PANEL

The Medical Device Directive and Software: The Implications
Agenda

- The MDD – Jan Talmon
- Usability issues – Sylvia Pelayo
- Evaluation issues – Elske Ammenwerth
- The Issues of Post-Market Surveillance – Michael Rigby
- Discussion
THE MEDICAL DEVICE DIRECTIVE
The Medical Device Directive

- Regulates medical devices
- Aims at maintenance and improvement of the level of protection provided by the devices of patients, users and third parties and attainment of the level of performance attributed to the devices by the manufacturers.
What is a medical device

- Any instrument, apparatus, appliance, **software**, material or other article, whether used alone or in combination, including 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
Relevant concepts

- Essential requirements (Annex I)
- The classification of devices into several categories. (Annex IX)
- Conformity assessment procedures (several annexes dependent on the classification of the device)
  - Exemption for custom-made devices and those intended for clinical investigations, but...
- Clinical evaluation
Essential requirements I

- Devices should be designed and manufactured such that they do not compromise the clinical condition or safety of patients, users or other persons.
  - Risk analysis to demonstrate that risks are outweighed by the benefits
- Reducing the risk of use error due to ergonomic features
- Education and training of intended users
Essential requirements I

- Devices must be designed according to state of the art safety principles
  - Eliminate or reduce risk as far as possible
  - Take adequate protection measures where risks remains
  - Inform users on the residual risks
- Conformity with the essential requirements must include a clinical evaluation (Annex X)
Essential requirements II

- For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.
Classification of software

- All non-invasive devices are in Class I, unless:
  - It seems that most software systems are in class I, except the software that may be part of a device that is in class II or III.

- Stand alone software is considered to be an active medical device (see clause 1.4 of Annex IX)
  - There are special rules for the classification of these active devices, but none seems to apply to software.
  - Hence stand alone software is class I
Requirements for CE marking

- Annex VII specifies the conformity assessment for class I devices
  - It includes the provision of technical documentation to national authorities

- Extensive technical documentation including
  - Pre-clinical evaluation
  - Clinical evaluation in accordance with Annex X

- Systematic procedure to review experience gained from devices in the post-production phase (post-market surveillance).
Clinical evaluation

- Conformity assessment must be based on clinical data.
- Evaluation of this data – where appropriate taking account of any relevant harmonized standards, must follow a defined and methodological sound procedure.
  - Critical evaluation of the scientific literature related to safety, performance, design characteristics and intended purpose of the device
  - Critical evaluation of all clinical investigations
  - Critical evaluation of the combined clinical data provided in the two studies mentioned above
What is clinical data

- **Safety or performance information** that is generated from the **use of a device**. Clinical data are sourced from:
  - Clinical investigations of the device concerned
  - Clinical investigations or other studies reported in the scientific literature of a **similar device** for which equivalence to the device in question can be demonstrated or
  - Published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.
Clinical investigations
Annex X part 2

- **Objectives**
  - To verify the performance of the device is in conformance with what is **claimed by the manufacturer**
  - To determine any **undesirable side-effects**

- **Ethical considerations**
  - Should be carried out in accordance with the Helsinki Declaration
Clinical investigations

• Methods
  ◦ There must be a **scientifically and technically sound** investigation plan
  ◦ The plan must be **appropriate**
  ◦ Be carried out under **normal operating conditions**
  ◦ All appropriate features, including safety and performances, and its **effect on patients** must be examined
  ◦ Must be performed under the responsibility of a **medical practitioner** or another qualified person
  ◦ The written report should contain a **critical evaluation** of all the data collected.
European databank

- As of 2012 a European databank should be established that contains regulatory data in relation to the MDD
- Data relating to clinical investigations are part of those regulatory data.
USABILITY ISSUES

Sylvia Pelayo
Evalab - Lille
Usability as mentionned in the MDD

- Essential requirements

“… reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety),

consider the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users”

→ Manufacturer should mitigate the risks of errors due to usability problems

To be compliant: IEC 62366: 2007 - Medical devices – Application of usability engineering to medical devices
Usability?

  - «The effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environment»

- Dimension of a product:
  - Measurable

- IEC 62366: 2007 - Medical devices – Application of usability engineering to medical devices
  - Limited to user interface and its safety
  - User satisfaction or efficiency are not considered
Usability engineering process?

Identify need for human centered design

Specify context of use

Evaluate designs

System satisfies specified requirements

Specify requirements

Produce design solutions

User centered design
ISO EN 13407: 1999

Specify requirements
Usability file?

“The manufacturer must analyze, specify, design, verify and validate usability, as related to safety of the device”
Usability engineering / risk management

Risk Management

- Risk analysis
  - Intended use / intended purpose identification
  - Hazard identification
  - Risk estimation

- Risk evaluation
  - Risk acceptability decision

- Risk control
  - Option analysis
  - Implementation
  - Residual risk evaluation
  - Overall risk acceptance
  - Communicate residual risk

Post- production information
- Post- production experience
- Review of risk management experience

UE Activities

- Process analysis
  - Specify intended use / intended purpose
  - Identify context of use
  - Identify primary operating functions (POF)

- Preliminary risk analysis

- Specify usability requirements

- Usability verification

- Usability validation

- Final risk analysis, evaluation of residual risks

- Evaluation of possible usability problems in use

R&D Process

- Product idea

- Use requirements

- Conceptual design

- Design specification

- Preliminary design (e.g. drawings)

- Detailed design

- Production / Market launch

- Post production information

Gruchmann & Borgert, 2007
Major challenges

- For manufacturers:
  - impression they have already implemented usability
Accompany a company in the evaluation of their device and the documentation of their usability file

- **First step**: collect the necessary information to prepare the usability validation plan
  - It's all good

- **Second step**: perform the
  - Usability verification
  - Usability validation
Really difficult to obtain accurate and consistent information to prepare the validation plan.

Risks of wrong use errors were obviously missing.

100 = no pain
0 = pain

Risk of reverse interpretation
Major challenges

- For manufacturers:
  - impression they have implemented usability
Major challenges

• For manufacturers:
  ◦ Impression they have implemented usability
  ◦ Difficulties in applying the standard
    • Suffering from the frequent meta usability problems of the standards
      • Specific terminology,
      • To general description,
      • Not enough illustration,
      • Reference to many other standards,
      • Etc.
    • Relying on a substantial conceptual and methodological framework requiring human factors expertise to be mastered
Major challenges

- For notified bodies and healthcare authorities:
  - Not always familiar with usability ➔ need for training courses
  - Difficulties to define the criteria and methods for the verification of compliance of the usability file with the standard
Software as a MD
Software as a MD

Specified users,
Specified goals,
Particular environment
Software as a MD

Specified users, Specified goals, Particular environment

No specified users
No particular environment
Different supports
Constantly evolving
Different parameterizations
Variety of work situations
Software as a MD

- Relation to the question of certification of Health IT?
  - Integration of usability in certification
    - Europe?
    - France?

- Demands for international (multicentric) usability evaluations / validations
  - Standardization of methods

- Usability based guidelines for good design of specific health IT applications?
  - CUI initiative
The Annex X
On Clinical Evaluation:
Content and Implications

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Mie 2011
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Panel on Medical Device Directive
References


Overview

1. What does the Directive says about clinical evaluation?

2. Example: What does this mean for CPOE evaluation?

3. Summary: Implications for health informatics
MDD Annex I: Demonstration of conformity

“Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.” (for all devices)

Does it perform as intended?

Is it safe for the patient (and the user)?
“... Clinical evaluation ... must follow a defined and methodologically sound procedure ...”

- Critically evaluation of the scientific literature
- Clinical investigation
MDD Annex X: Scientific literature

“... critical evaluation of the relevant scientific literature ... where:

- there is demonstration of equivalence of the device to the device to which the data relates, and
- the data adequately demonstrate compliance with the relevant essential requirements.”
Process of clinical evaluation

1. Identify Essential Requirements to be met

2. Identify available published clinical data relevant to the device or equivalent devices

3. Analyse if available clinical data is suitable to establish safety and performance of the device

4. Perform clinical investigation to generate clinical data to address outstanding issues

5. Bring all data together to reach conclusion about safety and performance of the device

Guidelines on medical devices, 2009
Example: CPOE as medical device

- Assumption: A CPOE system (computerized physician order entry) that offers decision-support during drug ordering and drug management is a medical device.

- CPOE system must meet essential requirements (performance and safety, see Annex 1).
Some questions

1. What are essential requirements for CPOE?
2. What does this mean for evaluation criteria?
3. What does this mean for the evaluation study?
4. How to deal with local adaptations?
1. What are „essential requirements“?

- “Does not compromise patient safety”:  
  - Works correctly, does not produce errors
- “Must perform as intended”:  
  - Offers expected functionality
  - As stated in documentation or promotions
- “Benefits and risks must be weighed”:  
  - Benefit: Improved medication safety, …
  - Risks: Adverse side effects
2. What does this mean for CPOE evaluation criteria?

- Functionality as promised:
  - Supports drug management
  - Offers certain type of decision support
- Correctness (does not produce errors):
  - Algorithms, data handling
  - Verification of rule base, alerts
- Usability and ergonomic features
- Unexpected side effects and their impact
- …
3. What does this mean for the CPOE evaluation study?

“Clinical investigation must follow a defined and methodologically sound procedure”:

- Written study protocol
- Adequate selection of qualitative and/or quantitative methods and study design
3. What does this mean for the CPOE evaluation study?

- Perform investigations “in situations similar to normal conditions of use”
- “Pre-clinical evaluation” usually not sufficient
- Include “adequate number of observations”
- Record & communicate serious adverse events
- Performed by “authorized qualified person”
- Written evaluation report
4. How do deal with local adaptations?

- CPOE vendor wants to confirm conformity of his CPOE system:
- MDD allows literature review instead of clinical investigation, but only where:
  - “there is demonstration of equivalence of the device to the device to which the data relates”
- There are several studies on CPOE. But:
4. How do deal with local adaptations?

- For CPOE of different vendors: CPOE systems are not “equivalent”:
  - Maybe comparable software functionality
  - But different rule bases
  - Different user interfaces
  - ….

- (See also different outcome of evaluation studies of different CPOE systems)
4. How do deal with local adaptations?

- Even for CPOE of the same vendor: Local adaptations may influence performance and safety!
4. How do deal with local adaptations?

Examples:

- Adaptations of the user interfaces
- Adaptations of drug information
- Adaptations of the rule base and of the alerts
- Different integration with other systems (LIS, HIS)
- Different usage patterns
- Different access rights
- ....
4. How do deal with local adaptations?

- So: Even when same product is used, local adaptations and organizational context are quite different.

- It seems thus challenging to use published data to prove the performance and safety of a given CPOE system.
Summary (1/4)

- Rising regulatory pressure that medical software used for diagnostic and therapeutic purposes has to undergo individual clinical evaluation before bringing it to the market.

- Strong pressure to develop “safe” software.

- Either literature review of “equivalent” software or clinical trials.
Each medical software that is a medical device needs a Clinical Evaluation Report!

Report has to be regularly updated with results from post-surveillance data.
Summary (3/4)

- Benefit of new regulation:
  - Early clinical evaluation will hopefully help to reduce risks and improve quality of medical software.
  - Strong emphasis on ergonomic aspects and usability, that are major sources of problems.

- Challenge:
  - How to interprete directive to medical software
  - Increased costs for the manufacturer
  - Problem of local adaptation
What can we (as health informatics community) contribute:

- Develop adequate methodologies for medical software evaluation
- Develop guidelines for software evaluation taking into account MDD
- Educate trained staff to conduct large-scale systematic field studies of clinical software.
- Develop performance and safety indicators
- Establish study registers
Further information

- EFMI Working Group on IT Evaluation
- http://iig.umit.at/efmi
THE ISSUES OF POST-MARKET SURVEILLANCE
A Learning System

- Need to protect Patients (and Clinicians)
- Need for constant Quality Improvement
- Ethical Imperative of using Knowledge in the System

- A Learning System, not a Blame System
Low Evidence Base-line – 1. MDD

Medical Devices Background

- less rigorous than drug trials
- ‘Similar product’ system under criticism
  - The ‘difference’ may be critical, e.g. material
- Difficult to learn from experience given diffusion of care
Low Evidence base-line – 2. HI

Health Informatics history

- Too much trust on claims, hopes, unfinished updates
- Lack of recognition of disruptive effects; clinician and patient dependency
- Low history of systematic evidence gathering
- No clearing house systems
Informatics and Information

- Informatics should by definition harness and use information!
- Opportunities for:
  - History and outcome tracking
  - Analysis in patient/clinician use context
  - Feedback and mutual learning
- Risk identification and reduction
Needs for Post-Marketing Surveillance

1. Trusted Third Party
2. ‘Possible incident’ reporting
3. Informed analysis
4. Product in context
5. No blame
6. Publication
1. Trusted Third Party

- To demonstrate independence
- To provide openness
- Developed expertise
- Funding cost is a fraction of the market cost, and of adverse outcome and litigation costs
- Mechanisms possible, need developing
2. ‘Possible Incident’ Reporting

- Low reporting threshold
- Do not need to provide detailed evidence, just concern/suspicion
- May be process issue (e.g. data disappeared) or outcome (wrong care provided)
3. Informed Analysis

- Specialist centre would develop intelligence
- Able to filter levels of concern
- Able to balance outliers and core concerns
- Statistical and application analysis developments
- Able to assess user and patient complexity effects
4. Product in Context

- Any product’s effectiveness is dependent on use
- Particularly true for health informatics
- Need to look at user type, training, support and maintenance, etc. as links in the chain
- Vendors do not have that full span
4. No Blame

- Must not attach blame (unless gross)
- Issue may be about brief; design; implementation; platform; training; etc.
- It is the problem which is the focus, not recrimination
- No liability issues (unless grossly negligent)
5. Publication

- Reports in; Analysis out
- Openness of process and issues reporting
- Reports may be **product based**, but also **process based** (e.g. implementation or training standards), or **domain based** (e.g. teledermatology)
Summary

- Health Informatics must be responsible and mature
- Learning is a key issue
- Need trust of public and professionals
- Responsibility in Science – if it has affects, be vigilant for adverse effects