

The challenge of security of health connected devices

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Two orange smartwatches are shown against a dark grey background. One watch is in the foreground, slightly out of focus, showing its side profile with a silver band. The other watch is in the background, also slightly out of focus, showing its front face with a dark screen displaying a blue and white abstract image. The watches are positioned on either side of the central text.

A MEDICAL AND SCIENTIFIC EVALUATION
and
AN ETHICAL EVALUATION

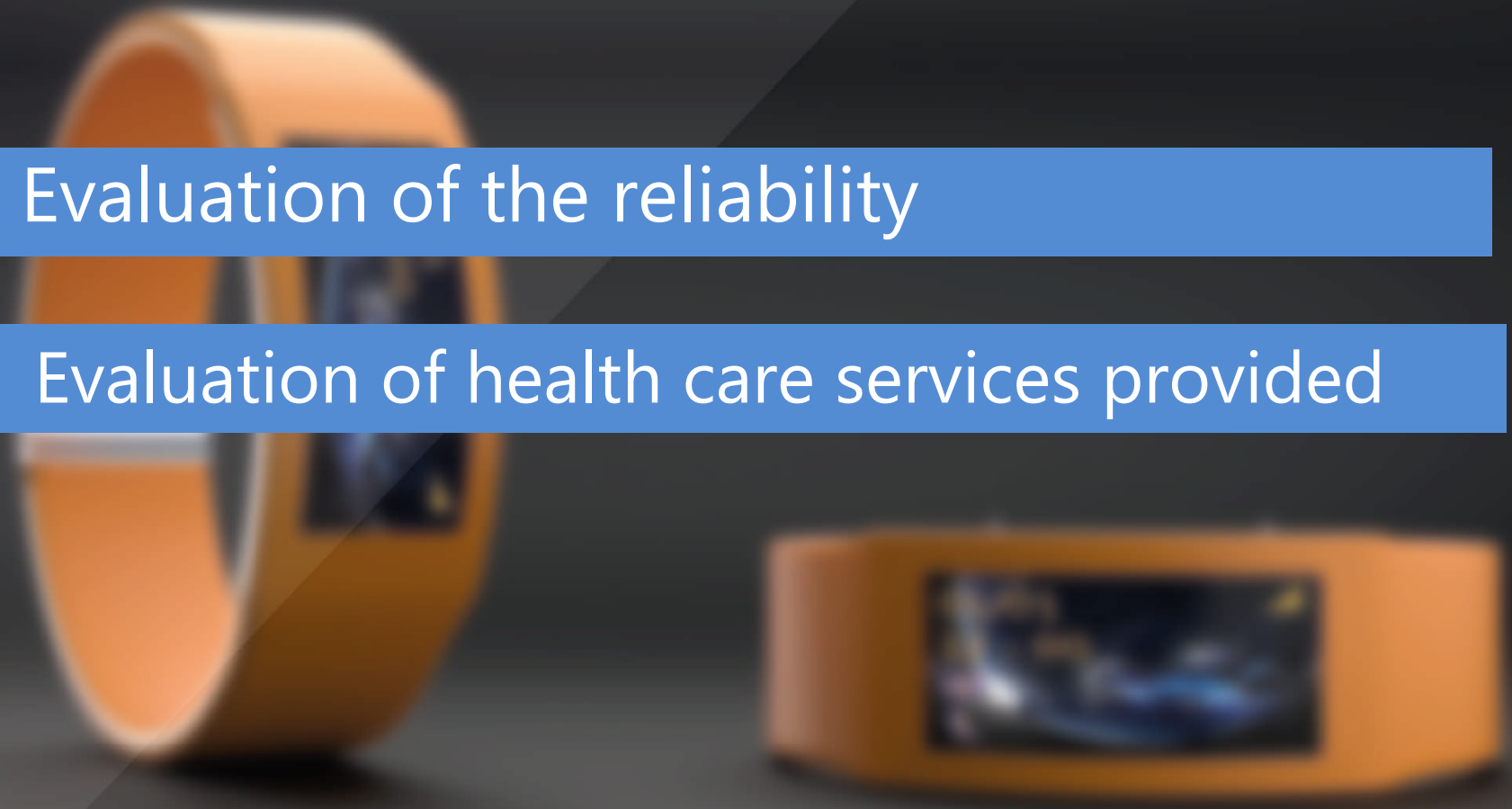


A MEDICAL AND SCIENTIFIC EVALUATION

- 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

CONCLUSION

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!