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Review article

Wearable sensors with possibilities for data exchange: Analyzing status and needs of different actors in mobile health monitoring systems

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A R T I C L E I N F O

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A B S T R A C T

Background: Wearable devices with an ability to collect various type of physiological data are increasingly becoming seamlessly integrated into everyday life of people. In the area of electronic health (eHealth), many of these devices provide remote transfer of health data, as a result of the increasing need for ambulatory monitoring of patients. This has a potential to reduce the cost of care due to prevention and early detection.
Objective: The objective of this study was to provide an overview of available wearable sensor systems with data exchange possibilities. Due to the heterogeneous capabilities these systems possess today, we aimed to systematize this in terms of usage, where there is a need of, or users benefit from, transferring self-collected data to health care actors.
Methods: We searched for and reviewed relevant sensor systems (i.e., devices) and mapped these into 13 selected attributes related to data-exchange capabilities. We collected data from the Vandrico database of wearable devices, and complemented the information with an additional internet search. We classified the following attributes of devices: type, communication interfaces, data protocols, smartphone/PC integration, connection to smartphone health platforms, 3rd party integration with health platforms, connection to health care system/ middleware, type of gathered health data, integrated sensors, medical device certification, access to user data, developer-access to device, and market status. Devices from the same manufacturer with similar functionalities/ characteristics were identified under the same device *family*. Furthermore, we classified the systems in three subgroups of relevance for different actors in mobile health monitoring systems: EHR providers, software developers, and patient users.
Results: We identified 362 different mobile health monitoring devices belonging to 193 device families. Based on an analysis of these systems, we identified the following general challenges:

- Few systems have a Conformité Européene (CE) marking class II or above, or approval from the US Food and Drug Administration (FDA)
- Few systems use the standardized Bluetooth Low Energy GATT profile for wireless transfer of health data
- Few systems support health middleware
- Approximately 30% of the device families provide the user access to the source data. However, only 16% allow the transfer of data through direct communication with the device (i.e., without using a proprietary cloud-based service)

Conclusions: Few of the identified mobile health monitoring systems use standardized, open communication protocols, which would allow the user to directly acquire sensor data. Use of open protocols can provide mobile

Abbreviations: API, Application Programming Interface; CE, Conformité Européene; CPAP, Continuous positive airway pressure; DIY, Do-It-Yourself; eHealth, Electronic Health; EHR, Electronic Health Records; EMR, Electronic Medical Record; FDA, Food and Drug Administration; GDPR, General Data Protection Regulation; GSR, Galvanic skin response; GATT, Generic Attribute Profile; HIPPA, Health Insurance Portability and Accountability Act; IMU, Inertial Motion Unit; mHealth, Mobile health; NFC, Near field communication; PHR, Personal Health Record; PHI, Protected Health Information; Precert, Digital Health Software Precertification; REST, Representational State Transfer; SIG, Special Interest Group; SpO_2, Peripheral capillary oxygen saturation; USB, Universal Serial Bus

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health (mHealth) application developers an alternative to proprietary cloud services and communication tools, which are often closely integrated with the devices. Emerging new types of sensors, often intended for everyday use, have a potential to supplement health records systems with data that can enrich patient care.

1. Introduction

We have witnessed an increase in various wearable health devices for the consumer market. Primary efforts have been aimed towards miniaturization and development of new features, and there has been less focus on data collection infrastructure, the use of standardized data transmission protocols, and providing sensor data for further use in various connected applications in areas of mHealth, gaming, industrial sector, etc. [1]. In a previous study we showed that for consumer-based activity trackers and smartwatches, the number of new devices and brands appearing every year is high and increasing [2].

The fast-paced development of new health sensors, patient tools, and various types of electronic health records (EHR), Electronic medical record (EMR), Personal health record (pHR), and health data middleware, in addition to patient empowerment supported technologies (e.g., using 3D printing and electronics prototyping tools), stimulates the need for improvements in interoperability and data-exchange capabilities. When we improve system interoperability across whole spectrum of health monitoring systems (i.e., EHR, sensors, middleware), then we also empower patients by letting them to choose the system with the best fit. The need for system interoperability improvement is also supported by the growing popularity of wearables, where continuously collected data can have a significant value for both long- and short-term health monitoring purposes [3].

Interoperability, in terms of communication capabilities with other devices, is often influenced by different made-by-design constraints, and the full potential of devices may remain unutilized. Technically educated users can present, design, and implement their own solutions, tailored to facilitate living with a specific health condition (e.g., diabetes [4], obstructive apnea [5]). The core functionality of such solutions is often based on unofficial access to captured data from sensors, and wearable devices. Given the prototype nature of these solutions, they are also referred to as Do-It-Yourself (DIY) projects [6]. Maintenance of these DIY projects is commonly provided by people who can personally relate to the disease or health condition. Existence of such technologically-focused initiatives, where the motivation is based on an ability to freely operate with sensor data, supports the promotion of standardized and open access protocols.

The emerging various sensor technologies and its utilization in various self-management services, can have a positive impact on related functionality such as medical decision support, provisioning of alarms and remote caregiver monitoring [7]. However, manual logging and registration of different observations and measurements may become an everyday inconvenience for patients and can be facilitated by automatic transmission of sensor-based readings when the protocols are known and access is enabled.

Introducing a health context to the wearable device brings in a several considerations in terms of law compliance. The main questions are: how to protect the data collected from these devices, how to ensure that the data is only being used for authorized purposes and how the collected data can be presented to the end user. Data protection laws, such as the EU General Data Protection Regulation (GDPR) and US Health Insurance Portability and Accountability Act (HIPAA), imposes eHealth application providers to address these compliance and data security issues. In the context of cloud-based health monitoring systems, all of these responsibilities are divided in a transparent manner between cloud providers and application developers, who must relate to a new legal situation in the area.

The purpose of this review is to systematically describe and analyze the current data-exchange capabilities of wearables, with a particular focus on health monitoring systems and data transfer. We have analyzed important parameters and commented on each of these, describing how different actors in mobile health monitoring systems relates to these wearable sensor systems (i.e., mHealth software developers, EHR providers, and patients).

2. Methods

2.1. Search protocol

The search approach was based on searching through the grey literature, where we targeted all wearables with integrated communication interfaces for data transfer. We identified the Vandrico database [8] as the primary source of data.

The Vandrico wearables database is a structured summary of wearables. As of May 2018, the database receives 1,000,000 views

Table 1
Collected attributes for wearables.

Attribute	Attribute description	Label
Keywords	Keywords related to device	–
Manufacturer	Name of the manufacturer/company producing the device	–
Short description	Short description of the device	–
Source of information	Source where the information about the device was obtained	–
System URL	URL of the system/manufacturer	–
System variety	Enumeration of models with similar characteristics	–
Type of wearable system	Device classification	A
Communication interfaces	Set of integrated communication interfaces for transmitting data	B
Data protocol	Indicates whether the device uses proprietary or standardized/open data protocols	C
Smartphone/PC integration	Types of systems the devices can be connected to	D
Direct integration with health platforms	Indicates whether device supports direct import of data to Google Fit and/or Apple Health	E
3rd party integration with health platforms	Device can be connected to one or more health platforms via 3rd party provider	F
Connection to Health Care System/Middleware	Device supports import of data to a health care system/middleware	G
Health data types	Enumeration of types of physiological data extracted from integrated sensors	H
Integrated sensors	Enumeration of sensors integrated within the device	I
Medical device	Indicates a certification or approval by corresponding agencies/authorities	J
User data access	Collected data are accessible either by directly inquiring the device or via cloud solution	K
Developer access	Indicates support for development of custom applications running on the device	L
Device availability	Indicates production status of the device	M

annually, and holds 431 devices from 266 companies, and is currently open for new device entries. Every device has to fulfill the following conditions in order to be accepted in the database. The device has to be wearable (i.e., worn on the body throughout its use), controllable (i.e., device must be controllable by the user either actively or passively), enhancing (i.e., device must augment knowledge, facilitate learning or enhance experience), and fully funded (i.e., device must be fully funded ideally with an availability date and price) [8]. Once a device is inserted into the database, it is classified into one or more categories. The updates occur at irregular intervals, and can be initiated by a public contributor not affiliated with Vandrico.

We also performed a web search to complement the data from the Vandrico database. Searches were also done in cases where the provided information from Vandrico was incomplete, outdated, or inaccurate. For many device records, we were able to extract missing information directly from the manufacturer's website. Such additionally information was generally related to certification and integrated sensor parameters, which are not recorded in Vandrico database.

2.2. Classification

Each included device was assigned one or more keywords to describe its purpose. Since manufacturers often release multiple generations of the same device with similar functionality, we documented the 'System variety' field, which lists models with similar functionality. In this article, we call such a group of similar devices a *device family*.

The taxonomy we use in this work is based on the taxonomy of Vandrico database itself. In addition to the original set of attributes tracked by Vandrico, we have added several new attributes with a focus on documenting data-exchange features of the devices in more detail. Three additional attributes were added to distinguish between data import options to different types of health data storages (E, F, G), see Table 1. Other attributes were added to indicate integrated sensors (I), set of collected health data types (H), and the possibility of data extraction (B, K). In addition, we also tracked whether the device supports transmission of data via open protocol (C), and which smartphone or PC applications the wearables are compatible with (D). We also reviewed the support for development of custom applications running on the device (L), which is a new characteristic with an increasing number of smartwatches on the market. Considering the focus of this review, we also included status of medical certification of the device (i.e., CE marking and FDA approval) (J). A list of these new attributes is shown in Table 1.

Based on our findings about attributes (E), (F) (G) and (K), we created a framework, which we further use to describe relations between different components in terms of communication capabilities. Fig. 1. visualizes directions of data flow and types of data transport between all identified components in this framework. Basic block of this schema is a *Wearable device* (Fig. 1.-I), as an origin of data being transferred throughout different systems. There are two components connected to a wearable device: *Smartphone Consumer Application* (Fig. 1.–II) and *Device's Cloud Service* (Fig. 1.–III). By a smartphone consumer application, we understand either a native application provided by a device's vendor (e.g., Fitbit [9]), or a 3rd party application directly communicating with the device using a software development kit, which is parameter that we track via Attribute K. Device's Cloud Service represents a device's vendors cloud-based solution for providing a remote access to the data and synchronization among multiple devices (e.g., Fitbit Cloud [9]). All three blocks (Fig. 1.–I, II, III) are interconnected since we observe, that the data transfer between a device and a cloud service can happen without a use of smartphone as a mediator, for example via Wi-Fi or GSM.

Another element in the schema is a block called *Health platforms.* Within this block we distinguish between Google Fit and Apple Health, since their integration capabilities are different. Apple Health, by design, only allows sharing of the data locally on the device via it's HealthKit API. Google Fit, on the other hand, can be integrated with smartphone apps and device's cloud service but also with other elements in the schema, which are *Middleware* (Fig. 1.–V) and *3rd Party Fitness Services* (Fig. 1.-VI).

3rd party fitness services (e.g., Strava [10]) often expand functionalities of device's cloud services in terms of sharing capabilities, improved statistics etc. They also allow to be connected to multiple device's cloud services with a capacity to process data collected from

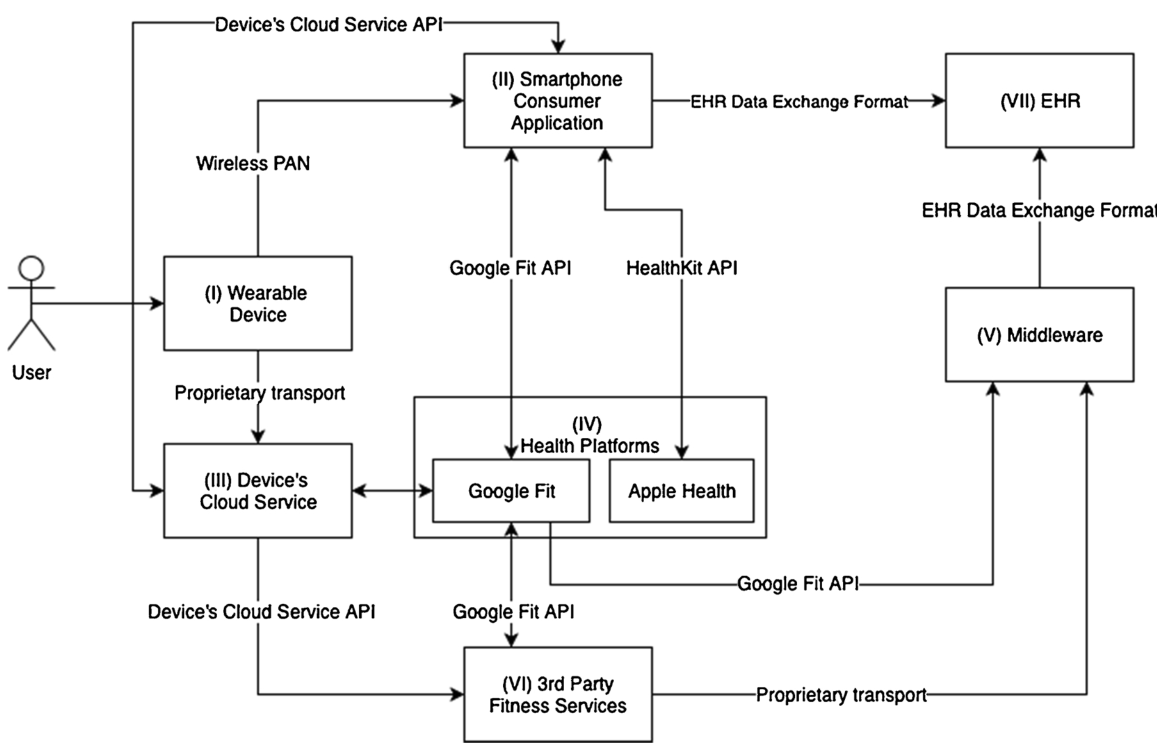

Fig. 1. Data flow between different components in the identified wearable devices; arrow and text denote the way data is transferred.

different devices.

Middleware (e.g., Tidepool [11]) has a capability to collect and analyze data from 3rd party fitness services via their respective APIs (Application Programming Interfaces) and also from some Health platforms - in our review, the Health platform supporting direct middleware connection is represented by Google Fit. Captured data are further provided in a standardized format, which is readable by an EHR (Fig. 1.–VII). We have added an additional link between EHR (e.g., Epic [12]) and smartphone consumer application (Fig. 1.–II) to indicate a possibility of a direct data transfer, if the EHR data transfer protocol is implemented in the smartphone application.

3. Results

The results section consists of two subsections. In the first section, we present each of the identified attributes specified in Table 1. In the second section, we present how different actors can utilize wearable devices in patient monitoring systems (i.e., mHealth software developers, EHR providers, and patients).

In total, we have included 310 devices from Vandrico database and in addition, we have identified 52 devices based on information from other sources (i.e., via manufacturer's website linked back from Vandrico and via Google search).

3.1. Identified attributes

In the description of each attribute, numbers in parenthesis indicate the percent of device families classified within a specific identified attribute value.

Type of wearable system (Attribute A)

Summary: The majority of wearable device families in our review are Trackers (96 device families (50%), 175 devices (48.5%)) and Smartwatches (46 device families *(24%), 111 devices (30.5%)). We have also registered Gloves (10 device families (5%), 15 device (4%)), Glasses (8 device families (4%), 22 devices (6%)), Insulin pumps (5 device families (2.5%), 9 devices (2.5%)), Earphones (4 device families (2%), 4 devices (1%)), Artificial pancreases (3 device families (1.5%), 3 devices (1%)), Industry tools (3 device families (1.5%), 5 devices (1.5%)), and Prosthesis (2 devices families (1.5%), 2 devices (0.5%)). 13 device families (6.5%), that include 13 devices (*3.5%*)were sorted into the category Other.*

In total we have identified 11 different categories. By an industry tool we understand a device, for which the target application is within industrial services and not for personal health (e.g. wearable assistants for stock management).

Specific examples of devices within each of these categories are Fitbit Flex (Tracker) [9], Samsung Gear (Smartwatch) [13], Sense Glove (Gloves) [14], Orcam (Glasses) [15], G4Roche Accu-Chek Combo (Insulin pump) [16], Bragi Dash (Earphones) [17], OpenAPS (Artificial pancreas) [18], Insulet Omnipod (Industry tool) [19], Touch Bionics I-limb Ultra (Prosthesis) [20] and Siren Socks (Other) [21].

Communication interfaces and data protocols (Attributes B, C)

Summary: Only a few producers are using standardized transmission protocols that enable 3rd parties to implement transfer of data from a wearable.

The majority of wearables integrate Bluetooth interface (144 device families (74%), 288 devices (79.5%)) for wireless communication with a remote device. Other interfaces include (35 device families (18%), 86 devices (24%)) USB, Wi-Fi (19 device families (10%), 36 devices (10%)), RF Radio (10 device families (5%), 18 devices (5%)), ANT+ (8 device families (4%), 22 devices (6%)), Near field communication (NFC) (8 device families (4%), 14 devices (1%)) and GSM (7 device families (3.5%), 11 devices (3%)).

Only a few devices (2 device families (1%), 16 devices (4.5%)) that utilize Bluetooth Smart technology, use the standardized Generic Attribute Profile (GATT) specifications, adopted by the Bluetooth Special Interest Group (SIG) [22]. Use of standardized GATT specifications makes it possible for developers of smartphone/smartwatch/desktop applications to easily integrate wearable devices into their existing application. Only one Wi-Fi-enabled device supported open protocols (i.e., protocol, that has its specifications available online, without a need to perform request to a vendor). Furthermore, open protocols were not supported by any devices using NFC, Ant+, USB, and RF Radio. Currently most of the wearable devices' manufacturers prefer proprietary data-transmission format. Consequently, only original software provided by the manufacturer can be used to use the data by communicating directly with the device.

Smartphone- and PC integration (Attribute D)

Summary: Smartphone Bluetooth compatibility issues might hinder some Bluetooth-enabled device manufacturers to support interoperability among whole spectrum of mobile devices.

The identified wearable devices can be divided into two main categories – consumer-level devices and research devices. Consumer-level devices often closely integrate with a smartphone device to provide advanced visualization of data, settings of personal goals, and in some cases further integration with other 3rd party services. The most commonly supported smartphone ecosystems are iOS (138 device families (71.5%), 271 devices (75%)) and Android (130 device families (67%), 263 devices (72.5%)). One of the main factors causing a slight dominance of the iOS platform, is a tight control of the whole Apple AppStore ecosystem by a single company (i.e., Apple) [23]. With Android, the platform and hardware diversity may cause compatibility issues when integrating Bluetooth-enabled devices. Only a few of all devices integrates with Windows-based phone OS (covering Windows Mobile, Windows Phone 8.1, Windows 10 Mobile), the 3rd player on the smartphone market, although holding only 0.15% market share (15 device families (7%), 46 devices (12%)).

Support for desktop operating systems can be found mostly among devices aimed for research purposes. Desktop operating systems which provide such support include Windows (45 device families (18%), 95 devices (26%)), OSX (28 device families (14%), 64 devices (17.5%)), and Linux (17 device families (8%), 49 devices (13%)).

Direct- and 3rdparty integration with health platforms (Attributes E, F)

Summary: Our results show that Google Fit integrates directly with slightly more devices (22 device families (11.5%), 45 devices (12.5%)) compared to Apple Health (16 device families (8%), 32 devices (9%)). However, these numbers make up approximately only 49 devices (13%) of the total amount of wearables we have covered in our research. The remaining 313 devices (87%) does not support any health platform (neither Google Fit nor Apple Health).

To provide a better understanding of possible communication channels, we created the diagram in Fig. 1 to visualize how data flows between the identified systems. The ultimate desirable transfer of data is a full link between the wearable device (Fig. 1.-I) and EHR (Fig. 1.-VII).

Google Fit [24] and Apple Health [25] are two major health platforms (also known as 'fitness platforms' or 'health-tracking platforms') associated with the Android and Apple ecosystems respectively. Health platforms represent types of health data storage, which can be effectively used to store collected data from wearables equipped with health sensors. Both platforms, as indicated in Fig. 1.-IV, are supporting two-way transfer of data between device's associated cloud services, smartphone consumer applications, and 3rd party services. Several 3rd party cloud-enabled fitness services, which act as a collectors of fitness data, with the ability to combine data from multiple devices, exist on the market (Fig. 1.-F). MyFitnessPal [26], MapMyFitness [27], WorkoutTrainer [28], Strava [10], and myFitnessCompanion [29] are some examples. These applications collect data from different device cloud services (Fig. 1.-III) and can transfer them further to middleware

(Fig. 1.-V) or health platforms (Fig. 1.-IV).

Connection to Health Care System/Middleware (Attribute G)

Summary: Middleware are sparsely supported; only (24 device families (12.5%), 50 devices (14%)) support at least one of the identified middlewares. This situation is partially caused by the limited access to user data for many wearables on the market, which hinders further use of the data.

Besides smartphone health platforms, several other server-based solutions are being utilized by different patient groups. The purpose of these solutions, often called middleware (Fig. 1.-V), is to capture, analyze and process data from 3rd party API providers and Health Platforms, and to provide it in a standardized format, readable by an EHR. In the review, we identified Shimmer [30], Tidepool [11,31], and Glooko [31], as representatives of supported middleware software. Shimmer is supported by 18 device families (9.5%) and 37 devices (11%) in our review. Similarly to another solution, Tidepool (supported by 6 device families (3%)), set-up has to be done individually per user. Therefore, administration of these systems requires a certain amount of technical knowledge. Both Shimmer and Tidepool are open source projects, which are constantly improved by a group of project developers. A third identified system called Glooko is supported by 8 wearable devices families (4%) and 19 devices (5%). Glooko is a proprietary solution targeting diabetes patients.

Health data types (Attribute H)

Summary: Accelerometer-derived data (physical activity, sleep data) represent the majority of identified health data gathered by wearable devices in our review. Advanced physiological-data sensors are usually integrated within devices that are made for research purposes.

We found the following physiological health parameters and derived parameters gathered by wearables covered in this review: Physical activity data (62 device families (32%), 157 devices (43.5%)), heart rate (41 device families (22%), 106 devices (29%)), sleep data (36 device families (18%), 90 devices (25%)), blood glucose (11 device families (10%), 18 devices (5%)), temperature (10 device families (5%), 14 devices (4%)), heart rate variability (6 device families (3%), 12 devices (3.5%)), blood pressure (4 device families (2%), 3 devices (1%)), EEG (4 device families (1.5%), 5 devices (1.5%)), breath rate (3 device families (1.5%), 3 devices (1%)), ECG (3 device families (1.5%), 3 devices (1%)), excess post-exercise oxygen consumption (2 device families (1%), 2 devices (0.5%)) and peripheral capillary oxygen saturation (2 device families (1%), 3 devices (1%)).

Integrated sensors in wearables (Attribute I)

Summary: Few wearables in the review have advanced sensors of physiological health parameters integrated (ECG, EEG, blood pressure etc.)

For each device, we reviewed integrated sensors. We found that accelerometers integrated within most device families in our list (107 device families (54.5%)). Together with gyroscope (57 device families (29%)) and magnetometer (17 device families (8.5%)), they are often integrated in wearables providing physical activity tracking capabilities. In some cases, this main set of physical activity related sensors are accompanied by a GPS (34 device families (17%)), compass (12 device families (6%)), and photoplethysmography sensor (16 device families (8%)) sensors. Accelerometers, together with gyroscopes and magnetometer, usually integrated within a single unit called inertial motion unit (IMU), also find a wide use in virtual reality accessories (e.g., gloves and head-tracking devices).

The remaining sensors include: Temperature sensors (10 device families (5%)), ECGs (8 device families (4%)), Barometers (7 device families (3,5%)), Cameras (4 device families (2%)), EEGs (4 device families (2%)), Blood pressure sensors (3 device families (1.5%)), Galvanometers (2 device families (1%)), Humidity sensors (2 device families (1%)), UV sensors (1 device family (0.5%)), and one Proximity sensor (1 device family (0.5%)).

Medical devices (Attribute J)

Summary: The wearable devices consumer-market comprises of a small number of certified medical devices. The demand for more certified devices with validated/tested measurement methods is steered by an expanding portfolio of associated health data analytics services.

Only 21 devices out of the 362 reviewed devices (5.7%) are classified as a medical device (i.e., have CE-marking class II or above, and/or FDA approval). The need for more devices with validated measurement methods increases with the inclusion of advanced methods of health parameters monitoring (e.g., heart rate) and integration of capabilities to share data with health care systems/middleware [2]. In addition, many associated companion applications provide advanced statistics, suggestions, and prognosis, which can be used by many users as a recommendation for future medical-related actions, and therefore should be classified as medical devices.

Access to user data from sensors (Attribute K)

Summary: There is a need to use standardized data exchange format to improve interoperability. There is also a need to produce more devices, which support direct transfer of data via local connection.

A total of 61 device families (30%) and 137 devices (37.6%) provide electronic (machine-readable) access to user-gathered data. Among these, 34 device families (17%) and 79 devices (21%) use a local area network connection for data transfer (including Ant +, USB, Wi-Fi, NFC, Bluetooth and RF radio transmissions). Furthermore, 35 device families (18%) and 91 devices (25%) support data transfer via its associated cloud-based web service. The combination of both of these options is offered by 11 device families (5%) and 36 devices (9.8%).

Possibility to develop native applications (Attribute L)

Summary: Few devices provide developer-tools to create applications running directly on the device. The possibility to create native applications running on the device is beneficial for software developers to fully utilize the capabilities of the device.

We have identified 28 device families (14%) and 62 devices (17%) with the capability to run custom-developed applications. This means that these manufacturers provide software for developers and the necessary tools to create 3rd-party software running directly on these devices. The portfolio of devices supporting developers access include smartwatches (e.g., Android Wear-based smartwatches), VR gloves (e.g., CyberGlove [32]), and recently also smart headphones (e.g., Bragi [17]).

Advantages of 3rd party applications include addition of user-interaction capabilities, such as custom display user-interface, further utilization of integrated sensors for various purposes (e.g., development of games working with data acquired in real-time), and ability to combine data from different sources.

Availability of the device (Attribute M)

Summary: In total, we have covered 193 wearable devices families consisting of 362 devices.

In our search we included devices which are currently in production (154 device families (80%), 315 devices (86%)), discontinued (16 device families (8%), 25 devices (6.5%)), or in a design phase (22 device families (11%), 24 devices (6.5%)). We also identified one fraud company that pretended to sell nonexistent physical activity trackers.

4. Discussion

We have covered 193 device families to make an overview of data-exchange possibilities of existing wearable devices. In the current situation, where new devices are constantly introduced to the market using various financing schemes (e.g., crowd funding, startup, traditional funding), it is challenging to cover the whole spectrum. We have made a review identifying major challenges and status of such devices, and find this representable for the situation today.

In many cases, the user is locked within a limited-options ecosystem of device manufacturers, which raises concerns about secondary use of personal data. Furthermore, application developers are usually not able to utilize the potential of the device.

Support for communication with both Android and iOS-based companion applications is sometimes provided, however applications may differ in the set of implemented functionalities. Differences in the implementation of Bluetooth Low Energy stack between Android OS versions tailored to individual smartphone device models is one of the main reasons for this.

It is expected that Bluetooth, which is receiving strong support across the whole spectrum of device manufacturers, and is the most utilized wireless interface for transfer of data, will become integrated to even more devices. At the same time, proprietary wireless management protocols through radio frequency communications will still be used by a specific subset of devices (e.g., blood glucose meters, insulin pumps) as demonstrated by several devices (e.g., Medtronic [46], Animas [47]) in our review. The reason given by the vendors are often related to security and privacy.

Cloud-based web services extensively utilize Representational State Transfer (REST) [48] technology to support interoperability with various 3rd-party client applications. Due to a massive use of REST in most resource-oriented web services (i.e., services supporting internetworking of resources), such services can be easily implemented in client applications on many platforms. However, utilizing REST APIs do not imply use of standardized data format for the data-transport. Device manufacturers often design their own proprietary data-schemes, which are used for transferring data. This represents a challenge when integrating multiple devices into one system. An example of health data integration tool, that could be used for facilitating exchange of health data, collected from some of the devices identified in this article, is an Open mHealth [49]. This framework puts a strong accent on interoperability among different mHealth applications and it is based on reusable components, which makes the integration with this framework easier for developers.

Only a small number of devices have been CE marked (class II or above) or are FDA approved. A large number of uncertified devices raise questions about the reliability of data, since the algorithms running inside the device are proprietary.

Some consumer health wearables have been used in multiple scientific studies and have established partnerships with EHR providers. An example of such a device is Fitbit, which has been used in multiple studies targeting different types of patients (e.g., diabetes patients [50,51], patients with obesity [52]) and integrated into existing infrastructure. Fitbit has also established partnership with the EPIC EHR system [12].

A relatively small percentage of devices support smartphone health platforms (e.g., Apple Health and Google Fit), for import of user-captured data. In addition, health data middleware as a next data-storage instance with rich data-mining capabilities is seldom used. Support of health data aggregators could enable easier and more secure data sharing with health care providers, without the use of 3rd party cloud-based services. In order to allow users to take advantage of modern smartphone health platforms (i.e., combined data view from multiple resources, standardized storage, etc.), such support should be integrated in more devices.

Advanced sensors, like heart rate sensor and UV sensor, are getting integrated into more wearable devices for daily use (e.g., wireless headphones). Consequently, higher-resolution metrics and continuous monitoring of different physiological parameters (e.g., continuous heart rate and SpO2 monitoring) will become more commonly accessible feature in upcoming wearable devices.

With an increasing data-ownership awareness among wearable devices users, it is important for device manufacturers to clarify secondary use of data. This include the possibility to use such devices without the need for transferring data via a cloud-based storage, by letting users opt-out from such data-collection service and rather access data directly. The introduction of GDPR and HIPAA regulations will likely enforce manufacturers to clarify the set of data being collected by the device, and allow developers and users to exchange and use data in an easy but secure way.

Analysis of the identified attributes from the perspective of the various stakeholders

Developers of mHealth-enabled applications

While many devices are shipped together with a smartphone companion application, that provides additional support and adds more functionality, the full potential of the devices may remain unutilized. Devices with access to user data enable mHealth software developers to create more comprehensive applications, that can make better use of the wearable devices in more diverse use cases. Examples include applications using data from wearable devices can be utilized within areas of chronic disease self-management, remote monitoring, fitness and wellness, education and other purposes.

Our review of wearable sensors indicate that few devices support transfer of data via local wired or wireless connection, and even fewer use standardized protocols such as Bluetooth Low Energy Health Profiles and Services. Therefore, the portfolio of devices that can be integrated into 3rd party mHealth software without a supporting cloud-based data collection service, is limited.

Several research projects [33], have investigated data-exchange capabilities of wearable devices via reverse engineering methods, and have been initiated as a response to an overall lack of options for standardized data transfer. One of the best known open-source projects in this area, Nightscout [4], supports transmission of real-time, sensor-based blood glucose readings of the users to a cloud-based storage, from where it can be remotely monitored by a caregiver.

In order to provide system-wide, platform-independent support, mHealth software developers often have to rely on associated cloud services, or aggregators and health platforms. Unfortunately, the diverse format of data output hinders generic integration in mHealth software, and might force developers to put additional effort into incorporation of each additional service.

Health platforms providers

Multiple factors have to be considered when integrating a wearable device into an EHR system. In this context we identified 3 critical features – data reliability, device certification, and data transmission risks.

When data originating from wearable device sensors are involved in clinical decision making, clinicians need to know its reliability [34]. This could be achieved by ensuring that standardization, privacy and security issues are considered [35], which can be further ensured by a certification process handled by a regulatory authority. While wellness devices do not require such certification, devices providing health data analytics are regulated and has to be cleared prior to their introduction to a market [36]. Pilot programs, such as a Digital Health Software Precertification (Pre-cert) program, have been established to facilitate the device entire clearance process, and speed up the delivery process of these devices and services to patients [37]. Currently, the Pre-cert program comprises of 9 companies including Apple [38], Fitbit [9], and Roche [39].

Special considerations also come into place when patients transfer data from wearables into EHR. Specific types of sensor readings (e.g., steps, and blood glucose levels), can be more easily understood together with a patient's activity, when compared to other sensors data, and therefore make patients with chronic conditions (e.g., diabetes) benefit from integrating such data into EHRs [40].

Lately, several devices with new types of integrated sensors (e.g., Galvanic skin response (GSR), Peripheral capillary oxygen saturation (SpO_2)) have appeared on the consumer market. Both developer- and user-level access to measurements made by these new sensors are often disabled due to hardware requirements, missing verification of a data prediction model, or unsatisfied requirements of regulatory authorities. An example of such device is the new Fitbit Ionic and Apple Watch smartwatch with an integrated SpO_2 sensor where the access to sensor readings is currently disabled and is expected to be re-enabled in a future software update.

Data protection laws and regulations significantly affect operations with data provided by wearable health devices. According to *Processing of special categories of personal data*, Article 9. of EU GDPR regulation [41], mHeath data are being considered as *Sensitive Personal Data* and implies explicit user consent to be collected and processed. Furthermore, *Data Protection by Design and Default* (Article 23.) imposes the data controller to *implement appropriate technical and organizational measures* using various restriction politics, techniques and rules. The US HIPAA Privacy rules [42] apply to health plans, health care clearinghouses, and health care providers, collectively called *Covered entities,* working with protected health information (PHI). *Covered entities* do not include wearable devices, as they are usually directly purchased by a consumer, and not being prescribed by a physician. Also, commonly collected physiological health and derived parameters, such as number of steps and heart rate, are not considered to be personal health information. However, once the data is transferred to the EHR, it automatically becomes covered by HIPAA as part of the patient record.

Patients

Smartphones are our new personal digital assistants, running various types of mHealth tools. Patients are therefore essentially interested in whether wearable devices are compatible with the smartphone they are currently using. In this context, Bluetooth-enabled devices have the biggest potential to be connected and to communicate the information to a smartphone, where the data can be further processed and interpreted by a companion application.

In a situation where patient carries multiple devices capable of data collection, a direct integration with health platforms, aggregating data from multiple wearable devices to a single place, becomes more and more important. Health platforms, capable of providing such functions, can advanced health data analytics and detailed insights into patient conditions. Today, patients can relate to Personal Health Record (pHR) in a form of tethered pHRs (e.g., MyChart [12]) or interconnected pHR (e.g., Microsoft Health Vault [43], Apple Health [25], Validic [44]), and these tools have become more frequently bundled with smartphone software.

Physiological sensors, like heart rate sensor and blood oxygen saturation (SpO_2) sensor, can serve as continuous monitoring tools of different health parameters, which can provide indications of various diseases. As an example, continuous monitoring of hypoxemia for detection of sleep apnea, which in normal conditions requires use of continuous positive airway pressure (CPAP) device, can be integrated in a relatively cheap consumer wearable devices equipped with SpO_2 sensor.

The wearable form factor is becoming more and more important for many patients when considering a new wearable device for purchase. More and more functionalities are being integrated into different types of wearable devices of daily use (e.g., headphones and wristbands). However, a new trend among wearable devices is using modular accessories [45]. Modular accessory system allows the extension of existing functionality by adding new sensors, and might also influence customers' decision process when buying a new device.

In this context, it is also worth mentioning examples of specific smartphone applications, that help with chronic disease self-management and use commercially available wearable devices. One of such examples is an mHealth platform iCardia [53], which is designed to support remote monitoring and health coaching of cardiac rehabilitation patients through Fitbit wearable sensor devices, smartphones, and personalized SMS text messages. Another example is a smartphone application Diabetes Diary [54], which helps diabetes patients to manage their disease better. Besides an integration with Runkeeper platform [55], the application also supports a companion application running on the Pebble smartwatch [56], which besides physical activity data also provided notifications, and overview of daily registrations.

5. Conclusion

We propose a wider use of standardized, open communication protocols, which would allow to directly acquiring user data from a wider range of wearable devices. Use of open protocols can provide mobile health (mHealth) application developers an alternative to proprietary cloud services and communication tools, which are often closely integrated with the devices. The emerging new types of sensors, often intended for everyday use, have a potential to supplement health records systems with data that can enrich patient care.

Summary Points

What was already known on this topic

- Wearable devices with an ability to collect various type of physiological data are increasingly becoming seamlessly integrated into everyday life of people.
- Interoperability, in terms of communication capabilities with other devices, is often influenced by different made-by-design constraints, and the full potential of devices may remain unutilized.
- The emerging various sensor technologies and its utilization in various self-management services, can have a positive impact on related functionality such as medical decision support, provisioning of alarms and remote caregiver monitoring.

What this study added to our knowledge

- Few devices support transfer of data via local wired or wireless connection, and even fewer use standardized protocols such as Bluetooth Low Energy health profiles and services.
- Lately, several devices with new types of integrated have appeared on the consumer market. Both developer- and user-level access to measurements made by these new sensors are often disabled due to hardware requirements, missing verification of a data prediction model, or unsatisfied requirements of regulatory authorities.
- Only a small number of devices have been CE marked (class II or above) or are FDA approved.
- A relatively small percentage of devices support smartphone health platforms (e.g., Apple Health and Google Fit), for import of user-captured data.

Limitations

Vandrico database holds a considerable amount of records. However, some of them are not fully up-to-date, and many recently released devices are not listed.

Declaration of competing Interest

The authors have no conflicts of interest to declare.

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