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
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. 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 usu nurses.
Learning from other industries

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

Five System Barriers to Achieving Ultrasafe Health Care
René Amalberti, MD, PhD; Yves Janssens, MD, Don Berwick, MD, MPP; and Paul Bates, 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 craftmanship-minded 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 adapting 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.
Incident reporting
Incident analysis
Complaints and litigation
Risk management standards
Safety culture as foundation and as driver
Checklists and bundles
Some major successes
Tackling safety across an organisation
Baines R. & al BMJ Qual Saf 2013…NO
Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study

Design Longitudinal retrospective patient record review study.


Results Multilevel analyses of 11 883 patient records showed that the rate of patients experiencing an AE increased from 4.1% in 2004 to 6.2% in 2008.

More than 50% of all AEs were related to surgery. Indications were found that differences in the risk of experiencing a preventable AE between hospital departments were larger in 2008 than in 2004, while differences between hospitals themselves were smaller.

Transforming healthcare: a safety imperative
Healthcare is unsafe…/… The IOM called in 2000 for a major national effort to reduce medical errors by 50% within 5 years, but progress since has fallen far short.
Major successes in focal clinical areas

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

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

Continuous progresses
• Surgery on patients over 85
• New Stroke care ...

The ‘power of innovation’
Of 100 systematic reviews
Median time to a change that would effect clinical decisions was 5.5 years.

Average cycle of Quality interventions in complex systems

Half life knowledge in software industry: 2.9 yrs
Half life knowledge in Healthcare: 5.5 Yrs
Half life knowledge in Civil Aviation: 13 Yrs
Half life knowledge in Nuclear Industry?: 17 Yrs

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
Safety in healthcare is a 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 whenever 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. All those, 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

Evolution of the pathology

Risk Management

OVER TIME

Care

Care

Care

Care

Episode

Discharge

Entry in the Episode

AE

AE

AE

AE
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

2013

Sweden
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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 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.
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
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

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
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)
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
'Someone 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
Cultural trait: 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.
Safety training: Peer-to-Peer
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
Cultural trait: 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.
Safety training: Peer-to-Peer
Training in teamwork to apply procedures and apportion the work even if abnormal events occur.
Priority to prevention strategies

Medical risk
Innovative medicine (grafts, oncology ...)
ICU, Trauma centers
Himalaya mountaineering
Combat A/C, war time
Professional fishing

Scheduled surgery
Chronic care

Radiotherapy, Biology
Blood transfusion

Anesthesiology ASA1

Food Industry

Fire Fighting

Chartered Flight

Civil Aviation

Drilling Industry

Processing Industry

Chemical Industry (total)

Nuclear Industry

Railways

10^{-2}

10^{-3}

10^{-4}

10^{-5}

10^{-6}

Very unsafe

Unsafe

Safe

Ultra safe

Fatal risk
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

- Overused
- Best Practice
- Risk control
- Aspects of regulation

- Underused
- Optimise the System
- Adaptation & Recovery
- Aspects of human factors, teams, resilience

- Under trusted
- Human factors, ergonomics, system improvement
- Mitigation

2016
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
Five system barriers to achieving ultra safe industry


- No limit in performance
- Increasing safety margins
- Excessive autonomy of actors
- Becoming team player
- Craftsman’s attitude
- Accepting to become equivalent actors
- Ego-centered safety protections, vertical conflicts
- Accepting to endorse residual risk at the executive level
- Loss of visibility of risk, froozing actions
- Accepting to question the success and change strategies

Emergency Oncology

Professional fishing

Traders in the global market place

Chemotherapy

Scheduled surgery

Wards, geriatrics

Radiotherapy

Blood transfusion

Biology

Chartered Flight

Civil Aviation

Scheduled flights

Railways (Europe)

Nuclear Industry

Chemical Industry (total)

Medical risk (average)

Very unsafe

2016

Ultra safe

Excessive autonomy of actors

Becoming team player

Accepting to become equivalent actors

Ego-centered safety protections, vertical conflicts

Loss of visibility of risk, froozing actions

Accepting to endorse residual risk at the executive level

Accepting to question the success and change strategies

Fatal risk

10^{-2}
10^{-3}
10^{-4}
10^{-5}
10^{-6}
$S_t$ (Safety total) = $S_i$ (Safety imposed) + $S_g$ (Safety managed)
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 $S_i$

$S_t = S_i + S_m$

Morel, Amalberti, Chauvin, Human factors, 2009
Amalberti R., Navigating safety Springer 2013
ULTRA ADAPTIVE to MARKET DEMANDS & NON STANDARDS CASES - LEARNING SYSTEMS

ULTRA SAFE SYSTEMS
Betting on Systems supervision

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

RESILIENCE
Betting on Individuals’ Competences /expertise

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

1%?
5%?
15%?

Incompatible with social risk acceptance

NON ADAPTIVE POOR LEARNING SYSTEMS

Little SAFE

ULTRA SAFE

2014

incompatible with market demands