Human Factors & Usability for complex Health Information Technologies

Why is it so important?

Marie-Catherine Beuscart-Zéphir

Evalab

- Evalab: http://evalab.univ-lille2.fr/

- Human Factors – Innovative Technologies for healthcare
  - 1993: first studies
  - 2001: Evalab
  - 2008 Clinical Investigation Center for Innovative Technologies

Lille academic hospital

Centre Hospitalier Régional
Universitaire de Lille

3600 beds
All specialties
Hospital Information System

University of Lille , Faculty of Medicine

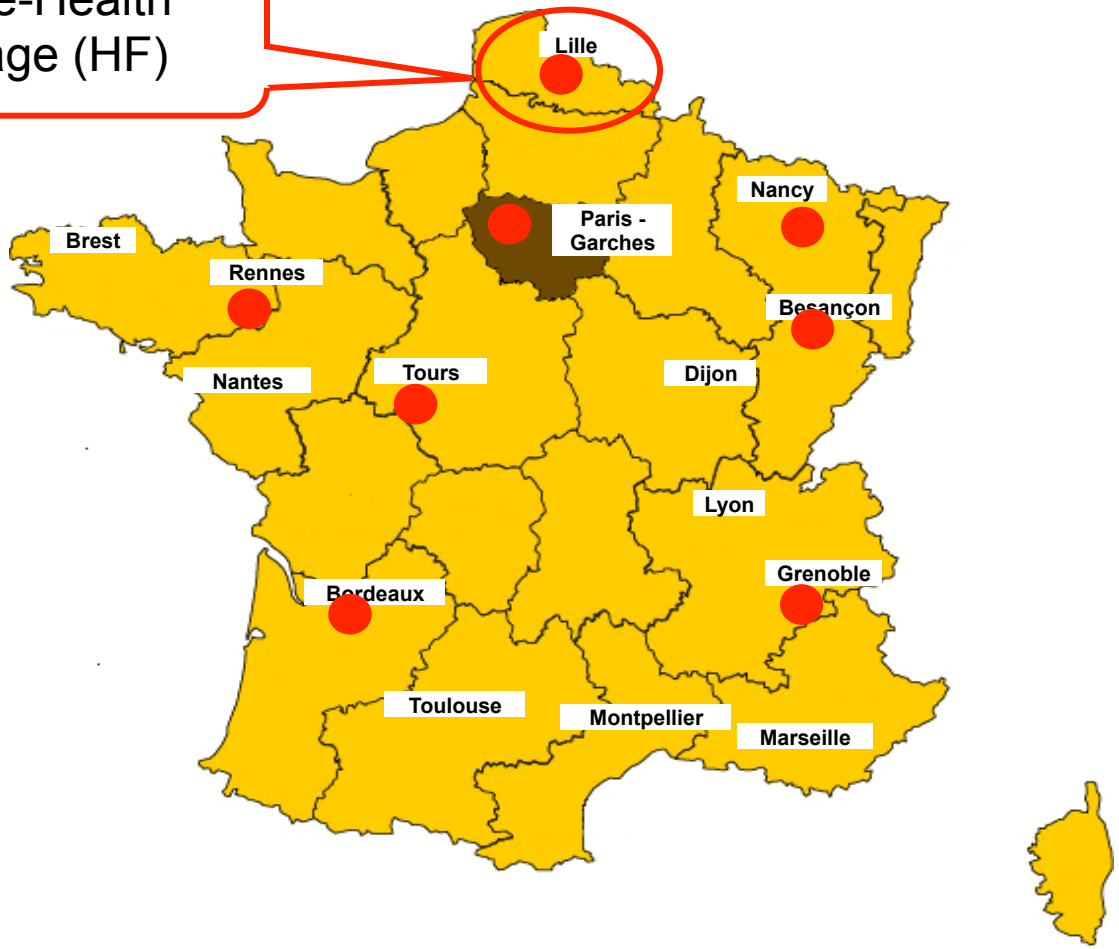
Lille 2
Université du Droit
et de la Santé

Research on Public Health, Epidemiology and Quality of care

CIC-IT network

Clinical Investigation Centers for Innovative Technologies

Lille: e-Health & usage (HF)



CIC LILLE IT

IMIA WG (HFEHI); EFMI WG (HOFMI)

HFE HI network:

FRA, NLD, DNK, NOR, PRT, USA, CAN and more

Lille 2006

Aarhus 2007

Trondheim 2011

Amsterdam 2008

Sonoma 2009

Context Sensitive Health Informatics

Human & Sociotechnical approaches

pre-Medinfo Conference

2013

17-18 August 2013, Copenhagen

Outline

1. Human Factors, Usability: what are we talking about (scope, definitions)

2. WHY? Human Factors issues for Health IT ambitions

3. WHAT & HOW? The Human-centered approach to Health IT projects

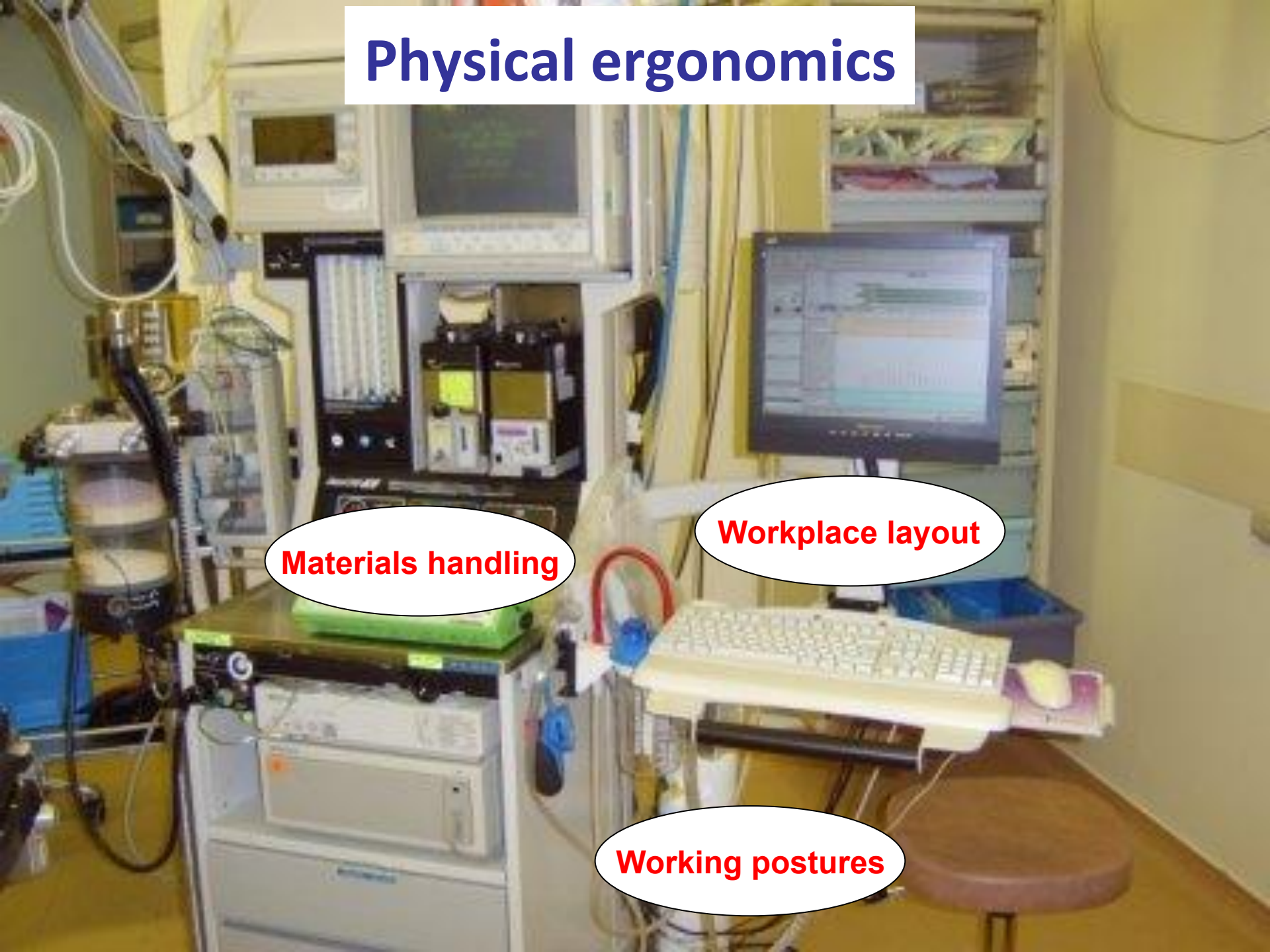
4. Further Challenges of the Human Factors approach to health IT projects

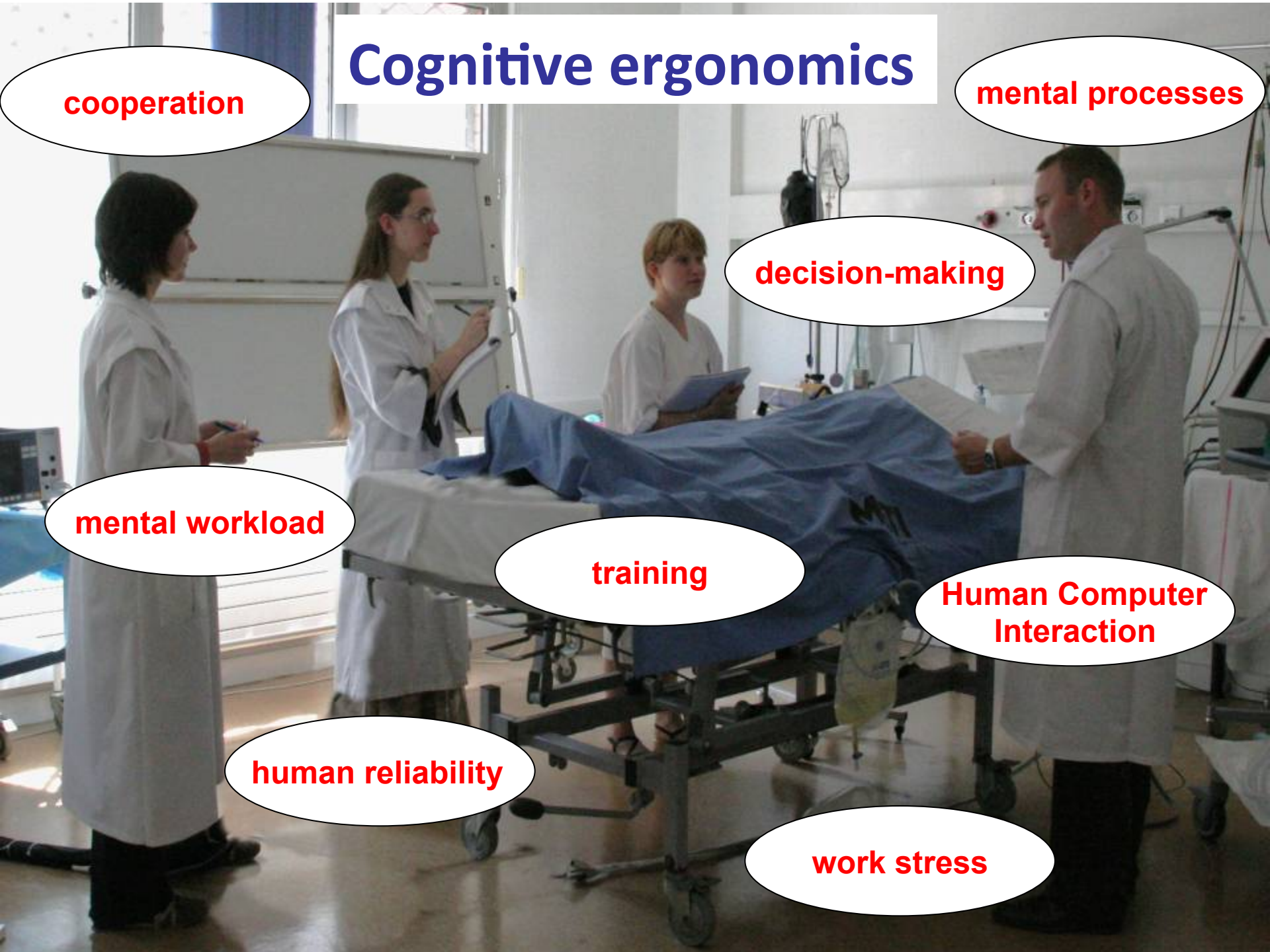
Human Factors?

- "Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system"*
- Ergonomists "apply **theory, principles, data and methods** to optimize human well-being and overall system performance"*and safety.
- →Human Centered Design of work systems*
- Several domains of specialization

. *International Ergonomics Association

Physical ergonomics




Cognitive ergonomics
cooperation
mental processes
decision-making
mental workload
training
Human Computer Interaction
human reliability
work stress

Organizational ergonomics

Accueil > Le CHRU de Lille > Organisation & Structure

Organizational structures

Pôle Anesthésie - Réanimation

Pôle Coeur, poumons, vaisseaux

Pôle Femme, mère et nouveau-né

Pôle Médico-chirurgical

Pôle Psychiatrie, médecine légale et médecine en mmilieu pénitentiaire

Processes

Pôle Rééducation, réadaptation et soins de suite

Pôle Spécialités médicales et gérontologie

Pôle Biologie, pathologie, génétique

Pôle Enfant

Policies

Pôle Imagerie, médecine nucléaire et explorations fonctionnelles

Pôle Neurosciences et appareil locomoteur

Pôle Réanimation

Optimization of Socio-technical systems

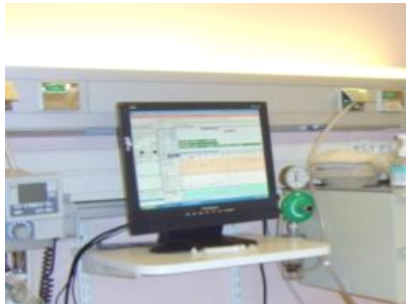
Pôle Santé publique, pharmacologie et pharmacie

Pôle Spécialités médico-chirurgicales

HF focus on the tool

Usability

Usability



- **Usability is the "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"**

  (International Standard Organization: ISO 9241)

  - **effectiveness: accuracy and completeness**
  - **efficiency: resources expended / accuracy and completeness**
  - **satisfaction: comfort and acceptability of the product**

- **A measurable dimension of the product**

Human Factors & Usability for health IT projects?

- (Re-) Design of health IT
  - Usability
  - Cognitive ergonomics
- Implementation of health IT
  - Organizational ergonomics

In sum

Human factors issues for Health IT ambitions

Particular characteristics of Healthcare Work Systems

Healthcare work

- Collect / retrieve, process, analyze medical **information** on the patient
- Make a decision (diagnosis, care plan)
- Carry out, adapt the care plan (surveillance)
- Collaborative and cooperative

Health INFORMATION Technologies: the ultimate tool for better healthcare work!

HF issues for IT solutions

- **COLLABORATIVE, COOPERATIVE**
- Health IT as support to collaborative and cooperative work?*

HF issue
1 to 1 → IT as a team partner

*Pelayo, S., Beuscart-Zéphir, M.C. (2010). Organizational considerations for the implementation of a computerized physician order entry. Stud Health Technol Infrom., 157, 112-117.
*Beuscart-Zephir MC, Pelayo S, Anceaux F, Maxwell D, Guerlinger S. (2006) Cognitive analysis of physicians and nurses cooperation in the medication ordering and administration process. Int J Med Inform 2006 Jul 5
*Beuscart-Zephir MC, Pelayo S, Anceaux F, Meaux JJ, Degroisse M, Degoulet P. (2005) Impact of CPOE on doctor-nurse cooperation for the medication ordering and administration process. Int J Med Inform 2005 Aug;74(7-8):629-41

HF issues for IT solutions

- COLLABORATIVE, COOPERATIVE
- **DISTRIBUTED TASKS & CONTROL**

- Health IT as support to collaborative and cooperative work?
- Health IT as an actor performing tasks and control?

HF issue
(Rigid) controller →IT as a clinician's partner

*Marcilly R., Leroy N., Luyckx M., Pelayo S., Riccioli, C. & Beuscart-Zéphir M.-C. (2011). Medication related Computer Decision Support System (CDSS): make it a clinicians' partner! Studies in Health Technology and Informatics. 166:84-94.

HF issues for IT solutions

- COLLABORATIVE, COOPERATIVE
- DISTRIBUTED TASKS & CONTROL
- **Not too SAFE**

- Health IT as support to collaborative and cooperative work?
- Health IT as an actor performing tasks and control?
- IT as safety champion? Technology induced errors?

HF issue
Usability!

Human Factors & Usability challenges for health IT solutions?

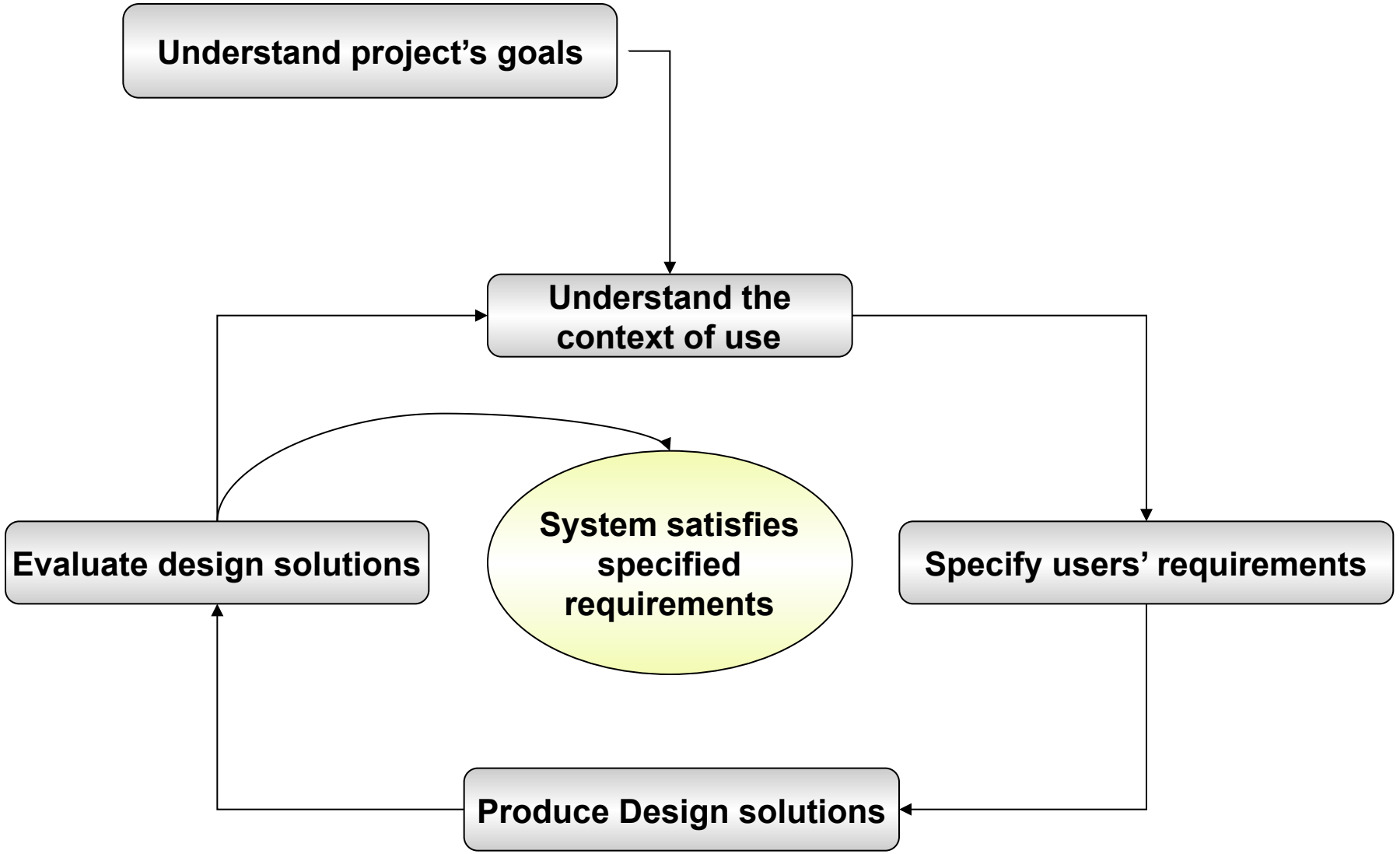
- IT as a clinicians' partner
- IT as a team player
- Usability!

In sum

Applying Human Factors and Usability

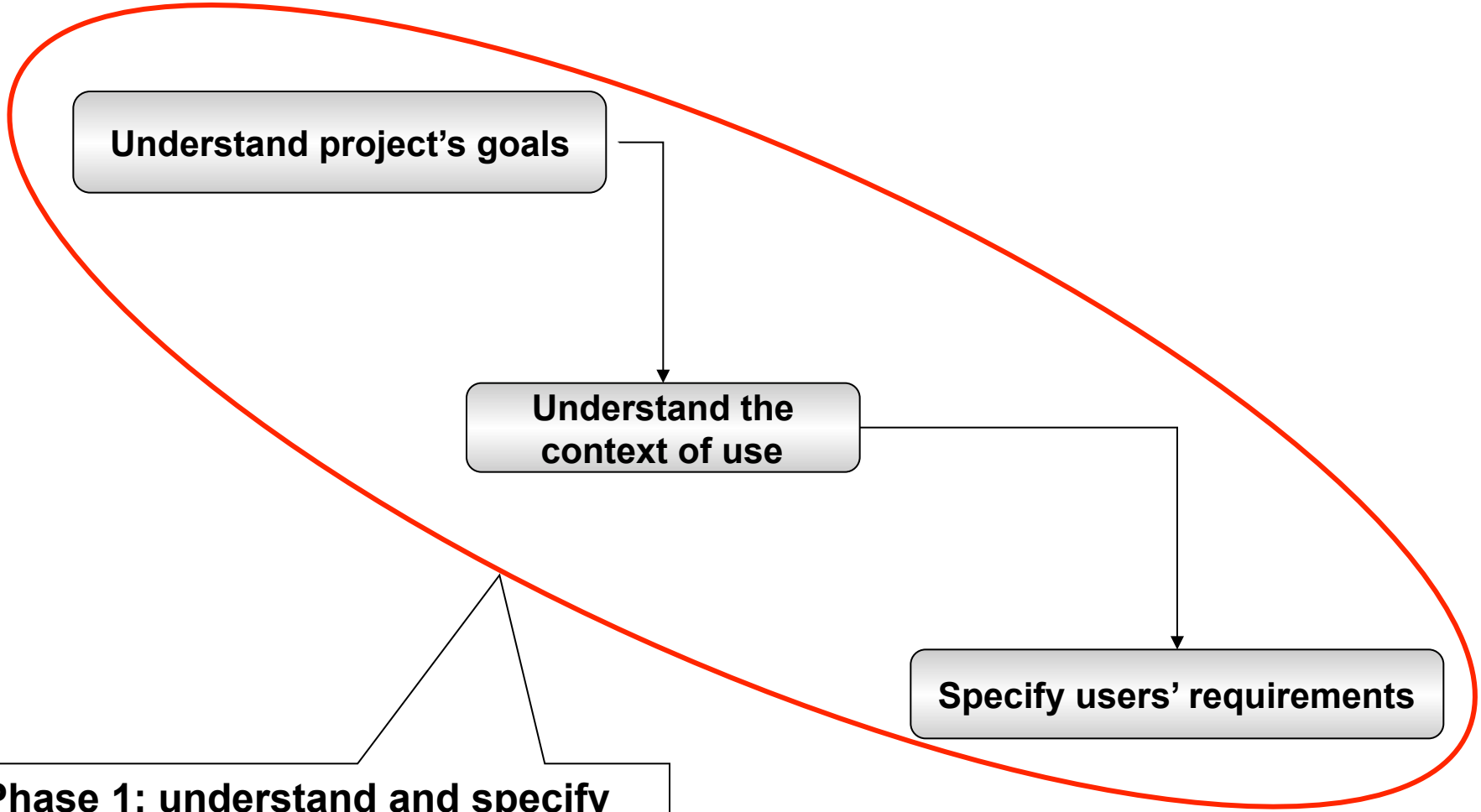
to Health IT projects

Human Centered strategy



ISO 13407

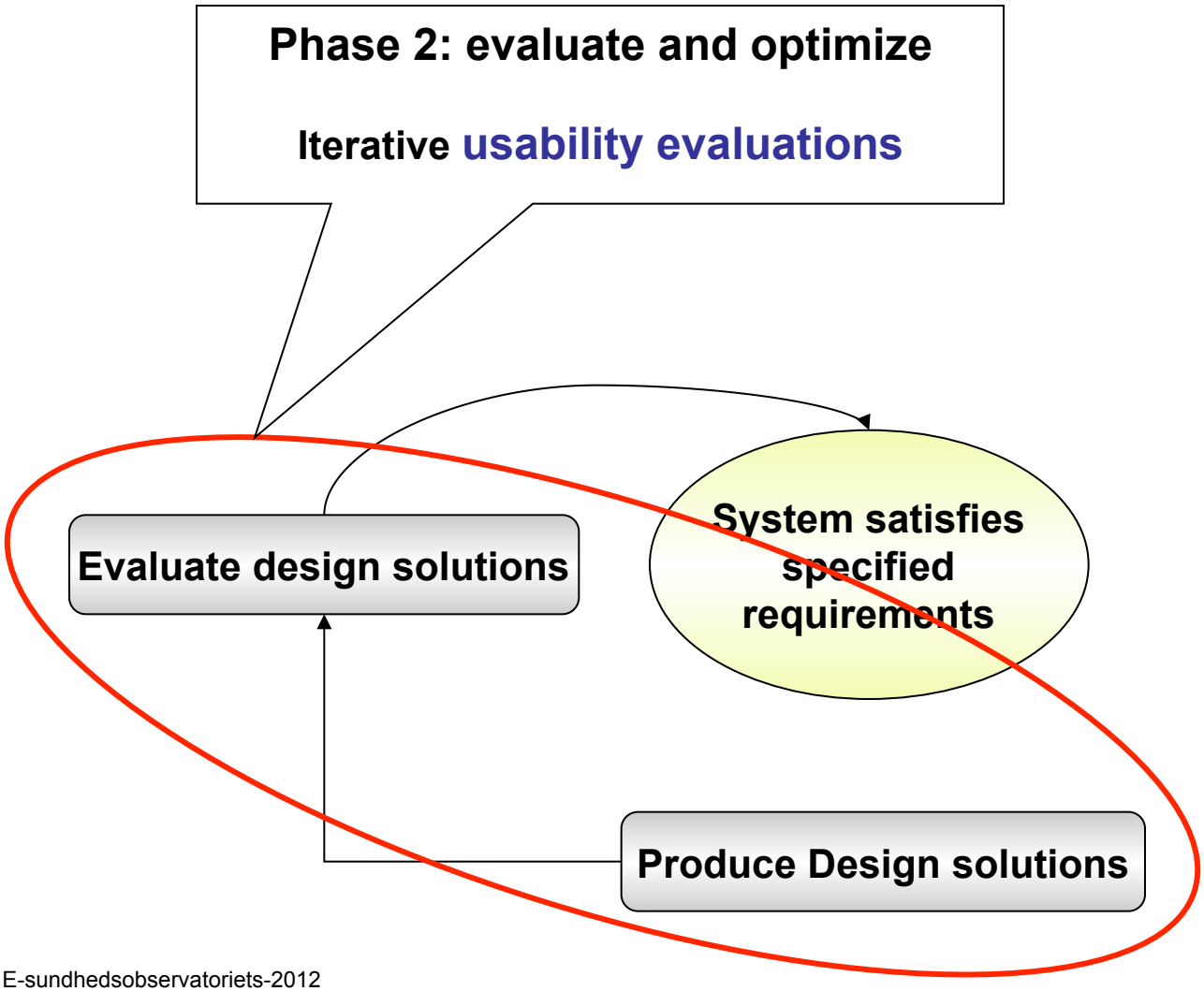
Human Centered strategy



Phase 1: understand and specify

Work system analysis
Recommendations and specifications
Usability goals

Human Centered strategy



« Understand the context of use »

Analysis of the work system

Understand , describe, model the current work system

Methods for work system analysis*

Data collection	Data analysis
Interviews: opportunistic, structured, semi structured	Coding scheme, protocol analysis, grounded theory,
Observations: naturalistic, ethnographic, structured observation (grid), time-stamped field notes, time an motion studies behaviors, verbalizations, incidents	Coding scheme cognitive pathways, communications, deviations from standard procedures Qualitative and quantitative analysis
Documents review, log files analysis, electronic documentation analysis	Coding scheme, models, patterns of usage
Cognitive Task Analysis, Hierarchical tasks Analysis	Diagrams, models
Questionnaires	Content and Statistical analysis
ETC	

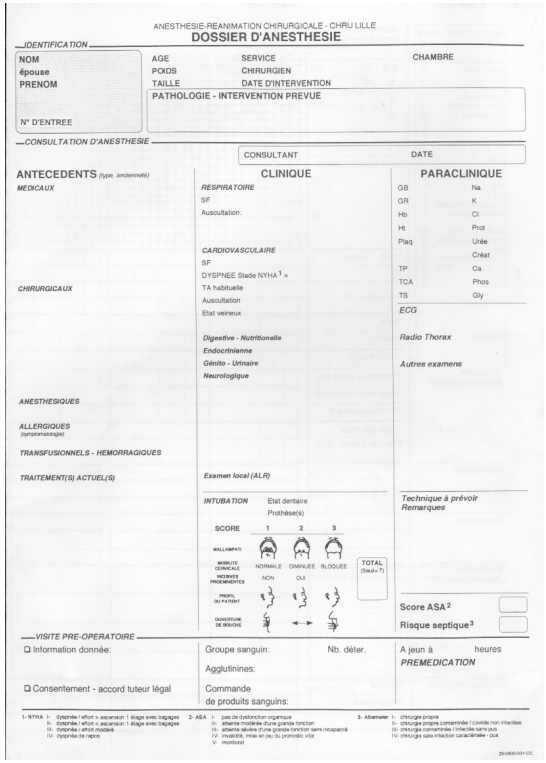
*Beuscart-Zéphir M.C., Elkin P., Pelayo S., Beuscart R., The Human Factors Engineering approach to biomedical informatics projects: state of the art, results, benefits and challenges, Methods of Information in Medicine, IMIA Yearbook of Medical Informatics special issue, 2007, pp.159-177

Example of work system analysis

IT project in anesthesia

*Beuscart-Zephir MC, Anceaux F, Crinquette V, Renard JM. (2001) Integrating users' activity modeling in the design and assessment of hospital electronic patient records: the example of anesthesia. Int J Med Inform 2001 Dec;64(2-3):157-71.
*Beuscart-Zephir MC, Anceaux F, Menu H, Guerlinger S, Watbled L, Evrard F. (2005) User-centred, multidimensional assessment method of Clinical Information Systems: a case-study in anaesthesiology. Int J Med Inform 2005 Mar;74(2-4):179-89
Marciniak B., Marcilly R., Aldegheri J. & Anceaux F. (2009). Impact of the Expertise on the Gathering of Information Contained in the Anesthetic File. /Proceedings of the 2009 Annual Meeting of the American Society of Anesthesiologists/, New Orleans, LA.

Understand the project



ANESTHESIE-REANIMATION CHIRURGICALE - CHRU LILLE

DOSSIER D'ANESTHESIE

IDENTIFICATION

NOM
épouse
PRENOM
N° D'ENTREE

AGE
POIDS
TAILLE
SERVICE
CHIRURGIEN
DATE D'INTERVENTION
CHAMBRE
PATHOLOGIE - INTERVENTION PREVUE

CONSULTATION D'ANESTHESIE

CONSULTANT
DATE

ANTECEDENTS (type, ancienneté)

MEDICAUX

CHIRURGICAUX

ANESTHESIQUES

ALLERGIQUES

TRANSFUSIONNELS - HEMORRAGIQUES

TRAITEMENT(S) ACTUEL(S)

CLINIQUE

RESPIRATOIRE
SF
Auscultation:

CARDIOVASCULAIRE
SF
DYSPNEE Stade NYHA[1] =
TA habituelle
Auscultation
Etat veineux

Digestive - Nutritionelle
Endocrinienne
Génito - Urinaire
Neurologique

Examen local (ALR)

INTUBATION
Etat dentaire
Prothèse(s)
SCORE 1 2 3
MALLAMPATI
MOBILITE CERVICALE
INCISIVES PROEMINENTES
PROFIL DU PATIENT
OUVERTURE DE BOUCHE
NORMALE DIMINUEE BLOQUEE
NON OUI
TOTAL (Seuils ?)

PARACLINIQUE

GB Na
GR K
Hb Cl
Ht Prot
Plaq Urée
Créat
TP Ca
TCA Phos
TS Gly

ECG

Radio Thorax

Autres examens

Technique à prévoir
Remarques

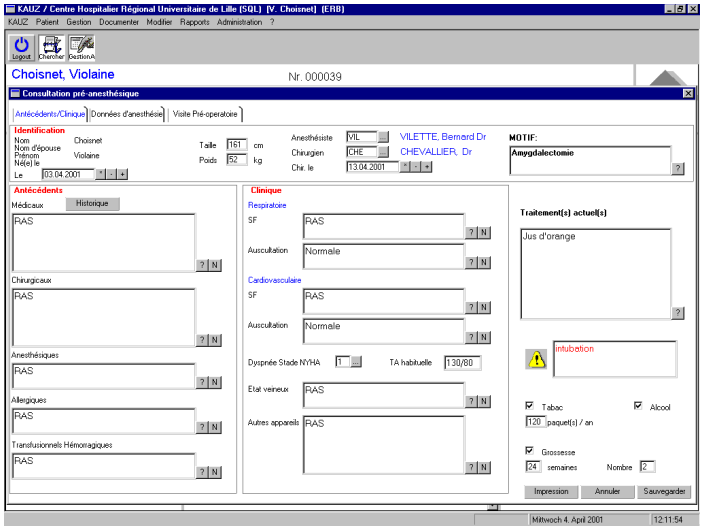
Score ASA[2]
Risque septique[3]

VISITE PRE-OPERATOIRE

Information donnée:
Consentement - accord tuteur légal
Groupe sanguin:
Agglutinines:
Commande de produits sanguins:
Nb. déter.
A jeun à heures
PREMEDICATION

1- NYHA I- Dyspnée / effort > ascension 1 étage avec bagages I- Dyspnée / effort < ascension 1 étage avec bagages II- Dyspnée / effort modéré III- Dyspnée de repos
2- ASA I- pas de dysfonction organique II- atteinte modérée d'une grande fonction III- atteinte sévère d'une grande fonction sans incapacité IV- invalidité, mise en jeu du pronostic vital V- moribond
3- Alternatives I- chirurgie propre II- chirurgie propre contaminée / cavités non infectées III- chirurgie contaminée / infectée sans pus IV- chirurgie sale infection caractérisée - pus

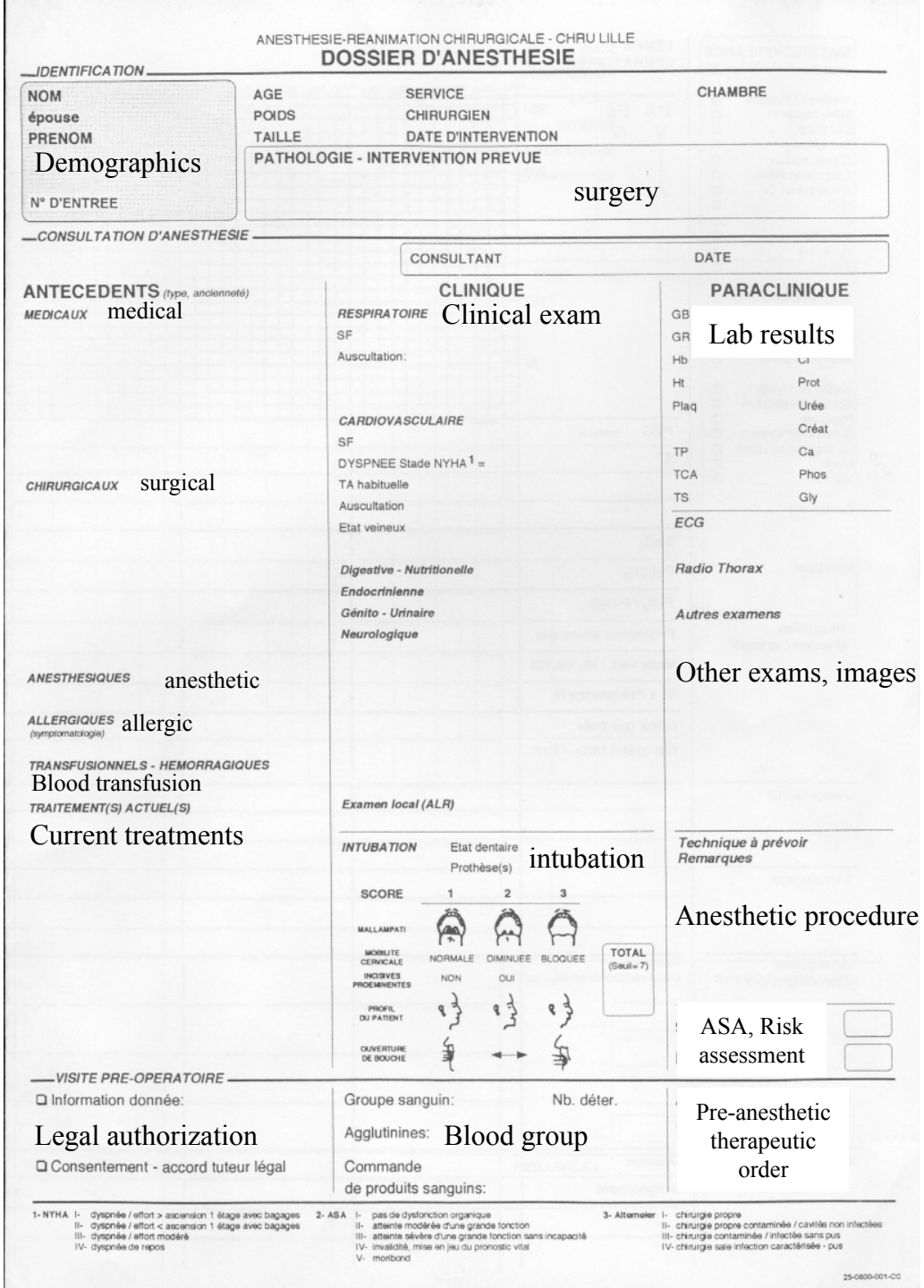
Anesthesia consultation record



Computerization of the anesthesia consultation record

Documented by the physician during the anesthesia consultation (clinical interview, clinical exam)

The anesthesia consultation paper record



ANESTHESIE-REANIMATION CHIRURGICALE - CHRU LILLE

DOSSIER D'ANESTHESIE

IDENTIFICATION

NOM
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Demographics
N° D'ENTREE

AGE
POIDS
TAILLE

SERVICE
CHIRURGIEN
DATE D'INTERVENTION

CHAMBRE

PATHOLOGIE - INTERVENTION PREVUE
surgery

CONSULTATION D'ANESTHESIE

CONSULTANT
DATE

ANTECEDENTS *(type, ancienneté)*

MEDICAUX medical

CHIRURGICAUX surgical

ANESTHESIQUES anesthetic

ALLERGIQUES *(symptomatologie)* allergic

TRANSFUSIONNELS - HEMORRAGIQUES
Blood transfusion

TRAITEMENT(S) ACTUEL(S)
Current treatments

CLINIQUE

RESPIRATOIRE Clinical exam
SF
Auscultation:

CARDIOVASCULAIRE
SF
DYSPNEE Stade NYHA [1] =
TA habituelle
Auscultation
Etat veineux

Digestive - Nutritionelle
Endocrinienne
Génito - Urinaire
Neurologique

Examen local (ALR)

INTUBATION Etat dentaire / Prothèse(s) intubation

SCORE	1	2	3
MALLAMPATI			
MOBILITE CERVICALE	NORMALE	DIMINUEE	BLOQUEE
INCISIVES PROEMINENTES	NON	OUI	
PROFIL DU PATIENT			
OUVERTURE DE BOUCHE			

TOTAL (Seuil = 7)

PARACLINIQUE

Lab results

GB	
GR	
Hb	
Ht	Prot
Plaq	Urée
	Créat
TP	Ca
TCA	Phos
TS	Gly

ECG

Radio Thorax

Autres examens

Other exams, images

Technique à prévoir
Remarques

Anesthetic procedure

ASA, Risk assessment

VISITE PRE-OPERATOIRE

❑ Information donnée:
Legal authorization
❑ Consentement - accord tuteur légal

Groupe sanguin: Nb. déter.
Agglutinines: Blood group
Commande de produits sanguins:

Pre-anesthetic therapeutic order

1- NYHA I- dyspnée / effort > ascension 1 étage avec bagages
II- dyspnée / effort < ascension 1 étage avec bagages
III- dyspnée / effort modéré
IV- dyspnée de repos

2- ASA I- pas de dysfonction organique
II- atteinte modérée d'une grande fonction
III- atteinte sévère d'une grande fonction sans incapacité
IV- invalidité, mise en jeu du pronostic vital
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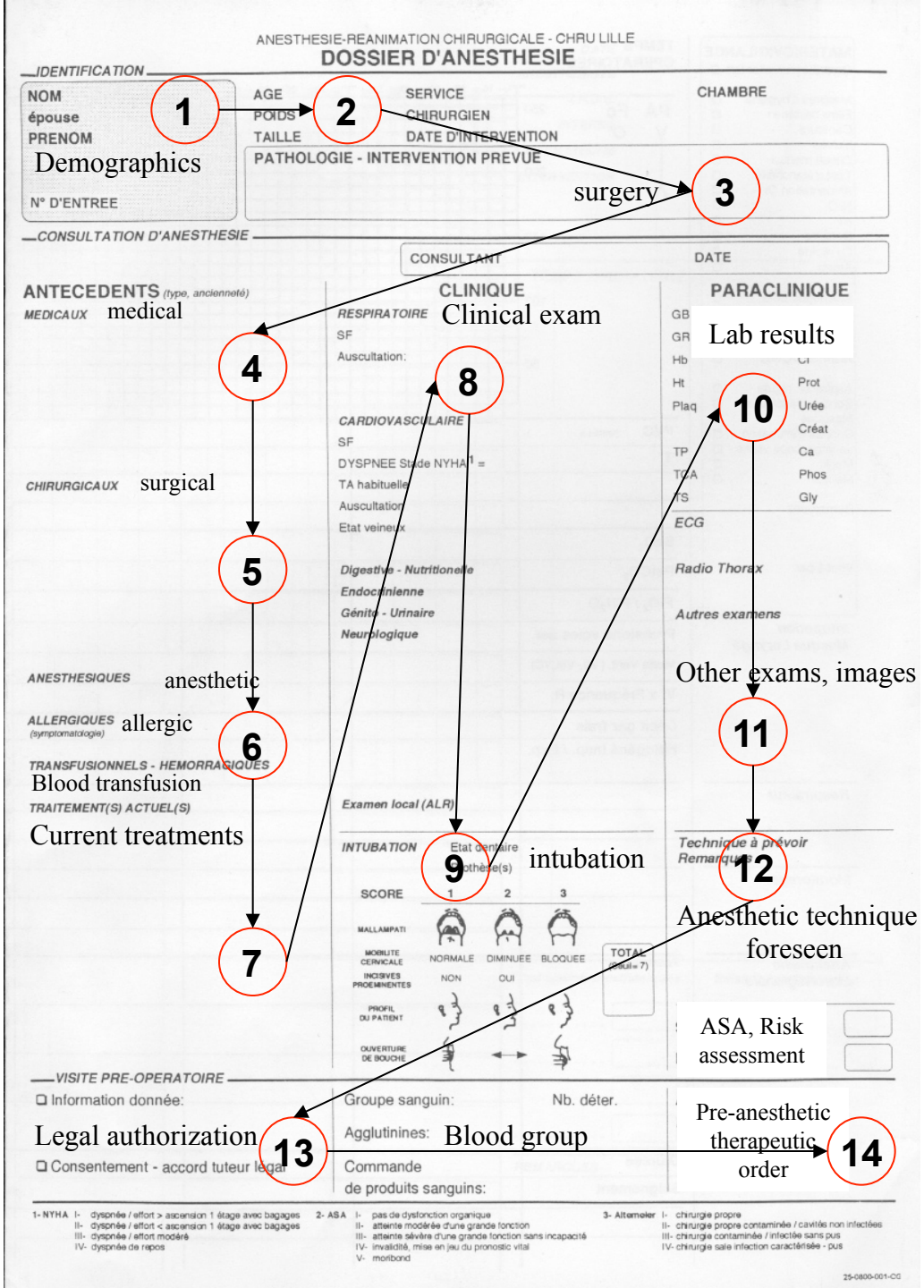
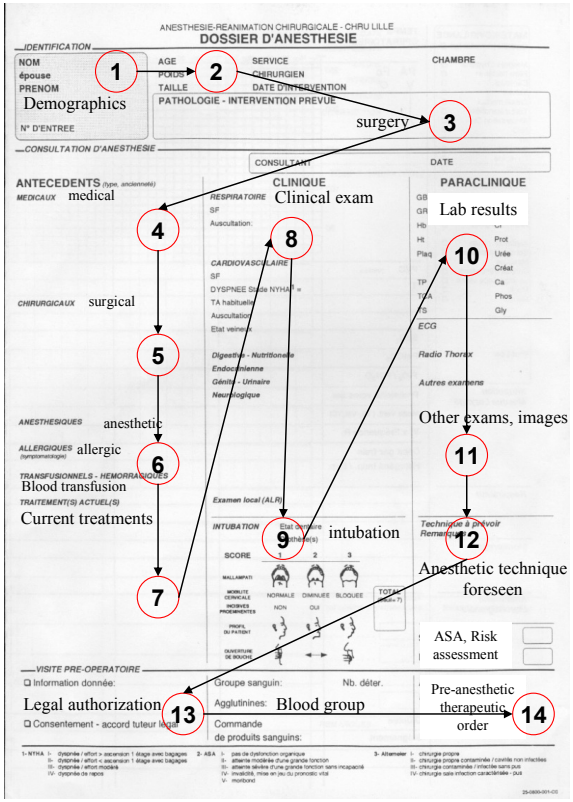
3- Altemeier I- chirurgie propre
II- chirurgie propre contaminée / cavités non infectées
III- chirurgie contaminée / infectée sans pus
IV- chirurgie sale infection caractérisée - pus

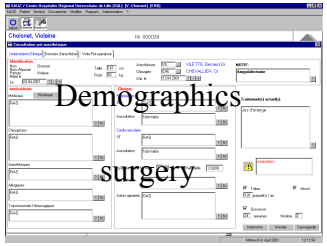
25-0800-001-CG

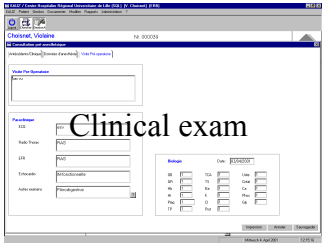
Users' requirements

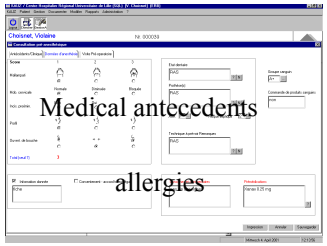
Users' explanation of their work

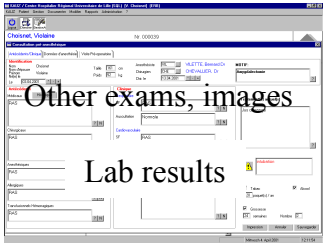


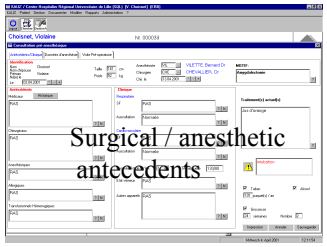


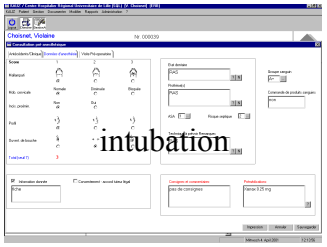


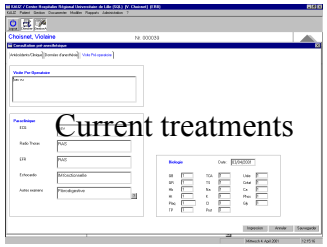


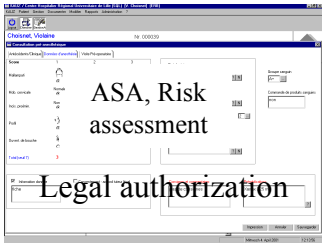


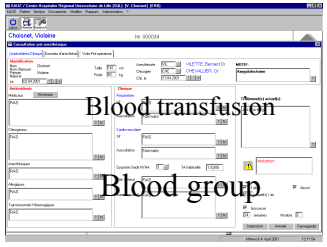


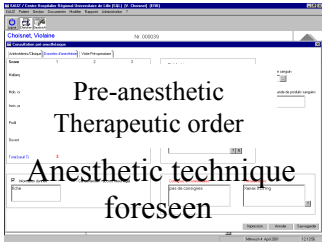






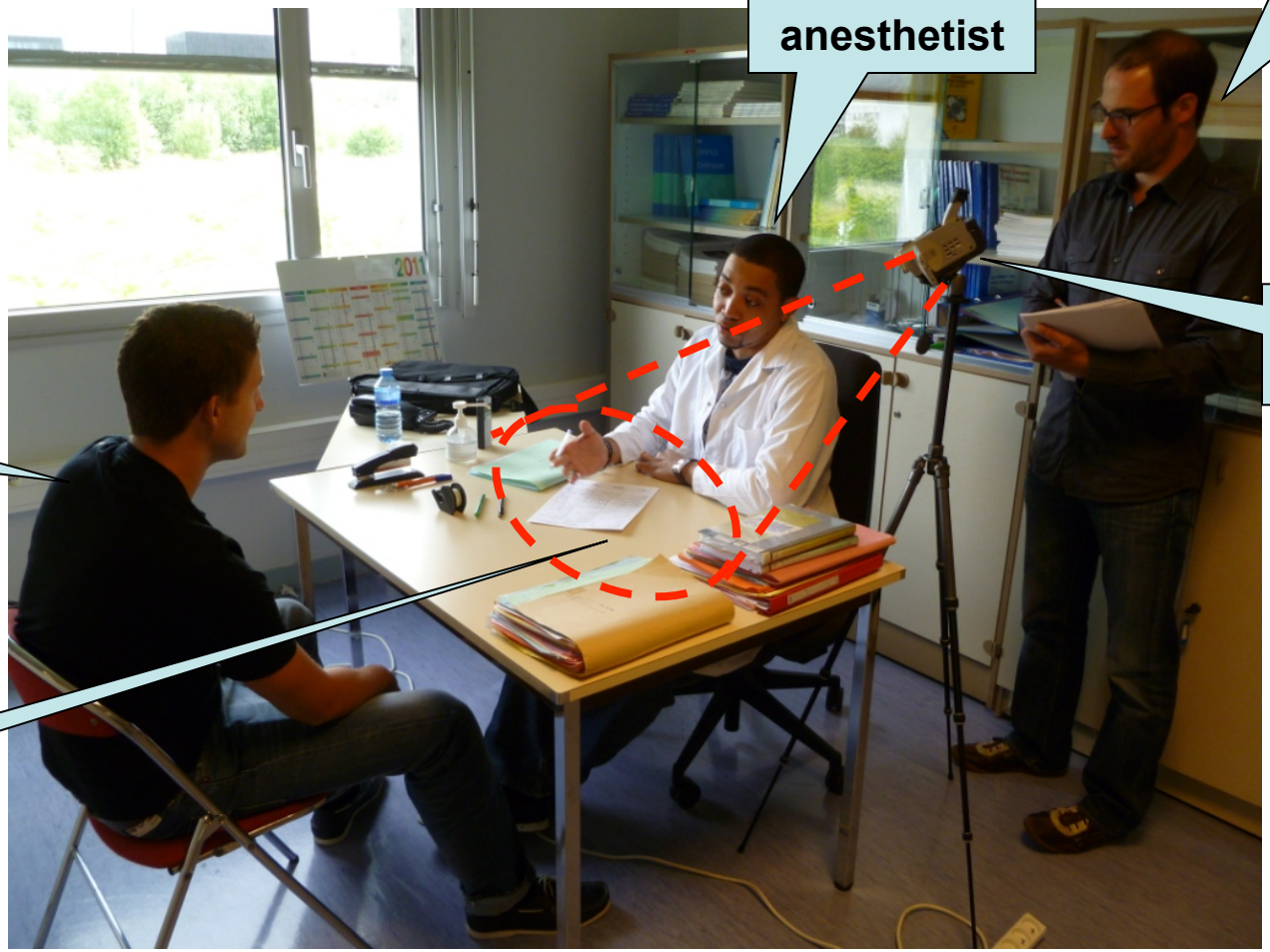






Users' requirements → Product

Observation setting

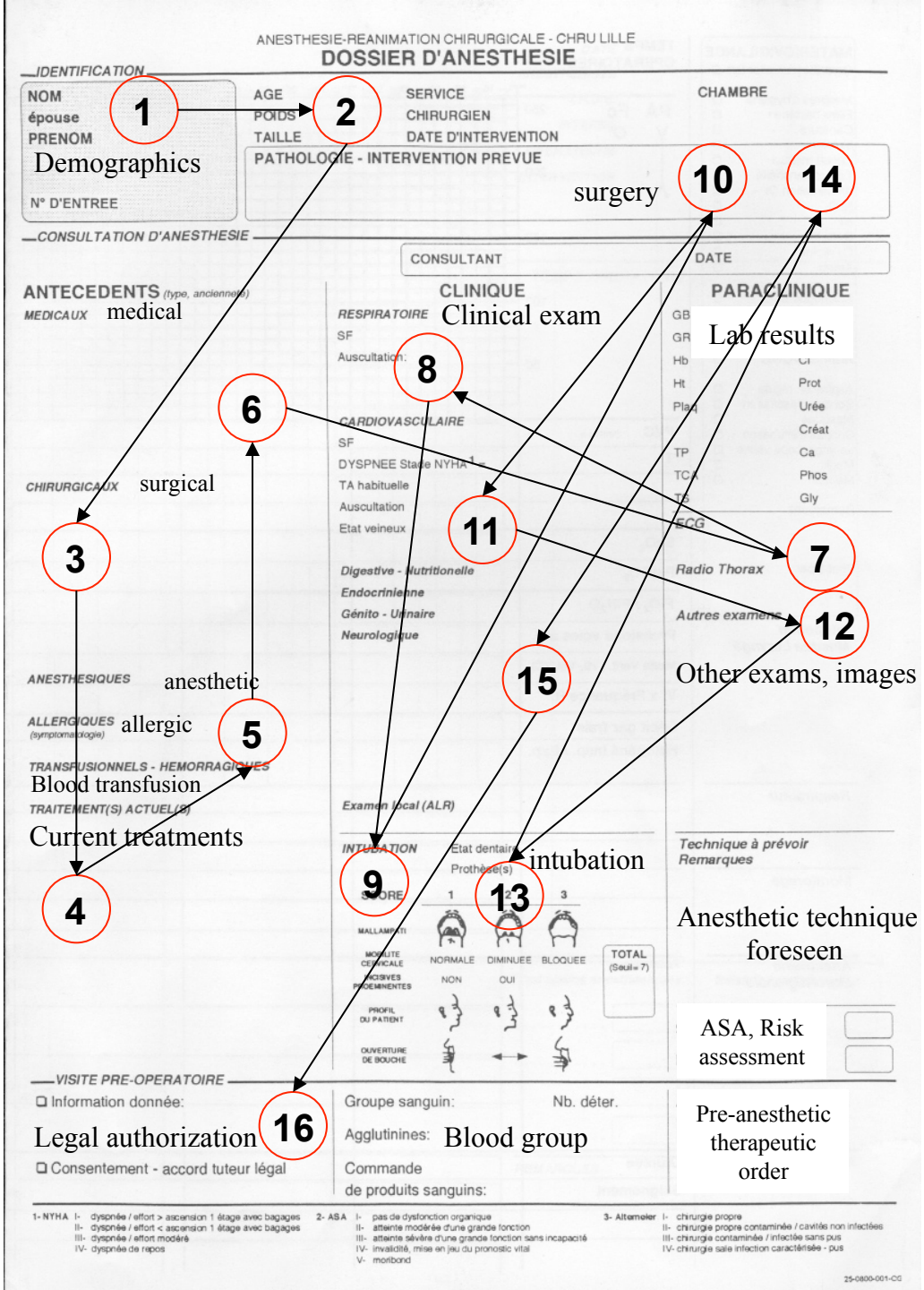


60 consultations
- 4 departments
- 11 anesthesiologists

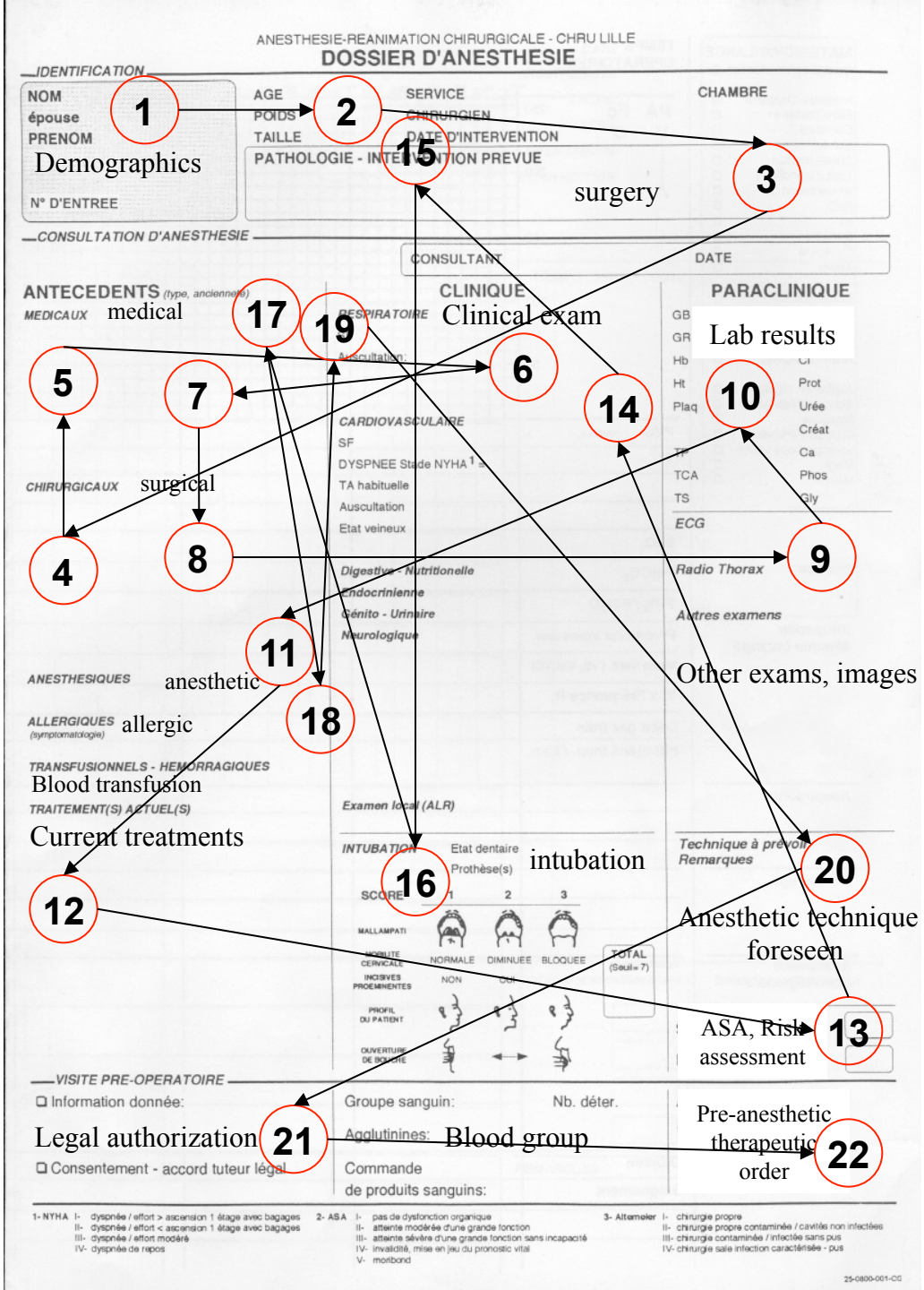
Results

No systematic order for documentation

Anesthetist 1, patient 5



Impact of clinical case complexity



Anesthetist 3, patient 11

Interpretation

- Main task = cognitive task
  - Exploring the patient's medical case to identify potential risks
    - EXPERTISE driven → identification of patterns
  - Make a preliminary decision on anesthesia procedure
  - Relies heavily on the clinical notes taken during the clinical interview
  - Communicate important information to the colleague in charge of the anesthesia

- Main task is NOT documentation of a form
  - Ancillary task

Interpretation & recommendations

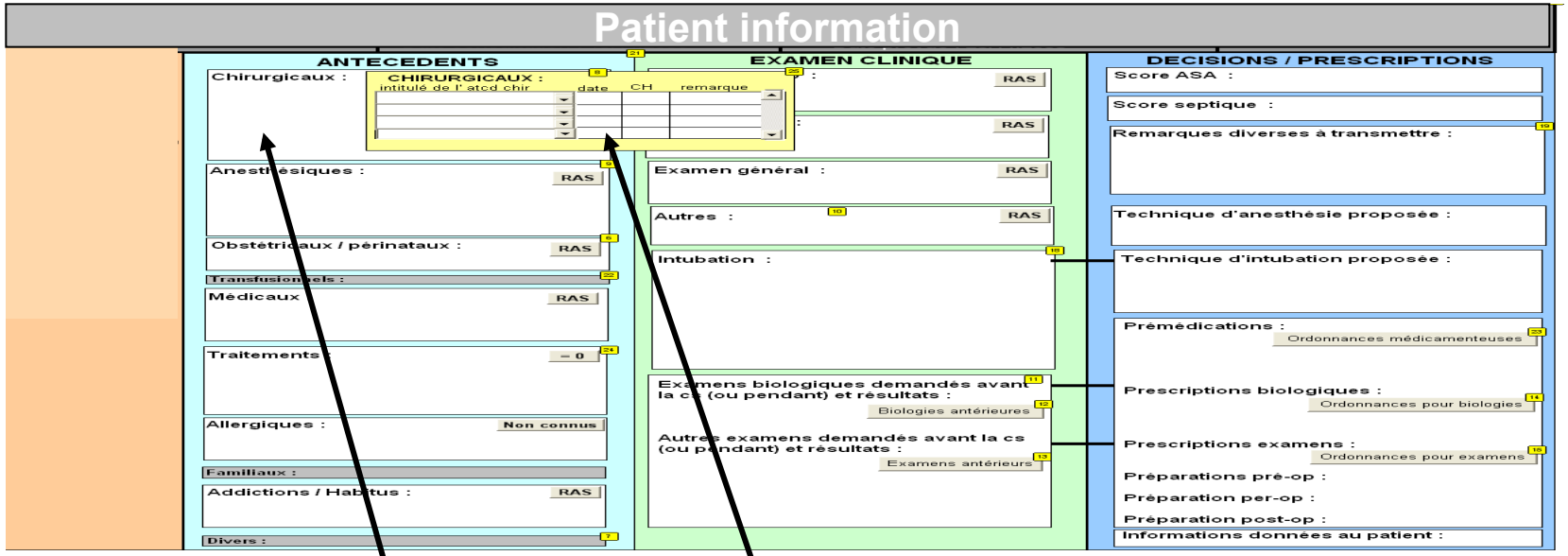
Main task = **cognitive task**

- Expertise – driven clinical interview
  - Explore, identify potential risks
  - Decision on anesthesia
- Main task is NOT documentation of a form
  - Ancillary task

Make the application a **clinician' partner**!

- Support expertise-driven clinical interview
  - Overview of information progressively documented
- Dissociate data entry and visualization
  - Support simultaneous documentation
  - Support rapid entry of (structured) data

One screen page dynamically updated



Select a field

Corresponding data entry window opens

Easy functions to highlight important information

Benefit of HF in this phase

- **Makes visible important cognitive activities**
  - Actual users' needs
- **Provides innovative ideas for design**
- **Allows preventing major (& common) usability problems in the design**

In sum

« Evaluate design solutions »

Iterative usability evaluations of design solutions

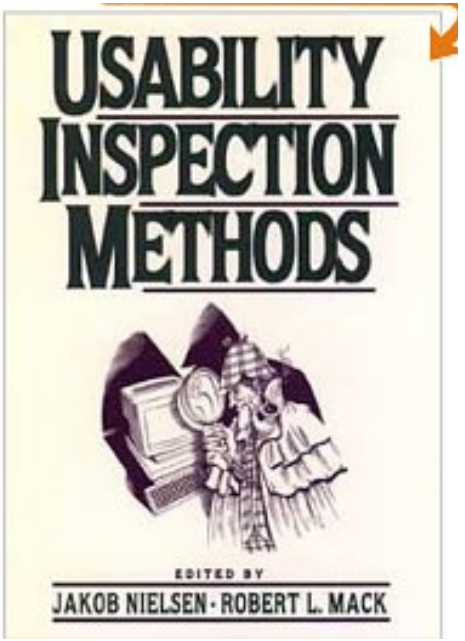
Methods for usability evaluations*

1/ Usability inspections

*Beuscart-Zéphir M.C., Elkin P., Pelayo S., Beuscart R., The Human Factors Engineering approach to biomedical informatics projects: state of the art, results, benefits and challenges, Methods of Information in Medicine, IMIA Yearbook of Medical Informatics special issue, 2007, pp.159-177

Usability inspections

Heuristic evaluation



- Goal: identify usability flaws in the HCI
  → recommendations
- In lab evaluation (no end users)
- 3-5 trained evaluators
- Systematic / scenario-based walkthrough
- Based on heuristics / ergonomic criteria
- Severity rating of problems (violations)
  - Frequency, impact, persistence

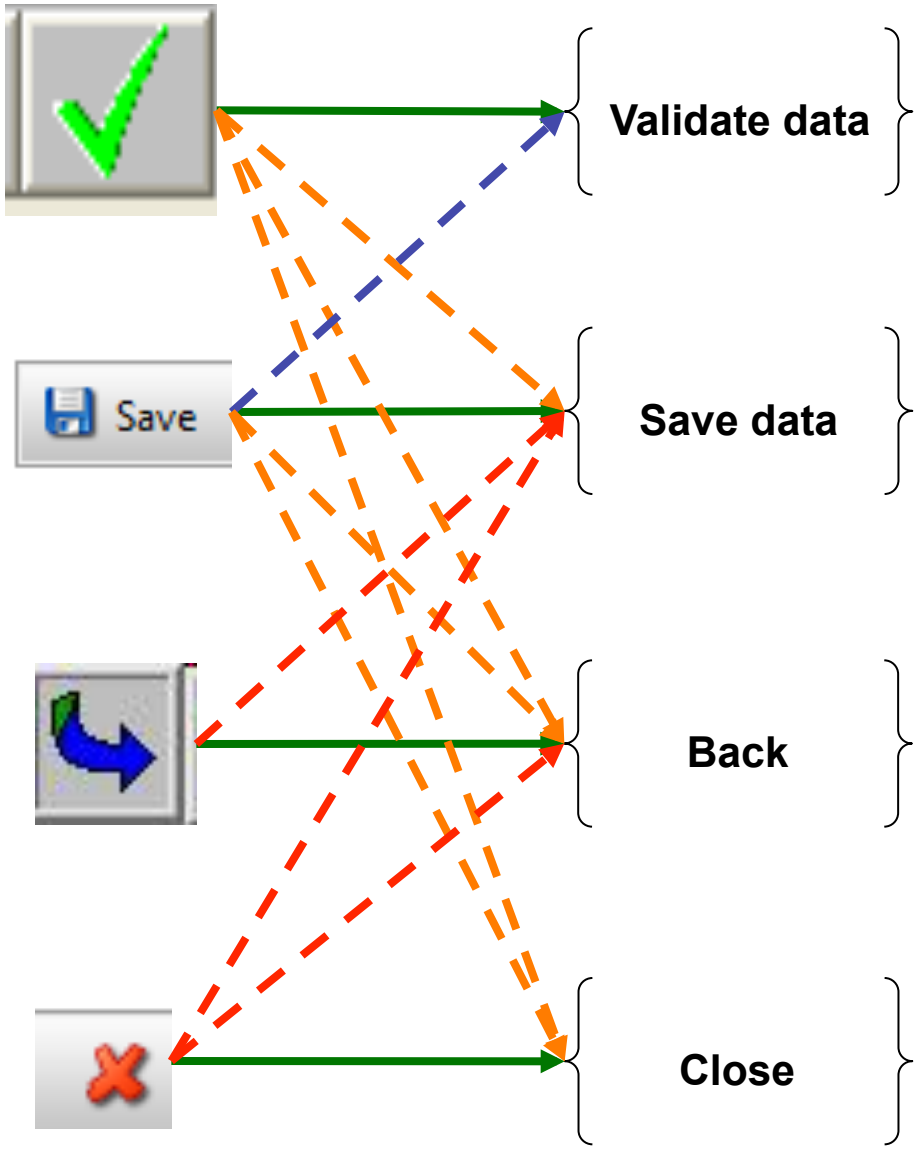
Illustration of frequent violations of ergonomics criteria

Validate data

Save data

Back

Close



Consistency

Protection against error

Heuristic evaluation & safety

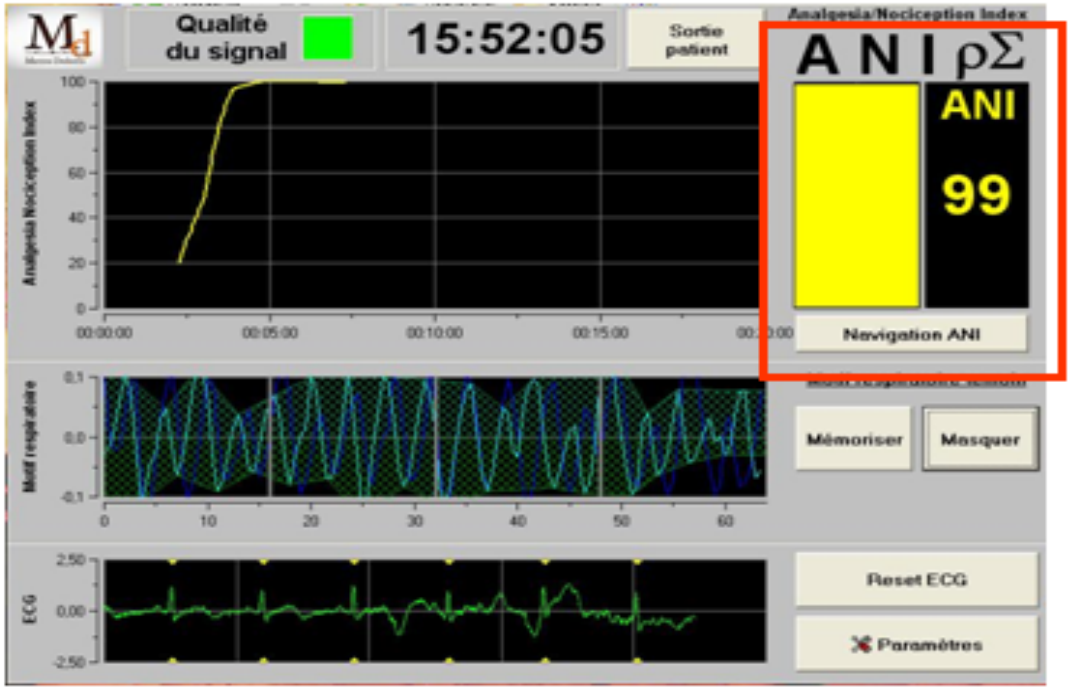
- Example of risk of “use error” identified through usability inspection
- Illustration

Heuristic evaluation & safety

- An innovative analgesia monitor named PhysioDoloris® equipped with a computer like interface

- A new pain indicator (A.N.I. Analgesia Nociception Index) for unconscious patients

Heuristic evaluation

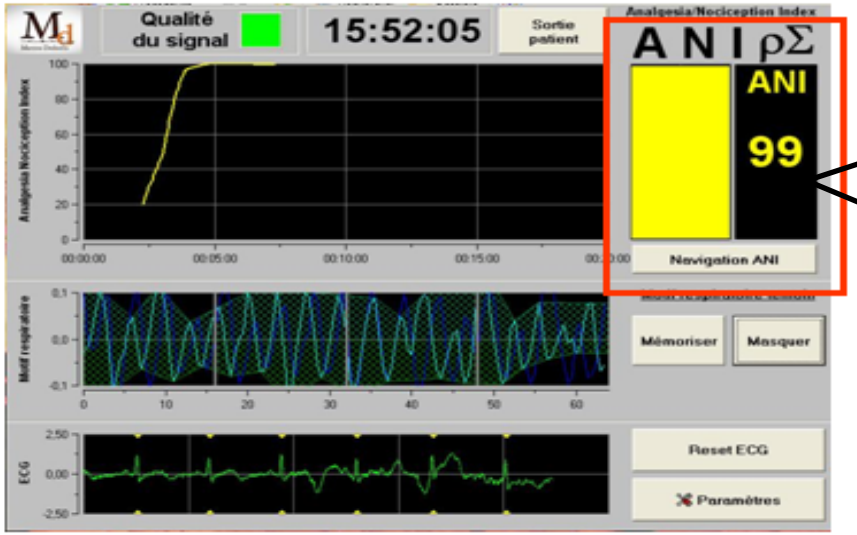


Metrodoloris – Heuristic analysis

Heuristic evaluation

Problem 15

Criterion	Problem description	Consequences	Recommandations	Severity level
Error management / Error protection	The HCI does not provide guidance to support a proper interpretation of the A.N.I	Risk of misinterpretation of the A.N.I. ; risk of injecting an inappropriate analgesic dose	Provide visual clues to support the good interpretation of the indicator	✸ ✸ ✸



100 = no pain
0 = pain

Risk of reverse interpretation

EVALAB

Metrodoloris – Heuristic analysis

April 2010

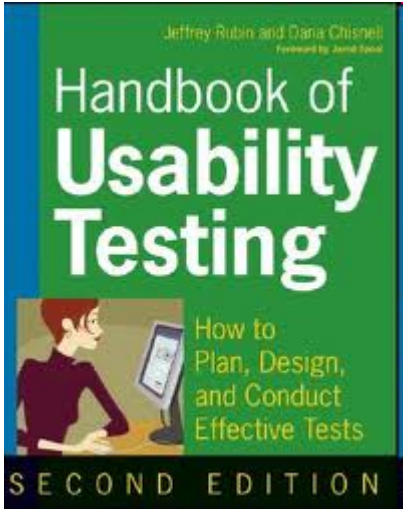
Iterative usability evaluations of design solutions

Methods for usability evaluations*

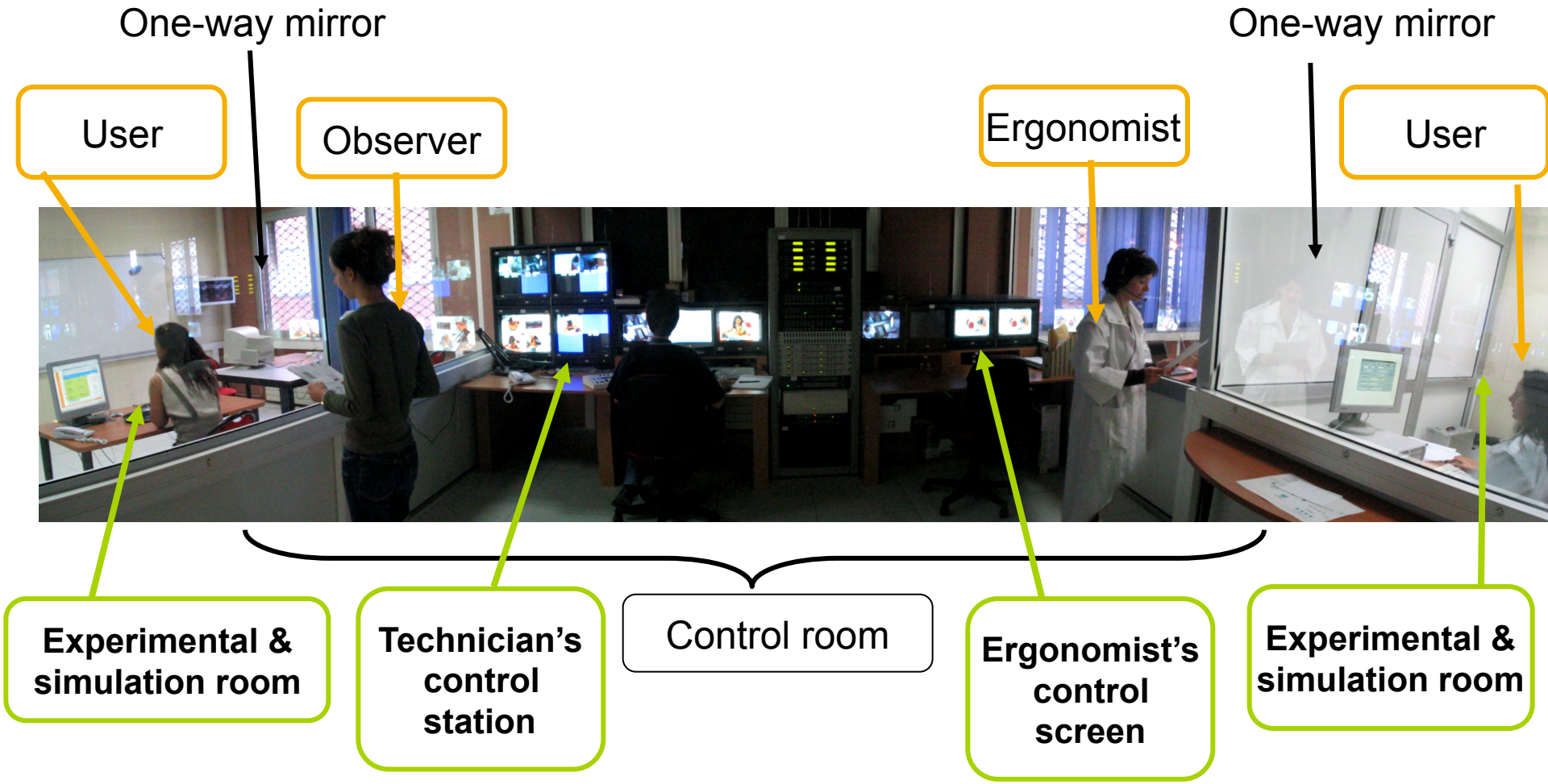
2/ Usability testing

*Beuscart-Zéphir M.C., Elkin P., Pelayo S., Beuscart R., The Human Factors Engineering approach to biomedical informatics projects: state of the art, results, benefits and challenges, Methods of Information in Medicine, IMIA Yearbook of Medical Informatics special issue, 2007, pp.159-177

Usability testing



- Evaluation objectives (usability goals)
- Sample (end users) selection
- Scenario
- Running the test: video recording, think aloud → protocols
- Adapted procedures: on site, handheld applications, portable labs, elderly, under time pressure etc.



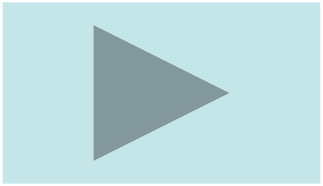
The Usability lab

The portable usability lab

Illustration of usability test

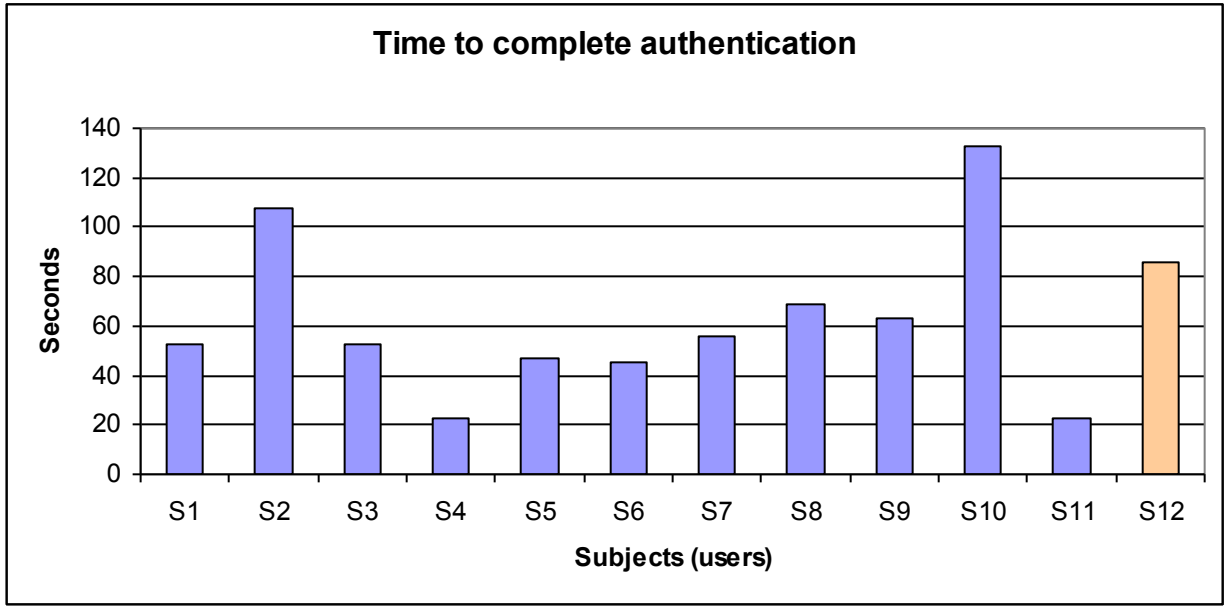
- The project: a health IT application for patients
- User-centered approach mandatory: requested in the call for proposal
  - Two iterations of usability evaluations (minimum)
- Predefined usability goals
  - 70% success for essential functions
  - on second iteration of usability evaluation (final prototype)
- Scenario

Video excerpt



- first usability evaluation iteration, early prototype
- authentication functions, elderly woman aged 82

Results



- Recommendations → reengineering
- Second iteration: all usability goals met

Iterative usability evaluations of design solutions

Methods for usability evaluations

3/ Usability questionnaires

Usability questionnaires

- SUS: System usability Scale
  - Quick and dirty (but valid!)
  - In combination with usability tests / inspections

- QUIS: Questionnaire for User Interaction Satisfaction
- SUMI: Software Usability Measurement Inventory
- WAMMI: Website Analysis and Measurement Inventory
- CUSQ: Computer Usability Satisfaction Questionnaires

- Focus on user satisfaction (confidence, intention to use)
  - General assessments
  - **Inadequate to identify usability flaws**

Benefits of HF in this phase

- Identification of usability flaws
- Recommendations to support re-engineering
  - COOPERATIVE activities
- Optimization of usability
  - Better acceptance
- Prevention of Use errors

In sum

Current HF Challenges for Health IT

Usability and safety

IT, safety, and usability

« IT improves quality and safety »

→ **USAGE** of IT improves quality and safety

Adoption

USE ERRORS
Technology Induced Errors*
Adverse Technology Events

Enhance

Prevent

HF & Usability

*Kushniruk AW, Borycki EM, Anderson JG, Anderson MM (2009) Preventing technology-induced errors in healthcare: the role of simulation. Stud Health Technol Inform.; 143:273-6.

New EU regulation*

COUNCIL DIRECTIVE 93/42/EEC
concerning medical devices
Modified by Directive 2007/47/EC
Applicable March 2010

'medical device' means **any instrument**, apparatus, appliance, **software**, material or other article, **whether used alone or in combination**, **including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes** and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

New EU regulation: usability & safety, IT & MD

- Some categories of IT applications considered a Medical device → subject to CE marking
- Usability file mandatory for CE marking
  - EN 62366:2007 standard
  - Based on Human Centered Design (ISO 9241-210)
  - Objective: identification and prevention of use errors

- Challenges:
  - Demands for international studies (multicentric usability evaluations in several countries)
- Applicability to Health IT →Certification & Health IT

Conclusion

How can YOU enhance Human Factors for health IT projects

- Integrate HF expertise in projects, adopt the user-centered approach
  - Join the HFE-HI network
- Impose the user-centered design approach in calls for proposal
- Incorporate usability evaluations in your procurement process
- Ask companies HOW they have achieved proper usability

Thank you for your attention

Questions?