Clarifying the blurring line between medical, wellbeing and lifestyle apps

Does my app collect health data?

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Abstract. The functioning of mHealth app is based on collecting, storing and processing users' data in order to: diagnose, monitor or prevent disease, for social and elderly care, research, and for lifestyle and wellness. In fact, they mostly process personal data that might be classified as health data to which a higher level of data protection applies. There is a general agreement that data processed by apps in medical context are health data. However, in the EU there is no clear delimitation between apps as medical device, lifestyle and wellbeing, which may confuse app developers regarding the question whether processed data are health data or not. Therefore, the question that this paper will try to answer is if a clear delimitation between apps as medical, lifestyle and wellbeing can contribute to better capture the notion of health data.

Keywords: Health data, mHealth apps, GDPR, medical device app, lifestyle and wellbeing apps,

1. Introduction

The proliferation of connectivity embedded in smart devices allows people to install and use different kinds of applications "apps". Some of these apps allow users to conduct self-diagnoses, to measure vital signs such as: heart rate, blood glucose level, blood pressure; for physical activities such as: running, walking or for fitness and dietary recommendations. All these apps are part of the mobile health (mHealth) concept defined as:

"a sub segment of eHealth that covers medical and public health practice supported by mobile devices. It includes the use of mobile devices for health and well-being services and information purposes as well as mobile health applications"[1].

In particular, the EU Green paper on mobile health[2] explains that lifestyle and wellbeing apps also fall within the scope of the definition. Actually, apps used in medical or health context are called mobile health applications (mHealth apps) and are generally[3] classified in two groups: (1) apps for the purpose of prevention, diagnosis and treatment of diseases (or medical apps); and (2) for lifestyle, fitness and well-being apps. Yet, the distinction is not always straightforward.

These apps are collecting, storing and processing users' data in order: to diagnose, monitor or prevent disease, for social and elderly care, research, and for lifestyle and wellness. Such data might be provided by the users, collected via sensors or through different monitoring devices that transfer the data to the apps. Traditionally, information (medical and health data) has been a central aspect of the health and medical sector. Nowadays, due to the significant uptake of smart devices and readily available application development frameworks, basically anyone can develop medical and health apps. The advances in both science of medicine and ICT have made it: easier and cheaper to collect, store, and analyse data and have led to more types of information being relevant for the care[4] (arising from the possibility to extract new information from seemingly trivial data).

As a matter of fact, most mHealth apps process[5] personal data. This processing of data triggers the applicability of the data protection law, as an instrument for protecting the right to privacy. Additionally, these data might fall in a special category of data - health data. Health data has long[6] been considered to be personal and deserv-

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[1] mHealth Digital Agenda for Europe –mHealth https://ec.europa.eu/digital-agenda/en/mhealth last visited 03.06.2015

[2] The Green Paper is available at: ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth p,4

[3] They are different classifications of mHealth apps in the literature and in the app stores. For the purpose of this paper we will adopt the abovementioned.

[4] Engaging Privacy and Information Technology in the Digital Age-James Waldo, Herbert S. Lin, and Lynette I. Millett, Editors, 2007

[5] Opinion 02/2013 on apps on smart devices, Article 29 WP, February 2013, http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2013/wp202_en.pdf

6 Privacy has been a part of medicine since the 4th century B.C, when the importance to protect medical and health data has been recognized via the Hippocratic oath "What I may see or hear in the course of the treatment or even outside of the treatment in regard to the

ing privacy protection. In the EU, the newly adopted General Data Protection Regulation (GDPR) qualifies them in a special[7] category of data to which a higher level of data protection apply, and their processing is very limited unless one of the exceptions applies[8].

The reasoning behind this is that misuse of health data might have long term consequences[9], which can lead to infringement to the right to privacy and to discrimination that could result in two types of concerns. The first one is a social concern — disclosure of health data potentially could lead to discrimination and to being socially ostracized. Whereas the second concern is economic — disclosure of health data to third parties can led to a) denial of health insurance (or increase the price of such insurance), b) disclosure to bank it may affect credibility prospects.

However, the definition in Article 9 and Recital 35 of the GDPR are very broad and it is not always easy to understand if collected data can be considered as health data. First the definition is characterized as comprehensive but non-exhaustive[10], that does not specifically address the question whether and to what extent information from mHealth apps fall within the scope of health data. Second, capturing the notion of health data collected by mHealth apps is more complex since apps collect various kinds of data, which could in combination be considered as health data. In fact, there is general agreement[11] that if data is processed by an app in a medical context is health data, but what is not clear is how to decide if the apps is used in medical context. One possible solution is to clarify the blurring line between apps as medical devices, lifestyle and wellbeing. Nevertheless, despite the existing uncertainties, the differentiation between personal data and health data is extremely important as the breaches concerning health data endanger the person's right to

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life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about." - Cross-Cultural perspectives of medical ethics- Robert M. Veatch, The Hippocratic oath: Text, Translation and Interpretation (Chapter 1)

[7] Article 9, Parg.1 General Data Protection Regulation 6 April, 2016

[8] Article 9, Parg.2, 3 and 4 General Data Protection Regulation 6 April, 2016

[9] Article 29 Working Party Advice Paper on Special Categories of Data (sensitive data). http://ec.europa.eu/justice/dataprotection/article29/documentation/otherdocument/files/2011/2011_04_20_letter_artwp_mme_le_bail_directive_9546ec_annex1_en.pdf , p 4

[10] EDPS Opinion 1/2015 Mobile Health, 21 May 2015. - https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-05-21_Mhealth_EN.pdf, p 6.

[11] EDPS Opinion 1/2015 Mobile Health, 21 May 2015. - https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-05-21_Mhealth_EN.pdf, p 2

privacy and non-discrimination in much more substantial way. Moreover, infringement of Article 9, predicts hefty fines[12] for controller(s) and processor(s) of health data of up to 4 % of the total worldwide annual turnover of the preceding financial year. Consequently this situation attracts controller(s) and processor(s) attention and the need for clarification.

Therefore, the question that this paper will try to answer is if a clear delimitation between apps as medical, lifestyle and wellbeing can contribute to better capture the notion of health data. The paper will be structured as follow: 1. Mapping the existing EU laws, Guidelines, Manuals relevant for delimiting medical device apps, lifestyle and wellbeing apps, furthermore we well briefly present the US approach on this issue. However, the aim of this section is not to criticise the existing law; 2. a review of the existing legislation, literature and opinions of Article 29 WP related to the definition of health data and 3. Conclusions and a proposal for future work

2. Delimiting apps as medical device, lifestyle and well-being

2.1 Medical device app

As previously mentioned, in the EU there are no binding rules for distinguishing[13] between medical devices, lifestyle and well-being apps[14]. However, legal requirement for a mobile app to be considered as medical device[15] is: to fall within the scope of

[12] Article 83, Parg.5, General Data Protection Regulation.

[13] See Green paper on mobile Health ("mHealth"), Commission staff working document on the existing EU legal framework applicable to lifestyle and wellbeing apps {COM(2014) 219 final} p.11

[14] See *Id*. p.3 Lifestyle and wellbeing apps primarily include apps intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals.

[15] 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: ◄ — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Article 1, 2(a) of the current Medical Devices Directive 93/42/EEC[16] "as software intended[17] by its manufacturer to be used specifically for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

However, the definition of a medical device has a wide scope and applies to many devices that are intended to be used within the entire health care sector including small simple devices but also large advanced systems. Moreover, for the reason that the app as software has an "intangible nature", the application of the requirements in the directives are not always entirely clear. In order to clarify the questions of application of EU Directives on medical devices and to provide guidance to the manufacturers of mHealth apps, the Commission regularly publishes legally non-binding guidelines and manuals[18]. The guidelines and manuals[19] constitute codes of practice that the companies launching mHealth apps need to take into account. The MEDDEV 2.1/6 [20] .guidelines defines the criteria for qualification and classification [21] of

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[16] Directive concerning medical devices 93/42/EEC - The primary purpose of these Directives is to provide common rules for the free movement of goods throughout the EU, and, at the same time, to ensure the same level of safety to all EU citizens using medical devices.

[17] Directive 93/42/EEC concerning medical devices Article 1 (2) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

[18] Due to the fact that these guidelines reflect positions taken by representatives of interested parties in the medical devices sector (Competent Authorities, Commission services, industry and Notified Bodies in the medical device sector) it is foreseen that they will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions. See European Commission web site – medical devices regulatory framework http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index_en.htm

[19] EC Manual on borderline and classification in the community regulatory framework for medical devices Version 1.16 (07-2014)

[20] Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices January 2012

[21] The word *qualification* in the guidelines means to determine whether an app shall be considered to be a medical device or not and in which category it belongs to: general medical devices, *in vitro* diagnostic medical devices or active implantable medical devices. The word *classification* in the guidelines means to determine which risk class the app belongs

standalone software (app), when they are used in a healthcare setting. Therefore for an mHealth app[22] to be qualified as medical device it must fulfil the following three conditions: 1) to have a medical purpose[23], which means only the intended purpose as described by the manufacturer of the product is relevant for the qualification and classification of any device and not by way it may be called; 2) that app is not incorporated in a medical device at the time of its placing on the market; 3) needs to be able to analyse existing information and to generate new specific information according to the intended use of the software and to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.[24]

The MEDDEV guidelines developed by the EC contain a number of important clarifications but they still lack to address different levels of sophistication of medical information systems that exist in different European member states. Therefore some of the EU Member states have issued national guidelines for qualification and classification of standalone software, such as (but not limited to) Swedish "Medical Information Systems - guidance for qualification and classification of standalone software with a medical purpose" [25] and UK Medical devices: software applications (apps)[26]. For clarification, these guidelines are completely based on the medical device directives and synchronised with the MEDDEV guidelines. In fact, the purpose of these guidelines is to address the issues which need to be clarified so that they can reflect the rapid development and describe the current situation on the particular market.

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to base on the vulnerability of the human body from the potential risks associated with the technical design and manufacture of the device under each medical device directive (class I, II or III for general medical devices or Common, list A, list B for *in vitro* diagnostic medical devices).

[22] To be software as computer program ISO/IEC 2382-1

[23] This issue regarding medical purpose was address by the European Court of Justice in the Case C-219/11 Brain Products GmbH v BioSemi VOF and Others[23] confirmed the fact that the purpose of the manufacturer is more relevant than the context for qualifying medical devices. See more ECJ Case C-219/11 Brain Products GmbH v BioSemi VOF and Others
http://curia.europa.eu/juris/document/document.jsf?text=&docid=130247&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=258748

[24] See page 6, Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices January 2012

[25] "Medical Information Systems - guidance for qualification and classification of standalone software with a medical purpose" https://lakemedelsverket.se/upload/eng-mpa-se/vagledningar_eng/medical-information-system-guideline.pdf

[26] UK Medical devices: software applications (apps)
https://www.gov.uk/government/publications/medical-devices-software-applications-apps

Despite the abovementioned conditions UK Medicines and Healthcare products Regulatory Agency has explained that there are number of words likely to contribute for qualification of an app as medical device, such as use of keywords as amplify, analysis, interpret, alarms, calculates, controls, converts, detects, diagnose, measures, monitors.[27]

However, despite the existing legal framework explaining which apps will be qualified as medical device and which not, reality is different and difficult for the reason that the line between apps is blurred. In order to understand how these elements should be applied in practice when assessing whether an app is considered as medical device or not, two examples will be used. The first one is an app used for communication between patient and doctor while giving birth.[28] This app is not considered as medical app because although it is not incorporated into a medical device, the intended use is to improve the quality of communication between the patient and caregivers and to perform an action on data limited to storage and simple search. In other word it cannot be qualified as medical device because it is not able to analyse existing information, its function is limited to storage of the data.

The second example is an app that uses an accelerometer or gyroscope in two different situations. In the first case it is used as a fall-detector for epileptic patients. Therefore is likely to be regulated as a medical device. This app has medical purpose, is not incorporated into a medical device and analyses data.[29] In the second case the same app that uses an accelerometer or gyroscope to alert someone if an elderly person has got up from a chair or bed does not have medical purpose because it is used in social or wellbeing context and it will be not qualified as medical device even though it is not incorporated into a medical device and analyses data.[30] This reasoning sheds light on the "context" as additional aspect of the qualification, besides the three abovementioned conditions.

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[27] UK Medical devices: software applications (apps) https://www.gov.uk/government/publications/medical-devices-software-applications-apps/medical-device-stand-alone-software-including-apps

[28] This app allows storing data on each moment of contraction during delivery, after a healthcare professional established that a woman is in the process of giving birth. Users can make notes and take pictures for the purpose of exporting them to an external website also providing documentation for a later stage. See EC Manual on borderline and classification in the community regulatory framework for medical devices Version 1.16 (07-2014)p.64

[29] UK Medical devices: software applications (apps) https://www.gov.uk/government/publications/medical-devices-software-applications-apps

[30] UK Medical devices: software applications (apps) https://www.gov.uk/government/publications/medical-devices-software-applications-apps

The issue regarding medical purpose and medical context has been addressed by the European Court of Justice in the CaseBrain Products GmbH v BioSemi VOF and Others[31]. To explicate, the case was about a BioSemi product called 'ActiveTwo' which is a system capable of recording electrical signals from the human body - from the brain (EEG), the heart (ECG) and the muscles (EMG). Although measurements of this nature are frequently taken in a healthcare context (electrocardiograms, electroencephalograms and so on), the product in question was not designed for the medical sector and the promotional material explicitly stated that it was not designed to be used for diagnosis and/or treatment. Brain Products, one of Bio Semi's competitors brought an action against BioSemi on the basis that, regardless of its intended use, the system manufactured by BioSemi must be regarded as a medical device for the purposes of the directive and, accordingly, must be certified as such. The Court has confirmed the fact that the purpose of the manufacturer is more relevant than the context for qualifying medical devices and has confirmed that the BioSemi application is not a health application?

2.2 Lifestyle and Well-being apps

For the reason that EU lack guidelines or manuals regarding lifestyle and wellbeing apps, we will analyze how this issue is solved in the U.S[32]. Moreover, this could contribute to solve the current issue in the EU. According to the US FDA "guidelines on general wellness", for an app to be considered as wellness app it needs to be intended only for general wellness use and to present a very low risk[33] to users' safety. This means that the app is intended to be used:

1) to maintain or encourage a general state of health or a healthy activity (such as weight management, physical fitness, relaxation or stress management, mental acuity, sleep management, or sexual function). In this case the keywords used to describe the functioning of the apps are to promote, to maintain, to encourage, to assist, to improve, to increase or to track. If the keyword is to treat or to restore then it is not considered as wellness app.

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[31] ECJ Case C-219/11 Brain Products GmbH v BioSemi VOF and Others http://curia.europa.eu/juris/document/document.jsf?text=&docid=130247&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=258748

[32] General Wellness: Policy for Low Risk Devices Draft Guidance for Industry and Food and Drug Administration Staff, U.S. Department of Health and Human Services issued on: January 20, 2015

[33] Whether a device is low risk for purposes of this guidance is determined by whether or not the product: 1) is invasive ; 2) involves an intervention or technology that may pose a risk to a user's safety if device controls are not applied, such as risks from lasers, radiation exposure, or implants; 3) raises novel questions of usability; or 4) raises questions of biocompatibility.

2) to be associated with a healthy lifestyle that helps to reduce the risk or impact of certain chronic diseases or conditions, more specifically is intended to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, may help to reduce the risk or may help living well of certain chronic diseases or conditions.

To conclude this section, there is a lack of binding rules regarding delimitation of apps, however from the existing cases and guidelines, to some extent can be drawn clear line between the apps. In particular, the app should be able to analyse data and generate new one, to be not incorporated in a medical device, and the most essential is to have a medical purpose which means only the intended purpose as described by the manufacturer or developer of an app is relevant. Actually, the intended purpose is more significant than the context in which the app is used. One way of presenting purpose is by labelling the app, in other words by using keywords as amplify, analysis, interpret, alarms, calculates, controls, converts, detects, diagnose, measures, monitors. Regarding the issue of delimiting apps as medical devices, the FTC[34] has created an interactive website. It is intended to help app developers and allows them to determine whether their app falls within the category of medical device by simply answering yes or no questions.

In addition, lifestyle and wellbeing apps can be also delimited from the medical devices apps, if they are associated with and used for maintaining healthier lifestyle. Moreover using keyword such as to promote, to maintain, to encourage, to assist, to improve, to increase or to track, in order to promote functioning of an app would likely contribute to the delimitation.

However, the current situation is undesirable. App developers or manufactures are in position to avoid compliance with the (strict) requirements for medical apps (certification of the app), by declaring the intended purpose that is most appropriate for them. Simply by using specific keywords, regardless of the context in which its actually used, they can have their apps enter a lighter regulatory regime.

Yet, they might avoid certifying the app as medical device[35], but the question if an app process personal data or health data is not avoidable. For the reason that in case of

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[34] Mobile Health Apps Interactive Tool - Developing a mobile health app? - Federal Trade Commissioner, Launched April 2016, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool

[35] For clarification, one of the exception for processing of health data is Article 9, Parg 2 (h) "processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3; ". Therefore the app as medical device will fall in the exception. However this is not in the scope of this paper and we will not engage in further discussion.

processing personal data or health data app developers must comply with the data protection law. The question "what is personal data and health data in the context of mHealth apps? lead us to the next part.

3 Personal data as health data

3.2 Personal data

According to Article 4 (1)[36] "'personal data' means "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier[37] or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;"

Some argue that the definition as is could mean that all data is potentially personal data. This stems from the fact that, data, which at one moment in time may contain no information about a specific person, may in the future be used, through advanced techniques (and/or linking the data with other data), to identify or individualise a person[38]. One possibility is through interconnecting databases, so when two or more de-identifying datasets are integrated, they may become identifying datasets[39].

Therefore, data that have been collected stored and processed from the users of the mHealth apps are most likely considered as personal data. One reason is that smart devices, on which mHealth apps are installed, are characterized as portable, frequently used, commonly always on and personal. Second, they typically have direct access to many different sensors and data, such as a microphone, camera and GPS receiver, together with the user's combined data including email, SMS messages and contacts[40]. Hence, for the reason that the app is installed on a smart device, which is mostly used

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[36] General Data Protection Regulation

[37] GDPR, Recital 30 "provided by their devices, applications, tools and protocols, such as internet protocol addresses, cookie identifiers or other identifiers such as radio frequency identification tags. This may leave traces which, in particular when combined with unique identifiers and other information received by the servers, may be used to create profiles of the natural persons and identify them.

[38] Article 29 Working Party, Opinion 05/2014 on Anonymisation Technique, adopted on 10 April 2014, WP216, p 9

[39] M. R. Koot, Measuring and Predicting Anonymity, Amsterdam: Informatics Institute cop., 2012, p 101 http://dare.uva.nl/document/2/107610

[40] Privacy in mobile apps - Guidance for app developers; ICO (Information Commissioners Office), December 2013 (page 3) https://ico.org.uk/media/for-organisations/documents/1596/privacy-in-mobile-apps-dp-guidance.pdf

by and connected with the owner of the device, allows this user to be identified, directly or indirectly[41]. A recent study shows that this is also possible due to the apps business model.[42]

Furthermore, some personal data is considered as special category of personal data[43]. In this category falls data that reveal racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation. The processing of this kind of data is prohibited, unless one of the exceptions applies.

3.3 Health data and mHealth apps

Health data as a special category of personal data has central position in this paper. It is defined as data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status[44]. Moreover recital 35 provides a comprehensive explanation of what falls within the scope of the definition:

> Personal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council () to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject inde-

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[41] The guidelines for mobile apps (Privacy in mobile apps) A good example in the mobile environment would be a unique device identifier such as an IMEI number: even though this does not name the individual, if it is used to treat individuals differently it may fit the definition of personal data.

[42] The Price of Free: Privacy Leakage in Personalized Mobile In-App Ads ; College of Computing Georgia Institute of Technology Wei Meng, Ren Ding, Simon P. Chung, Steven Han, and Wenke Lee, February 2016

[43] GDPR, Article 9 (1)

[44] Article 4, Parg.15

pendent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.

At first sight it seems that reading the recital will straightforwardly solve the question if data generated by mHealth apps fall within the scope. In fact, this definition is very broad. It is characterized as comprehensive but non-exhaustive[45], that does not specifically address the question whether and to what extent information from mHealth apps falls within the scope of health data. Also, capturing the notion of health data collected by mHealth apps is more complex since the apps collect various kinds of data which could in combination be considered as health data. The Article 29 WP in the advice paper "health data in apps and devices" [46] has provided some clarification on this issue.

General agreement is that "medical data or data about the physical or mental health status of a data subject that are generated in a professional, medical context is health data. In particular, it entails data about diagnosis and/or treatment by providers of health services, diseases, disabilities, medical history and clinical treatment. For example data from an app that measures blood pressure or heart rate is considered as health data. Regardless, if testing is performed by medical professionals or by apps freely available on the commercial market and irrespective whether app is marketed as medical devices or not.

Yet, health data is much broader term then the medical term. Some argue that "what constitutes health is more difficult to define than what constitutes illness"[47]. Thus, the definition has been interpreted that it's not always necessary data to be related with "ill health" or "disease risk "in order to be considered as health data. For example the results from a blood test which is performed to diagnose health, qualify as health data no matter if the outcome of the test is within the health limits or not.

Furthermore, information about a person's obesity, high or low blood pressure, hereditary or genetic predisposition, excessive alcohol consumption, tobacco consumption,

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[45] EDPS Opinion 1/2015 Mobile Health, 21 May 2015. - https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-05-21_Mhealth_EN.pdf, p 6.

[46] "ANNEX-health data in apps and devices" of the Article 29 WP http://ec.europa.eu/justice/data-protection/article-29/documentation/otherdocument/files/2015/20150205_letter_art29wp_ec_health_data_after_plenary_annex_en.pdf

[47] A cross-cultural comparison of health status values, D L Patrick, Y Sittampalam, S M Somerville, W B Carter, and M Bergner , Am J Public Health. 1985 December; 75(12): 1402–1407

drug use or any other information if there is a scientifically proven or commonly perceived risk of disease in the future is also considered as health data.[48] Consequently, any information, which could possibly affect or predict the health status of a person, would be considered as health data. For example data process from apps used for tracking exercise habits or diet might be considered as health data. This steam from the fact that is possible to draw conclusion from the correlation between certain lifestyle factors and diseases.

Personal data generated by lifestyle and wellbeing apps, basically, fall within the grey area between personal and health data. In other word, they are personal data but it is not clear if can be regarded as health data. On this issue Article 29 WP has concluded that data generated from lifestyle and wellbeing app is considered as health data when is[49]: 1) inherently/clearly medical data, as explained before 2) raw sensor data that can be used in itself or in combination with other data to draw a conclusion about the actual health status or health risk of a person. Nevertheless if seemingly innocuous raw data is tracked over a longer period of time, might fall within the definition of 'health data'; 3) conclusions are drawn about a person's health status or health risk (irrespective of whether these conclusions are accurate or inaccurate, legitimate or illegitimate, or otherwise adequate or inadequate). For example data from an app that tracks footstep solely as a way of measuring the users sport activities, will be not considered as health data if: is not stored by the app developer, in order to create a profile that evaluates the user's physical fitness or health condition, nor it is combined with other data. However if the app is used to measure or predict health risks (hearth attack) and to enable medical follow up, then data is considered as health data.[50]

This issue has been also address in the Code of conduct on privacy for mobile health application[51]. However it does not provide a more detailed clarification how to capture the notion of health data, than the one already explained by the Article 29 WP. Moreover the Code provides guidance for app developers on how European data pro-

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[48] "ANNEX-health data in apps and devices" of the Article 29 WP http://ec.europa.eu/justice/data-protection/article-29/documentation/otherdocument/files/2015/20150205_letter_art29wp_ec_health_data_after_plenary_annex_en.pdf p.2

[49] *Id.* p.5

[50] European mHealth Initiative, Draft Code of Conduct on privacy for mobile health applications, p.2 - On 7 June 2016, the Code of Conduct has been formally submitted for comments to the Article 29 Data Protection Working Party. Once approved by the Working Party, the Code will be applied in practice: App developers can sign it on a voluntary basis, thereby committing to following its rules.

[51] *Id.*

tection legislation should be applied in relation to mHealth apps[52]. In fact, it is a Privacy Impact Assessment (PIA)[53], in a form of questions intended to help app developer, to determine whether the main requirements of the Code are respected, and whether good privacy practices are followed before making the app available.

Thus, it is evident that despite the existing law, opinions and clarification, it's challenging to capture the notion of health data. This on one hand is due to the highly technical and complex technology used in the apps, which on the other hand is continuously developing and improving. Considering the fact that there is no simple definition of health data, one of the proposed solutions is to be decided case by case[54]. Accordingly, controllers of personal data would be responsible and should be accountable how they legally define processed lifestyle and well-being information. The main reasoning behind is that, in most cases, they possess crucial knowledge, necessary to qualify such information as health data or not[55].

3. Conclusion

There is a lack of binding rules regarding delimitation of apps, however grounded on the existing cases and guidelines, deciding on case by case bases, it might be possible to drawn clear line between the apps. Clear delimitation of apps will to some extent contribute in capturing the notion of health data, especially, data generated by medical devices apps. On the other hand whether data generated by lifestyle and wellbeing apps is health data or not should be assessed case by case.

Therefore it might be recommendable to be incorporated in one website, same as the FTC[56] a) legal requirements, manuals and guidelines regarding classification of app as medical device; b) US guidelines on wellness apps (due to the lack of EU one) as well as c) the Opinion of Article 29 WP on "health data in apps and devices" and Code of

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[52] *Id.* p.1

[53] *Id.* p.19

[54] See Opinion 1/ 2015 Mobile Health, 21 May 2015, European Data Protection Supervisor; https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-05-21_Mhealth_EN.pdf p.6

[55] *Id.* p.8

[56] Mobile Health Apps Interactive Tool - Developing a mobile health app? - Federal Trade Commissioner, Launched April 2016, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool

mobile health application. In this case, the app developers by simply answering “yes or no”, on question arising from all above-mentioned sources, can decide the category of the app and if processed data is health data or not.