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PHM-Ethics and ETICA: Complementary Approaches to Ethical Assessment

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Abstract. The chapter undertakes a comparison of different approaches to the ethical assessment of novel technologies by looking at two recent research projects. ETICA was a FP7 sister project to PHM-Ethics, responsible for identification and ethical evaluation of information and communication technologies emerging in the next 10-15 years. The aims, methods, outcomes and recommendations of ETICA are compared to those of PHM-Ethics, with identification of linkages and similar findings. A relationship is identified between the two projects, in which the assessment methodologies developed in the projects are shown to operate at separate, but complementary levels. ETICA sought to reform EU ethics governance for emerging ICTs. The outcomes of PHM-Ethics are analyzed within the policy recommendations of ETICA, which demonstrate how the PHM-Ethics toolbox can contribute to ethics governance reform and context-sensitive ethical assessment of the sort called for by ETICA.

Keywords. ETICA, PHM-Ethics, ethics, anticipatory, emerging technology, ICT, personal health monitoring, ambient intelligence, governance

Introduction

As novel technologies are developed and implemented in various contexts of use, normative issues accrue which must be addressed at local, national and international levels. Within the EU, this need for 'ethics governance' is met through a variety of approaches including research, policy, and ethics review committees. The EU approach to governance has been found lacking in its ability to respond to the challenges presented by emerging information and communication technologies (ICT), both in terms of proactive identification and resolution of normative issues, and in the development of context-sensitive solutions and understanding of norms and moral values. The 7th Framework Programme (FP7), sponsored by the European Commission, placed calls for the development of approaches for ethical, social and legal assessment of emerging technologies to address the limitations of current governance.

PHM-Ethics and ETICA were among the research projects that responded to these calls. ETICA was a sister research project to PHM-Ethics, which focused on the ethical implications of a broad set of emerging ICTs. Through a shared orientation towards policy and development, the two projects provided concrete recommendations and practical tools for ethics governance based upon interdisciplinary theoretical and empirical perspectives and methodologies. This chapter focuses on the similarities

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between these complementary projects, in terms of overlapping aims, methods, outcomes and recommendations.

Responsible innovation requires the integration of ethical, social and legal perspectives into ICT research, development and regulation. Despite their disparate technological foci, the sister projects provide complementary analyses and assessment tools for the improvement of innovation and ethics governance within the EU. Consideration of their outcomes and recommendations together will therefore strengthen practical activities aimed at proactively identifying and resolving ethical implications of Personal Health Monitoring (PHM) in particular, and emerging ICTs in general.

The structure of the chapter reflects the exploration of linkages between the two FP7 research projects, achieved through comparison of aims, methods, ethical issues and outcomes. The chapter opens with a brief summary of each project, followed by a thematic summary of their aims and scope in Section 2. Interdisciplinary methods of identification and evaluation of ethical, social and legal issues are then reviewed in Section 3, followed by a comparison of the ethical issues of Ambient Intelligence (AmI) in ETICA, and PHM in PHM-Ethics, respectively. Section 5 compares outcomes and the assessment methodologies built and validated in each project, concluding that as part of ongoing dissemination activities the two methodologies should be united to improve ethics governance and responsible research and innovation in the EU. The primary contribution of both projects was the creation of compatible methodologies for the ethical assessment of emerging ICTs, representing a unified European perspective.

1. Project Summaries

Before detailed comparisons can be made between the projects, it is helpful to summarize their aims, scope, methods and outcomes.

1.1. ETICA[2]

ETICA (Ethical Issues of Emerging ICT Applications) was a European Commission funded research project under the 7th Framework Programme (GA 230318) which ran from April 2009 to May 2011. Its objective was to identify and evaluate emerging ICTs, potential applications, and their ethical implications. These activities, supported by critical evaluation of existing ethics governance in the EU, led to policy recommendations intended to facilitate proactive and acceptable evaluation of the ethics of emerging ICTs [1]. The project included partners from universities throughout Europe to ensure a broad European perspective.[3]

Review of ICT ethics literature led to the identification of eleven emerging technologies with predicted ethical relevance: Affective Computing, Ambient Intelligence, Artificial Intelligence, Bioelectronics, Cloud Computing, Future Internet,

[2] Further information on ETICA, including project deliverables and reports can be accessed via the ETICA website at: http://ethics.ccsr.cse.dmu.ac.uk/etica.

[3] Project partners: De Montfort University (UK), VTT Technical Research Centre (Finland), Delft University of Technology (Netherlands), ForschungsZentrum Karlsruhe (Germany), University of Namur (Belgium), Steinbeis University Berlin (Germany), Eötvös Károly Public Policy Institute (Hungary), University of Lodz (Poland).

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Human/Machine Symbiosis, Neuroelectronics, Quantum Computing, Robotics and Virtual/Augmented Reality. Technologies were defined as "high-level socio-technical systems that have the potential to change the way humans interact with the world" [1, p.4]. Emergence hinged upon current research and development, which indicates technologies that will be socially and economically relevant in the next 10-15 years.[4] The identified emerging technologies are expected to overlap in future ICT developments, and are believed to exist in an enabling hierarchical relationship [1, p.15], in which ethical implications are shared across multiple technologies. A methodology for identification and evaluation of the technologies, ethical, legal and social issues, and limitations of current governance was described and validated within the project. Once identified, ethical issues of the eleven technologies were ranked according to severity judged from an interdisciplinary perspective.

Recommendations were aimed towards policy-makers and industry which sought to improve current ethics governance approaches. While policy-makers were recommended to establish an environment in which participatory ethics governance is required and supported, industry, researchers and civil society organizations (CSOs) were encouraged to use the tools provided by policy-makers to undertake ethical assessment before implementation of emerging ICTs.

1.2. PHM-Ethics[5]

The main aim of the collaborative PHM-Ethics research project was to "conduct scientific interdisciplinary research to analyze the dependencies between ethics, law and psychosocial sciences in personalized health monitoring in relation to the major types and steps of this very dynamic part of IT-development from a European perspective" [2, p.8]. PHM was defined as "all technical systems collecting, processing, and storing data linked to a person. It allows monitoring parameters of that person and can lead to health-related information of that person" [3, p.6]. An integrated European approach to the combined regulation of ethical, philosophical, legal and psychosocial constraints was developed [2]. PHM-Ethics was funded under the European Commission's 7th Framework Programme (GA 230602).

Strong emphasis was placed on the creation of a reflexive, open-ended PHM-Ethics 'toolbox' for ethical, legal and psycho-social assessment of emerging PHM applications in future contexts. An assessment methodology was developed to meet this goal consisting of five components:

1. **Dependencies Map**. A multi-layered, complex network of relationships that illustrates dependencies and relationships between parties involved in PHM.
2. **Taxonomy**. A classification system which categorizes PHM technologies and applications representing the state of the art in PHM. It generates groups with similar characteristics and allows users to makes distinctions between similar technologies.
3. **Psychosocial Assessment Module**. An integrated module for psycho-social health technology assessment. It consists of a map highlighting selective

[4] The 10-15 year period was chosen to reflect the technology development life cycle. Technologies currently in development are expected to be implemented and impact on humans and society in that timeframe.

[5] Further information, deliverables and dissemination activities can be found on the project's web-site: http://ethics.p-h-m.org/. First paragraph taken from the PHM-Ethics Final Report.

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psychosocial issues of relevance when applied to a PHM application. It covers various domains of technology perception and psychosocial outcome criteria.

4. **Ethical Assessment Module**. A module which allows evaluating existing and upcoming PHM technologies from an ethical point of view. Ethical values and principles are put into perspective with Personalized Health Monitoring. It provides questions in the fields of privacy, autonomy, freedom of choice, justice, and further content relevant in PHM ethical assessment.
5. **Legal Framework**. A comprehensive legal report that describes the legislation at the European level, regarding telemedicine and/or health monitoring. It takes into account the consequences of recent decisions by the European Court of Justice important for PHM, dealing with privacy and reimbursement of monitoring systems. Limitations and gaps in current regulation and governance schemes are identified, along with differences in ethical constraints between EU directives and national legislation [2, p.8-9].

Each methodological component can be viewed as an assessment tool to be applied to future PHM applications and contexts. The tools are complementary in the sense that results from one can be used to inform application of the others. For example, the created methodology allows for assessment at multiple levels of the taxonomy, guided by the interrelationships identified in the dependencies map. They can also be considered provisional, as it is the intention of the project consortium to update the taxonomy and dependencies map in light of future PHM developments. While created for PHM, the project consortium has started to test the methodology with other emerging ICTs[6] in accordance with the goals of FP7 [2].

Recognizing the importance of context in understanding the future ethical implications of PHM, an ethical assessment questionnaire was created which explores ethical implications according to stakeholders. The ethical assessment methodology created in the project, although general enough to be applied to a diverse range of future PHM applications, nonetheless provides a tool for individualized context-sensitive assessment.

If widespread adoption of this methodology by EU policy-makers and industry occurs, a reduction in the time between development, ethical assessment and implementation is expected. Facilitation of a proactive approach to ethics governance, in which context-sensitive participatory assessment occurs simultaneously with development, is therefore the overall goal of PHM-Ethics. The developed tools assist in both identifying and managing emerging ethical issues of PHM through engagement of stakeholders in these processes. Furthermore, an evidence base is created for evidence-based policy-making through assessment with the PHM-Ethics toolbox.

2. Project Aims

The 7th Framework Programme emphasizes the need for ethically and socially aware innovation in the EU. PHM-Ethics and ETICA both contributed to this need through the development of a European perspective on the ethics of PHM and emerging ICT, respectively. The necessity of a unified European perspective is based upon recognition of the central role played by ICT in society, business and research.

[6] For example, the dependencies map technique has been used in considering e-commerce in Saudi Arabia in PhD research by Fahad Aleid at De Montfort University.

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Acknowledging that all ICT has potential ethical and social implications, incorporation of a diversity of stakeholder perspectives in ethics governance becomes paramount in societies guided by democratic ideals. The establishment of an EU perspective in these projects allows for recognition of the shared values between member states, and contributes to the establishment of widely acceptable standards for responsible research and innovation.

2.1. Contributions to European Discourse

The importance of proactively identifying and dealing with ethical problems arising from ICT innovations was emphasized in both projects. Proactive ethical assessment of emerging ICT is required to prevent foreseeable ethical problems from occurring. While the predictions made in the projects may never come to pass, the position of uncertain proactivity is preferable to merely reacting to ethical problems as they occur [1]. Researchers, policy-makers and civil society tend to undertake actions meant to shape the future in desirable directions without absolute certainty over its course [4,5]; proactive ethical assessment should be seen in this light.

The aims of ETICA and PHM-Ethics need to be viewed with the desirability of proactive ethics in mind. Future-oriented research is seen as inherently uncertain; foresight and scientific predictions are not analogous. The contributions of these projects are done a disservice when conceptualized as merely predictions, to be evaluated on the basis of whether or not they come true. Rather, foresight research contributes to discourse on the future of European societies as shaped by emerging ICT innovations. Each project provides an overview of possible ethical issues emerging from ICT currently in development or on the horizon. When considered alongside analysis of the limitations of current regulation and governance frameworks, the projects provided a well-grounded basis for future discourse and ethical assessment within specific future contexts, as created by the interaction between policy-makers, civil society and emerging ICTs.

2.2. Technological Scope

The scope of ETICA was much broader than that of PHM-Ethics. Both projects focused on technologies, as opposed to artefacts or applications. A distinction was made between these three in ETICA, seen as a spectrum proceeding from general to specific [1]. To use 'smart homes' as an example: PHM is a technology, sensors around the home are artefacts, and fall detection combining data from various sensors is an application.

ETICA focused on 'high-level' technologies [1, p.4], and based ethical analysis on general defining features of each technology as opposed to specific applications. However, general descriptions of emerging applications were created to assist with ethical analysis. Although PHM was not identified as such in ETICA, many (but not all) PHM applications would fit under its definition of Ambient Intelligence.

PHM-Ethics, although very broad in its definition of PHM, was comparatively focused by exploring a specific area of use (health and medicine). Even so, the technical possibilities and ethical implications of the many sub-fields and applications of PHM preclude an insightful evaluation at the artefact or application level. General procedural codes were therefore developed for application to PHM as a high-level

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technology. This focus was appropriate considering the early stage of development and implementation at which PHM currently exists; broad EU regulatory frameworks are still feasible.

2.3. Analytical Disciplines

The analytical perspectives taken varied in the projects, although similarities were found. Both ETICA and PHM-Ethics analyzed emerging technologies from ethical and (EU) legal perspectives, with awareness of current challenges in these areas based on research into existing and analogous technologies. PHM-Ethics developed a psycho-social analytical module, while ETICA included perspectives on gender. Technology Assessment informed a critical analysis of current governance schemes in ETICA, and formed the basis for the ethical assessment tool (EAT) developed in PHM-Ethics [6]. The influence of the interdisciplinary approach was seen clearly in PHM-Ethics in the Dependencies Map, which revealed interrelationships between ethics, law, medical informatics, and psycho-social and medical sciences [2].

2.4. Procedural and Substantive Aims

In contrast to prior procedural governance approaches[7], neither project sought to provide a comprehensive list of ethical issues and solutions for emerging ICTs or PHM, respectively. Rather, each sought to provide early indication of potential ethical issues for policy-makers and civil society, with recommendations for further discourse between stakeholders to seek solutions. Beyond providing a basis for discussion of the issues, the projects developed methodologies for the incorporation of ethical, social and legal methodologies into innovation and governance.

It is useful to distinguish between the procedural and substantive aims of the projects. Procedural aims relate to the development of methodologies and assessment tools for future ethical assessment, while substantive aims consist of the identification and evaluation of ethical, social and legal issues of the respective technologies. While links between the substantive outcomes of each project are highlighted below, greater importance is placed on procedural outcomes due to the transience of substantive results. Ethical issues based upon defining features of the technologies were highlighted in each project, yet these issues will change according to future developments and contexts. A list of future issues can therefore never be considered comprehensive or complete. While the substantive outcomes of each project are important for sketching our current understanding and concerns with the future, and for guiding discussion of these issues, the generic methodologies developed in each project assume more importance for their ability to shape future discourse. The procedural outcomes of each project are "future-proof" in the sense that they have been designed for application to both predicted and unforeseeable future technologies, applications and contexts.

The relative importance of procedural versus substantive outcomes can best be seen in the recommendations from each project, which emphasize the inclusion of ethical perspectives in development and regulation. The resulting discourse can be guided by the substantive contributions of each project, facilitated in ETICA by the establishment of an ICT Observatory, and in PHM-Ethics by updates to the Taxonomy and Dependencies Map. Furthermore, both projects contributed to the improvement

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and standardization of ethical assessment procedures in the EU through development of validated interdisciplinary assessment methodologies and policy-oriented recommendations [7,8]. For these procedural outcomes to be successful, ethical assessment must precede technology implementation [2], made possible through widespread adoption of the projects' recommendations and assessment tools.

2.5. Context-sensitivity

A reason for the guarded value attached to the substantive outcomes of each project is the importance of context and stakeholder perspectives in understanding ethical issues and concepts. The predictions of each project therefore quickly lose 'currency' as ICT development changes over time [1, p.26].

Both projects share a concern with the lack of context-sensitivity in current governance approaches, which reflects hermeneutic epistemological and ontological commitments [9–11]. Norms are prescriptive statements given content and relative importance within specific contexts by stakeholders. Current governance approaches treat norms as statements separable from context, amenable to logical deduction [1,12]. Norms and ethical issues are often formulated in committees by experts far-removed from day-to-day practice, and are limited by the expert's frame of reference, leading to the exclusion of relevant perspectives and emphasis on sectoral and specialist interests [1]. Such a situation is unacceptable in societies that claim to be democratic.

Approaches which seek to provide general specifications of norms applicable across multiple contexts therefore fail to capture the importance of context in articulating and comprehending norms. In light of this concern, emerging technologies need to be assessed within specific contexts of use, in which stakeholders unique to that context can be identified and included in development and regulation. Through civil participation, ethical, social and legal issues of practical importance can be identified and headed off. ETICA and PHM-Ethics sought to redress the imbalance in current governance through the creation of assessment methodologies and tools which emphasize context-sensitivity and broader stakeholder involvement in research, development and regulation. Both projects therefore respond to the ethical challenges of the future by preventing the emergence of ethical problems.

3. Research Methods

As both projects aimed to contribute to European discourse through the creation of tools for the ethical assessment of emerging technologies, their methods must be understood in terms of development and validation of the methodologies. Innovation development is viewed as an open-ended process, which necessitates reflexive assessment tools open to revision on the basis of unforeseen technologies and ethical, social and legal implications [13]. Initial identification of PHM and emerging ICTs, and initial understanding of their normative implications was necessary to build the first iteration of the tools, which are intended to be updated as technological and ethical developments occur [1,2]. The initial research was condensed in the course of both projects into practically useful assessment tools [2].

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3.1. Identification of Emerging Technologies and Ethical, Social and Legal Issues

Review of relevant academic and governance literature on ethical, legal and social perspectives provided the groundwork in both projects for identification of technologies, applications, and their implications. ETICA created descriptions of each technology consisting of defining features, applications in development, areas of use and ethical, legal and social issues identified in the literature. The identification of technologies and issues was descriptive, led by a dual discourse analysis of academic literature in the field of ICT ethics, as well as EU governmental and funding publications [14–16]. Technologies were arranged in a matrix which assisted identification of ethical issues. Bibliometric analysis of the reviewed literature indicated avenues for ethical analysis through identification of the frequency with which ethical concepts appeared, as well as relationships between technologies and concepts in the literature [15].

PHM-Ethics consisted of three phases, the first of which identified ethical, psychosocial and legal implications of emerging PHM applications. Issues were identified through a descriptive literature review and empirical research, which contributed to the creation of the Taxonomy and Dependencies Map.

The PHM-Ethics Dependencies Map identifies specific stakeholders and areas in which ethical, social and legal issues may arise in the future. 'Dependencies' were identified between nodes representing the stakeholders, application areas and relationships relevant to implementation and regulation of PHM (in the EU). Several levels of relationships were identified in the map, with the highest level consisting of connections between: People, Society, Government, Operation (of the technology), Law, Medics and Allied Professionals, Health Informaticians, Social Scientists and Philosophers, Healthiness, and PHM Instruments.

The scope of the potential ethical, legal and social issues of PHM is incredibly large as reflected in the Dependencies Map, which necessitated the creation a 'critical dependencies map' of issues and relationships of critical importance which should be considered before the development cycle ends [17]. A similar approach was taken in ETICA in creating an enabling hierarchy of technologies, with potential ethical implications ranked in terms of severity. Although both projects relied upon descriptive methods for identification of technologies and issues, thereby avoiding adoption of a single ethical perspective, some prescription was necessary in assigning relative importance to each finding. In both cases issues were ranked according to severity, conceived in terms of likelihood of occurrence in the near future, or of such normative importance as to necessitate immediate attention to prevent widespread or particularly catastrophic ethical problems. The influence of prescription in the identification and evaluation of ethical issues should not be underplayed; classifying a predicted outcome as 'ethical' necessarily invokes norms. Prescription does not, however, represent a weakness in the initial findings of the projects; rather, it is a necessary component for an initial normative overview of PHM and emerging ICT ethics, provided by expert members of the consortia.

3.2. Critical Review of Current Governance

In both projects EU legislation and approaches to ethics governance (e.g. ethics review committees, FP7 programs, Technology Assessment) were critically reviewed to identify procedural gaps and limitations to overcome through development and

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implementation of the assessment methodologies [16,18]. The reviews revealed both short and long-term problems related to context-sensitivity, reliance upon expert opinions in governance, ethical "blind spots" which preclude consideration of emerging ethical issues, and various legal challenges to be overcome in implementing PHM and emerging ICT, such as liability law reform [1, p.5; 2]. Areas of conflict were also identified between values and principles embodied in EU directives and the ethical issues identified earlier in the project; these legal barriers are predicted to require legal reform before implementation of the technologies can proceed [16,18], otherwise conflicts in values between EU institutions and stakeholders in ICT development and deployment will create ethical problems [19].

3.3. Initial Ethical Analysis

Following the reviews of ethical, legal, social and governance issues, ethical analysis occurred in both projects to create an initial overview of the ethical implications of PHM and emerging ICT. Different methods of analysis were used in each project, although similarities did exist. Both projects created and validated assessment methodologies for this purpose, meaning assessment tools were created and then used (and tested) to develop initial ethical understanding of the projects' respective fields

Future ethical scenarios are often represented through thought experiments or case scenarios, which reduce the technology to its ideal or defining characteristics for ethical analysis. This approach was used in ETICA (technology descriptions) and PHM-Ethics (case scenarios). Idealized versions of the technologies and applications in development were considered in imagined contexts of use. While unfailing predictions of the future remain necessarily out of reach, this type of illustrative analysis was helpful in relating possible futures to current practices and concepts to ensure relevant issues were not ignored.

3.3.1. ETICA

Ethical analysis in ETICA focused on describing, evaluating and ranking the ethical issues identified earlier in the project through analysis of the matrix of emerging applications. Technology-level analysis identified broad ethical issues not yet on the agenda of EU policy-makers and developers.

A separate ethical analysis was conducted for each technology guided by the technology descriptions [1]. Defining features and application areas and examples were discussed for each technology, followed by cross-referencing the bibliometric analysis to ensure all related concepts and issues were considered.[7] A concluding discussion was then written which summarized the possible ethical issues and their relative severity for each technology. This process was not conducted entirely by a single consortium partner; rather, ranking occurred in a second round of analysis focusing on ethical standards, principles and values identified in EU and national level ethical reviews, advisory reports and policies [16,19,20]. The second analysis used legal, gender, ethical and Technology Assessment perspectives in evaluating the technology descriptions and the results of the initial ethical analysis, which was based on the literature review, bibliometric and technology description analyses [15].

[7] Defining features and applications were constructed in Work Package 1, and are available for review on the ETICA web-site.

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Ranking was necessary to ensure issues of immediate or severe importance to policy-makers were highlighted. Common issues, principles and concepts were identified across the range of technologies, which is unsurprising considering the enabling technological hierarchy established in ranking the ethical issues [19].

3.3.2. PHM-Ethics

The second phase of PHM-Ethics was dedicated to the assessment of PHM from ethical, legal and psycho-social perspectives. Assessment tools from ethical, legal and psycho-social perspectives were developed and used for this purpose. In comparing analysis in PHM-Ethics and ETICA, the most relevant feature is the ethical assessment tool (EAT), which is based upon interactive Technology Assessment (iTA) [6].

Development of the methodology required adaptations to iTA to meet the challenges of policy-oriented ethics research related to context sensitivity and stakeholder participation. The EAT incorporates an open-ended (revisable) questionnaire in which stakeholders identify (the relative importance of) moral values and principles affected by a PHM application in a specific context. Crucially, the EAT separates participatory evaluation from theoretical analysis. Ethical analysis is limited to experts—the methodology is therefore participatory only so far as stakeholders help develop context-sensitive understanding by identifying, evaluating and ranking moral values and principles, ensuring a wide range of perspectives are considered in ethical analysis.

3.3.3. Comparison of Analytical Methodologies

The approaches taken in PHM-Ethics and ETICA stand in contrast to iTA, in which experts act as discourse moderators, "setting the horizon for contexts, not determination of issues, based upon the interpretation of narrative information" [1]. Ethicists therefore structure the discourse with reference to ethical theory and concepts, but do not determine the ethical issues or their relative importance—this task is left to the stakeholders (e.g. users, developers, policy-makers). ETICA goes beyond iTA in encouraging experts to not only moderate discourse but to "construct the norms" which condition a specific context. Ethical issues can then be predicted by comparing the constructed norms to knowledge of the R&D process of a specific application. The issues can then be resolved through R&D. This role is slightly different than the one prescribed in PHM-Ethics because appropriate resolution of foreseeable ethical issues is left to stakeholders in R&D in ETICA, whereas experts conducting PHM-Ethics' EAT both identify ethical issues and recommend solutions through policy and development [1,6,7]. Importantly, both projects identify experts as crucial in grasping the context-sensitive interpretation of norms, values and principles in ethical analysis. Such an approach was found to be missing from many current governance frameworks [2,7].

Despite the analytical role of experts in both projects, a single ethical perspective was not dominant in ETICA or PHM-Ethics—theoretical insights from normative frameworks such as utilitarianism, deontology and virtue ethics were used where appropriate. Issues were not cast in terms of controversial concepts such as rights, human dignity, risks or moral obligations, although these and similar concepts often appeared in current EU legislation [16,18]. This approach ensured analysis was not limited to the issues considered important by consortium members.

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3.3.4. Validation of Identification and Analysis Phases

The assessment tools and initial ethical analyses of both projects were validated through empirical research which assessed the relative importance of the issues to stakeholders. The empirical studies also contributed previously unidentified ethical issues and norms. ETICA conducted two focus group sessions with members of the public, an online questionnaire of FP7 project coordinators, and a Technology Assessment conducted by project partners [1]. PHM-Ethics validated all five of its components through consideration of case scenarios at consortium meetings, although validation was impossible for the report on legal and ethical constraints due to its descriptive nature [8]. Improvements were made to the EAT through small-scale interviews. The psycho-social module was also validated through empirical research with students at consortium universities [8,13].

4. Initial Ethical Issues

As identified through the initial ethical analyses, the ethical implications of PHM and emerging ICTs mostly consist of pre-existing ethical issues, principles and concepts, as opposed to genuinely new contributions [7,15,18]; however, the need for extensions or other revisions to pre-existing concepts and principles was noted [1,15]. Although ETICA studied eleven technologies in total, significant overlap was found between its analysis of AmI and PHM-Ethics' analysis of PHM.

ETICA classified AmI according to six defining characteristics:

> "(1) embeddedness and invisibility of the sensors and computational devices, (2) interconnectedness of the sensors and computational devices, (3) the AmI system is adaptive, that is, the system adapts to its circumstances, (4) the system is personalized, tailored to the needs of its users, (5) the system is anticipatory, that is, it can anticipate its users needs and desires, and (6) the system is context-aware, it can recognize specific users and its situational context and can adjust to the user or context" [15, p.37].

In ETICA, privacy, surveillance, data protection, autonomy, freedom, equity and liability were seen as important ethical concepts in understanding the implications of AmI [15], and by extension PHM. Every one of these topics was reflected in PHM-Ethics. The more intense focus of PHM-Ethics could therefore be seen as reinforcing the validity of the conclusions of ETICA related to AmI.

Collection, storage, transfer and fair use of data took central importance in both projects. Contextual surveillance of health and daily behaviors made possible through both technologies is a major problem for the privacy of users [15]. Profiling, behavior monitoring and social sorting are made possible through such surveillance [15,21,22], which has been compared to a modern panopticon [23,24] due to its 'long memory' and influence on the behavior of users [18]. The sensitivity of data brought into existence by PHM creates the potential to peer deeply into the personal lives of users, revealing information about their health which is seen in legislation as a sensitive topic requiring extra protection [25,26]. Unforeseen combinations of PHM applications may create opportunities for non-health monitoring, in which the combination of monitoring data about multiple individual parameters provides insight into daily behaviors and the user's private life [17]. This extension of PHM systems to new users and unintended uses is referred to as 'usage creep' [17, p.20; 27]. At its most extreme, usage creep

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could lead to biometric profiling through the linkage of biometric data with PHM and AmI systems, enabling tracking of individuals [15,28]. All of these imagined scenarios involve infringement of expectations of privacy, and further complicate protection mechanisms such as informed consent, which rest upon the adequacy of knowledge about risks and benefits. Trust in 'systems' is considered a crucial element in avoiding perceptions of surveillance in PHM, justified or not [15,17,29,30].

PHM and AmI may also have implications for user autonomy, defined as "the ability to construct one's goals and values, and to have the freedom to make one's decisions and perform actions based on these decisions" [22, p.94]. While the scenarios imagined in ETICA are relatively benign, such as a 'smart refrigerator' ordering undesirable groceries, the implications for PHM are more severe, ranging from risks of social isolation to technological dependency in carrying out daily behaviors [22,31–35]. In both cases the user experiences the technology infringing upon or removing their control over a situation. The possibility of autonomy infringements increases as emerging technologies are used to replace humans in mundane or difficult activities, a problem recognized in ETICA's analyses of Robotics and Ambient Intelligence [15]. Replacements are enabled by (for example) the intentions of the developer or perceived socioeconomic benefits (e.g. cost savings in healthcare) [6,15]. If problems occur in situations in which human work is supplemented or replaced by emerging technologies, it is also unclear where liability rests for the failure of the system [15].

Equity was also a concern in ETICA, with relevance for ongoing assessment conducted by PHM-Ethics. If PHM comes to be used widely for preventative purposes, the predicted benefits to health associated with early diagnosis could further widen the healthcare gap between developed and developing nations [15]. An argument can be made that equitable distribution is required, which guarantees that PHM is available regardless of socioeconomic status or nationality.

A majority of attention in PHM ethics literature is dedicated to applications for the elderly and chronically ill, particularly Ambient Assisted Living [3,36]. When focusing on these demographics, the ethical implications identified tended to describe issues of "ageing and technology," as opposed to personalized health monitoring as a unique development in ICT and healthcare [3]. However, ethical assessment of PHM must consider other demographics because the target audience of PHM is manifold, as seen through intended uses in both managing existing conditions and preventing or hastening the diagnosis of developing conditions [3].

The stakeholders in the ethics of PHM are not limited to users alone; family members [37], medical personnel, data custodians, and a variety of institutions including insurers and telecommunication companies are involved in the collection, movement and usage of PHM data. This much is reflected in the literature reviewed in PHM-Ethics, which typically focused on the impact on social systems rather than users [3]. Engagement of these often ignored stakeholders in future ethical assessment is necessary according to the methodologies developed in these projects.

5. Recommendations and Outcomes

The defining feature of future-oriented ethics governance and research in the EU is that the inherent uncertainty of the future precludes confident identification of the ethical, social and legal implications of emerging technologies. Furthermore, norms and

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implications occur in specific contexts, and rely upon stakeholders for meaning and relative importance. Current governance approaches (and the experts responsible for them) do not always recognize these limitations. ETICA and PHM-Ethics both aimed to improve this situation.

Evidence of the shortcomings of existing governance can be seen in the gulf between issues of importance as identified by experts and civil society. The ETICA focus groups mentioned above involved members of the public, who were introduced to emerging ICT and asked to identify and evaluate moral values, principles and ethical implications. While this step served to validate the results of the identification phase of ETICA, it also revealed discontinuity between public and expert concerns [1]. The gap reveals potential problems with the relationship between researchers and civil society. It may be that sufficient effort is not dedicated to the dissemination of findings (in comprehensible language), or that the public is not interested or unaware of the existence of such research. Researchers may also be failing to familiarize themselves with public opinion through (for example) empirical research.

Regardless of the specific cause(s) of the gap, both projects sought to lessen it through the creation and dissemination of assessment methodologies and governance recommendations which require public engagement and participatory development. These efforts can be placed within practice-oriented and participative trends in ICT research in recent decades, seen best within approaches such as Participatory Technology Assessment [38,39] and Empirical Ethics [40–42], both of which engage members of the public in the assessment (and development) process.

The desire for improvement of governance schemes is reflected in the outcomes of both projects, which focus on the limitations of current approaches. In comparison to PHM-Ethics, ETICA provided broad policy and development oriented recommendations to create an environment in which proactive ethical assessment is possible. ETICA's recommendations are aimed at policy-makers as well as industry, researchers and CSOs, recognizing their diverse roles in ICT governance: policy-makers formulate regulatory frameworks which govern ICTs as they emerge, while industry, researchers and CSOs are "innovators and users of ICT…who ought to be proactive in their consideration of ethics" [1, p.3]. In contrast, the recommendations made by the more tightly focused PHM-Ethics project are, although primarily policy-oriented, focused mainly on the specifics of stakeholder engagement and context-sensitive assessment. The recommendations of PHM-Ethics therefore operate best in a supportive environment of the kind recommended by ETICA, and flesh out the latter's broad recommendations with practical guidance and tools. With that said, PHM-Ethics' recommendations operate at a broader level as well by emphasizing the importance of establishing a regulatory framework which encourages "interactive ethical assessment," in which contextual understanding of norms and stakeholder participation in assessment and development take primary importance.

5.1. ETICA Recommendations

The ETICA project aimed separate recommendations at policy-makers and industry, researchers and CSOs.[8] An institutional framework was detailed which assists in delegating the responsibilities for ethical assessment across stakeholder groups through discourse [1]. In general, policy-makers were recommended to establish an

[8] Full details of ETICA's recommendations can be found in [1,7].

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environment in which participatory ethics governance is required and supported, while industry, researchers and CSOs were encouraged to use the tools provided by policy-makers to undertake ethical assessment before implementation of emerging ICTs. The recommendations detail the responsibilities and activities required in conducting an 'Ethical Impact Assessment' prior to implementation of an emerging ICT [1].

Policy-makers were recommended to (1) provide a regulatory framework which will support Ethical Impact Assessment for ICTs, which encourages industry and government to recognize and respond to the ethical implications of technological developments; (2) establish an ICT Ethics Observatory, which updates the initial ethical assessments performed by ETICA and disseminates updated analysis alongside theoretical and normative information required for Ethical Impact Assessment; and (3) establish a forum for stakeholder involvement, which institutionalizes the discourse between industry, policy-makers and civil society to ensure a broad range of perspectives and societal concerns are reflexively considered in development and ethics governance.[9] The rationale for these recommendations is that the establishment of an "institutional framework, background, repository and societal discourses" creates favorable conditions for the "incorporation of ethics and reflexivity into technical work and application usage" [1].

Once favorable conditions are established, industry, researchers and CSOs are recommended to (1) incorporate ethics into ICT research and development through discourse with a diverse range of stakeholders in which ethical issues are identified and norms specified, demonstrating that fulfillment of "legal requirements is not always sufficient to address ethical issues"; and (2) facilitate ethical reflexivity in ICT projects and practice, affirming the context-dependency and transience of ethical issues, solutions and norms. Ethical implications of future technologies are most effectively solved through prevention rather than reaction [4,43], so the incorporation of an ethical perspective in development and research is crucial to ethically responsible innovation.

5.2. PHM-Ethics Recommendations

In a similar way to ETICA, the PHM-Ethics project identified problems with current ethics governance which can be resolved through implementation of participatory assessment and context-sensitive understanding in ethics governance, achieved through discourse with a variety of stakeholders. These recommendations can be enacted with national and EU policy. However, through dissemination of the developed assessment tools, PHM-Ethics aims to improve current governance through a change of mindset, rather than solely through policy advice.

Additionally, cross-border legal barriers to the optimal implementation of PHM were identified which suggest organizational, regulatory, ethical and legal solutions. In the short term, medical liability legislation, working conditions for healthcare professionals, informed consent and electronic health records require clarification and revision in response to the challenges of cross-border PHM usage. In the long term, policy-makers need to reconsider national and international positions on respect of privacy, the relationship between health professionals and patients, and economic and organizational challenges, especially those relating to reorganization of healthcare and

[9] The upcoming FP7 research project CONSIDER (Civil Society Organisations in Research Governance, GA 288928) aims at establishing a stakeholder forum of the kind described here. Consortium partners from the Centre for Computing and Social Responsibility at De Montfort University are involved in the project.

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the (perhaps troubling) introduction of a relationship between industry and patients in healthcare [18]. While specific solutions are not suggested, the details of each challenge are explored in the PHM-Ethics' Report on Ethical and Legal Constraints [18], which suggests avenues forward for policy-makers, researchers, developers and other stakeholders.

5.3. Realization of Recommendations

The majority of recommendations in ETICA for policy-makers and industry relate to the creation and involvement in an environment supportive of ethical assessment of emerging ICT. The activities undertaken in each research project have already contributed to some of the specific recommendations offered in ETICA. These activities, along with the relevant recommendations, are highlighted here.

ETICA recommended the establishment of a regulatory framework, "to provide appropriate tools and methods to identify and address ethical issues" [1]. A stakeholder forum which utilizes these tools is recommended, in which "consensus concerning good practice in the area of ICT and ethics" can be reached by bridging the gap between civil society, experts and policy-makers [1, p.6]. PHM-Ethics contributed to both recommendations with its tools for assessment, which may prove to be applicable to emerging ICTs beyond PHM. The PHM-Ethics toolbox could therefore be utilized by policy-makers in creating a supportive regulatory framework, and establishing the methodology of a stakeholder forum.

The creation of an ICT Ethics Observatory that provides "a community-owned publicly accessible repository and dissemination tool of research on ICT ethics," which gives "examples of approaches and governance structures that allow addressing ethical issues" has been started by ETICA in its maintenance of a project web-site (http://ethics.ccsr.cse.dmu.ac.uk/etica) [1, p.6]. The tools provided by PHM-Ethics could be included on the site as an example of a context-sensitive, participatory approach to governance. Both projects emphasize the importance of keeping the Observatory current, through updates to the PHM-Ethics taxonomy and dependencies map reflecting new developments in ICT, and the application of ETICA's methodology to future emerging ICT. This is being partly realized by an ICT Ethics Observatory which is being developed in the context of a new UK EPSRC funded project on a Framework for Responsible Research and Innovation in ICT (http://www.responsible-innovation.org.uk), and will be further developed in the upcoming RESPONSIBILITY (Global Model and Observatory for International Responsible Research and Innovation Coordination, GA 321489) project.

The industry-oriented recommendations made by ETICA are met in part by the methodological contributions of PHM-Ethics. ETICA recommended incorporation of ethics into ICT research and development to create context-sensitive specifications of ethical issues and norms through stakeholder engagement [1]. The EAT requires this type of discourse, in which as many stakeholders are engaged as possible, to include at least developers and potential users. Stakeholder discourse, in which norms, values and principles can be exchanged, is therefore encouraged under PHM-Ethics, which is unsurprising considering the influence of interactive Technology Assessment in the development of the EAT.

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5.4. Complementary Assessment Tools and Implementation in EU Governance

While ETICA provided an extensive set of policy and industry oriented recommendations, its assessment tools are somewhat less useful once discourse has been established between stakeholders. This situation is perhaps unsurprising—ETICA was not designed to provide a conclusive list of emerging ICTs and their ethical implications, but rather to act as an "early warning system" within broad policy advisory schemes [7]. This gap has been met by PHM-Ethics, with its focus on providing evidence for evidence-based policy. ETICA and PHM-Ethics maintained complementary and occasionally overlapping research agendas: the former at the level of policy and general foresight, the latter at the level of context-specific ethical assessment and identification of general ethical issues and themes relevant to that context.

The different levels of assessment are reflected in the ethical assessment tools developed in each project. While ETICA developed a broad early warning methodology based on foresight, PHM-Ethics' ethical assessment tool consists of two parts: in the first, stakeholders (technicians, politicians, health care workers, users) are interviewed with a questionnaire consisting of generic questions relating to the characteristics, aims and implications of emerging technologies, which encourage stakeholders to identify and evaluate context-specific norms and principles [6]. The interview data, conceived of as moral values relevant to ethical assessment, is then entered in a matrix of 'moral values to be realized' and 'stakeholders'. The matrix assists in the identification of ethical issues relevant to a specific application or context, which must then be specified and balanced by stakeholders. The tool is meant to be used before widespread implementation, meaning the outcomes of the matrix can inform development of the application in question [13].

If the PHM-Ethics toolbox proves to be applicable to other emerging technologies, then it can take up the work of ethical assessment where ETICA leaves off. Specifically, it provides an assortment of modules to identify and evaluate ethical issues arising in specific contexts through discourse with stakeholders. While these tools are currently limited to PHM, their underlying methodologies can be tested with the technologies highlighted in ETICA. If successful, PHM-Ethics has created a set of tools for context-sensitive ethical assessment of emerging technologies, which builds upon and encourages the sort of discourse recommended by ETICA. The two projects are therefore complementary; the former provides a methodology for ethical assessment and solutions at a context-specific, development stage, while the latter provides a methodology for early warning of ethically relevant emerging technologies at a policy level. PHM-Ethics can therefore build upon the findings of ETICA in developing its tools for context-specific ethical assessment through recognition of broader ethical issues. If considered together in revising EU ethics governance, the two projects form a multi-level package of policy and practice oriented assessment methodologies.

6. Conclusion

ETICA and PHM-Ethics have been shown to be complementary in their aims, methods and outcomes. Apart from developing a knowledge base and assessment methodology, a change in mindset towards ethical assessment is required to realize the integrative

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aims of context-sensitive assessment promoted by both projects. Reflexivity is required, in which norms are understood from the perspective of a particular stakeholder in a specific context. Current governance emphasizes the triumph of "the better argument," favoring abstract, universal, context-free arguments to integrate different perspectives. In place of the dominance of abstraction, reflexive understanding, stakeholder participation, and context-bound norms must be given equal consideration in integration. Without a reflexive mindset, the ideal of context-sensitive governance will remain elusively out of reach.

Despite having officially completed research activities in 2011, both projects continue to engage in dissemination activities in an attempt to change the mindset and methodology of ethical assessment of emerging ICTs in the EU. Each consortium maintains a web site, with ETICA's offering acting as groundwork for an ICT Ethics Observatory which is being developed in the context of a new UK EPSRC funded project on a Framework for Responsible Research and Innovation in ICT (http://www.responsible-innovation.org.uk). Interdisciplinary validation workshops and dissemination conferences have occurred across the EU, complemented by numerous peer-reviewed journal and conference publications [1,2]. It would appear that consortium partners in ETICA and PHM-Ethics take their obligation to contribute to responsible innovation in the EU through improvement to ethics governance and ethically-sensitive technology development seriously. However, going forward the projects should emphasize the relationship between their outcomes, which when combined form a robust package of methodologies for ethical assessment of emerging ICTs.

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