

# Mobile Health (MH) Working Group – Projects Update

HL7 September 2019 WGM

By Matthew Graham (Mayo Clinic)

September 18, 2019



# Mobile Health Work Group Co-Chairs

- Gora Datta [gora@cal2cal.com](mailto:gora@cal2cal.com)
- Matt Graham [graham.matthew@mayo.edu](mailto:graham.matthew@mayo.edu)
- Nathan Botts [nathanbotts@westat.com](mailto:nathanbotts@westat.com)
- Frank Ploeg [r.f.ploeg@umcg.nl](mailto:r.f.ploeg@umcg.nl)

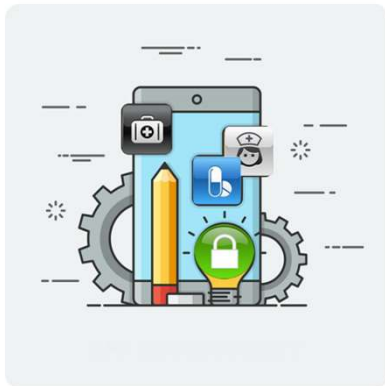
# MH Sessions

- Wednesday Q1 – Introduction & Overview
  - State of Mobile Health
  - Connectathon Update – Keith Boone
- Wednesday Q2 – Project Updates
- Wednesday Q3 – Mobile Health Data Exchange Standards
  - ONC/NIH All of Us Project –Keith Boone /Christina Caraballo
  - AMA Integrated Health Model Initiative (IMHI) Self Measured BP
- Thursday Q1 & Q2 – cMHAFF Working Session

## Mobile Health - Projects

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

# Consumer Mobile Healthcare Application Functional Framework (cMHAFF)

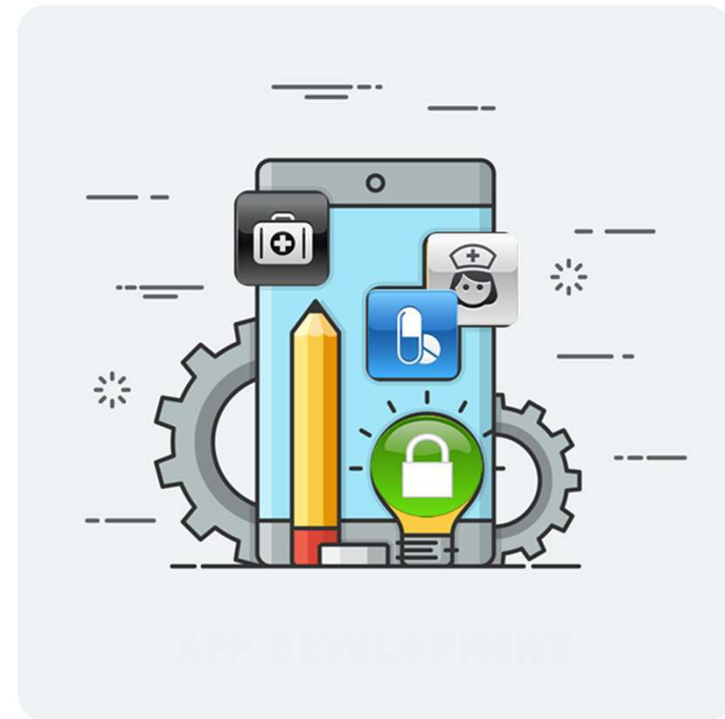


Mobile Health  
September 2019  
HL7 Atlanta GA WGM  
[cMHAFF Project \(HL7 Confluence\)](#)



# 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 cMHAF? 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

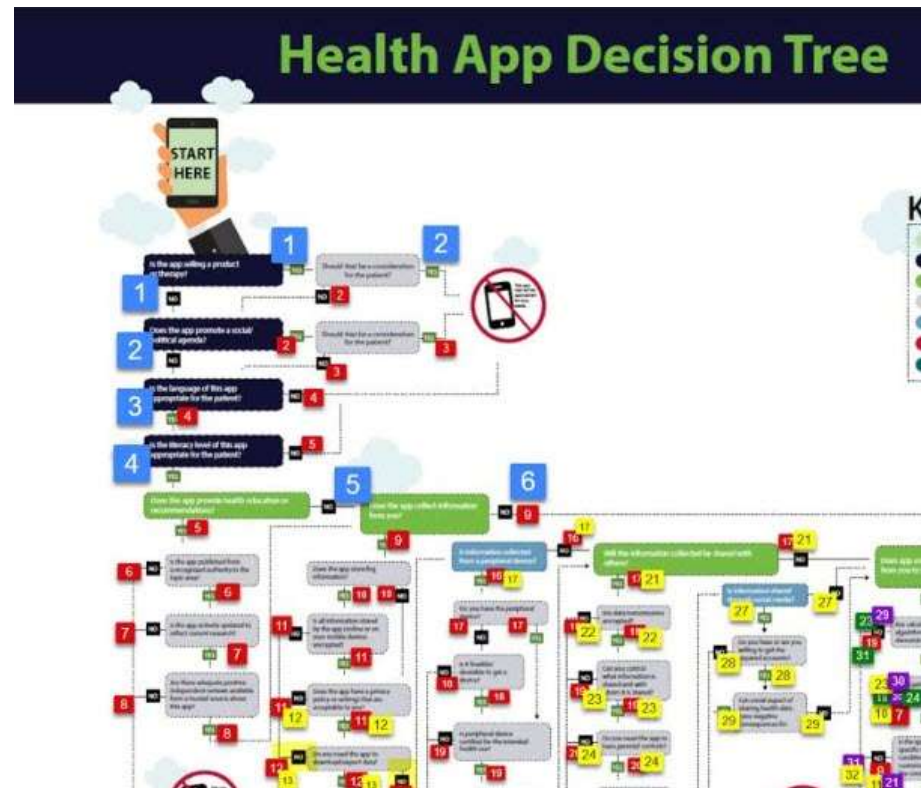


## CMHAFF Next Steps

- CMHAFF to Normative PSS Approved
- Continued development of the CMHAFF Web Guide (<https://cmhaff.healthservice.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



# 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

Health App Decision Survey Results

Recommendation	ORG	CERT	PRIV
 <p>App is promoting a social/political agenda, and that should be a consideration for the patient.</p> <p>Frank's Diabetes App</p> <p>Notes: Testing for CMHAFF conformance</p> <p>Date Finished: 2/7/2019 2:52:27 PM</p> <p>Last Question: A4</p>	<p>Is the app selling a product or therapy? Yes</p> <p>Should that be a consideration for the patient? No</p> <p>Does the app promote a social/political agenda? Yes</p> <p>Should that be a consideration for the patient? Yes</p> <p>Is the language of this app appropriate for the patient? N/A</p> <p>Is the literacy level of this app appropriate for the patient? N/A</p>	<p>Does the app provide health education or recommendations? N/A</p> <p>Is the app published from a recognized authority in the topic area? N/A</p> <p>Is the app actively updated to reflect current research? N/A</p> <p>Are there adequate positive independent reviews available from a trusted source about this app? N/A</p>	<p>Does the app collect information from you? N/A</p> <p>Does the app store/log information? N/A</p> <p>Is all information stored by the app (online or on your mobile device) encrypted? N/A</p> <p>Does the app have a privacy policy or settings that are acceptable to you? N/A</p> <p>Do you need the app to download/export data? N/A</p> <p>Does the app download/export data into a format that you can easily &amp; reliably access? N/A</p> <p>Does the app require external accounts (email, text, social media, etc.) for information collection? N/A</p> <p>Is it feasible/ desirable to get required account? N/A</p>

# Universitair Medisch Centrum Groningen

- 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 [Assesment spreadsheet](#) on confluence

# Children's Hospital of Philadelphia

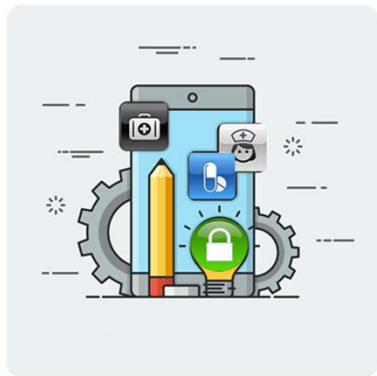
- Used CMHAFF to test validation of the My CHOP patient navigation app
- Pilot conducted between March – April 2019
- CHOP Team found it valuable as a tool for reviewing their health app requirements and considering current maturity.
- Opened new considerations in understanding how to manage nulls, scoring across domains, and some statements that may be too prescriptive.

## Sample of U.S. Policies & Guidelines Assessed

- ISO TC215> ISO/TR 17522:2015 Provisions for health applications on mobile/smart devices
- 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 Mobile Health Workgroup / Monday, January 7, 2019 /  
Categories: Home

## HL7 Consumer Mobile Health Application Functional Framework (CMHAFF)

An HL7 Standard for Trial Use

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 CMHAFF use in testing and potential for certification of health apps.

Search

### HL7 CMHAFF Sections

Introduction	1
Overview ^	5
Exemplary Use Cases	9
Environmental Scan	9
Conformance Criteria ^	1
General Considerations	1
App Development ^	1
Regulatory Considerations	1
Risk Management	1
Usability & Accessibility	1
Technical Support	1
App Implementation ^	1
Product Information	1
Launch App	1
App Usage ^	1
Authentication	1
User Authorization	1
Pairing or Syncing	1
Security for Data at Rest	1
Security for Data in Transit	1
Data Provenance	1
Data Exchange	1
Notifications and Alerts	1

Check out our first draft of the CMHAFF web guide and pilot site at:  
<https://cmhaff.healthservice.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



bsi.

Kanta





# School Healthcare Information Framework utilizing Technology (SHIFT)

- New Mobile Health Project White Paper /PSS
- Birds of a Feather Session – Tuesday 5:15 PM – L501
- [SHIFT Project \(HL7 Confluence\)](#)

## SHIFT - SCOPE

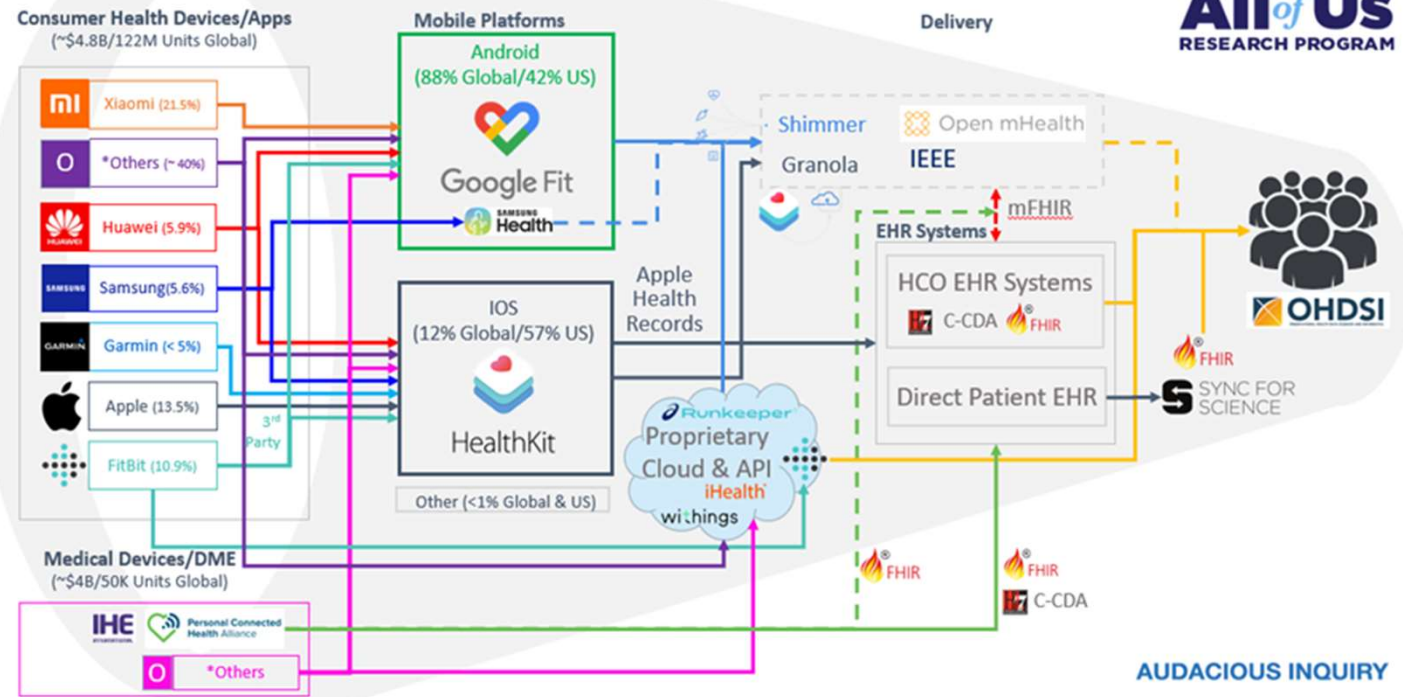
- The scope of the SHIFT Project is to create a Framework that addresses the needs of various stakeholders who are involved in the health and well-being of students to facilitate learning and activities in the school environment. The White Paper envisions the set of healthcare standards that will support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

# Mobile Health App Data Exchange Project Scope

- 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



# 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.
- 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
  - TBD
- Mobile Health App Data Exchange
  - TBD