

FONCSI

PATIENT SAFETY, PRESENT AND FUTURE

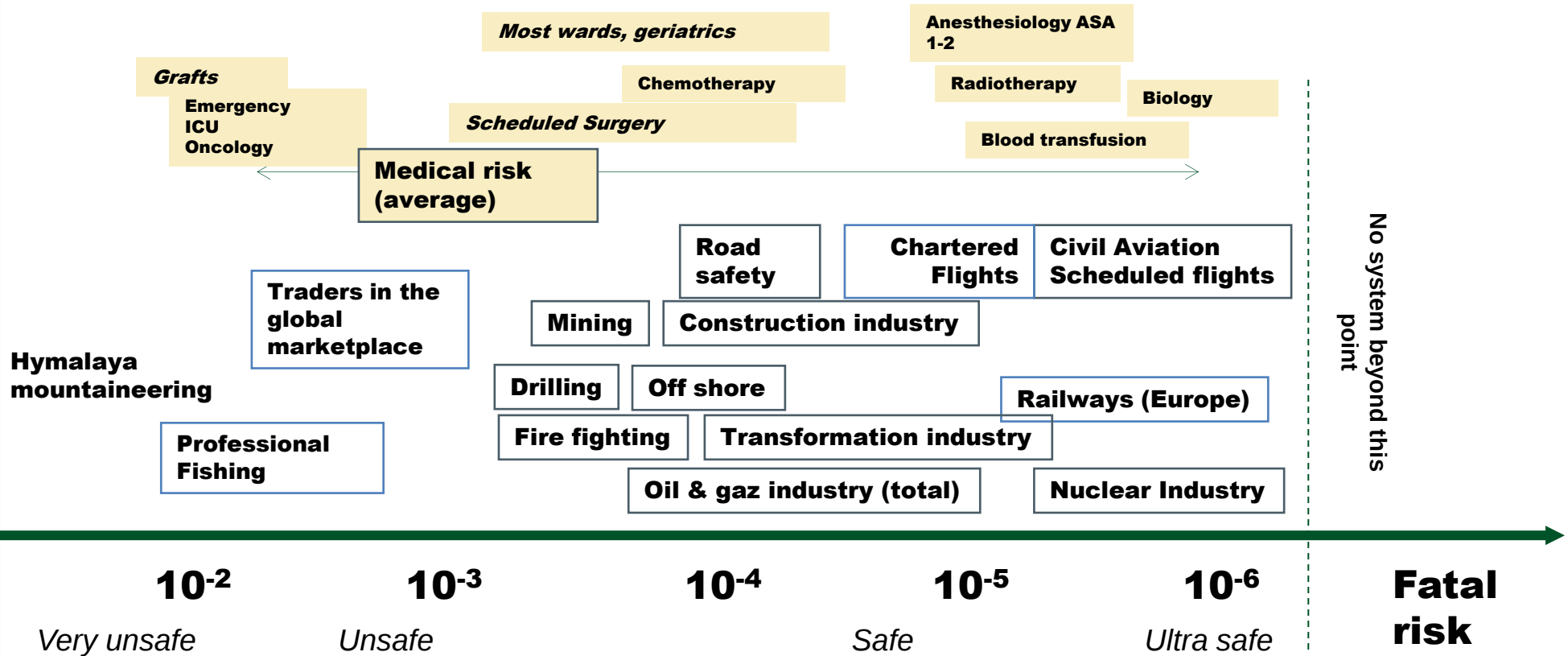
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FONCSI, CEO Foundation For Industrial Safety Culture

HAS, Medical French Accreditation Agency, Senior Adviser Patient Safety

AIEA - February 23

RISKS IN HUMAN ACTIVITIES



COUNTLESS EXAMPLES OF CARE FALLING BELOW STANDARDS

⊙ While outcomes are good

- 228 patients reported 183 service deficiencies, each of which doubled their risk of harm (Taylor et al, 2008)
- 20% of patients received less than satisfactory care often experiencing harm (Hutchinson et al, 2013)
- 15% of out patient appointments are conducted with important information missing (Burnett et al, 2013)

⊙ Poor reliability of basic processes endemic in most systems

THE DARK AGES

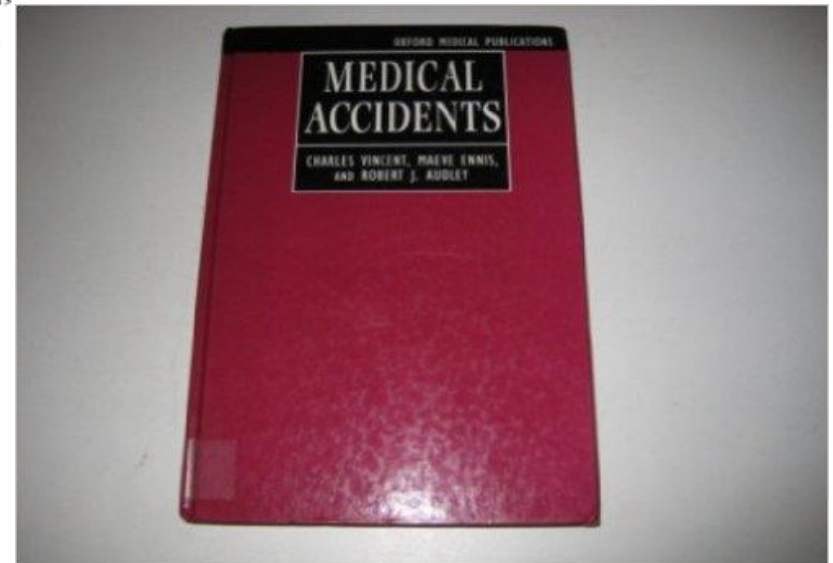
Research into medical accidents: a case of negligence?

C A Vincent

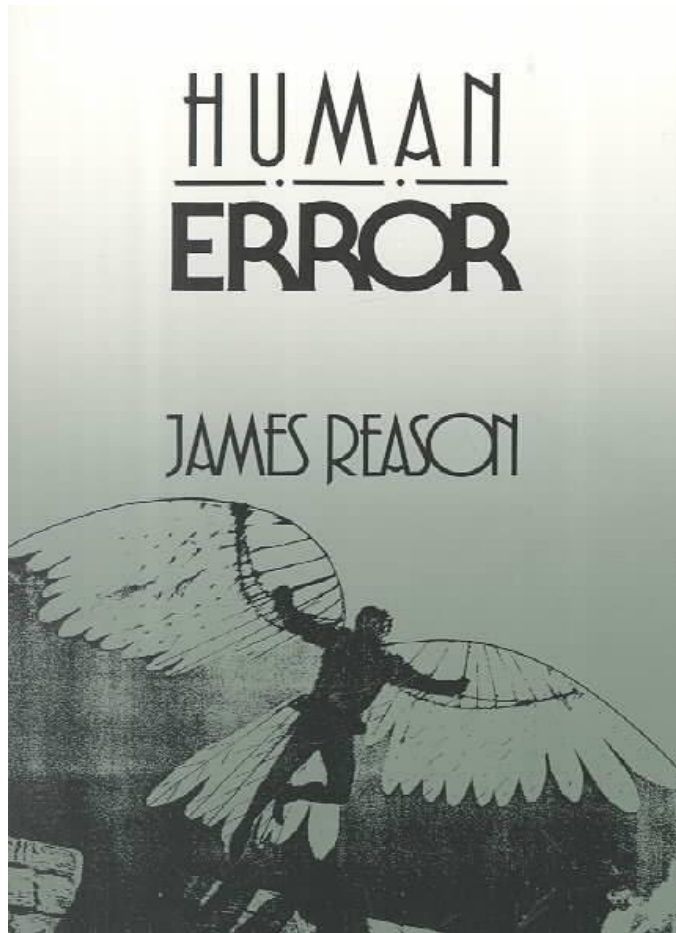
Public awareness of medical accidents is growing, as the rapidly rising rate of litigation and the corresponding increase in defence society subscriptions testify.¹ In many activities—for example, aviation, road and rail travel, industry—errors and accidents are the object of

emphasis is on packaging and the medication errors. The authors discussing the actual errors are usually nurses.¹⁰⁻¹³

BMJ VOLUME 299 4 NOVEMBER 1989



LEARNING FROM OTHER INDUSTRIES



PATIENT SAFETY AND THE RELIABILITY OF HEALTH CARE SYSTEMS

Series Editors: Paul Barach, MD, MPH, and
Donald M. Berwick, MD, MPP

IMPROVING PATIENT CARE

Five System Barriers to Achieving Ultrasafe Health Care

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

Although debate continues over estimates of the amount of preventable medical harm that occurs in health care, there seems to be a consensus that health care is not as safe and reliable as it might be. It is often assumed that copying and adapting the success stories of nonmedical industries, such as civil aviation and nuclear power, will make medicine as safe as these industries. However, the solution is not that simple. This article explains why a benchmarking approach to safety in high-risk industries is needed to help translate lessons so that they are usable and long lasting in health care. The most important difference among industries lies not so much in the pertinent safety toolkit, which is similar for most industries, but in an industry's willingness to abandon historical and cultural precedents and beliefs that are linked to performance and autonomy. In a constant drive toward a culture of safety. Five successive systemic barriers currently prevent health care from becoming an ultrasafe industrial system: the

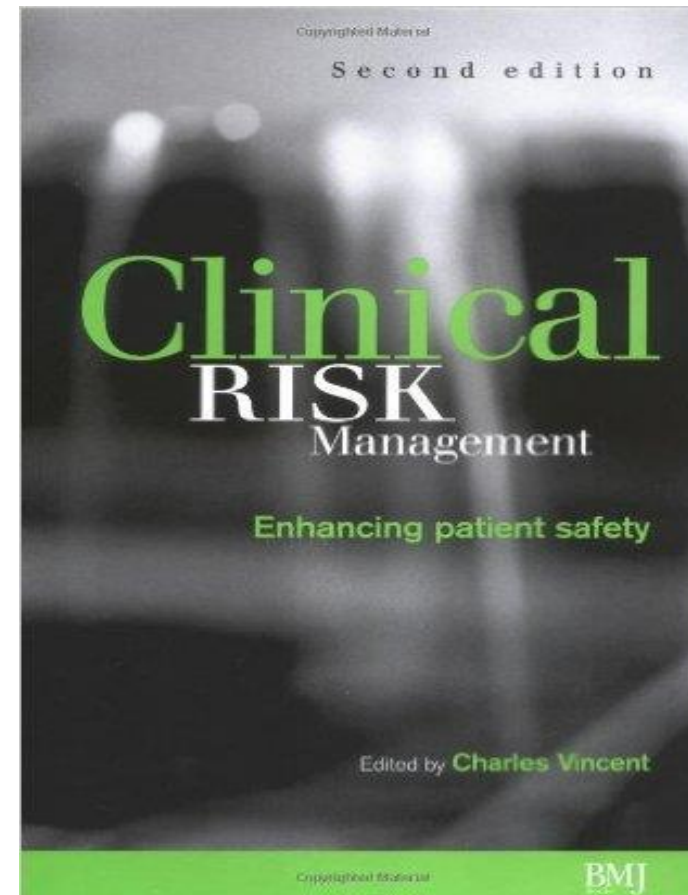
need to limit the discretion of workers, the need to reduce worker autonomy, the need to make the transition from a craftsmanship mindset to that of equivalent actors, the need for system-level (senior leadership) arbitration to optimize safety strategies, and the need for simplification. Finally, health care must overcome 3 unique problems: a wide range of risk among medical specialties, difficulty in defining medical error, and various structural constraints (such as public demand, teaching role, and chronic shortage of staff). Without such a framework to guide development, ongoing efforts to improve safety by adopting the safety strategies of other industries may yield reduced dividends. Rapid progress is possible only if the health care industry is willing to address these structural constraints needed to overcome the 5 barriers to ultrasafe performance.

Ann Intern Med. 2005;142:756-764.
For author affiliations, see end of text.

www.annals.org

CLINICAL RISK MANAGEMENT MID 90s

Incident reporting
Incident analysis
Complaints and
litigation
Risk management
standards

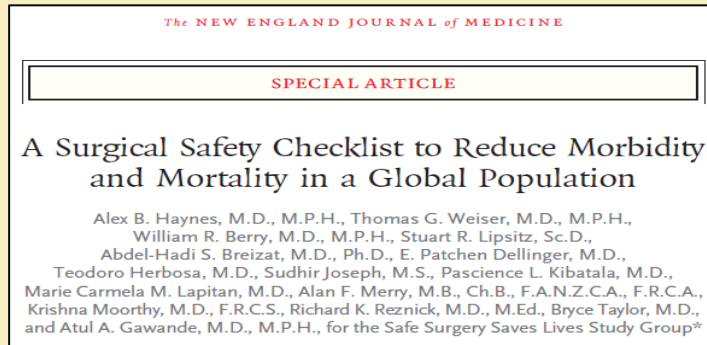


SAFETY CULTURE, MULTI-FACETED INTERVENTIONS AND TEAMWORK (2005 -2011)

- ⊙ Safety culture as foundation and as driver
- ⊙ Checklists and bundles
- ⊙ Some major successes
- ⊙ Tackling safety across an organisation

◆8

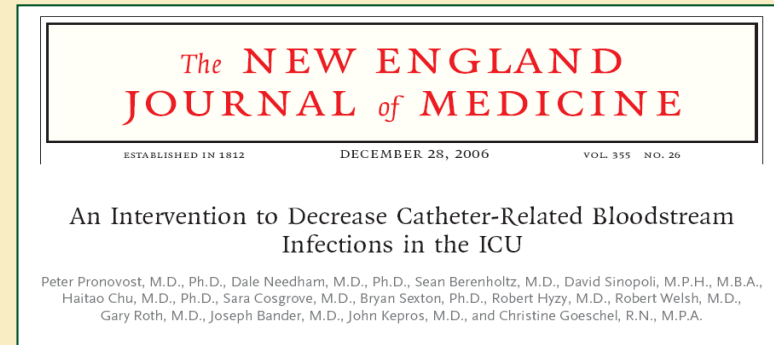
Operating theatre



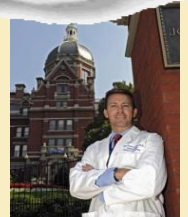
- Major complication rate decreased 36%
- Mortality decreased 47%
- Post-op infection decreased 48%



Intensive care



- Central line infection rates decreased 66%
- Quarterly infection rate in most ICU's <1%
- Estimated saving of \$175 million
- Potentially more than 1500 lives saved



Quality Approach

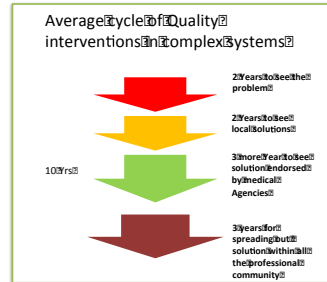
Offering best standards
of care
Extreme rapid pace of
innovation
No-limit ambition

Safety approach
Avoiding accidents

Max bar

The power of innovation?

Of 100 Systematic Reviews
Median time to change that
would effect clinical
decisions was 5.5 years.



24-10-2011

Bologna

8

Min Bar

Continuous progresses

- Surgery on patients over 85
- New Stroke care ...

Continuous progression of Life duration
With Healthy life
Growing complexity for care

Increase risk, increase complexity

- Impossible national conformity with continuous change in Quality ambition
- Need multiple adaptation, rapid pace of change

More accidents

NEW CHALLENGES

- ⊙ Harm has been defined too narrowly
- ⊙ Progress is slower than anticipated
- ⊙ Only part of the healthcare system has been addressed
- ⊙ Interventions are idealistic
- ⊙ Safety and quality improvement equated
- ⊙ ... and healthcare is changing rapidly

**AEs associated with the
Care environment**

***AEs associated with
poor care***

**Poor shared information
and partnership with
patients**

Poor Access

***Incredible errors
Never events***

EDITORIAL

Safety in healthcare is a moving target

Charles Vincent,¹ Rene Amalberti²

Safety in healthcare is a constantly moving target. As standards improve and concern for safety grows, we come to regard an increasing number of events as patient safety issues. In this respect, healthcare differs from almost all other safety-critical industries. What we regard as harm in, for instance, civil aviation remains the same whatever advances may occur in aviation technology or practice. In contrast, innovation and improving standards in healthcare alter our conceptions of both harm and preventability.

drug events in the community that cause admission to hospital, polypharmacy and general harm from overtreatment.⁸ All these, in the past, might have been regretted, but now receive greater attention by being viewed under the safety umbrella.

The perimeter of safety is, therefore, expanding. This is welcome for patients as it reflects rising standards and aspirations. However, the shifting perimeter does present problems, both conceptual and practical. The definition of harm seems increasingly difficult to pin down

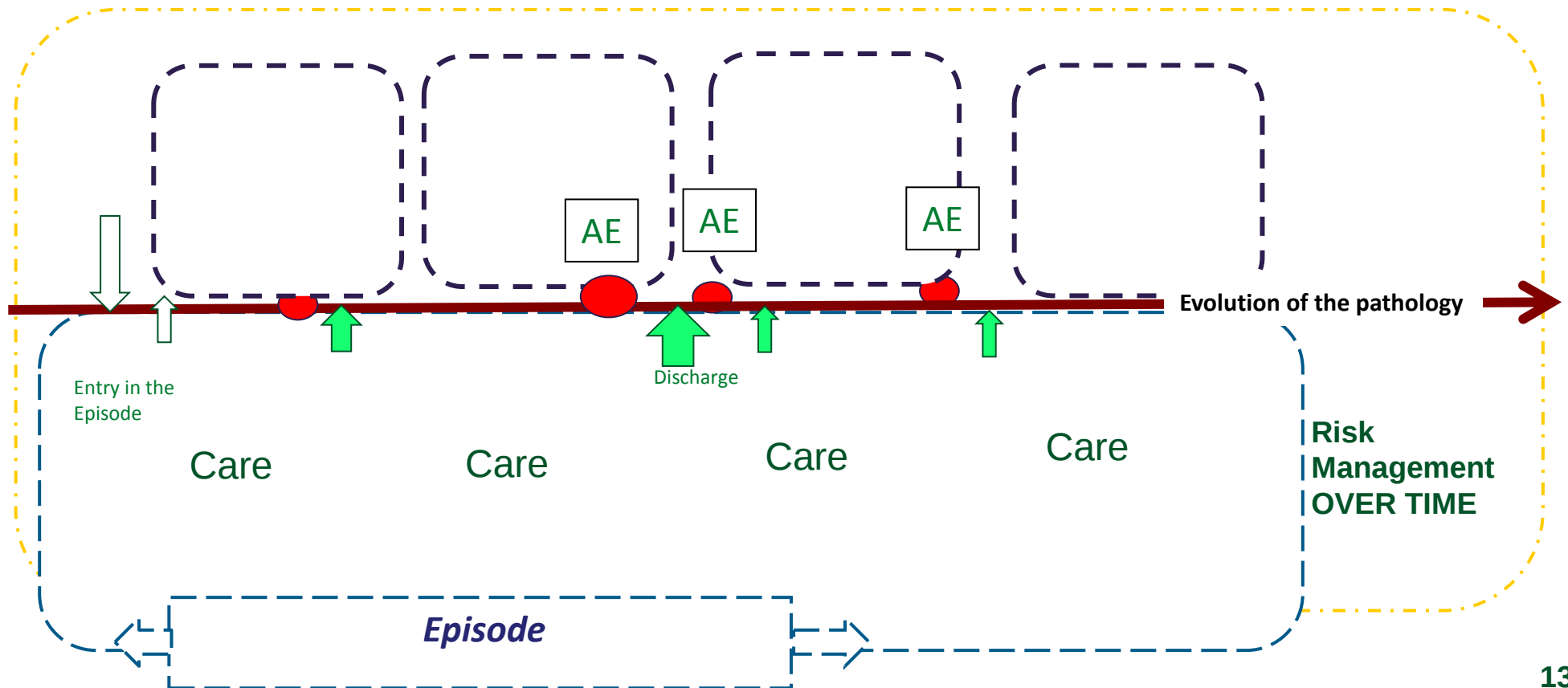
Safety is the management of risk over time (which includes the reduction of harm)

Primary care

Hospital

Rehabilitation

Integrated vision



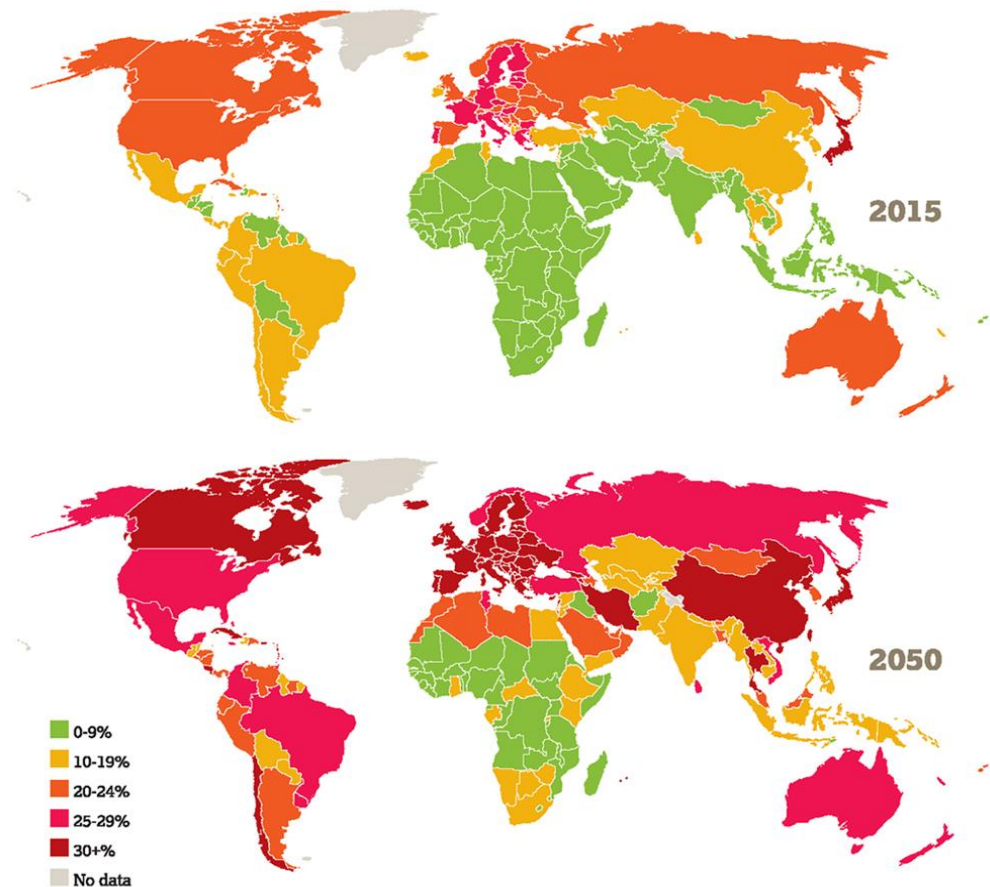
System changes

- ⊙ Sociological changes
 - acute diseases becoming chronic,
 - Massive ageing
 - Patients becoming experts
- ⊙ Technical innovations (day surgery is only one example) all leading to a drastic and rapid reduction of the average length of stay.
- ⊙ More public transparency
- ⊙ More supervision by authorities via administrative and medical databases

Leading to new challenges

- ⊙ Imposing a rapid shift from safer medical acts to safer patient's journey

	Percentage of population over 60		
	2015	2030	2050
Japan	33,1	37,3	42,5
Spain	24,4	33,5	41,4
Portugal	27,1	34,7	41,2
Greece	27	33,2	40,8
Italy	28,6	36,6	40,7
Germany	27,6	36,5	39,3
China	15,2	25,3	36,5
Switzerland	23,6	30,6	34,5
Chile	15,7	23,7	32,9
Canada	22,3	29,4	32,5
France	25,2	29,9	31,8
Iran	8,2	14,4	31,2
Ireland	18,4	24,4	31
UK	23	27,8	30,7
Denmark	24,7	29,3	29,9
Sweden	25,5	28,3	29,6
Norway	21,1	26,2	29,5
Russian Federation	20	24	28,8
Australia	20,4	24,6	28,3
India	8,9	12,6	28
USA	20,7	26,1	27,9
Columbia	10,8	18,3	27,6
Mexico	9,6	14,9	24,7
Oman	4,4	9,4	24,5
Argentina	15,1	21,5	23,6
Morocco	9,6	15,1	23,4
Qatar	2,3	7,9	19,8
Malaysia	8,2	13,2	19,2
Indonesia	8,2	13,2	19,2
Jordan	5,4	8,6	15,8
South Africa	7,7	10,5	15,4
Botswana	5,9	7,9	15,7
Cameroon	4,8	5,2	8,1
Angola	3,8	4,2	5,5



Source Global Age Watch 2015

Need for Rethinking Patient Safety

Change definition, define Patient safety as the management of risk over time

Patient safety is the art of controlling risks of time to minimize harm (isolated or cumulative) in relation to benefits

With this definition, patient safety is not a 'zero default' approach with total elimination of any harm or incidents.

Managing safety is not aimed simply at compliance with procedures, whatever the value of these procedures

Understand risk and harm through the patient's eyes

Incidents important but only one aspect of a wider perspective

Adopt the five levels of care and its implication for safety priorities

Consider a broader view of Harm including poor care, the burden of treatment and psychological harm

Consider the balance of benefit and harm within an episode of care

Examine episodes of care and consider both risk and harm within an extended timescale.

Need to encompass a timeframe sufficient to embrace initial assessment, provision of treatment, monitoring the result, and responding to complications while continuing to deliver care.

Adopt different safety models dependent on context

Accept different safety models : There is no one universal model of safety in healthcare that can apply across every setting.

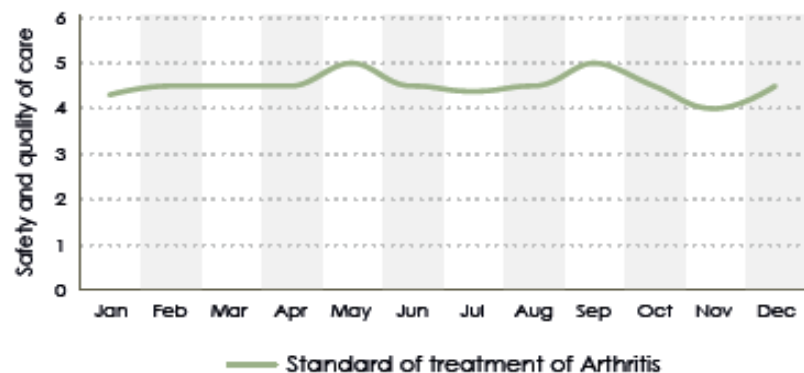
Use a wider range of safety strategies and interventions

Adopt the compendium of strategies

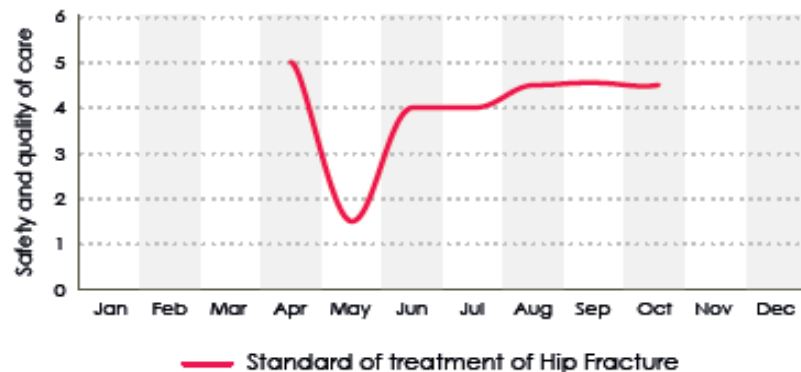
HARM THROUGH THE PATIENT'S EYES

- ⊙ Harm is conceived very broadly encompassing both serious disruption of treatment and distressing events.
- ⊙ Harm includes serious failures to provide appropriate treatment as well as harm that occurs over and above the treatment provided.
- ⊙ Harm is seen not in terms of incidents but as a trajectory within a person's life.

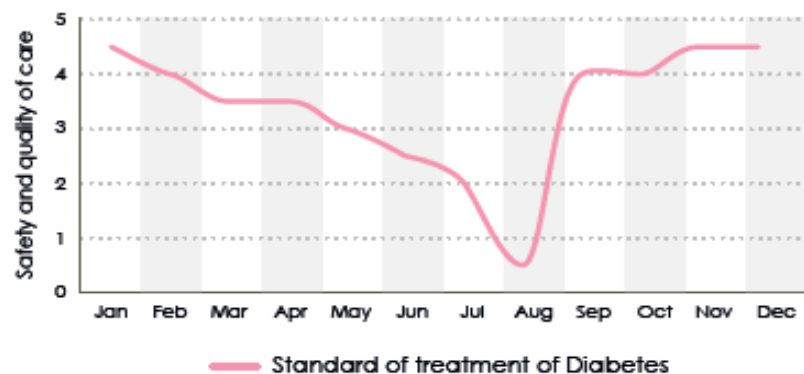
Treatment of Arthritis



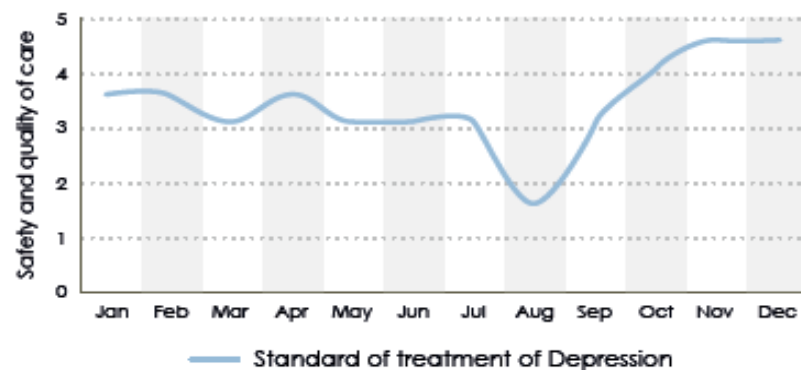
Treatment of Hip Fracture



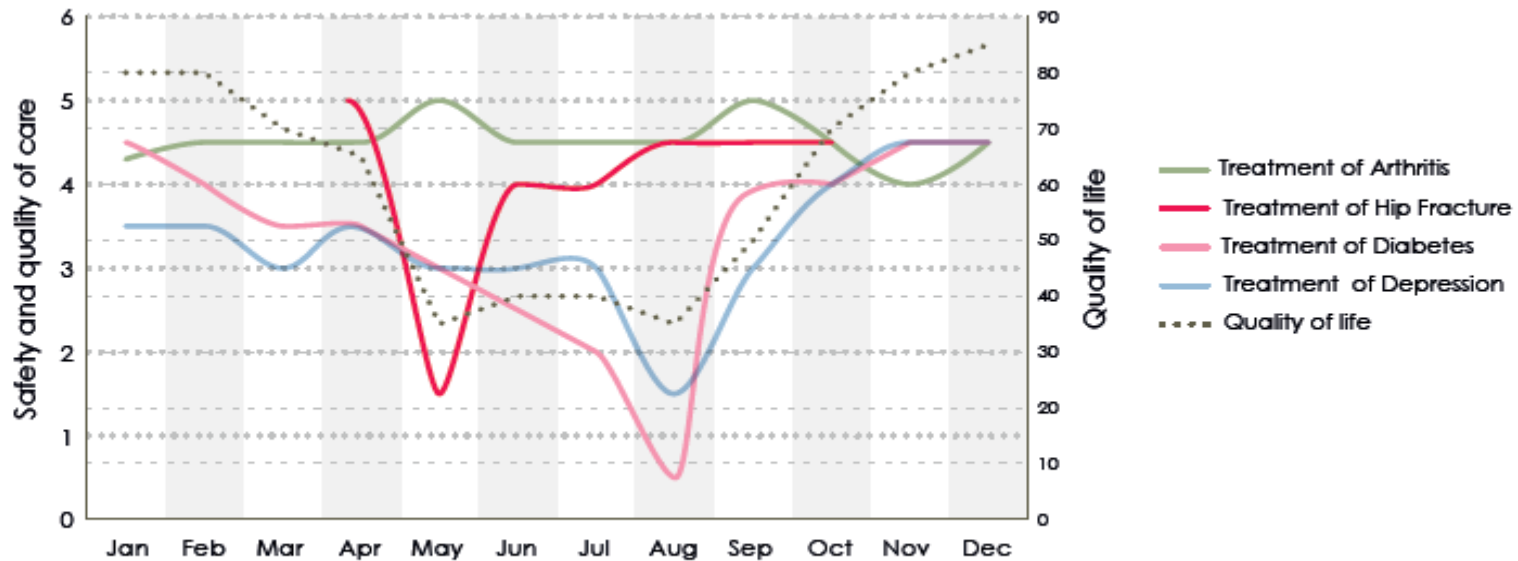
Treatment of Diabetes



Treatment of Depression



THE MANAGEMENT OF RISK OVER TIME



Does this look like an incident?

DECLUTTERING HEALTHCARE

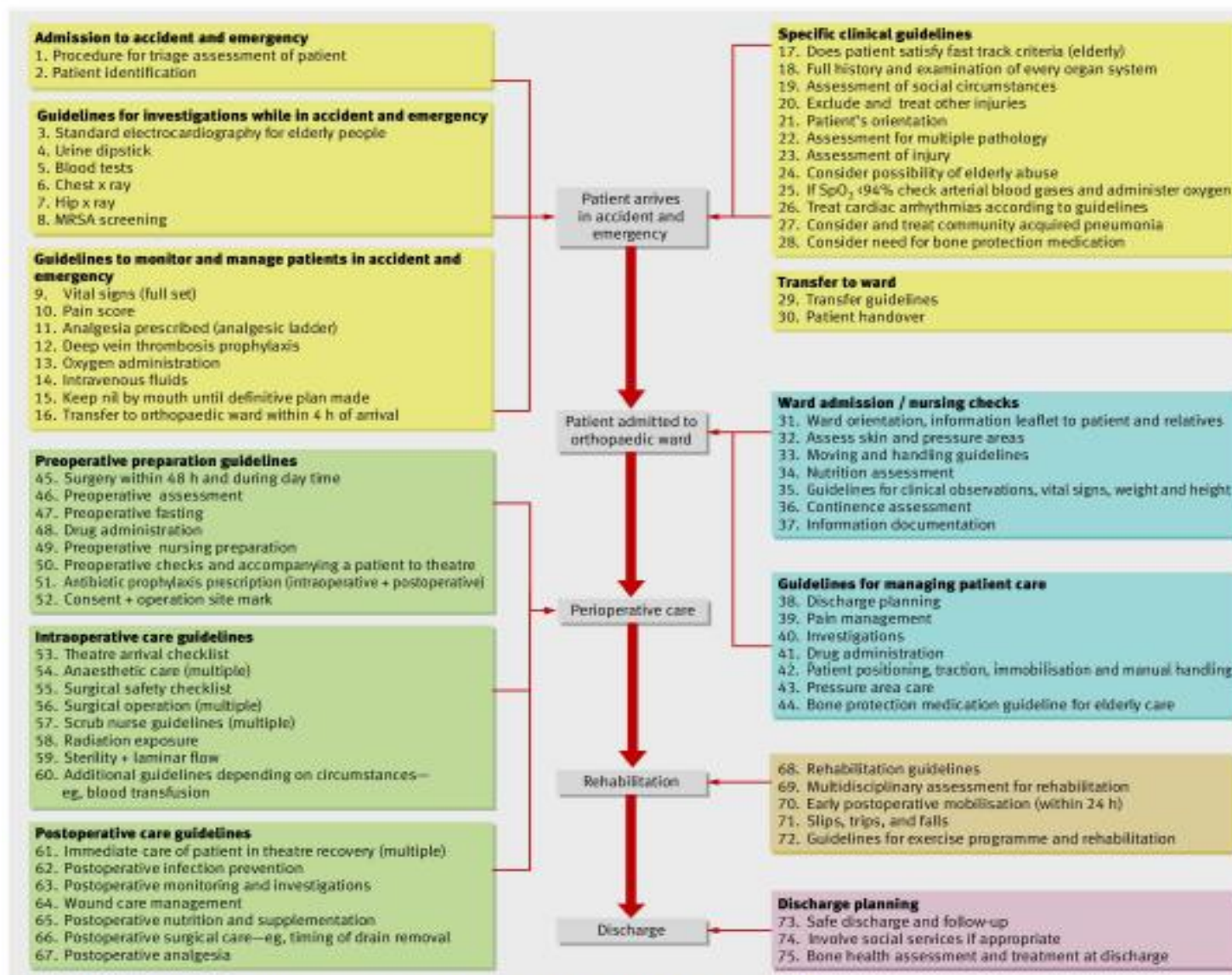
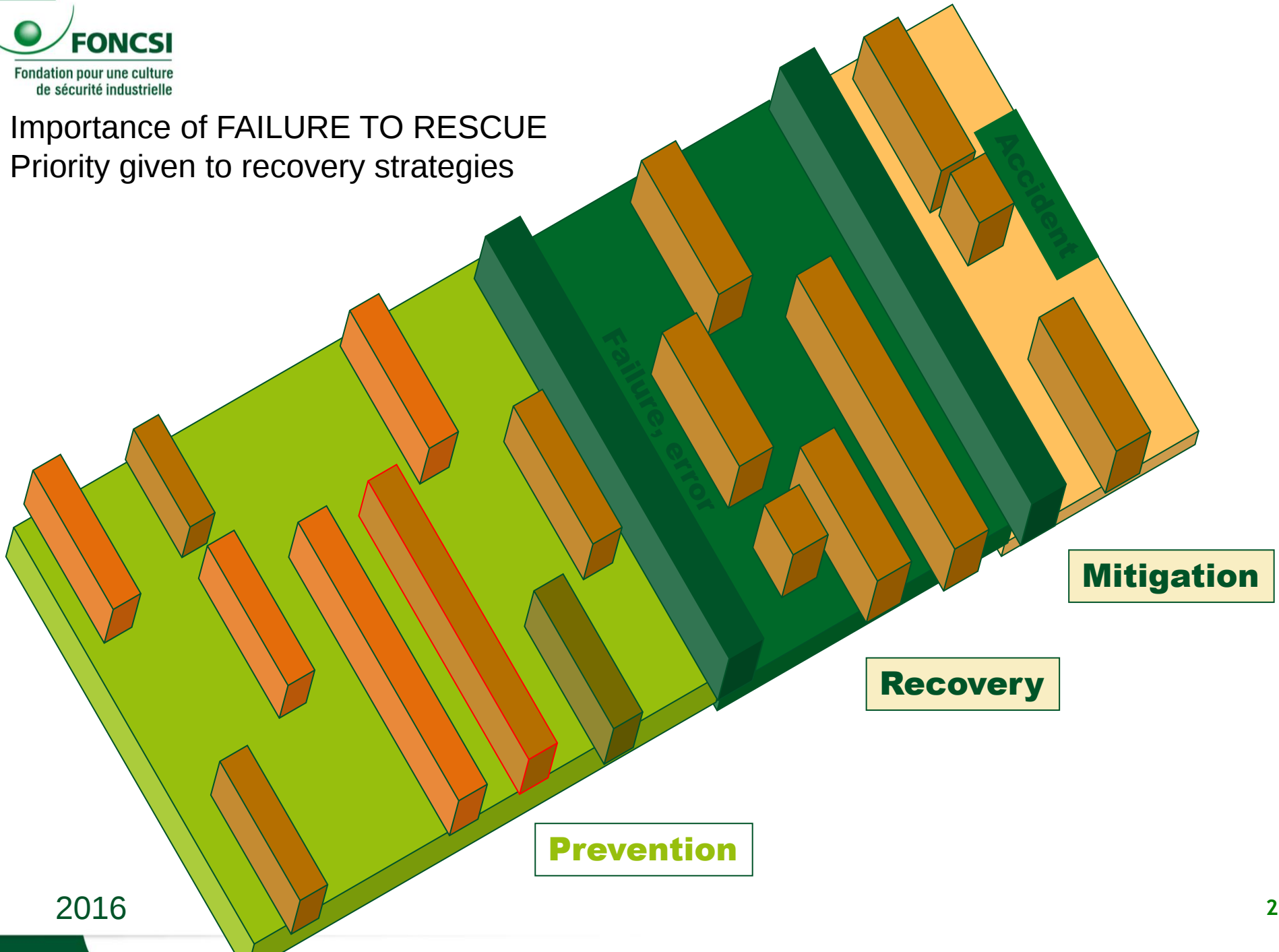


Fig 1 Typical patient journey for an elderly patient with fractured neck of femur

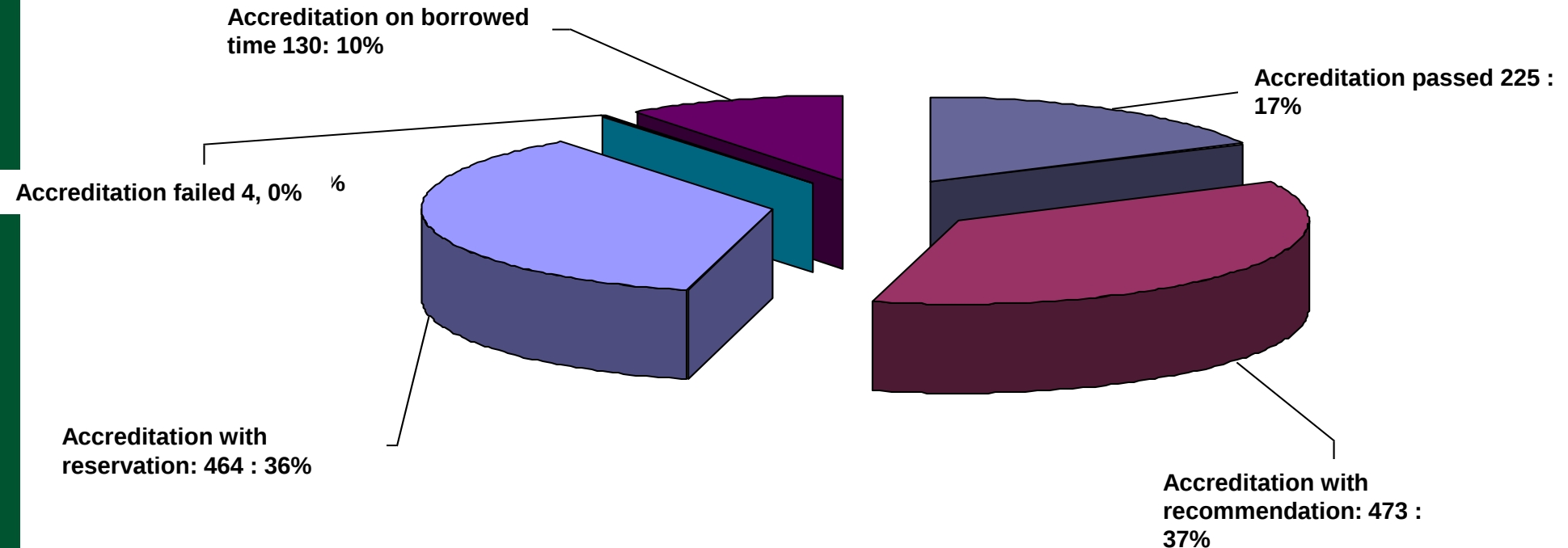
Importance of FAILURE TO RESCUE Priority given to recovery strategies



Result of French Hospital Accreditation

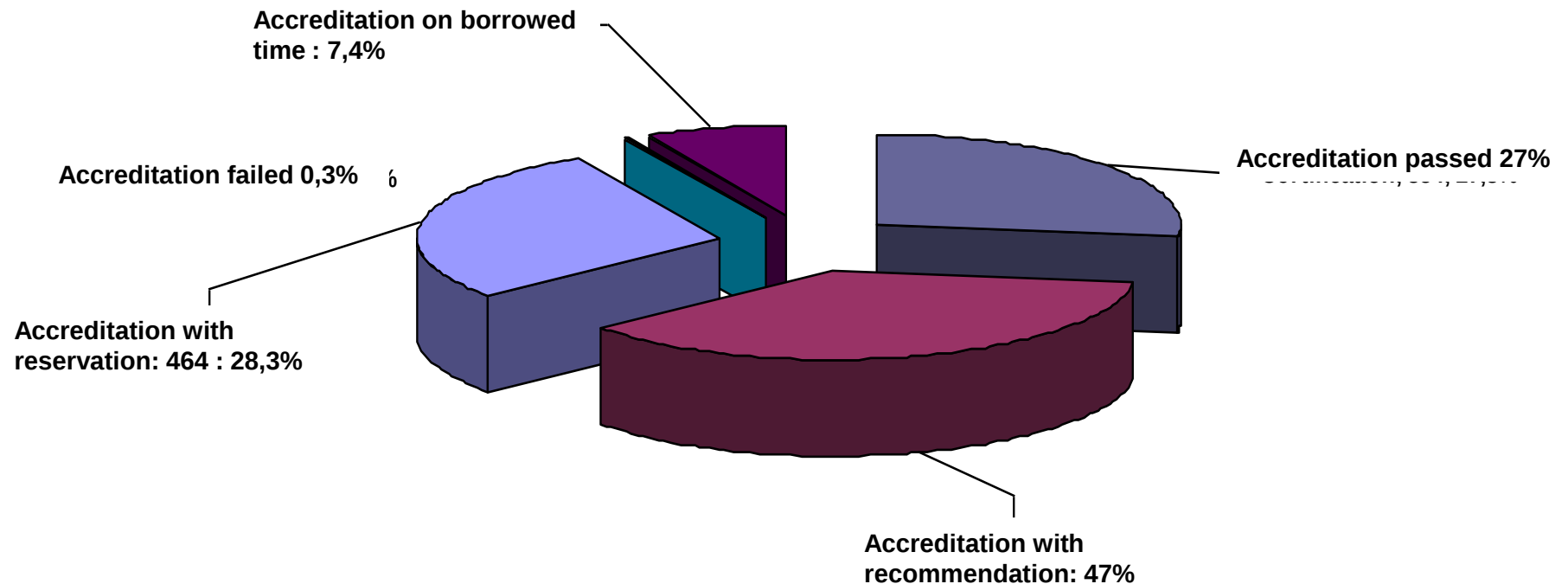
(Initial accreditation visit, HAS 2010-2014)

Sample of 1296 Hospitals, public and private



Living with non compliance is tolerated (and even the norm)

RESULT OF FRENCH HOSPITAL ACCREDITATION (AFTER A SUPPORT PERIOD OF 3 TO 18 MONTHS)



1296 Hospitals, public and private

ENHANCING MONITORING AND ADAPTATION AT THE CLINICAL AND EXECUTIVE LEVELS

- ⊙ Managers constantly adapt and firefight. How much is necessary and how much unnecessary and due to poor systems?
- ⊙ Develop planned approaches to adaptation and recovery rather than relying on ad hoc improvisation.
- ⊙ Executive training in risk scenarios and trade offs between safety and other objectives



Safety issues

Fondation pour une culture
de sécurité industrielle

Quality scheme

Legal binding requirements & policies,
Professional standards, guidelines &
Recommendations

Border line Tolerated Conditions of Use
(BTCU) implicitly acknowledge by Internal
and External Audits

Increasing doubts about the value of
supervisory control and compensatory
mechanisms. Loss of trust in
management.

MAX BAR

**ACCEPTABLE
BAR**



**ACCEPTABLE
BAR**

MIN BAR

Working authorization engaged

All applicable regulations are
followed

**Safety maintained
at top thanks to
reorganization -
compensation
strategies**

*COMPENSATORY
SOLUTIONS
Management, culture, staffing,
expertise ...*

Compensatory safety actions hide
degradation of working conditions

Safety engaged
Partial
compensation

ADAPTING SAFETY MODELS TO THE REAL FIELD

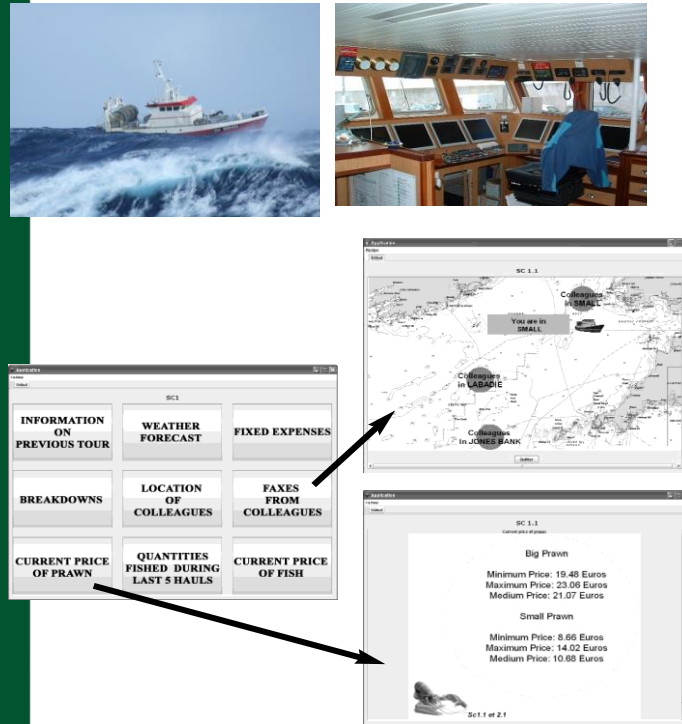
EXAMPLE

Professional deep-sea fishing as practiced by 20 to 24-meter trawlers (vessels usually manned by five fishermen, for fishing tours of four to fourteen days) 20-27 meters

Studying the fishing skippers' decision-making process by placing them in situations of conflict between production and safety.

Information :

- weather report, failures, damage to the fishing gear, occupational accidents, information on previous fishing tour, fax from colleagues on quantity of catch, selling price of prawn auction prices, localisation of colleagues, fixed expenses,...



*What are the **elements considered in priority** by captains for making decision on continuing fishing Vs giving up in extreme fishing conditions ?*

Morel, Chauvin, Safety Science 2007
Morel, Amalberti, Chauvin, Human Factors 2008
Morel, Amalberti, Chauvin, Safety Science, 2008

SAME EXAMPLE.. CONTINUE



Professional deep-sea fishing as practiced by 20 to 24-meter trawlers (vessels usually manned by five fishermen, for fishing tours of four to fourteen days) 20-27 meters

Are fishermen insensitive to safety aspects?



NO... of course... they hope getting safer

They ask for better tools for traffic collision avoidance (with cargos), and safer bridge working conditions for sailors (on trawlers)

*Morel, Chauvin, Safety Science 2007
Morel, Amalberti, Chauvin, Human Factors 2008
Morel, Amalberti, Chauvin, Safety Science, 2008*

ANOTHER EXAMPLE

Civil aviation



- ◎ 1994, A310: YR-LCA, Tarom A310, lost control during final approach on Paris Orly airport. Flight 381 was approaching to Paris-Orly runway 26 and the captain was at the controls. He decided to perform an automatic approach and landing. Before lining up with the runway, the aircraft adopted an unusual position due to a crew's wrong comprehension of an order given to the autopilot. Recovery came two long minutes after the plane entered into quasi loopings.
- ◎ 1995, A310 : Tarom flight ROT 371 took off from Bucharest-Otopeni runway 08R for a flight to Brussels . The crew was distracted and forgot monitoring aircraft attitude. The plane banked progressively, and when the crew realized the problem, they were unable to recover, 60 fatalities.

What do you think the international Authorities have decided afterwards?

☉ Fire fighting

- ☉ Group Intelligence
- ☉ Give priority on team work, leadership and adaptation to unexpected conditions
- ☉ Lessons drawn from accident analyses are primarily about ways in which the situation has been managed and could be managed better in future. (Recovery rather than Prevention)
- ☉ Five characteristics of High Reliability Organizations responsible for the "mindfulness" that keeps them working well when facing unexpected situations.
 - Preoccupation with failure
 - Reluctance to simplify interpretations
 - Sensitivity to operations
 - Commitment to resilience
 - Deference to expertise



Consider different Safety models and associated intervention strategies

ULTRA ADAPTIVE

Context : Taking risks is the essence of the profession : Sea fishing, Military war time, Drilling industry, Tradeurs (banking), Oncology, Emergency medicine

Cultural trait: Fighter spirit, cult of champions and heroes

Safety model : Power to experts

'Give me best chances and safest tools to survive in these adverse conditions and make exploits'

Safety training: Peer-to-Peer

Learning through shadowing, acquiring professional experience, "training for zebra", working on knowing one's own limitations.

Priority to recovery and mitigation strategies

HRO model

Context : Risk is not sought out, but it is inherent in the profession. Marine, Shipping Oil Industry, Processing industry, Fire-fighters, Scheduled medicine

Cult of group intelligence and adaptation to changing situations.

Safety model : Power to the group, Ability of the group to organize itself (roles), to provide mutual protection to its members, to apply procedures, to be suspicious of excessively routine simplification of the situation, to adapt, perceive changes in the context and make sense of it.

Training in teamwork to gain knowledge of the capacity of the group and adaptability in terms of applying procedures to suit the context.

Priority to recovery strategies

ULTRA SAFE

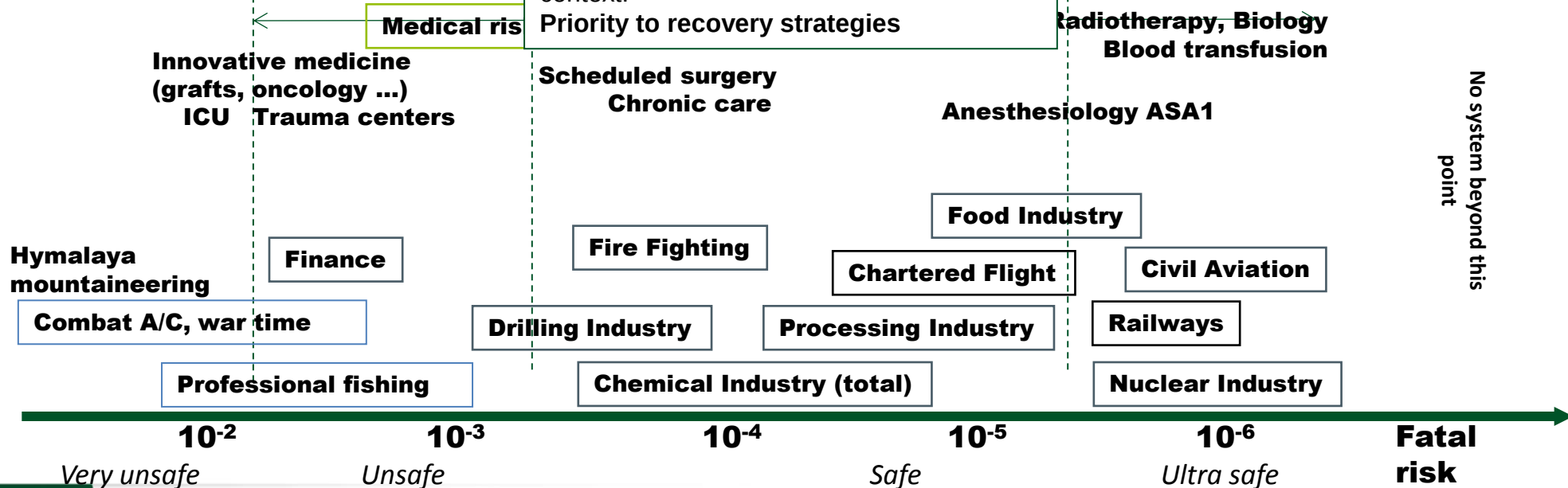
Context : Risk is excluded as far as possible: Civil aviation, Nuclear Industry, Public transportation, Food industry, Medical Lab, Blood transfusion

Cult of applying procedures and safety organized by an effective supervisory organization.

Safety model : Power to the regulators of the system to avoid exposing front-line actors to unnecessary risks.

Training in teamwork to apply procedures and apportion the work even if abnormal events occur.

Priority to prevention strategies



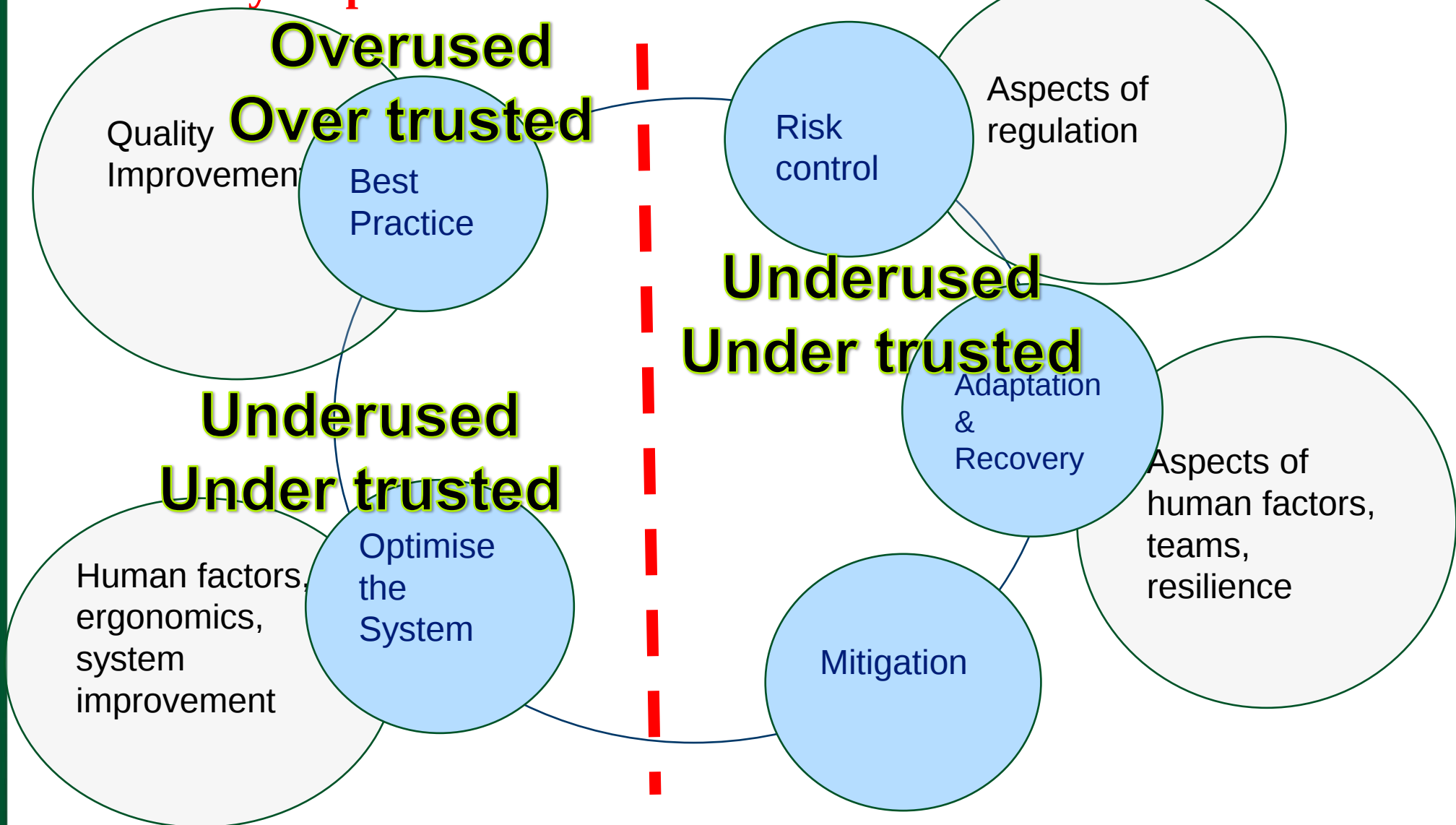
Arbitration in healthcare

- **In Europe : Among patients who died during hospitalization after major surgical procedures, 8.5% are admitted to an ICU at some point in their hospital stay. Mortality overpasses 4% for all patients and 20-30% for geriatrics patients ASA3.**
- **In the US, this figure was 7 times greater, 61% admissions in ICU. Mortality is 2,1% for all patients and 10-15% for geriatrics patients ASA3.**
- **These finding also point to the financial costs of healthcare in the US. In 2013, ICU services alone accounted for 4% of all US health care expenditures, or nearly 1% GDP.**

Using a wider range of Safety Strategies

Safety improvement

Risk Management



An incomplete taxonomy

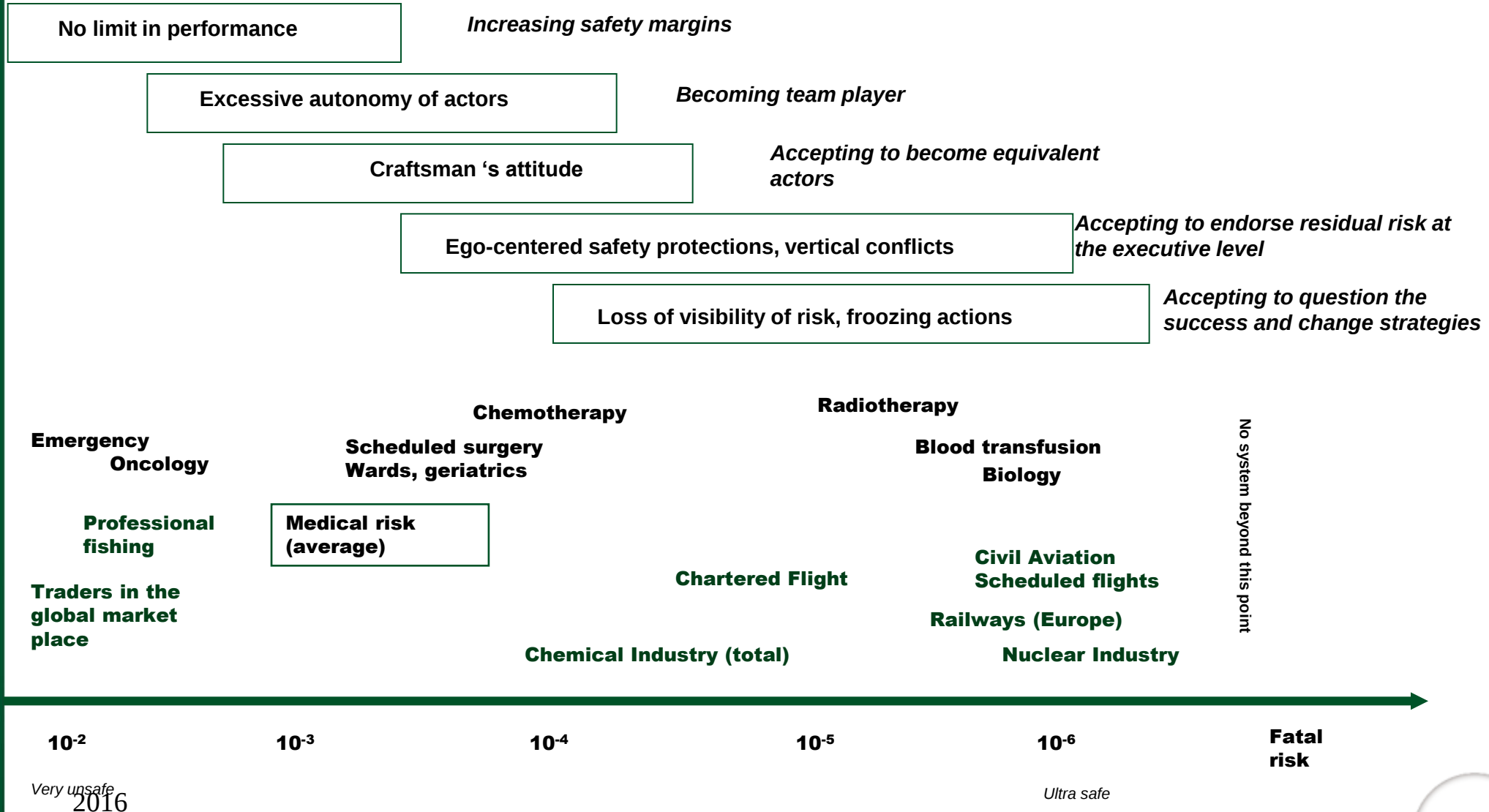
The trick is not to be bound by any one strategy but to blend to context

PLAYING ON A PALETTE OF STRATEGIES AND INTERVENTIONS TO MAKE ORGANISATIONAL ADJUSTMENTS

	Strategy	Interventions	Level of Implementation			Degree of use	Challenges
			Frontline	Organisation	System		
Optimisation strategies	Safety as best practice: aspire to standards	Focal safety programme to reduce specific harms	✓			Used ++	Allocate more time to implementation
		Improve reliability of targeted processes	✓			Underused +	Reduce disparity within settings
		Improve continuous professional education to adopt best practices	✓	✓		Used +	Limited time allocated to education and training
		Develop more sophisticated guidelines for complex patients			✓	Underused	Personalised medicine in progress
	Improvement of systems and processes	Staff training, assessment and feedback	✓	✓		Used +	Excessive use of temporary staff
		Standardisation and simplification of key processes	✓	✓	✓	Underused ++	Increasing volume of policies and wasteful processes
		IT to support decision making	✓	✓		Used +	Usability and integration into workflow remain problematic
		Automation of processes	✓	✓		Underused +	Reluctance to adopt
		Improved equipment design	✓		✓	Used +	Manufacturers not sufficiently engaged in safety
		Formalising team roles and responsibilities	✓	✓		Used	Models available but seldom implemented
		Standardisation and enhancement of handover	✓			Used	Models available but seldom implemented
		Improve working conditions : light, noise, physical environment	✓	✓		Used +	Ample margin for progress
		Reduce interruptions and distractions	✓	✓		Underused ++	Not considered as a problem
		Improve organisation and level of staffing		✓	✓	Underused +	Economic constraints and fixed professional roles
		Creation of new roles and posts to improve coordination		✓	✓	Underused +	Economic constraints and fixed professional roles
Risk management strategies	Risk control	Withdraw services		✓	✓	Underused ++	Political constraints and potential adverse social impact
		Reduce demand		✓	✓	Underused ++	Political constraints and potential adverse social impact
		Place restrictions on services		✓	✓	Underused ++	Political constraints and potential adverse social impact
		Place restrictions on individuals		✓	✓	Underused ++	Response often too late and too punitive
		Place restrictions on conditions of operation	✓	✓	✓	Underused +	Does not conform to healthcare culture
		Prioritisation of care either temporarily or permanently	✓	✓		Underused ++	Politically difficult at local level
	Monitoring, adaptation and response	Improve safety culture	✓	✓		Underused +	Often advised but seldom effectively implemented
		Improve detection of deterioration	✓	✓		Underused +	In progress with increasing attention to failure to rescue
		Develop emergency response systems	✓	✓		Used +	Many examples but could be more widely employed
		Develop team cross checking and monitoring	✓	✓		Used +	Models available and huge potential for increased use
		Briefings and anticipation of hazards	✓	✓		Used +	Models available and huge potential for increased use
		Improve organisational response to pressures and threats to safety	✓	✓		Underused +	Needs exploration, study and development
		Negotiate response to regulatory demands		✓	✓	Underused	Adversarial relationship between providers and regulators
	Mitigation	Policy of explanation, apology and support for injured patients	✓	✓		Used +	Policies exist but practice lags behind
		Rapid response to physical harm	✓			Used +	Rapid response in hospital but may be slower in community
		Psychological support for patients and families	✓	✓		Underused +	Policies exist but practice lags behind
		Peer to peer support programmes for staff	✓	✓		Underused ++	Models exist but few examples of effective implementation
		Formal support and mentoring for staff	✓	✓		Underused ++	Models exist but few examples of effective implementation
		Insurance of staff and organisation against claims		✓	✓	Used ++	Widely used but not linked effectively to safety initiatives
		Proactive response to complaints and claims		✓		Underused ++	Models exist but few examples of effective implementation
		Proactive response to media		✓	✓	Underused	Some examples of good practice but frequently difficult
		Open dialogue with regulators		✓	✓	Underused ++	Huge scope for improved and more productive relationships

Five system barriers to achieving ultra safe industry

Amalberti., *Ann Intern Med.* 2005;142, 9: 756-764.



UNDERSTANDING RESILIENCE

RESILIENCE $S_T = S_I + S_M$

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

**Observed
Safety**

NORMS / QUALITY +

**Error avoidance
BBS/CBS/HRA**

**Based on
Rules
Regulations
Constraints**

ADAPTATION

**Surprises
management**

**Based on
Human Intelligence
Human expertise
Adaptive learning
systems**

PARADOXES OF RESILIENCE

de sécurité industrielle

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 – A TENTATIVE MAPPING EXERCISE

ULTRA ADAPTIVE

to MARKET DEMANDS & NON STANDARDS CASES -
LEARNING SYSTEMS

Incompatible with
social risk acceptance

1%?

Cherry Picking
Percentage of NO GO & working situations
excluded by the model

5%?

15% ?

RESILIENCE
Betting on
Individuals'
Competences
/expertise

HRO

Betting on sense
making
Cognitive maps,
global vision
Procedures
& team
regulations

**ULTRA SAFE
SYSTEMS**
Betting on
Systems
supervision

incompatible
with market
demands

NON ADAPTIVE

POOR LEARNING SYSTEMS

2014

Little SAFE

ULTRA SAFE

