How a quality system had to be implemented for the hospital sterilisation, in France?

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Chairman of AFS
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Lyon - France
1982

Recommendations for implementation a CSSD
1982

Training on sterilisation organized for hospital staff by CEPH, recognized by the Ministry
1993 : premier Diplôme Inter Universitaire organisé par l’Université de Lyon/ Grenoble (dans la Fondation Mérieux - Annecy)
The re-use of single use devices is strictly forbidden

- Two circulars (1986, 1994)
  - investigations by authorities
  - sentence of managers, surgeons and pharmacists in some hospitals
Every health establishment has to be accredited
Sterilisation is one of the points to be fullfilled

Ordonnance n° 96-346 du 24 avril 1996, portant sur la réforme de l’hospitalisation publique et privée
Three major events

- The contaminated blood scandal
- BSE and CJD → first circular for the prevention of transmission of NCTA (1994)
- The « Clinique du Sport scandal »
  (Mycobacterium xenopi - 1997)

The health authorities became suddenly aware of the importance of sterilisation!
1997: ministry circular for implementing quality in hospital sterilisations

- The bases are given
  - quality system to be established
  - validation of the processes to be performed

- Inspections by health authorities (Pharmacy inspection) are managed

- The results are different according to the spots, some are very poor (no central service, dry-heat sterilisation, no validation performed...)

- Some hospitals had to close their Sterilisation Unit
B. KOUCHNER statement, minister of health

« One cannot support the idea that patients may have different qualities of care if the instruments have been processed by industry or by hospital »
- critical m.d.

⇒ sterilisation or HL disinfection
- d.m. semi-critical m.d.

⇒ IN disinfection or sterilisation
- non critical m.d.

⇒ LL disinfection
Consequences (1)

- In any place where sterilisation is performed, at hospital, the preparation of sterile medical devices is under the responsibility of the hospital Pharmacy.

- Sterilisation =
  - pre-disinfection on the spot
  +
  - cleaning, checking, packing, Under the responsibility of the Pharmacy
  - sterilisation, monitoring,
  - distribution and storage

Article L 5126-5 CSP modifié par la loi N° 2002-73 du 17/01/02 de modernisation sociale.
Consequences (2)

- The management of sterile medical devices at hospital is under the responsibility of the hospital Pharmacy

- purchase
- distribution
- storage
- information

Under the responsibility of the Pharmacy

Article L 5126-5 CSP modifié par la loi N° 2002-73 du 17/01/02 de modernisation sociale.
The strength of such a system is that the head of sterilisation has the same power as the surgeon, since both of them are hospital practitioners.
Here we are, Pharmacists, coming to you, in the depths of Faculties, to administer some....
Who is authorized to work in a CSSD?

- Pharmacist
- Help-pharmacists (« préparateurs »)
- Nurses
- Help-nurses (« aide-soignants »)
- Technicians: computer, servicing
- Eventually an expert in quality

Trained to sterilisation practices
Consequences (3)

- The sterilisation of medical devices must be performed in a quality system, defined by the Good Sterilisation Practices
  - organization
  - premises (surfaces, airborne contaminations...)
  - personnel
  - techniques

Arrêté du 22 juin 2001 relatif aux Bonnes Pratiques de Pharmacie Hospitalière – Ligne directrice N° 1 : Bonnes pratiques de stérilisation
Consequences (4)

- The validation of every processes has to be performed according to
  - NF EN 554
  - NF EN 550
  - NF EN ISO 14 937

→ Big market!
The activity « sterilisation » is subjugated to authorization, after application and inspection of the premises and organization by health authorities (Pharmacy and Conseil de l’Ordre des Pharmaciens inspection).
Consequences (6)

- A responsible for quality assurance in sterilisation must be appointed in every institution
- A documentary evidence of the implemented quality assurance must be submitted to authorities

Décret N° 2002-587 du 23 avril 2002 relatif au système permettant d’assurer la qualité de la stérilisation des dispositifs médicaux dans les établissements de santé et les syndicats inter-hospitaliers
Consequences (7)

- All these measures are mandatory
- The hospital managers had to consider them
  - organization in CSSD
  - implementing a quality system
- plants to be closed
- groupings
- sub-contracting with the private companies
Authorizations for sterilisation: the results in 2003

- 2908 establishments have a pharmacy
- 1384 have subjugated the authorization for sterilization
- 145 are not authorized (10.5 %)

mainly for reason of their premises (quality of air)
Some major events have been necessary for the evolution of sterilisation in hospitals. The rules are very stringent. Now, sterilisation is performed in a Quality System everywhere.
French are amazing: we are fond of liberty, individualism, but we stress on regulations...
We wish other countries such stringent rules so that sterilisation is recognized. Quality = reliability.
« The sterility of a product is not negotiable, because the security of the patient is not negotiable »