

# The Impact of new technologies on the risk of accident

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- In 1997, in a Paris's Hospital, a patient died in ICU because an alarm failed on a monitoring and assistance machine. After investigation, this machine was proved to be new and meeting all new European standards. These new standards, contrary to the previous French standard, allow all alarms to be turned off (the old French standard forced the manufacturer to keep at least one alarm on: blood pressure, respiratory rhythm, or heart beat).
- Once the risk identified, the APHP chose to contain and neutralize the risk, by imposing in its procurement policy a waiver to European alarm setting standards, with the obligation to comply with the older French standard.
- Yet, a new death occurred for the same reason in 2000. After investigation, the APHP noted that (i) a significant number of these machines in operation in France had returned to European standards after maintenance operations carried out by the manufacturer (without the local maintenance department of the hospital being informed, as was the case for the machine the second death was blamed on), and (ii) some machines had been bought outside procurement tenders, using waivers motivated by emergency situations. These machines also complied with European standards.

## Outline of the presentation

- Usual Conflict between Quality and Innovation:  
What means for safety?
- The logic of Medical systems
- Controlling the introduction of Innovation

## Sources of Safety

- **Improve Quality**
  - **Select best practices (EBM)**
  - **Avoid complications and errors**
- **Create innovation**
  - **Change solution (innovation)**

# Incomparable range of gains for Innovation Vs Quality

## Aviation

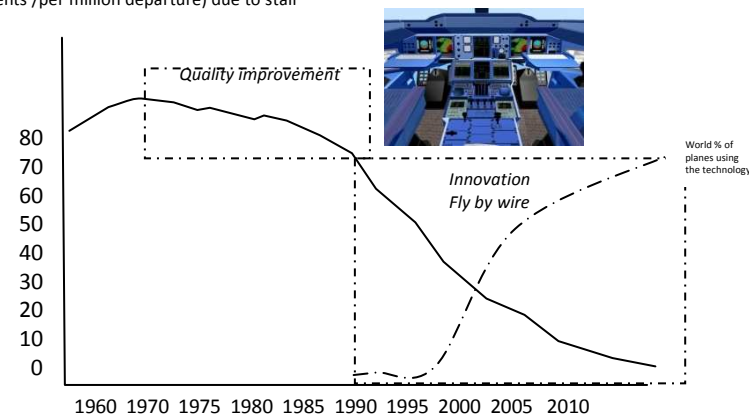
- Three decades of Quality approach to reduce stall-induced accidents : 20% improvement
- Late80's : introduction of automated aircraft, fly-by-wire technology, NO more stall...
- ...

## Medical :

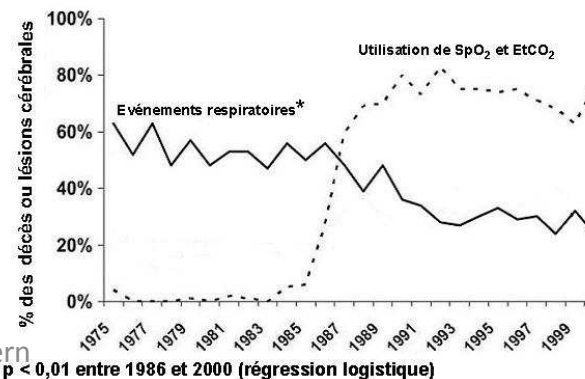
- The introduction of ciclosporin in the early 80s increased the 1 year graft survival from 10% to 55%.
- Anaesthesia related mortality has decreased about 10-fold over the past 20 years.
- “Pulsed” rather than continuous x-rays in minimally invasive surgical procedures reduce patient dose by 50-75%.
- Automated exposure controls that match the dose to body size and thickness reduce dose from 10-30% for routine CT examinations and, up to 50% for CT cardiac examinations.

Sarter, N., Amalberti, R. (Ed.), (2000). *Cognitive engineering in the aviation domain*. Hillsdale- New Jersey: Lawrence Erlbaum Associates.

Accidents /per million departure) due to stall



Evolution of Fatality rate associated with Respiratory adverse events during anesthesia  
Effect of the introduction of monitoring in the decrease of AEs



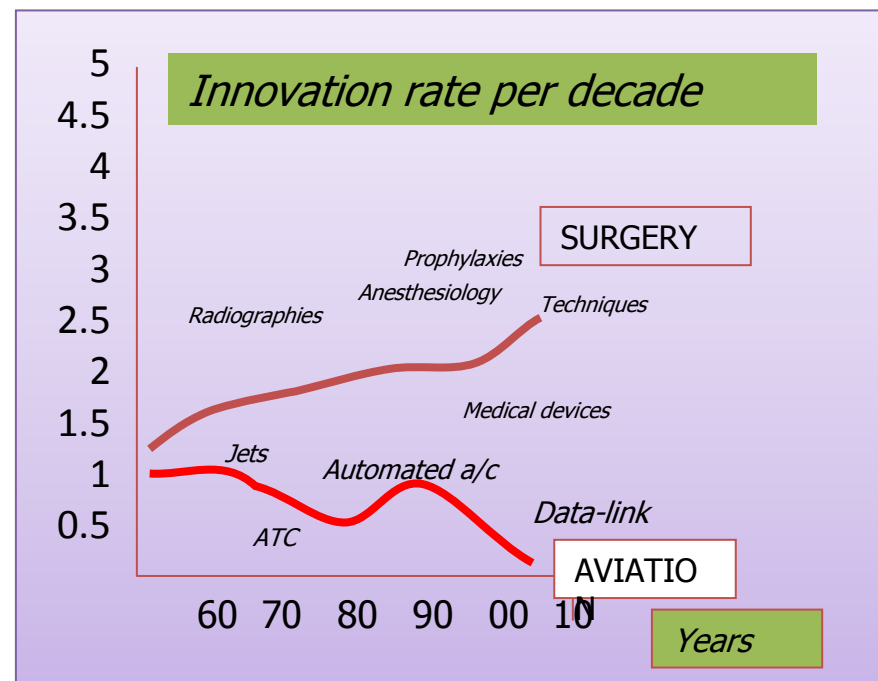
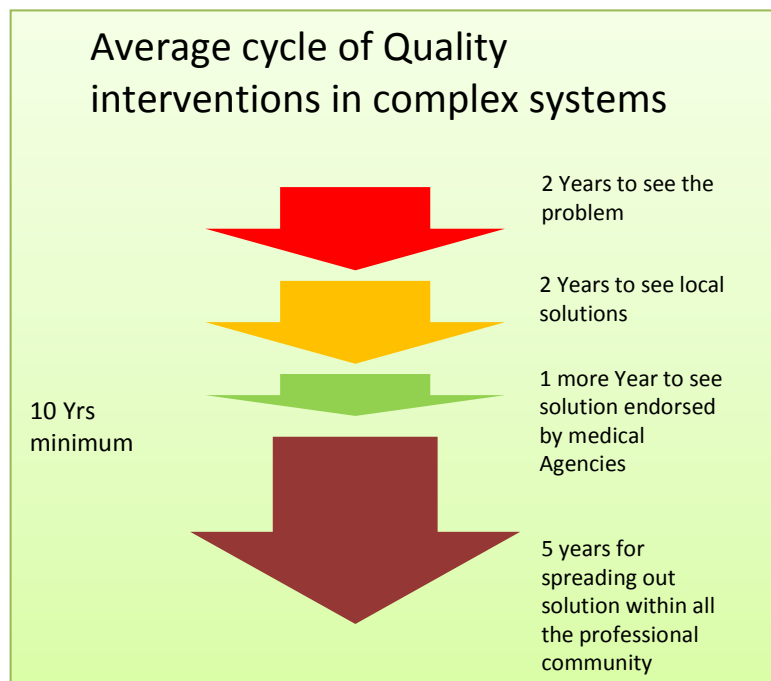
\* p < 0,01 entre 1986 et 2000 (régression logistique)

# Conflict Quality –Innovation Always to the detriment of Quality process



- The power of Journals
- The power of the market and the lobbies
  - Medicine is among the very few industrial systems (with cars, software...) where innovation is marketed directly with the end-users (doctors, patients' associations)

# Pace of innovation and the 'collision' of cycles



## **INNOVATION, not only products of devices**

- **Continuous innovation of practice, usage, organization of medical system as important as innovation of technical tools.**
  - Larger flow
  - Larger consequences (system consequences, coupling, transitional unstability)
  - Little controls and supervision especially when part of recurrent trainings ( individual or center dependant initiatives, no formal license to use...)
- **Any learning process of a new usage- even for a validated tool, drug, device- is somewhere a step of innovation for the individual.**



Excerpt of the Summary of the report ASN n° 2006 ENSTR 019 -  
IGAS n° RM 2007-015P

Accident of Epinal, serial Overdoses of patient undergoing  
radiotherapy for prostate cancer

- « En mai 2004, le protocole de radiothérapie conformationnelle appliqué aux tumeurs de la prostate a été modifié, afin de se servir plus largement des possibilités du logiciel de dosimétrie en place depuis 2000. Il passe ainsi de l'utilisation de coins statiques à celle de coins dynamiques<sup>1</sup>. Ce changement suppose de modifier également le paramétrage assurant le calcul d'intensité d'irradiation, ce qui ne sera pas fait pour certains malades. **(Modification of protocol)**
- A ce stade, l'erreur aurait pu être corrigée si le calcul indépendant du nombre d'unités moniteurs (UM) et la dosimétrie in vivo, qui permet de vérifier la dose réelle reçue par le malade, avaient été maintenus. Malheureusement ces lignes de défense sont levées, l'utilisation des coins dynamiques les rendant inopérantes en l'état. **(Suppression of defenses)**
- La décision n'est pas préparée : la traçabilité des opérations, l'écriture préalable du protocole, l'adaptation à cette nouvelle pratique en amont de la dosimétrie in vivo et du calcul indépendant d'UM n'ont pas été effectuées. De plus, les manipulateurs ne disposent d'aucun guide d'utilisation en français adapté à leur pratique quotidienne. Ils n'ont pas été formés correctement à la modification effectuée : deux démonstrations individuelles ont été faites à deux manipulateurs, l'une exacte, l'autre entachée d'erreur. Ceux-ci ont transmis l'information, l'un à deux, l'autre à trois collègues, qui ont à leur tour reproduit fidèlement ce qu'ils avaient appris. La responsabilité des manipulateurs n'est donc pas en cause. **(Poor traceability, inadapted training)**
- La période pendant laquelle a eu lieu le surdosage des 23 malades, se situe **entre le 6 mai**
- **2004 et le 1er août 2005. Après cette date, un nouveau logiciel de dosimétrie remplace** définitivement l'ancien, dont l'ergonomie ne permettait pas d'empêcher ce type d'erreur. »

# Innovation and Usage

## Multiple deviances

### Patient undergoing Prostate cancer

- Prostate Cancer
- Dose prescription 80Gy
- Fractions 40
- Dose per Fraction 2GY
- Energy 20X
- Flow 400UM/Min
- Config 5 beamlets /star, isocentric
- Intensity-modulated radiation therapy (IMRT)

*Adélaïde Nascimento, 2009, PhD*



**Instruction : Comment the solution; should you adopt the same strategy?**

**14 Medical physicians from 5 institutions**

*The participating institutions include a broad range of radiation oncology departments in terms of the nature and number of machines they have in their center (classic, 3D-CRT, IMRT, tomotherapy), the staffing, the number of patients treated per day, and the type of practice (academic vs community based).*

*Results : Two centers not equipped with IMRT  
Multiple discussions on Dose, time, equipments,..., use of filters, local specificities, multi variation in the usage....*

### 5. BIG ONE & NEW CYCLE

**RISK MANAGEMENT,  
ARBITRATION,  
SAFETY REQUESTED**

**4. PROGRESSIVE  
END OF PROFITS**

END  
OF  
THE  
CYCLE

TECHNOLOGY  
BREAKDOWN

System under growing Media and Justice scrutiny

EMERGENCE OF A  
NEW COUPLING  
PARADIGM

### 3. TIME OF JUSTIFICATION

**RISK EMERGENCE,  
TRANSPARENCY REQUESTED**  
*Enforced in service experience*

**BIG ONE**

0 10 20 30 40 50 60  
NEXT INDUSTRIAL CYCLE

### 2. TIME OF HOPE

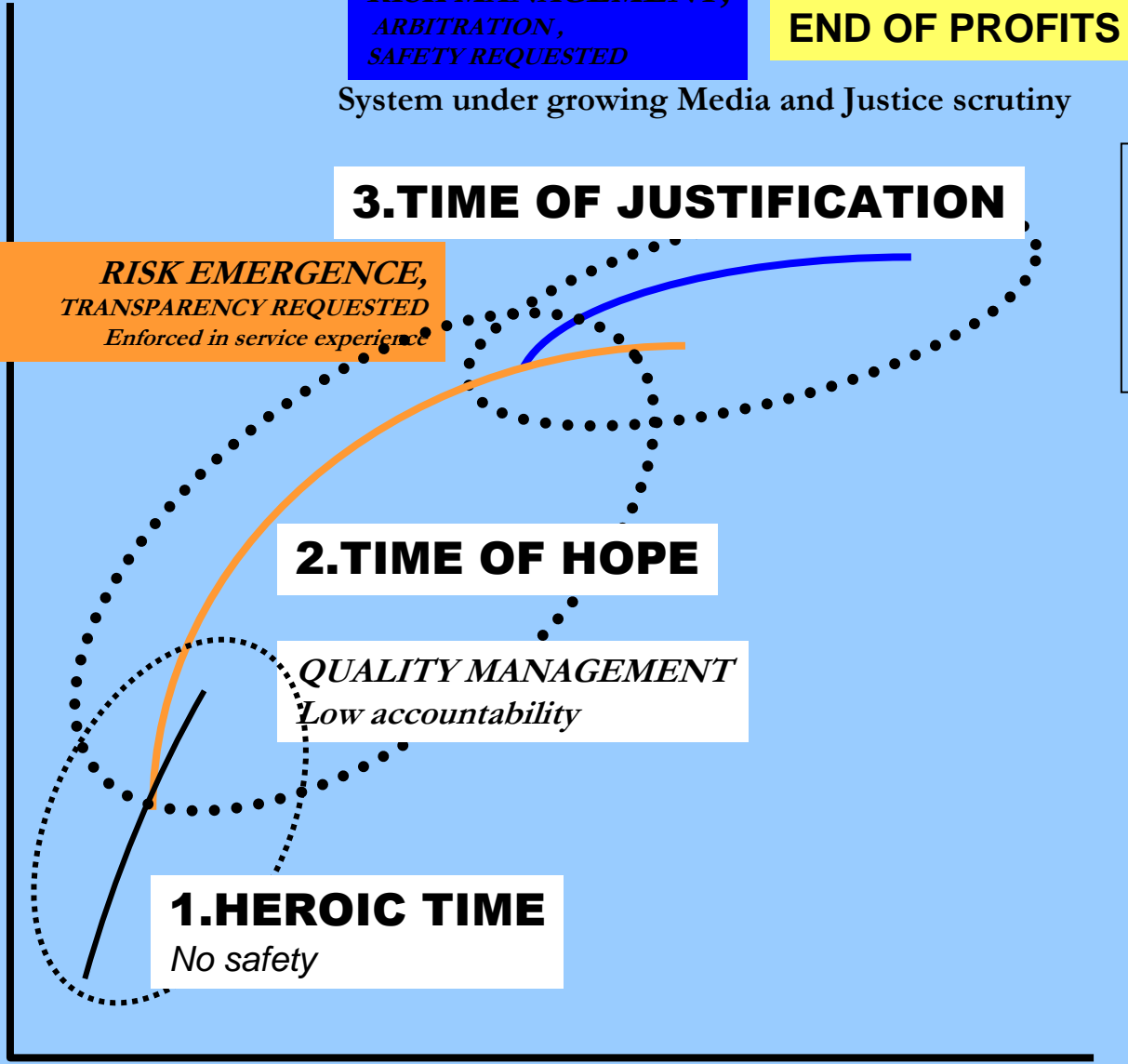
**QUALITY MANAGEMENT**  
*Low accountability*

### 1. HEROIC TIME

*No safety*

0 10 20 30 40 50 60 70 80 90 100 110

Years  
Order of magnitude



## Conclusions (1)

- **The matter is not to suppress innovation, ...or abandon Quality**
- **The two approaches aim at complementary goals**
- **The matter is to control the interactions with resilient models**
  - **During the life of systems**
  - **During the life of each professional actors**

## Four golden rules used by Industry to cope with innovation

- **Control the cycle of Innovation to remain compatible with the cycle of Quality**
- **Stop marketing end-users. All marketing strategies of innovation only addressed to supervisory boards, authorized experts, regulators, private and public authorities.**
- **Test the product and the usage prior to introduction . Flight-test centers in charge of testing the use. Develop training syllabi in operational conditions.**
- **License professionals prior to introduction (mandatory recurrent course, education required).**

**How many can we transfer to medicine??**

## Conclusion (2)

- **A System Problem**
  - Prevalence of innovation in medical progress
  - The 'Tree' (marketing authorizations, drug and devices) hides 'the forest' (supervision / licensing to use)
  - Free market, competition, lobbying
- **A Culture problem**
  - Autonomy, absence of centralized governance
  - Quality and Patient Safety second rank priorities
- **Limited changes**
- **Room for progress exists, but needs a long way to go, changing minds and culture.**
  - No directive or recommendation will solve out the problem in isolation