

Ethical and Legal Aspects of Patient Data Handling

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Abstract

The objective of AAL and home care is a better care for frail individuals (elderly chronic and disabled patients) in a home care setting. To improve this kind of care means to allow the citizens to stay at home as long as possible, delaying the institutionalization of people, possibly avoiding it for a high percentage of them. Institutionalized elderly citizens are at high risk of cognitive impairment, functional loss, social isolation, or death.

Integrating information deriving from different sources and implementing it with knowledge discovery techniques allows medical and social actions to be appropriately performed with reliable information, in order to improve quality of life of patients and care-givers. To stay at home means to keep independency, self-sufficiency, social network role.

The major ethical issues arise about the handling of sensitive data about health and data about everyday activity patterns. Explicit informed consent must be asked to the participants in order to record their sensitive medical data and also all other types of data. There are still many open questions, as for example how long the data should be stored if no alarm or unusual situation occurs, who should have the right to access such data, should the data be stored locally or in a central data storage.

All the procedures must conform to relevant EU legislation and to national legislations related to the principle of respecting confidentiality. Since a proportion of considered clients are presumably affected by some degree of cognitive impairment, special precautions must be taken as regards such patients. The restrictive rules applied in case of Clinical Trials are to be used (Directive 2001/20/Ec of the European Parliament and of the Council of 4 April 2001 relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for clinical use): “In the case of other persons incapable of giving their consent, such as persons with dementia omissis the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial. The notion of legal representative refers back to existing national law and consequently may include natural or legal persons, an authority and/or a body provided for by national law”.

In the management of sensitive data it is necessary to define some levels of security: *confidentiality* (i.e. ensure that only those that are properly authorised may access the information), *integrity* (i.e. ensure that information cannot be altered by insertion, deletion or replacement), *authentication* (i.e. ensure that a correct identification of the user has been done), and *non-repudiation* (i.e. prevent some of the parts to negate a previous commitment or action). All these issues are again affected by EU and national legislations.

In the paper we will discuss these aspects in more detail and show on an example of a completed project in the area of home care how we approached the problem.

Acknowledgement

This work has been supported by the research program No. MSM 6840770012 of the Czech Technical University in Prague (sponsored by the Ministry of Education, Youth and Sports of the Czech Republic).

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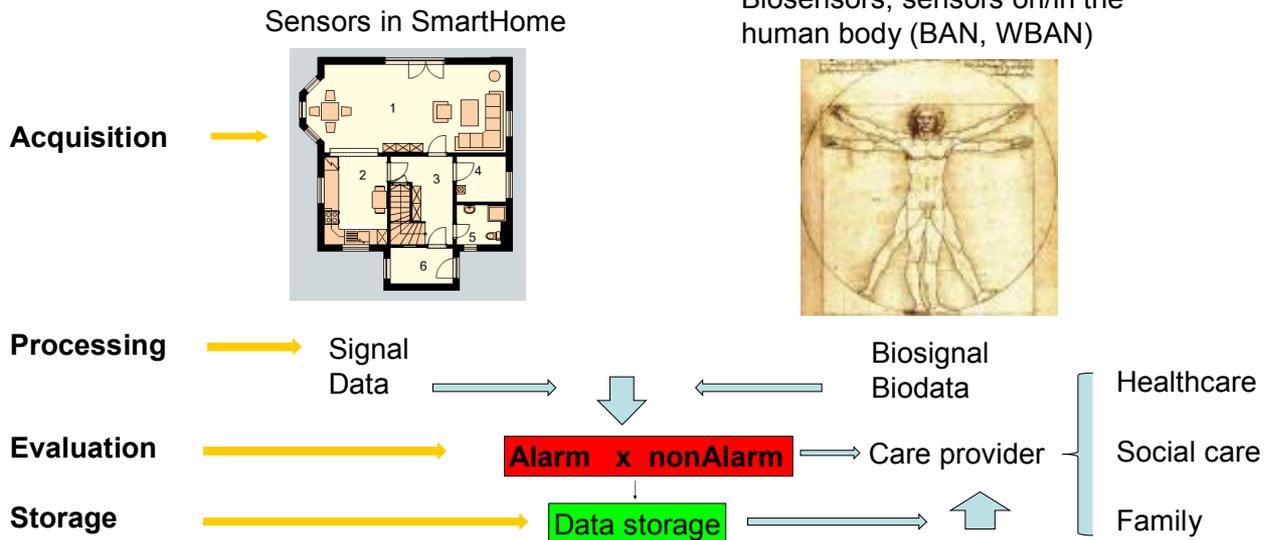
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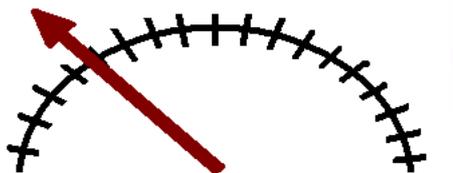
Background

Healthcare, Social Care and Homecare applications involve complex structures of interacting processes and professionals that need to exchange information to provide the care services. Information managed inside the distributed systems should not be freely accessed and must be subject to very complex privacy. In the poster we address the ethical issues that must be considered in design of a distributed Healthcare, Social Care and Homecare applications.

We use the complex term of „data handling“ for process of data acquisition, data processing, data evaluation and data storage.



Surveillance



BIG BROTHER



I want to know everything about you, your ECG, your blood pressure, your position in your room, etc. O.K.?!

I don't care about you, if You need help, let me know, O.K.?!

COST

REALITY

Informed consent for „data handling“

Client agrees and signs consent form, that information about him/her is gained, processed, evaluated and stored under strict condition, under rules, he/her knows well.

Important ethical issues

Data storage

- Who has the right to access the data
- Where should the data be stored
- How long should the data be stored – in case
 - Everything is evaluated as normal
 - An alarm is indicated
- Should we store all raw data or completely aggregated or partially aggregated

Data privacy
Data security



Potential abuse of data!

