Objective

‘Analysis of the necessity of marking instruments and implants.’

- technical feasibility on manufacturer side
- regulatory requirements
- practical application in hospitals

Core question:
What is the right level of track & trace?
Team + Leadership

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Co-Chairs: Herve Ney + Volker Zeinar
Agreements of the work team at the Kick-Off in Rome:

**Concentrate on**
- 1. phase → Instruments (direct marking)
- 2. phase → Implants (marking of packagings)

**Step 1 : Clarify the level of track & trace**
- set level vs. single item level
- evaluate the business driver
- analysis of the processes (where do we need which information?)

**Step 2 : Data content**
- which information are necessary?
- evaluation of existing guidelines / recommendations

**Step 3 : Data carrier and methods of marking**
- DataMatrix (laser etched, Infodot), RFID, …
- advantages, disadvantages, prerequisites, …
Instruments Cycle

Manufacturer

Hospital purchase / logistics

- Ordering
- Delivery
- Goods receipt
- Consignment
- Stock management
- Asset management
- ...

Loaner Sets

Transport

Preparation

- Cleaning
- Dis-/assembling
- Maintenance
- Substitution
- Set configuration
- completeness check

Sterilization

- Creation of 'Steri Batches' (e.g. labels)
- Documentation
- special Software

OP theatre

- Application
- Docum. per patient (steri batch, e.g. labels)

Macro Logistics
marking of packagings

Transport

Transport

Micro Logistics
marking of prod. itself

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Conference calls

Definition of the process steps within the instruments cycle

Development of a questionnaire in supplement to instruments cycle
  - at which process step?
  - do we need which information?
    - on which level?
    - and for what (business case)?

Using the questionnaire for personal interviews of hospitals (CSSD) or sterilization service providers
  - 4 interviews per WT member / country

Up to now 27 interviews have been carried out
  - 7 countries: US, F, CH, DE, I, A, JP

Software for data capturing and summary of the results
WT activities: site visits hospital CSSD

CSSD = Central Sterilization Service Department

Hospital European Georges Pompidou, Paris
- 830 beds (300 cutting beds)
- 146,000 sterile sets per year
- pilot: track&trace on instrument level → based on DataMatrix
  (laser etched and micro percussion)

Problems raised during the tests
- positioning of the code (small codes difficult to find)
- quality of the laser etched code (legibility, contrast, reflection, ...)
- life time of the code (e.g. cleaning with aggressive base → problems after 3 cycles !)
- reading distance and speed
- not all instruments are suitable to carry a DataMatrix

Advantages of traceability on instrument level
- sets assembling by non-qualified staff
- automated data capturing possible
- reasonable costs
Impressions HEGP

micro percussion
Hospital Bichat, Paris
- 1,000 beds (600 surgical beds)
- 29,000 sterile sets + 210,000 wrapped packs per year
- pilot: track&trace on instrument level → based on RFID

Problems raised during the tests
- tag positioning (perfect for right-handed person / not acceptable for left-handed)
- welding quality (tags dropped, antenna unsufficiently protected, …)
- short read/write distance – tags sometimes difficult to find
- not all instruments are suitable to carry a tag
  → alternative DataMatrix or single-use instruments
- how to handle the existing stock?
- attach tags afterwards → CE marking, guarantee, …?

Advantages of traceability on instrument level
- packaging help (staff information, not qualified staff)
- limit instruments crossing between different trays
- manage the instruments of the hospital, incl. maintenances
Impressions Bichat

imbedded RFID tags
WT activities: site visits hospital CSSD

- University Hospital Rouen, France
  - participant of site visits in Paris
  - experience: track&trace on instrument level → based on 'InfoDot'
  - InfoDot = sticker with DataMatrix placed on the instruments (alum. foil)
  - 60,000 instruments on stock / 35,000 stickered with Infodot
  - replace progressively qualified staff for assembling operations by non-skilled staff (not unusual in France: OR nurses responsible for set assembling)

- Why did we visit French hospitals?
  - legal regulation regarding traceability is existing
  - due to Creutzfeldt-Jakob Disease (CJD) cases it must be able to identify "the last 5 patients with whom an instrument was used"
  - 3 risk groups:
    - normal patients
    - risk surgeries (at the brain or eyes or bloody teeth)
    - CJD patients (not allowed to use instrum. any more)
Direkt Marking Solutions

- **DataMatrix**
- micro percussion
- or laser etched

- RFID tag

- DataMatrix InfoDot

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Study of the 'The Patients Association, UK'
- title: 'Tracking Medical Devices and the Implications for Patient Safety'
- survey has been proceeded in 2004
- questionnaire (13) has been sent out by eMail, > 120 replies

Executive summary of the survey
- agreement about the need to have track&trace systems in place when the new off-site 'sterile service Super Centers' are built (97%)
- automated data capture would help improve stock control systems (84%)
- only a third always knews when a device went missing (37%)
- it's impossible to track back and locate a single individual instrument (39%)
- paper based tracking systems are still in use (33% CSSD + 66% OP)
- automated tracking systems would improve patient safety (79%)

"With 'sterile service Super Centers' being developed, the patient safety case becomes overwhelming."
Next steps

- **Breakout session (June 14th)**
  - start to review the results of the interviews
  - discuss key findings + conclusions
  - identify differences between US – EU – AP
  - identify knowledge gaps and define ways to close the gaps

- **Site visits in the UK, probably London**
  - what will change after establishment of ‘sterile service Super Centers‘ ?
  - visits will be organized by GS1 UK
    - 1st day : visit hospitals CSSD
    - 2nd day : discussion of the results from the breakout session
      (WT members which couldn’t attend in Minneapolis)

**Important for the progress of the work team:**

**Engagement of the WT members, especially from manufacturer + hospital side !**
Thank you for your attention!

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