

IOM Workshop on the Business Case for Quality Improvement



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Is There A Business Case???

YES!!!

Benefit-Cost of Patient Safety

- n Patient Safety Program in total
 - National Patient Safety Center, Regional Patient Safety Officers, Facility Patient Safety Managers, All RCA teams
 - \$130k per facility (0.1%)

If this is a facility's budget



This is Patient Safety's Share





Costs of Adverse Events

n IOM report

- Preventable adverse events account for 2% of healthcare resources (Assumes only 50% are preventable – probably should be higher)

n Falls with fractures

- \$25k to \$35k per fx; one-third die in a year

n Adverse drug events

- \$5k per event; \$3 m per year at B & W hospital

n Nosocomial infections

- Upwards of \$5k per episode



Cost Saving and Avoidance

n Hand Hygiene initiative

- \$1k investment yielded \$60k avoided care cost
 - Benefit cost ratio of 60

n Falls program

- \$25k investment yielded \$115k in fewer fx
 - Benefit cost ratio of 5

n Ventilator Humidification system

- Safer design and recurring savings of \$100k/year
 - Permanently “endowed” patient safety salary



Is There A Business Case?

n **YOU BET!!!**

n RCA/40person-hrs X 12RCA/yr =

0.25FTEE



Is There A Quality/Safety Problem?

n Yes-

But Whose?



Awareness and Shame May be Largest Hurdles

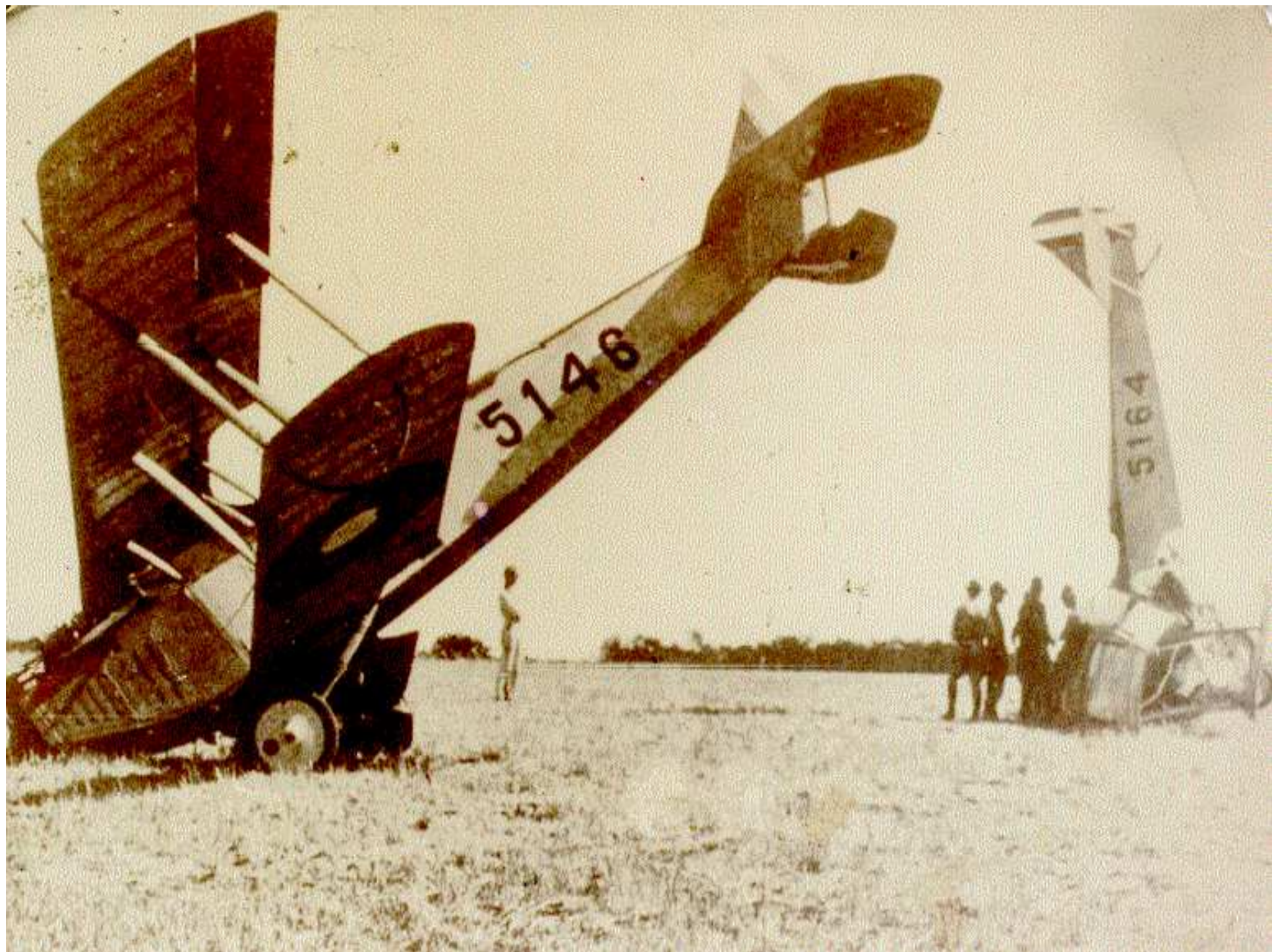
- n Survey at VHA and Data From Other Private Healthcare Organizations
 - Only 27% Agreed that Errors were a Serious Problem
 - 49% “Ashamed” by Error
- n IOM report concurs



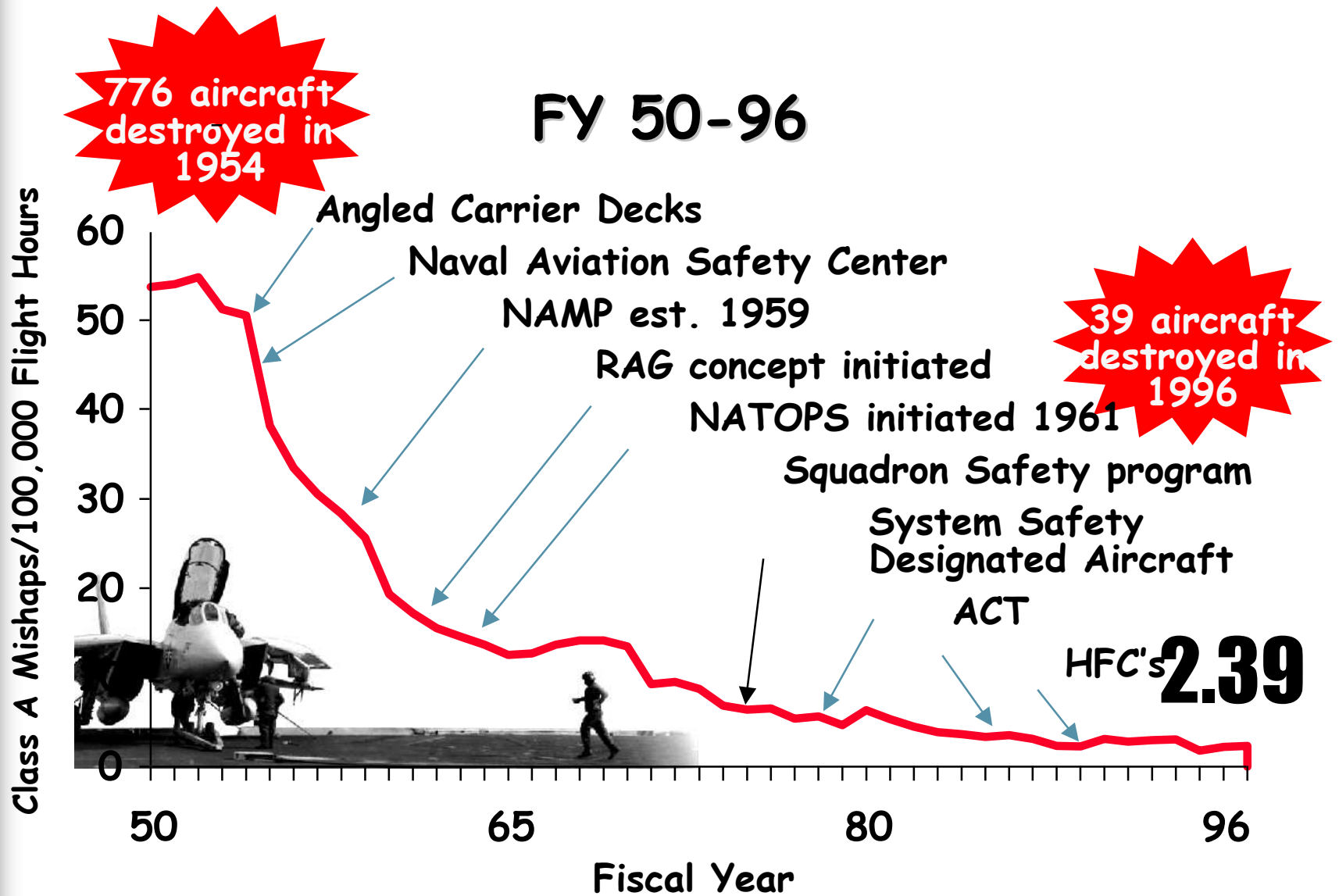
Where Healthcare Was/Is

- n Cottage Industry Mentality
- n Virtually Total Reliance on:
 - Professional/Individual Responsibility
 - Individual Perfection
 - Train and Blame
- n Little Understanding of Systems Relative to People and Processes
 - Ignorance vs Arrogance

Culturally Different!!!!



NAVAL AVIATION MISHAP RATE





Goal Selection

n Clear

- Not Confused With Tactics

n Compelling

- Relevance To Those Who Must Take Action
- Early Stakeholder Involvement in Goal Definition

n Reinforced By Leadership

- Visible Participation
 - All levels – not hierarchical

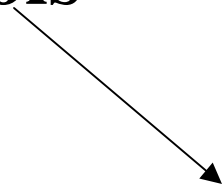


Obstacles To Addressing Problem

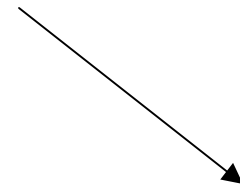
- n Problem Recognition/Ownership
- n Fear
 - Punitive/Blame/Shame
 - Cost
- n Don't Know What To Do
- n Lack of 'Evidence'

Changing Culture

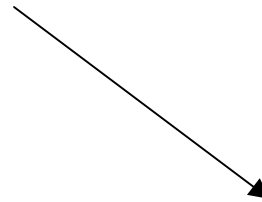
Tools



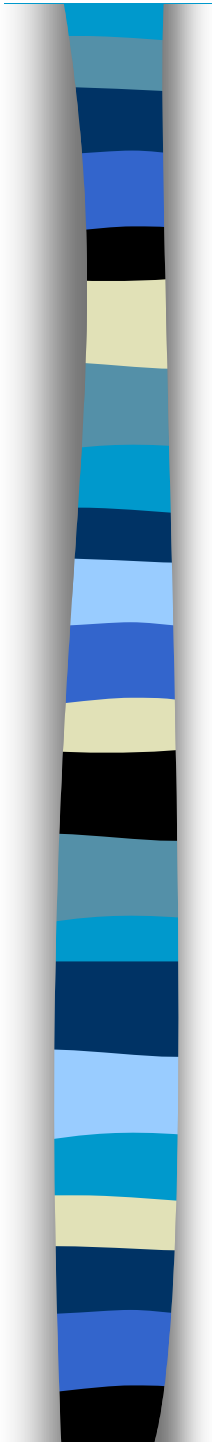
Behavior



Attitude



CULTURE!!!





Removing Fear

n Blameworthiness

- Criminal Act
- Substance Abuse
- Intentionally Unsafe Act
- Assure Perception of Fairness

n Confidentiality



Prioritization – Transparency (Internal & External)

n Risk Based

- Severity
- Probability

n Must Make Sense

- Business Processes
- Regulatory Environment

Safety Assessment Code (SAC)

SAC Score Work Chart

ACTUAL SAC

		SEVERITY			
		Catastrophic	Major	Moderate	Minor
PROBABILITY	Frequent	<input checked="" type="radio"/> 3	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1
	Occasional	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 1
	Uncommon	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 1
	Remote	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 1

POTENTIAL SAC

		SEVERITY			
		Catastrophic	Major	Moderate	Minor
PROBABILITY	Frequent	<input type="radio"/> 3	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1
	Occasional	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 1
	Uncommon	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 1
	Remote	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 1

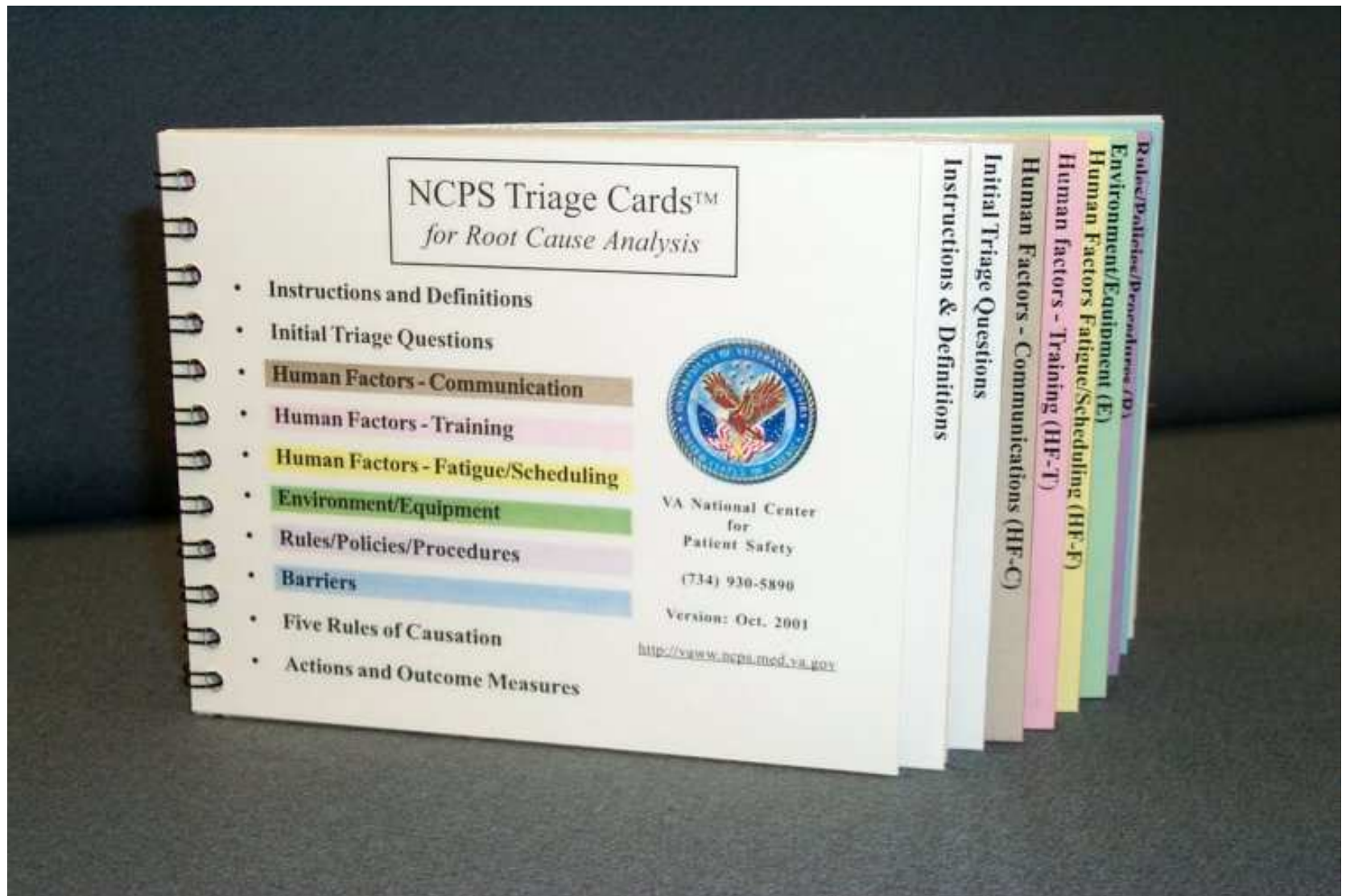
Display Definitions



Systematic Reviews

- n Cause and Effect
- n Human Error Must Have Preceding Cause
- n Failure to Follow Procedure By Itself Is **NOT** a Root Cause
- n Negative Descriptors Aren't Actionable
- n Failure To Act Is not Cause Without Pre-existing Requirement To Act
- n Why, Why, Why

Triage Cards





Management Involvement

- n Formalized, Not Ad Hoc
 - Regular Part of Agenda For All Levels
- n Safety Permeates the Fabric of All Activities
- n Relentless

Patient Safety – Getting Action

Case Number:		RCA Team Action Plan (Q. 19)			Edit Mode
Return to Main Menu		Root Cause/ Contributing factor	Action	Outcome Measures	Mgmt Concur & Notes Add/Edit Concur
Basic Information (Q. 1-7) Charter Memo Previous Event (Q. 8) Immediate Action (Q. 9) Init. Understanding (Q. 10) Resources Needed (Q. 11) Personnel Needed (Q. 12) References (Q. 13) Final Understanding (Q. 14) Root Cause Table (Q. 15) Prev. Interventions (Q. 16) Reporter Feedback (Q. 17) Lessons Learned (Q. 18) Actions/Outcomes (Q. 19) Costs and Methods (Q. 20) Attachments (Q. 21) Concurrence (Q. 22)		1 Time limitations led to no training for the nurse on the lengthy 200-page manual for the pacemaker resulting in a useless medical device due to a meaningless error code.	Add/Edit Action File dissatisfaction complaint with the company, recommend product design change. Notify VISN, NCPS. <input type="checkbox"/> eliminate <input checked="" type="checkbox"/> control <input type="checkbox"/> accept Date: 12/31/1999 Person Assigned: J Elaine, RN	# 1 Add/Edit OM Safety Alert sent to all users through NCPS. Date: 12/31/1999 Person Assigned: D Galtieri	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
		2 Because the staff nurse was not trained prior to her first use of the pacemaker she was forced to change to another pacemaker when the error code appeared resulting in delayed treatment and putting the patient at risk.	Add/Edit Action Staff re-trained on this feature. Training incorporated in all new training for this product. Notify all physician-staff involved with the external pacemaker of the Safety Alert and error code ##XX. <input type="checkbox"/> eliminate <input checked="" type="checkbox"/> control <input type="checkbox"/> accept Date: 12/31/1999 Person Assigned: K Williams	# 1 Add/Edit OM Inservice attendance records (ETS) will show that staff who use the product, and all staff in intensive care units have received training before first use. Date: 2/1/2000 Person Assigned: C McMillen	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
		3 The pacemaker company's trouble-shooting card did not include the error code feature resulting in the error code's first appearance in critical use for a patient.	Add/Edit Action Discuss implementation concerns with the company and the need for a product design change.	# 1 Add/Edit OM Receive written acknowledgement from the company of resolution of the dissatisfaction complaint.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No



Action Assessment

- n Characteristics of Actions
 - Temporary vs. Permanent
 - Procedural vs. Physical
- n Action Evaluation
 - Process
 - Outcome



Essential Elements For Sustainable Improvement

- n Appropriate Goal Identification & Selection
- n Transparent Prioritization
- n Identification of Real Causes
- n System-based Countermeasures That Address Underlying Causes
- n Stronger Actions That Are Explicit
- n Measurement of Actions
 - Process & Outcome
- n Top Leadership Involvement/Visibility





In Perspective - Einstein

Problems – “The significant problems we face cannot be solved at the same level of thinking we were at when we created them.”

“Insanity: doing the same thing over and over again and expecting different results”

Value – “Not everything that can be counted counts, and not everything that counts can be counted.”

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Abstract

Objectives To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Design Systematic review of randomised controlled trials.

Data sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.

Study selection: Studies showing the effects of using a parachute during free fall.

Main outcome measure Death or major trauma, defined as an injury severity score > 15 .

Results We were unable to identify any randomised controlled trials of parachute intervention.

Conclusions As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.

Introduction

The parachute is used in recreational, voluntary sector, and military settings to reduce the risk of orthopaedic, head, and soft tissue injury after gravitational challenge, typically in the context of jumping from an aircraft. The perception that parachutes are a successful intervention is based largely on anecdotal evidence. Observational data have shown that their use is associated with morbidity and mortality, due to both failure of the intervention^{1,2} and iatrogenic complications.³ In addition, "natural history" studies of free fall indicate that failure to take or deploy a parachute does not inevitably result in an adverse outcome.⁴ We therefore undertook a systematic review of randomised controlled trials of parachutes.

Methods

Literature search

We conducted the review in accordance with the QUOROM (quality of reporting of meta-analyses) guidelines.⁵ We searched for randomised controlled trials of parachute use on Medline, Web of Science, Embase, the Cochrane Library, appropriate internet sites, and citation lists. Search words employed were "parachute" and "trial." We imposed no language restriction and included any studies that entailed jumping from a height greater than 100 metres. The

accepted intervention was a fabric device, secured by strings to a harness worn by the participant and released (either automatically or manually) during free fall with the purpose of limiting the rate of descent. We excluded studies that had no control group.

Definition of outcomes

The major outcomes studied were death or major trauma, defined as an injury severity score greater than 15.⁶

Meta-analysis

Our statistical approach was to assess outcomes in parachute and control groups by odds ratios and quantified the precision of estimates by 95% confidence intervals. We chose the Mantel-Haenszel test to assess heterogeneity, and sensitivity and subgroup analyses and fixed effects weighted regression techniques to explore causes of heterogeneity. We selected a funnel plot to assess publication bias visually and Egger's and Begg's tests to test it quantitatively. Stata software, version 7.0, was the tool for all statistical analyses.

Results

Our search strategy did not find any randomised controlled trials of the parachute.

Discussion

Evidence based pride and observational prejudice

It is a truth universally acknowledged that a medical intervention justified by observational data must be in want of verification through a randomised controlled

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Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials



In Perspective - Goethe

“Knowing is not enough; we must apply.
Willing is not enough; we must do.”



In Perspective - Meade

“Never doubt that a small group of thoughtful committed people can change the world; indeed it’s the only thing that ever has!”