# Controlling violations to protocols & recommendations

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ISQUA & HAS


# Outline

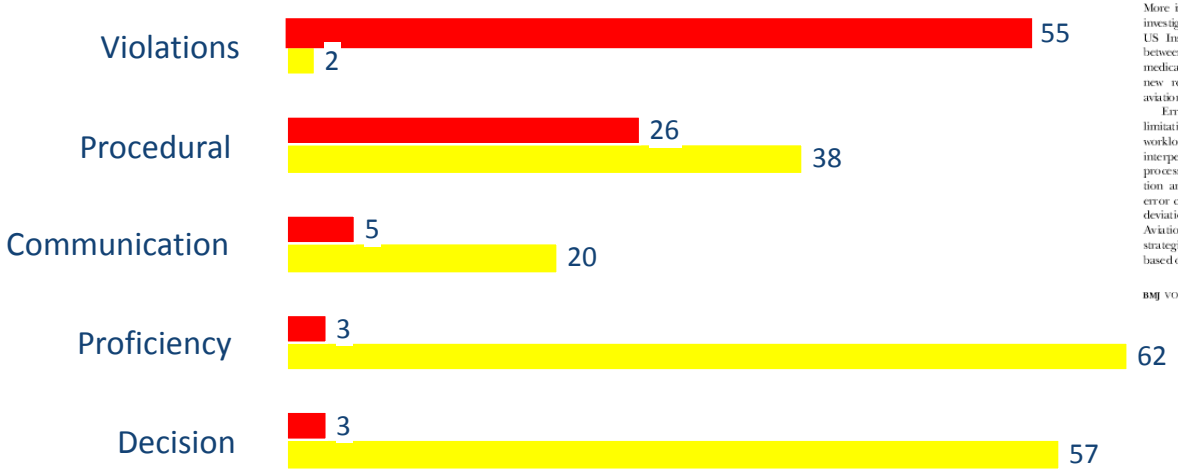
- We will see
  - HOW MANY violations and deviances we have in healthcare
  - WHY we have them
  - HOW to cope with
  - WHAT place for simulation training

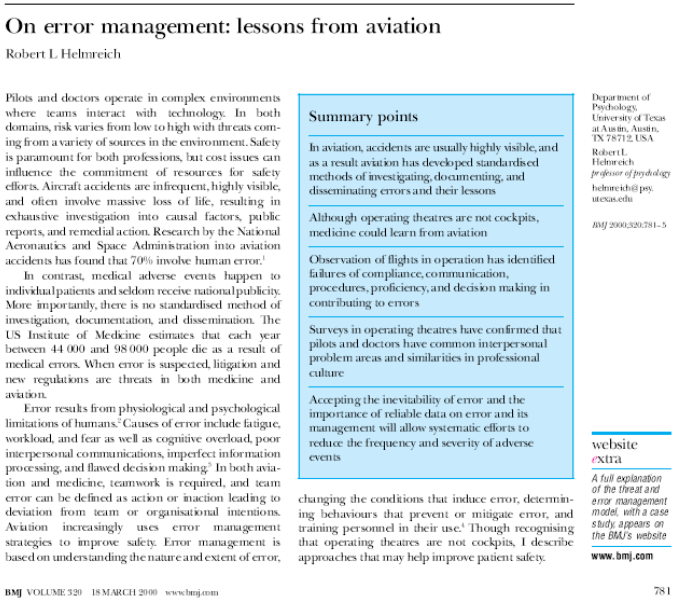
# SIZING THE PROBLEM

# Error rate and consequence for flight (5000 flights)

**(LOSA-Line-Oriented Safety Audit)**

- Average of 2 errors per hour
- Little consequence for violations



On error management: lessons from aviation

Robert L Helmreich

Pilots and doctors operate in complex environments where teams interact with technology. In both domains, risk varies from low to high with threats coming from a variety of sources in the environment. Safety is paramount for both professions, but cost issues can influence the commitment of resources for safety efforts. Aircraft accidents are infrequent, highly visible, and often involve massive loss of life, resulting in exhaustive investigation into causal factors, public reports, and remedial action. Research by the National Aeronautics and Space Administration into aviation accidents has found that 70% involve human error.[1]

In contrast, medical adverse events happen to individual patients and seldom receive national publicity. More importantly, there is no standardised method of investigation, documentation, and dissemination. The US Institute of Medicine estimates that each year between 44 000 and 98 000 people die as a result of medical errors. When error is suspected, litigation and new regulations are threats in both medicine and aviation.

Error results from physiological and psychological limitations of humans.[2] Causes of error include fatigue, workload, and fear as well as cognitive overload, poor interpersonal communications, imperfect information processing, and flawed decision making.[3] In both aviation and medicine, teamwork is required, and team error can be defined as action or inaction leading to deviation from team or organisational intentions. Aviation increasingly uses error management strategies to improve safety. Error management is based on understanding the nature and extent of error, changing the conditions that induce error, determining behaviours that prevent or mitigate error, and training personnel in their use.[4] Though recognising that operating theatres are not cockpits, I describe approaches that may help improve patient safety.

**Summary points**

In aviation, accidents are usually highly visible, and as a result aviation has developed standardised methods of investigating, documenting, and disseminating errors and their lessons

Although operating theatres are not cockpits, medicine could learn from aviation

Observation of flights in operation has identified failures of compliance, communication, procedures, proficiency, and decision making in contributing to errors

Surveys in operating theatres have confirmed that pilots and doctors have common interpersonal problem areas and similarities in professional culture

Accepting the inevitability of error and the importance of reliable data on error and its management will allow systematic efforts to reduce the frequency and severity of adverse events

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website extra

*A full explanation of the threat and error management model, with a case study, appears on the BMJ's website*

www.bmj.com



%ERROR CONSEQUENTIAL FOR FLIGHT

ERROR RATE

# Venous thrombo-embolism risk and prophylaxis

- 68 183 patients were enrolled; 30 827 (45%) were categorised as surgical, and 37 356 (55%) as medical
- On the basis of American College of Chest Physicians - ACCP-criteria, 35 329 patients were judged to be at risk for venous thromboembolism -VTE-, including 19842 surgical patients and 15 487 medical patients.
- Of the surgical patients at risk, 11 613 (58·5%) received ACCP-recommended VTE prophylaxis, compared with 6119 (39·5%) at-risk medical patients

Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study

Alexander T Cohen, Victor F Tapson, Jean-Francois Bergmann, Samuel Z Goldhaber, Ajay K Kakkar, Bruno Deslandes, Wei Huang, Maksim Zayaruzny, Leighl mary, Frederick A Anderson Jr, for the ENDORSE investigators*

Summary

Background Information about the variation in the risk for venous thromboembolism (VTE) and in prophylaxis practices around the world is scarce. The ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) study is a multinational cross-sectional survey designed to assess the prevalence of VTE risk in the acute hospital care setting, and to determine the proportion of at-risk patients who receive effective prophylaxis.

Methods All hospital inpatients aged 40 years or over admitted to a medical ward, or those aged 18 years or over admitted to a surgical ward, in 358 hospitals across 32 countries were assessed for risk of VTE on the basis of hospital chart review. The 2004 American College of Chest Physicians (ACCP) evidence-based consensus guidelines were used to assess VTE risk and to determine whether patients were receiving recommended prophylaxis.

Findings 68 183 patients were enrolled; 30 827 (45%) were categorised as surgical, and 37 356 (55%) as medical. On the basis of ACCP criteria, 35 329 (51·8%; 95% CI 51·4–52·2; between-country range 35·6–72·6) patients were judged to be at risk for VTE, including 19 842 (64·4%; 63·9–64·9; 44·1–80·2) surgical patients and 15 487 (41·5%; 41·0–42·0; 21·1–71·2) medical patients. Of the surgical patients at risk, 11 613 (58·5%; 57·8–59·2; 0·2–92·1) received ACCP-recommended VTE prophylaxis, compared with 6119 (39·5%; 38·7–40·3; 3·1–70·4) at-risk medical patients.

Interpretation A large proportion of hospitalised patients are at risk for VTE, but there is a low rate of appropriate prophylaxis. Our data reinforce the rationale for the use of hospital-wide strategies to assess patients' VTE risk and to implement measures that ensure that at-risk patients receive appropriate prophylaxis.

Introduction

Venous thromboembolism (VTE) is a common complication during and after hospitalisation for acute medical illness or surgery. Pulmonary embolism accounts for 5–10% of deaths in hospitalised patients, making VTE the most common preventable cause of in-hospital death.[1,2] In addition to the acute risk of mortality, VTE is associated with long-term risks of post-thrombotic syndrome[3] and chronic thromboembolic pulmonary hypertension.[4] These complications contribute substantially to patient morbidity and the cost of management.

Evidence-based consensus guidelines for VTE prophylaxis have been available for more than 15 years.[5] Despite the existence of these guidelines, VTE prophylaxis remains underused.[6,7] Existing studies have assessed compliance with prophylaxis guidelines within defined institutions or countries,[8,9–11] but to date, the proportion of at-risk patients who should receive prophylaxis globally remains unknown.

We did the multinational, observational, cross-sectional Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting (ENDORSE) study, a chart audit of medical and surgical patients in a large sample of hospitals worldwide. The study was designed to assess the number of patients at risk for VTE in the acute care hospital setting and to determine the proportion of these at-risk patients who received prophylaxis as recommended by the American College of Chest Physicians (ACCP) evidence-based consensus guidelines.[5]

Methods

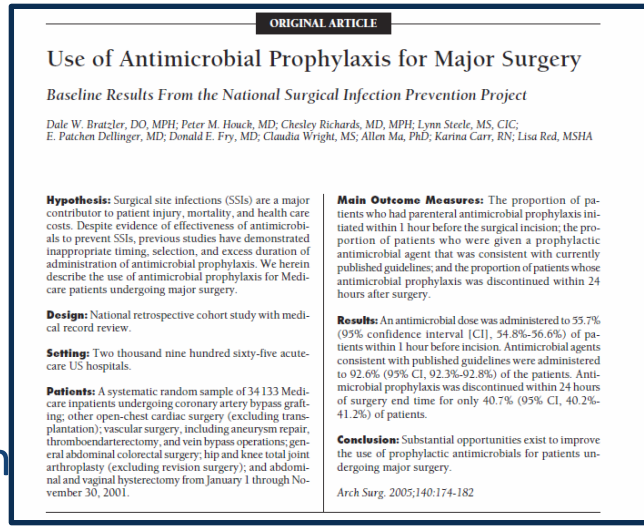
Procedures

Hospitals were considered eligible for enrolment if they contained more than 50 beds, admitted patients for the treatment of medical illnesses and exacerbations of chronic diseases, and scheduled routine major surgical procedures. Non-acute and single specialty hospitals were excluded.

Hospitals were selected at random from authoritative lists of acute care hospitals in 32 participating countries. In the USA, a list of acute care hospitals from the American Hospital Association was used.[12] The European Hospital Register was used to identify eligible hospitals in major European countries.[13] For other countries, equivalent lists were obtained from the respective national hospital association or government health authorities. The study coordinating centre provided lists of randomly selected hospitals to the principal investigators, who contacted the hospital director at each site. Random number tables were used to select the sample of study hospitals by use of SAS version 9.1.

# Surgical site infections (SSIs) and antimicrobial prophylaxis

- Despite evidence of effectiveness of antimicrobials to prevent SSIs, numerous studies have demonstrated inappropriate timing, selection, and excess duration of administration of antimicrobial prophylaxis
- Two thousand nine hundred sixty-five acutecare US hospitals.
- An antimicrobial dose was administered to 55.7% of patients within 1 hour before incision.
- Antimicrobial agents consistent with published guidelin were administered to 92.6% of the patients.
- Antimicrobial prophylaxis was discontinued within 24 hours of surgery end time for only 40.7% of patients.



ORIGINAL ARTICLE

Use of Antimicrobial Prophylaxis for Major Surgery

*Baseline Results From the National Surgical Infection Prevention Project*

*Dale W. Bratzler, DO, MPH; Peter M. Houck, MD; Chesley Richards, MD, MPH; Lynn Steele, MS, CIC; E. Patchen Dellinger, MD; Donald E. Fry, MD; Claudia Wright, MS; Allen Ma, PhD; Karina Carr, RN; Lisa Red, MSHA*

**Hypothesis:** Surgical site infections (SSIs) are a major contributor to patient injury, mortality, and health care costs. Despite evidence of effectiveness of antimicrobials to prevent SSIs, previous studies have demonstrated inappropriate timing, selection, and excess duration of administration of antimicrobial prophylaxis. We herein describe the use of antimicrobial prophylaxis for Medicare patients undergoing major surgery.

**Design:** National retrospective cohort study with medical record review.

**Setting:** Two thousand nine hundred sixty-five acutecare US hospitals.

**Patients:** A systematic random sample of 34 133 Medicare inpatients undergoing coronary artery bypass grafting; other open-chest cardiac surgery (excluding transplantation); vascular surgery, including aneurysm repair, thromboendarterectomy, and vein bypass operations; general abdominal colorectal surgery; hip and knee total joint arthroplasty (excluding revision surgery); and abdominal and vaginal hysterectomy from January 1 through November 30, 2001.

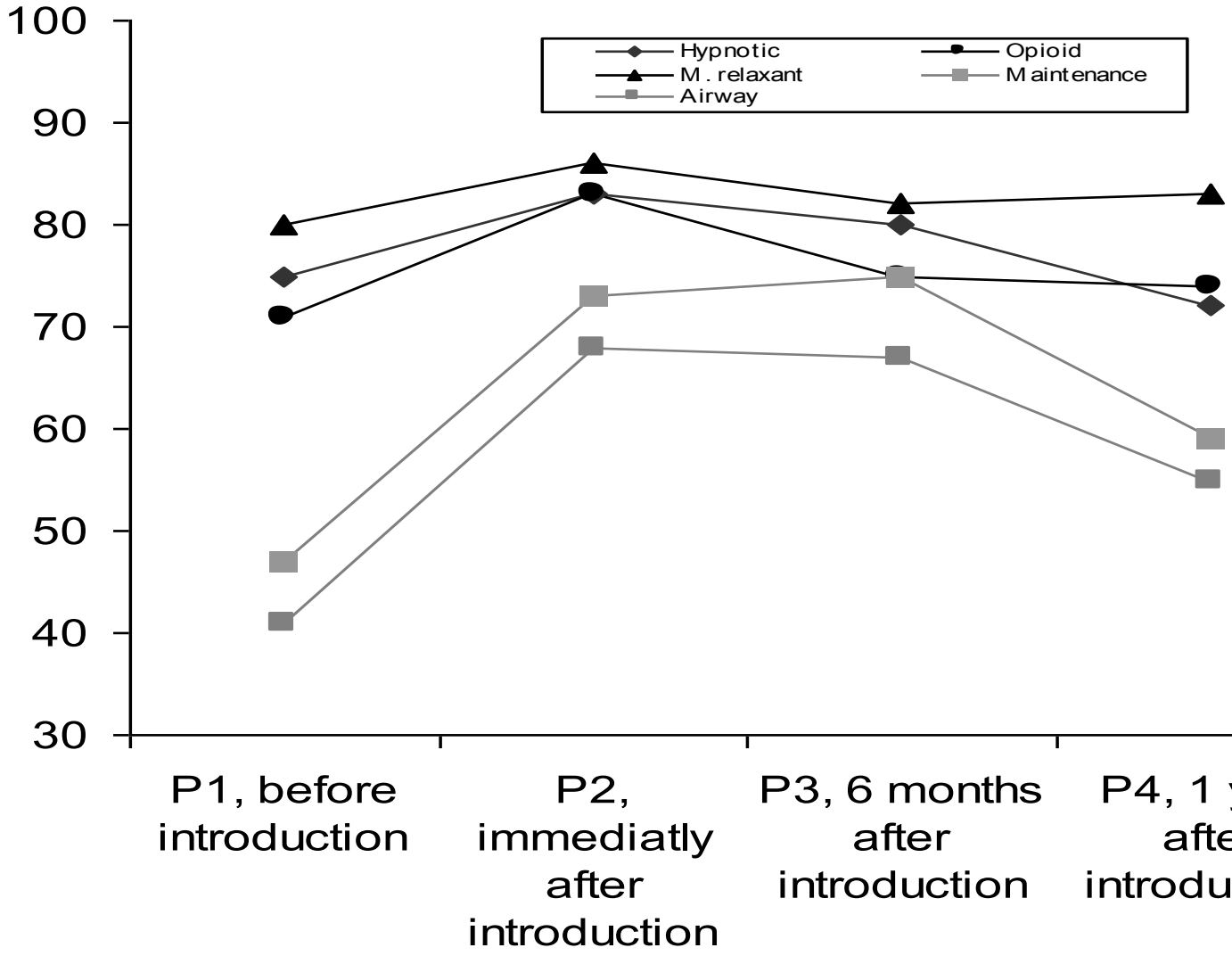
**Main Outcome Measures:** The proportion of patients who had parenteral antimicrobial prophylaxis initiated within 1 hour before the surgical incision; the proportion of patients who were given a prophylactic antimicrobial agent that was consistent with currently published guidelines; and the proportion of patients whose antimicrobial prophylaxis was discontinued within 24 hours after surgery.

**Results:** An antimicrobial dose was administered to 55.7% (95% confidence interval [CI], 54.8%-56.6%) of patients within 1 hour before incision. Antimicrobial agents consistent with published guidelines were administered to 92.6% (95% CI, 92.3%-92.8%) of the patients. Antimicrobial prophylaxis was discontinued within 24 hours of surgery end time for only 40.7% (95% CI, 40.2%-41.2%) of patients.

**Conclusion:** Substantial opportunities exist to improve the use of prophylactic antimicrobials for patients undergoing major surgery.

*Arch Surg. 2005;140:174-182*

# Case study : the natural lifespan of a safety policy




The natural lifespan of a safety policy: violations and system migration in anaesthesia

Guillaume de Saint Maurice,[1] Yves Auroy,[2] Charles Vincent,[3] René Amalberti[4]

**ABSTRACT**

**Background** Safety rules continue growing rapidly, as if constraining human behaviour was the unique avenue for reaching ultimate safety. Safety rules are essential for a safe system, but their multiplication can have counterproductive effects.

**Objective** To monitor, in an anaesthesia ward, compliance with a process-oriented safety rule, and understand barriers and facilitators which help and hinder physicians from following guidelines.

**Methods** The rule stipulated that the day before surgery anaesthetists had to record in the patient's file the drugs to be used for the anaesthesia (induction, maintenance, airway control). Compliance was assessed before introduction of the rule, immediately after, at 6 months and at 12 months. All medical staff were blinded to the protocol.

**Results** 717 patient records were included. The results showed an initial compliance with policy, reaching 86% for some items (never 100%). Reduction began within 6 months and returned almost to initial levels within a year. One individual showed poor compliance throughout the study but even initially compliant doctors experienced a reduction. Compliance was higher for complex surgery but lower for unscheduled surgery and when job pressure was greater.

**Conclusions** Compliance eroded over time. A major trigger of erosion seemed to be lack of continued compliance by a senior member of staff. Rules and procedures constitute fragile safety barriers, and it may be better to forego introducing a new safety rule if it is not considered as a priority by staff and is therefore vulnerable to sacrifice in case of conflict with competitive demands.

improvements in clinical outcomes. Many of these procedures are certainly implicated in safety incidents but, by themselves, are not the sole cause. Interventions to improve such clinical processes may be valuable in reducing the overall level of risk in the system, although vulnerabilities in such processes are seldom by themselves sufficient to cause patient harm. Nevertheless, such rules tend to be acceptable, provided the intervention is low cost, easy to implement and with low risk of harm; then, the strength of evidence need not be high to justify implementation. The decision usually refers to this as the 'proportionality of burden of proof.'[2]

The main problem with rules is not so much their potential intrinsic value but compliance with them. The compliance with even proven safety recommendations remains low.[3] The problem of compliance may be much greater with rules without a clear evidence base and have no immediate negative feedback on the patient when not followed.

Non-compliance to safety rules is, however, less easy to define, as the expected level of compliance depends on the type of instruction, the nature of the work, and the social and organisational context. In healthcare, for instance, evidence-based medicine is the source of guidance for practice but not of mandatory guidelines.[4] In some cases, therefore, strict observance is understood to be necessary, whereas, in others, some flexibility is tolerated or even expected. However, serious violations are likely to be severely penalised in all circumstances. Although there are many degrees of non-compli-

# A MODEL FOR UNDERSTANDING WHY AND COPING WITH DEVIATIONS

# Systemic Migration to Boundaries


SAFETY BY DESIGN

Violations and migrations in health care: a framework for understanding and management

R Amalberti, C Vincent, Y Auroy, G de Saint Maurice

INDIVIDUAL BENEFITS

VERY UNSAFE SPACE

'Illegal normal'
Real life standards

Safety regs & good practices
Certification/ accreditation
standards

'Illegal Illegal'
Space

BTCUs
Usual Space
of Action

Market demand

Expected safe space of
action
as defined by
professional standards

Never
Sometimes

Always
sometimes

Never
never

Always always

Technology

Individual
concerns
*Time on duty,*
*Life quality, ...*

ACCIDENT

PERFORMANCE

# Concept of Border-line Tolerated Conditions of Use (BTCU)

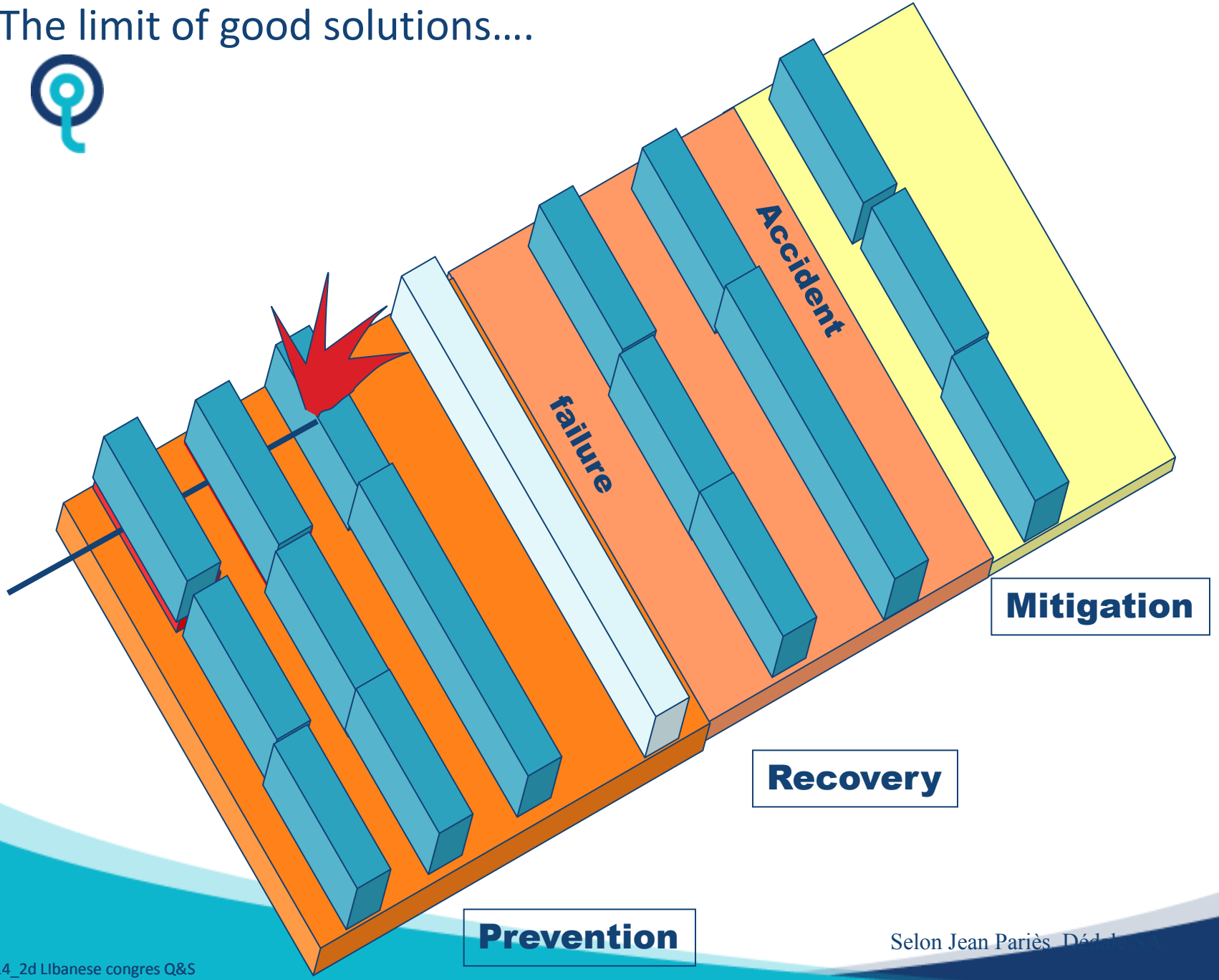
- **The BTCU becomes the ‘stabilized usual level of performance**
  - We do them regularly with only rare adverse outcomes.
  - We come to feel safer and safer.
  - We come to the BTCU as normal and safe.
  - First there are benefits rather than problems.
  - Risks are known and supposedly under control.
  - Practices are rarely penalized.

# Five causes of migrations

- **Constraint on the legal goal/ legal procedure**
  - Unachievable goal
  - Time missing, sub-system missing, sub-system inoperative – failure
- **Facilitation of group cohesion**
  - **Give priority to please the team members, or reduce burden on them i.e., wild and improvised « initiations » of new members**
- **Resilience of old procedure(s)**
  - **Cost oriented conservatory strategy**
  - **Safety oriented conservatory strategy: Feeling that the new procedure breaks routines, and has the potential to degrade safety compared to present**
- **Search for external acknowledgement of your own ‘s expert status**
- **Disputable rule**
  - **Any time a legal system is about to change (pretransition phase), or under official spot for improvement , the ease to violate is mutiply by x**

# COPING WITH THE PROBLEM
# WHAT SHOULD BE DONE

# The limit of good solutions….

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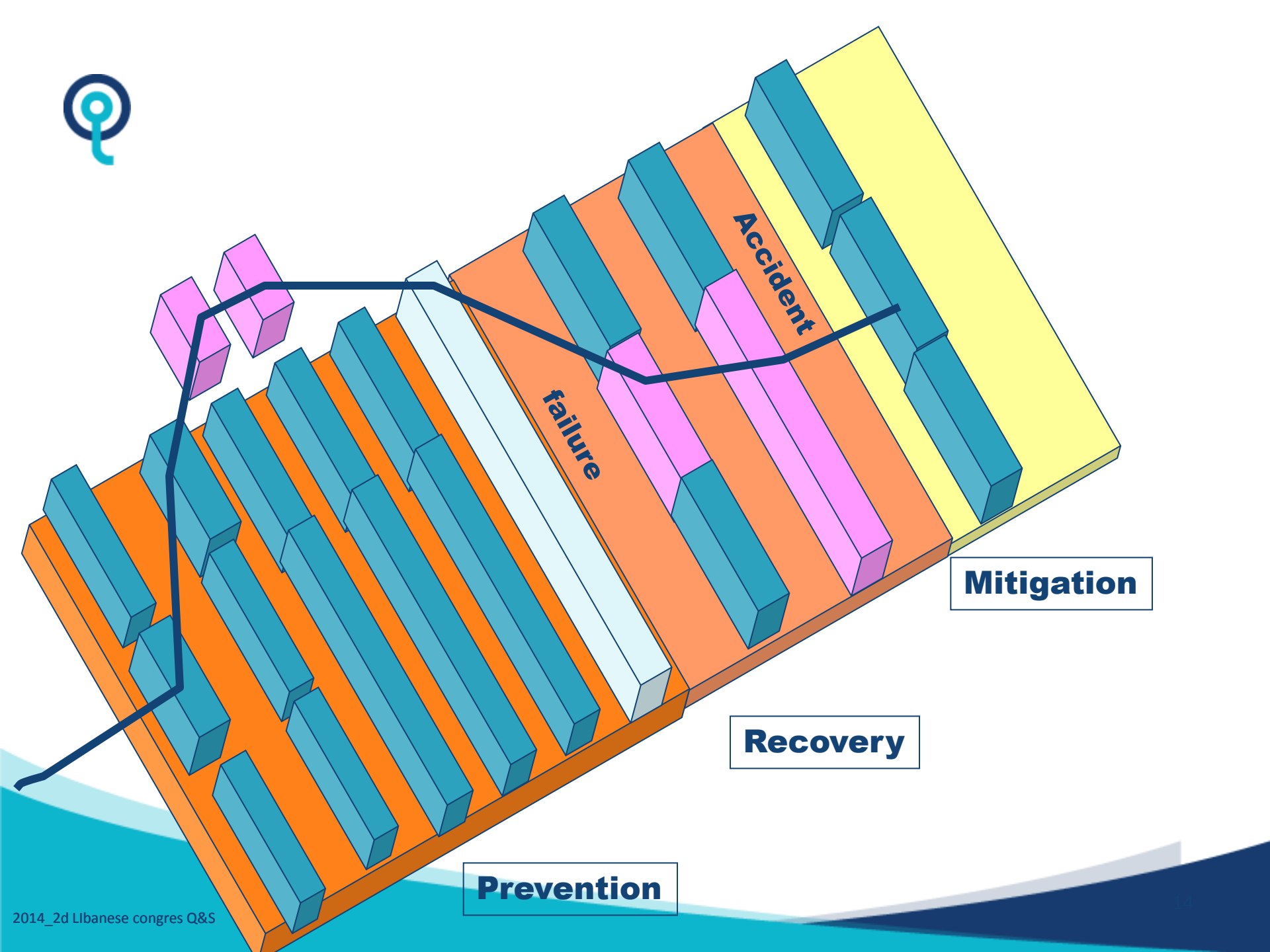
failure
Accident
Mitigation
Recovery
Prevention

# The Result of Migration is Well Known

- **There is great reluctance to monitor** these new practices with indicators, since no one really knows what to do with the results obtained
- It is essential to remember that **all stakeholders in the system migrate and deviate** from standards, even if migrations are different, depending on whether they occur at Senior Management level, in Departments, or with actors on the field.

# Test your rule prior to implementation

| | SCOPE | DESIGN VULNERABILITIES | | | | | EVALUATION |
|---|---|---|---|---|---|---|---|
| Gradation of relevance | Non comprehensive effect on patient outcome | Tolerance of non compliance by hierarchy | Easiness of Sacrifice in Adverse conditions of work | Additional resources needed (Staff, material) | Conflict with other policies | Side effects | No planned evaluation of outcome<br><br>Whole vision |
| Under control | Clear link with medical outcome and disease control | NEVER<br>Staff blamed or debriefed anytime a deviation is detected | Scarcely sacrificed | NO | NO | NO | Outcome and disease oriented |
| Potential risk, need specific action before implement ation | Ambiguous link with medical outcome | Always, when there is no adverse event associated with the deviance | Sometimes sacrificed<br>Anticipate conditions | YES<br>Additional resource given | YES<br>This new policy should have a greater importance for Authorities and Justice | YES | Process oriented<br>Targeting<br>Immediate precursors<br>( as resulting from *preliminary hazard analysis (PHA)* or *failure mode and effect analysis (FMEA)* |
| Definitively Weak | Purely process driven centered | ALWAYS, whatever consequences | Always sacrificed<br>Management will not care | YES<br>Unsolved because of costs<<< | YES<br>The conflicting policy has a greater importance for Authorties and Justice | YES, side effects are even more severe | Process oriented<br>Targeting<br>Facilitating factors (causal with outcome link not obvious) |

# Designing Safer Safety Policy

| | P1 | P2 | P3 | P4 | P5 | P6 | P7 |
|---|---|---|---|---|---|---|---|
| Score your matrix | 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 | | | | | | | |

# Take home points

**Control deviances and violations**

- If a system is designed with only a limited sphere of safe operation, violations are very likely to occur under the conditions of actual performance.
- Violations cannot be eliminated but they can be managed. Working conditions, staffing, and medical knowledge always evolve and change over time.
- Borderline tolerated conditions of use (BTCUs) are best thought of as an understandable—although not necessarily desirable—adaptation to these changes.
- Simply considering BTCUs as unacceptable behaviors requiring disciplinary action is unhelpful; a better strategy is to monitor performance continually and to identify both violations and system migrations at an early stage.
- Dialogue between clinicians and managers is a key factor in establishing a shared safety culture. Violations and potential system migration must be discussed openly.