The challenge of security of health connected devices

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A MEDICAL AND SCIENTIFIC EVALUATION

and

AN ETHICAL EVALUATION
A MEDICAL AND SCIENTIFIC EVALUATION

- Identical to that of medical devices
- In clinical trial
- In observational studies in real life
Clinical trials

- Evaluation of the reliability
- Evaluation of health care services provided
Clinical trials

- Ideally controlled randomized double-blind vs placebo
- Specific models have to be found as for many medical devices
Observational studies

• Evaluation of the health care service provided in "Real life"
• Adaptation of the health connected device to real conditions of use
AN ETHICAL EVALUATION

- Of the contract
- Of individual freedoms
A CONTRACT ASSESSMENT

- What is the purpose of the contract?
- What is the purpose of the Health connected device?
- Is it clearly defined?
- Is it legal?
A CONTRACT ASSESSMENT

• What is the legal value of the consent?
• There is an agreement between the parties but is there a potential risk of error or “dol” ?
• Error on the substantial quality of the object
• Dol : deceit on the substantial quality of the object
A CONTRACT ASSESSMENT

- Capability to contract
- Will certain health connected objects be reserved for adults or will require a parental agreement?
- We are in the fiction but ...
AN EVALUATION OF PERSONAL FREEDOMS

• Which guarantees are brought so that are protected:
• The confidentiality of the data;
• The integrity of the data;
• The availability of the data.
AN EVALUATION OF PERSONAL FREEDOMS

• Has the personal data record been officially declared?
• The rights of the people are respected:
  • Right of information;
  • Access right;
  • Right of rectification;
  • Right in the safety (security);
  • Right in the oversight (forgetting).
AN EVALUATION OF THE PUBLIC Liberties

• The security of the system
  Who is the master of the system
  What would happen if he decide:
  • To stop the system
  • To modify data

• Where is located the system and which law is applicable

• Whay-t sovereignty on the system
Health connected objects are a real revolution likely to impact on the organization of the health system.
• The medical and scientific evaluation of their properties is an essential prerequisite.
• The evaluation of their impact on the liberties is just as much.
• What obviously differentiates them from traditional medical devices is

Their societal impact!