Research in quality and patient safety: Key issues and challenges

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France

Four tremendous changes expected in the health care system within the next 10 years
## Only 40% of communality of the medical system in 2020 compared to 2010

- **Financial : Present health care system in great financial trouble: need radical moves and improvements at acceptable cost growth : growing opposable rec.**

- **Technical : Considerable in-hospital changes**
  - **80% or surgery as day-surgery**
  - **20% of interventions or even more moving to offices and out clinic facilities**
  - **Massive transfer of post op care to Primary care**

- **Sociological : tremendous demographic changes**
  - **Emergence of new professions/ interventionists (cardiologists, gastroenterologists, radiologists…) . 60% of diagnosis, 40% of therapies made with imagery in 2020**
  - **more female doctors, rapid desertification of medical care in rural environment , growing delegation of care to nurses and growing remote medicine (thanks to ITs)**
  - **Older patients, longer time for caring chronic disease**

- **Societal**
  - **Enhanced transparence to the public**
  - **Revolution of Its, growing traceability and surveillance, big brother**

The challenge of 2020 (Continue)

- **The success of patient pathway more important than any individual success of a given care**

WE HAVE DONE A LOT TO IMPROVE PATIENT SAFETY

Reduction of nosocomial infections
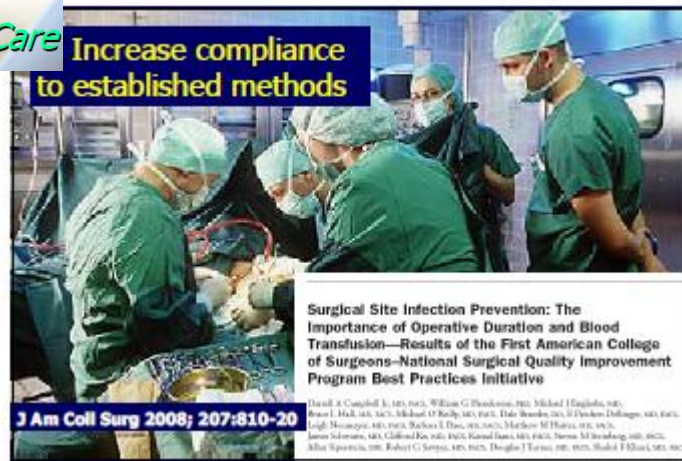
ENSURE CORRECT-SITE, CORRECT PROCEDURE, CORRECT-PATIENT SURGERY

World Health Organization

SURGICAL SAFETY CHECKLIST (ADVANCED DRAFT)

PRIOR TO INDUCTION OF ANAESTHESIA → *PRIOR TO SKIN INCISION* → *PRIOR TO PATIENT LEAVING THE OPERATING ROOM*

SIGN IN

- ❑ PATIENT CONFIRMED
  - • IDENTITY
  - • SITE
  - • PROCEDURE
  - • CONSENT

- ❑ SITE MARKED / NOT APPLICABLE

- ❑ ANAESTHESIA SAFETY CHECK COMPLETED

- ❑ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ❑ No
- ❑ YES

DIFFICULT AIRWAY / ASPIRATION RISK?
- ❑ No
- ❑ YES, AND EQUIPMENT / ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ❑ No
- ❑ YES, AND ADEQUATE IV ACCESS / FLUIDS PLANNED

TIME OUT

- ❑ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE

- ❑ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - • PATIENT
  - • SITE
  - • PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ❑ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

- ❑ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT–SPECIFIC CONCERNS?

- ❑ NURSING TEA... (INCLUDING ... CONFIRMED? ... ANY CONCER...

ANTIBIOTIC PROP... MINUTES?
- ❑ YES
- ❑ NOT APPLICA...

ESSENTIAL IMAGIN...
- ❑ YES
- ❑ NOT APPLICA...

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ❑ THE NAME OF THE PROCEDURE RECORDED

- ❑ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)

- ❑ HOW THE SPECIMEN IS LABELED (INCLUDING PATIENT NAME)

- ❑ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED

- ❑ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR

Two of more patient-specific identifiers
- ASK Patient's name
- Patient's birth date
- Assigned ID number / four or five digit number
- Radio frequency identification (RFID)
- Bar coding
- (blue?)Wristband…

SAFER DRUG MANAGEMENT

- Moving towards standardized concentrations
- Reengineering for safety
- Educate

SAFER DRUG MANAGEMENT (CONTINUE)

MEDICAL CENTER HOSPITAL
500-600 W. 4TH STREET   ODESSA, TEXAS   Ph. 333-7111

FOR: Vargas, Ramon   AGE: _____
ADDRESS: _____   DATE: 6/23/95

Plendil 20mg   # 120 –
20 mg P.O. Q6hrs

NO REFILLS ☐
REFILLS
LABEL ☐

Ferrous Sulfate 300mg   # 100
300mg P.O. TID c̄ meals.
Humulin N
30 units SQ QAM.
Ram/Golle

PRODUCT SELECTION PERMITTED   DISPENSE AS WRITTEN

D.E.A. #

720 037 2/89

erika brown – HFES – 24 april 2002

"Although it allegedly calls for Isordil, the pharmacist filled it as Plendil. The jury's $450,000 judgment, finding both the cardiologist and pharmacist negligent, is believed to be the first of its kind nationwide to focus solely on bad handwriting." –

- Read-back, hear back
- Check lists
- Improved medication order
  – Sound-Alike / Look-Alike Drug (SALAD) Week
  – Banned Items (BANDEM) Week
  – Physicians eligible Handwriting Week
  – High-alert Medication (HAM) Week

SAFER COMMUNICATION, TEAMWORK, AND CO-ORDINATION

- In industries which operate continuous processes, continuity is maintained across shifts changes via shift changeover
- Shift changeover typically includes:
  - A period of preparation by outgoing personnel
  - SHIFT HANDOVER (a period of communication)
  - Cross-checking of information by incoming personnel

National Patient Safety Goals

A Model for Building a Standardized Hand-off Protocol

Vineet Arora, M.D., M.A.
Julie Johnson, M.S.P.H., Ph.D.

Department Editors:
Marcia M. Piotrowski, R.N., M.S., Peter Angood, M.D., Paula Griswold, M.S., Gina Pugliese, R.N., M.S., Sanjay Saint, M.D., M.P.H., Susan E. Sheridan, M.I.M., M.B.A., Kaveh G. Shojania, M.D. Readers may submit National Patient Safety Goals inquiries and submissions to Steven Berman (sberman@jcaho.org) and Marcia Piotrowski (marcia.piotrowski@med.va.gov).

In July 2003, the Accreditation Council for Graduate Medical Education (ACGME) set limits for resident duty hours. Although the main driving force was to reduce sleep deprivation and improve patient safety, one unintended consequence was the increase in the number of handoffs during patient care. The discontinuity of care that thereby results has the potential to undermine the beneficial effects of work hour limitations. The safety of the hand-off process has been called into question by a number of different sources and studies which suggest that handoffs are often characterized by communication failures and environmental barriers.

The handoff is also the subject of a Joint Commission on Accreditation of Healthcare Organizations National Patient Safety Goal, which went into effect January 1, 2006. Written as a new requirement of Goal 2, Improve ... registers, ... a standards and ... spond to ... age 647). ... that occur ... ings, the ... residen- ... Because ... uning or ... there is ... actice of ...

Article-at-a-Glance

Background: The Joint Commission has made a "standardized approach to hand-off communications" a National Patient Safety Goal.

Method: An interactive 90-minute workshop (hand-off clinic) was developed in 2005 to (1) develop a standardized process for the handoff, (2) create a checklist of critical patient content, and (3) plan for dissemination and training.

Conclusion: To date, 7 of 10 residency programs have participated. Analysis of these protocols demonstrated that the hand-off process is highly variable and discipline-specific. Although all disciplines required a verbal handoff, because of competing demands, verbal communication did not always occur. In some cases, the transfer of professional responsibility was separated in time and space from the transfer of information. For example, in two cases, patient tasks were assigned to other team members to facilitate timely departure of a postcall resident (to meet resident duty-hour restrictions), but results were not formally communicated to anyone. The hand-off clinic facilitated the incorporation of "closed-loop" communication by requiring that follow-up on these tasks be conveyed to the on-call resident.

Discussion: This model for design and implementation can be applied to other health care settings.

Improving clinical handovers: creating local solutions for a global problem

Julie K Johnson and Vineet M Arora

QSHC

Evaluation of a Preoperative Checklist and Team Briefing Among Surgeons, Nurses, and Anesthesiologists to Reduce Failures in Communication

Lorelei Lingard, PhD; Glenn Regehr, PhD; Beverley Orser, MD, PhD; Richard Reznick, MD, MEd; G. Ross Baker, PhD; Diane Doran, RN, PhD; Sherry Espin, RN, PhD; John Bohnen, MD; Sarah Whyte, MA

Objective: To assess whether structured team briefings improve operating room communication.

Design, Setting, and Participants: This 13-month prospective study used a preintervention/postintervention design. All staff and trainees in the division of general surgery at a Canadian academic tertiary care hospital were invited to participate. Participants included 11 general surgeons, 24 surgical trainees, 41 operating room nurses, 28 anesthesiologists, and 24 anesthesia trainees.

Intervention: Surgeons, nurses, and anesthesiologists gathered before 302 patient procedures for a short team briefing structured by a checklist.

Main Outcome Measure: The primary outcome measure was the number of communication failures (late, inaccurate, unresolved, or exclusive communication) per procedure. Communication failures and their consequences were documented by 1 of 4 trained observers using a validated observational scale. Secondary out-comes were the number of checklist briefings that demonstrated "utility" (an effect on the knowledge or actions of the team) and participants' perceptions of the briefing experience.

Results: One hundred seventy-two procedures were observed (86 preintervention, 86 postintervention). The mean (SD) number of communication failures per procedure declined from 3.95 (3.20) before the intervention to 1.31 (1.53) after the intervention ($P < .001$). Thirty-four percent of briefings demonstrated utility, including identification of problems, resolution of critical knowledge gaps, decision-making, and follow-up actions.

Conclusions: Interprofessional checklist briefings reduced the number of communication failures and promoted proactive and collaborative team communication.

FATIGUE MANAGEMENT

Anesthesia and fatigue

Australian Incident Monitoting Study, 1987-1997 MORRIS & Morris, Anaesth.Intensive Care 2000

Nature of incidents

Fluid error

Drug error

Dose error

Obstructions

Relative percentage of adverse events
- No fatigue
- Fatigue

5   10   15   20   25   30%
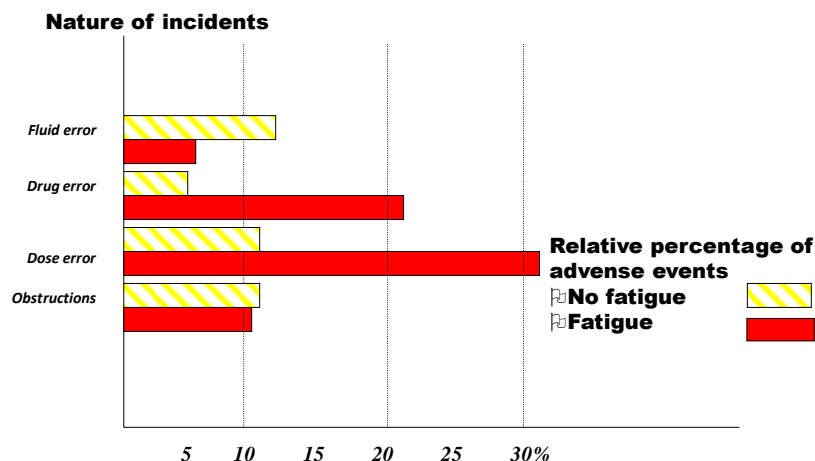
Effects of the European Working Time Directive on anaesthetic training in the United Kingdom

D. J. Sim,[1] S. R. Wrigley[2] and S. Harris[3]

1 Specialist Registrar in Anæsthesia, Derriford Hospital, Plymouth PL6 8DH, UK
2 Consultant Anaesthetist, Derriford Hospital, Plymouth PL6 8DH, UK
3 Specialist Registrar in Intensive Care, Royal Prince Alfred Hospital, Sydney, NSW 2050, Australia

Summary

Decreases in the hours worked by trainee anaesthetists are being brought about by both the New Deal for Trainees and the European Working Time Directive. Anticipated improvements in health and safety achieved by a decrease in hours will be at the expense of training time if the amount of night-time work remains constant. This audit examined the effects of a change from a partial to a full shift system on a cohort of trainee anaesthetists working in a large district general hospital in the South-west of England. Logbook and list analyses were performed for two 10-week periods: one before and one after the decrease in hours. An 18% decrease in the number of cases done and an 11% decrease in the number of weekly training lists were found for specialist registrars. A 22% decrease in the number of cases done and a 14% decrease in the number of weekly training lists were found for senior house officers. Furthermore, a decrease of one service list per specialist registrar per week was seen, which will have implications for consultant manpower requirements.

Keywords *Workload*: anaesthesia. *Training*.

The NEW ENGLAND JOURNAL *of* MEDICINE

ORIGINAL ARTICLE

Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units

Christopher P. Landrigan, M.D., M.P.H., Jeffrey M. Rothschild, M.D., M.P.H., John W. Cronin, M.D., Rainu Kaushal, M.D., M.P.H., Elisabeth Burdick, M.S., Joel T. Katz, M.D., Craig M. Lilly, M.D., Peter H. Stone, M.D., Steven W. Lockley, Ph.D., David W. Bates, M.D., and Charles A. Czeisler, Ph.D., M.D., for the Harvard Work Hours, Health and Safety Group

Adopt a Safety culture

Five Attributes of a Safety Culture	
Attribute	**Definition**
An Informed Culture	"Those who manage and operate the system have current knowledge about the human, technical, organizational and environmental factors that determine the safety of the system as the whole."
A Reporting Culture	"An organizational climate in which people are prepared to report their errors and near-misses."
A Just Culture	"An atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information—but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour."
A Flexible Culture	"Adapting effectively to changing demands. . . . {I}n many cases it involves shifting from the conventional hierarchical mode to a flatter professional structure, where control passes to task experts on the spot."
A Learning Culture	"The willingness and the competence to draw the right conclusions from {the organization's} safety information system, and the will to implement major reforms when their need is indicated."

QSHC ONLINE — Institutional resilience in healthcare systems
J Carthey, M R de Leval and J T Reason
Qual. Health Care 2001;10;29-32
doi:10.1136/qhc.10.1.29

QSHC ONLINE — Diagnosing "vulnerable system syndrome": an essential prerequisite to effective risk management
J T Reason, J Carthey and M R de Leval
Qual. Health Care 2001;10;21-25
doi:10.1136/qhc.0100021..

QSHC ONLINE — Assessing safety culture: guidelines and recommendations
P Pronovost and B Sexton
Qual. Saf. Health Care 2005;14;231-233
doi:10.1136/qshc.2005.015180

DEVELOPING PSIs TO MEASURE EFFECTIVENESS
OCDE: Criteria used to review potential indicators and select an initial data set

A. Importance to patient safety:	~	**Impact on health.** What is the impact on health associated with this problem? Does the measure address areas in which there is a clear gap between the actual and the potential levels of health?
	~	**Policy importance.** Are policymakers and consumers concerned about this area?
	~	**Susceptibility to being influenced by the health care system.** Can the health care system meaningfully address this aspect or problem? Does the health care system have an impact on the indicator independent of confounders like patient risk? Will changes in the indicator give information about the likely success or failure of policy changes?
B. Scientific soundness	~	**Face validity.** Does the measure make sense logically and clinically? The face validity of each indicator in this report is based on the clinical rationale for the indicator, and on the past usage of the indicator in national or other quality reporting activities.
	~	**Content validity.** Does the measure capture meaningful aspects of the quality of care?
C. Potential feasibility	~	**Data availability.** Are comparable data to construct an indicator available on the international level?
	~	**Reporting burden.** Does the value of the information contained in the indicator outweigh the cost of data collection and reporting?

ADOPT INFORMATION TECHNOLOGY

- Electronic patient record (EPR).

- Personal health record

- Decision-support tools

- Electronic handoffs

WE DID A LOT....
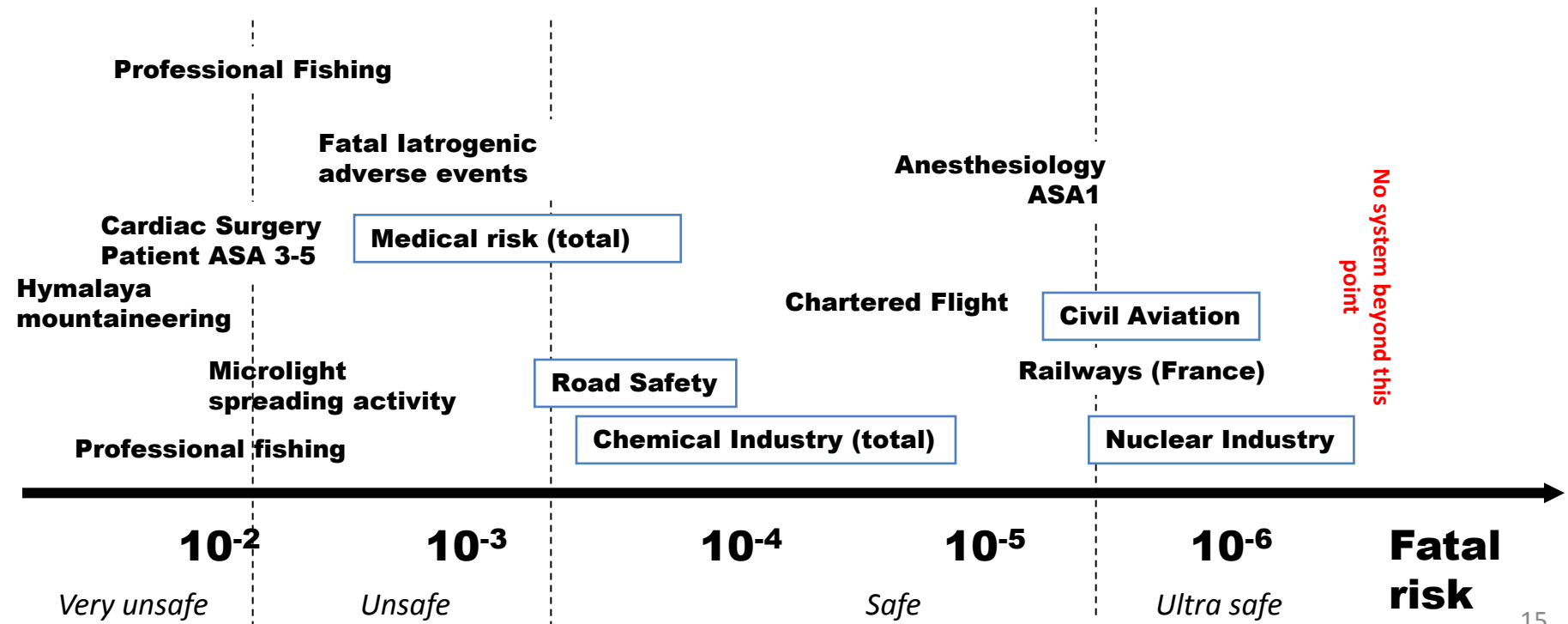*TRYING TO LOOK LIKE ULTRA SAFE INDUSTRY*

BUT ARE WE GETTING SAFER?

Risk in human activities

Five System Barriers to Achieving Ultrasafe Health Care

PATIENT SAFETY AND THE RELIABILITY OF HEALTH CARE SYSTEMS
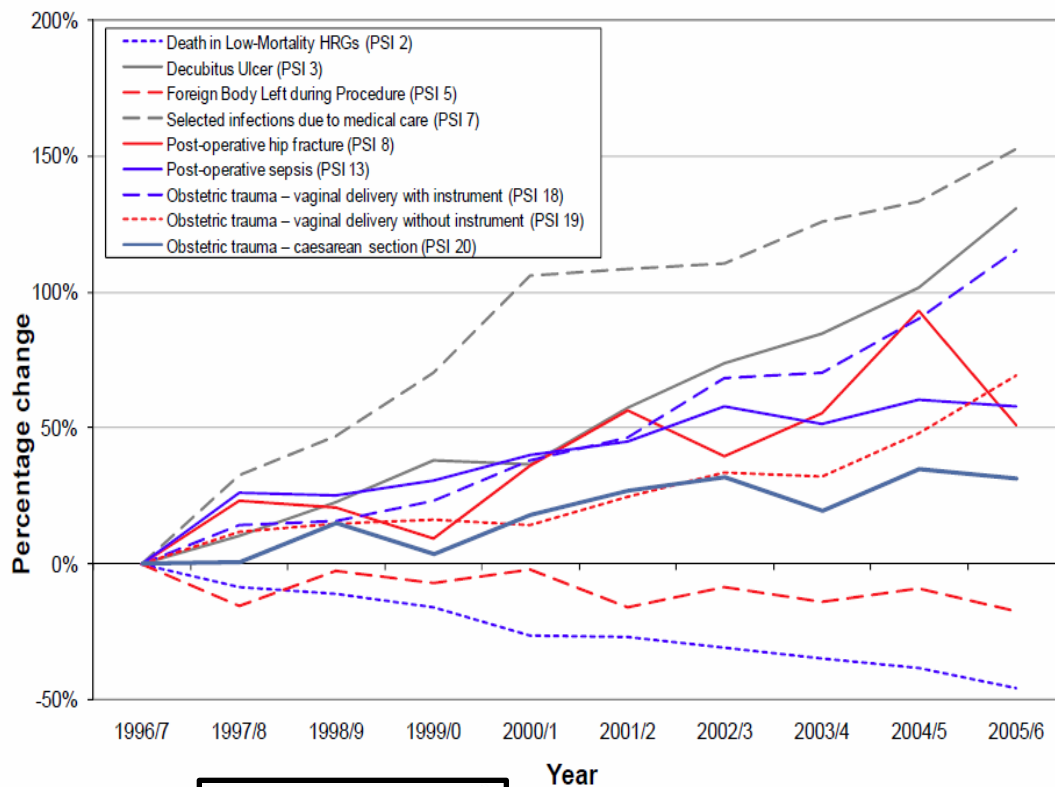Series Editors: Paul Barach, MD, MPH, and Donald M. Berwick, MD, MPP

IMPROVING PATIENT CARE

René Amalberti, MD, PhD; Yves Auroy, MD; Don Berwick, MD, MPP; and Paul Barach, MD, MPH

Professional Fishing

Fatal Iatrogenic
adverse events

Anesthesiology
ASA1

Cardiac Surgery
Patient ASA 3-5

Medical risk (total)

No system beyond this point

Hymalaya
mountaineering

Chartered Flight

Civil Aviation

Microlight
spreading activity

Road Safety

Railways (France)

Professional fishing

Chemical Industry (total)

Nuclear Industry

10^{-2} 10^{-3} 10^{-4} 10^{-5} 10^{-6} **Fatal risk**

Very unsafe *Unsafe* *Safe* *Ultra safe*

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Are we getting safer? The answer could be NO...

- **The United States Agency for Healthcare Research and Quality has made important advances by adding safety indicators.**

- **In UK, rates are actually increasing in all but two of the nine indicators so far translated.**

- **"Deaths in Healthcare Resource Groups" (HRGs) appear to be decreasing significantly.**

- **"Foreign Body Left during Procedure" is also decreasing slightly, but this indicator has been found to include many cases which are not related to patient safety.**

- **The remaining indicators appear to suggest that care is getting steadily less safe**

The answer is not that simple
We maybe do not understand what mean the figures

NEW CUYAMA
Population   562
Ft above sea level   2150
Established   1951
                    _____
          TOTAL 4663

Jes Søgaard 1982

The Patient Safety tree

In-Disease complications

Out_disease complications Infections, falls...

Timely and relevant Access

>90% of Quality problem and so called failures
Traditional focus of efforts
Improving continuously
Priority for professionals

Patients out of the loop Surprises, deception

9% of problems?
Usual dumb focus

Never events

<0.01% of problems
Priority for media scrutiny
Not improving / could worsen

Three interpretations, three strategies

1. **Poor results of patient safety figures are inconsistent : mix of process vs. outcomes related AEs, mix of severe vs. non severe AEs, mix of preventable vs. non preventable AEs. Forget this matter, and focus on medical strategies and associated benefits**

2. **Poor results are true : but they are inescapable consequences of a highly performing medicine : more patient included, more aggressive strategies. The problem is not that much to reduce the absolute number of AEs, but to keep them at an acceptable level when adopting innovative and performing medicine. The strategy mainly consists in identifying and suppressing the 'bad apples'**

3. **AEs are unacceptable (Victim's vision) : They must be reduced by all means, including slowing down innovation**

Four steps to make a system safer

1. MAPPING RISK

Mapping risk

Designing defenses and barriers

Risk Mapping and Risk analysis
Main methods

- **Preliminary hazard analysis (PHA)**

- **Failure mode and effect analysis (FMEA)**

- **failure mode effect and criticality analysis (FMECA)**

- **Hazard and operability study (HAZOP)**

- **Hazard analysis and critical control point (HACCP)**

- **probabilistic risk assessment (PRA)**

Reporting systems

- **Class 1 : based on staff**

- **Class 2 : based on patients**

- **Class 3 : based on traces**
  - **3a : medical records**
  - **3b : automatic surveillance system**

We excessively trust PREVENTION

Prevention

Failure

Acc...

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Variation in Hospital Mortality Associated with Inpatient Surgery

Amir A. Ghaferi, M.D., John D. Birkmeyer, M.D., and Justin B. Dimick, M.D., M.P.H.

ABSTRACT

BACKGROUND

Hospital mortality that is associated with inpatient surgery varies widely. Reducing rates of postoperative complications, the current focus of payers and regulators, may be one approach to reducing mortality. However, effective management of complications once they have occurred may be equally important.

METHODS

We studied 84,730 patients who had undergone inpatient general and vascular surgery from 2005 through 2007, using data from the American College of Surgeons National Surgical Quality Improvement Program. We first ranked hospitals according to their risk-adjusted overall rate of death and divided them into five groups. For hospitals in each overall mortality quintile, we then assessed the incidence of overall and major complications and the rate of death among patients with major complications.

RESULTS

Rates of death varied widely across hospital quintiles, from 3.5% in very-low-mortality hospitals to 6.9% in very-high-mortality hospitals. Hospitals with either very high mortality or very low mortality had similar rates of overall complications (24.6% and 26.9%, respectively) and of major complications (18.2% and 16.2%, respectively). Rates of individual complications did not vary significantly across hospital mortality quintiles. In contrast, mortality in patients with major complications was almost twice as high in hospitals with very high overall mortality as in those with very low overall mortality (21.4% vs. 12.5%, P<0.001). Differences in rates of death among patients with major complications were also the primary determinant of variation in overall mortality with individual operations.

CONCLUSIONS

In addition to efforts aimed at avoiding complications in the first place, reducing mortality associated with inpatient surgery will require greater attention to the timely recognition and management of complications once they occur.

The worst hospitals are not those exhibiting the highest rate of Aes but those not so efficient in taking care of complications due to AEs

Adopt a new vision of Adverse Event analysis

The silo technical vision
Time continuity
Specialty dependant

The Integrated patient life's journey vision
Stats from end (AE) and look backwards on the evolution of the disease

Causes of Aes
Understanding causes

AE

Consequence of Aes
Managing complications

Consequence of AEs

Good care recoveries

Good & bad care recoveries

More or less effective rehabilitation

Potential AE
Drug errors
Poor Strategy
Poor Compliance...

long term Mortality
Amenable Mortality

Time horizon

Patient life's journey trough out the medical system

The patient 's medical episode vision
Consider a longer period of time
Analysis extended backward and forward to the previous and next transition of care

2. Confronting the model to the real life

Detecting deviance

Adapting the barriers to real conditions

The 'power of innovation'

Of 100 systematic reviews

Median time to a change that would effect clinical decisions was 5.5 years.

Figure 2. Overall survival time (95% CI) free of signals for updating.

Median Survival (95% CI) 5.5 (4.6–7.6)

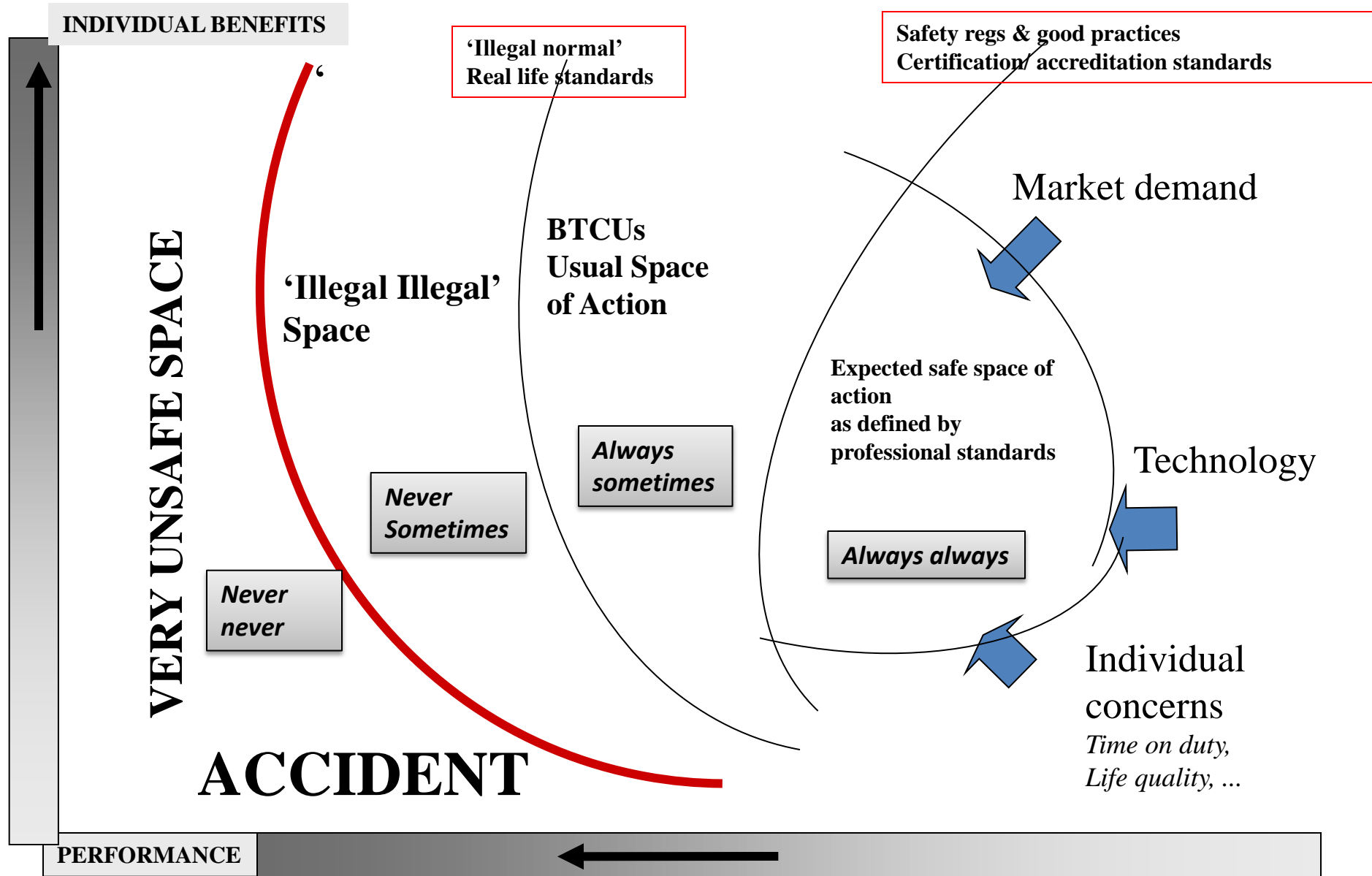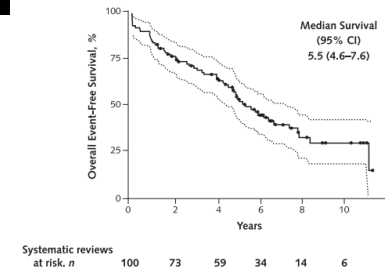| Systematic reviews at risk, n | 100 | 73 | 59 | 34 | 14 | 6 |

The immediate decrease in survival at time zero reflects the 7 systematic reviews for which signals for updating had already occurred at the time of publication. The low number of reviews at risk after 10 years reflects the fact that the sample spanned 1995 to 2005 and censoring occurred on 1 September 2006. Thus, only reviews published before September 1996 and having no signals for updating could have more than 10 years of observation.

Average cycle of Quality interventions in complex systems

2 Years to see the problem

2 Years to see local solutions

1 more Year to see solution endorsed by medical Agencies

10 Yrs minimum

5 years for spreading out solution within all the professional community

Innovation rate per decade

SURGERY

Radiographies

Prophylaxies

Anesthesiology

Techniques

Medical devices

Jets

Automated a/c

ATC

Data-link

AVIATION

60 70 80 90 00 10

Years

The 'STreet lamp strategy'

LIGHT

DARKNESS

The two-sides of the street lamp

- **Adopt a triangle strategy**
- **Plan three indicators including two for side effects when designing a new safety rule**

Examples

Blood Transfusion

NHS PS targets
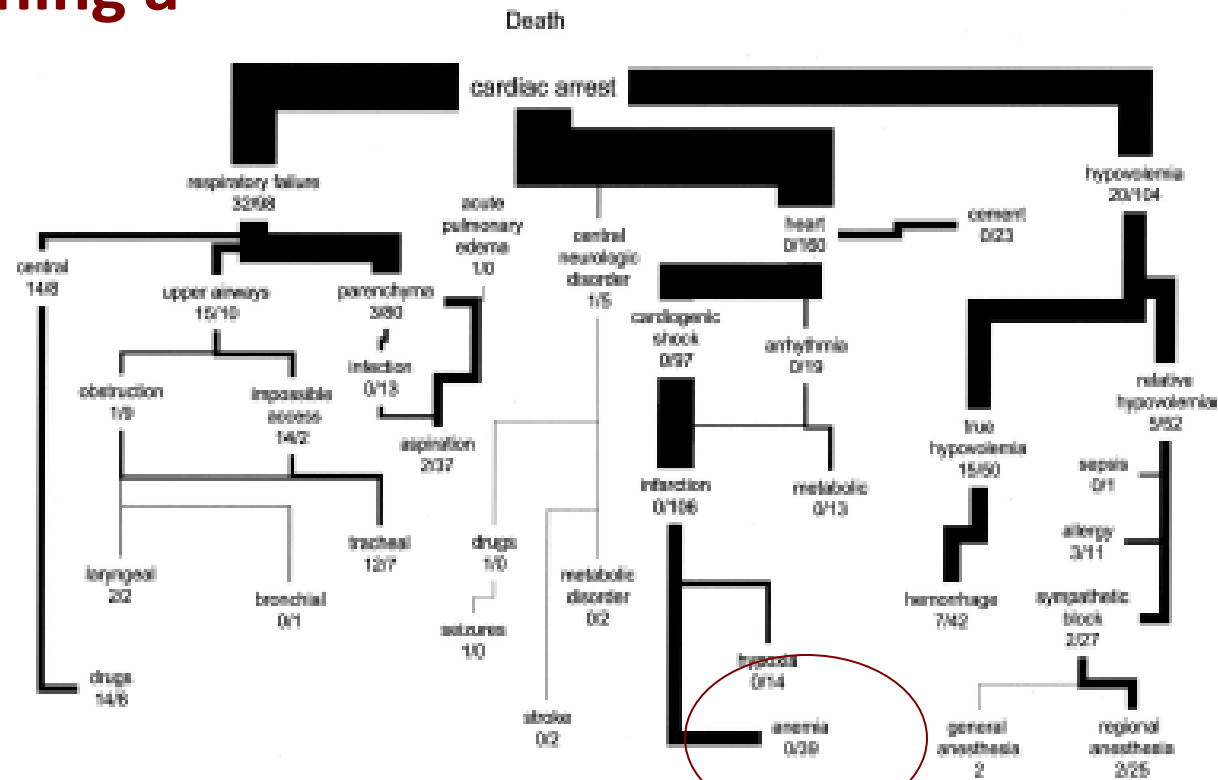
Survey of Anesthesia-related Mortality in France

André Lienhart, M.D.,* Yves Auroy, M.D.,† Françoise Péquignot,‡ Dan Benhamou, M.D.,§ Josiane Warszawski, Ph.D., M.D.,‖ Martine Bovet,# Eric Jougla, Ph.D.**

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The 'Tuesday' paradigm

- **Design Principle: Staff's highest bid** *(best effort)* **in thinking safety**
  - Design ideal policy based of best conditions, full staff, best competences ('the Tuesday morning when all staff is present').
  - Process oriented interventions, nice to do

- **... Not working at nights, week-ends, holidays periods...**

- **Examples**
  - Pain management with a permanent infusion of anaesthetic drugs using a crural cath.
  - New cleaning protocols for endoscope tools (prion-resistant)
  - Washing hand protocols before 2001 and the generalization of hydro-alcoholic solutions

The limit of good solutions....

Accident

failure

Mitigation

Recovery

Prevention

Selon Jean Pariès, Dédale SA

failure

Accident

Mitigation

Recovery

Prevention
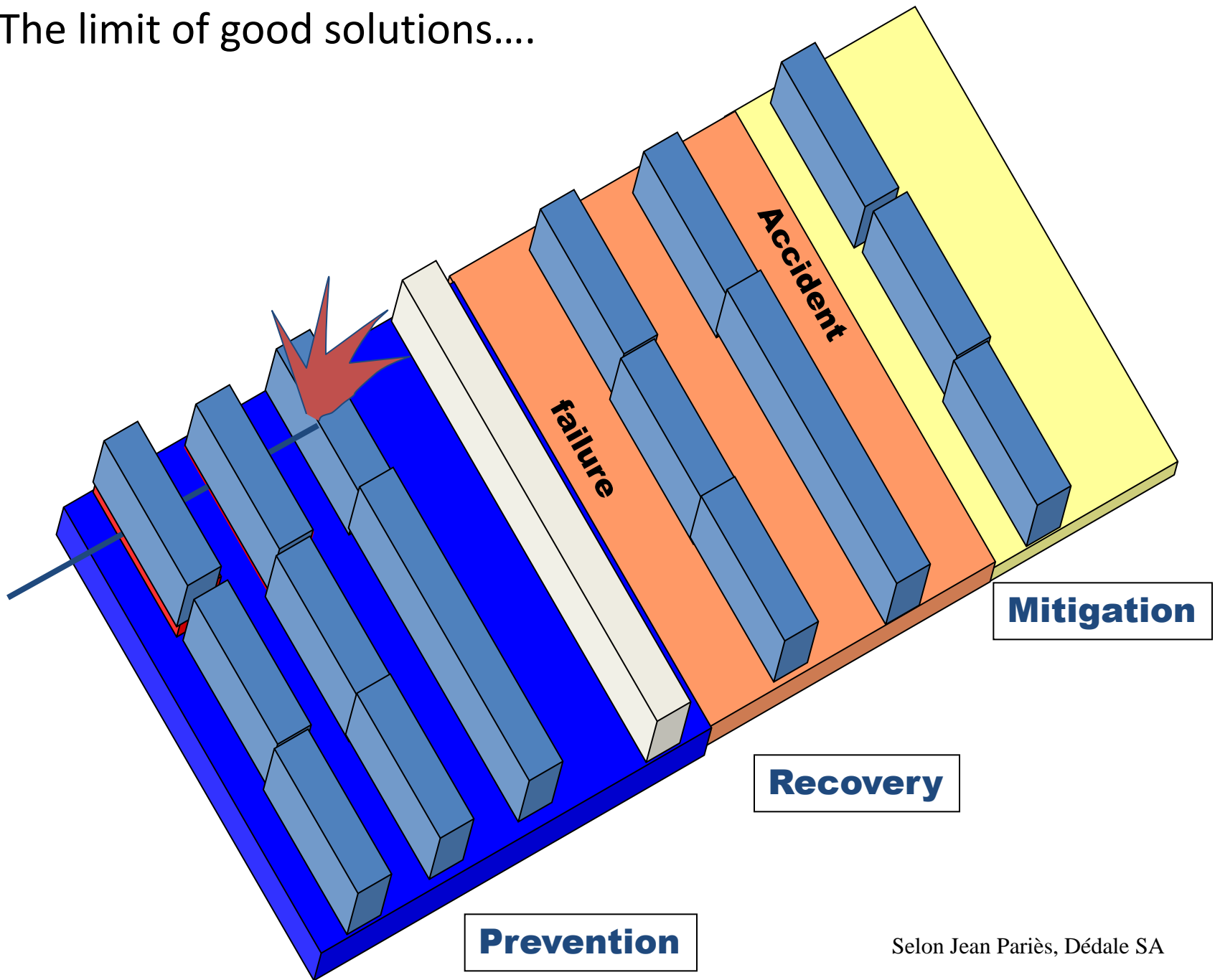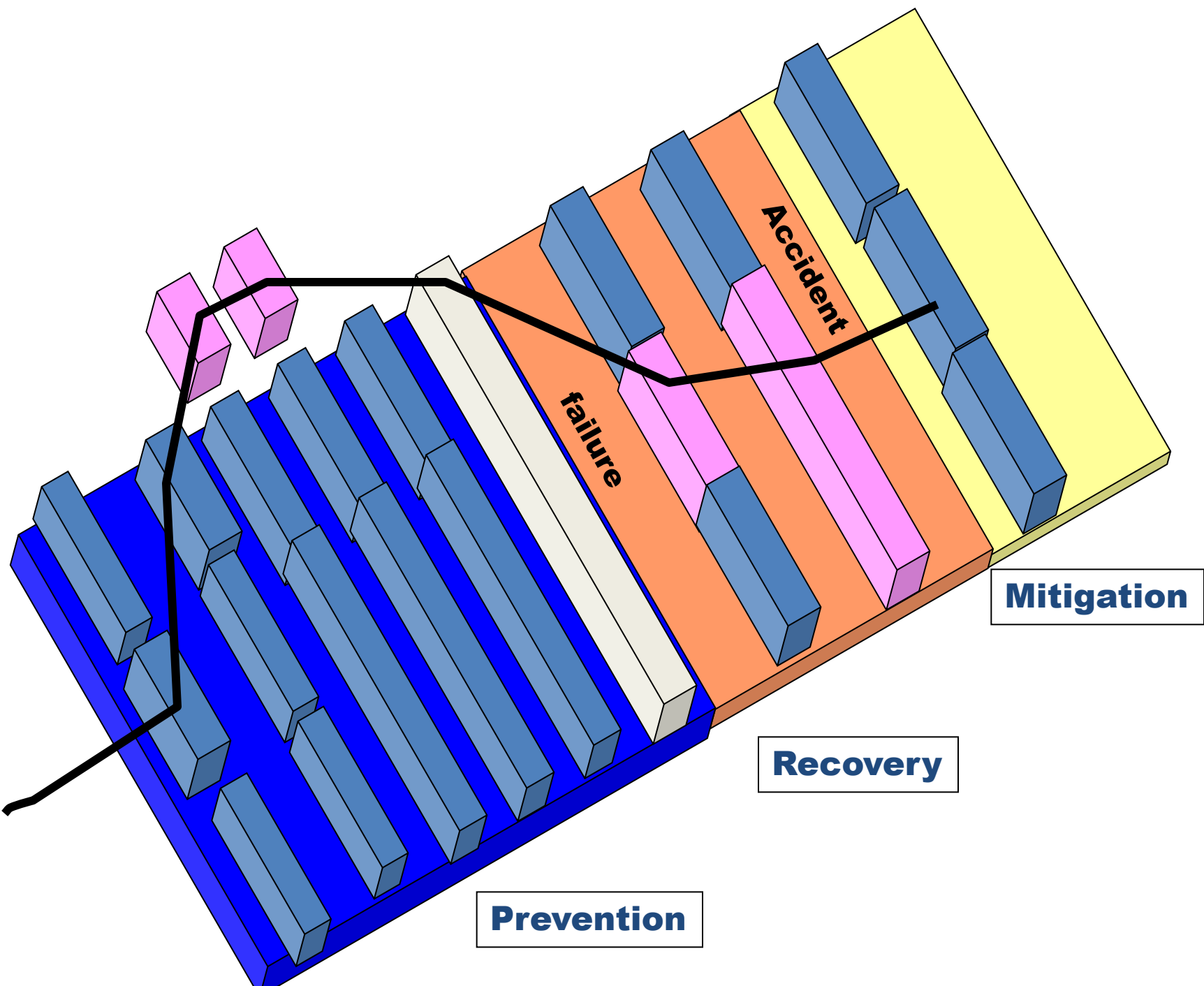
Designing Safer Safety Policy

Score your matrix	P1	P2	P3	P4	P5	P6	P7
	Perceived efficacy	tolerance to non compliance	Easiness of Sacrifice	Extra resource needed	Conflict with other policy	Side effects	No measure of outcome
NO IDENTIFIED RISK	DESIGN SOUNDS PERFECT - HIGH BENEFITS EXPECTED						
CUMMULATION OF DRAWBACKS							
ONE ISOLATED ORANGE	YOUR POLICY SHOULD WORK provided you control Drawback						
Any Of TWO POSITIVE	YOUR DESIGN NEEDS SIGNIFICANT MODIFICATION TO LIMIT POTENTIAL						
Any OF THREE POSITIVE							
Any OF FOUR POSITIVE	YOUR DESIGN HAS NO CHANCE TO BE BENEFICIAL FOR SAFETY						
Any OF FIVE ORANGE	YOU ARE CREATING RISK WITH YOUR SAFETY POLICY						
ANY RED							

3. ADOPTING A SYSTEM APPROACH

The pionnering model

PATENT ERRORS

IN-DEPTH DEFENSES

ADVRSE EVENT

Exemples

Orgnization and design

Work pressure

Working conditions
Fatigue
Staff shortage...

The REASON's Swiss Cheese model, 1991

35

Time (hours, days, months)

Margins

Patient's tempo : time lost by patient to make decision to consult the doctor, and clearly tell the symptom during the consultation (at the right moment, with the right priority), symptoms and expectations

GP's and Office's tempo: time spent by doctors to see the patient (access , visit) listen to symptoms, negotiate with and educate the patient in a short time of consultation, that must deal with various personal and patient's competitive priorities and demands

Patient's tempo : delayed decision to follow prescriptions, and make examination

System's tempo : time lost to get a rendez vous and results back from biology, radiology or specialists,

Disease and treatment's tempos: expected window of time during which medical actions should take place to remain in control of the disease

Patient's tempo : time lost with poor compliance, nomadism, etc.

Reduction of symptoms
Control of the disease

Complications, Lost of control

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No limit in performance · *Increasing safety margins*

Excessive autonomy of actors · *Becoming team player*

Craftman 's attitude · *Accepting to become equivalent actors*

Ego-centered safety protections, vertical conflicts · *Accepting to endorse residual risk*

Loss of visibility of risk, froozing actions · *Accepting to question the success and to change strategies*

Blood transfusion

Anesthesiology ASA1

Fatal Iatrogenic adverse events

Cardiac Surgery Patient ASA 3-5

Medical risk (total)

Hymalaya mountaineering

Chartered Flight

Civil Aviation

Microlight or helicopters spreading activity

Road Safety

Railways (France)

Chemical Industry (total)

Nuclear Industry

No system beyond this point

| 10^{-2} | 10^{-3} | 10^{-4} | 10^{-5} | 10^{-6} | Fatal risk |

Very unsafe

Ultra safe

Why Civil Aviation is an Ultra Safe System

- **A old established worldwide regulation**
  - **OACI**
  - **EASA, FAA**
  - **IATA**
- **A rich industry, betting and affording technical innovations**
- **An immense standardization of materials**
  - **Very few manufacturers**
  - **Incredible family standardization inside each manufacturers' fleet**
- **An immense worldwide standardization of personnel**
  - **Licencing and training identical worldwide**
  - **Recurrent imposed**
- **A permanent regulation and control of actions (big brother)**
  - **ATC**
  - **Black boxes, systematic flight analysis, LOSA**
  - **Voluntary reporting is just for accessory additional information**
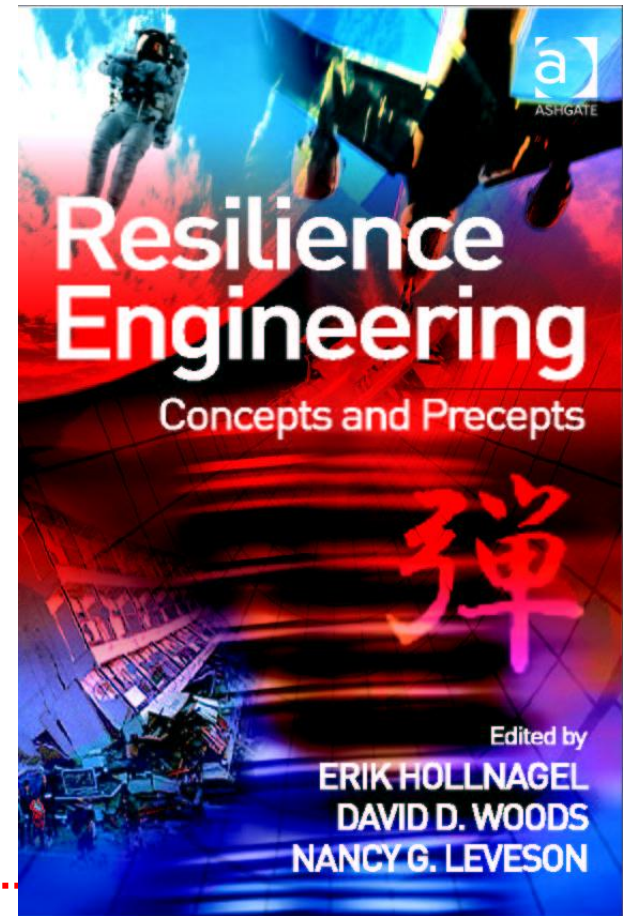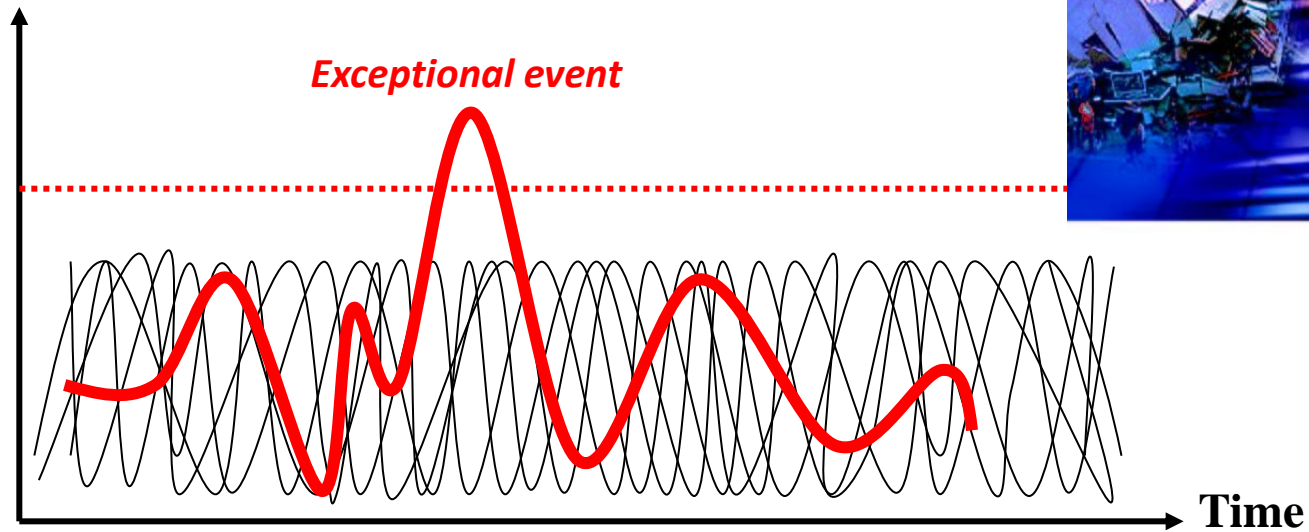
> **How many of theses traits apply to Medicine?**

4. RESILIENCE

The inductive turkey

From Bertrand Russell
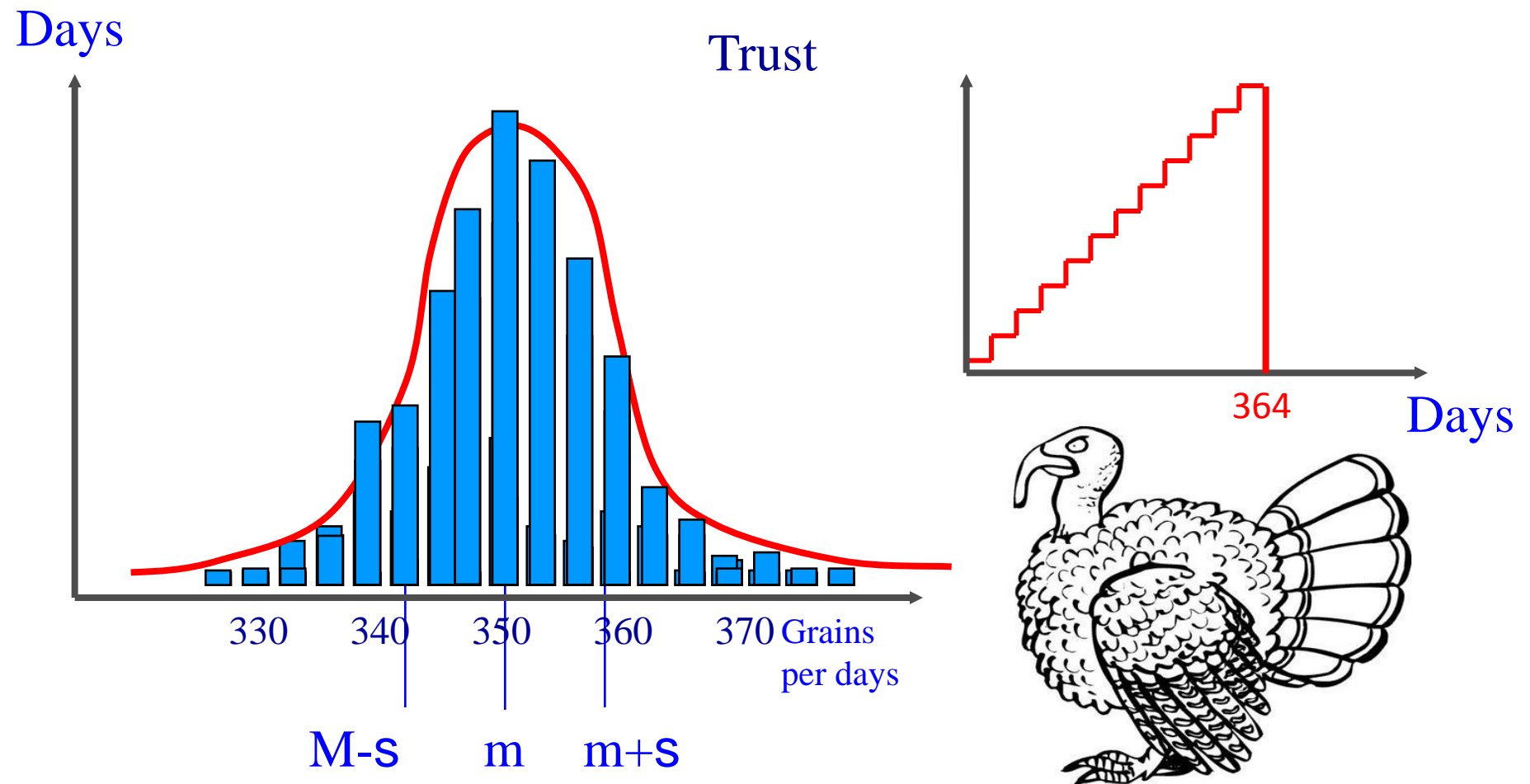
Performance range

Exceptional event

Time

Understanding resilience
Resilience $S_t = S_i + S_m$

S_t (Safety total) = S_r (Safety imposed)+ S_g(Safety managed)

NORMS / QUALITY   +   RESILIENCE

Observed Safety	Error avoidance BBS/CBS/HRA Based on Technology Regulations Constraints	Surprises management Based on Human expertise Adaptive learning systems

Amalberti, R. Optimum system safety and optimum system resilience: agonist or antagonists concepts? In E. Hollnagel, D. Woods, N. Levison, Resilience engineering : concepts and precepts, Aldershot, England: Ashgate, 2006: 238-256

Significant safety improvements always detrimental to S_m

Craftman industry $\quad S_{t=} \quad S_i \quad + \quad S_m$

Safety improvement

Ultrasafe systems $\quad S_{t=} \, S_i \, + \, S_m$

The next challenge : Preverving S_m while Improving S_i

$$S_{t=} \, S_i \, + \, S_m$$

Toward a strategic view on medical safety – a tentative mapping exercise
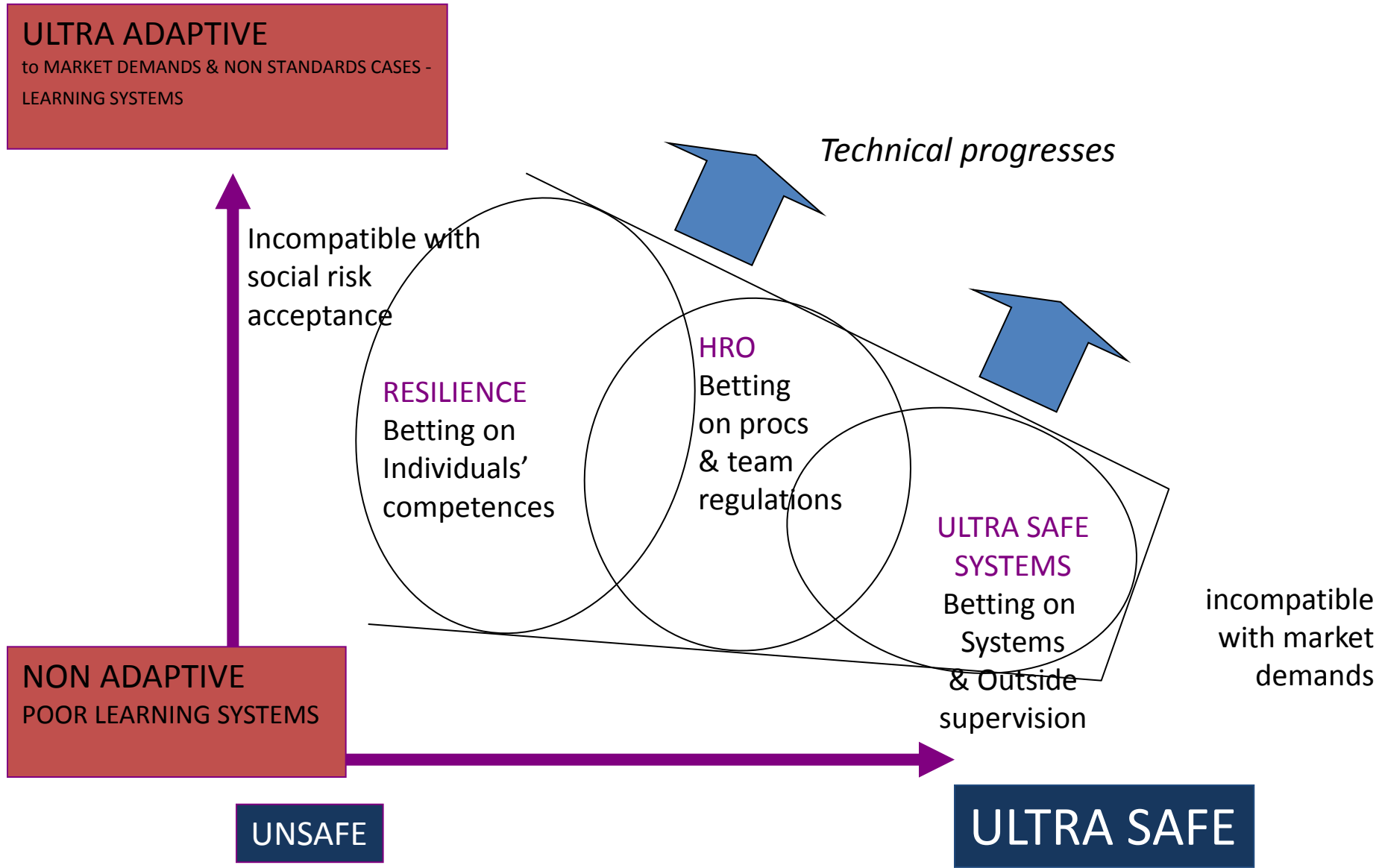
CONCLUSION

- **Healthcare is still *performance driven* rather than *safety driven***
  - **We are using an immature model of safety**
    - We train our staff to be as safe as possible when being exposed to the unexpected
    - We change the rules of the game every day, so no measure make sense
    - We use intuitions rather than formal model to map risks, hence we are only protected against our believes
    - We over trust prevention to the detriment of recovery and mitigation
    - We trust local champions although safety improvement is likely related to the equal distribution of same values (even minimal) to all staff and settings at the nation level
  - **Turning to be truly safety driven could be significantly consequential for the performance model**
    - Stabilizing environment : reduce exposition of professionals to risks, keep them working with the expected (protocol driven)
    - Turning to equivalent actors
    - Slowing down the pace of innovation
  - **Not certain we are ready to make a decision for such a choice**
  - **However, IT's could likely introduce more supervision hence accelerate normalization.**