MOBILE HEALTH APPS CONFORMITY ASSESSMENT & CERTIFICATION GUIDANCE CONCEPT NOTE

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BACKGROUND

The proliferation of Digital Health tools, including mobile health apps and wearable sensors, holds great promise for improving human health[1]. The impact of Digital Health on patient care is accelerating with the increasing adoption of mobile health apps and wearable sensors. As per US-FDA: "The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine."

As of 2019, there are between 400,000 to 500,000[2] health, wellness and fitness apps that run on smartphones, watches, tablets, and other mobile devices, available for download from platform-specific application stores such as the Apple App Store (iOS) and Google Play (Android). This number has rapidly grown from 325,000[3] apps in 2017.

It is envisaged that soon we will have clinicians prescribing mobile health apps to patients, similar prescribing medicines or medical devices[4]. In fact, Germany will soon pass a law in 2020 that will enable German doctors to prescribe health apps[5]. Other countries are also marching down this path.

However, before this becomes as common as prescribing a medicine or a medical device by a provider, the mobile health app needs to safe/secure/accurate not only for the individual user/patient/family member but also for the clinician/payer/provider/regulatory community. Given the era of cybersecurity and its impact on healthcare[6], it is critical that the healthcare informatics standards community looks into this matter now.

PROBLEM

Mobile health apps have access to highly detailed, personally identifiable and clinical information about end-users. Security and privacy are big issues, raising questions about permission control and confidentiality, as well as the integrity of the infrastructure and the individual. There is also a need to clarify how to ensure practicalities of data storage and management, availability and maintenance of the network, as well as compatibility and interoperability. [7]

However, there is no established mobile health app certification process. It is a possibility that we will see a proliferation of non-standardized, country-specific, siloed certification process being established over the next few years. We are already seeing efforts[8] in this area.

[1] https://www.fda.gov/medical-devices/digital-health
[2] https://research2guidance.com/hipaa-gdpr-and-connected-health-interview-with-jovan-stevovic-ceo-of-chino-io/
[3] https://research2guidance.com/325000-mobile-health-apps-available-in-2017/
[4] https://www.medicaleconomics.com/news/finding-mobile-health-apps-work-doctors-and-patients
[5] https://pharmaphorum.com/news/germanys-new-law-allows-doctors-to-prescribe-apps-with-health-benefits/
[6] https://healthinformatics.uic.edu/blog/cybersecurity-how-can-it-be-improved-in-health-care/
[7] https://www.himss.eu/himss-taxonomy-topics/mhealth?page=1
[8] https://www.sspa.juntadeandalucia.es/agenciadecalidadsanitaria/en/safety-and-quality-strategies-in-mobile-health-apps/

STANDARDS IN THIS AREA

In June 2018, HL7® released a STU (Standards for Trial Use) that provides guidance to mobile health app developers in developing a safe and secure mobile health app:

HL7 Consumer Mobile Health Application Functional Framework ***(cMHAFF****), Release 1*

- The primary goals of 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.
- The HL7 confluence project site is: https://confluence.hl7.org/display/MH/cMHAFF+Project
- Additional/current information about cMHAFF is available here: https://cmhaff.healtheservice.com/

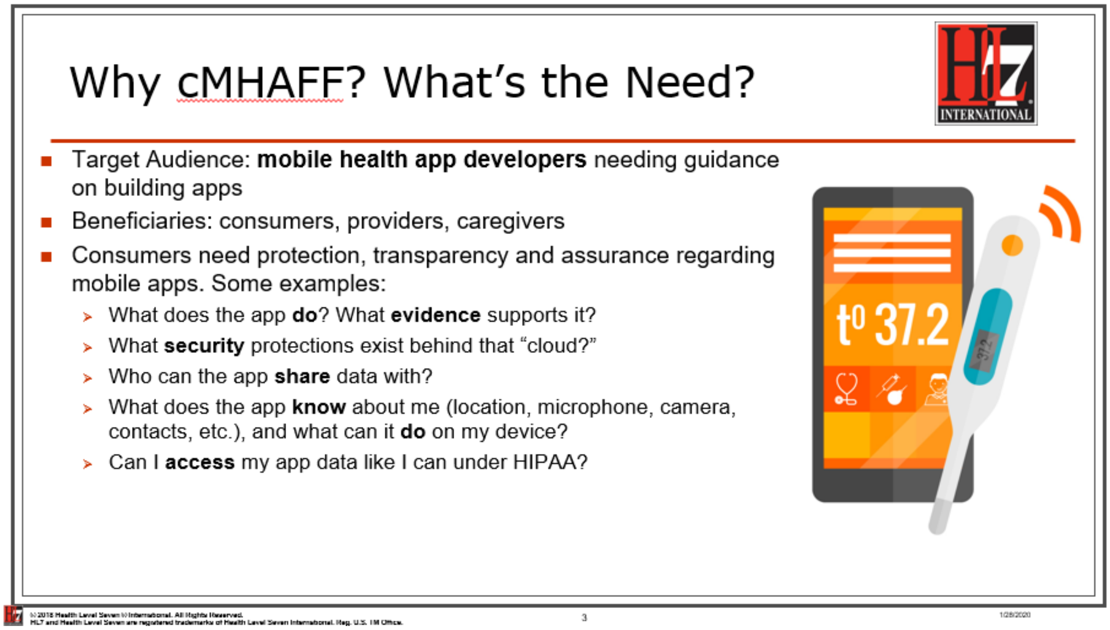
cMHAFF is primarily directed at developers and vendors of mobile health apps for consumers, to assist them in building and marketing apps that educate consumers and protect their privacy, security, data access, etc.

The standard will not address the clinical content of such apps (e.g., "Does it give good advice?"), but will provide a framework for security, privacy, and the integration of data generated from apps into Personal Health Record (PHR) and Electronic Health Record (EHR) systems, as well as into other types of data repositories (e.g., personal data stores, population care systems). Health Apps reference applications running typically on smartphones, but also on other consumer devices such as watches, fitness devices and tablets.

cMHAFF provides a framework for assessment of the **common foundations** of mobile health apps:

- ➢ Product Information (disclosures/transparency)
- ➢ Security (including individual integrity)
- ➢ 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.



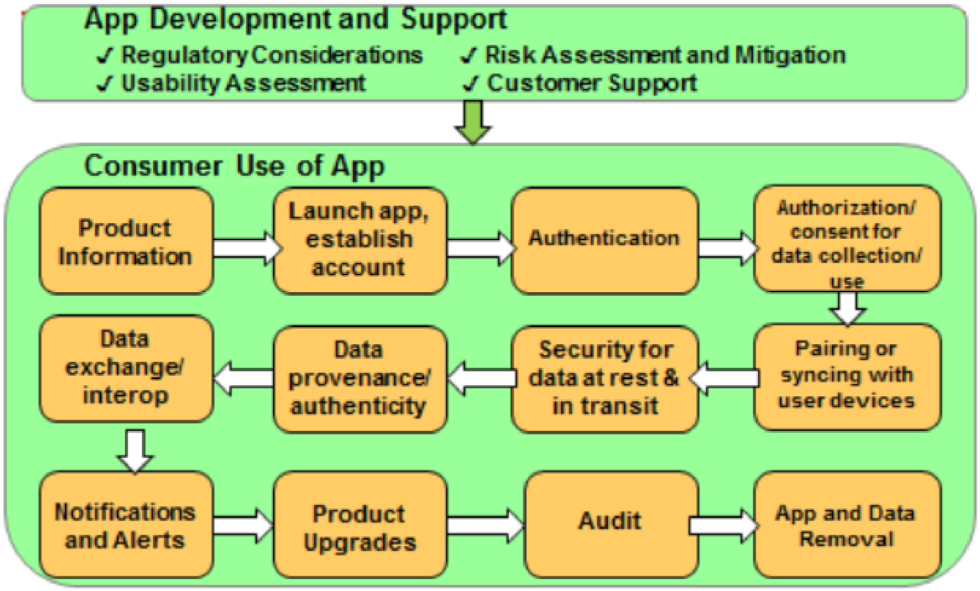
Why cMHAFF? What's the Need?

- 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?

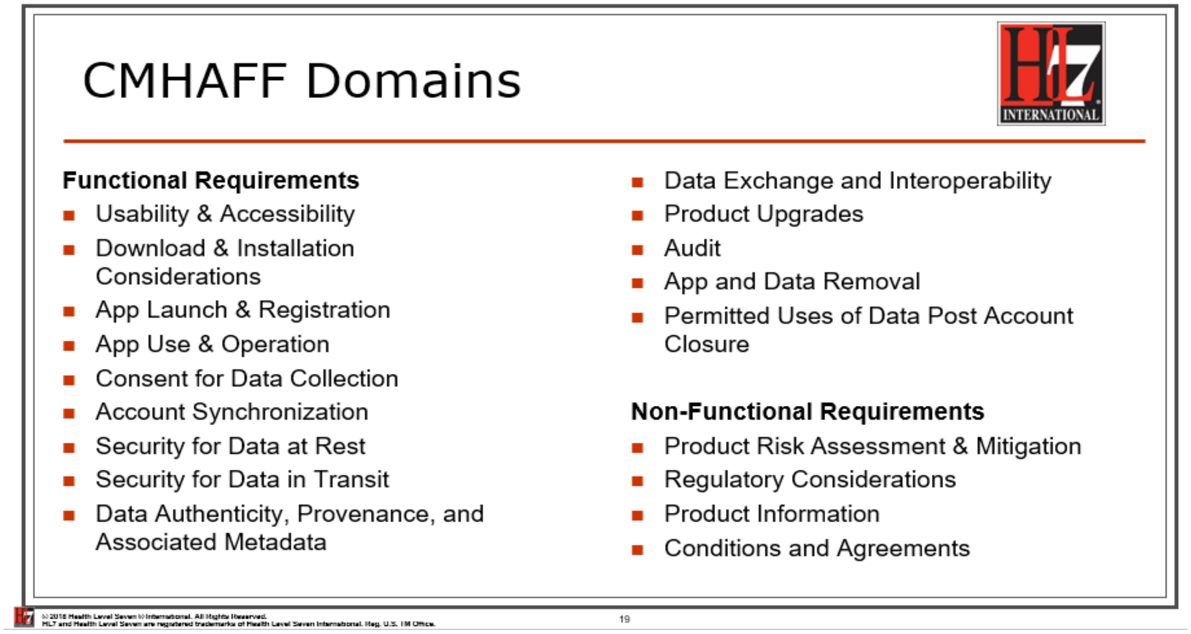
3 1/28/2020

CMHAFF focuses specifically on consumer mobile apps that run on devices such as smartphones, tablets, and wearables. It is focused on the general capabilities, that can be thought of as "horizontal" features that are applicable to most or all apps, rather than to the specific health, clinical, or medical functionality of an app.

CMHAFF Sections and Mobile 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
Pairing or syncing with user devices
Security for data at rest & in transit
Data provenance/ authenticity
Data exchange/ interop
Notifications and Alerts
Product Upgrades
Audit
App and Data Removal

The key domains covered by cMHAFF are:



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

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cMHAFF was developed after reviewing and taking inputs from a variety of international sources:

- U.S. Policies & Guidelines
  - US Health Insurance Portability and Accountability Act (HIPPA)
  - FDA Playbook on Medical Device Cybersecurity
  - NIST Special Publication: 1800-1
  - FTC Cross-Device Tracking Considerations
  - FTC Guidance for mHealth Developers
- ISO Guideline
  - ISO TC215> ISO/TR 17522:2015 Provisions for health applications on mobile/smart devices
- European Guidelines
  - French mHealth Good Practice Guidelines
  - German Mobile Health Assessment Criteria
  - Andalusian App Recommendations
  - U.K. PAS277 Quality Criteria
  - Finland PHR Cert Criteria
  - GDPR (2018 EU law)

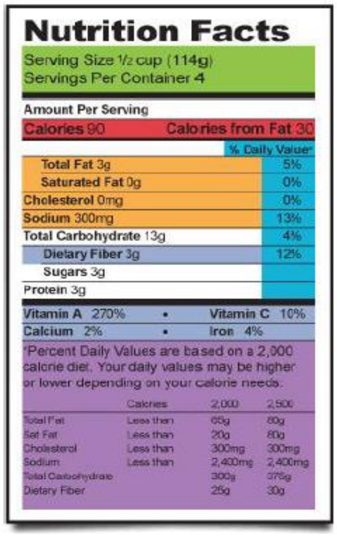
There is also an ongoing ISO/TC215 **TS:ISO 82304-2 Quality Criteria for Health and Wellness Apps**)[9] that is currently under way. The project team intends to present their work as a Technical Specification (TS) by November 2020. *The project was commissioned by EU Commission as "Health and Wellness Apps – Quality and reliability criteria across the life cycle – Code of Practice".*

THE DRAFT TECHNICAL SPECIFICATION IS SLATED TO BE RELEASED IN OCT/NOV 20220.

[9] https://www.nen.nl/Standardization/Health-and-wellness-apps.htm

cMHAFF mLabel: Labelling of Apps

A key feature of cMHAFF is mLabel – a visual summary of the features of the app. This will aid in its assessment whether by an end-user or by a prescriber/regulator. This is very similar to the well-known food product “Nutrition Facts” or “Drug Facts” labels, as depicted below, we all are well accustomed to.



Nutrition Facts

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

Amount Per Serving

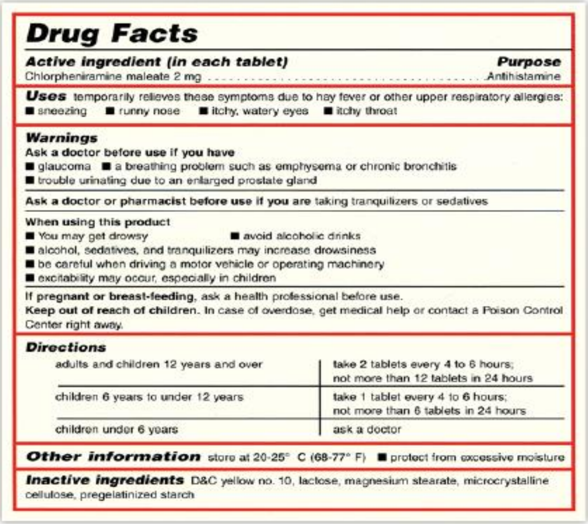
Calories 90 | **Calories from Fat** 30

	% Daily Value*
Total Fat 3g	5%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 300mg	13%
Total Carbohydrate 13g	4%
Dietary Fiber 3g	12%
Sugars 3g	
Protein 3g	

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	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	80g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g



Drug Facts

Active ingredient (in each tablet) — ***Purpose***
Chlorpheniramine maleate 2 mg .... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ You may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

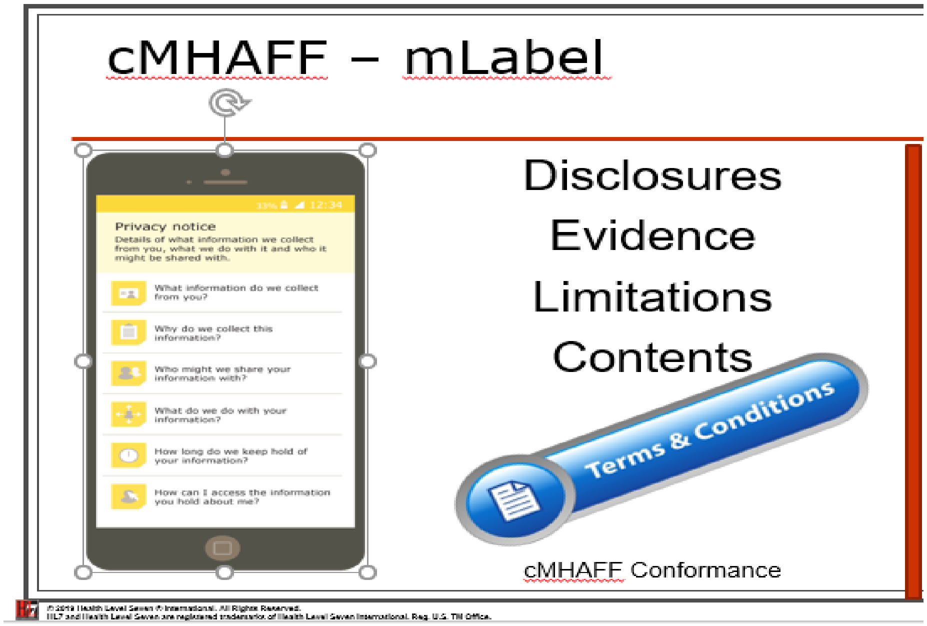
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

For cMHAFF, each “topic” (the sections of conformance criteria) would be represented by an entry, for example a table. We envision an easy-to-understand combination of graphical symbols and colors (red = bad/fail, yellow = middle/partial, green = good/present, gray = not applicable). The label’s information would be provided by a combination of self-attestation (by the app provider) verified by a third party (e.g., assessment or certification body), and possibly supplemented by third party testing (e.g., technical requirements for interoperability, security, etc.).

Here is a future/projected view of cMHAFF: mLabel



cMHAFF – mLabel

Disclosures
Evidence
Limitations
Contents

33% 12:34
Privacy notice
Details of what information we collect from you, what we do with it and who it might be shared with.
What information do we collect from you?
Why do we collect this information?
Who might we share your information with?
What do we do with your information?
How long do we keep hold of your information?
How can I access the information you hold about me?
Terms & Conditions

cMHAFF Conformance

Unlike Nutrition Fact or Drug Fact labels, mLabel is dynamic in nature. Its digital representation will allow for representing local/regional/country-specific information and regulations. The hyper-link capability, when present on a mobile device (as a part of a mobile health app), will allow the user to quickly drill-down and locate additional information about the app.

ISO/TC215 WG1, in collaboration with HL7 Mobile Health WG, is evaluating developing an ISO/TC215 technical specification (TS) document for mLabel.

CONFORMITY ASSESSMENT[10,11]

IEEE Conformity Assessment Program (ICAP) develops and implements programs that couple standards development activities with conformity assessment activities to help accelerate market adoption while reducing implementation costs.

Conformity assessment involves a set of processes that show your product, service or system meets the requirements of a standard. When applied to product, it involves testing to an established performance standard, as well as inspection, quality management, surveillance, accreditation and declaration of conformity. Undergoing the conformity assessment process has a number of benefits:

- It provides **consumers** and other stakeholders with added confidence, security and integrity.
- It gives your **company** a competitive edge.
- It helps **regulators** ensure that health, safety or environmental conditions are met.

RECOMMENDATION

It is recommended that a "consortium" of following entities be established to create standards to address issues related to a uniform conformity assessment framework and subsequent certification of mobile health apps:

- IEEE Standards Association (lead entity)
- ISO/TC215
- ISO CASCO
- CEN/TC251
- HL7 International
- ITU-T
- US-FDA (Food & Drug Administration)
- EU-EMA (European Medicines Agency)
- HIMSS
- IHE
- WHO
- US-NIST
- International Medical Device Regulators Forum (IMDRF)
- Multilateral Agencies
    - The World Bank

[10] https://standards.ieee.org/products-services/icap/index.html#programs
[11] https://www.iso.org/conformity-assessment.html

  - Asian Development Bank
  - African Development Bank
- Other competent international authorities/bodies

As notes earlier in the document, not having a collaborative approach amongst various global stakeholders runs the risk of seeing a "proliferation of non-standardized, country-specific, siloed certification process being established over the next few years" in the mobile health app space.

Another aspect that was briefly mentioned earlier and is critical for mobile health app usage, by both patients and healthcare providers, is the impact of cyber security on these apps[12].

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- (founding) Co-Chair HL7 Mobile Health
- Convenor ISO/TC215 Standards & Conformance
- Convenor ISO/TC215 WG#10 Traditional Medicines
- Convenor ISO/TC215 Outreach & Communications
- Chair IEEE Healthcare: Blockchain & AI Virtual Series
- Chair SUSTECH2021: 8th IEEE Conference on Technologies for Sustainability
- Chair IEEE Southern California Council
- Chair IEEE Southern California CyberSecurity
- Secretary IEEE-USA US Government Communities of Interest (USG CoI)
- Treasurer IEEE Orange County Section
- Vice Chair IEEE OC Section EMBS Chapter
- Industry Director, Smart Pandemic Management, University of California @ Berkeley
- Executive Director, P3 Innovation Center (CA based non-profit)

[12] https://www.nccoe.nist.gov/news/security-recommendations-mobile-health-apps