Leadership Corner: First Newsletter & Sub-Groups

By Gora Datta

On behalf of the HL7 Mobile Health Work Group co-chair team (Gora Datta, Matthew Graham & Nadine Manjaro), it is my pleasure and honor to welcome the readers to the 1st edition of the HL7 Mobile Health Work Group (MHWG) Newsletter.

Even though as an HL7 WG, we are yet to celebrate our 1st anniversary (which will be in September 2013), we have taken off in full swing!

Our WG mission is to “create and promote health information technology standards and frameworks for mobile health”.

Our weekly WG conference call is held every Friday at 11am EST (US). Our wiki address is: [http://wiki.hl7.org/index.php?title=Mobile_Health](http://wiki.hl7.org/index.php?title=Mobile_Health)

Join us at the HL7 Mobile Health ListServ and write to us at "mobilehealth@lists.HL7.org".

Given the global interest and the varied scope of mobile health, the MHWG members decided, early on, to establish Sub-Groups (within the MHWG) to tackle different areas of concentration. At present, we have the following Sub-Groups:

- Definition, Scope and Context (DEF)
- Education and Communication (EDU-COM)
- External Standards Gap Analysis (EXT-STD)
- Low to Medium Income Countries (LMIC)
- Security (SEC)
- Standards Gap Analysis - PHR/Mobile (STD-GAP)
- Use Case Development/ Scenario (UCD)

We envision the activities of the HL7 MHWG to be more horizontal in nature that cuts across the various vertical domain focused WGs within HL7. Mobile Health is more than healthcare on a mobile devices!

As a WG, we see ourselves not only working with other Work Groups within HL7 but also collaborating with other organizations globally to create and promote health information technology standards and frameworks for mobile health; thus enabling (health) care and access to one and all – urban or rural, low income or high income – across the globe and beyond!

Gora Datta is (founding) co-chair HL7 Mobile Health Work Group, HL7 Ambassador & Group Chairman & CEO, CAL2CAL Corporation

In this issue:
- Leadership Corner & Vision
- Meetings, Sub-Groups, Wiki
- Mobile Health Standards and Consumer Health
- Mobile Health Information and Public Health
- Policy updates in USA
- Industry updates cases in US
- Mobile Health Events
The concept of a Mobile Health Work Group (MHWG) started in April 2012. Between April and September 2012, a team of interested parties met weekly and later nominated interim co-chairs. During this time, the work group defined its Mission and Charter and submitted its application to become an official work group. However it was not until the September 2012 Working Group Meeting in Baltimore that the MHWG elected co-chairs and officially launched as a HL7 work group.

The first official duties of the group began with meeting with other HL7 work groups to understand their requirements for mobile health based on known gaps. As a result of those meetings, MHWG began work activities with a gap analysis of existing HL7 and non-HL7 standards related to mobile health. Other activities include developing the work group’s education and communication plans. The focus of the early activities is to find the gaps for mobile health then address the gaps either through implementation guides or new standards.

The MHWG defined its action plan for the rest of 2012 and 2013. Initial areas of focus include: defining mobile health, reviewing internal and external HL7 standards and developing internal and external HL7 communication regarding MHWG activities. Other work activities include a review of Mobile Health around the world, developing mobile health security guidelines, defining mobile health scope and context and developing mobile health use cases. Use cases will cover patient’s and practitioner’s point of view, public health and solutions for developed and low to middle income countries.

The 2013 plan includes a more in-depth analysis of the standards with scenarios and more defined use cases. Business requirements for low income countries will also be developed. One example use case will address public health for disease outbreak. The team will also consider and develop regional specifications for mobile health. The team will narrow its focus to specific areas of work. Then project scope statements and project plans will be developed and executed over the rest of the year into 2014.

The Mobile Health Work Group is ready to address the challenges impacting mobile health. We will begin by surveying the landscape of mobile health then defining standards and guidelines to address any gaps. MHWG will collaborate with others organizations to further the development of mobile health. We will work to ensure open and transparent communications within and external to HL7 and to educate the public about mobile health.
The global mobile health market was estimated to have approached 1 billion dollars in 2011 with the United States (U.S.) alone generating revenues of approximately $600 million. A significant portion of this market is made up of Mobile Health tools targeted to consumers. The proliferation of mobile health devices and applications witnessed in the last year within the consumer market, spurred by “mobile app” markets supported by mobile device makers such as Apple and Google leave no doubt as to the impact that these tools will have on the way that people manage their health, health information, and health communications with their care providers, family and friends. This shift to increased self-management of health by consumers will change a patient’s relationship with their doctor and the way healthcare is practiced.

Mobile health resources broadly range between applications and devices that help consumers manage lifestyle, fitness and medical aspects of their health through wireless mediums of communication. HL7’s newly launched Mobile Health Workgroup’s charter includes goals for identifying data standards and functional requirements that are specific to the mobile health environment and assisting in promoting mobile health concepts for interoperability as adopted and adapted for use in the mobile environment. As the consumer mobile health market continues to grow it will be important for the mobile health workgroup to consider the unique aspects of consumer use of mobile health tools so that application developers, vendors, users, certification bodies and policy makers can be informed by and apply adopted standards where appropriate.

Domains of particular importance to consumers will include standards that address issues of privacy, security, health information communication, and standards related to safety and quality. The current laws and standards in place to ensure patient’s privacy and health information security will need further review to determine whether mobile mediums and messaging technologies create unique situations that are not yet addressed. A prominent U.S. based law related to this issue is the Health Insurance Portability and Accountability Act (HIPAA) of 1996. In short, this law describes the rules that covered entities need to follow when sharing and managing personal health information of the patients who use their services. Issues related to the growing use of mobile-specific communication mediums such as Short Message Services (SMS or “texting”) for healthcare communication require experts and administrators to reassess some of the original language of these statutes in order to make sure that it appropriately addresses the situations that these new instances of healthcare imply. As we create opportunities to increasingly educate and communicate with patients about their health we do not want to limit these innovations, but need to make sure that we are still protecting their privacy and security rights.

The wearable device market is also being bolstered by a trend that is estimated to grow to upwards of a 1.5 billion dollar market by 2014. This burgeoning field has created the need for new health network architectures and standards and is frequently being referred to as medical body-area networks (MBANs). In the U.S., the Federal Communications Commission (FCC) has recently allocated spectrum for the MBANs that wearable devices will use to communicate passive, physiological data. The FCC has also worked to develop a Mobile Health task force with priorities focused on addressing issues related to health network spectrum access as it affects rural health environments, international harmonization and experimental licensing test beds for mobile health testing and innovation.

Depending on the type of care or information provided by mobile health tools, vendors will need to obtain governmental approval in order to ensure public safety. The lines between mobile health tools and medical devices are so blurred now that it would be hard to separately classify them. Medical devices may be innocuous to the degree that they provide convenient health information or used specifically for direct life support of the consumer. A majority of current mobile health tools are predominately used to either record or disseminate health information or gather passive health data such as blood pressure monitoring. However, as mobile health tools advance and as consumers increasingly rely on them for consultation and health support it will be important to ensure public safety. Accordingly, standards for the development of mobile health tools will need to speak to and be harmonized with governmental standards both to increase consumer safety and to provide guidance to developers as they seek to test and market their tools out to the broader market.

It’s an exciting time in consumer health and much of this excitement can be attributed to technologies such as mobile health that are making personal health information and devices more accessible to the consumer and the provider. Important to the concept of health networks such as those supported by MBANs is the notion that there is a shift in the point of care for the patient. The point of care has classically been located at the hospital or clinic. Mobile health is beginning to shift this model so that the point of care is more frequently a matter of where the person happens to be located at that time. It is also important to note that these tools help to increase the accessibility of Healthcare to populations where direct access to Healthcare professionals is limited and so health management is more frequently left in the hands of the consumer. In understanding this shift to the consumer, mobile health standards will need to take into the account the social and technical environments in which mobile health technologies will function and evolve.

REFERENCES

Nathan Botts is Senior Study Director for Center for Health IT, Westat and Chief Technology Officer at HealthATM
The advent of mobile devices and applications has given the Healthcare industry an opportunity to revise the communications that occur between healthcare providers and patients. Question: What, if any, of that information could also serve as new data sources to help lay the groundwork for improving public health? And what issues need to be carefully considered?

Early success stories reveal the positive impacts of using mobile devices for reminders and monitoring. One example is the Cleveland Clinic’s use of mobile devices to remotely monitor patients with chronic diseases. Their results:

- Patients with heart failure were able to visit their doctors 27% more often, enabling their physicians to better detect conditions requiring medical attention;
- Patients with diabetes increased their number of days between appointments by 71%;
- Patients with hypertension increased their days between appointments by 26%.


Mobile devices are also currently being used in healthcare to help manage:

- Chronic conditions – including management of diabetes, chronic heart disease, or asthma;
- Prevention – which can include smoking cessation and medication adherence;
- Health and wellness – such as exercise monitoring or diet control;
- Other dimensions of Healthcare.

From a health information management perspective, several areas need to be examined when considering the use of mobile technology including: privacy and security, the means by which information is captured, the quality of the information, the information’s relationship with the health record (including regulatory compliance), its use in helping to make patient care decisions, and its subsequent use in research and analytics. All of these mobile health–related areas present a challenge – and an opportunity – for the field of public health.

Vera Rulon MS, RHIT, AHIMA Fellow is the director of strategic communications for Pfizer Medical Communications and is a past president of AHIMA
Policy updates in USA: FDA, FCC and ONC By Kosta Makrodimitris PhD, CF-FDA, CP-EHR

More than a year ago in July 19, 2011 FDA published a guideline to request public comments on regulating mobile medical applications. In general FDA plans to regulate a small subset of medical devices that pose high risks for patient safety:

- Controlling the intended use, function, modes, or energy source of the connected medical device are used as an accessory to a regulated medical device.
- Transforming or making the mobile platform into a regulated medical device using attachments, display screens, sensors or other such similar components.
- Creating alarms, recommendations or creating new information (data) by analyzing or interpreting medical device data.

This guidance does not specifically address wireless safety considerations, classification and submission requirements related to clinical decision support software, or the application of quality systems to software. The FDA intends to address these topics through separate guidelines. FDA does not consider to regulate EHR/PHR, Electronic medical textbooks, information for wellness.

President Obama signed the bipartisan Food and Drug Administration Safety and Innovation Act (S. 3187), in July 2012. The law allows the FDA to move ahead with plans to regulate mobile medical applications. In parallel, the Department of Health and Human Services is assigned to develop a report on an "appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications that promotes innovation, protects patient safety and avoids regular duplication."

In March 2012 ONC-HIT (DHHS) initiated a Mobile Devices Roundtable: Safeguarding Health Information. HL7 PHR/EHR team provided comments after working together to evaluate a comprehensive approach to security and privacy.

The public comments were provided from the HL7 perspective on the following areas:

- Trustworthiness of Mobile Device information sources.
- Possibility of Consumer and other alterations of professionally-sourced data.
- Possibility of insufficient/unexpected Governance or Management of professionally-sourced data.
- Interoperability standardization within health information exchange environments.
- Functionality (or capability) – nuances of various information exchange systems.
- Various types of Mobile Devices.
- Amount or Type of Data.
- Labeling of mobile devices (and corresponding software) as "regulated" by the FDA.
- Configuration of the parameters that control mobile device information delivery and/or display.
- Location of Data-At-Rest.
- Consents, Authorizations, and other Governance issues.
- Mobile Device functionality and/or data covered under HIPAA regulations – Or not?
- Management of lost, stolen, or misplaced mobile devices.
- Location Awareness Services.
- Use of multiple mobile devices.
- Difference between patient-entered & patient-sourced data.

In June 2012, the FCC (Federal Communications Commission) created a Mobile Health Task Force from a group of the nation’s leading mobile healthcare IT industry, including government and academic experts, according to a recent press release. This group generated a report with recommendations on Mobile Health technology use, released on September 24th. Last month mHealth task force (FCC, industry, government) offered recommendations for Mobile Health adoption and strategies. Subsequently FCC released document to act on these recommendations and here is the related blog.

FCC and other agencies (FDA, ONC, FTC..) are working together to ensure patient and consumer safety and security. The Federal Communications Commission (FCC) regulates interstate and international communications by radio, television, wire, satellite and cable. The FCC manages radiofrequency (RF) communications to ensure that RF devices operate efficiently and without interference. In healthcare the FCC authorizes a wide variety of RF-based medical devices including both implanted devices and patient monitoring devices. It also authorizes carriers whose networks are used by a wide variety of mobile devices to access, store or transmit health information.

The Mobile Health universe is complex, interconnected and multidisciplinary. Policies affect many stakeholders nationwide and globally. See below the Figure 1 for Mobile Health stakeholders and dimensions.

Dr. Kosta Makrodimitris is Advisor and Strategist in Biomedical/Health Informatics, Policy, Standards & Innovation. He worked at Johns Hopkins, IT/Analytics industry and the government (US-FDA, DHHS and MD state).
Figure 1

Mobile Health Dimensions & Stakeholders

Technology
- Health IT
- Devices/Mobiles
- Telemedicine
- Security

Policy
- Gov(federal-local)
- Advocacy-Lobbies
- Prof. Associations
- Standard Dev Orgs

Science
- Universities
- Informatics
- Engineering
- Health/Bio

Business
- Providers
- Payers
- Vendors
- Telecom/Health

Society-Culture
- Consumers
- Patients
- Foundations
- Media-News-Arts
We intend in the future to include and describe many representative Mobile Health applications nationwide and globally. Here are some popular Mobile Health applications and cases in US:

**INDUSTRY**
1. Mobile EHR, voice recognition - patients/doctors
2. HealthVault - Personal Health Record Mobile
3. IndiGO - for mapping patients health risk
4. Mobile Application: diabetes, chronic disease
5. PHR, iTriage - Medicity coordination of care
6. Patient App, health info, management tips
7. Mobile charge and capture for Physicians
8. Mobile solution to manage healthcare, HIPAA
9. Secure Real-time Mobile Video, HIPAA
10. The 2net Platform for wireless health solutions
11. Mobile Health platform as open ecosystem
12. Chronic diseases Nantworks, vital data Airstrip
13. PRIME - mobile access to patient & workflows
14. Private-secure platform to connect doctors
15. The calPHR & calDR for developing countries

**PUBLIC HEALTH US AGENCIES**
1. NIH/NCI (smokefreetxt, quitstart teen)
2. CDC (tips and emergency SMS, ASPA)
3. SAMHSA (Treatment Locator information about mental health and substance abuse centers)
4. CMS & states (mobile-facing initiatives, such as the mobile version of the InsureKidNow.gov)

**CURRENT TRENDS**

Mobile Health applications in US market will see revenues grow from $230 million in 2010 to $392 million in 2015, according to research from Frost & Sullivan. The study projects there will be 82 million tablet users by 2015, up from 10 million in 2010.

Global Data research found that the global Mobile Health market was worth $1.2 billion in 2011, and will reach $11.8 billion by 2018.

**REFERENCES**
- Analysis of the U.S. Broadband mHealth Applications Market - Frost & Sullivan: Unlocking the Door to Mobile Health App Opportunities mHealth applications in US and globally
- Telehealth and Telemedicine – Global Opportunity Assessment, Competitive Landscape and Market Forecasts to 2018

Dr. Kosta Makrodimitris is Advisor and Strategist in Biomedical/Health Informatics, Policy, Standards & Innovation. He has worked at Johns Hopkins, IT/Analytics industry and the government (US-FDA, DHHS and MD state).

Matthew Graham is Technical Specialist working at Mayo Integrated Clinical Systems (MICS) on the CDM Reports Project as team lead and systems architect. He is interim co-chair HL7 Mobile Health Work Group.
MEETINGS, WEBSITE

The HL7 Mobile Health Work Group general meetings are held on Friday weekly at 11am EST(US).

HL7 Mobile Health Sub-Groups have regular meetings weekly and biweekly. Check the wiki below for more information.

WEB: www.HL7.org/Special/committees/mobile
WIKI: wiki.HL7.org/index.php?title=Mobile_Health
ListServ: mobilehealth@lists.HL7.org

Volume 1, Issue 1 - Publication Date: 2013-02-21

Editor:
Kosta Makrodimitris

Co-Chairs:
Nadine Manjaro, Gora Datta, Matthew Graham

Editorial Board:
John Ritter, Nathan Botts, Ann Wrightson

Next issue
May-June 2013:

Industry updates 1
Mobile Standards 2
Literature review 3
History-Innovation 4
Mobile Health in EU, AU 5
HL7 Mobile Health meeting in Atlanta 6