

MEASURING WELLBEING: DEALING WITH TECHNOLOGY-ENABLED MEASUREMENT AND THE CONFLICTS BETWEEN PRIVACY AND INCIDENTAL FINDINGS

MEDIÇÃO TECNOLÓGICA DO BEM-ESTAR: GESTÃO DE CONFLITOS ENTRE A PRIVACIDADE E AS DESCOBERTAS ACIDENTAIS

MEDICIÓN TECNOLÓGICA DEL BIENESTAR: MANEJO DE CONFLICTOS ENTRE PRIVACIDAD Y DESCUBRIMIENTOS ACCIDENTALES

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ABSTRACT

Measuring quality of life and wellbeing is a huge challenge that we have just only started to address, as digital technologies tend to find new ways of measuring it and the researchers develop new methods, scales, and surveys. However, in these cases, incidental findings and ethical issues may appear. In order to better address possible conflicts arising in this context, this article provides a brief review of concepts (e.g. wellbeing, quality of life), followed by an attempt to pave the way for the future drawing on guidelines regarding improved technology-enabled measurement of wellbeing.

Keywords: wellbeing, quality of life, surveys, scales; ethical issues, incidental-findings.

RESUMO

Medir a qualidade de vida e o bem-estar é um enorme desafio que apenas começamos a enfrentar, pois as tecnologias digitais tendem a encontrar novas maneiras de medi-los e os investigadores desenvolvem novos métodos, escalas e inquéritos. No entanto, nesses casos, dados incidentais e questões éticas podem surgir. Para abordar melhor os possíveis conflitos que surgem nesse contexto, este artigo fornece uma breve revisão de conceitos (por exemplo, bem-estar, qualidade de vida), seguido de uma tentativa de pavimentar o caminho para o futuro, baseando-se em diretrizes em relação à melhoria da medição do bem-estar via tecnologia.

Palavras Chave: bem-estar, qualidade de vida, inquéritos, escalas, problemas éticos, descobertas acidentais.

RESUMEN

Medir la calidad de vida y el bienestar es un gran desafío que acabamos de comenzar a abordar, ya que las tecnologías digitales tienden a encontrar nuevas formas de medirlo y los investigadores desarrollan nuevos métodos, escalas y encuestas. Sin embargo, en ambos casos, pueden aparecer datos incidentales y problemas éticos. Con el objetivo de abordar mejor los posibles conflictos que surgen en este contexto, este artículo proporciona una breve revisión de conceptos (por ejemplo, bienestar, calidad de vida), seguida de un intento de allanar el camino para el futuro basándose en pautas con respecto a la medición mejorada del bienestar gracias a la tecnología.

Palavras-chave: bienestar, calidad de vida, encuestas, escalas, cuestiones éticas, descubrimientos accidentales.

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INTRODUCTION

The quality of life and wellbeing have been concerning academic and scientific areas for decades. According to the World Health Organization, quality of life is defined as “the individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (World Health Organization, 1999) and wellbeing can be understood “as a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity” (World Health Organization, 1999)

In comparison to WHO’s definitions, the Organization for Economic Co-operation and Development (OECD) describes eight points that can be used to measure the quality of life and wellbeing: health status, work-life balance, education and skills, social connections, civic engagement, environmental quality, personal security, subjective wellbeing (Organization for Economic Co-operation and Development, 2009). A person can achieve these points in various ways, but the subjective wellbeing requires a specialized work once it relates to mental health.

In academic and scientific research, quality of life (QoL) and wellbeing (WB) are usually assessed through surveys (Burckhardt, & Anderson, 2003). However, nowadays, the technology advance makes it possible to measure these topics and improve the results. Sensor, mood and facial recognition and other innovations can be used for doctors, psychologists, psychiatrists, formal and informal caregivers in health care.

In a more specific area, the demographic change increased the concern for older people’s quality of life and wellbeing. Beyond the cited concept, QoL for older adults stands for the feeling of security and independence; to be listened to, valued and respected; getting help; living in a place which suits them and their lives (van Leeuwen et al, 2019). Wellbeing for older people revolve around the concept of successful ageing based on objective indicators such as absence of physical impairments, cognitive disabilities, and social restrictions (Rowe & Kahn, 1997).

The older people’s QoL and WB are a preoccupation of the DAPAS project. Deploying AAL Packages at Scale (DAPAS) aims to develop a new system to support older adults with needs for care and their informal caregivers and care service providers. (DAPAS, 2019) For this purpose, a trial has been developed, reassuring a co-creation methodology, which will involve the end-users once they have an active role on the project. One of the project’s criteria is the maintenance and improvement of older people quality of life and wellbeing. To certify the accomplishment of this goal, the project will use questionnaires, scales and a technology properly developed to measure the participant wellbeing and compare results, before, during and after the continuous use of the system for a year.

However, some concerns arise, giving the possibility of incidental findings reveal a poor wellbeing. These findings may lead to some ethical issues. The collected data and its ethical analysis lead to some questions: should, for example, the technology user (i.e., the older adult) be informed about the findings? How should he/she be informed so that it does not add to the problems? Who else should be informed and in what sequence to guarantee the end-user privacy and the appropriately dealing with the general data protection rules? At what stage, does the researcher need to break the privacy for the safety of the person? It is thus necessary to investigate on how to deal with these possible privacy conflicts.

The concepts of gaining information through technology enabled devices are relatively new, but the research on the matter, in general, have already published some material about it. For

this reason, this paper aims to collect the investigation that it is already done in this field and re-read it, focusing on trying to answer these ethical issues.

In order to assemble a comprehensive literature review and to apply these concepts and results in the development of DAPAS System, this paper will provide a short overview about the concepts of wellbeing and quality of life, regarding aspects on subjective wellbeing. Secondly, a brief review on how wellbeing and quality of life of older people can be measured and useful to academic and scientific research, namely using scales, surveys, and technology. Finally, we will analyse the ongoing ethical discussions concerning technology-enabled measurements and the conflicts between incidental findings and privacy individual rights. Thus, the main question for this paper will be on how to deal with the incidental findings that may arise when the wellbeing is measure, using questionnaires or technology, that could cause conflicts between individual privacy and the necessity of report the discovery.

1. A SHORT OVERVIEW ABOUT QUALITY OF LIFE AND WELLBEING: CONCEPT AND MEASUREMENT

According to Prilleltensky (2005) and Theofilou (2013), the wellbeing and quality of life are growing areas of research. Scientific studies set wellbeing as the focus of healthcare interventions, being a complex construct, encompassing different psychological and social dimensions.

This literature review was destined to answer some questions and concerns that appeared during the development of the DAPAS Project. This project aims to develop a new ICT system that will help older people and their caregivers to deal with the daily activities, maintaining their independence and improving their feeling of security. (DAPAS, 2019).

This system brings together a series of devices focused on the human centered design, improving quality of life to older people, and reducing the caregiver burden. The DAPAS project is co-funded under the Active Assisted Living (AAL) program, aiming to develop solutions related to ambient intelligence technology to enable people, especially older adults, to live in their preferred environment for longer, by providing some proactive and situation-aware assistance to sustain the autonomy and reducing the caregiver burden. This includes the development and use of pervasive systems and ubiquitous computing (ubicomp) which refer to the convergence of communication technologies, computing devices and interfaces that adapt to the needs and preferences of the user. (Sun et al., 2009).

A part of the DAPAS solution also focuses on wellbeing, which is implemented using an application and an activity tracker. The wellbeing detection allows people with need for support care to monitor their wellbeing and observe the wellbeing status of the previous days with the use of age-appropriate statistics (DAPAS, 2019).

Thereby lies the importance of a thorough description of QoL and WB concepts and effective ways for applying and measuring them is so important for a successful trial. To know how to measure and assess these data is crucial to prove that the project is impacting the lives of the participants. This can be done comparing the results, before, during and after the trials.

World Health Organization establishes in its Constitution some guidelines and relevant concepts that guide the research worldwide. Quality of life and wellbeing are also a preoccupation and considered important to international health. Quality of life is a subjective and individual perception of the person position in life, taking into consideration their own culture and values (International Health Conference, 2002). Wellbeing is related to these tree

aspects: physical, mental, and social wellbeing, not only related to health per se, but with happiness and satisfaction of life, which are resources that they need to face a psychological, social and/or physical challenge (Shah & Marks, 2004, 2004).

Physical wellbeing consists not only the skill to practice physical activities, but also mainly the capacity to be part of the society, without physical limitations. (Capiro, Sit & Abernethy, 2014) Mental health is also related to wellbeing. For Galderisi et. al. (2017), mental health is a dynamic state of internal equilibrium that enables individuals to use their abilities in harmony with the universal values of society. This dynamic state also has an influence on the older persons and the new challenges to deal with and the changes to accept. (Galderisi et. al., 2017)

In social wellbeing, the term "social exclusion" must be discussed deeper. Social exclusion is considered the extreme phase of the process of a person's marginalization, when this person is unable to participate in society because of a lack of resources, that are normally available to the general population. Thus, in its original form, the term social exclusion was used to describe processes of social disintegration (Clavel 1998), i.e. the various fragmentations of the connections between the individual, society and the state (Castel 1995).

The term is understood as a descending path, with successive ruptures in the individual's relationship with society. (Costa, 1998). This is a complex and heterogeneous concept, that may have an impact on various sectors of personal life. Bruto da Costa (1998) describes five sectors: in the economic, it is basically "poverty", understood as a situation of multiple deprivations, due to lack of resources; cultural and pathological factors, including psychological or mental ones; self-exclusion because of self-destructive behavior and, social aspects.

The social aspects of social exclusion are related to social bounds. It is a situation of interactive deprivation, characterized by isolation, sometimes associated with a lack of self-sufficiency and personal autonomy. Combating social exclusion requires action at various levels (Costa, 1998). Digital technologies and innovation can be one of these ways of combating, as will be discussed below, the DAPAS system has also been developed with a solution in mind to bring isolated people closer to their relatives and formal caregivers.

One concept is integrated onto the other, as it has impact on a person's life and how to deal with difficult periods, the elderly, for example. As demonstrated, wellbeing surely includes more than just contentment (Delle Fave et al., 2018), also meaning developing as a person, acquiring capacities, being fulfilled, contributing to the community, leading socially useful lives (Diener, Scollon & Lucas, 2009) and being integrated.

In other sense, other researchers highlight the Wellbeing theory, which breaks down the wellbeing construct into five domains: positive emotion, engagement, relationships, meaning and accomplishment (Dodge et al., 2012). According to this perspective, wellbeing happens when a person realizes their potential, can be resilient in dealing with normal stresses, takes care of their physical wellbeing and has a sense of purpose, connection and belonging to a wider community. It consists, therefore, in a fluid way of being and nurturing needs throughout life (Forgeard et al., 2011).

These definitions convey the multi-faceted nature of wellbeing and can help individuals, NGOs, enterprises, and policy makers to move forward in their understanding of this popular term. These actors were impacted by the demographic change and started to focus their research and policies on how to guarantee all these aspects to achieve older people WB.

Concerning the older people, wellbeing may mean successful ageing or ageing well ((Rowe & Kahn, 1998, 1998), by implying freedom from disease and disability, high cognitive and physical functioning, and active engagement with life (World Health Organization, 2). Although some losses and negative aspects tend to be inherent characteristics of ageing. The older

people tend to have cancer, diabetes, deafness, osteoporosis (or other diseases that may cause mobility reducing) and diseases related to mental health like depression, Alzheimer and Parkinson. Having a decrease in some physical abilities and being vulnerable to a larger number of diseases is part of the ageing process.

In literature, it is usual to find wellbeing as a part of health definition. But, as demonstrated, good healthy alone is not a synonym for QoL and WB. These two aspects encompass other factors related to life satisfaction and contentment. (Shah & Marks, 2004)

Besides this health decrease related to ageing, it is possible to have good quality of life even at an advanced age. The innovation research is able to develop technology that could help improving the wellbeing, by measuring it and indicating that something might be wrong with the user. Thus, caregivers and specialized people will be able to act more quickly, which would improve their quality of life and well-being. This is one of DAPAS System aims.

The DAPAS System has taken into consideration these concepts and created an ICT system that aims to improve older people QoL and WB. The features have been designed to overcome the usual problems and difficulties of older adults, while facilitating: their communication with friends, family, and caregivers; their management of commitments, e.g., agenda and medication reminder; serious games to improve their cognitive health; a home base station to facilitate the call on emergency situations; an alarm system for the stove and sensors to open the doors; information to caregivers about the older person's WB. If the user informs that he is not feeling well, the caregiver may be notified and take the necessary measures to assist the person in need. (DAPAS, 2019)

The wellbeing feature in DAPAS starter version consists in a platform to receive the user's feedback about their moods. The platform is a list of emojis with different moods, every time the user starts the DAPAS system, he is asked "How you are feeling today?" and must answer the question choosing an emoji for each of the following emotions: very happy, happy, neutral, sad, or very sad. If the user presses the very sad emoji three, the application suggests talking with someone, and directs to the videocalls or messages application. (DAPAS, 2019)

The project objective is to test these features and evaluate if they are working well and if they do in fact improve older people QoL and WB. Thus, the research challenge begins to be how to find the correct instruments to assess and measure these two concepts.

The Organization for Economic Co-operation and Development (OECD) describes eight points that can be used to measure the quality of life and wellbeing: health status, work-life balance, education and skills, social connections, civic engagement, environmental quality, personal security, subjective wellbeing (Organization for Economic Co-operation and Development, 2009).

So, an intrinsic part of QoL and WB, health is the first point to be assessed. Statistics demonstrate that healthy ageing is a key aspect of happiness in old age. (World Health Organization, 2015) Certainly, an overview about the health population status and life expectancy is assessed by public health data. But, focusing on measure this point in a person, the EuroQol group, in 2009, publicized the EQ-5D-5L, a standardized instrument for measuring generic health stat. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. (EuroQol, 2009)

The EQ-5D descriptive system is a preference-based HRQL measure with one question for each of the five dimensions that EQ-5D include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The answers given to ED-5D can be converted into EQ-5D index a utility scores anchored at 0 for death and 1 for perfect health. It is a generic QoL

instrument which has been extensively validated and been shown to be sensitive, internally consistent, and reliable in the general population and other patient groups (Ferreira, Ferreira & Pereira, 2013)

Other point highlighted by the OECD is the work-life balance of older adults. Promoting active ageing in the workplace has become a concern (World Health Organization, 1997), because the proportion of older workers in the European Union will increase during the next few decades. The challenge is to keep these people active and with a good quality of life in the workplace. Although the health and physical abilities may deteriorate over time, other aspects related to age are invaluable for the labor market: older workers have larger work experience, more professional competences, tacit knowledge, etc. Ageing makes the workers in many ways better and stronger than before. Digital services and assistive technologies may provide a perfect solution for them to remain active at work for longer and with enhanced quality of life (Angeloni & Borgonovi, 2016).

The work-life balance is a qualitative aspect of QoL and WB, but also could be assessed by the SF-36. The Short Form Health Survey (Rand, 1994) was designed for use in clinical practice and research, health policy evaluations, and general population surveys. (Bulamu, Kaambwa & Ratcliffe) This instrument comprises 36 questions in eight different sub-score areas. Regarding work life balance it questions about limitations on daily activities and health problems felt during the work. The participant must answer if there has been a decrease in the time spent working or if he felt in any way limited. (Ware, Snow, Kosinski & Gandek, 1993)

The eighth OECD point, subjective wellbeing, could also be assessed by the SF-36 instrument. In summary, subjective wellbeing is considered the individual's internal subjective assessment, based on cognitive judgments and affective reactions. This concept can be divided in other dimensions, like the psychological, social, and spiritual aspects of wellbeing, fully related to consistency and temporal stability. Veenhoven (1994) describes subjective wellbeing as the degree to which a person judges the overall quality of her or his life, generally in a favorable way. To measure it, the SF-36 comprises 36 questions in eight different sub-scores related with the subjective wellbeing themes: physical and social functioning, physical and emotional role limitations, mental health, energy, pain, and general health perceptions. (RAND, 1994)

The other OECD points could be measured using the health-related quality of life that in synthesis is defined as "an individual's or group's perceived physical and mental health over time". (Centers For Disease Control And Prevention, 2018)

The lifelong learning and continuing education concepts are related to social inclusion, cultural integration, active citizenship, and personal development of older people. The challenge is to create a new mentality in educational and social actions in order to connect the older people to the new technologies, ensuring that these are appropriate for their necessities. (Dantas et al., 2017). There are models associated with this issue like the Technological pedagogical content knowledge (TPACK) (Koehler & Mishra, 2009) and Unified theory of acceptance and use of technology (UTAUT) (Cimpermann, 2016). In the same way, social interactions are very important to increase QoL. They are defined as a mutually orientated act of two or more people, an exchange of feelings and experiences, that is, any behaviour that tries to affect or take account of each other's subjective experiences or intentions (Lopez, Liria, Parra & Góngora, 2016.). For sure, these interactions are very important in old age. Some studies even indicate that having a large social network may have a positive effect on mental health and even help to ward off diseases such as Alzheimer and that technology can increase these types of connections. (Pillai & Verghese, 2009)

The term civic engagement relates to both political participation and civic volunteerism and includes voting, being a candidate, being involved in political campaigns, community work, helping the community and being updated about what is happening in the public affairs (Diament, 2008). Studies show that such actions are very important to ageing adults as it may have a positive effect on their self-perception, highlighting their continued value within society (Mohan, 2019).

Environmental quality is a much-debated theme. This is a large concept that includes the general environment, good conditions of living space housing, comfort, size, facilities, interactions with neighbours, etc. In order to achieve this subject, the older people could reach financial autonomy and security, safety and appropriate health and social support (Gobbens & Van Assen, 2018, 2018). Personal security is a related topic QoL. Surely everyone wants a secure society where it is possible to live without fear. However, for older people, feeling safe is not only related to criminal issues. It is necessary to create an environment where they feel independent and self-sufficient, but this is hard when you worry or feel scared of falls and something else happening and not being able to get the appropriate help. This is especially acute for older adults living alone and to those whose family does not live nearby. (Cáritas Diocesana de Coimbra, 2015)

To measure these points, the health-related quality of life questions can involve two different levels: the individual level, and the community level. The first one includes physical and mental health perceptions (e.g., energy level, mood) and their correlates - including health risks and conditions, functional status, social support, and socioeconomic status. The second one, health-related quality of life includes community-level resources, conditions, policies, and practices that influence a population's health perceptions and functional status. (Centers For Disease Control And Prevention, 2000)

The DAPAS project will use these instruments (with the exception of TPACK and UTAUT) in the pilot sites, that will occur in Portugal, Luxembourg and Austria, to compare the improvement or maintenance of participants health and wellbeing during the trial. A case report form has been designed, including these questionnaires, to collect data from each participant. That way the effectiveness of the DAPAS features and the impact in the participants quality of life can be validated.

However, as these instruments are related to some personal aspects of the participant's life, some issues may appear like conflicts between privacy and incidental data findings. For this reason, a desk research about how to deal with some ethical challenges was made, to guarantee the participant data protection and attendance in case of a negative result concerning his or her quality of life and wellbeing. The next chapter will present the research results.

2. ETHICAL CONCERNS ABOUT QOL AND WB MEASUREMENTS: CONFLICTS BETWEEN PRIVACY AND INCIDENTAL DATA FINDINGS

In order to guarantee the compliance of the ethical, privacy and protection issues, research and projects using pilots must study the law and regulations involving these aspects, to ensure its correct enforcement during implementation. The main legislation to be addressed is the Regulation (EU) 2016/679 of the European Parliament and of the Council (EPCEU, 2016),

which lays down rules related to the protection of natural persons regarding the processing and the free movement of personal data.

Additionally, national, and international legislation should be observed, with the objective of protection and compliance of the ethical aspects:

- Art. 8 of the Convention of the Council No. 5 for the protection of human rights and fundamental freedoms (CE, 1950).
- Helsinki Declaration in its latest version for the statement of the ethical principles for medical research involving human subjects, including research on identifiable human material and data. (WMA, 1964).
- Council of Europe Convention 108: Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. (CE, 1981).
- The Charter of Fundamental Rights of the European Union, and in particular Article 1 (Human dignity), Article 3 (Right to the integrity of the person), Article 7 (Respect for private and family life), Article 8 (Protection of personal data); (EU, 2012a) ii) Treaty on European Union, and in particular Article 6 of the common provisions concerning respect for fundamental rights (EU, 1992).
- Directive 97/66 EC concerning the processing of personal data and the protection of privacy in the telecommunications sector. (EU, 1997).
- Directive 99/5/EC: Radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. (EU, 1999).
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector. (EU, 2002).
- UNESCO: Universal Declaration on Bioethics and Human Rights. (UNESCO, 2006).
- Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC; (EU, 2006).
- Article 29 Data Protection Working Party, Opinion 4/2007 on the concept of personal data. (EU, 2007).
- The Constitutions of the country of the people involved in this data recollection. In democratic countries, the constitution describes the fundamental specially related with dignity, personal integrity, personal rights, and civil rights. It is a source for the other national legislation about protection of the rights of older people and persons involved with then. (WHO, 2008) .
- The "European Group on Ethics in Science and New Technology (EGE – more specifically, through "Opinion n° 26 - 22/02/2012 - Ethics of information and communication technologies, more related to the protection of privacy and protection against personal intrusion in ICT. (EU, 2012b).
- The Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data repeals Council Framework Decision 2008/977/JHA, entered into force on 5 May 2016 and EU Member States have to transpose it into their national law by 6 May 2018. (EU, 2016a).

- The EU General Data Protection Regulation (GDPR) Regulation 2016/679 (EU, 2016b) is the most important change in data privacy regulation in 20 years. Its main objectives are to harmonize data privacy laws across Europe, to protect and to empower all EU citizens' data privacy and to reshape the way organizations across the region approach data privacy. Guarantee that all the data collected is complying with what is required by the GDPR is fundamental to comply with the ethical principles.

The regulatory landscape of data privacy was the main concern that led to the creation of the most powerful regulation in this area. The primary imposition was the extraterritorial applicability meaning that GDPR has an extended jurisdiction. It applies to all companies processing the personal data of data subjects residing in the European Union, regardless of the company's location. (GDPR, 2018)

Another major change in the law is the "right to be forgotten". With this innovation, the participants or users may ask to erase all his/her data. The cessation of further dissemination of the data and potentially halting the sharing and processing of his data by third parties may be challenging for projects and technical developers (GDPR, 2018). In this case, the ethical issues may arise when there is a conflict between the subject's rights and the public interest. The legislation is clear regarding this point and demands the controllers to compare the subjects' rights to "the public interest in the availability of the data" when considering such requests. Finally, the concept of "privacy by design" is another challenging aspect of the GDPR. The technology must consider involving the potential end-users from the start of the design throughout the whole project until the trials and the evaluation. This of course implies that all the data protection and privacy issues must be considered not only for the trials but for the different phases of the technological development. (EU, 2016)

However, besides these points, not all of them new, but necessary regarding the protection of human rights, other concepts must be taken into consideration.

The need for consent is the highest requirement in trials and technological development. All the collected data must be fully understood and accepted by the person involved, guaranteeing the voluntary basis. Before the interview or test starts, the persons involved must be informed about the type of monitoring and recording instruments that will be applied. A full explanation may be required to guarantee that the person has the complete acknowledge about the data involved and if the person agrees with this collection. The information passed to the person must address eventual risks and possible difficulties and researchers must not be hesitant in doing this as clearly as possible. (EU, 2016) The regulation still determines that the data and relevant part of any recordings must be deleted or destroyed if the test subject requests. (EU, 2016) As a result, the Informed Consent was also modified to be strengthened and clearer for the persons involved. It is required that companies and other organizations use short and easy terms and conditions. (EU, 2016)

The anonymity is also considered a solution to comply with the ethical aspects of trials and surveys. All information gathered must be kept confidential and be secured against unauthorized access. For this reason, the privacy by design required by the regulation must be applied. It is necessary to provide, since the beginning, and make procedures to protect the data for unauthorized access and for loss and damage. (EU, 2016)

The GDPR aspects are completely in line with a set of values and principles.

The values include "transparency, accountability, explicability, auditability and traceability, and neutrality or fairness" (Dolic, Casto & Moarcas, 2019). The transparency is related to the clearness of the information that will be collected and the necessity to explain all the benefits and malefic of the technology. Accountability is human responsibility regarding technical tools.

It is a responsibility of the researcher behind those technological tools to ensure that the rights of the participants are protected. (Committee On Human Research, 2011) Explicability is the necessity to inform and make understandably the tools and their features. Auditability is related to the open and clear access to what the technical items can with the data. As the noun says, traceability is the quality of having an origin or course of development that may be found or followed. Finally, AI-based systems must be based on neutrality or fairness to assure that factors influencing outcomes are not unfairly prejudiced. (Dolic, Casto & Moarcas, 2019)

In the same way, the GDPR is also connected to ethical principles. The first one is, respect for autonomy, which describes that every person can decide about the benefits and issues and decide autonomously on the participation. In consequence of this power of choice, the other three principles are related to the balance between benefits and risks. The beneficence means that a trial or survey must bring some benefits to the person involved, balancing benefits against risks and costs. The third one is the avoidance of harm. In the case where harm may still happen, it should not be disproportionate to the benefits of the trials. The fourth relates to justice in the sense of the fair distribution of benefits, risks and costs and equality as the notion that participants in similar positions should be treated similarly. (Jahn, 2011) In this context, Ethics address the issues of what is the most right, fair, and just to do in some cases. It becomes more challenging when it is related to human emotions. In many kinds of psychological research, an incidental finding may be exceedingly unlikely (Committee On Human Research, 2011).

When the results show lack of wellbeing, incidental findings can rise ethical issues, especially if these tools are not medically approved and were not designed for diagnostics by the appropriate medical practitioner. In this case, besides dealing with the incidental findings, the researcher in charge must take the responsibility for observing the laws and regulations.

However, even when the GDPR and other laws, as well as the general ethical guidelines, are all complied with, incidental findings may still raise additional concerns regarding the balance between rights and protections, privacy, safety, and public interest. This is an important area in care studies that must be understood and studied.

Incidental findings are defined as observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose or variables of the study. (Illes et al., 2006) They are results outside the original purpose for which a test or procedure was conducted, this means, external of the primary finding. They are known as secondary findings, as they were not the primary target of the test or procedure. (Bioethics Commission, 2016)

Incidental findings may be anticipated or unanticipated. (Ells & Thombs, 2014) An anticipated incidental finding is one that is predictable and directly related to the test or pilot. The defining characteristic is that the possibility of finding them is known. An unanticipated incidental finding includes findings that could not have been anticipated given the current state of scientific knowledge. (Illes et al, 2006)

The Presidential Commission for the Study of Bioethical Issues provides some examples of these types of findings:

- Primary finding: "Practitioner aims to discover A, and result is relevant to A." ((Bioethics Commission, 2016).
- Secondary finding: "Practitioner aims to discover A, and also actively seeks D per expert recommendation". ((Bioethics Commission, 2016).
- Anticipated incidental finding: "Practitioner aims to discover A, but learns B, a result known to be associated with the test or procedure at the time it takes place". ((Bioethics Commission, 2016).

- Unanticipated incidental finding: "Practitioner aims to discover A, but learns C, a result not known to be associated with the test or procedure at the time it takes place". ((Bioethics Commission, 2016).

In this research, only the anticipated incidental findings, as defined by the premise of the Bioethics commission, will be considered. In research projects like DAPAS, which deal with the wellbeing and quality of life of older people, an incidental finding obtained through a survey or other wellbeing measure may be the discovery of a depression or other psychological problem, which until then was neither known by the person nor previously diagnosed. Although this finding is a direct result of the research and impacts on the wellbeing of the person, it was not the first objective of the procedure.

In that way, Illes et al. (2016) and Ells and Thombs (2014) described the best practices for dealing with anticipated incidental findings. Illes et al. (2006), adapting some of the ethical approaches to incidental findings proposed the following general recommendations:

- If the incidental findings are predictable, the researcher must determine the potential for incidental findings and establish a process to handle discovery and reporting of such findings.
- Dealing with incidental findings may have a cost and may require, for example, the inclusion of a professional competent to evaluate it.
- Determine in advance, the threshold for reporting incidental findings.
In the same way, Ells and Thombs (2014) also developed key points about the incidental findings.
- Clinicians and researchers should anticipate and plan for incidental findings.
- Evidence-based best practices are needed to guide decisions regarding disclosure of incidental findings.
- Patients' preferences about disclosure of incidental findings should be considered. (Thorogood et al., 2014).

To sum up, the framework consists of steps that represent key decisions to be taken by researchers: anticipation of findings and information provision. Potential incidental findings must be anticipated from the start and addressed at the informed consent stage.

The DAPAS investigators decided that during the tests, incidental findings must be appropriately analysed to determine whether it may cause some negative issue for the person involved. If need be, the analysis may need to involve an appropriate care professional such as a psychologist. The participant must know about the finding and his opinion must be considered.

For the law doctrine, these dilemmas are considered the hard cases. They are indeed. Depending on the case, the researcher must guarantee that all the ethical steps and prescribed legislation is followed. Each of these steps, should be justified not only with reference to costs and/or logistical considerations, but also with reference to researchers' moral obligations and the principle of reciprocity (Bunnik et. al., 2017).

CONCLUSIONS

Research, studies, and trials often access data which is related to the most intrinsic feelings of a person, so ethical concerns arise, and they must be rightfully addressed within the implementation process. That is why the project must be updated with regulations concerning these aspects, to guarantee the compliance of ethical, privacy and protection issues arising

from eventual incidental findings. Despite being unrelated to the initial purpose of the study, incidental findings must not be ignored. On the contrary, they must be addressed by the project's ethics committee, especially if they are likely to be anticipated. Respect for the older person's autonomy and rights must always be kept, as well as taking into account how can they benefit from the experience and more importantly, protecting them from any harm.

A careful and successful monitoring of these standards, within the technology-enabled measurement of wellbeing and quality of life procedures, will thus assure not only better suitability of the already established ethical criteria, but also prevention of major issues and complications resulting from eventual neglect or mistakes. Ultimately, based on existing ethical principles, researchers or in charge managers should aim to adopt a fair and equitable approach in each specific situation, especially when it comes to incidental findings related to human emotions and subjective or psychological wellbeing.

REFERENCES

- Angeloni, S., Borgonovi, E. (2016) An ageing world and the challenges for a model of sustainable social change. *Journal of Management Development*. Vol. 35 No. 4, pp. 464-485
- Bioethics Commission (BC). (2016) For Researchers: Incidental and Secondary Findings. Report made by the Presidential Commission for the Study of Bioethical Issues. Available at: <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Researcher%20Primer%20Incidental%20Findings%2010.30.16.pdf>
- Bulamu, N.B., Kaambwa, B. & Ratcliffe, J. A systematic review of instruments for measuring outcomes in economic evaluation within aged care. *Health Qual Life Outcomes* 13, 179 (2015). <https://doi.org/10.1186/s12955-015-0372-8>.
- Bunnik, E., van Bodegom, L., Pinxten, W., Beaufort I., & Vernooij, M. (2017) Ethical framework for the detection, management and communication of incidental findings in imaging studies, building on an interview study of researchers' practices and perspectives. *BMC Med Ethics*, Feb 6;18(1):10.
- Burckhardt, C. S., & Anderson, K. L. (2003). The Quality of Life Scale (QOLS): reliability, validity, and utilization. *Health and quality of life outcomes*, 1, 60. doi:10.1186/1477-7525-1-60
- Capio C.M., Sit C.H.P., Abernethy B. (2014) Physical Well-Being. In: Michalos A.C. (eds) *Encyclopedia of Quality of Life and Well-Being Research*. Springer, Dordrecht. https://doi.org/10.1007/978-94-007-0753-5_2166
- Cáritas Diocesana de Coimbra (CDC). (2015) Preventing Falls: A Guide to Implementing Effective Community-Based Fall Prevention Programs, 2nd Ed., National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention, Atlanta.
- Centers for Disease Control and Prevention (CDCP). (2000) Measuring healthy days: Population assessment of health-related quality of life. 2000 Centers for Disease Control and Prevention, Atlanta, Georgia.
- Centers for Disease Control and Prevention (CDCP). (2018) HRQOL Concepts. Centers for Disease Control and Prevention, Atlanta, Georgia.
- Cimperman, M., Brenčič, M. M., and Trkman, P. (2016). Analyzing older users' home telehealth services acceptance behavior—applying an extended UTAUT model. *Int. J. Med. Inform.* 90, 22–31. doi: 10.1016/j.ijmedinf.2016.03.002
- Clavel, Gilbert, 1998: *La Société d'Exclusion. Comprendre pour en sortir*, Paris: Éditions L'Harmattan
- Committee on Human Research (CHR). (2011) Incidental findings in research with human participants: Ethical challenges for psychologists. *Psychological Science Agenda*, April 2011. Available at: <https://www.apa.org/science/about/psa/2011/04/human-research>
- Costa, Alfredo Bruto da, 1998: *Exclusões Sociais*, Lisboa: Gradiva.
- Council of Europe (CE). (1950) Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5, available at: <https://www.refworld.org/docid/3ae6b3b04.html>

- Council of Europe (CE). (1981) Convention 108: Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Available at: <https://rm.coe.int/1680078b37>
- DANTAS, C. Staalduinen, W. et al. (2017) Older workers, technology and the balance of power: an ethical review (464-467). In.: Proceedings of the 12th ACM International Conference on Pervasive Technologies Related to Assistive Environments ACM, New York, NY, USA 2017.
- DAPAS. General Folder. Deliverables & Results. 2019. Available at: <https://dapas-project.eu/>
- Delle Fave, A et al. (2018) Promoting Well-Being in Old Age: The Psychological Benefits of Two Training Programs of Adapted Physical Activity. *Front. Psychol.* 9:828. doi: 10.3389/fpsyg.2018.00828
- Diament, M. (2008) Friends Make You Smart, Boosting social interaction is key to your mental health AARP Bulletin Nov, 21, 2018. Available at: <https://www.aarp.org/health/brain-health/info-11-2008/friends-are-good-for-your-brain.html>
- Diener E., Scollon C., Lucas, R. (2009) The Evolving Concept of Subjective Wellbeing: The Multifaceted Nature of Happiness. In: Diener E. (eds) *Assessing Well-Being. Social Indicators Research Series*, vol 39. Springer, Dordrecht.
- Dodge, R., Daly, A.P., Huyton, J., Sanders, L.D. (2012) The Challenge of Defining Wellbeing. *International Journal of Wellbeing*. Volume 2, n. 3. Available from: <https://internationaljournalofwellbeing.org/index.php/ijow/article/view/89>
- Dolic, Z., Castro, R., Moarcas, A. (2019) Robots in healthcare: a solution or a problem? Study for the Committee on Environment, Public Health, and Food Safety, Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg.
- Ells, C., Thombs, B. (2014) The ethics of how to manage incidental findings. *CMAJ* 2014. DOI:10.1503/cmaj.140136
- European Parliament And The Council Of The European Union (EPCEU). (2016) Regulation (EU) 2016/679 Of The European Parliament And Of The Council. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN>
- European Union (EU) (1992) Treaty on European Union (Consolidated Version), Treaty of Maastricht, 7 February 1992, Official Journal of the European Communities C 325/5; 24 December 2002, available at: <https://www.refworld.org/docid/3ae6b39218.html>
- European Union (EU) (1997) Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31997L0066>
- European Union (EU) (1999) Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31999L0005>
- European Union (EU) (2002a) Treaty on European Union (Consolidated Version), Treaty of Maastricht, 7 February 1992, Official Journal of the European Communities C 325/5; 24 December 2002, available at: <https://www.refworld.org/docid/3ae6b39218.html>
- European Union (EU) (2002b) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002L0058>
- European Union (EU) (2006) Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC. Available at: <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32006L0024>
- European Union (EU) (2007) Data Protection Working Party, Opinion 4/2007. This Working Party was set up under Article 29 of Directive 95/46/EC. It is an independent European advisory body on data protection and privacy. Its tasks are described in Article 30 of Directive 95/46/EC and Article 15 of Directive 2002/58/EC. Available at <https://www.clinicalstudydatarequest.com/Documents/Privacy-European-guidance.pdf>
- European Union (EU) (2012a) Charter of Fundamental Rights of the European Union, 26 October 2012, 2012/C 326/02, available at: <https://www.refworld.org/docid/3ae6b3b70.html>

- European Union (EU) (2012b) Opinion n. 6 - Ethics of information and communication technologies. Brussels, 22 february 2012. Available at: <https://publications.europa.eu/en/publication-detail/-/publication/c35a8ab5-a21d-41ff-b654-8cd6d41f6794/language-en/format-PDF/source-77404276>
- European Union (EU) (2016a) Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.119.01.0089.01.ENG
- European Union (EU) (2016b) General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1.
- EUROQOL. (2009) EQ-5D. Available at: <https://euroqol.org/>
- Ferreira, P. L., Ferreira, L. N & Pereira, L. N. (2013) CONTRIBUTOS para a Validação da Versão Portuguesa do EQ-5D. *Acta Med Port.* Nov-Dec;26(6):664-675. Available from: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/viewFile/1317/3807>
- Forgeard, M. J. C., Jayawickreme, E., Kern, M. & Seligman, M. E. P. (2011) Doing the right thing: Measuring wellbeing for public policy. *International Journal of Wellbeing*, 2011, 1(1), 79-106. Available at: <https://internationaljournalofwellbeing.org/index.php/ijow/article/view/15>
- Galderisi S, Heinz A, Kastrup M, Beezhold J, Sartorius N. A proposed new definition of mental health. *Psychiatric Pol.* 2017 Jun 18;51(3):407-411. English, Polish. doi: 10.12740/PP/74145. Epub 2017 Jun 18. PMID: 28866712.
- GDPR. (2018) GDPR Key Changes. An overview of the main changes under GDPR and how they differ from the previous directive. Available at: <https://gdpr.report/news/2018/03/06/data-protection-directive-versus-gdpr-understanding-key-changes/>
- Gobbens R., van Assen M. (2018) Associations of environmental factors with quality of life in older adults. *The Gerontologist*. Vol. 58(1): 101-110.
- Illes, J., Kirschen, M. P., Edwards, E., Stanford, L. R., Bandettini, P., Cho, M. K. (2006) Incidental findings in brain imaging research. *Science*, 2006, 311, 783-784.
- International Health Conference (IHC). (2002). Constitution of the World Health Organization. *Bulletin of the World Health Organization*, 80 (12), 983 - 984. World Health Organization. Available at: <https://apps.who.int/iris/handle/10665/268688>.
- Jahn, W. (2011) The 4 basic ethical principles that apply to forensic activities are respect for autonomy, beneficence, nonmaleficence, and justice. *J Chiropr Med.* 2011 Sep; 10(3): 225-226. Published online 2011 Aug 27.
- Koehler, M. J., & Mishra, P. (2009). What is technological pedagogical content knowledge? *Contemporary Issues in Technology and Teacher Education*, 9(1), 60-70. Available from: https://www.researchgate.net/publication/241616400_What_Is_Technological_Pedagogical_Content_Knowledge
- López, M. D., Liria, R. L., Parra, J.A, Góngora, D. P (2016) Skills for Successful Ageing in the Elderly. Education, wellbeing and health. In.: SpringerPlus, 2016 5:768 DOI 10.1186/s40064-016-2434-8. Available at: https://www.researchgate.net/publication/314714526_Skills_for_Successful_Ageing_in_the_Elderly_Education_wellbeing_and_health
- Mohan J., Bolton, V. (2019) Volunteering and civic engagement: a virtuous circle, but a privileged one? Available at: <https://www.birmingham.ac.uk/research/tsrc/blog/volunteering-and-civic-engagement.aspx>
- Organization for Economic Co-operation and Development (OECD). (2009) *Compendium of OECD Well-Being Indicators*. Available at: <https://www.oecd.org/statistics/measuring-well-being-and-progress.htm>
- Pillai, J. A., & Verghese, J. (2009). Social networks and their role in preventing dementia. *Indian journal of psychiatry*, 51 Suppl 1(5), S22-S28.
- Prilleltensky, I. (2005) Promoting wellbeing: time for a paradigm shift in health and human services. *Scand. J. Publ. Health* 33, 53-60.
- RAND. (1994) Health care surveys: Short Form Health Survey, 1994 Available at: https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/survey-instrument.html

- Rowe J. W., Kahn R. L. (1997). Successful aging. *Gerontologist* 37, 433–440. 10.1093/geront/37.4.433
- Rowe, J. W., & Kahn, R. L. (1998) *Successful ageing*, 1998, New York: Pantheon Books.
- Shah, H., & Marks, N. (2004) *A wellbeing manifesto for a flourishing society*. London: The New Economics Foundation.
- Sun, H., De Florio, V., Gui, N., Blondia, C. (2009) Promises and Challenges of Ambient Assisted Living System. Conference Paper. January 2009 DOI: 10.1109/ITNG.2009.169 · Source: DBLP.
- Theofilou P. (2013). Quality of Life: Definition and Measurement. *Europe's Journal of Psychology*. Vol. 9(1), 150–162.
- Thorogood, A., Joly Y., Knoppers B., Nilsson T., Metrakos, P., Lazaris A., & Salman A., (2014) An implementation framework for the feedback of individual research results and incidental findings in research. *BMC Medical Ethics*, volume 15, article number: 88.
- UNESCO. (2006). Universal declaration on bioethics and human rights. Paris. June 2006 at <http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>.
- van Leeuwen, K. M., van Loon, M. S., van Nes, F. A., Bosmans, J. E., de Vet, H., Ket, J., ... Ostelo, R. (2019). What does quality of life mean to older adults? A thematic synthesis. *PloS one*, 14(3), e0213263.
- Veenhoven, R. (1994) Is happiness a trait? Tests of the theory that a better society does not make us any happier. *Social Indicators Research*, 1994, 32, 101–162
- Ware JE, Snow KK, Kosinski M, Gandek, B. (1993) SF-36 Health Survey. Manual and interpretation guide. Boston: The Health Institute, New England Medical Center.
- World Health Organization (WHO). (1997) WHOQOL Measuring Quality of Life. Geneva: World Health Organisation. Available at <https://apps.who.int/iris/handle/10665/63482>
- World Health Organization (WHO). (2001) The World Health Report 2001: Mental health: new understanding, new hope. World Health Organization. 2001. Available at https://www.who.int/whr/2001/en/whr01_en.pdf?ua=1
- World Health Organization (WHO). (2008) The Right to Health. Fact sheet n. 31. Office of the United Nations High Commissioner for Human Rights. New York, 2008. Available at: <https://www.ohchr.org/Documents/Publications/Factsheet31.pdf>
- World Health Organization (WHO). (2015) World report on ageing and health. WHO Library Cataloguing-in-Publication Data, 2015.
- World Medical Association (WMA). (1964) Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: WMA General Assembly, Seoul, Korea, October 2008. Available at: <https://www.wma.net/wp-content/uploads/2018/07/DoH-Oct2008.pdf>