Ethical Assessment in E-Health

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Abstract—While innovative e-Health and m-Health technologies and solutions will eventually change the way health and social care are delivered, it raises many challenges regarding what sort of ethical concerns need to be addressed in order to provide imperative regulations and guidance to healthcare professionals and developers. This paper discusses key ethical challenges identified as part of an ongoing research project funded under the European Commission's Future Internet – Private Public Partnership (FI-PPP) initiative. The Future Internet Social Technological Alignment Research project (FI-STAR) is concerned with the validation of Future Internet technology developed under earlier FI-PPP projects and involves seven early trials in the healthcare domain. The project is supported by 26 European partners with a further extension of 10 partners or so pending. The challenges discussed in this paper include ethical-legal frameworks, privacy and international harmonization. The suggestions discussed in this paper include an overarching e-Health ethical framework, an ethical impact assessment and an ethical matrix. The ethical matrix can be used as a tool to illuminate the diverse requirements among the seven uses cases and to narrow down potential strategies to address the ethical challenges.

Keywords— e-Health, m-Health ethics, FI-PPP, FI-STAR, Future Internet, Healthcare Internet ethics, Internet of Things, Ethical Assessment, Research ethics, Ethical Matrix

I. INTRODUCTION

Long-term society needs and the emergence of the Internet have fuelled the emergence and spread of e-Health technologies and solutions, including electronic health records (EHRs), electronic prescribing (ePrescription), mobile health (m-Health) devices and applications, middleware, and cloud services. As healthcare models are changing from a hospital centred, practitioner focused set up to a distributed, patient centred approach and as more and more technology and virtualization are involved in the delivery of care, it is crucial to focus on ethical issues relating to the protection of personal health data, patient empowerment, informed consent, trust, equity and accessibility. The Future Internet Social Technological Alignment Research project (FI-STAR) provides an excellent study ground of various ethical implications. This paper provides an overview of ethical key challenges that drive the demand for appropriate ethical assessment tools and evaluation strategies and consequently will trigger the quest for more comprehensive solutions towards ethical guidance beyond the state of the art.

A. The Changing World of Healthcare

The increase in the elderly population has resulted in a rise in the prevalence of multiple chronic diseases such as diabetes, dementia, heart disease and cancer and subsequently continues to increase healthcare costs [1,2,3,4]. Medical and pharmaceutical advances and improved social care have prolonged the life expectancy. The increasing prevalence of long-term conditions presents many challenges to the health and social care system. Innovative e-Health technologies have started to change the way health and social care are delivered and will continue to change the relationship between healthcare professionals and patients in many ways. E-Health enables care to be provided remotely. Patients may use telemedicine to improve the quality of their life and reduce the risk of living in social isolation. E-Health technologies have also been adapted to specific needs and age groups. In a recently published infographic, the European Commission (EC) has highlighted that the current m-Health market is sustained by 6 billion subscriptions worldwide with around 100,000 m-health applications readily available for download [5].

B. Distributed People-Centred Healthcare System

Cost constraints and lack of up to date interoperable IT systems may have resulted in a fragmented healthcare delivery system in some places. A fragmented healthcare system gives rise to several problems such as poor availability of information resulting in higher numbers of emergency admissions, unnecessary medicine errors and poor patient outcomes [6]. There is strong advocacy for a shift from hospital managed inpatient treatment to community-based, people-centred, self-managed care with a strong emphasis on risk avoidance and prevention in order to increase ownership

and reduce the financial burden on future generations [7,8]. In a distributed people-centred healthcare model, services are designed around the needs of individual patients. It involves a collaborative process whereby healthcare professionals but also "machines" work together with the patients to share decision-making, agree on goals, identify and tailor personal support needs, develop and implement actions plans, and monitor progress [7, 9]. In this model, data can be collected remotely, analysed hierarchically, and information can be shared in order with the patient's preferences or the professional's requirements [6]. A people-centred healthcare system will require effective sharing of health and medical information, ideally in real time. Therefore questions have to be raised with regards to ethical standards, which have to be applied when exchanging personal data between humans (for example formal and informal carers), machines and across national borders. The transition of management responsibilities in distributed and self-managed care systems will also trigger a shift in liability, which will give rise to ethical concerns, triggering further ethical discussions.

C. Technological Advancement

A new wave of advances in technology is paving the way for the development and deployment of the Internet of Things (IoT), which refers to a global infrastructure whereby physical and virtual things are interconnected based on interoperable information and communication technologies [10]. The Internet of Things is an integral part of the Future Internet and is as such of interest to FI-STAR. Many smart, innovative networked devices such as bio-sensors, Radio Frequency Identification (RFID), Bionomics, etc. are hitting the healthcare industry on a continuously competitive market [10]. The advent of low cost wireless broadband connectivity and the growing coverage with 3G and 4G mobile services and 5G on the horizon means that the Internet will eventually provide a platform for a worldwide network of devices to communicate and share information. These interconnected devices will enable more and more remote patient monitoring and diagnostic services, extend the reach of specialty healthcare professionals, and will allow real-time tracking and monitoring of patients and healthcare professionals and informal caregivers. There is clearly a growing need for ethical guidance regarding the principles to securely connect healthcare devices to networks, and managing, retrieving, and analysing related data. The health care industry has so far been reluctant to adopt public cloud technology due to data protection and security concerns, confidentiality issues, relatively poor broadband penetration and slow Internet speeds across many areas of Europe [12,13]. The lack of widespread adoption might have been one of the reasons why Google discontinued Google Health in 2011, three years after it was launched. Also with regards to the service provision it needs to be highlighted that virtual machines may be located in data centres around the world, hence why data sovereignty remains an issue. One of the relevant issues seems to be legislation that for example does not allow the transfer of health data of European citizen outside the European Union. Although

companies such as Microsoft have set up data centres in Europe, there have been growing security concerns related to recent security breaches. However, the global cloud computing market in healthcare is forecasted to increase at a compound annual growth rate (CAGR) by 20.7% from 2012 to 2017 [14]. Migration to the cloud seems to be inevitable. A potential solution might be a reverse cloud approach following the software-to-data paradigm, which aims at sending software to the data rather than data to the software [12].

D. FI-STAR

FI-STAR is a major research project funded by the EC under the 7th Framework Program The project started in April 2013 and will remain active until June 2015. Based on the 'software to data' paradigm, the aim of FI-STAR is to validate the FI-PPP core platform concept by establishing early trials in seven use cases across Europe. Table 1 describes the seven use cases. The seven use cases provide a good example of the real world application of a wide range of e-Health technologies [15].

TABLE I.
FI-STAR USE CASES

Use case	City	Country
Virtualization of operating theatre environments and real time data integration for monitoring and reduction of errors	Munich	Germany
Provision of a network capable to connect to different applications and devices	Bologna	Italy
Telehealth network for diabetes patients	Tromsø	Norway
Interactive online facilities for access and quality of care	Krakow	Poland
Online cardiology service for people with heart failure	Bucharest	Romania
New interactive future Internet-based services for people with mental health problems	Bibao	Basque Country, Spain
2D bar-coding for real time reverse medicament supply chain	Leeds	UK

II. ETHICS IN EUROPEAN UNION (EU) FUNDED PROJECTS

Ethics is central to e-Health research under Horizon 2020, according to the latest European research framework program. Ethical reviews form part of the research proposal evaluation [16]. The European Charter of Fundamental Rights guarantees the right to the integrity of the person (Article 3), the respect for private and family life (Article 7), the protection of personal data (Article 8) and the freedom of the arts and sciences (Article 13) [17]. Under the EU Data Protection Directive (95/46/EC), entities processing personal data must comply with the data protection obligations, which include ensuring that the processing of data must be fair and lawful; for limited and specified purposes; the processed data must be adequate, relevant and not excessive in relation to the purposes for which they were collected; accurate; not kept longer than necessary; in accordance with the rights of the subject; secure; and not transferred across country borders without adequate security and protection [18]. Cross-border transfer of personal data gives rise to security and legal issues. The EU Data Protection Directive also lays down specific requirements on

the transfer of personal data to countries within and outside the European Economic Area (EEA). The Directive states that "personal data can only be transferred to countries outside the EU and the EEA" when an adequate level of protection is guaranteed [17]. All partners of the FI-STAR project are obliged to adhere to these ethical principles and guidelines. As a technology-centred healthcare project, there are several ethical topics to be addressed in FI-STAR, such as informed consent, equity, accessibility, trust, privacy, and cross boundary harmonisation. Given that FI-STAR aims to design, implement and operate medical modular architecture based on virtualization and IoT technologies, ethical issues in relation to virtualization must also be addressed.

A. Informed Consent

Informed consent is required in FI-STAR following European and national regulations. Consent will often be the legal basis for processing personal data in use-case trials and practices, but special attention must be paid in case of processing of personal health and medical data: the processing of these is in principle prohibited, unless special grounds apply (Article 8 of Directive 1995/46/EC). It has to be ensured that the patients are adequately informed and are provided with a free choice to provide their informed consent. Informed consent can be obtained either via paper or online. Although obtaining consent online may be the most adequate form in specific applications, the remote nature of online environment might pose new challenges: People might give reluctant or uninformed consent and there is the increased risk of fraud [19]. Participation in EU funded project should be voluntary [17]. Hence, it is important that prior to consent, researchers must clearly explain to participants the research goals, expected duration, the patients' rights to refuse participation at any time with no consequences, foreseeable risks or discomforts, benefits to the subjects or to others, guaranteed insurance, treatments or compensation if injury occurs, and person to contact for answers pertinent to questions about the research and participants' rights. Vulnerable people such as very young children, cognitively impaired, severely-injured patients are unable to provide informed consent. However, legally authorised representatives will be identified for granting permission for research participation for these people [16].

B. Equity and Accessibility

The seven FI-STAR use cases service around 6 million people throughout Europe. Given the scale of this cross-cultural research, consideration attention should be given to equity and accessibility. The gap between the rich and poor has not narrowed despite attempts to tackle health inequalities [19]. Health disparities are typically drawn along the same line as socio-demographic inequalities, such as education level, household income, geographic location (rural or urban), race and ethnicity [21]. Similarly, barriers to adoption of e-Health technologies include not only socio-demographic inequalities, but also limitations of access, computer and health literacy, quality and cost. The term "Digital Divide" refers to the gap in the access to computers and the Internet, often coined as information "haves" and information "have-nots". As Information and Communication Technologies (ICTs) become more widely available, people are able to access the Internet at home and in public places such as offices, schools, and libraries. However, despite the increase in Internet access, some groups of people (people who cannot read or write, people living in rural areas and others) continue to face barriers in accessing and using health and medical information online [21]. Furthermore the level of broadband connectivity is not uniform across Europe, especially between the urban and rural areas [22].

C. Trust and Privacy

Trust and concern about confidentiality and security are major issues to consider in e-Health, m-health and telehealth technologies and applications. Moreover there is the danger that online healthcare and medical information is of low quality, too complex or even false [23]. The EC established a set of quality criteria for health related websites within the eEurope 2002 action plan [24]. This initiative was subsequently replaced by the eEurope 2005 action plan [25]. The 2002 action plan covered a set of key quality criteria for promoting high quality, accessible health related information to European citizen [23]. These criteria, which are relevant and useful for FI-STAR and other projects, include:

1) *Transparency and honesty*
Provider of information should be held responsible for the content of the website. Purpose and objective of content provision should be clearly defined and stated. All sources of funding should be declared [24].
2) *Authority*
Information about the sources of scientific evidence and date of publication should be clearly identifiable [24].
3) *Privacy and data protection*
The processing of personal data should be clearly defined in accordance with the EU Data Protection Directives 95/46/EC [24].
4) *Updating of information*
Health related data should be regularly updated. The relevance of such content should be verified, with date of up-date clearly stated [24].
5) *Accountability*
Effort should be made to ensure that personalised medical advice is made in good faith and that advisors are suitably qualified to offer advice [24].
6) *Accessibility*
Guidelines should be established regarding usability and accessibility for the target audience [24].

e-Health standards and certification will be key for the successful deployment of new technologies. The widely accepted HONcode was established by the Health on the Net Foundation, a non-governmental organization [26]. The HONcode comprises a code of ethics that help to standardize the reliability of health and medical information published on

websites. The HONcode certification is an ethical standard aimed at ensuring that health and medical information is correct, transparent, useful and objective.

D. Cross Boundary Harmonisation

Although healthcare legislation varies from country to country across Europe, integrating research projects such as epSOS have taken the first steps to address the ethical and legal challenges with regards to a cross-cultural perspective [27]. Outcomes of epSOS will be highly relevant for the deployment of e-health and m-health solutions across Europe, which will enhance people's mobility and autonomy. As discussed previously under European regulations it has to be ensured that citizens are adequately informed and are given a free choice to provide their informed consent in order to use patient data for any given purpose. Herein lies a fundamental difference with the current US legislation hence why health data from European citizen must not be transferred outside Europe. In the US there have been controversial discussions around the "legitimate expectation of privacy" lately referring to a US Supreme Court ruling in 1979 which still stands [28, 29]. In Smith vs. Maryland the court ruled that personal information provided to a telephone registry could be used freely by any third party for different purposes than originally intended by the owner without any need to obtain further informed consent [28]. This makes the US process incompatible with the EU Data Protection Directive (95/46/EC).

E. Virtualization and Ethics

Virtualization is a process in which a software creates self-contained virtual machines (VMs), including a thin layer of software called a hypervisor, that dynamically allocate computing resources to each virtual machines so that multiple operating systems can be run concurrently on a single physical computer [30]. In true virtualization, the absence of reality means there is lack of accountability from undesirable consequences [31]. A major challenge for those involved with e-Health will be to determine whether it is possible to develop a moral machine that is capable of making ethical decision. Anderson and Anderson [32] describe machine ethics as an interdisciplinary field of research that is concerned with addressing the ethical dilemmas surrounding the behaviour of machines towards human users or other machines rather than human's use of machines. This throws up the question, whether ethical principles guiding the development of new technologies should be "proactive" or "reactive" [33]?

III. ETHICAL IMPACT ASSESSMENT

E-Health encompasses more than the mere delivery of health services and information through the Internet as a medium for dissemination, it involves a coordinated effort to improve the health and wellbeing of individuals, their families and the communities [34,35]. The e-Health field is rapidly evolving. To date, there has been no proposal for a comprehensive ethical framework that is capable of addressing all aspects of e-Health relationships, behaviours, interactions and communications, including people-to-people (P2P),

machine-to-people (M2P), and machine-to-machine (M2M). The Four Principles approach developed by Beauchamp and Childress [36] is a one of the widely used frameworks for medical ethics issues and clinical setting. Although the Four Principles are not specifically designed for e-Health [37], its guiding principles are considered to be universal and have been tested by FI-STAR in order to assess the ethical impact of FI-PPP technology. The Four Principles are as follows:

1) *Respect for autonomy*
Healthcare professionals must respect the decision-making capacities of patients and research subjects and enable them to make independent, informed choices [36].
2) *Non maleficence*
Healthcare professionals must have a duty to protect patients to avoid inflicting and imposing harm [36].
3) *Beneficence*
Healthcare professionals must consider balancing benefits of treatment against the risks and costs [36].
4) *Justice*
Healthcare professionals must distribute benefits, risks and costs fairly. This principle addresses the issue of inequalities in access to healthcare [36].

A. E-Health Impact Assessment Essentials

Prior to the design and development of new e-health and in particular m-Health solutions, ethical issues need to be considered in order to guarantee the applicability of any research outcome. An ethical impact assessment is an important tool to assess the suitability, appropriateness, applicability and effectiveness of e-Health technologies and solutions [37]. Typically this involves engaging various stakeholders such as patients, healthcare professionals, caregivers and small and medium-sized enterprises (SMEs) in identifying ethical issues and discussing ways to deal with them. Although stakeholders can have different perspectives, values and experiences, stakeholder engagement is a key way of gathering valuable information and ideas. Ethical tools are required to be "comprehensive, transparent and democratic procedures" such as for example an expert workshop that enables relevant ethical issues to be addressed during public consultation and decisions to be reflected upon systematically [37].

B. Ethical Matrix

Professor Ben Mepham, Director of the Centre for Applied Bioethics at the University of Nottingham and a member of the Food Ethics Council developed an ethical matrix based on Beauchamp and Childress' [36] three principles, namely autonomy, wellbeing (beneficence) and justice [38]. Although the ethical matrix was initially designed to facilitate ethical discussion among those who are interested in novel biotechnologies, the matrix may be used by researchers in the e-Health field to conduct an ethical assessment in cross-cultural research, assess the ethical impacts of individual technologies, investigate different legal norms and discuss and resolve differences in perspectives. The ethical matrix can be

used to easily determine which ethical concerns appear to be common among a heterogeneous group of collaborators and which ethical concerns to take into consideration when designing the e-Health solution.

An early scoping exercise has been conducted in context with innovative FI-STAR e-Health solutions. Table 2 summaries the advantages and limitations of the ethical matrix in the case of FI-STAR. Table 3 presents the ethical matrix for the Basque Country Use Case. The Basque Country Use Case looks at providing telecare for mental disorders and it targets specifically bipolar disorder, a chronic disorder with a prevalence of 2.1% to 4.1%. The proposed FI-STAR e-Health solution focuses on patients' empowerment by providing specific telecare capabilities and multi-channel interactions between the patients and the public regional health service provider (OSAKIDETZA), using their preferred available end user devices and communication channels. The use case aims to provide a new service based on advanced communication channels to treat, monitor and support people with mental disorders and their caregivers. The main actors involved in this use case are: (i) treatment participants: patients aged 18 to 50 years and their caregivers/relatives; and (ii) professionals: psychiatric personnel (i.e. psychiatrics, psychologists, and psychiatric nurses) and call centre nurses. In order to evaluate the impact of the proposed solution in the provision of telecare services, OSAKIDETZA will set up the validation phase as a single blind, randomised clinical trial. In order to assess the different ethical perceptions of the stakeholders and use case participants, the impact of national and European regulations and cross cultural implications and the implications of the applied technology, an Ethical Assessment based on the Ethical Matrix was conducted. While telecare has the potential to improve the confidence of patients with mental disorders and free up time for carers, there is a need to ensure that patients' rights to choice and privacy are respected. The use of telecare service should not restrict a patient's autonomy. There is also a need to balance between patient's safety and privacy.

IV. CONCLUSION

Innovative e-Health technologies will play a vital role in shaping the future of our societies. Although healthcare legislation varies from country to country across Europe, integrating research projects such as epSOS have taken the first steps to address the ethical and legal challenges from a cross-cultural perspective [27]. However, there is a growing demand for a tool to enable ethical impact assessments and comparative analysis of ethical requirements in order to assure compatibility or highlight areas of incompatibility. FI-STAR has tested the concept of an Ethical Matrix as proposed by Mepham, based on the work of Beauchamp and Childress. The Ethical Matrix is clearly suitable to map and identify relevant ethical issues and to single out areas of concern or areas where further consolidation is required. This also potentially includes norm incompatibilities such as different legal interpretations. However more research needs to be undertaken to identify the limitations of the method and to improve the scalability.

TABLE II.
ADVANTAGES AND LIMITATIONS OF ETHICAL MATRIX METHOD
FOR FI-STAR USE CASES

Advantages	Limitations
1) A good tool for discussion. The majority of participants realised that they were able to detect ethical aspects and did not need to receive a check list with ethical issues from the ethics advisor. 2) Draw upon people's attitudes, feelings and beliefs. Scientists could express their beliefs and feelings during the workshop. Most of them considered only the bioethical aspects of the use cases and ignored the ethical aspects of ICTs. Even for medical doctors the ethical aspects of cloud computing were not considered important. 3) A broad range of issues could be discussed. During the workshop different aspects were discussed, including the hospital being considered as a stakeholder for the first time, the principles of autonomy application and the difficulty of making differences between hospital and patient. 4) A productive way of discussing about ethics. Bring diverse groups together to discuss ethical issues. This was by far the biggest advantage of the workshop. Scientists from the same field were interacting more frequently. Interactions among scientists from different fields were rare or missing. However, the workshop enabled them to interact and look at both aspects of the use case: medical and ICTs. 5) All relevant factors were considered. 6) Workshop enabled experts from different disciplines to discuss and reflect on ethical issues. 7) Construction of ethical argumentation.	1) Equal time was allocated to stakeholders even though they might vary in importance. Not all stakeholders were of equal in importance. The discussion was long due to the fact that all cells in the ethical matrix needed to be filled in. 2) Main points of discussion may be influenced by group composition. 3) Difficulty in gaining an in-depth knowledge of each topic. 4) The lack of time was a decisive factor which influenced the course of discussion. It was difficult to reach a decision within three hours.

TABLE III.
ETHICAL MATRIX FOR FI-STAR'S BASQUE COUNTRY USE CASE[a]

	Beneficence	Non-maleficence	Autonomy	Justice
Hospital	• Efficient use of the health system resources (by reducing hospitalization relapses, emergency admissions and visits to primary and secondary care). • Prevent emergency department overuse. • Reduce the waiting list.	• FI-STAR e-Health solution can help to audit access to patients' health information. • Verify a patient's identity.	• Personalised treatment for patients according to the disease, functionality and social habits of the patients. • Scalability of systems (the performance of the system is independent on the number of patients).	• This use case facilitates the implementation of the data protection law. • With correct treatments, complaints from patients or their relatives can be reduced.
IT Specialists	• Expertise in the implementation of scalability systems. • Improve monitoring and traceability of systems. • Flexibility in future application development.	• FI-STAR e-Health solution can help to audit access to patients' health information. • Confirm a patient's identity. • Protection against massive cyber attacks.	• Allow system planning implementation based on periodic data monitoring.	• Quicker answer to possible requirement about traceability of information.
Medical Doctors	• Fewer face-to-face appointments. • More contacts with the patients. • More and quick information about the clinical state of patients. • Automatic alarms about the clinical state of the patients. • A systematic program of psychological treatment.	• More details about health measurements on a daily basis. • Conduct treatments in a friendly environment. Patients can use the telecare system to initiate a response in case of emergency. • This system reduces loss of information that might result from a change in the clinical team or other treatment elements.	• Less time is spent in each treatment because explanations of the illness are recorded in videos. • The cognitive therapy task can be analysed at a convenient time and during subsequent consultation with the patients. • This system allows easier graphical study of the evolution of the symptomatology of the patients.	• FI-STAR e-Health solution improves security to meet justice requirements (all records of treatment and mails are stored in secured system). • If the treatment provided for these patients is effective, it can be extended to the target population that might benefit from the treatment.
Industry	• An aim of the psychoeducation modules is to improve the medication adherence.	• Standardization of the biometrical devices.	• Guidelines for defining and establishing interoperability requirements.	
Patients	• Improvement in treatment. • Improvement of patients' knowledge of their illness. • Prevention of manic or depressive relapse. • Improvement of functionality. • Better management of anxiety and problem solving. • Knowledge about the pharmacological treatment and the possible side effects.	• Help to empower patients in their disease treatment through active participation.	• Patients can access their clinical information and know who and when their records have been accessed. • Patient can access the psychoeducation modules at their own convenience. • Patients can complete and send the task, at their own convenience, to the clinician. • Patients have an off-line possibility to contact the clinician.	
Families and Relatives	• Reduce family burden. • Accurate information about the disease is being sent to patient's families and relatives so that they can participate in some psychoeducational sessions about the bipolar disorder.	• Help to ease worries about the disease and understand the needs, wishes and goals of the patient's family. • Learn how to manage some situations or problems that could occur.	• Families and relatives can contact the clinician by internal email. • Improvement in patient's condition.	
Scientific Community	• Develop a digital protocol repository for several diseases. • Possibility of analysing the effectiveness of the system.			

[a.] Most concerns or information presented in this table was related to the special health condition of the patients involved in terms of traditional bioethics. Some columns were not filled due to various reasons, including: a) the category 'medical doctors' could not be entirely differentiated from 'scientific community'; and b) the definition of scientific community was not clear for all the participants.

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