Mobile Sensors in Healthcare: Technical, Ethical, and Medical Aspects

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Abstract

Mobile sensors play an increasing role in healthcare, although it is not always clear yet what they can reliably be used for. While some specialties in medicine like cardiology have already integrated apps and smartwatches in their international guidelines, others are still struggling to find infrastructures that are compliant with healthcare standards. The main concerns are data quality and data privacy, which are both handled with different requirements in the consumer market than they are in healthcare. Specific adjustments will make mobile sensors an important part of future healthcare.

1 Mobile Sensors in Healthcare

Over the past 10 years, the use of mobile sensors for private use has been a tremendous success story (Gartner.com, 2021). An increasing number of individuals are following the self-tracking trend that enables them to not only document steps and sleep but also measure temperature, blood pressure, oxygen saturation, and ECGs (Kent, 2020). Most of these procedures were formerly limited to the healthcare environment and its very specific set of rules.

Today we are witnessing the long-predicted emancipation of both patients and healthy individuals who now control their healthcare data and its interpretation. Appointments with healthcare professionals tend to begin with the patient presenting the results of their self-investigation and asking the healthcare professional for their opinion on the data instead of beginning with the statement that they have "not

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felt very well for some time." While this can be a significant advantage in terms of patient involvement and the patient's future compliance with therapeutic decisions, it can weaken efforts to treat the patient if the professional diagnosis deviates from the one predicted by the patient or by public symptom tracker algorithms (Miller et al., 2020). Thus, the challenge for healthcare professionals is to use these data and tools in a way that creates additional value without sacrificing the high standards of healthcare.

Every piece of information that triggers therapeutic decision-making, including apps used as digital therapeutics, has to be validated and approved according to present legal frameworks, comparable to the standards of pharmacological trials. Patients trust the healthcare system in general, and it is crucial that future diagnostic tools and digital therapeutics adhere to the same high-quality requirements that apply for drugs and diagnostic tests (Gille et al., 2015).

There are several reasons why such rules are still a matter of discussion. One likely reason is that most physicians lack specific technical knowledge. Healthcare professionals have not been trained to use or develop sensor technology, data formats, encryption, algorithms, and databases. This is changing slowly, but for obvious reasons, healthcare professionals do not have the same expertise as IT specialists. Therefore, a medical device certification that healthcare professionals can rely on without having the specific knowledge to understand all the technical details is needed.

A second reason is the power that most companies that produce wearable devices have in the field of marketing and sales. The "traditional" healthcare system cannot, and most likely does not, want to match this. This leads to individuals being more convinced by the results of a smartwatch than by a physician's diagnosis that is based on "old" methods. In the end, health is probably the most relevant topic for most people, and they will choose the safest and most effective approach, which in some instances will involve digital therapeutics and mobile sensors.

Thirdly, the involvement of commercial wearables from the consumer market in healthcare areas reflects a merge between "lifestyle" and healthcare. At first, individuals get used to trust their devices, navigating them from A to B and providing them with important information 24/7. Subsequently, they expect that the information about their health status will be as accurate as their navigation data. To address this assumption, more prominent disclaimers on devices and apps not suitable for healthcare should be mandatory.

For these reasons it is crucial that the healthcare system and its representatives work to create a framework for the responsible use of wearables in healthcare. This framework must be fortified by published data and a strong set of rules, as is the case in a first version of the European medical device regulation of 2021 (European Parliament and Council of the European Union, 2017).

2 Technical Aspects

This chapter will not focus on technical standards and details but will rather address a number of simple technical questions that are often missed when plans are made to move mobile sensors from the consumer into the healthcare market.

Some of the best-selling wearable devices in the consumer market have a battery life of less than 24 h (Apple Watch battery, 2021). People charge them every night and hopefully do not forget to put them on in the morning. This means that their high-tech sensor is not monitoring vital signs during a significant part of the day. Taking into account that sleep is a highly interesting condition and, for example, sleep apnea is an important diagnostic target, this technical shortcoming hinders diagnostics.

In a hospital setting, such a short run time would require nurses to remove the device once a day, charge it, and reinstall it on the patient. In times when human resources are scarce, this is not an option. That is why a sensor designed for healthcare purposes should run at least 7 days in any mode that is available for the device.

Charging has to be as simple as possible and easy to handle even for individuals with poor sight or restrictions on movement. This is why many companies went from systems with miniaturized plugs to wireless charging cradles that can be handled by most user error-free. Magnetic connections to support the correct positioning of plugs or wireless cradles became a widespread standard too.

If such a sensor is carried continuously, it must be waterproof because showering will be necessary during intervals of 7 days, and it should not be destroyed by water if the individual has forgotten to take it off.

Wearing such a sensor device continuously is realistic only if it is very comfortable. This applies to hearables (in-ear sensors) as much as to bracelets or patches. Bracelets might have an advantage in this respect, because with very soft silicone or comparable materials, there is a chance that most people would indeed accept a device on their wrist (Larsen et al., 2020).

This is already the case with watches. But if the device is intended to be worn at night, it should not make any sounds or vibrating alerts or emit light signals. Everything that potentially interrupts sleep will sooner or later trigger the individual to take off the device.

A final aspect related to design is somewhat trivial but can make the difference between highly compliant individuals and a great sensor that is not acquiring data because the device is not on the person who is supposed to wear it: It should be "cool"! At least it should not stigmatize people by showing that they have health problems. Instead it should signal that they are being supported with most up-to-date methods of staying fit and healthy. The reaction of others has to be "Hey, how can I get this service?" rather than "Oh, I feel sorry for you, your condition must be severe" (Ahmad et al., 2020).

The success of such devices will also depend on marketing, even though this is not the focus of science and healthcare. But if we look at the pharmaceutical

industry, we see that drugs are sold and effectively applied only if healthcare professionals are familiar with them and patients really take them in the intended way.

Once the design aspects are successfully taken care of and patients are wearing their device continuously to address a specific healthcare question or just to record baseline data, connectivity arises as the next big challenge. Most consumer devices are linked to a specific app provided by the company that built the device. This environment provides users with conveniently visualized information about their health status. Irrespective of the quality of this information, it is generated within the commercial system of a commercial company that needs the consumer's data to improve their own algorithms. This system is perfectly fine for the consumer market if individuals consent to share their data, but it is not acceptable for healthcare, where an individual's data is highly protected (Yue et al., 2016). Therefore, hospitals should host an infrastructure that enables them to link wearable devices and store the data on designated servers for their healthcare data. If the data is analyzed externally, it has to be de-identified, exported, and then reimported and re-identified. Simple analytics can easily be handled on hospital premises (Brasier et al., 2020).

A similar infrastructure is required for outpatients. A number of specific technical solutions are already in place for these patients One of the earliest drivers was the field of cardiology, which began providing "home monitoring" of implanted devices in the early 2000s. Data was transferred to the referring cardiologist via specific Bluetooth access points that connect to the device when it was close. These devices transmitted the data to a central hub and routed it to the responsible site. Most of the time this meant that the access point was located next to the patient's bed (Wilkoff et al., 2008). Other devices that are primarily used at home, such as scales or resting blood pressure monitors, are equipped with modules that transfer the data by the Global System for Mobile Communications (GSM) standard via a hub to the healthcare facility.

The most common setting at present is a link between the sensor and a smart device equipped with GSM and Bluetooth connectivity (most often a smartphone) that is running a specific app designed for this purpose. For healthcare applications, it is crucial that the data be transferred in a safe and reliable way to the healthcare infrastructure without being decrypted and processed by third-party servers. Alternatively, the data can stay on the individual smart device until it is exported and sent to a specific recipient. This is frequently the case with glucose measurements or blood pressure monitors (Funtanilla et al., 2019).

In any of these solutions it is crucial that data privacy is ensured and that the system is certified for healthcare use. It has to be taken into account that medical sensors will not only record a person's medical data, but inadvertently private, nonmedical data too. Therefore patients need certainty that this data will exclusively be used in a medical context or remain inaccessible for any other purposes. Further, it should not be the responsibility of the patient to read through extensive legal documents about the potential use of their data and then click on "accept," hoping that they have made the right choice.

Finally, even with the highest data safety and quality, physicians rely on algorithms to visualize and sometimes interpret the data before they can draw meaningful conclusions. It is not possible to transfer achievements from the consumer market to healthcare without further adaptation because often the ground truth for algorithms developed for the consumer market is based on healthy persons. Data is repeatedly collected, while healthy people are counting steps, climbing stairs, running, and swimming until the algorithm is able to identify the activity and then recognize and quantify it autonomously. But patients most often differ from healthy persons. They walk slower (e.g., if they have heart failure), their gait is less smooth (e.g., if they have hip problems), or their steps are much smaller (e.g., if they have Parkinson's disease) (Patel et al., 2009; Moayedi et al., 2017). Heart rate variability, an important parameter for calculating respiration based on pulse wave signals, becomes less pronounced as people age or if they develop cardiovascular, infectious, or psychiatric diseases (Umetani et al., 1998; Ahmad et al., 2009; Gorman & Sloan, 2000). Unfortunately, many patients are burdened with one or more of these circumstances. This is why the available algorithms have to be tested and validated for the intended use with real patients and not in labs with healthy people. As a result, information about the sensitivity and specificity of the measurements has to be made available with a specific focus on false negative results that would indicate that a person is healthy when in fact they are not. Again, this is not so relevant for consumer market use, when a device indicates that the heart rate while running is 65 beats per minute although it is actually 155 beats per minute. But if a patient has a heart rate of 155 beats per minute and the device calculates only 65 beats per minute, that could lead to delayed diagnostics and therapy, potentially putting a patient's life at risk.

An important question for many developers in this field concerns the threshold that defines whether an algorithm or a device is considered a medical device according to the present regulations. Certification might appear to be a significant hurdle to go through, but it can also help position the product in the long run.

It is important to understand that both algorithms and hardware can be certified medical devices. For example, most blood pressure monitors are certified devices that include both hardware and software. However, the situation is different for algorithms that screen for atrial fibrillation using smartphones or smartwatches. In that case, the algorithm analyzing the video signal of the sensor is certified. This means that it can run on a number of smart devices and still be considered a certified medical device. This approach can use the omnipresence of smartphones and make possible a low-level approach to medical services that would not have been possible without the presence of smartphones almost everywhere in the world.

3 Ethical Aspects

Because of technological change, unforeseen amounts of health-related data are being generated continuously, and we as a society and as healthcare professionals

must reach agreements about standards for data privacy and quality, data ownership, and aspects of data exploitation.

Data usage is not only driven by scientific interests but also by commercial interests (EY, 2019). Well-annotated healthcare records and raw data from specific patient groups are needed to feed machine-learning algorithms and neural networks that are programmed to provide shortcuts to the right diagnosis, choose the right treatment, or even prevent disease.

Differences exist in how different national societies view the potential uses of patient data. Currently, the European rules are the most restrictive and protective (Pernot-Leplay, 2020). But of course this topic is a global one and needs to be addressed as such. The baseline of a potential global agreement should be a careful balance between the privacy of the individual and the value added to the global society if the data were to be used for research and development purposes. Another important issue is how the individual donating their data will be rewarded for doing so. For example, they could receive free diagnostics and treatment or financial compensation if the resulting product is commercially successful.

A second question concerns who is liable for the consequences of digital healthcare solutions. While this topic is well regulated within the pharmaceutical industry, it is not yet well defined for digital solutions. As a simple example, consider the decision support systems that are on their way into routine healthcare. If such a system does not recognize the correct diagnosis or, even more problematically, leads the wrong way and causes unnecessary tests with adverse events, who is the responsible party? The IT specialists who programmed the algorithm? The data providers who did not annotate well enough? The company that sells the algorithm? The body that certified it as a medical device? Or the physician in charge of the patient? But how can a physician be responsible for an algorithm that they are unable to control or even understand? In accordance with the procedures established for the pharmaceutical industry, companies producing software should be liable for adverse events if they could have been prevented. Experts in the field are discussing the idea of a Hippocratic Oath for software engineers in healthcare (Kostkova et al., 2016; Grote & Berens, 2020).

Interestingly enough, there is no general agreement on who owns healthcare data. A dominant opinion is that this data belongs to the individual patients and can only be used with their consent (MIDATA, n.d.). On the other hand, data that was acquired in past decades could be used to develop strategies that will help large numbers of future patients if it were available for research and development. A third group of potential data owners are healthcare professionals and insurance companies. This argument partly dates from the time when health records and results belonged to the physician and the patient had to ask if they could have access to it. But nowadays, as patients are increasingly storing their health data in personal accounts, this system appears to be more and more obsolete.

Data cooperatives are an interesting approach that provide individual ownership at the same time that they provide access to datasets. There are different models in the current market. Some cooperatives provide a financial benefit for their members if they sell their data and others finance their organization with the revenue they earn

from sharing data and providing it for public research (MIDATA, n.d.; HealthBank, n.d.).

In the end, the ethical dilemma is the possibility that data privacy will become something that only wealthy people can afford while others are forced to sell their data to finance their individual healthcare.

4 Medical Aspects

The unprecedented granularity of healthcare data will change our approach to many diseases because it is likely that, for example, simultaneous recordings of several vital signs will indicate pathological changes much earlier than traditional diagnostics. Now that low-cost mobile devices are available, this will be possible even in middle- and low-income countries. The first potential smartphone-based digital diagnostic tools are already well established and are recommended by international guidelines. For example, apps to screen for atrial fibrillation have been used for years now. They help detect unknown atrial fibrillation, and if oral anticoagulants are indicated, they prevent strokes (Hindricks et al., 2021).

The possibilities and the expected added value that derives from continuous monitoring are immense. Most likely, AI-driven algorithms will be able to identify not only that something is wrong but also come up with a potential diagnosis.

For example, with a regular pneumonia, an increase in heart rate and respiration rate would be expected, as would lower oxygen saturation and blood pressure. However, in patients with COVID-19, interestingly enough, a decrease in heart rate (instead of an increase) has been observed (Capoferri et al., 2020). Together with other typical clinical and imaging findings, this formed a specific pattern for the diagnosis of COVID-19.

It is expected that devices that obtain more specific disease patterns and more data during healthy episodes of individuals will be able to detect deviations from an individual's baseline earlier and prevent diseases or at least chronic damage. Once we can combine the kind of sensor data that is already available and familiar with additional data like lab values from sweat samples or other biofluids, we might better understand the course of some diseases.

At the same time, references for some of our vital signs will have to be adapted because new measurement techniques will allow much more insight. For example, once blood pressure can be measured continuously from photoplethysmography signals, we will not be limited to 24 h of intermittent measurements taken by an inflating cuff. By combining this data on blood pressure with simultaneously recorded other vital signs, we will be able to see a much more detailed picture of an individual's physiology.

5 Conclusions

Wearables will change our view of diseases, our role as healthcare professionals, and our therapeutic standards. The transformation of devices from the consumer market to medical grade devices requires adaptation of multiple parameters, ranging from software and algorithms to hardware and images. An adapted Hippocratic Oath for software developers and medical technology IT specialists is being discussed that should address shared responsibility for the intended use.

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References

Ahmad, S., Tejuja, A., Newman, K. D., Zarychanski, R., & Seely, A. J. (2009). Clinical review: A review and analysis of heart rate variability and the diagnosis and prognosis of infection. *Critical Care, 13*(6), 232. https://doi.org/10.1186/cc8132

Ahmad, A., Rasul, T., Yousaf, A., & Zaman, U. (2020). Understanding factors influencing elderly diabetic patients' continuance intention to use digital health wearables: Extending the technology acceptance model (TAM). *Journal of Open Innovation: Technology, Market, and Complexity, 6*(3), 81. https://doi.org/10.3390/joitmc6030081

Apple Watch battery. (2021). *Apple Watch Series 7 Battery Information*. Retrieved from https://www.apple.com/watch/battery

Brasier, N., Geissmann, L., Käch, M., Mutke, M., Hoelz, B., De Ieso, F., & Eckstein, J. (2020). Device- and analytics-agnostic infrastructure for continuous inpatient monitoring: A technical note. *Digit Biomark., 4*(2), 62–68. https://doi.org/10.1159/000509279

Capoferri, G., Osthoff, M., Egli, A., Stoeckle, M., & Bassetti, S. (2020). Relative bradycardia in patients with COVID-19. *Clinical Microbiology and Infection, 27*(2), 295–296. https://doi.org/10.1016/j.cmi.2020.08.013

European Parliament and Council of the European Union. (2017, 5 April). *European Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*. Retrieved from https://eur-lex.europa.eu/eli/reg/2017/745/2017-05-05

EY. (2019). *Realising the value of healthcare data: A framework for the future*. Retrieved from https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-value-of-health-care-data-v20-final.pdf

Funtanilla, V. D., Candidate, P., Caliendo, T., & Hilas, O. (2019). Continuous glucose monitoring: A review of available systems. *P T., 44*(9), 550–553.

Gartner.com. (2021, January 12). *Gartner forecasts global spending on wearable devices to total $81.5 billion in 2021 [Press Release]*. Retrieved from https://www.gartner.com/en/newsroom/press-releases/2021-01-11-gartner-forecasts-global-spending-on-wearable-devices-to-total-81-5-billion-in-2021

Gille, F., Smith, S., & Mays, N. (2015). Why public trust in health care systems matters and deserves greater research attention. *Journal of Health Services Research & Policy, 20*(1), 62–64. https://doi.org/10.1177/1355819614543161

Gorman, J. M., & Sloan, R. P. (2000). Heart rate variability in depressive and anxiety disorders. *American Heart Journal, 140*(4), S77–S83. https://doi.org/10.1067/mhj.2000.109981

Grote, T., & Berens, P. (2020). On the ethics of algorithmic decision-making in healthcare. *Journal of Medical Ethics, 46*, 205–211.

HealthBank. (n.d.). *Introducing healthbank: Take control of your health*. Retrieved from https://www.healthbank.coop

Hindricks, G., Potpara, T., Dagres, N., Arbelo, E., Bax, J. J., Blomström-Lundqvist, C., Boriani, G., Castella, M., Dan, G.-A., Dilaveris, P. E., Fauchier, L., Filippatos, G., Kalman, J. M., La Meir, M., Lane, D. A., Lebeau, J.-P., Lettino, M., Lip, G. Y. H., Pinto, F. J., … ESC Scientific Document Group. (2021). ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The task force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European heart rhythm association (EHRA) of the ESC. *European Heart Journal, 42*(5), 373–498. https://doi.org/10.1093/eurheartj/ehaa612

Kent, R. (2020). Self-tracking health over time: From the use of Instagram to perform optimal health to the protective shield of the digital detox. *Social Media + Society, 6*(3). https://doi.org/10.1177/2056305120940694

Kostkova, P., Brewer, H., de Lusignan, S., Fottrell, E., Goldacre, B., Hart, G., Koczan, P., Knight, P., Marsolier, C., McKendry, R. A., Ross, E., Sasse, A., Sullivan, R., Chaytor, S., Stevenson, O., Velho, R., & Tooke, J. (2016). Who owns the data? Open data for healthcare. *Frontiers in Public Health, 4*, 7. https://doi.org/10.3389/fpubh.2016.00007

Larsen, L., Lauritzen, M., Gangstad, S., & Kjaer, T. (2020). The usages of small electronic devices and health: A feasibility study. *JMIR Formative Research, 5*(1), e20410.

MIDATA. (n.d.). *My data—Our health*. Retrieved from https://www.midata.coop

Miller, S., Gilbert, S., Virani, V., & Wicks, P. (2020). Patients' utilization and perception of an artificial intelligence-based symptom assessment and advice technology in a British Primary Care Waiting Room: Exploratory pilot study. *JMIR Human Factors, 7*(3), e19713.

Moayedi, Y., Abdulmajeed, R., Duero Posada, J., Foroutan, F., Alba, A. C., Cafazzo, J., & Ross, H. J. (2017). Assessing the use of wrist-worn devices in patients with heart failure: Feasibility study. *JMIR Cardio, 1*(2), e8.

Patel, S., Lorincz, K., Hughes, R., Huggins, N., Growdon, J., Standaert, D., Akay, M., Dy, J., & Bonato, P. (2009). Monitoring motor fluctuations in patients with Parkinson's disease using wearable sensors. *IEEE Transactions on Information Technology in Biomedicine, 13*(6), 864–873. https://doi.org/10.1109/TITB.2009.2033471

Pernot-Leplay, E. (2020). China's approach on data privacy law: A third way between the U.S. and the EU? *Penn State Journal of Law & International Affairs, 8*(1).

Umetani, K., Singer, D. H., McCraty, R., & Atkinson, M. (1998). Twenty-four hour time domain heart rate variability and heart rate: Relations to age and gender over nine decades. *Journal of the American College of Cardiology, 31*(3), 593–601. https://doi.org/10.1016/s0735-1097(97)00554-8

Wilkoff, B. L., Angelo Auricchio, A., Brugada, J., Cowie, M., Ellenbogen, K. A., Gillis, A. M., Hayes, D. L., Howlett, J. G., Kautzner, J., Love, C. J., Morgan, J. M., Priori, S. G., Reynolds, D. W., Schoenfeld, M. H., & Vardas, P. E. (2008). Expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): Description of techniques, indications, personnel, frequency and ethical considerations: Developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European

Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association. *EP Europace, 10*(6), 707–725. https://doi.org/10.1093/europace/eun122

Yue, X., Wang, H., & Jin, D. (2016). Healthcare data gateways: Found healthcare intelligence on blockchain with novel privacy risk control. *Journal of Medical Systems, 40*, 218. https://doi.org/10.1007/s10916-016-0574-6