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Sterilization: Light and Shadows

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Lyon, second urban area in France

- **Lyon** urban area :
  1 .6 million inhabitants
- 19 public hospitals
  (5.313 beds and 23.000 personnels for the Hospices Civils de Lyon)
- 1 military hospital
- 39 clinics or private hospitals

Lyon : the good eating, good drinking (Beaujolais), and Guignol city…

A new and temporary CSSD


Hello , you all !
ICED TEA

The discovery of sterilisation

A. Van Leewenhoek, 17th century

D. Papin, 18th century

the inevitable result of several, seemingly unconnected, historic events

C. Chamberland, H.V. Regnault 19th century

L. Pasteur, 19th century

Also an intuitive discovery

Nicolas Appert,17th - 18th century

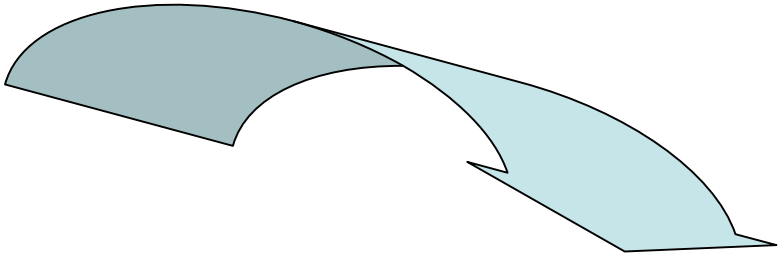
Sterilisation is a science but it is also an art

well-founded scientific data

Sterilisation

intuition, empiricism, approximation

Sterilisation is a highly specialised medicotechnical service within the hospital



Classification of recommendation categories based on the level of evidentiary proof available (CDC)

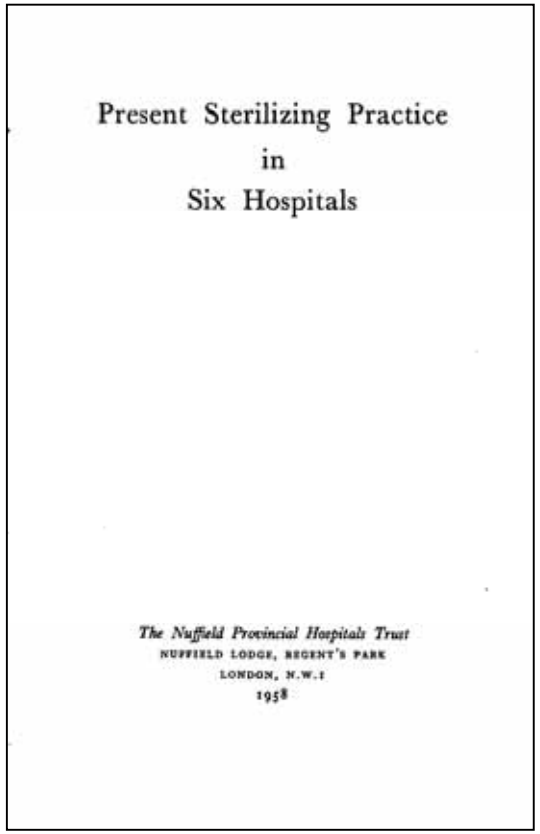
- ***Category IA****:* highly recommended; corroborated by well-documented experimental, clinical or epidemiological studies
- ***Category IB*** *:* highly recommended; corroborated by well-documented experimental, clinical or epidemiological studies and sound theoretical proof
- ***Category II****:* suggestions to be applied and corroborated by suggestive, clinical or epidemiological studies or by theoretical proof
- ***No recommendations, non-resolved problem*****:** practices for which no proof has been furnished or on which no consensus has been
- **And an extra one :**
  "non-founded recommendation"

This presentation could be named equally…

"In the kingdom of the dogmas"

"Between science and obscurantism"

Is medical device sterilisation really necessary ? Would conductance of surgery with non-sterile instruments inevitably lead to infection ?


Present Sterilizing Practice
in
Six Hospitals

The Nuffield Provincial Hospitals Trust
NUFFIELD LODGE, REGENT'S PARK
LONDON, N.W.1
1958

Savage (1937, 1944), Walter (1948), Bowie (1955)

Knox (1961) : "no doubt that there was a clear relationship between the high number of nosocomial infections and serious shortcomings in sterilisation"

"The imperfections in sterilisation practices may be a major contributory factor in the high rate of hospital infections"

The risk of surgical site infection

C.D.C. Prevention of Surgical Site Infection - Guideline - 1999

Risk = $\frac{\text{dose of bacterial contamination X virulence}}{\text{patient's resistance}}$

- Microorganisms > **10^5 per gram of tissue** → risk of infection ↗↗↗↗
- If foreign material at the site : number considerably reduced (e.g. 100 staphylococci per gram of tissue introduced through contaminated silk sutures)

One could therefore think…

- It is not absolutely necessary that instruments should be sterile for surgery,
- being merely clean would suffice.
- But what about other factors in the equation :
  - virulence factors (production of exo- and endotoxins, intrinsic virulence) ?
  - patient's resistance (very young / very old, nicotine addiction, corticotherapy) ?

Are there statistics available on the relationship between non-sterile or “inadequately” sterilised medical instruments and nosocomial infections ?

Mortality statistics for France

- Population: 64,102,000 inhabitants, 530,000
  →**annual deaths 8.2 ‰**
- Number of anaesthetics administered : 8,000,000
- Number of surgical procedures : 7,000,000
- **Global perioperative mortality: 0.7 ‰ of surgical interventions**
- **Global mortality due to nosocomial infections :** 4,000
  →**0.6 ‰ of surgical interventions**
- **Mortality due to lack of sterility** of the medical devices used : **unknown**

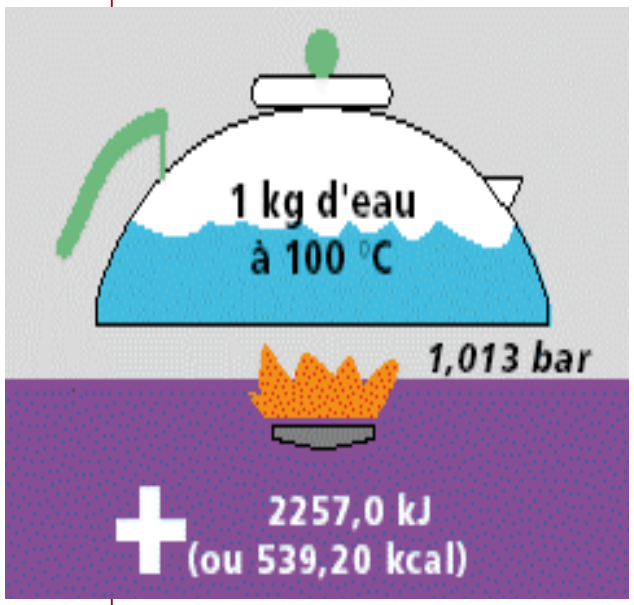
The mortality rate attributed to lack of sterility of the medical devices used is completely unknown

What would happen if the instruments were not sterilised ?

- However, the answer to that can be easily guessed !

→ *This is why medical device sterilisation is featured among the* ***type IB recommendations*** *despite the paucity of publications on this topic*

Do we really know what is the real sterilisation agent (sterilant) ? Is it the steam or the water ? Is water at 134°C able to sterilise on its own ?



Steam condensation : releases 539 kcal → coagulation and hydrolysis of the macromolecules contained in pathogens

At 134°C water only contains around 114 calories
→ Is it able to produce the same effects as steam on pathogenic agents?

What is the sterilant?
Very few studies on the physical properties of steam as conducted for sterilisation

Does a reference pathogen on which all sterilisation theories are based really exist ? Is it the most suitable ?

- Highest level of resistance to heat ***Geobacillus stearothermophilus,*** ***ref*: D_{121}= 1.5 min, Z = 10°C**

- Imaginary Micro-Organism (IMO): D = 1.5 min and Z = 10°C

- Spore resistance variation : $1.2 < D_{121} < 6$ min, $7°C < Z < 23°C$
- Depending on the quality of their support

→ *a higher value in the region of 2.5 to calculate the F0 value needed ?*

→ ***recommendation of the no-recommendation type; non-resolved problem.***

In conformance with its definition, are all forms of sterilisation able to kill pathogenic agents?

- **Sterilisation** = inactivation of the entire spectrum of microorganisms (vegetative form or resistance form)
- If not = **disinfection**
- Limit of life = **110°C** *(G. stearothermophilus)*
- Microorganisms discovered in volcanic lava at 300°C-1000°C = artefact in fluorescence microscopy
- Prion resistance : exceptionally high temperatures (> 134°C, steam, up to 800°C, dry heat)

Prion is not a living microorganism but rather a protein that embodies a new pathogenic agent

Does the sterile state, as expressed by the Sterility Assurance Level (SAL) set at 10^{-6} , guarantee safety? Why not 10^{-3} or 10^{-9} ?

- It is not not clear !
- Comparison of sterilisation with industrial risk levels
  - **Amateur or artistic systems** : safety level ≈ 10^{-3}
  - **Professional systems**, **with an average degree of certainty**, have a safety level ≈ 10^{-3} - 10^{-5}
  - **Professional systems, with a very high degree of certainty**, safety level ≈ 10^{-6}
- Sterile state 10^{-6} applied to food preserves (6x 10^{-9} marketed each year worldwide), → 6,000 deaths/year → sterility level set at 10^{-9}

The more certain one is, and the more one is on the plateau, the more intolerant one is of any residual risk

Can quality assurance really be applied to sterilisation whose outcome cannot be evaluated?

The sterile state cannot be demonstrated

→ "special process" (standard ISO 9001) requiring a certain number of special precautions :

- → validation of sterilisation processes
- → conductance of the process by qualified personnel
- → continuous process control,
- → ongoing monitoring and
- → recording of the process parameters

→ Yes, quality assurance can be applied to the production of a quality that cannot be demonstrated

“One can only sterilize well what is clean”. Is cleaning necessary prior to sterilisation?

“Washer-sterilizers” (AMSCO)

→ it was possible to sterilise soiled objects.

→ waste sterilisation before discarding it (biologist)

→ *The destructive power of steam is such that this is not surprising but that is not the case for any other sterilisation process*

→***The saying “One can only sterilise well what is clean” is not exactly correct***

“Cleaning must precede sterilisation”

What does "clean" mean ?
No definition of this exists.

- No shortage of standards in the field of m.d. sterilisation.
- But… no standard defining cleanliness
  - Visual cleanliness ?
  - Microscopic cleanliness ?
  - Microbiological cleanliness ?
  - Chemical cleanliness ?
  - In respect of proteins ? Lipids ? Carbohydrates ?
- What limit should be set ?

→ ***we are talking about a clean instrument without having defined just what this is***

→ ***recommendation of the no-recommendation type ; non-resolved problem***

Should a neutral or an alkaline detergent be used ?
Why has no consensus been reached ?

- Some products and methods used for sterilisation are able to inactivate prions
- **Alkaline detergent** :
  - better at cleaning stainless steel instruments
  - generally not recommended for aluminium.
  - effectiveness in inactivation or detachment of prions
- **Neutral detergent** :
  - compatible with the aluminium of containers
  - less good at cleaning stainless steel instruments
  - fewer studies on effectiveness on prions have been conducted
- One could be a carrier of pathogenic prions but without developing disease and that 95 % of infections were subclinical

→ *Use routinely methods that are able to inactivate or destabilise prions*

→ *Ideal future solution : alkaline detergents compatible with aluminium and certain delicate instruments ?*

→ ***Recommendation of the no-recommendation type ; non-resolved problem***

What is the purpose of the disinfection phase during cleaning?

- **Pre-disinfection** (= soaking into a detergent immediately after use) : in France / French-speaking countries,

  → *handling the instruments without any risk to staff*

  → *no need of disinfection by rinsing with hot water in the w.d. => time saving*

- In other countries, pre-disinfection = unnecessary step (instrument **disinfection phase** by the w.d.)

  → *Is pre-disinfection unnecessary?*

  → *paramount importance of non-dryness of biological contaminants on instruments*

“One can only sterilise well what is dry”. Is dryness needed prior to sterilisation ?

- Steam condensation during the sterilisation cycle

  → packaging and instruments inevitably soaked all along the different phases

  →*The saying “One can only sterilise well what is dry” is not correct*

“The items to be sterilised must not be moist while awaiting sterilisation”, *or*

“Moist hydrophilic packaging cannot guarantee preservation of the sterile state”

Does uncontrolled aerobiocontamination in the packing zone pose a risk of non-sterility?

The Central Sterile Supply Department (CSSD) is not an operating theatre !

→ operating theatre : a patient has portals of entry for pathogens

→ CSSD : the instruments are sterilised and the sterile state is preserved by the packaging.

→ No publication providing evidence that the quality of the air within the CSSD has any role in assuring successful sterilisation results

→ More favourable option : air of a quality amendable to control (Class 8 ISO in France), but this benefit has not been demonstrated

→ non-founded recommendation

A bag cannot be folded within another bag?

"A bag should never be folded within another bag, and that a bigger bag be chosen when selecting the bag to be sealed around the first bag"

→ more condensation

- No reason put forward
- No demonstration of a particularly fragile point

→ *That recommendation must be consigned to the realm of aesthetics*

→ **Non-founded recommendation**

Does observance of a particular steriliser loading configuration have any concrete significance ?

- Paper sides against the paper sides of the bags = logical precaution
- Recommendation superfluous indeed
  → no risk of obstructing the next bag
  → R*ecommendation obsolete, nay inappropriate*

- Loading configuration for validation scrupulously observed routinely ?
  → no possibility of reproduction of the load configuration type
  → only minimal temperature differences within the load
  → cold point virtually impossible to define

→ L*ogical approach : any item that risks becoming wet should be placed at the bottom of the load !*

→ non-founded recommendation

Is it justified not to fill the steriliser chamber by more than 66 % ?

- Recommendation valid before 1997 (publication of the first standards for validation of medical device sterilisation in sterilisers for porous and hollow loads, when the sterilisation process was not yet validated)

  → *precautionary measure taken because of ignorance*

  → *there is no longer any reason to uphold such a ban*

→ ***non-founded recommendation***

Why is the packaging not reused ?

- *"Contact with steam at a high temperature "tightens the pores" of paper" → the steam would no longer enter it,*
- *"The pores would become so dilated" → allow penetration by microorganisms*

- Nuffield Report (1958) → the antimicrobial properties and free passage of steam were perfectly preserved

- *"The resistance and porosity of paper and nonwovens is not at all, or only a little, affected by being subjected once or twice to steam at 134°C"*

→ no longer the need to reconfigure the packaging for a load that had to be repeated in a steam steriliser following an initial defective cycle ; not yet validated

→ why not contemplate reuse of sterilisation bags or nonwovens if the absence of perforation has been fully demonstrated ?

→ non-resolved problem

Is sterilisation of textiles in a load of instruments strictly prohibited ?

- Difference between the sterilisation cycles used for instruments from those employed for textiles :
  - in the past : very different
  - now : almost identical.
- Validation (EN ISO 17 665-1)→ what can and cannot be done: validation of such or such a type of load for such and such a type of cycle

- Main problem : possible instrument corrosion caused by a poor rinsing of the residues of certain types of additives or neutralisation agents used for washing textiles

→ ***This is the reason why separate loads continue to be advocated, even if a common load would qualify for validation purposes***

→ ***recommendation of the no-recommendation type ; non-resolved problem***

Why the absolute requirement that the steam be saturated and dry for sterilisation ?
Does a B & D test showing a slight shortcoming suggest that the supplies to be sterilised in this steriliser would not be sterile ?

- Reference tables : based on dry saturated steam.
  Tolerance 1K ⇔ 90 hPa.
- Plateau of 18 min at 134°C
  → Fo = 430 min = extremely high level of overkill
  → destruction of a spore population of 10^{280} = several billion times the volume of the earth !
- Implications of the unsaturated steam (132°C instead of 134°C, f.e., caused by air residual) on spore destruction ?
- Prion inactivation affected by superheated or saturated steam ?

If the risk of prions can be fully excluded, it is in the interest of quality that the specified parameters should be observed even if one knows for a fact that the tolerance could be much greater

Why persist in wanting to destroy more than 10^{12} spores since in practice one cannot encounter more ?

- Paradoxes in the field of sterilisation :

"What has happened in this union between the surgeon and the food microbiologist, therefore, is a sort of amorphous mixture of incompatible and contradictory goals, derived from both partners :

- we are dealing with probabilities of survival and deny that any survival is permitted ;

- our plots on semilog charts do not have a "zero" value, and we insist on zero chances ;

- we insist on sterility (absolute) for some devices and instruments, and tolerate much less severe standards for others because of expediency ;

- it takes some significant dose of microbes to initiate infections in most humans, and we aim foçr complete kill (or at least, if we find any survivors we consider it a "failure") ;

- infinitesimally few infections are caused by sporeformers, and we become paranoid about the survival of an occasional spore ;

- we try to sterilize instruments and devices to the nth degree even when we know that we will expose them to a contaminating environment for four, five and six hours.

And like many marriages in trouble, we seek counsel". (Green)

- Overkill parameters should be used as a standard approach

- Thermal plateau period 3.0 min at 134°C → destruction of > 10^{40} spores population of *G. stearothermophilus*

- Maximum population of *G. stearothermophilus* possible to find : ≤10^{9}

  → a thermal plateau of 1 min would be enough to kill this population and obtain a sterile state

- So why use such overkill parameters ?

  "The more certain one is, and the more one is on the plateau, the more intolerant one is of any residual risk"

→ *type IB recommendation*

Is the prion protein not destroyed after 17.5 min instead of the fateful 18 min at 134°C ?

- Studies on conditions governing prion destruction : very different circumstances that hardly permit comparison, except those studies conducted by Taylor
- Exact influence exerted by time not identified
- Influence of temperature studied step by step
  - → optimal temperature for prion destruction = 134°
  - → less effective at 136°C and much less at 138°C

- ***We must rigorously observe the specified parameters, since we do not know what the effects of any estimates would be***

→ non-resolved problem

Why the absolute requirement that water of a very high quality be used to generate the steam since, by definition, steam only contains water ?

- **Physicochemical quality**: no effect on steam quality when replacing the water used for the steriliser steam generator with brine comprising 10 % chloride

- The problem is caused by predominance of water droplets carried by the steam and containing impurities

→ ***there is every reason to want to use water of the highest possible level of purity***

- **Microbiological quality :**
- risk of endotoxin : no effect of contamination when surgical instruments are placed in the chamber of a steriliser whose steam generator had been artificially contaminated with endotoxins
- Water highly contaminated during one or the other stages → no detectable contamination
- $10^6 \approx 50$ IU endotoxins, water containing up to $3*10^7$ bacteria/mL could therefore be tolerated !

→ ***sterile products can be obtained with water of a very poor quality***

→ ***but that does not mean that the overall quality need be reviewed !***

Does water at the bottom of a container mean that the sterile state cannot be preserved ?

- Two types of problems:
  - risk of creating a humid atmosphere → possible passage of *Pseudomonas aeruginosa* or similar bacteria
  - increased risk of corrosion of the instruments enclosed in the container
- *"A cardboard box whose exterior walls had been moistened, contaminated with a suspension of Staphylococcus aureus, Escherichia coli and Pseudomonas pyocyanae and enclosed in a polyethylene bag containing water did not show any evidence of lack of sterility of its contents after three months"* (Nuffield Report)
- Neither of these two risks quantified, or even seriously studied for instrument containers.

  → *Why is a container harbouring water at its bottom considered to be non-sterile if it is equipped with a hydrophobic filter or a system of chicanes ?*

  → *Why is packaging or nonwovens thought to be non-sterile if water is found within them ?*

→ *non-resolved problem*

What happens at midnight of the expiry date ?

- When :
  - good storage conditions
  - no intrinsic ageing process of the medical device
  - no incident during the storage period or tampering with the packaging
  - one knows that the expiry date has been determined on the basis of non-corroborated scientific criteria
- is it wrong to use such a medical device whose expiry date has been reached ?

  → *How many instances of resterilisation of containers or bags take place just because the use-by date, which is sometimes set inappropriately short, has been reached ?*

  → *Has a figure been put on the costs, both in terms of material and personnel input ?*

→ ***non-resolved problem***

Are the standards regulating the manufacture of medical devices and utilisation of control mechanisms, or even the validation procedures, really justified, or are they mainly the work of lobbies ?

- Members of the standardisation committees = the representatives of industry
- Why so few, or indeed not a single hospital user, participating in the committees or attending the committee meetings ?
  → *expenditures not covered by their establishment*
  → *a contribution has to be paid to the standardisation body*
- Why are those who convene such meetings often representatives of industry ?
- Why are organized the meetings in faraway countries ?
  → *the hospital users can't come !*
- For ISO/TC198/WG3 : majority of the 40 members are representatives of industry, including the leading manufacturers of equipment used for control of sterilisation processes

Is it any wonder that certain approaches are being advocated by the standards ?

Last but not least: is sterilisation a hospital activity ?

"I think that the core hospital activity lies not in the provision of catering or laundry, or even sterilisation, services. Its core activity is to focus on the patient. Sterilisation is becoming increasingly more expensive because of the technical requirements it has to meet. In an age where resources are in short supply, such resources as available should be used for the benefit of the patients and not invested in technology"

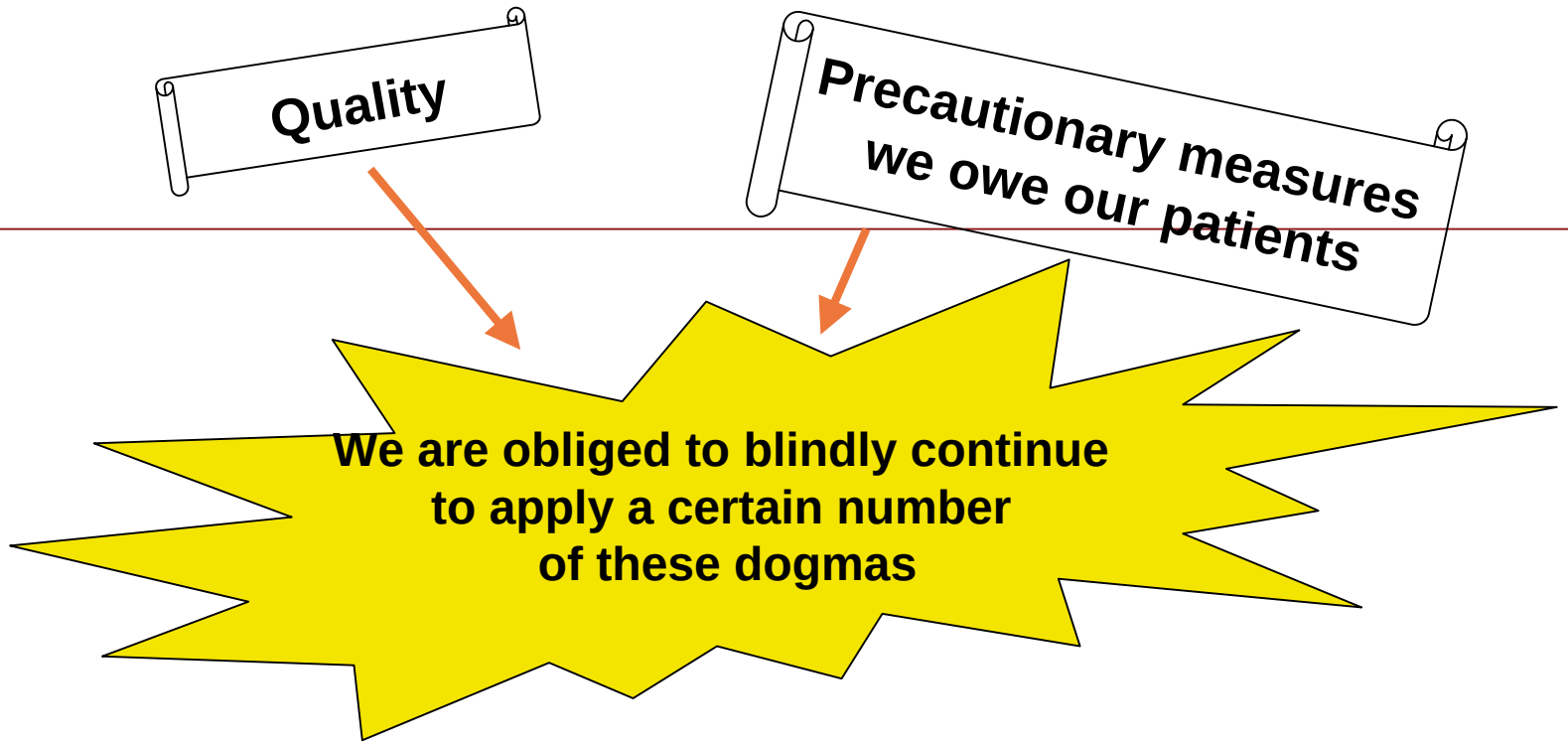
- Does redefining the core hospital activity mean dispensing with sterilisation ?
- Sterilisation, = indirect care activity

  →It is therefore not unacceptable to have indirect care activities conducted by healthcare professional in a healthcare medical / technical establishment
- Sterilisation is a backup activity to the surgical activity and, as such, cannot be dissociated from the latter
- Industrial subcontracting has its place and role under certain circumstances

→ let's stop outsourcing our services. Let's internalise them!

Some conclusions…

- “What sometimes holds true in one CSSD is sometimes a crime in another CSSD”
- “There are still many things to be done and verified so that Sterilisation can ultimately move beyond obscurantism and that practices be predicated on Evidence Based Medicine”
- The shadows in sterilisation derive from the poorly pondered beliefs enshrined in several dogmas
- Is too much being done? Or not enough ?
- How many deaths or infections result from inadequate sterilisation ?
- Research in this field is of interest to only very few people (university or industrial setting) → no huge profits



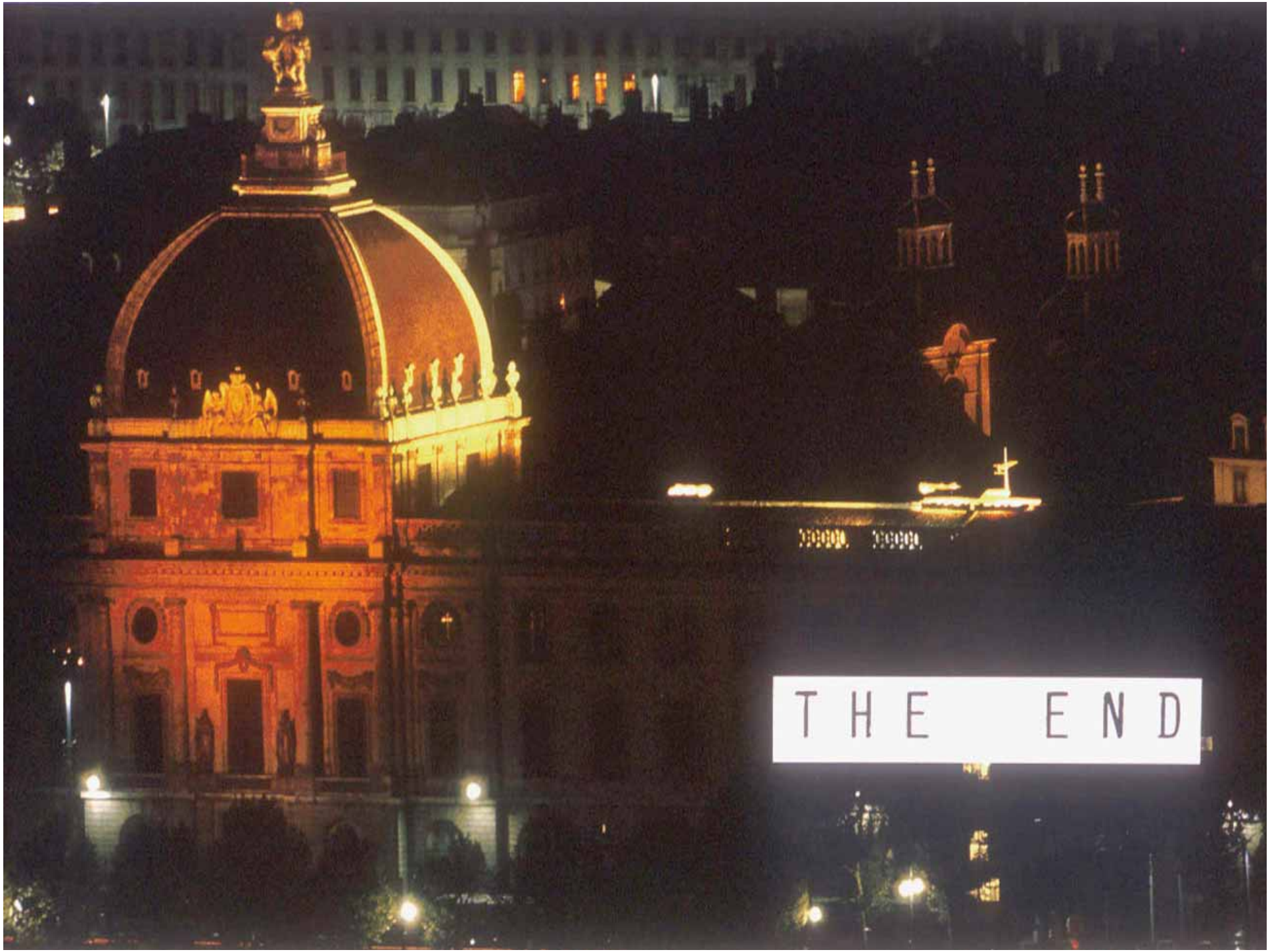
→ *Nothing forbids us from reflecting on matters, from each taking responsibility*

→ *nothing is more harmful than the attitude of applying dogmas without engaging in even minimal risk assessment. We are paid to do so, otherwise a computer will do it better than us*

“There is still much to be learned about sterilisation”

… believing in everything

…accepting anything, anyhow, from anyone….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