Safety of medical devices

Perspective of the users and controllers in laparoscopy

Ir. L.W. Meinders

Dutch Healthcare Inspectorate
Rijswijk
www.igz.nl

Program

• Introduction
• Inspectorate of healthcare
  • Patient safety and medical devices
  • Use of instruments: Minimally invasive surgery
  • Risk management user and manufacturer related
• Conclusion
Inspectorate of Health Care (1)

Responsible for the enforcement of
+ 800,000 professionals
+ 3000 institutes
+ 1000 manufacturers (medical devices, medicines)

IGZ

Inspectorate of Health Care (2)

140 inspectors
350 employees
5 professi
4 districts
Inspectorate of Health Care (3) Tasks

• enforcing statutory regulations relating to public health;

• advising and informing the Minister of public health on matters relating to public health either on request or on its own initiative.

Inspectorate of Health Care (4) Strategy

- Information on analysis per programme based on specific situation in the valid FASE 1
- Violation
- Compliance
- Intervention & Sanctions FASE 3
- Tussenuitstelmaatstappe en voorzien van besluit

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National action plan

- All hospitals must have implemented a risk management system in 2008;
- Introduction of a system of safely reporting incidents in healthcare institutions;
- Active publication of inspection reports on the internet
Hospital Central Sterilization Departments (CSS) are responsible for the safe reprocessing of used instruments so that they can be reused again within a short time span. A prerequisite for this reuse is that the instruments are properly cleaned and sterilized after each use.

In everyday practice, CSS personnel receive new instruments that are not designed well for easy cleaning and therefore are a potential risk to the patients.

Adverse events in laparoscopy

- Medical device related
- User related
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Minimally invasive surgery

“Project MIS”
Background

• Technical complex
• Demands other skills
• Higher demands used equipment and instruments
• Other complications and risks

Problem

• Incident reporting to the Dutch healthcare inspectorate
• Serious adverse events and death often in young patients
• Investigation (2003) (EUR/TUD): Quality used equipment often inferior:
  – 22% isolation failures
  – 36% light cable failures
Objective

- Level of education and professional practice
- Policy, use and maintenance of instruments used in minimally invasive surgery

How?

- Questionnaires to CSSD, gynaecology and surgical departments of all hospitals in the Netherlands
- Questionnaires to all medical doctors performing laparoscopy in gynaecology and surgery
- Auditing of 20 hospitals, chosen randomly
Reusable instruments in hospitals

Risks related to products lifecycle:

- Acquisition
- Cleaning
- Inspection
- Sterilization
- Use

Acquisition

- Material Advisory Commission 68%
- CSSD member 43%
- Laparoscopic equipment evaluated in commission 23%

example:
- Instructions fur use:
  - Not available 10%
  - Not usable 30%
Cleaning

- Protocol
  - Preparation instruments after surgery (OR) 19%
  - Cleaning laparoscopic instruments (CSSD) 82%

- Cleaning equipment
  - Special connectors cleaning laparoscopic instruments 58%
  - Flow control 7%

- Cleaning in weekend 66%

Quality control (1)

- Control result cleaning procedure 91%

- Procedure control isolation defects diathermy instrument and cables 61%
  - Visual 35%
  - Measurement 26%

- Procedure optical instruments 80%
  - Visual 65%
  - Measurement 15%
Quality control (2)

- Sterilization
  - Helix test 16%
  - Bowie&Dick 58%
  - Other test 9%
  - No 17%

Project conclusions

- Maintenance and control of laparoscopic instruments is insufficient because of
  - Shortcomings Users
  - Shortcomings Manufacturers
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**User safety**

- Practitioners
  - Expertise
  - Qualification
  - Training

  **Only if you are competent you are authorized!**

- Procedures
  - Instructions
  - Quality system (internal: e.g. safe incident reporting, risk management; external: system, expertise)
Device safety

- Manufacturer
  - (Intrinsic) safety
    - Risk analyses
    - Design (Essential requirements MDD)
  - Post Marketing Surveillance
    - Introduction
    - Instructions
    - Repairs
    - User errors
    - Near incident reporting (vigilance system)

Vigilance; where users, manufacturer and authorities meet

- Manufacturer
  - Implementation of a process for systematic review of experience gained in the post-production phase and initiation of appropriate corrective actions
  - Notification of incidents and near-incidents
- Competent authority
  - Risk evaluation
  - Monitoring manufacturer
- User
  - Incident reporting!
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Patient safety

• Patient safety = teamwork
  – All involved responsible!
  – Also Physicians
  – Also Logistics
  – Also CSSD
  – ….
  – And manufacturers!
Conclusion

- Risk management should be part of the safety culture in hospitals
- Manufacturers are not only responsible for designing safe medical devices but also for instructing users adequately in safe use
- Vigilance plays a key role in medical device safety: user reporting is important!

Thank You!