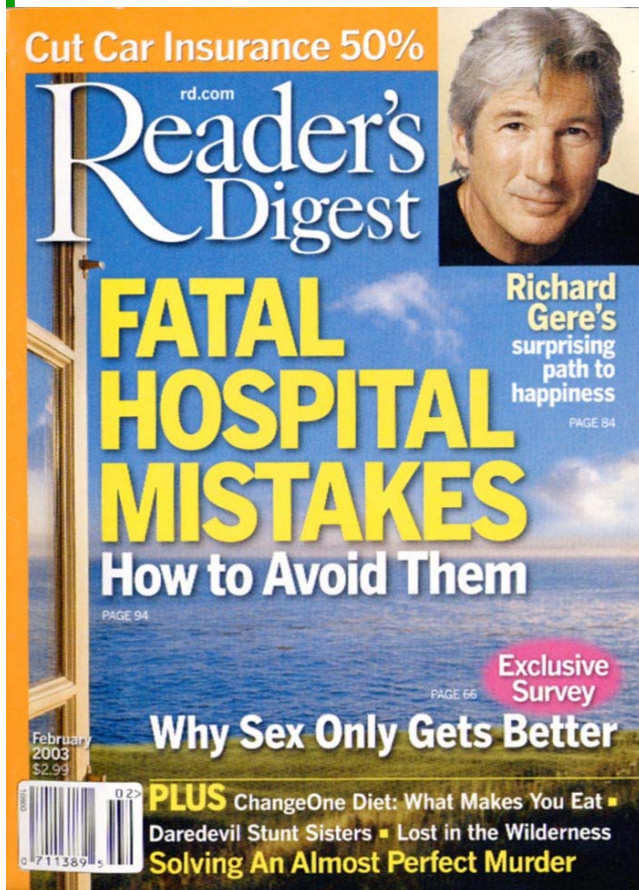


Thinking Systemic in Patient Safety



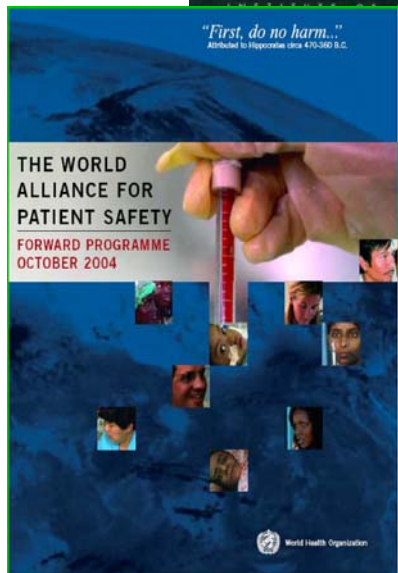
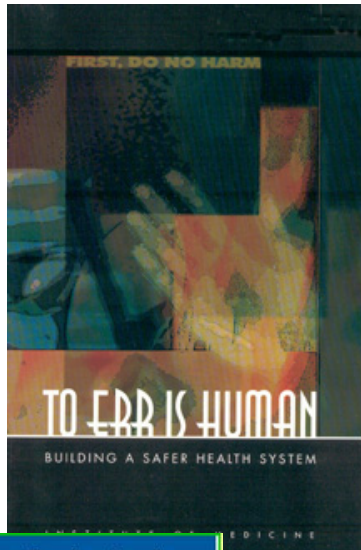
René Amalberti
IMASSA / HAS

Safety in the medical field

The challenge of the unstable

- **Work never stops,**
- **Hospitals never close even when facing excessive demand or/ and (chronic) staff shortage,**
- **Patients are not standards products,**
- **Need for a continuous and intensive synergy among a great variety of workers (including beginners) inside and outside the hospital.**

Major advances in the past decade (1995-2005)



- **Creating room for problem awareness**
 - Better publicity
 - Making Preventable Adverse Events an official and tractable area of focus for doctors and CEO's
- **Identifying the most frequent loopholes**
 - Drug Adverse events
 - Nosocomial infections, etc.
 - Surgery AEs, etc.
- **Designing safety plans, supporting and multiplying local incentives**
- **Increasing the surveillance of the system (reporting, audits, accreditations, etc)**

Four Competitive Safety Models to establish a Safer System in the industry

- **System Risk Assessment and Human Reliability Assessment (SRA/HRA)**
- **Behavior-Based Safety models and Culture-Based Safety models (BBS/CBS)**
- **Systemic and organizational models (Swiss Cheese and further models)**
- **Resilience**

Safest industries have trusted SRA/HRA, BBS/CBS models

1. Identifying the scale and the origins of Aes

**A prerequisite of HRA and BBS
models**

Identifying AEs Methods

- **Field Observations**
- **Chart reviews**
 - **Standards Vs Trigger tools (IHI)**
- **Reporting systems**
 - **Class 1: based on Medical staff**
 - **Class 2: based on Patient**
 - **Class 3: based on ITs**
- **Walk rounds**
- A broadly applicable senior management tool that incorporates front-line insights into operational decisions and guarantees feedback loops.



Limited validity of spontaneous incident reporting of class 1



Barriers to incident reporting in a healthcare system

R Lawton and D Parker

Qual. Saf. Health Care 2002;11:15-18
doi:10.1136/qhc.11.1.15



Doctors mistrust systems for reporting medical mistakes

Caroline White

BMJ 2004;329:12-
doi:10.1136/bmj.329.7456.12-d

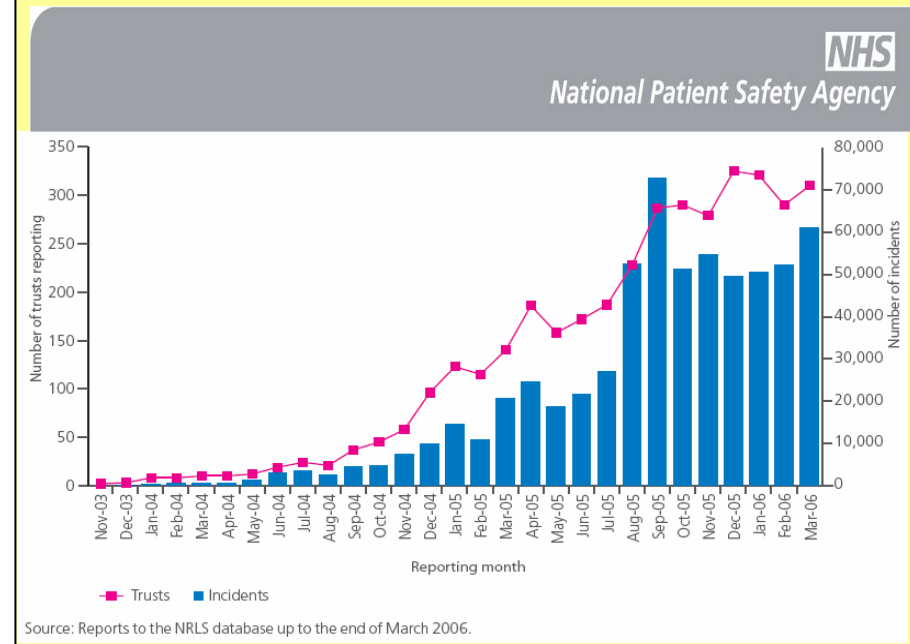
- **Massive underreporting**
= unknown denominator
- **Instability of error and AE definitions :**
poor validity of available information

Barriers to incident reporting

- **Fear for juridical disclosure**
 - Safe reporting (professionals immune from disciplinary action)
- **Complexity, understaffing**
 - System design (avoid cumbersome & time consuming systems)
 - Voluntary Vs Mandatory system, too many systems...
 - Severe Under Staffing in the analysis process
- **Incorrect mental representation of errors and AEs**
 - Instability of the definition of medical error and AEs

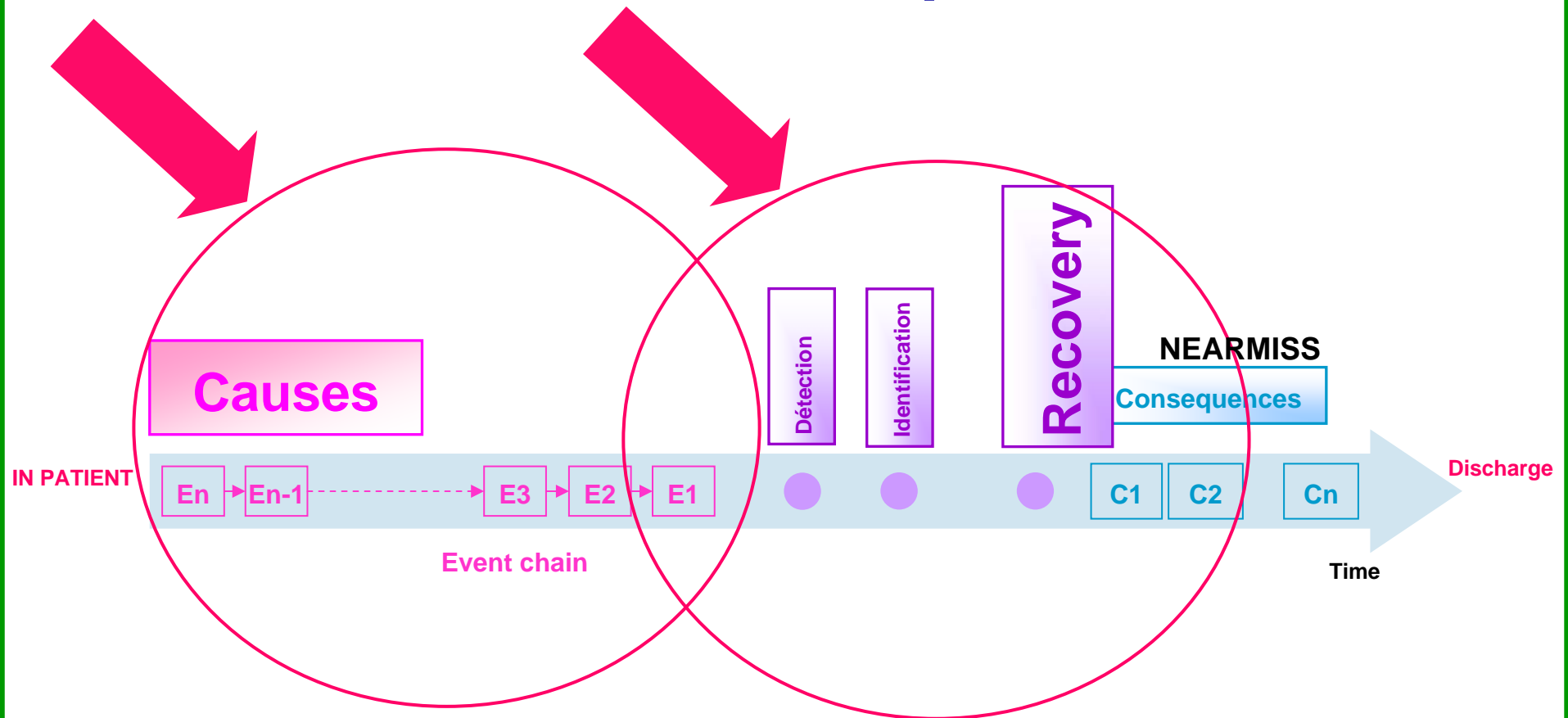


For what goal?



- **National alerting system**
 - The UK experience
- **Local Learning system**
 - RCA Vs System analysis

The power of nearmiss : focusing on the two sides of the problem

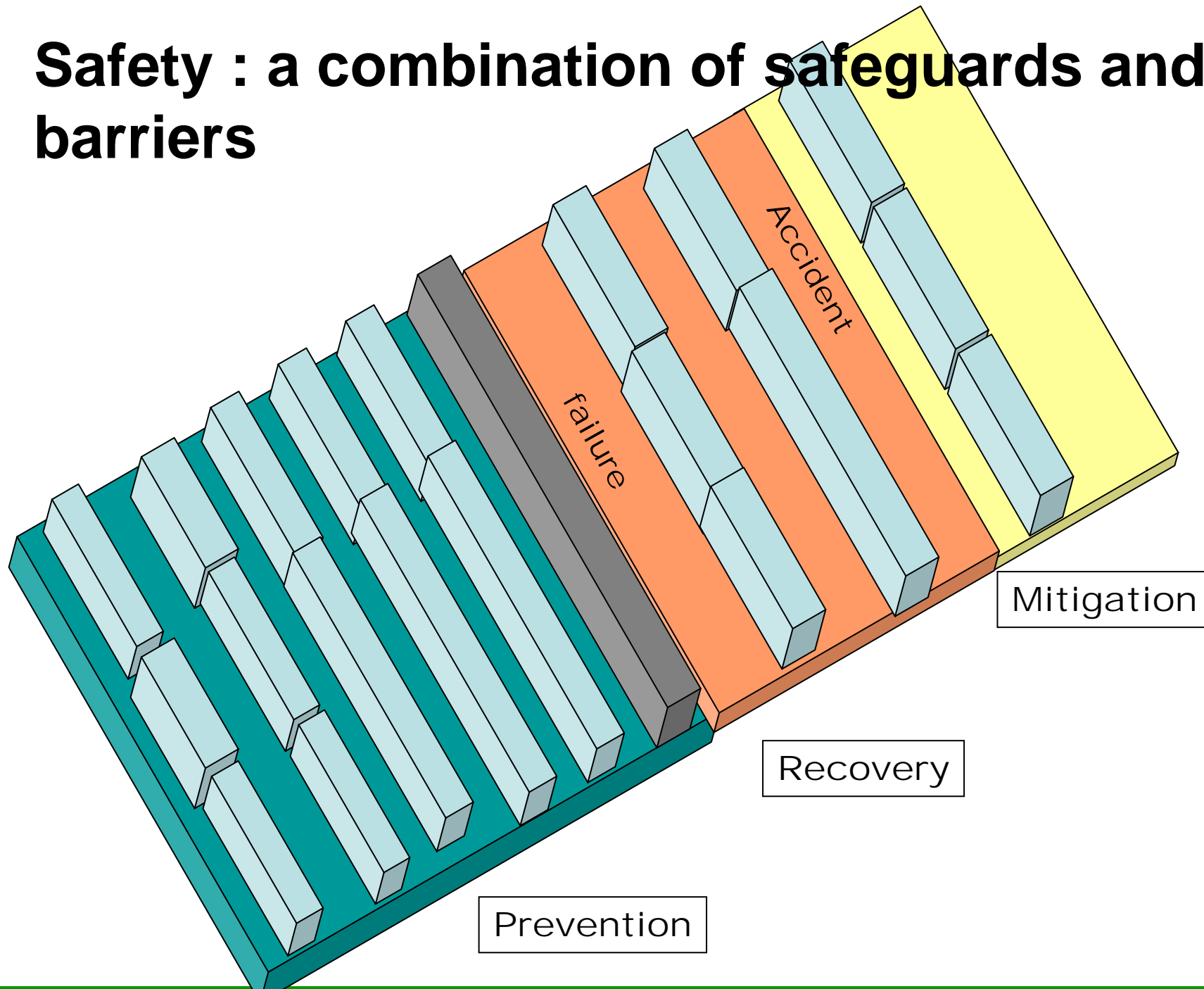


2007's new French certification program of doctors using nearmiss, EPR (Evénement porteur de risque, Risk-related events)

2. Human Reliability Assessment Models

**Reducing obvious causes of errors
adopting ITs, improving ergonomics of drugs, materials, and work
organizations**

Safety : a combination of safeguards and barriers



A series of 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)***

Reducing variability

- **Continuous quality improvement**
- **Protocols**
- **Prescriptive strategies**

Next challenges

- **Person and Establishment Certification**
- **Stronger professional alignment**

After Paul Barach, June 2004, Jackson Medical Hospital, Miami



Improving document structure

- explicit reminders influence completeness of orders

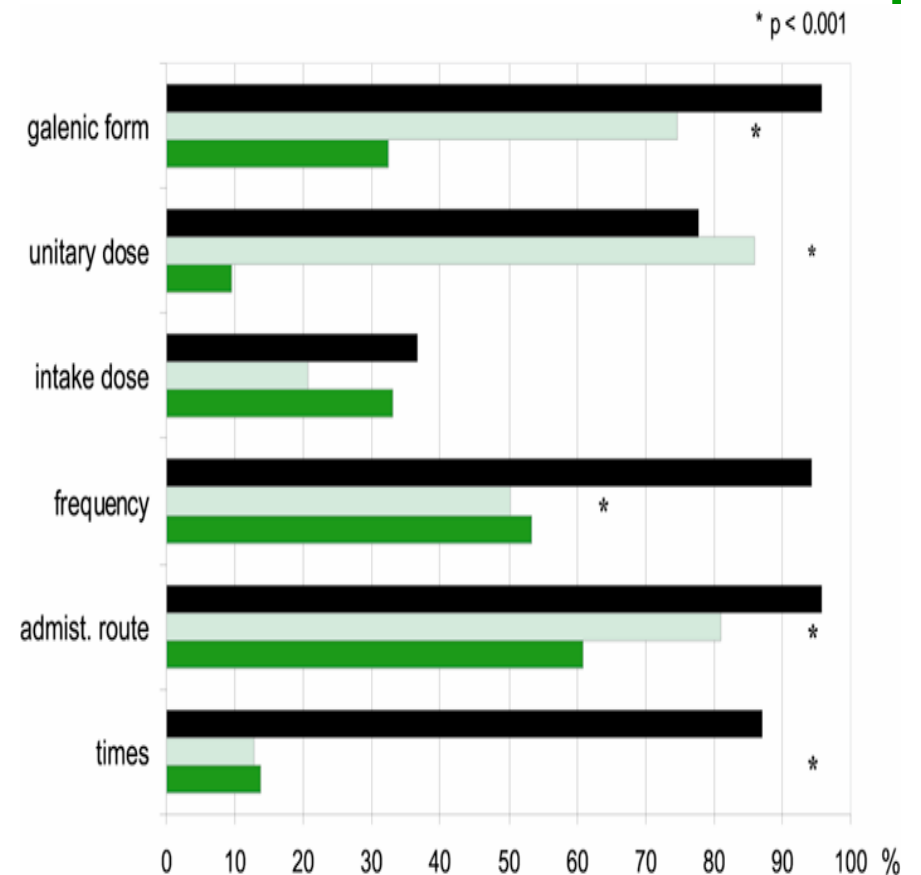
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| Date | Forme galénique et nom du médicament | Dosage unitaire | Répartition | Visa Méd. | Visa Inf. |
|------|--------------------------------------|-----------------|-------------|-----------|-----------|
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| DATE | ORDRES MEDICAUX | Donnés par Dr | Exécutés par l'infirmière |
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| | | | |

Measuring human-error probabilities in drug preparation: a pilot simulation study

P. Garnerin · B. Pellet-Meier · P. Chopard · T. Perneger · P. Bonnabry



Developing Information Technology systems (ITs)

- **Four main objectives**
 - Electronic patient record (EPR).
 - Personal health record
 - Decision-support tools
 - Electronic handoffs

HIT and MIS: IMPLICATIONS OF HEALTH INFORMATION TECHNOLOGY AND MEDICAL INFORMATION SYSTEMS

*Evaluating the potential advantages and considering the risks
associated with electronic health care records.*

By PETER G. GOLDSCHMIDT

bmj.com

**Using information technology to reduce rates of
medication errors in hospitals**

David W Bates

BMJ 2000;320:788-791
doi:10.1136/bmj.320.7237.788

QSHC
ONLINE

**Methodology and rationale for the measurement of
harm with trigger tools**

R K Resar, J D Rozich and D Classen

Qual. Saf. Health Care 2003;12:39-45
doi:10.1136/qhc.12.suppl_2.ii39

Developing Information Technology systems (ITs)

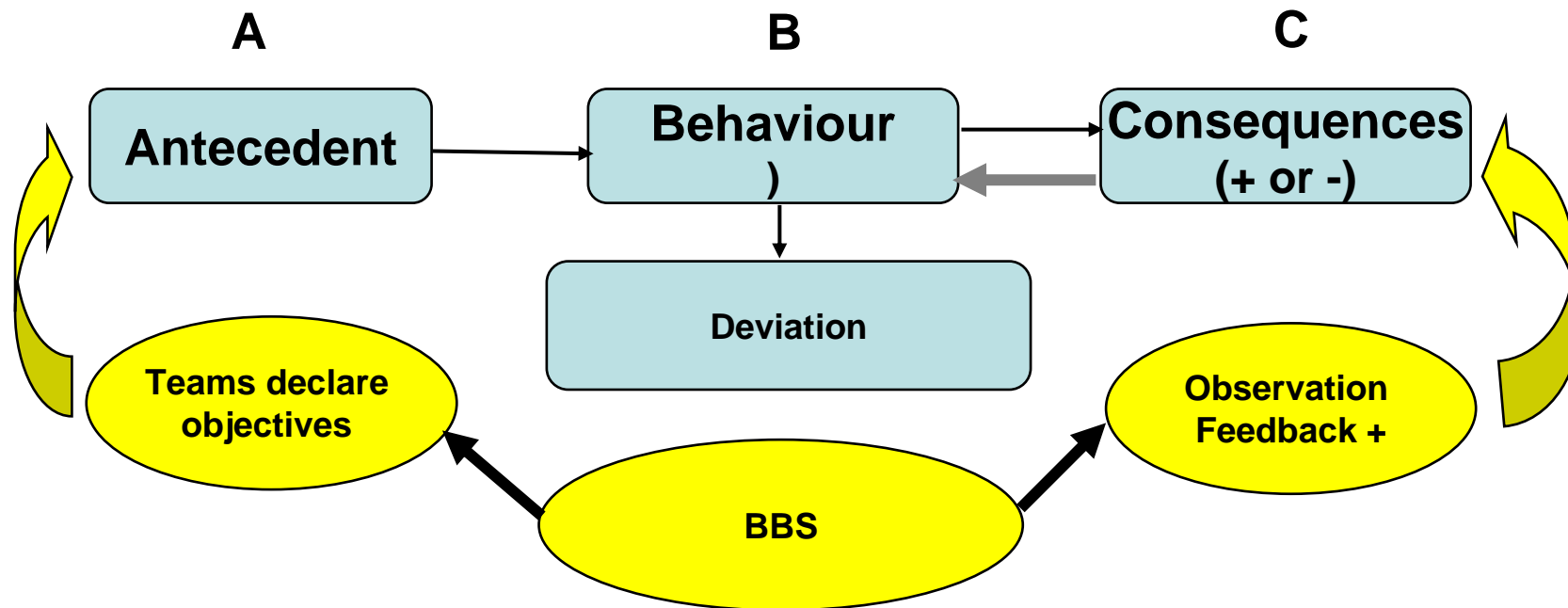
- Great enthusiasm, great disappointment
 - Scalability
 - Usability and Human factors studies should become first priority (not commercial issues)
- Harmonization required,

Selecting Indicators for Patient Safety at the Health Systems Level in OECD Countries

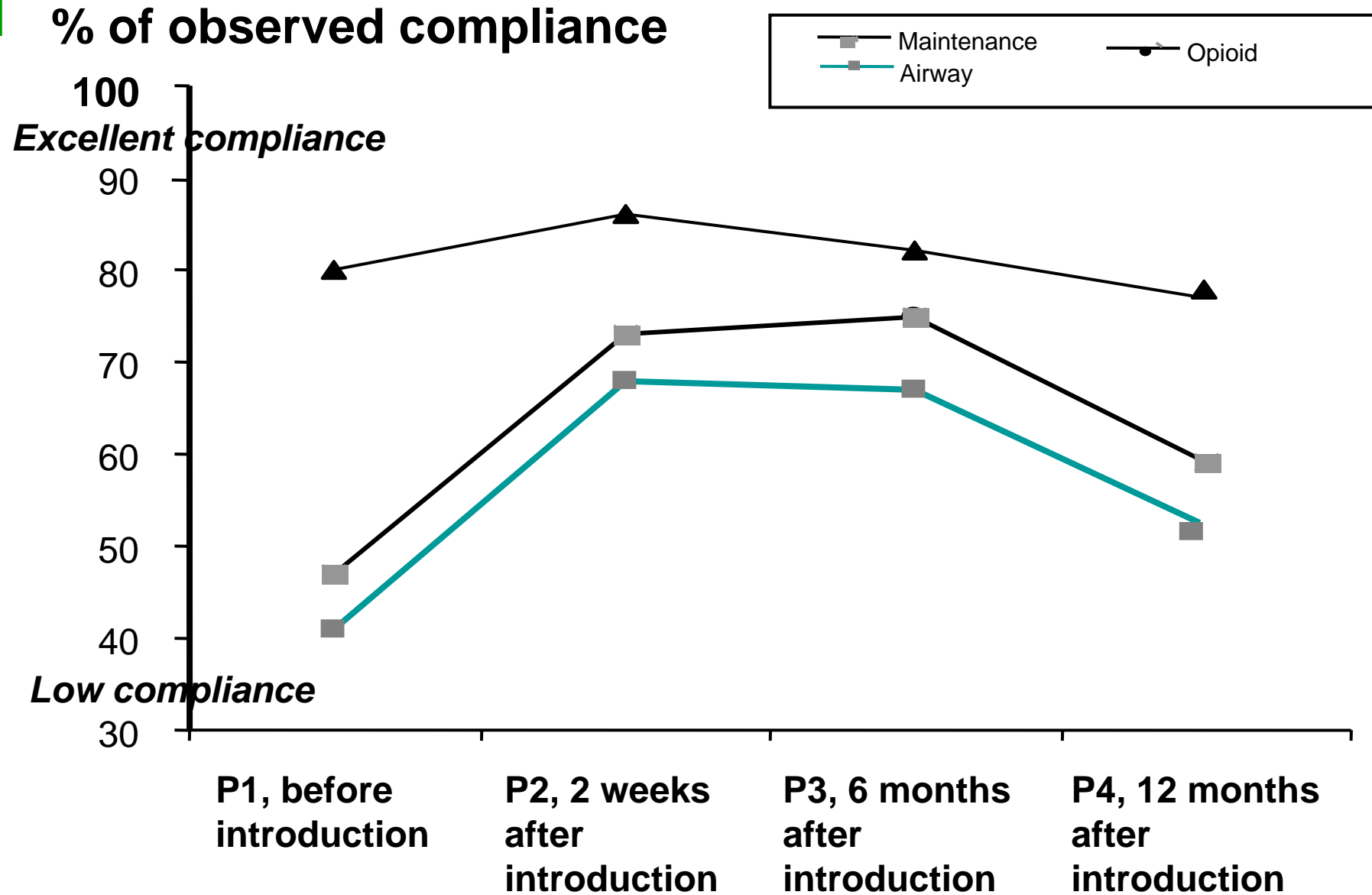
- [http : //www. oecd. org/dataoecd](http://www.oecd.org/dataoecd)
- Selection of 59 potential PSIs for their:
 - Importance to patient safety
 - Scientific soundness, and
 - Potential feasibility.
- A final list of 21 indicators was selected

3. Behavior-Based Safety (BBS) and Culture-Based Safety (CBS) models

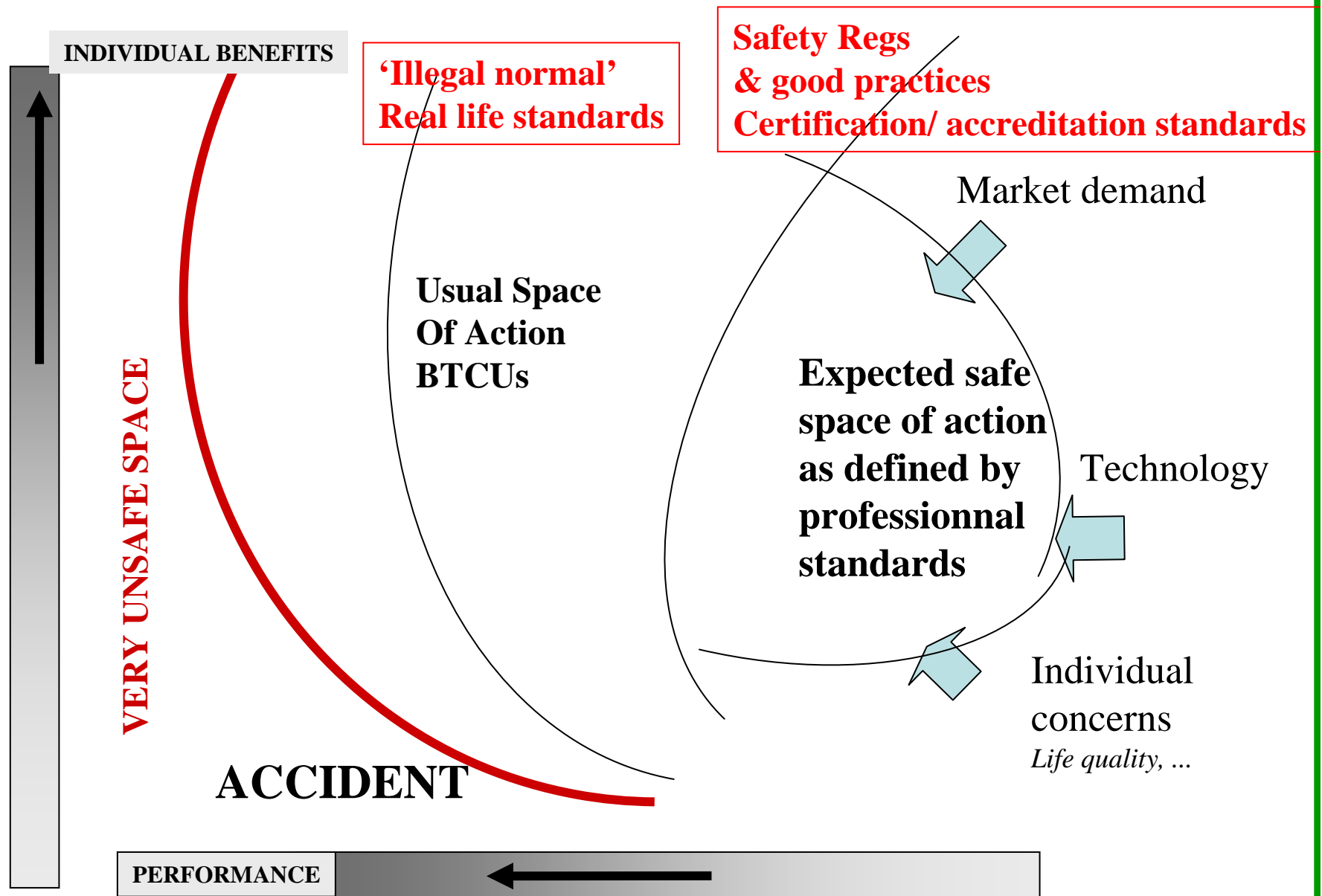
Principles



The natural lifespan of a safety policy



A comprehensive framework model



Usual causes of migrations

Application to the medical cases

- **Constraint on legal procedure**
 - Unachievable goal
 - Exceptional conditions: compliance higher for difficult cases; lower for routine cases'
 - Time missing, sub-system missing, sub-system inoperative – failure
- **Violation prone Individuals**
- **Facilitation of group cohesion**
- **Resilience of old procedure(s)**
 - Cost oriented conservatory strategy
- **Disputable rule**

Two solutions

Accepting reasonable risk in design
Facilitating pair-to-pair dialogues

**BTCUs
Violations**

VERY UNSAFE SPACE

ACCIDENT

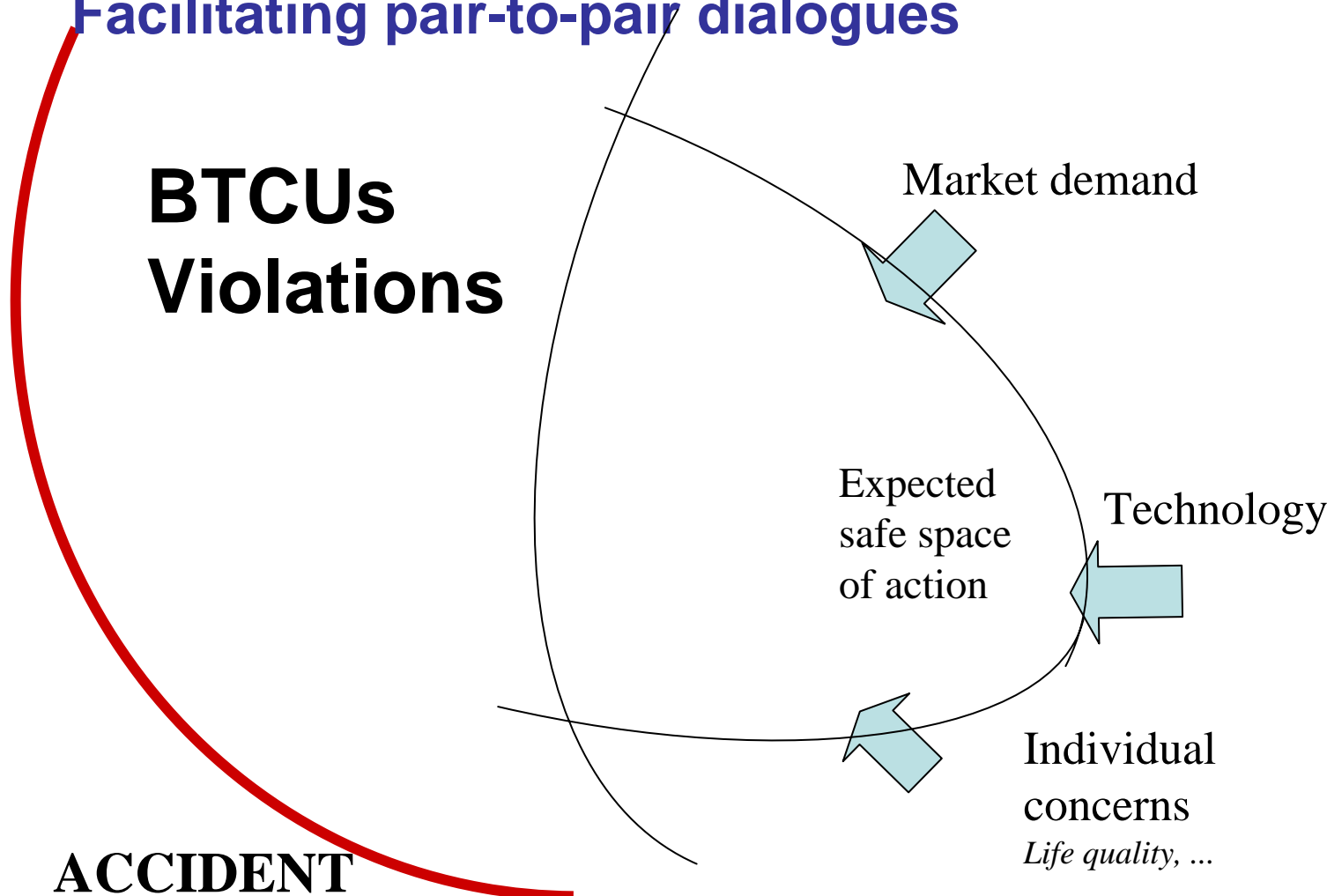
Market demand

Expected
safe space
of action

Technology

Individual
concerns
Life quality, ...

PERFORMANCE



Evolutions

BBS

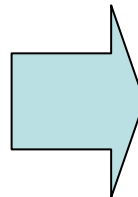
1970's – 80's

Behaviour Based Safety (BBS)

(observation & feedback programs)

Anchored on individual behaviour
influenced by consequences

Limited to rule compliance



CBS

1990's – 00'

Culture Based Safety (CBS)

(culture on working position)

Intergrating leadership, attitudes,
and management style,

Encompass positive generative safety
attitudes

Two Approaches, two philosophies

- **Focusing on Workers at Working positions**

- Addressing teamwork attitudes, co-operation, communication, reporting, error management, adherence to procedures, minimization of deviance
- Blame free organizations considered as a prerequisite
- Belief : changing workers' perception on risk will improve safety,
- errors and violations management as a main target
- Often associated in the industry with
 - BBS (Behaviour-based safety programs) and CBS (Culture-based Safety programs) strategies (Chemical industry, Nuclear, ...)
 - Error management, Crew behavior, Non technical skills, maintenance in industry, *
 - Accepting errors as a natural outcome of human activities, maximizing error recovery but refusing deviances (Just culture, Marx)
- Measurement : questionnaires, and audits : e.g. SAQ



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

ORIGINAL SCIENTIFIC ARTICLES

The Impact of Aviation-Based Teamwork Training on the Attitudes of Health-Care Professionals

Eric L. Geagan, MD, MPH, Randy A. Scales, PhD, Daniel J. France, PhD, MPH, Theodore Spafford, PhD, John A. Meyer, Jr, MD, PhD, Bill Nissen, MD, F. Andrew Gaffney, MD, Bruce Seddon, MD, C. Wright Parnon, MD, MBA, FRCG

BACKGROUND: Both the Institute of Medicine and the Agency for Healthcare Research and Quality suggest patient safety can be enhanced by implementing aviation-based teamwork training. Crew Resource Management (CRM) in health care, CRM emphasizes key areas: managing fatigue, creating and managing teams, recognizing adverse situations and flagging them, and communication, decision making, and performance feedback. This study evaluates participant reactions and attitudes to CRM training.

STUDY DESIGN: From April 22, 2003, to December 11, 2003, clinical teams from the trauma unit, emergency department, operating rooms, cardiac catheterization laboratory, and labor-and-delivery underwent an 8-hour training course. Participants completed an 11-question End of Course Culture (ECC) designed to measure perceived level of teamwork and adherence to CRM standards.

BMC Health Services Research

Research article

The effect of executive walk rounds on nurse safety climate attitudes: A randomized trial of clinical units

Eric J Thomas¹, J Bryan Sexton², Torsten B Neilands³, Allan Frankel⁴ and Robert L Helm

Address: ¹Department of Biotechnology and Clinical Evaluation, USA, ²Center for Systems, Frederick, USA, ³Center for Systems, Frederick, USA, ⁴Center for Systems, Frederick, USA
Email: Eric J Thomas* - erj@frederick.gov; Allan Frankel - afrankel@frederick.gov
* Corresponding author

Published: 11 April 2005

BMC Health Services Research

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NEWS and VIEWS

In This Issue:

1. Improving Self-Care: The Courage to Step Forward

2. The Contribution of Error/Deviation

Part 1: The Causal Organization

3. To Err is Human, What Comes After?

Implementing Just Culture:

The Courage to Step Forward

How do you ever make a mistake that your performance when we may not know

of their future? And most importantly, what system of accountability best supports optimal

performance? Have you ever made a mistake that your performance when we may not know

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- **Focusing on Managers and organizations**

- Addressing the management style
- Adopting a learning and generative culture
- Belief : changing organizations will improve safety
- Origin : learning attitudes associated to HROs and the Westrum model of pathological/ bureaucratic/ generative culture /Reason's CAIR model



Measuring safety climate in health care

R Flin, C Burns, K Mearns, S Yule and E M Robertson

Qual. Saf. Health Care 2006;15:109-115
doi:10.1136/qshc.2005.014761



A typology of organisational cultures

R Westrum

Qual. Saf. Health Care 2004;13:22-27
doi:10.1136/qshc.2003.009522



Redirecting traditional professional values to support safety: changing organisational culture in health care

J S Carroll and M A Quijada

Qual. Saf. Health Care 2004;13:16-21
doi:10.1136/qshc.2003.009514



Available online at www.sciencedirect.com

ScienceDirect

Safety Science 45 (2007) 725-743

SAFETY SCIENCE

www.elsevier.com/locate/safsci

The use of questionnaires in safety culture research – an evaluation

Frank W. Guldenmund *

Safety Science Group, Delft University of Technology, Adjlabans 1, 2628 BX Delft, The Netherlands

Adopt a Learning Generative culture

(R. Westrum)

| <i>Pathological</i> | <i>Bureaucratic</i> | <i>Generative</i> |
|------------------------------|-------------------------------------|--------------------------------|
| Information is hidden | Information may be ignored | Information is actively sought |
| Messengers are "shot" | Messengers are tolerated | Messengers are trained |
| Responsibilities are shirked | Responsibility is compartmented | Responsibilities are shared |
| Bridging is discouraged | Bridging is allowed but discouraged | Bridging is rewarded |
| Failure is covered up | Organization is just and merciful | Failure causes inquiry |
| New ideas are crushed | New ideas create problems | New ideas are welcome |

Safety culture surveys

- Safety Attitude Questionnaire (SAQ)
- AHRQ Hospital Survey on Patient Safety Culture (HSOPS)
- VA Palo Alto/Stanford PSCI
- VA Patient Safety Questionnaire
- Flin/modified ORMAQ
- Itoh/Hospital Safety Culture Questionnaire
- Patient Safety Climate in Anesthesia
- Safety Climate Survey
- Culture of Safety Survey
- Children's Hospital of Boston Trainee Supplement
- Allina Hospitals and Clinics
- Teamwork and Patient Safety Attitudes Questionnaire
- Safety Climate Scale

The relationship between climate/culture factors and safety is far from convincing

- **The UK National Audit Office has recently reported on the state of patient safety in NHS trusts. While offering an encouraging prognosis, this is far from a clean bill of health.**
- **The report states that “The safety culture within trusts is improving ... However, trusts are still predominantly reactive in response to patient safety issues and parts of some organisations still operate a blame culture” (p 2).**



Measuring safety climate in health care

R Flin, C Burns, K Mearns, S Yule and E M Robertson

Qual. Saf. Health Care 2006;15:109-115
doi:10.1136/qshc.2005.014761

Are available industrials tools transferable to healthcare?

- **Considerable care needs to be taken when adapting measures from these very proceduralised high risk industries.**
 - Not only is the nature of the work very different, but the organizations have well defined hierarchical management structures with clear reporting relationships.
 - Leadership issues are much more problematic to measure in health care
- **Moreover, the safety climate studies in industry all focus on worker injury rather than product (cf patient) damage. Determining reliable outcome measures for these healthcare studies appears to be challenging; sometimes the focus is on workers' behaviours, which might be regarded as safety process measures, and in other cases some kind of adverse event is used.**
- **Last, but not least, Managerial attitudes in the industry, including the safest industry, not necessarily a good demonstration of 'ideal' safety culture**



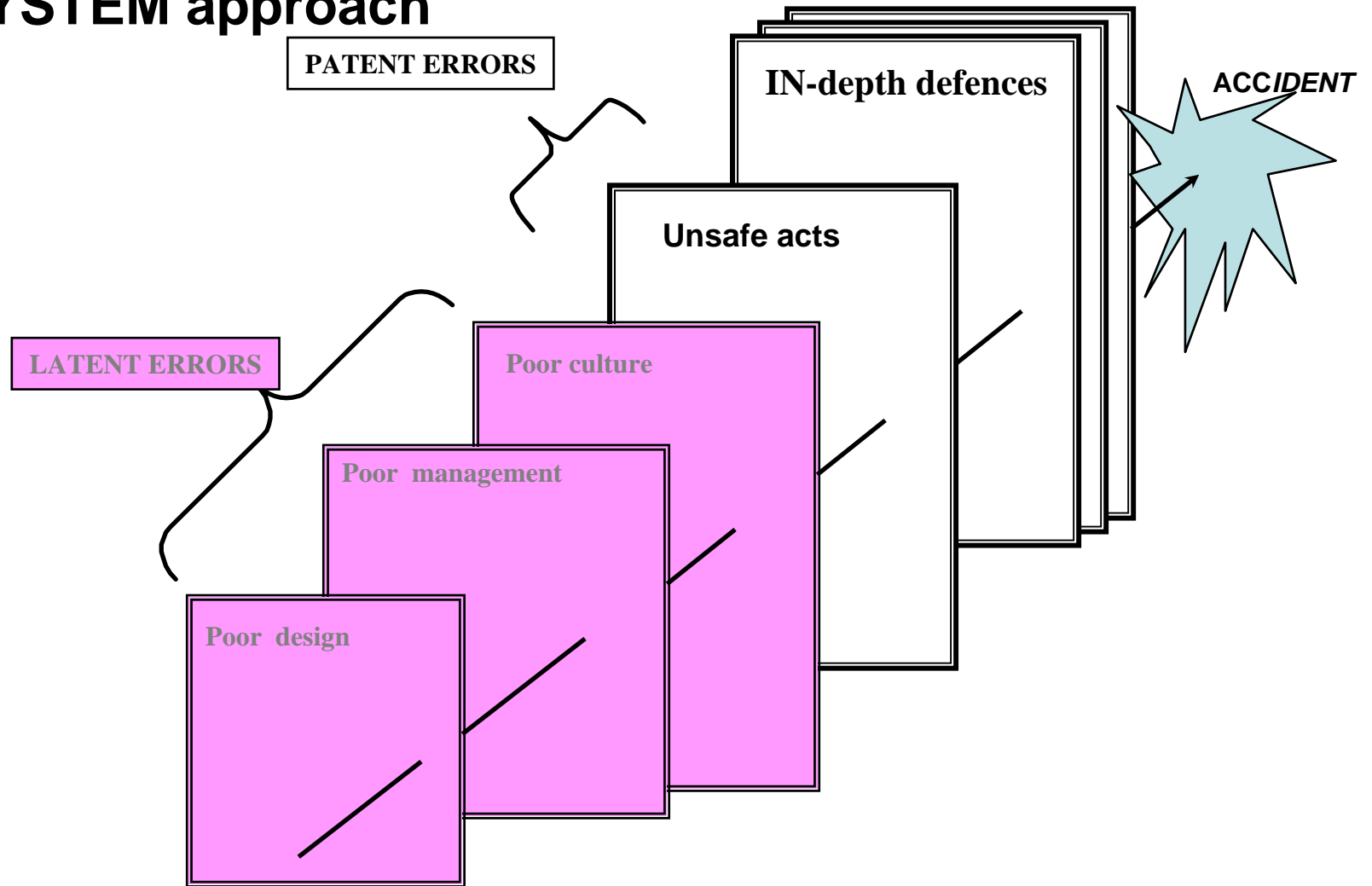
Measuring safety climate in health care

R Flin, C Burns, K Mearns, S Yule and E M Robertson

Qual. Saf. Health Care 2006;15:109-115
doi:10.1136/qshc.2005.014761

4. Systemic safety models

The SYSTEM approach



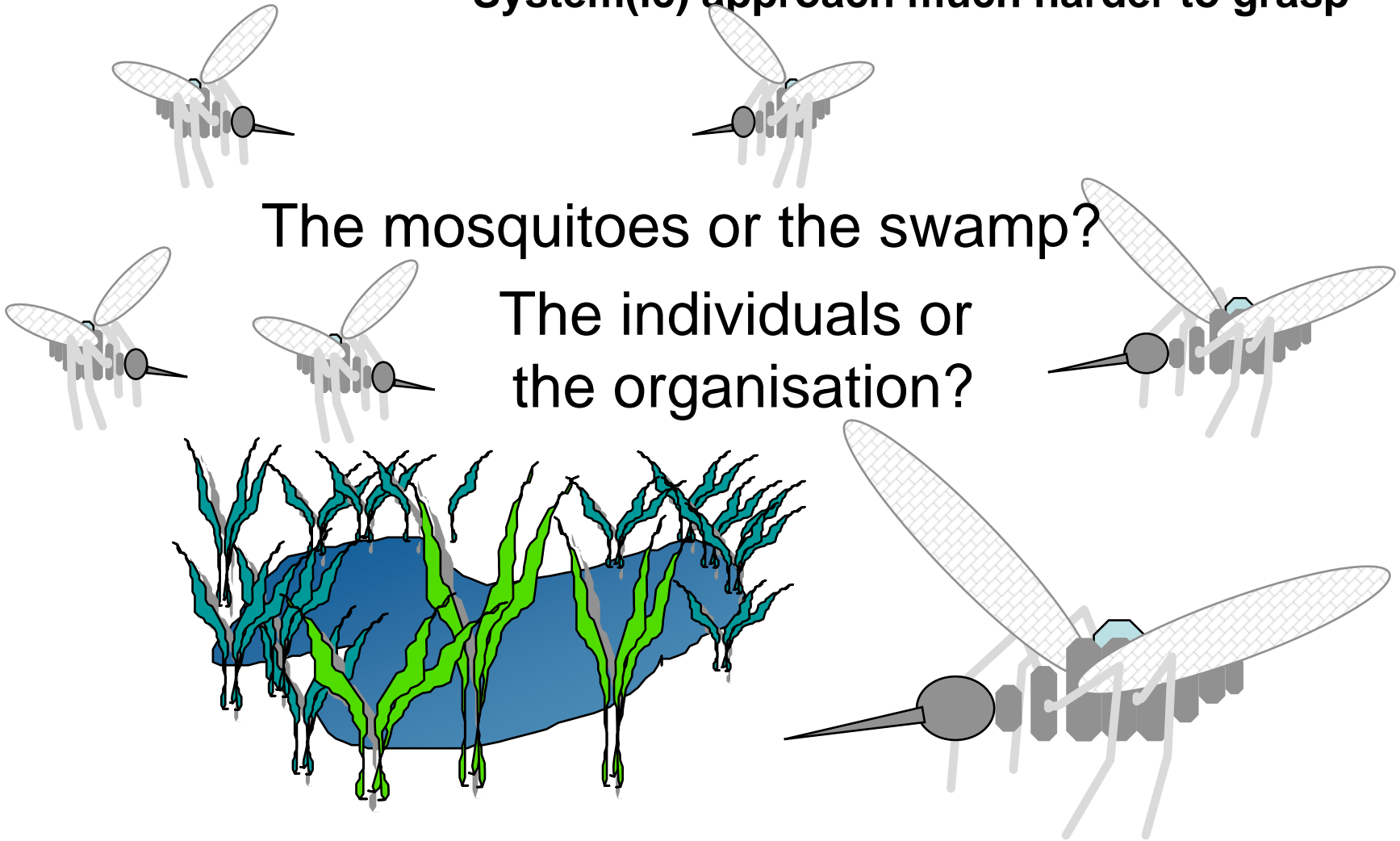
After REASON

The Person Vs System approach

Priority has been given to person approach and local organization
System(ic) approach much harder to grasp

The mosquitoes or the swamp?

The individuals or the organisation?



Three challenges for Systemic Approaches in Healthcare

- Redefining the scope of Patient safety
- Understanding what makes a socio-technical system safer
- Foreseeing side effects of models

Two models for patient safety?

The 'Technical' model

- **Goal: reduction, and ideally avoidance, of preventable adverse events (AEs)**
 - promoting the no-arm to patient approach
 - practice and system oriented
 - in theory easy to measure (non compliance with rules or best practices)
- **Tools: Standardization of practice**
 - Diagnosis of deviance, audits (inside the hospital)
 - Micro 'Quality'
 - Safety culture, Equivalent actors
- **Indicators**
 - Objective accountability
 - Less deviations, less AEs
 - Safety culture questionnaire (professionals)

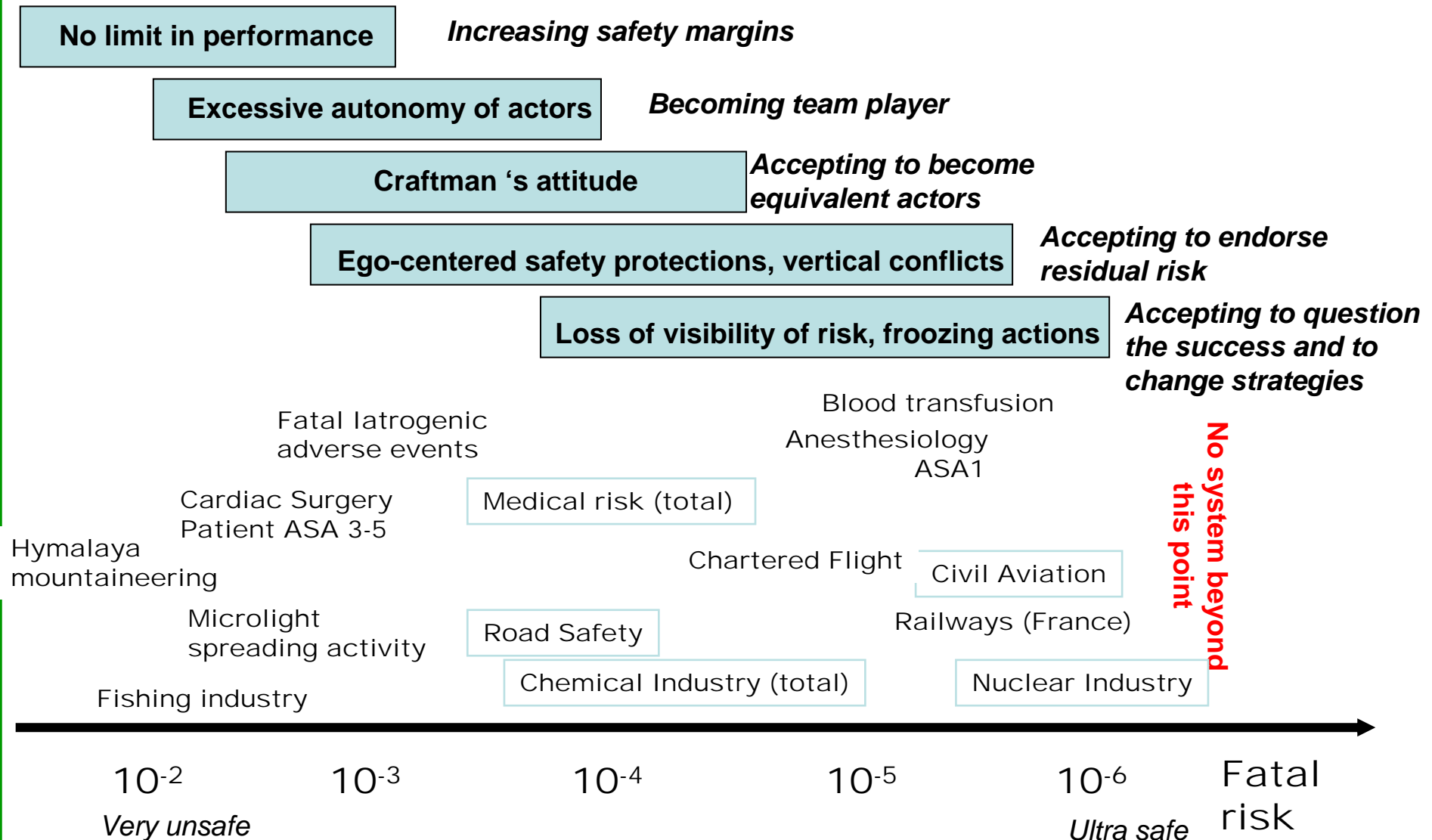
The 'Customer Service' model

- **Goal: Patients' satisfaction**
 - associated with the maximum medical chance given to each individual patient
- **leads to consider**
 - risk of preventable AE inside and outside the hospital
 - Global care concept,
 - access to care (including choice of doctors and hospitals, distance, waiting time and out-of pocket cost),
 - technical and human quality of medicine (platform, competence, commitment of medical staff)
- **Tools:**
 - Diagnosis of Micro and **Macro** QUALITY performance (idem Technical model)
 - Medical and juridical Governance and organization
 - Social security, access to care
- **Indicators**
 - Objective accountability
 - Rate of medical lawsuit
 - Opinion questionnaire (Inpatients and outpatients, citizens)

Why Civil Aviation is an Ultra Safe System

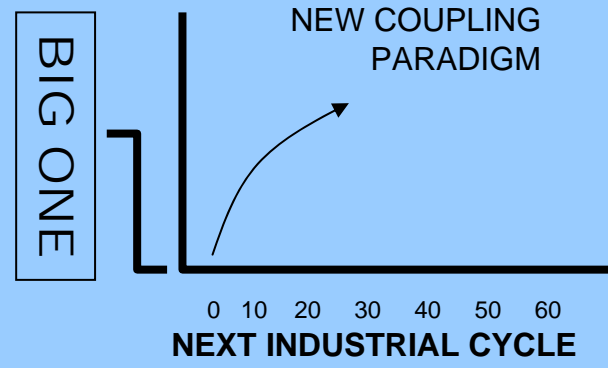
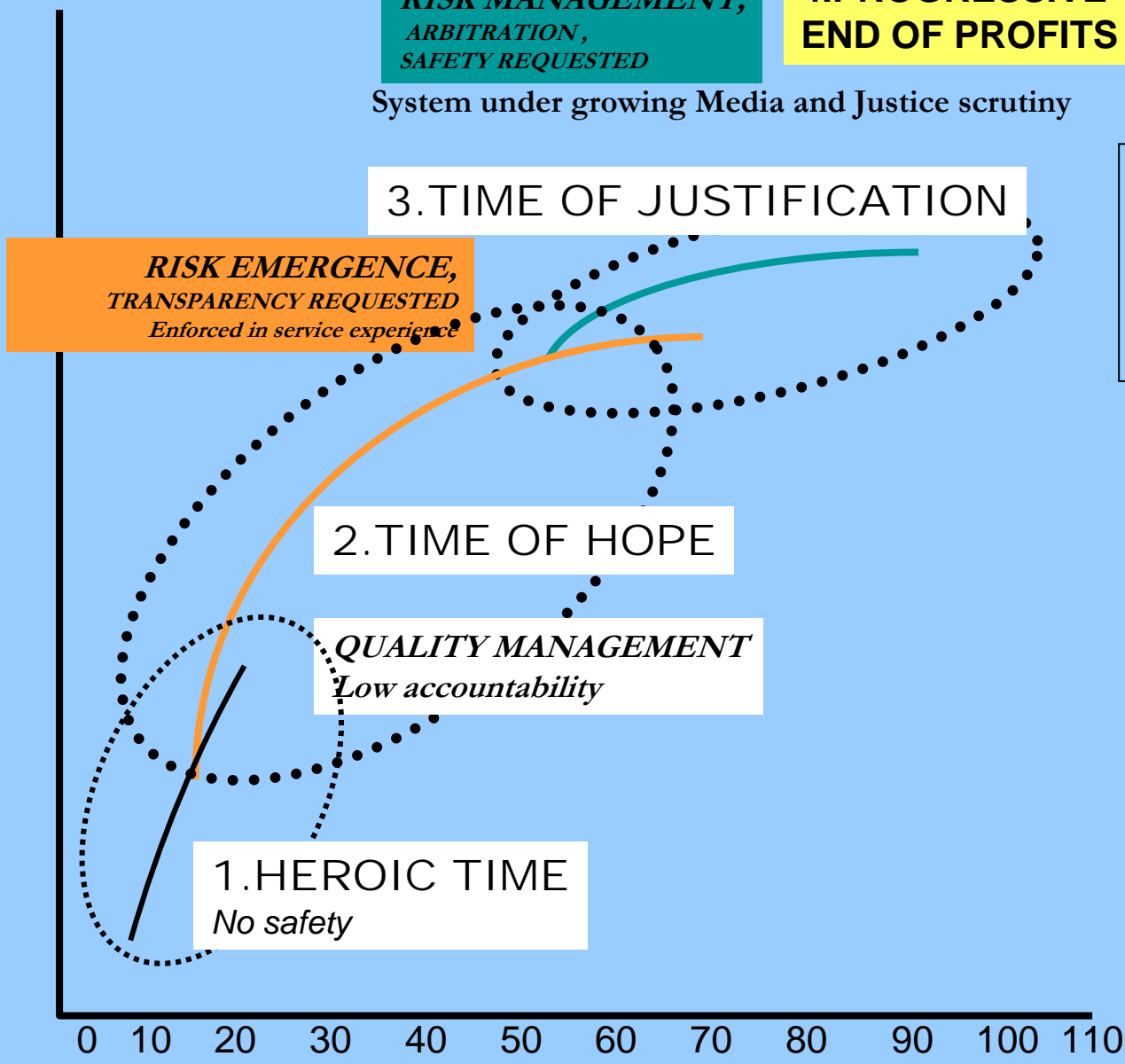
- **A old established worldwide regulation**
 - OACI
 - EASA, FAA
 - IATA
- **A rich industry, betting and affording technical innovations**
- **An immense standardization of materials**
 - Very few manufacturers
 - Incredible family standardization inside each manufacturers' fleet
- **An immense worldwide 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?



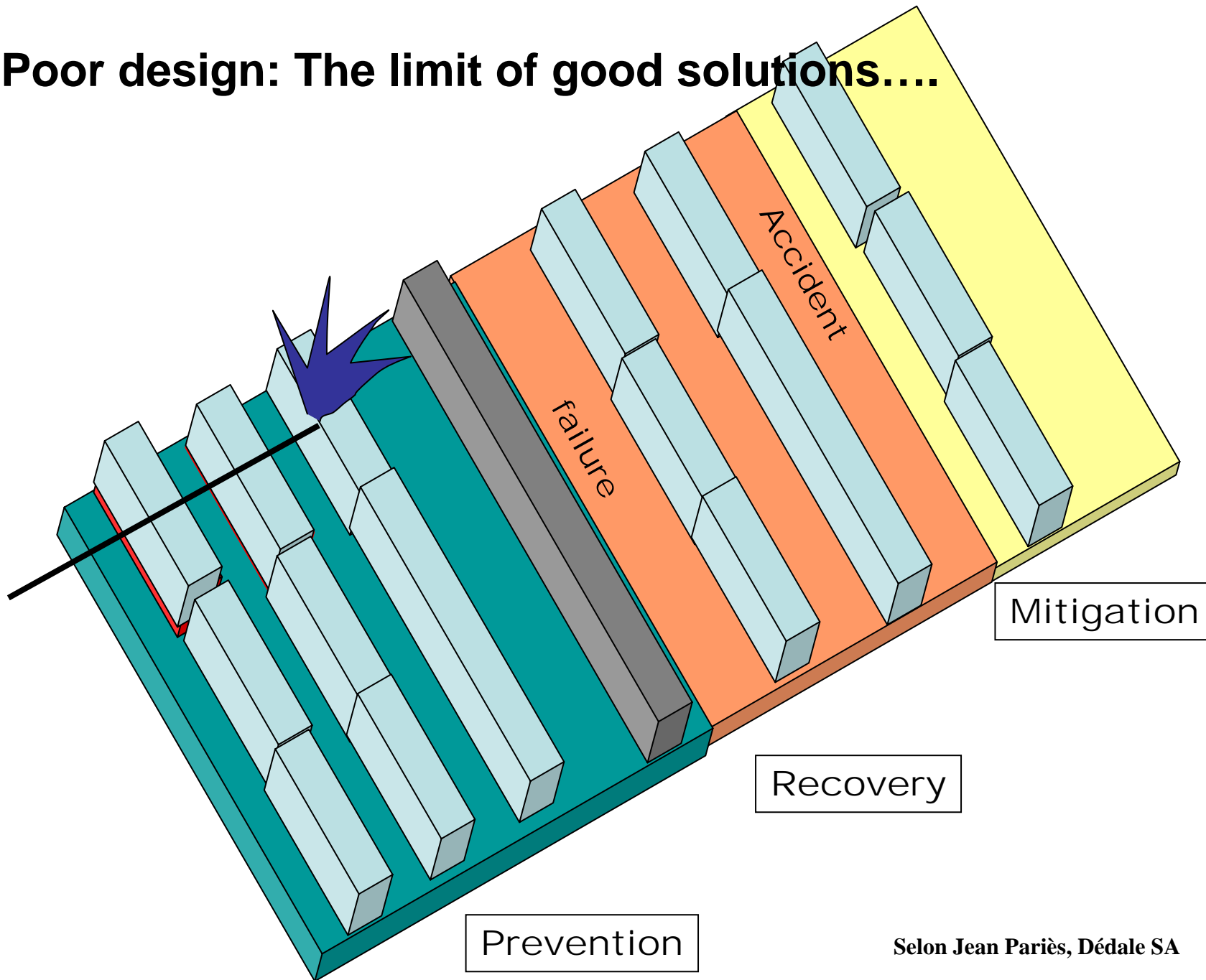
5. BIG ONE & NEW CYCLE

Safety level



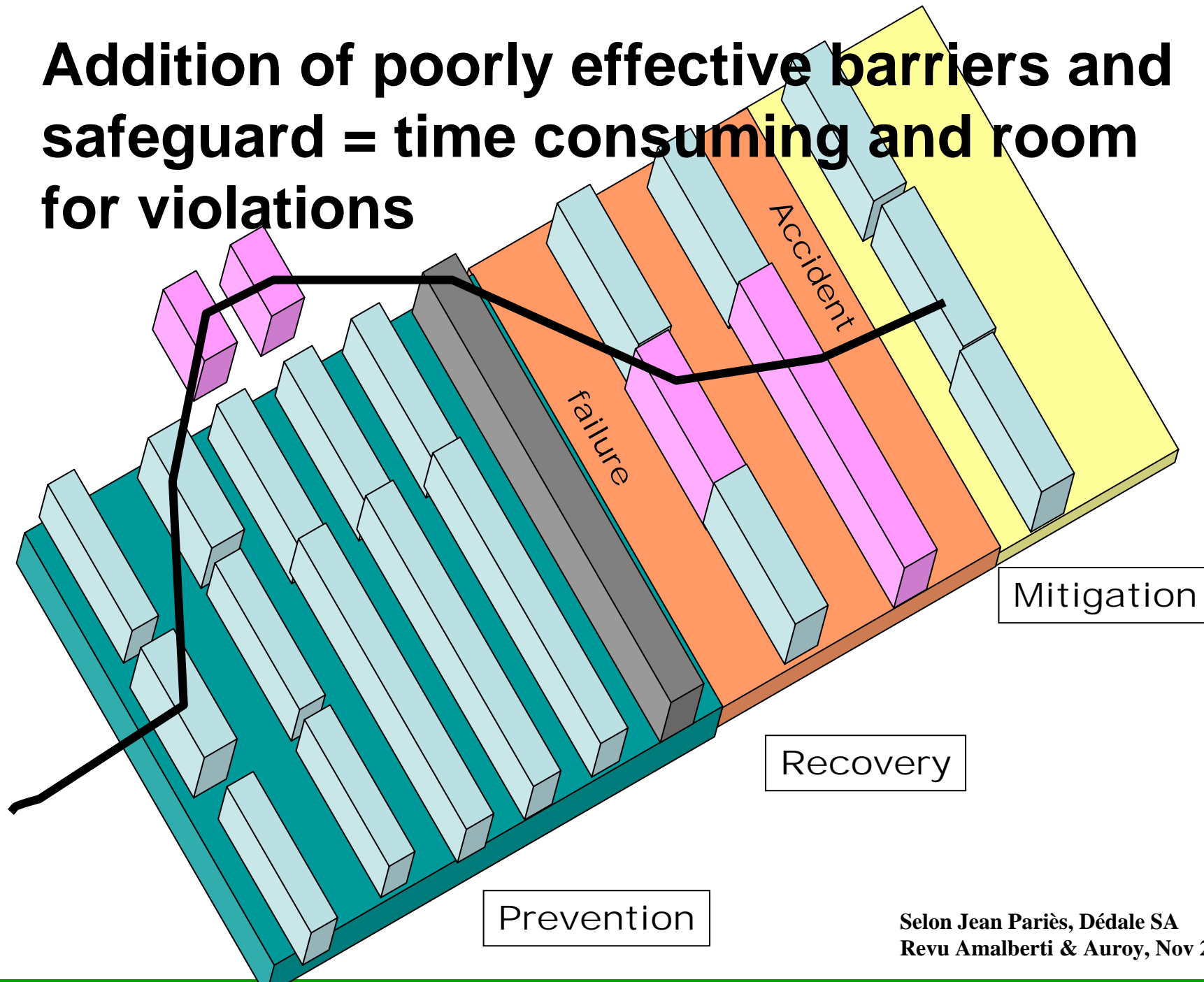
Years
Order of magnitude

Poor design: The limit of good solutions....



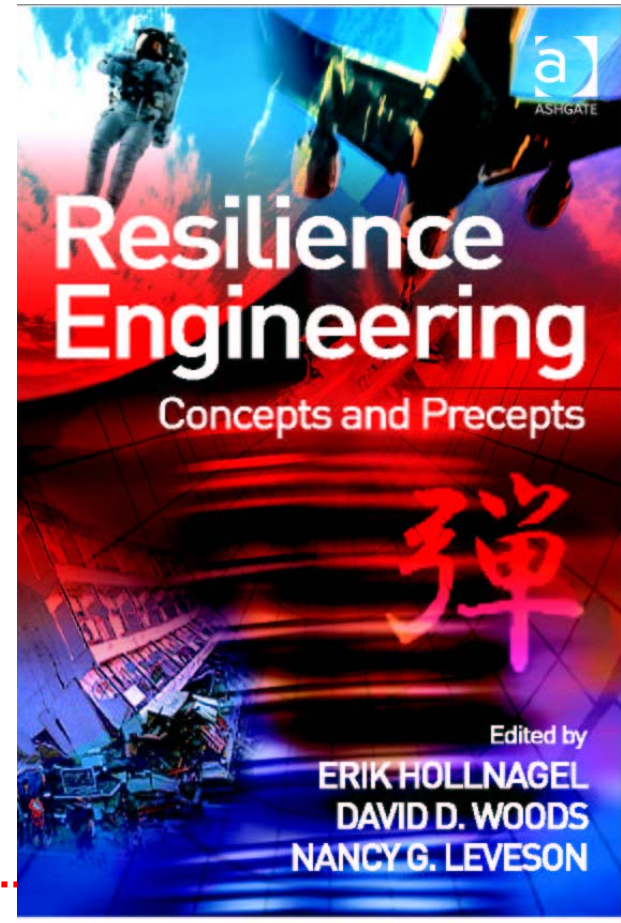
Selon Jean Pariès, Dédale SA

Addition of poorly effective barriers and safeguard = time consuming and room for violations

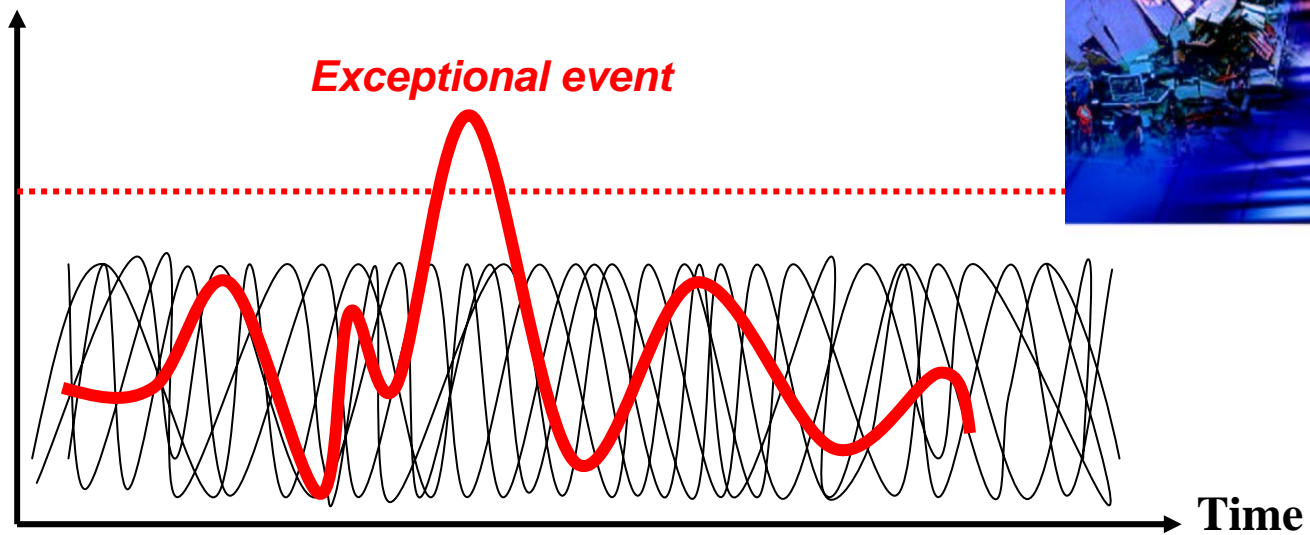


Selon Jean Pariès, Dédale SA
Revu Amalberti & Auroy, Nov 2001

5. Resilience models the challenge of the unstable



Performance range



Two Safety philosophies for safety interventions strategies

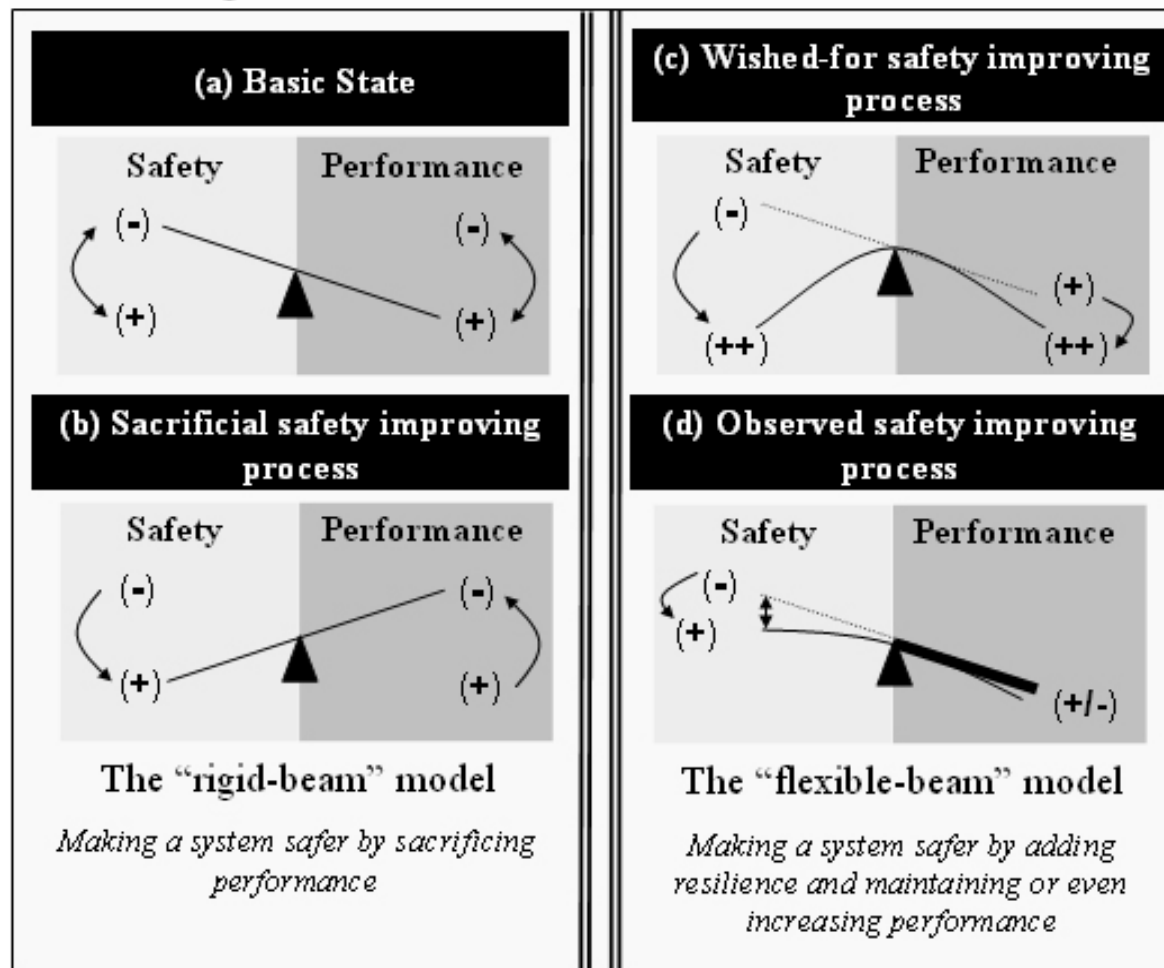
Morel, Amalberti, Chauvin, 2008, Human factors & 2008 Safety science

Philosophy 1

The “rigid-beam” model

Philosophy 2

The “flexible-beam” model



Understanding resilience

$$\text{Resilience } S_t = S_i + S_m$$

$$S_t \text{ (Safety total)} = S_r \text{ (Safety imposed)} + S_g \text{ (Safety managed)}$$

**Observed
Safety**

NORMS / QUALITY +

RESILIENCE

**Error avoidance
BBS/CBS/HRA**

**Based on
Technology
Regulations
Constraints**

**Surprises
management**

**Based on
Human expertise
Adaptive learning
systems**

Paradoxes of Resilience

Significant safety improvements always detrimental to S_m

Craftman industry

$$S_t = S_i + S_m$$

Safety improvement

↓
Ultrasafe systems

↓

$$S_t = S_i + S_m$$

The next challenge : Preverving S_m while Improving S_i

$$S_t = S_i + S_m$$

Toward a strategic view on medical safety

Effectiveness,
Competitiveness
Adaptation to
unexpected

RESILIENT
SYSTEMS

RESILIENCE

Corridor of acceptable systems

Unstable conditions
of activity, fast pace
of changes

HRO

ADAPTIVE
SYSTEMS

Transitioning
strategy

NON ADAPTIVE
SYSTEMS

Poor
systems

Improvement required

Poor
systems

Ultra safe
systems

Stable conditions
of activity, slow pace
of changes

10^{-2}

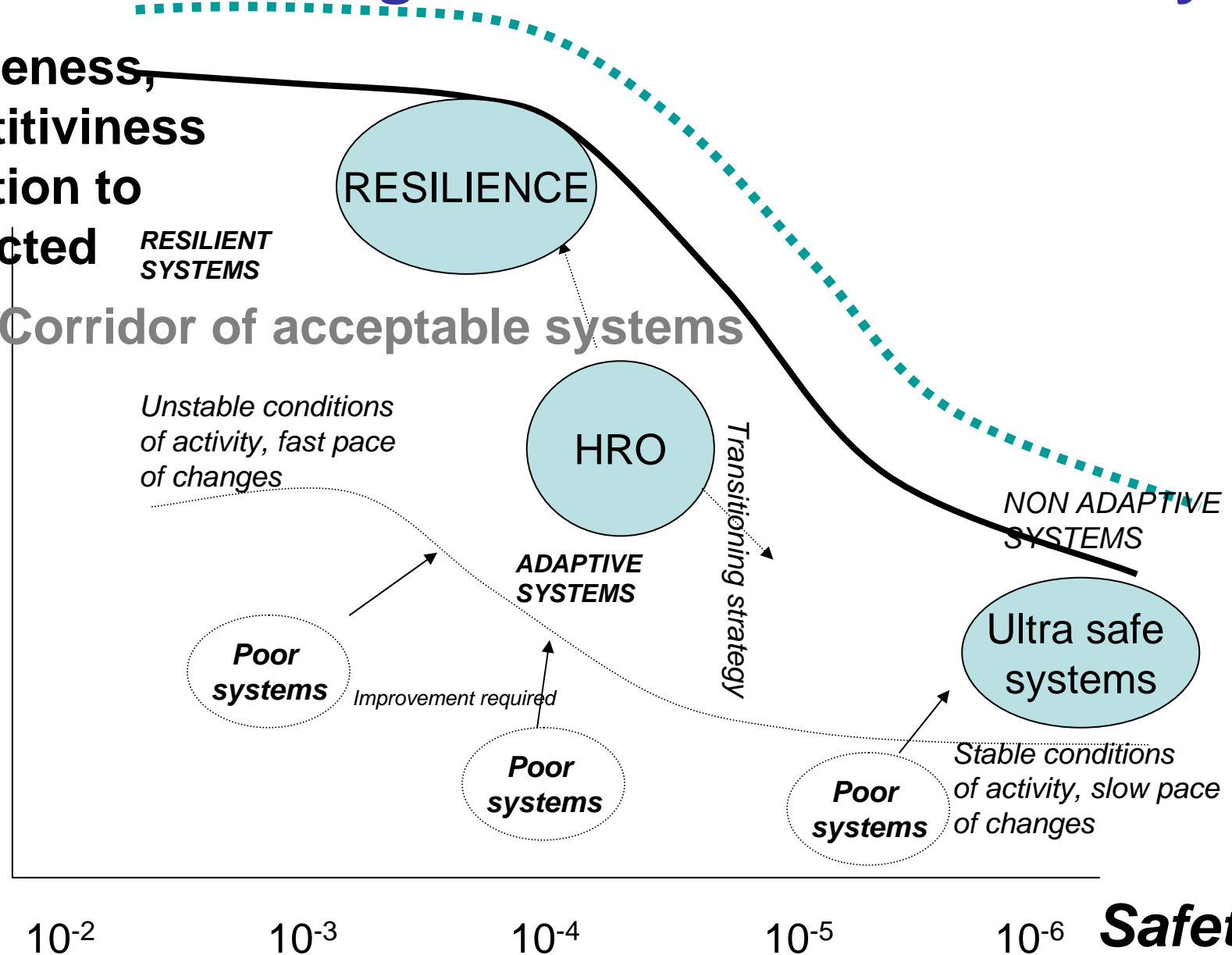
10^{-3}

10^{-4}

10^{-5}

10^{-6}

Safety



Conclusions

- **Patient safety stuck to present figures for systemic reasons**
 - Better present hope : Improvement by factor 2 to 5
 - When safer industries are 1,000 times better...
- **Time for a true systemic approach in parallel to current approaches**
 - Can accelerate improvement by factor 10 to 100
- **Adopt systemic priorities**
 - Revise the scope of patient safety
 - Adopt equivalent actors
 - Understand and accept side-effects