Contract no. 224306

LABONFOIL

Laboratory Skin Patches and SmartCards based on foils and compatible with a Smartbiophone

INSTRUMENT: Large-scale integrating project (IP)

D13.2 ETHICAL ISSUES

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RE	Restricted to a group specified by the consortium (including Commission Services)	☐
CO	Confidential, only for members of the consortium (including Commission Services)	☒

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1. ABSTRACT

The objectives of this Deliverable is to describe how LABONFOIL addressed both the ethical issues associated with the nature and outcomes of the Labonfoil project but also to investigate the risk perception of Information Society and Nanotechnologies, particularly when applied to medical diagnostics. These work wwas performed under the WP13 involving intensive interviewing with clinicians, scientist and the society.

2. INTRODUCTION

Ethical issues related to the collection and use of human specimens for research purposes have been the subject of considerable discussion. Human specimen collections contain links to patient identities and other personal information. The privacy and confidentiality of personal information associated with human specimens are important considerations. In Spain we worked according with the specific laws: *Ley Orgánica 15/1999 de Protección de Datos de Carácter Personal, Real Decreto 1720/2007 and Ley 14/2007 de Investigación Biomédica.*

The Hospital Cruces Labonfoil participants prepared the essential requirements in order to carry out the future research.

The Research Ethics Committee in Euskadi is the CEIC-E (*Euskadi's Ethical Committee*). This Committee is responsible for policy and approval processes. It also looks at any problems or ethical issues that require a response. As research progressed, further ethic issues arised, so Investigators went back to the CEIC-E to have any changes approved.

The Research Ethics Committee in Euskadi is multidisciplinary to ensuring that it has the range of expertise and the breadth of experience necessary to provide competent and rigorous review of the submitted research proposal.

The principal ethical issues to look out for and consider at any or all the stages of research were:

- Voluntary participation-self determination-autonomy.
- Consent.
- Privacy, confidentiality, anonymity, security, time.
- No-harm principle.
- Doing good.
- Dissemination of findings.

3. EXPERIMENT DESCRIPTION

Submission of the Project to CEIC-E (Euskadi's Ethical Committee) for evaluation. The Hospital Cruces Labonfoil participants prepared the essential requirements in order to carry out the future research:

- Application Form.
- Commitment document for the participation in the Project.
- A report to indicate the relevance of the clinical and technological aspects of the project for the Health System.
- A document including the Medical Oncology Group experience in terms of Teaching, Health Care and Research.
- A Spanish summary of the scientific report including an abstract, the methodology and associated work plan, ethical issues related to the collection and use of human specimens for research purposes…
- The financial report (Spanish).
- The Information Sheet for participants: The Medical Oncology team prepared a model information sheet document including the project background information, the aims of the study, the type of samples required and the privacy and confidentiality of personal information associated with human specimens.
- The informed consent for the patient's participation: Before performing any test, doctors must obtain permission from the patient in a manner that is informed, voluntary and competent. For that purpose, the Medical Oncology group prepared a model Informed consent document for the Ethical Committee evaluation.

4. RESULTS

4.1 Patient recruitment and CEA determinations

In order to recruit the voluntary patients for CEA determinations, the researches at Hospital de Cruces sent all the requirements to The Euskadi's Ethical Committee who reviewed the documents. The Ethical approval was received before the beginning of the project.

In regard to the principal ethical issues to look out for and consider it has been proceeded as described below:

Voluntary participation:

The voluntary participation requires that people not be coerced into participating in research. All research participants of the Labonfoil were adults and volunteers. They were free to decide what they engage with and they made aware at the beginning that they could leave the project at any time and that no coercion will be used to keep them on board. The

clinicians gave them clear information and showed them the ways to contact to let the clinicians know they no longer want to be part of the research. It has to bear in mind that If a participant leaves the project he can also request that his data should be also removed from the project's records and the researches should move away the data. This possibility must be shown in the informed consent that the patients sign.

Consent:

The principle of the consent is that people should know what they are getting into. This includes time that is required and the effort on their part. Consent issues are related to voluntary participation and the giving out of sufficient information to would-be participants to enable them to make a reasonably-informed decision about self-determined participation. The primary objective is to conduct research openly and without deception.

Consent carries with it an implication of the researcher's skill and capacity to actually carry out the research properly. This is important because the researcher, if unsuitably qualified for the research involved, may cause unintended and potentially serious harm. Participants discovering this later may well have a case against the researcher and others involved in the research process.

There are two different forms of consent, which are defined by the way in which consent is recorded:

- Written consent.
- Oral consent (which may be off-the-cuff and not recorded, or recorded by video/audio prior to a data generation session).

The information sheet should also include in it a paragraph about voluntary participation. Researches should inform participants of their right to refuse to participate or withdraw from investigation whenever and for whatever reason they wish, with or without their data. It should also tell the participant how they can contact the researches and how they can leave the project (phone, letter, telling a researcher, or simply not responding to a subsequent request for access, for example).

The information document should also include details of the level of privacy that the researchers are offering and how they will manage this. If the researches are going to see the participant on more than one occasion, for example to carry our repeat interviews or other data collection, then consent should be revisited at each event or at least at regular intervals. It does not need to re-sign papers, but the participant should be asked prior to, or at, each subsequent event or at some other time, if they wish to continue in the research. This means that consent is ongoing.

In the Labonfoil project research involved the need to secure samples (blood) so, participants were informed of their rights over the samples and data derived from them. The organisation of the researches is the responsible of this material and the use, preservation and disponsal of samples should be in accordance with the terms of consent given by the donor and the legislation.

In regard to the information about the research, it not always needs to give out full information of the project. A balance must be struck between too little and too much

information. This may referred to as partially informed consent or reasonably informed consent.

In this project we used the written and reasonably informed consent.

Privacy, confidentiality, anonymity, security, time:

Research privacy is governed by two techniques: anonymity and confidentiality. These protect participants from being identified in publications.

Researches need to consider who will have or need access to the data; who will be involved in the analysis of the data; where it will be kept securely; what future need for access to participants may occur, and if you wish to re-use the data in the future for other studies.

Confidentiality means that no participant is named or otherwise identified in publications, which includes talks, papers, posters, photographs or any other publically-disseminated material, just as in the anonymity scenario. But, the names of the participants and other identifiers are recorded on the data collection sheets, tapes or other records. Such records must be kept in a secured location. Researchers would not identify participants even in discussion with colleagues unless the participant agrees to this. In the consent process, an agreement may be made about how long records will be kept and how they will be destroyed. Agreement would also need to be sought if others are to be involved in the analysis as this may potentially void confidentiality agreements.

Anonimity means that no participant is named or otherwise identified in publications, which includes talks, papers, posters, photographs or any other publically-disseminated material. As well as this public protection, the names of the participants and other identifiers are not recorded on the data collection sheets, tapes or other records. Researchers would not identify participants even in discussion with colleagues unless the participant agrees to this. Each participant is allocated a code or key identifier by the researcher and this coded identifier is used on the records.

Security is an important issue if researches have offered confidentiality, and an even more important issue if they have offered anonymity. The researches are responsible for maintaining the level of privacy that they have offered. For confidentiality, it must keep all the data records in a secure, preferably locked place. Security issues also involve the transfer of data by phone, by email or by other electronic means.

In regard to the time, the researches must discuss with participants in the consent process, and later, how long they will need to keep the data and identifiers on the records. Sometimes researches may only need them for the duration of the study. They make sure to destroy them as agreed by suitable means that will maintain the confidentiality or anonymity that offered.

The “No Harm” principle and Beneficence:

The No Harm principle (Primum non nocere) is based on the idea that participants should not come to harm by their participation in research. While everyone agrees that this is

worthy and to be pursued, it is not always easily accommodated. A researcher does not intentionally go out to cause harm, it is the risk of harm that it should try to minimize.

Harm can be physical, mental, emotional, or it can involve social, employment, political, religious or other sorts of harm. It should be considered that it is a primary ethical obligation to avoid doing harm to the lives, communities or environments with the research.

The principle of beneficence, or of doing good, is based on the idea that researches should have the welfare of the research participant as a goal of any trial and the participation ought to benefit the participant or others either now or in the future. Beneficence had been identify as one of the core values of health care ethics.

Dissemination of findings:

This is an ethical area that is often overlooked by researchers but ethics issues may also arise in disseminating findings. It must be highlighted the potential risk to researchers, participants and others as a result of dissemination when submitting the proposal to the Research Ethics Committee. The researches assume it is their right and responsibility to publish the work, but it must think carefully, in some cases, how to achieve this safely. While the researches cannot be ultimately responsible for every perspective put on their work, they need to consider how they may reduce the risk of this happening. There are no definitive solutions to this, but it must be ethically considered.

Sources

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4.2 Skinpatch analysis and Ethical issues in workplace drug testing

Ethically workplace drug testing (WDT) remains a sensitive issue because of the difficulty of balancing safety and productivity requirements of the workplace against the

essential need to prevent the invasion of privacy and discrimination of the workers. The opposing ethical arguments of workplace drug testing (WDT) arise out of the collision between workers' and employers' interests, as personal liberty and dignity clash with questions of social responsibility and economic productivity.

In addition there are data protection issues and strict requirements for the assurance of reliable test quality. The range of testing currently carried out in European workplaces includes:

- Pre-employment testing.
- Probable cause testing.
- Reasonable suspicion testing.
- Periodic testing.
- Random testing.
- Testing on return from treatment.
- Testing related to transfer or promotion.
- Voluntary testing.

While all these forms of drug testing raise issues of ethical concern, it is random testing that is accompanied by vehement arguments for and against, which are discussed in the following paragraphs.

The Safety Argument

The most frequently used argument for WDT and one of the least controversial is to ensure safety. Workers in "safety-sensitive" positions should not be under the influence of drugs because of the danger to themselves, their colleagues and third parties. There is however no universally accepted definition of what constitutes a safety-sensitive job. As a result, the employer has some leeway in deciding which.

Workers should be subjected to tests for safety reasons. This leeway is open to interpretation in different European countries and in various branches of industry.

In a case in Denmark, and in the transport industry where safety concerns are paramount, the labour court agreed with a ferry company's definition of "safety-sensitive" covering the entire crew of their ships and rejected the unions' complaint.

In Switzerland on the other hand, the Data Protection Commission ordered a major pharmaceutical company to end their testing programme for trainees because of a lack of safety interest, although work with chemicals is often seen as typically safety-sensitive.

The safety argument has been extended from the traditional question of health-related safety to "business-related safety". It is argued that inappropriate use of drugs and alcohol can create "businesscritical" situations, in which poor decisions could cost the company large amounts of money. However this argument is not accepted in all European countries, which is reflected in the varying extent of testing and the legal restrictions on testing.

For example in France, Norway and the Netherlands, only workers in “traditional” safety-sensitive positions are subjected to testing in any form. Accordingly there is less testing and there are more legal restrictions in these countries.

The Moral Argument

Some supporters of WDT take a moral stance partially because of the illegal status of some of the drugs and the opinion that the use of drug use of any sort is morally reprehensible.

In moral arguments usually no distinction is made between drug use and abuse. Whilst this may be appropriate for the moral point of view, the consequences for the worker of a positive drug test should be relevant to the drug use pattern of the individual.

In these instances the employer takes on a social responsibility to influence the values of the workers.

Employers often argue that testing is the only way to tell if a worker is using drugs. This argument reveals that the moral argument differs considerably from the safety, business and prosecution arguments in that it is not related to performance.

Discrimination

For business-critical and morally based testing programmes to be plausible everybody working in the company or organization should be tested. Every employee’s work is relevant to the productivity of the company and moral concerns apply to every human being. For this reason testing programmes which only apply to trainees are open to the accusation of being discriminatory to youth.

As an alternative to testing all people working in an organization, a policy can be introduced of only testing in case of suspicion of drug use. Many union organizations, for example in the DeutscherGewerkschaftsbund (DGB) in Germany, the ÖsterreichischerGewerkschaftsbund (ÖGB) in Austria and the ConfédérationGénérale de Travail (CGT) in France favour this approach, which is compatible with performance-based reasons for testing i.e. for safety, for business and for fear of prosecution.

Concerns pertaining to WDT are often aimed at the moral arguments for testing which can also be discriminatory. The moral stance can lead to discrimination of people with drug dependencies, but the current policy emphasis on aid programmes is intended to counter this bias. The moral argument can also lead to discrimination of people with a certain lifestyle rather than a health problem, because it does not distinguish between use and abuse.

The moral argument also interacts very closely with a further criticism of WDT. Urine analysis, like the moral stance, does not distinguish between users and abusers as it does not give any indication of impairment. It only shows that drugs have been consumed, but not what effect they may have on a worker’s performance.

Deterrence

Increasingly the aim of introducing a WDT programme is deterrence from drug use of any kind. This contrasts with the attitude in the late 1980's when drug testing was perceived as a tool to detect and dismiss drug-abusing workers. Deterrence as the aim of a WDT programme is compatible with both performance-based reasons and the moral motivation to test outlined above, because of its inherent preventive component.

Some European employer organisations, for example the SchweizerischerGewerkschaftsbund (SGB) in Switzerland, SvensktNäringsliv in Sweden and the London Chamber of Commerce in the United Kingdom adopted a deterrence programme, which including sanctions but at the same time offered of assistance for those with drug problems.

Privacy

A major ethical consideration presented by WDT opponents is that the testing process amounts to an unwarranted invasion of privacy. WDT impacts on privacy in relation to the right to personal (i.e. bodily) integrity. National legislation on this matter is often the same as that for personal searches, which requires the consent of the person concerned in order to be lawful.

However, the question of consent is a controversial one. Many guidelines for WDT require that informed consent be obtained before testing. However, as workers are usually dependent on their employers, free consent to WDT is not possible. Therefore signing a contract containing a testing clause cannot constitute a free and informed decision by the person concerned.

On the other hand, in the United Kingdom failure to comply with drug testing which is included in the employment agreement can be interpreted as a disciplinary offence (Alcohol Concern 2002). Some European constitutions, for example in Belgium and Finland, hold that fundamental rights such as the right to privacy are indivisible and that the individual cannot consent to waive such rights. An extension of the privacy debate is related to whether employers have the right to dictate employees' conduct during off-duty periods. One situation in which WDT is held to impact on privacy is when performance-based arguments for testing are used. Employers contend that if the workers' free-time activities have a negative influence on their work performance, the employer is justified in controlling this.

The moral argument for testing in any case assumes the employers' right to influence the workers' private sphere as part of the employers' responsibility to society. Proponents of WDT argue consistently that privacy issues are less significant than the gains for the individual, the company and for society resulting from reduced drug use. The counterargument asserts that employers who control what employees do in their own time are overstepping the mark of their social responsibility. Opponents of WDT point to articles guaranteeing the right to a private life in most international charters of human rights, such as of Universal Declaration of Human Rights (article 12) and the European Convention on the Protection of Human Rights (article 8).

Data protection

The privacy issue links WDT to the question of data protection. WDT involves collecting sensitive data, both on use of drugs, sometimes illegal drugs and also information on medication taken which might influence the test result. Legislation pertaining to WDT has often been concerned with the data protection issue. The collecting and holding of such information is therefore not only subject to strict controls in many European countries but also the subject of international agreements such as European Union Guidelines 95/46 and 97/66 on data protection or the ILO Code of Practice on the Protection of Workers' Personal Data (1996).

In some European countries this issue is resolved by strengthening the role of the occupational physician. In Finland, France, Belgium, Germany and Austria the result of the test is communicated to the occupational doctor, not to the employer. The doctor is only allowed to inform the employer whether the person is fit for work or not, but not what the result of the drug test was.

In terms of rights, there is a further argument which particularly applies to any kind of systematic testing programme (as opposed to testing only on suspicion). Arguably one of the greatest achievements of Western European culture is that legal systems are based on the assumption "innocent until proven guilty". However if someone refuses to take a drugs test, they are largely assumed to "have something to hide". Thus the method to prove someone's innocence is turned on its head and believed to prove their guilt.

Pre-employment testing

A further rights-based controversy in WDT is the question of pre-employment testing. Around 80% of WDT conducted in the world is carried out as part of the recruitment process, i.e. before an employment relationship exists between worker and employer. Legally in many countries the protection which is afforded to workers does not apply to job applicants. Opponents of WDT however claim that a job candidate is even more precariously placed vis-à-vis the employer, because their only alternative to taking the test is effectively to withdraw from the job competition.

Testing in the transportation sector

One area in which testing is much less controversial is the transportation sector. There are strict regulations concerning drug use by pilots including a mandatory eight hour period of abstinence before flying. All European Union countries have a legal limit for alcohol for drivers, and Spain and the United Kingdom even have lower limits for commercial drivers than for private individuals. Even in countries where workplace drug testing is conducted with difficulty, testing of drivers is carried out routinely.

For example, Dutch, French and Belgian legislation is very restrictive concerning WDT, but all three countries permit and frequently use random roadside testing.10

By contrast in the United Kingdom, where WDT meets with more support, random roadside testing is illegal. A police officer must have grounds for suspicion before a driver can be tested for alcohol use.

There are however significant differences between alcohol testing and testing for other drugs. The breath test for alcohol (and subsequent blood tests) is accepted as a measure of impairment, and from this it is possible to set a limit under which it is considered less dangerous to drive. There is also a significant public safety aspect to testing drivers, and alcohol is consumed more frequently and by more people than illegal drugs. As far as driving and drugs other than alcohol is concerned, there have been several inquiries in recent years (both national ones, for example in the United Kingdom and Austria, and also the European Union project ROSITA) on the possibility of introducing a limit for drug use similar to the one for alcohol. Experts universally conclude that for drugs other than alcohol there is insufficient evidence relating drug test results to impairment. The recommendations are therefore either not to test drivers for drugs other than alcohol, or to establish a zero drug limit for drivers, as is already the case in Germany.

Quality

Many reservations about WDT are based on doubts about the quality of tests and testing procedures. The danger of “false positives” is a real one. Consuming large amounts of poppy seeds may lead to a positive test for heroin, or taking ibuprofen can result in a positive test for cannabis. It is generally agreed that the initial immunoassay technique of urinalysis must be confirmed by a more reliable.

test such as gas chromatography, which can only be done in a properly equipped laboratory. In addition to this, a positive test result should only count as such after a Medical Review Officer has considered all the medical information relative to the individual case and ruled out any other possible source of the test.

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5. CONCLUSIONS

The impact on LABONFOIL project of ethical issues related to the collection and use of human specimens for research purposes have been described. The fact that human specimen collections contain links to patient identities and other personal information might produce a collision with the personal privacy and confidentiality. Therefore, in Spain we worked according with the specific laws: *Ley Orgánica 15/1999 de Protección de Datos de Carácter Personal, Real Decreto 1720/2007 and Ley 14/2007 de Investigación Biomédica.* The Hospital Cruces Labonfoil participants prepared the essential requirements in order to carry out the future research and get the approval of The Research Ethics Committee in Euskadi is the CEIC-E (*Euskadi's Ethical Committee*).

We also have studied the impact of Ethics in the Skinpatch potential market and regulation. The ethical impact has been described in this Deliverable, whereas the ipact on the exploitation was described in D14.2 Final exploitation plan. Here, we described that workplace drug testing (WDT) remains a sensitive issue because of the difficulty of balancing safety and productivity requirements of the workplace against the essential need to prevent the invasion of privacy and discrimination of the workers. The opposing ethical arguments of workplace drug testing (WDT) arise out of the collision between workers' and employers' interests, as personal liberty and dignity clash with questions of social responsibility and economic productivity.