Brief Report

Integrating Patient-Generated Health Data from Mobile Devices into Electronic Health Records

Best Practice Recommendations by the IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

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Abstract

Background

An increasing number of wearable medical devices are being used for personal monitoring and professional health care purposes. These mobile health devices collect a variety of biometric and health data but do not routinely connect to a patient's electronic health record (EHR) or electronic medical record (EMR) for access by a patient's health care team.

Methods

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM) developed consensus recommendations for consideration when interfacing mobile health devices to an EHR/EMR.

Results

IFCC C-MHBLM recommendations cover personalized monitoring and privacy concerns, data security, quality assurance of data transfer, and incorporation of alert triggers to warn users of important health conditions.

Conclusions

Considerations for interface ease-of-use, display of patient data in the EHR/EMR, and needs-based training programs for healthcare staff to understand the critical requirements, proper

use, and integration of mobile health devices with EHR/EMRs are provided. Cooperation between healthcare providers, device manufacturers, and software developers is also recommended to drive future innovation in mobile health device technology development.

Introduction

The field of medicine stands as one of the disciplines most significantly influenced by the widespread availability of mobile devices. The use of mobile devices by health care professionals has transformed many aspects of clinical practice [1,2]. Mobile devices have become commonplace in health care settings and at home, leading to rapid growth in the development of medical software applications [3]. These tools can enhance patient experience, engagement, activation, and satisfaction by allowing patients to view and understand their health data through visual or auditory representations provided by the software applications [4,5]. Yet, we have not achieved a shared understanding of important mHealth constructs or how to conceptualize and operationalize them [5,6]. Patient centered mobile health (mHealth) is therefore seen as a challenging opportunity with still open questions related to the conceptual realization [5]. With all the new data available from these burgeoning mobile devices and their partner software applications, a challenge has arisen on how best to integrate these myriad data into a patient's electronic health record (EHR) or electronic medical record (EMR) to maximize positive clinical impact while minimizing complexity. Institutions may employ different EMRs that may not communicate with each other, while a patient's EHR may follow them between healthcare systems, state and international borders. These mobile health data recommendations apply to both EHRs and EMRs and are referenced as EHR/EMR in this guidance.

Healthcare data monitoring systems can be classified as follows: Remote Health Monitoring Systems (RHMS), which include systems that can send and/or receive their data remotely; Mobile Health Monitoring Systems (MHMS), an RHMS extension that uses smartphones or other mobile devices for local data processing on demand; Wearable Health Monitoring Systems (WHMS), where mobility is further enriched through wearable devices/sensors; Smart Health Monitoring Systems (SHMS), where "smart" denotes the approach and associated devices. In these systems, MHMS can leverage the local processing capabilities of mobile devices to analyze collected data and determine whether critical conditions exist. In such cases, an immediate alert is generated and communicated to medical staff, whereas normally, data upload is not done in real-time to reduce power consumption [7].

The World Health Organization defines mHealth as "medical and public health practice supported by mobile devices." Mobile health technologies refer to a variety of wearable devices that include "wellness devices" that monitor biometric and health data – heart rate, sleep, exercise and pedometers, "personal emergency response systems" – medical alert systems, dementia-related monitoring cameras, motion and fall detection, and "remote patient monitoring" – telehealth and medication tracking (telemedicine: healing from a distance) [8].

For these recommendations, mobile health technologies are digital applications, wearable devices and monitoring equipment that collect continuous or periodic data. This data is transferred and stored in the manufacturer's servers and can be accessed through software applications on a phone, computer, or other connected equipment, like Chromebooks or iPads, to allow for analysis and trending of personal health data.

Mobile devices and applications offer numerous potential advantages for healthcare professionals demonstrating their efficacy in enhancing clinical decision-making and fostering improved patient outcomes, whereby the effectiveness of health interventions based on mobile phone or tablet applications varies largely between indications [9,10]. Mobile health is a new way of communication, and we have not achieved a shared understanding of important mHealth constructs, or how to conceptualize and operationalize them [5,6]. Alongside the potential benefits, it is imperative to establish robust quality and safety standards, as well as validation practices, for mobile medical applications. This ensures their appropriate utilization and seamless integration into medical practice, especially considering the advancing sophistication of these tools. Recent advances in wearable devices have attracted significant attention due to their ability to provide continuous physiological information for continuous health monitoring by detecting biological signals. To make sense of the collected biological data and improve the effectiveness of these biosensors, scientists have integrated machine learning (ML) into wearables to analyze large data using various ML algorithms. Also, new information and communication technologies using the Internet of Things (IoT) have contributed significantly to integrating various areas of the healthcare sector with mobile technology. Thus, the technology could become a powerful medical tool to support the healthcare sector at all levels of care [11,12].

Wearable devices can provide real-time feedback regarding a person's health conditions; hence, they can provide an objective alternative to manage and monitor chronic disease progression, such as with the elderly, with rehabilitation, and for those with various disabilities. Wearable sensors are widely used in healthcare, due to their hardware capacity, small footprint and lower cost compared to equivalent medical instruments capable of monitoring the same vital signs. Furthermore. wearable technology decreases the cost of intensive treatment by allowing rehabilitation outside of the hospital in an ambulatory environment. According to recent estimates, wearable technology will flourish over the next 25 years, resulting in a global cost savings of over $200 billion in the healthcare industry and a considerable reduction in clinician/patient interaction time. Reports suggest that the number of wearable devices in use in 2020 was approximately 600 million, and current trends predict the number to increase to 928 million in 2021, and to reach 1100 million in 2022 [13].

What data is collected by mobile health devices?

The capability to download medical applications on mobile devices has unlocked a wealth of clinical and medical resources. These applications cover a wide range of functionalities, including electronic prescribing, diagnosis and treatment support, clinical guidelines, decision support aids, textbooks, and literature search portals. Mobile health devices collect biometric and personal health data from the wearer, such as heart rate, body temperature, activity (sleep/wake/exercise), alerts such as falls, and medication tracking. Some devices may collect analytes like glucose (CGM – continuous glucose monitors) through minimally invasive sensors that sample interstitial fluid under the skin or oxygen saturation through spectrophotometric scans of capillary blood under a wearable device. While called "continuous", mobile health devices sample the wearer, periodically or intermittently, every several minutes. Software applications can analyze data to calculate average, minimum/maximum, and trends, such as rate of rise or fall. The software can also predict future events, like hypoglycaemia, based on the rate of glucose fall and alarm the wearer before an event. Having alert system triggers for certain extreme or life-threatening conditions such as severe hypoglycemia, a patient fall, or significant cardiac arrhythmias, can activate a medical emergency response or follow-up for the affected patient. This may require having a command center that monitors those life threatening indicators around the clock and activate appropriate response when required. Biometric data can also be linked to information provided by the wearer about their health status through software applications - type of exercise, duration of exercise, sleep and wake times, meals and caloric intake, as well as menstruation cycle/fertility or general wellness (sick, fever, healthy).

Why is interfacing of mobile health data important?

Interfacing mobile health data is vital for advancing healthcare delivery, improving patient outcomes, and fostering innovation in medical research. It bridges the gap between technology and healthcare, creating a more integrated, efficient, and patient-centered healthcare ecosystem.

Several issues challenge the future integration of mobile devices and applications into health care practice. Mobile health devices don't currently interface with an EHR/EMR). While personal data is viewable by the device owner, software applications store the data in the manufacturer's computer servers rather than transmit the data to an EHR/EMR. This allows the manufacturer access to a tremendous amount (big data) of personal health information that could be mined for predictive health and population health trends. Yet, a person's primary health team can access only the data if trends are viewed from a software application during an office visit or data is printed as a summary report. Some institutions have developed research interfaces to devices, like CGM, that allow upload of a person's data during a healthcare visit. Still, routine interfacing of CGM and other wearable devices and monitors is not expected for a few years. Lacking an interface, many institutions scan printed summary reports into the EHR/EMR to allow clinicians access to the personal data trends. This is a manual process and can lead to lost data (if not scanned) or worse, the possibility of scanning data to another person's EHR/EMR. The security of personal health data is a concern for any interface that could allow computer hackers access to personal health data. So, encryption and other security measures to protect the confidentiality of health data must be considered. Fidelity of the data is also a concern during transmission to ensure that health data will be accurately recorded in the EHR/EMR. It should be pointed out that most of today's medical data lack interoperability: hidden in isolated databases, incompatible systems and proprietary software, the data are difficult to exchange, analyze and interpret. This slows down medical progress, as technologies that rely on these data – artificial intelligence, big data or mobile applications – cannot be used to their full potential [14].

Securing mobile devices is a complex task that requires constant vigilance. Although security technologies are advancing and healthcare professionals are increasingly focusing on cybersecurity, healthcare organizations must always prioritize data protection in an environment of growing threats. Basically, healthcare professionals are responsible for protecting the privacy, security, and confidentiality of electronic health information [15]. To counter this threat, it is essential to adopt effective mobile security solutions and implement new security measures as soon as they become available. Healthcare professionals and IT companies must also conduct regular audits to ensure the security of their systems and data.

Where should mobile health data reside and be displayed in the electronic medical record?

Biometric data collected from a personal mobile device should be recorded and displayed in the EHR/EMR where other vital signs such as pulse, heart rate, and blood pressure are recorded during a patient visit. It is essential to distinguish vital signs recorded by healthcare professionals from data received from a personal mobile health device. This is particularly important when mobile health devices collect analytes like glucose. The quality of clinical laboratories is highly regulated by the Clinical Laboratory Improvement Amendments law in the US and ISO standards and local regulations in various countries globally. So, the display of CGM data should be separated from the display of laboratory, blood gas, or glucose meter results since CGM is not regulated like a laboratory test. One possibility would be to display CGM data with other monitoring data, such as oxygen saturation from pulse oximeters. This would allow the separation of health data collected from personal mobile devices from regulated laboratory test results in the EHR/EMR. However, clinicians may want to monitor data side-by-side with laboratory results to compare trends - such as CGM trends displayed next to laboratory glucose trends. So, EHR/EMR support staff should develop future report displays that allow clinicians to customize their views of data while clearly labeling what information in

the EHR/EMR came from mobile health technologies versus regulated laboratory test results for future laboratory and healthcare inspections.

Key Recommendations

1. **Personalized monitoring and Privacy concerns**
   Mobile health technologies empower people to take charge of their healthcare by monitoring personalized data about themselves. It also ensures compliance with privacy regulations and guidelines to safeguard patient confidentiality. EHR/EMR should comply to local laws or code of ethics for patient confidentiality, like HIPAA, "Health Insurance Portability & Accountability Act", an American federal law that sets standards to protect medical records and other personal health information.
2. **User Interface**
   Biometric, monitoring, and other personal health data collected from mobile devices should be made accessible to the primary care team and clinicians respecting national legal regulations. User-friendly interfaces between mobile health devices and EHR/EMR should be developed.

3. **Data Security**
   Implement robust data security measures to protect patient information during transmission and storage. International guidelines and cooperation should address encryption protocols, authentication mechanisms, and access control policies. Mobile health technology interfaces must ensure secure transmission and accuracy of data recorded in the EHR/EMR.

4. **Staff Training**
   Develop targeted training programs for healthcare staff to effectively utilize and integrate mobile health devices with EHR/EMRs though not limited to device setup, data entry, troubleshooting, and data interpretation. Thus, training should emphasize the importance of distinguishing mobile health device data from regulated laboratory test results. Ensure mobile health data, alongside other monitoring data, like pulse oximetry and vital signs, is recorded appropriately in the EHR/EMR, and not in the laboratory result section of the EHR/EMR.
5. **Quality Assurance**
   To establish quality assurance protocols to ensure the accuracy and reliability of data obtained from mobile health devices. This may involve periodic calibration, validation studies, and performance monitoring as per international standard or equivalent guidelines. Emphasize user education of self-calibrating mobile devices for regular correlation against laboratory testing or standard methods to be informed about the accepted tolerance for calculated inaccuracy in order to be empowered to make decisions to either correct for bias or replace the device.
6. **Alert Triggers**
   Incorporate alert triggers for mobile health devices that target industry stakeholders, users, and regulatory boards:
   - Industry stakeholders must ensure consistency in data formats and metrics across various devices and develop seamless integration protocols for EHR/EMR systems to effectively incorporate mobile health data. Alert designs should be easily understandable and actionable for both healthcare providers and patients. Additionally, a robust framework for privacy and security to protect patient data is essential.
   - For users and patients, mobile devices must be user-friendly, with clear instructions accessible to individuals with varying levels of technical proficiency. It is crucial to provide resources and training that empower users to understand and respond appropriately to alert triggers. Alerts should deliver meaningful and actionable information, and there is a need for customer support to assist users in managing and interpreting these alerts.
   - By addressing key inputs and implementing recommendations, regulatory boards can work to develop minimum standards to enhance the effectiveness and reliability of mobile health device alerts and alert documentation, ensuring they provide valuable contributions to patient care and safety.

7. **Technology Development and Mutual Collaboration with Industry**
   Encourage collaboration between healthcare providers, device manufacturers, and software developers to promote adherence to integration guidelines and drive innovation in mobile health technology for mutual progress and patient care benefit. Additionally, establish mobile health device standards based on best practice for industry stakeholders, users, and regulatory bodies to proactively address emerging issues, facilitate timely updates, and ensure compliance with evolving standards. This proactive approach ensures timely intervention, enhances integration processes, and supports continuous improvement in patient care and technology standards.

References

1. Perry B, Herrington W, Goldsack JC, Grandinetti CA, Vasisht KP, Landray MJ, Bataille L, DiCicco RA, Bradley C, Narayan A, Papadopoulos EJ. Use of mobile devices to measure outcomes in clinical research 2010-2016: A systematic literature review. Digital Biomarkers. 2018;2(1):11-30. doi:10.1159/000486347.
2. Knight SR, Ng N, Tsanas A, Mclean, K, Pagliari C, Harrison EM. Mobile devices and wearable technology for measuring patient outcomes after surgery: A systematic revies. NPJ Digit Med. 2021;4(1):157. doi:10.1038/s41746-021-00525-1.

3. Liu C, Zhu Q, Holroyd KA, Seng EK. Status and trends of mobile-health applications for iOS devices: A developer's perspective. JSS. 2011;84(11):2022-33. doi:10.1016/j.jss.2011.06.049.
4. Laing SS, Alsayid M, Ocampo C, Baugh S. Mobile health technology knowledge and practices among patients of safety-net health systems in Washington State and Washington, DC. J Patient Cent Res Ev. 2018;5(3):204-17. doi:10.17294/2330-0698.1622.
5. Bruce C, Harrison P, Giammattei C, Desai S-N, Sol JR, Jones S, Schwartz R. Evaluating patient-centered mobile health technologies: Definitions, methodologies and outcomes. JMIR Mhealth Uhealth 2020;8(11):e17577. doi:10.2196/17577.
6. Short CE, DeSmet A, Woods C, Williams SL, Maher C, Miccelweerd A, Müller AM, Wark PA, Vandelanotte C, Poppe L, Hingle MD, Crutzen R. Measuring engagement in eHealth and mHealth behavior change interventions: Viewpoint of methodologies. J Med Internet Res. 2018;20(11):e292. doi:10.2196/jmir.9397.
7. Carchiolo V, Longheu A, Tinella S, Ferrara S, Savelli N. Data collection via wearable medical devices for mobile health. In: Proceedings of the 13th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2020). Volume 5: HEALTHINF p.586-92. doi:10.5220/0009100705860592.
8. Bradway M, Carrion C, Vallespin B, Saadatfard O, Puigdomènech E, Espallargues M, Kotzeva A. mHealth assessment: Conceptualization of a global framework. JMIR Mhealth Uhealth 2017;5(5):e60. doi:10.2196/mhealth.7291.
9. Ventola CL. Mobile devices and apps for health care professionals: Uses and benefits. P T.2014;39(5):356-64.
10. Chong SOK, Pedron S, Abdelmalak N. An umbrella review of effectiveness and efficacy trials for app-based health interventions. NPJ Digit Med. 2023;6(1):233. doi:10.1038/s41746-023-00981-x.
11. Fortunati S, Giliberti C, Giannetto M, Bolchi A, Ferrari D, Donofrio G, Bianchi V, Boni A, De Munari I, Careri M. Rapid quantification of SARS-Cov-2 spike protein enhanced with a machine learning technique integrated in a smart and portable immunosensor. Biosensors. 2022;12(6):426. doi:10.3390/bios12060426.
12. Almotiri SH, Kahn MA, Alghamdi MA. Mobile health (m-Health) system in the context of IoT. 2016 IEEE 4th International Conference on Future Internet of Things and Cloud Workshops (FiCloudWO). Vienna, Austria. 2016. p.39-42. doi:10.1109/W-FiCloud.2016.24.
13. Vijayan V, Connolly JP, Condell J, McKelvey N , Fardiner P. Review of wearable devices and data collection considerations for connected health. Sensors. 2021;21(16):5589. doi:10.3390/s21165589.
14. Lehne M, Sass J, Essenwanger A, Schepers J, Thun S. Why digital medicine depends on interoperability. NPJ Digit Med. 2019;2:79. Doi:10.1038/s41746-019-0158-1.
15. Hewitt B, Dolezel D, McLeod A Jr. Mobile device security: Perspectives of future healthcare workers. Perspect Health Inf Manag. 2017;14(Winter):1c.