Use of App

- Product Information
- Launch app, establish account
- Authentication
- 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
- Notifications and Alerts
- Product Upgrades
- Audit
- 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></td>
<td></td>
<td><strong>GENERAL INFORMATION</strong></td>
</tr>
<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

Terms & Conditions

Nutrition Facts

Serving Size ½ cup (114g)
Servings Per Container 4

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>Calories 90</th>
<th>Calories from Fat 30</th>
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</thead>
<tbody>
<tr>
<td>Total Fat 3g</td>
<td>% Daily Value 5%</td>
<td></td>
</tr>
<tr>
<td>Saturated Fat 0g</td>
<td>% Daily Value 0%</td>
<td></td>
</tr>
<tr>
<td>Cholesterol 0mg</td>
<td>% Daily Value 0%</td>
<td></td>
</tr>
<tr>
<td>Sodium 300mg</td>
<td>% Daily Value 13%</td>
<td></td>
</tr>
<tr>
<td>Total Carbohydrate 13g</td>
<td>% Daily Value 4%</td>
<td></td>
</tr>
<tr>
<td>Dietary Fiber 3g</td>
<td>% Daily Value 12%</td>
<td></td>
</tr>
<tr>
<td>Sugars 3g</td>
<td>% Daily Value 12%</td>
<td></td>
</tr>
<tr>
<td>Protein 3g</td>
<td>% Daily Value 12%</td>
<td></td>
</tr>
</tbody>
</table>

Vitamin A 270% • Vitamin C 10%
Calcium 2% • Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Calories
<table>
<thead>
<tr>
<th>Calories</th>
<th>Total Fat</th>
<th>Saturated Fat</th>
<th>Cholesterol</th>
<th>Sodium</th>
<th>Total Carbohydrate</th>
<th>Dietary Fiber</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,000</td>
<td>Less than</td>
<td>Less than</td>
<td>Less than</td>
<td>2,400mg</td>
<td>300g</td>
<td>25g</td>
</tr>
<tr>
<td>2,500</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>350g</td>
<td>30g</td>
</tr>
</tbody>
</table>
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
A Summary of the EU Regulatory Landscape

2016
- Medical Device Directives
- Data Protection Directive
- ePrivacy Directive
- eCommerce Directive
- Unfair Commercial Practices Directive
- Consumer Rights Directive

2017
- MDR tightens & clarifies MDD
- GDPR substantially enhances privacy
- Guidelines for App Developers (PAS277-like)

2018
- Medical Device Regulations
- General Data Protection Regulation
- Code of Conduct on mHealth app privacy
- Possible Safety Directive
- Possible Accessibility Directive

2019
- Implementation date expected 2020 (Med Devices); 2022 (in-vitro diagnostic devices)

2020
- 

Currently voluntary
Related U.S. & Global Industry Efforts

ONC ISA Task Force and PGHD Whitepaper

OWASP Mobile Top 10 Security Risks

FTC/FDA/OCR Mobile App Developer Guidance Tool
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 January 2018 STU ballot: on its way to STU!
- 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
  - Web Meeting
    - WebEx Link: https://westat.webex.com/westat/j.php?MTID=mdd11dffddaca42a8a5625535b49fc3bd
    - Phone 770-657-9270, passcode 465623

- Project Lead: Nathan Botts

- Join us to publish and start using cMHAFF!