

“FROM THE HIPPOCRATIC OATH TO ELECTRONIC DATA STORAGE”: ETHICAL ASPECTS FOR M-HEALTH PROJECTS IN AUSTRALIA

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ABSTRACT

This paper discusses the issue of ethics when it comes to trialling m-health applications in a hospital environment in Australia. Our team has developed a personalised health monitoring application for smart phones using wireless bio-sensors to monitor and instruct patients. This paper discusses some of the Australian guidelines regarding ethical aspects of running technological trials of such mobile health projects on cardiac patients. Ethical issues regarding mobile health projects can be generally divided in two parts. The first one concerns any potential dangers to the patient's health. Although testing can also be done on healthy test subjects, the best way to acquire real-life test-data is to perform tests on actual cardiac patients. The second one is the privacy aspect in the doctor-patient relationship as some patients do not want to be identified as having a disease or do not want to have their records kept on file and used in scientific publications. Nevertheless, to show the benefits of this personalized m-health monitoring, a technical trial has to be conducted and research data needs to be published in a verifiable way.

This paper gives an introduction into ethical regulations, organizations and issues in Australia. It describes, in detail, the issues involved in conducting technical trials in Australian hospitals. The paper gives several recommendations on how to deal with ethics in personalised m-health monitoring projects.

KEYWORDS

Mobile health, Australian Healthcare, Ethics, Mobile Privacy, Telemedicine, Personalized Health Monitoring.

1. INTRODUCTION

The use of mobile- health (m-health) applications to monitor patients is a booming business worldwide. The market is estimated to be \$81 billion (USD) in the United States alone [1]. This paper discusses our experience in dealing with ethical aspects for our m-Health project in Australia. We have developed a mobile health application [7]. It is part of a wireless body area network (BAN), which can monitor and instruct Cardio Vascular Disease (CVD) patients. The system can warn medical professionals in case of an emergency situation. The device is equipped with wireless sensors, such as a wireless ECG/accelerometer, a unit that is capable of detecting falls and movement. Combined with an ECG monitor this can serve as a basic security for the patient. The device can also be extended with sensors for blood pressure measurements (systolic/diastolic), scaling, oxygen saturation (O2sat) measurements and other sensors that turn out to be necessary. Although the first focus is on cardiac patients, this is merely a design choice. The application can support all sorts of patients and can be flexibly personalized to the user's needs or standards when necessary. This is also where the strength of this project lies; the device is not only autonomous but personalized as well. A lot of devices are currently on the healthcare market but not too many can be flexibly adjusted and personalized to the patient needs.

A m-health application should be tested before being introduced on the Australian. As soon as clinical tests commence, patients and doctors get involved and therefore a thorough look at the ethical aspects is required. This paper serves as a guideline through the ethical aspects of this process.

The ethical aspects of m-Health projects can be divided into two separate parts. The first part concerns any potential endangerments to the patient's health. Although testing can also be done on healthy subjects, the best way to acquire real-life test-data is to perform tests on real-life cardiac patients. The second part concerns the privacy issue. There is a strong privacy aspect in the doctor-patient relation and some patients do not want to be identified as having a disease or do not want to have their records kept on file and used in scientific publications. Nevertheless, to show the benefits of this project a research/clinical trial has to be conducted and the research data has to be published in a verifiable way.

The first section will give a brief introduction into ethical regulations, organizations and issues in Australia. The second section will go into detail about conducting trials in Australian hospitals. The third section will address the guidelines and regulations presented by the NSW universities when it comes to research involving human beings. This paper will conclude with some recommendations on how to deal with ethical aspects in Australian m-Health projects, although most principles are globally applicable.

2. ETHICS IN RESEARCH INVOLVING HUMANS IN AUSTRALIA

Ethics is derived from the Greek word 'ethos', meaning habit or custom and that is exactly what it is about. Ethics in healthcare has a strong connection with the Hippocratic Oath, pledged by graduating medical professionals since the 11th century, but possibly earlier. The Oath has been, like ethics, updated throughout the centuries. The modern version dates from 1964; generated by Dr. Louis Lasagna. The Oath always contained, and still does, a lot of ethical issues. E.g. the modern Oath states [9]:

"I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God."

Most ethical committees, guidelines and standards in healthcare are directly derived from the Conference of Helsinki, held in 1964 by the World Medical Association (WMA). Australia has, like most Western countries, also ratified the conference statements and is therefore obliged to follow and implement them in their healthcare and legal system. The main conference statement is twofold and states that ethics are there to protect human beings as well as serving as a guideline throughout research for Good Clinical Practice (GCP) [18].

Nowadays, the standards provided by the Helsinki Conference, which were actually assembled in Scotland, are loosely based on the Belmont Report [15] from 1979. The Belmont report identifies three basic ethical principles for researchers. These three principles are summarized under the topic names 'respect', 'benefice' and 'justice'. In general, at this juncture, respect means that every human being in a research has to be treated as an autonomous individual and that researchers have to take care and are responsible for people who are not (or less) able to make their own well-based decisions. The meaning of 'benefice' is twofold and broader than the original intention of the word. In the context of the Belmont Report it means:

- a) do no harm (derived from the Hippocratic Oath) and
- b) try to maximize possible benefits and minimize possible harms. The term justice relates to "fairness in distribution", with regards to both the burden and the profits derived from the research. No research subject should get an unequal treatment by comparison with others nor should any researcher benefit more from the research than he or she has put effort into it.

There are numerous agencies and organizations working on the ethics topic in Australia, all of them with their own point of view, mission statements and rules. It would go beyond to the scope of this paper to discuss them all. We focus on the guidelines from two major organizations that deal with ethics in trials.

The first organization that comes into play is the Australian Government with their counseling division, The National Health and Medical Research Council (NHMRC) [14]. It resorts under the Ministry of Health and Aging. The NHMRC also has a subcommittee called the Australian Health Ethics Committee (AHEC), but all large decisions and publications go through the NHMRC, therefore the main focus will be on them. Furthermore, the NHMRC (currently) consists of twenty-nine experts and advises both the Australian government, as well as the private sector, on ethical issues and legislation on a regular basis. It is difficult to state when the help of the NHMRC might be required and when it turns out to be superfluous. The NHMRC

therefore holds the definition that its counseling and advice is required whenever a (scientific) research significantly “(...) involves or impacts upon humans.”

The second organization is the Australian Medical Association [2], the largest organization for registered medical practitioners and medical students. From their mission statement it can be read that: “*The AMA exists to: (...) promote and advance ethical behavior by the medical profession and protect the integrity and independence of the doctor/patient relationship (...)*”. The AMA would like to profile itself as having good ethical guidelines following both the governmental statements as the medical professionals’ Oath of Hippocrates.

It was expected that patient organizations like Diabetes Australia and the National Heart Foundation Australia were frequently asked to cooperate in a diversity of clinical trials. They either do not have procedures in place for ethical guidelines or they rely on the knowledge and guidelines from the medical professionals and hospitals. Either way, both their websites speak about the attention ethics should get, but neither one of them has any guidelines for their members and/or users online on their website [13] [5].

Before an identification of the guidelines for clinical trials can be made, it is necessary to see what a clinical trial exactly is and what types of medical trials are used in (medical) research. First of all, a distinction must be made between therapeutic and non-therapeutic trials. The first one will actually give possible benefits to the patient in question, the second one will (only) give knowledge and insights to the people (medical professionals, patients) involved. From this distinction a follow-up is constructed when it comes to the difference between clinical and non-clinical trials. A clinical trial is a trial that closely cooperates and/or intervenes with the care already received by the patient. A clinical trial can thus be seen as an extra supplement in the treatment process. A non-clinical trial is a trial where only the device/unit/medicine/etc. that has to be tested is used, without any other related medical treatment for the patient.

The Australian legislation on ethics states that every company, organization or research facility, which is involved in running tests with human beings, is required to have its own ethical committee, called a Human Research Ethical Committee (HREC). If a research group is formed in close cooperation between organizations, they are allowed to have a shared HREC. Nevertheless, every organization is responsible for its own (part of the) HREC, whether it is a shared one or not. Every organization is legally responsible for the tasks performed and the decisions made by its HREC. The main tasks of the HREC’s are advising researchers on ethical processes and issues during an initiating or ongoing research. Some tasks might be, reviewing research proposals, giving permission to start a research, stopping a research, making company policies, developing ethical guidelines and complaint management. HREC’s in Australia are monitored by the AHEC and are obliged to report on annual basis in the form of a written account. The AHEC gives an annual report to the NHMRC based on the information and reports they have received from the public HREC’s. This information is used by the NHMRC for statistical purposes, as well as redeveloping and adjusting the ethical guidelines for research involving humans. Sometimes ethical interests may conflict with the legal system of a country. The guidelines state that if under any circumstances it is the case, legal issues always override ethical issues, thus coming in the first place.

Although ‘endangering’ patients is a broad description, it is also an obvious one. Medical devices can endanger and harm patients later on in the routine use phase if for some reason they malfunction, but this can also already happen during the testing process. This endangerment can consist of malfunctioning of the m-Health prototype (software, network and/or hardware errors), wrong operation by the medical experts, wrong operation by patients or simply wrong expectations. Specifically in the United States a lot of medical monitoring devices contain the text: “This is not a life saving device”. Whether this is to prevent potential claims or just because the medical device really is not a life saving device is unknown to the authors. Giving a false alarm is also considered as a malfunction of the device but will not directly cause any harm to the patient. Giving a lot of false alarms may be potentially hazardous because a medical professional in the emergency central may think that when an alarm sounds it is a false one again, although it is not and the patient actually is in danger.

According to the Australian legislation with regards to the classification of patient data, there are three different categories currently in use, based on the (possible) identification of the data. The first category, and the most important one, is ‘identifiable medical data’. In this category the medical record and history are directly traceable back to the patient. The second category is ‘potentially identifiable medical data’. Although this personal data is encrypted, it is not done using a one-way encryption key. There is still a possibility of deciphering the encryption and thus tracing the medical data back to a person. The third and last category is

‘de-identified medical data’. There is absolutely no way of relating to or tracing back this medical data to an actual patient. If a researcher chooses (or is forced to, due to circumstances) to use one of the first two data-types, he has to motivate to HREC why he couldn’t use ‘de-identified patient data’.

Privacy is generally described as ‘the right to be left alone’, [19] but there is a much larger definition. Privacy also entitles a person to have private life, to do things in anonymity. It is described as a fundamental human right. In Australia, as in most civilized countries, the relationship between doctors and patients is kept private. This means that everything the patient tells his doctor, or the doctor finds out during the examination of the patient cannot be foretold without explicit approval from the patient. This results in the fact that researchers are never allowed to use identifiable data in any publication, research or statistics without approval of the patient. Of course there are some cases when public health or safety issues are at stake that a medical professional is allowed to break this commitment and inform appropriate instances without the patient’s consent.

Privacy is legislated in Australia through the Privacy Act 1988 [3]. Besides providing a legal structure for privacy issues, the statement also enfold the, in Australia very well known, eleven Information Privacy Principles (IPP’s). The principles can be translated to correspond to medical research. The principles are summarized in the author’s own words.

- Principle 1: Data may solely be collected in a legal manner and may not be collected at all unless it is absolutely necessary.
- Principle 2: Researchers need to inform a person, when possible, if his/her data is going to be used in a research, publication, etc.
- Principle 3: Researchers are only allowed to collect data that is relevant to their research. They are obliged to dispose any ‘collateral’ gathered data.
- Principle 4/5/6: Researchers are responsible for the process of gathering and storing the medical data used in their research.
- Principle 7/8: Data used for research has to be accurate and has to be kept accurate. Inaccurate data should not be used or be identifiable as such.
- Principle 9: Only use data if it is useful and serves a purpose that corresponds to the research.
- Principle 10/11: Data provided to third party members, this includes giving insights, should follow the corresponding guidelines. And moreover, only relevant information may be provided.

If for some reason it turns out to be impossible for a researcher to meet the requirements provided by [3] or its IPP’s, the researcher needs to communicate this to the HREC. The HREC needs to give explicit clearance for the researcher to continue his research.

3. CONDUCTING TECHNOLOGICAL TRIALS

A lot of companies and committees give advice on how to conduct a good trial in an ethically responsible way. Of course a lot also is based on common sense. Even more guidelines and statements are available throughout the Internet. Nevertheless, in Australia most guidelines are based on some fundamental documents provided by the government. The documents of direct relevance for m-health projects are

- National Statement on Ethical Conduct in Research Involving Humans [10],
- Guidelines under Section 95 of the privacy Act 1988 [12],
- The Privacy Act 1988 [3],
- ISO 14155 – Clinical Investigation of Medical Devices for Human Subjects” [8]
- Joint NHMRC/AVCC statement and Guidelines on Research Practice [11].

Every guideline mentions the fact that above all, researchers should practice respect and integrity towards the test subjects in their trials. The three principles from the Belmont report are repeated over and over again. It comes down to the fact that in trials, as in most research, it is utterly important to be reasonable and sensible when it comes to the degree of burden for the test subjects and the profits for the researchers (justice and beneficence). Here the term of justice has a great overlap in this context with beneficence. Above all, it holds for every research, that the advantages must be greater than the disadvantages and this question should be re-evaluated every time something substantially changes in the research outline.

When it comes to using patient data/medical records for any other purposes than treatment, consent is always required. If, for some reason (e.g. comatose situation), the patient is currently unable to provide such

an approval, relatives, or other people indicated by Advance Directives (AD's), are allowed to give the approval for the use of the data to the doctor instead. In case the (medical) data is de-identified or gathered at a publicly accessible place, e.g. counting people with prostheses at a railway station, the subject's consent is not required. Although, for the reason of completeness, a doctor can still include it in his/her research. In some communities, e.g. in Australia's indigenous communities, it might be essential to not only ask the patient himself for consent but also the community or a community leader, just to use this one patient's data. It is the responsibility of the researcher to discover whose consents are required for the test subject to participate safely in a research.

An important fact, that needs to be emphasized explicitly, is that when it comes to using patients in a research, patients are always allowed to stop at any time they want. The patient also needs to be informed fully in advance of the research on what the consequences are for stopping a program in the midst of the research curriculum. Of course, the patient also holds the right at all times, to refuse participation and moreover, it is of ethical importance that this does not change the doctor-patient relationship in any possible way. Before a research commences, a researcher is required to be absolutely sure that he explained everything related to the research to the test subject ('s relatives) that might be of his (future) interest. A research can never start without the patient knowing everything he has to know, including of course the purpose of the research. This previous statement is included into the guidelines to help preventing patient from getting false hope, i.e. patients should know what reality is, what to expect and know that panacea aren't invented yet. This is one of the toughest aspects when it comes to ethical issues.

All the conditions mentioned above should be verified by the company's HREC. The HREC holds the responsibility to end a research or give a green light for continuation. A trial can never start without the approval and 'go ahead' from a company's HREC. The AHEC's guidelines state that in trials the researcher is responsible for de-identifying the patient data. This is a peculiar situation; one would expect that the doctor (being the supplier of the medical data, as well as the gatekeeper) would be the one responsible for this task. Perhaps this is the case because by letting the doctor de-identify the data, too much valuable information might get lost in the process? If Australian employees/citizens (doctor, researcher or both) perform a trial outside of Australia, they should seek both approval from their own HREC as well as from the one, or a similar one, in the country where the research is performed.

Before a trial commences and the HREC gives its approval, the researchers have to present an extensive report containing a research protocol and outline, including worst-case scenarios. Every researcher needs to sign this report and the HREC needs to verify that all persons involved are both qualified and experienced enough to perform the research. Furthermore the researchers are obliged to convince the HREC of the importance and necessity of their trial, for obvious reasons, trials for fun are not allowed. The HREC needs to be a 100% sure of the validity of the data submitted and is required to obtain, as researchers are required to give, regular status updates during the process. Besides keeping the eleven Information Privacy Principles in mind, researchers and the HREC are required to follow the "Personal Privacy Protection in Healthcare Information Systems (AS4400-1995)" [4] act when it comes to data processing and storage.

When it comes to privacy, the HREC has to ensure that the Privacy Act of 1988 is followed thoroughly. This means, amongst other things, that the use of test subjects and their medical data is strictly limited to the purpose of the research it is provided for. The HREC has to guarantee this. If, for some reason, the identity of test subjects is required to be known, or moreover, to be published, the additional guideline of "Privacy in Medical Research 1988" [12] has to be followed. This guideline states that one of the most important things in handling medical data is the traceability of it. Besides the fact that research data needs to be verifiable, it also needs to keep track of where the data has been, currently is and will be in the nearby future. Therefore, the researcher needs to have a list and a protocol in place of everybody who has/might have access to the data and what form of access, e.g. read-only or alternation possibilities as well. Before a research is approved by the HREC, it must be known to this committee what will happen with every piece of data after the research, whether it will be used later on or not. State regulations enforce researchers to keep track of their medical data for at least fifteen years after the research has ended. When a research, for example on new medications, has the potential to develop into hazardous situations after this fifteen year guideline, the government is allowed to require the researchers to maintain the data for several additional years.

The International Organization for Standardization ISO 14155-1/2 provides standard guidelines for performing medical research. Although there are links from the ethical guidelines to the ISO document, the ISO document itself does not really give much information about ethics. The ethics differ too much worldwide to provide a good usable standard for it. Nevertheless, the ISO document gives some good tips on

how to perform a good medical research and it is worthwhile looking into anyway. Part 1 (ISO 14155-1) discusses the general requirements for conducting a medical research like keeping track of the research data and having a fail-safe system for traceability put in place. Of course, all the requirements that hold for every research, like reproducibility and verification are also thoroughly mentioned. Part 2 (ISO 14155-2) discusses what a report used in and/or describing a medical research should contain; again the relations with ethical aspects are unfortunately limited. The ethical aspects that are mentioned are privacy and information system management. A good advice that will most certainly be supported by the HREC's, is to force researchers to keep comprehensive track of version-changes in the reports and research and let every researcher resign the report when for some reason something changes. The guideline also goes into the reporting of vigilance, which is of course of utter importance when it comes to trials. Their guidelines do not provide walk-troughs for normal trials, possibly because there are too many different kinds and variations of research in this field. That is why the ISO limits its scope to things that can be standardized worldwide, and sticks to topics like report writing. Standardizing ethical aspects worldwide would definitely be a nice idea but is practically undoable.

4. ETHICAL GUIDELINES IN NSW UNIVERSITIES

Our University has, like every research conducting organization in Australia, a HREC installed [17]. It describes guidelines for conducting medical research or other research involving humans. It is a member of the NSW University HREC Network in which fifteen HREC's from universities in New South Wales participate and discuss ethical issues. It can be seen at a glance that the guidelines are directly derived from the National Statement [10] and the Joint NHMRC/AVCC [11] guidelines. Our University stresses out that staff members always have to get consent from the HREC before initiating any research involving humans. In general the HREC requires staff members to file their research when it potentially involves 'dangerous situations', 'privacy related situations', 'ethically sensitive situations' or any other situation that the researcher might think requires approval.

The HREC prioritizes and classifies researches involving humans, according to a risk-assessment schedule for researches, which can be found at [16]. In this schedule there are three distinct categories in use:

- A low-risk category, which is about: "(...) *Anonymous or de-identified surveys, interviews involving non-personal or non-intrusive information*".
- A medium risk category, meant for: "*Research involving children, other organizations (hospitals, schools, private companies), or minority groups, (...) UTS students, (...) deception, covert observation or concealment, (...) ethnographic study*".
- A high risk category: "*Research involving vulnerable populations – those whose resources are compromised in some way (i.e. socially isolated, elderly), or who are at risk of being 'over-studied', etc. Research with potential for physical or psychological harm, clinical trials (...)*".

From this it can be easily seen that a m-Health application like ours will be considered a high risk research by the University's' HREC.

Furthermore the university stresses out the importance of following 'natural justice' during any research, meaning as much as a procedural fairness for participating test subjects and involved researchers. The HREC sometimes grants clearance for a research before the actual full application is filed for, but only under very exceptional circumstances. For every other step in the research the UTS has to officially clear the researchers and their research before they can commence.

5. CONCLUSION

Ethics is a topic where most people have an opinion on. Almost everyone has a 'gut-feeling' whether some clinical practice feels right or not. Ethics is not rock solid science, nor is it measurable. It's easy to form an opinion and write a statement accordingly, even in a delicate field like healthcare. The author of this paper likes discussion and has always been interested in ethical issues. Writing a paper about uncolored guidelines provided by government instances turned out to be harder than expected, one really has to keep focused and

not accidentally block out issues that are considered common knowledge or irrelevant by some, but might as well be of great importance to others.

It might be interesting to look into what warning signs have to be present on a medical device to make clear what it is meant for and what its exact capabilities are. As mentioned before, a lot of medical devices in the United States mention “this is not a life saving device”. Is this also true for m-health applications? It does not really directly save your life, but can certainly contribute to the procedure. Further research is required on what warning texts should be on the device and in the manual before entering the market.

With regards to our m-Health application, some things might become an issue, like endangering patients. A strong recommendation is to aim for low-risk patients in a first phase. Even if the final focus is the monitoring of high-risk patients, it is expected that low-risk patients will give the same data/results. The only disadvantage is that it might take a while for an event to occur. Of course when weighted against the fact that no high-risk patients’ lives are depending on our device, the low-risk patients group prevails. Furthermore, keeping the test subject’s identities to the researchers only saves us a lot of trouble. When the diversity of the researchers group is large enough there would be no problem with regards to verification of the research data. Keeping the identities of the patient’s secret saves a lot of time and effort and is most definitely the safest solution when it comes to ethics. Some issues like getting consent from a patient are not a big issue since there are enough high-risk cardiac patients in Australia and we believe that a lot of them are more than willing to cooperate.

It would be interesting to verify the actual efficiency and effectiveness of HREC’s. A HREC is, for example, required to have a member with a religious background (National Statement, Section 2.6E). Is this really necessary and when is a religious background religious enough? Furthermore, the extensive requirements to the filling of the HREC make it impossible for sole entrepreneurs to perform a trial on their own. You have to be with at least nine people from very various backgrounds to occupy a HREC to fulfill the NHMRC’s needs.

The ISO 14155-1/2 document is derived and generated from medical guideline document EN540 (European Standard) in 1996 [6]. When the ISO document is compared to the EN 540, its comprehensiveness is very diminutive. The ISO organization is known for its well guided documents worldwide. Why is there so little medical guideline, especially when it comes to ethics?

It is an ongoing discussion when medical professionals are expected to break their silence with regards to the private doctor-patient relationship when the society or others are in danger. There are some rules and procedures in place, but none of them are very strict and most of them can be explained in an ambiguous way. It would be interesting to have a look at in what cases society’s stakes are higher than the patient’s interests. As can be read in Section 3, when there is a conflict between the legal system and the ethical system, the justice system overrules the ethical system. Why is this rule put in place? Are the ‘legal laws’ more important than the ethical ones? And who made this decision? Shouldn’t it be the case in a modern society that the rules are there for the people and not the other way around? There is also a contradiction in the guidelines from the government and the one from the AMA. The government states the interests of society always goes above the interests of an individual. The AMA ethical guideline (paragraph 1.2C) states:

“Recognize that considerations relating to the well-being of individual participants in research take precedence over the interests of science or society”.

So for the AMA the individual does go above the society. Of course, it is probably not as black and white as is summarized in their guidelines. Still this would be an interesting point to use for further research.

Ethics is a very dynamic field and differs per country, even per organization or person. Although some ethics are written down in a country’s legal system, there is always some space left for different interpretations. Which is good, as can be read in the “are the rules there for the people?” segment in the Recommendations and Further Research section. The government supports discussion on ethical aspects and leaves a lot of things open to be filled in by the research groups themselves. This can be derived from the fact that the government allows companies to constitute their own HREC’s.

The basic assumption made by companies, research institutes and the government will always be, that research is performed with the best interests for humanity kept in mind all the time. That reality works a bit differently can already be deducted from the fact that it is necessary to have legislation on this topic. Additional guidelines are necessary and convenient for everyone involved to keep everyone’s interests in mind, thus enabling the possibility to gain the highest advantage for everyone.

This paper mainly addresses ethical issues with regards to medical research involving human beings. Nevertheless most principles, statements and guidelines can be read in a much broader sense. A lot of the

things applying to medical research would also apply to other kinds of research or just basic ways of normal human behavior. In conclusion it can be said that every ethical aspect and the success of the clinical trials both begin and end with Good Clinical Practice, good thinking and common sense.

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