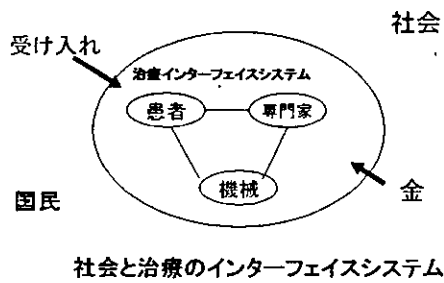


相関が認められた時に考える4つの可能性

可能性	相関	相関を生み出すもの
1. 偶然	見せかけ	無作為の誤差
2. 偏り	見せかけ	系統的誤差
3. 相関	本当	攪乱
4. 原因-結果	本当	因果関係

医療の技術評価

新たな側面の必要性



医療におけるテクノロジー・アセスメントの諸例とその主要な問題点(●印)

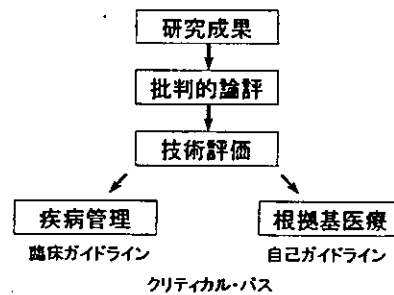
例	医学判断学	医学経済学	医学教育学	医療社会人類学	医学史学	生命倫理学
	有効性 安全性	経済性	倫理性	社会性	歴史性	倫理性
CTスキャン	●●	●	●		●	
大腸がん集団検診	●	●	●	●	●	●
肺がん集団検診	●●	●	●	●	●	●
心臓移植術	●●	●	●	●	●	●
男女産み分け術	●	●		●	●	●

定量的 ← → 定性的

テクノロジー・アセスメントのフォーマット

アセスメント	腎移植・心移植・肝移植・肺移植
・有効性 5年生存率 社会復帰率 生活の質(QOL)	
・安全性 術死亡率	
・経済性 費用効果	
・倫理性 術死ばらつき	
・社会・倫理性 死の定義	
・代替技術 人工臓器 異種移植	
・結論と今後の方向性	

概念関連図





Patient Safety Curriculum

“Why are We Here and How did We Get Here?”

John Gosbee, MD, MS

VA National Center for Patient Safety

John.Gosbee@med.va.gov www.patientsafety.gov



DAY ONE (Thursday)

8-9:15	Why are we here and how did we get here?
9:15-9:30	BREAK
9:30-10:30	Module A (Intro) in sub-sections
10:30-11	Module A small group activity
11-11:10	BREAK
11:10-12	Module B (human factors engineering)
12-12:30	Module B small group hands-on exercise
12:30-1:30	Lunch
1:30-3	Module D (RCA) small group exercise and discussion
3-3:15	Break
3:15-4:00	Module C (patient safety interventions)
4-4:30	Alternative teaching frameworks
4:30-5:30	Reception and “hands-on” patient safety exhibits



DAY TWO (Friday)

✘ 8-9:15

- Review of Day One
- Module F – Modified case conferences
- Module H – Outcomes Card idea

✘ 9:15-9:30 Break

✘ 9:30-10:45

- Module E – Swift and long term trust
- Module G – Modulette (work rounds) approach

✘ 10:45-11 Break

✘ 11-12 Small Group break out sessions

✘ 12:12:30 Report out from groups and evaluation



My Patient Safety Curriculum Experience

- ✘ Developed an aerospace medicine & engineering course - 1987
- ✘ Medical, nursing, engineering, and pharmacy learners
- ✘ Sophomores in college → Senior VP's of device companies
- ✘ Range of response
 - "The best learning of my life!" While nearly being hugged
 - "Refund my tuition money you wasted!" While nearly being spit upon

*Gosbee JW. Human Factors Engineering is the Basis for a Practical Error-in-Medicine Curriculum. In C. Johnson (Ed.) Tech Rpt G99-1. Univ. of Glasgow.
http://www.dcs.gla.ac.uk/~johnson/papers/HECS_99/Gosbee.htm



Faculty Introductions

- ✂ Each will give one crucial “nugget”
- ✂ Linda Williams
 - VA National Center for Patient Safety - NCPS
- ✂ Ed Dunn
 - VA NCPS
- ✂ Anne Tomolo
 - Cleveland VA and Case Western Reserve Univ
- ✂ Susan Lott
 - Shreveport VA

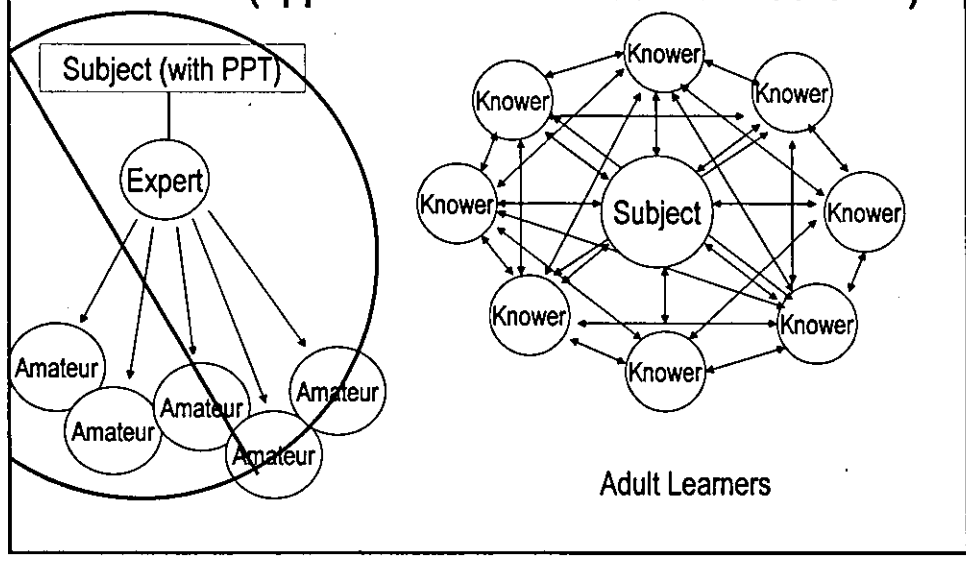


Your Introductions

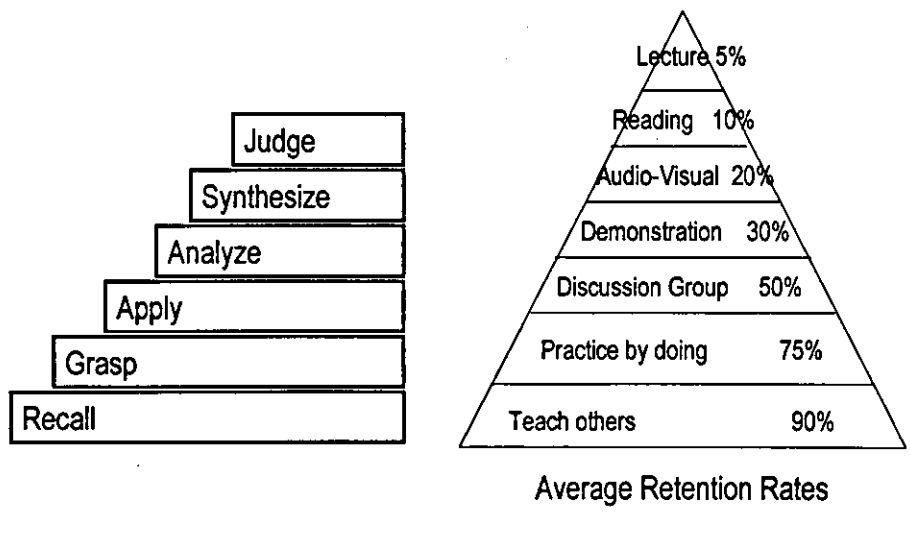
- ✂ **Verbally:**
 - Name, Title, and organization
 - One sentence: Why did you come?
- ✂ **Fill out the pre-assessment form in your folder**

Talking with Adult Learners

(applies to residents as much as CME)

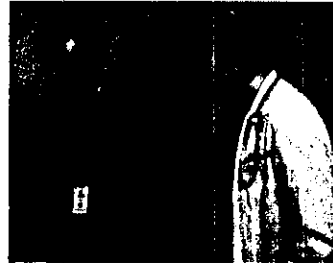


Talking with Adult Learners



Goals of the VA Curriculum

1. Residents are active agents of change towards systems and quality approach; away from "blame and train" model
2. Residents incorporate understanding of human performance and high reliability organizations into
 - Patient care
 - Patient safety activities
3. VAs help affiliated residency programs provide great education (as outlined in ACGME core competencies)



Objectives of the VA Curriculum

1. Understand the scope and gravity of patient safety events (adverse events)
2. Know theoretical & practical reasons why "blame and train" approaches fail
3. Become familiar with the basics of safety and human factors engineering
4. Understand importance of discovering root cause towards developing proper interventions
5. Become familiar with human factors engineering techniques that determine root causes and how this is crucial to the design of effective interventions
6. Understand major categories of patient safety interventions, as well as the limitations and pitfalls of automation as a countermeasure



Other Rationale for Doing This

- ✘ Meeting Guidelines and Standards
 - Federal and state regulations for VA and university hospitals
 - Joint Commission (they are considered employees)
- ✘ Academic and Policy Groups
 - AAMC, IOM (both reports), QuIC
 - AAOS, ACS, ACP, etc
- ✘ It is the right thing to do
- ✘ VA (and others) can't "fix" most safety challenges without resident participation



Resident/Fellow Participation in Patient Safety Activities - Baseline

- ✘ Analysis of National RCA database (many caveats)
 - Residents as RCA team members < 30 (< 0.1%)
 - All physicians ~ 15%!
- ✘ Details: Questionnaire of 7 VA sites
 - RCA team members = 7 (four from Atlanta)
 - RCA interviewee or consultant = 18
 - HFMEA interviewee or consultant = 6
 - Misc activities (action plans, safety committee) = 31



I will Start with Distinctions

- ✂ Some of the next two days are not exactly like other curricula
- ✂ The following are interrelated, and are not easily pulled apart
 - Your safety mindset and conceptual framework (as teacher)
 - Format of how to best teach (inculcate) this
 - Determining content of introductory and advanced modules



How is this Curriculum Different From Others?

- ✂ It borrows heavily from other academic programs struggling with teaching the systems mindset
 - Many useful tips, tools, and stories to share
- ✂ Human factors engineering is the “basic science” to safety/quality as microbiology is to infection control
- ✂ Between intentionally unsafe acts and normal (innocent) errors is a sizable set of events
 - Called (by Marx): at-risk behaviors

Error is not useful Word

- ✘ I admit it fills the literature...
- ✘ "Errors" are thought to be the end of an analysis
- ✘ Naming something "error" gives illusion of control
- ✘ For the VA safety program, the word is specifically excluded
 - Harm and hazard to patient are key foci
 - Adverse Event and Close Call
- ✘ See literature by
 - Richard Cook, MD (Univ Chicago)
 - Sidney Dekker (guide to effective investigations)

For Example: Comparison with Society of Academic Emergency Medicine (SAEM)

SAEM Pt Safety Goal	NCPS Comments	NCPS Pt. Safety Goal
Understand the concept that med is a high risk industry, error is common and perhaps inevitable	Error is inevitable, harm is not; "error" quickly becomes a troublesome term	Become an agent of change towards systems thinking...
Learn the scope and magnitude of error in Medicine	Strictly speaking, scope and magnitude are the same in medicine as for anywhere	Become an agent of change towards systems thinking...
Understand how traditional medical educ interferes with the ability to acknowledge and respond to error	Given limited time for this curric & slipperiness of this assertion, this goal is not in our "top ten"	N/A

**For Example: Comparison with Society
of Acad Emergency Med Goals (cont.)**

SAEM Pt Safety Goal	NCPS Comments	NCPS Pt Safety Goal
Understand that future improvements in medicine rely on recognizing error	Error reporting systems are great in concept, almost never true in reality. Larger issues are clear analysis, creative remedy development, and unwavering honest follow-up	Residents incorporate understanding of human performance and high reliability organizations into...
Demonstrate understanding by participating in Quality Improvement activities to identify medical error.	Add "safety" as a specific set of activities; Ironically, some quality improvement personnel/processes have not been allies (why?)	...incorporate understanding of human performance and HRO into: patient safety activities


Evolution of the Material in this Workshop

- ✂ 1994-99 Developed and taught - Michigan St Univ
- ✂ 2000-2001 Developed and taught – NCPS
- ✂ 2002-3 Combo of above, modules piloted 10 VA/Univ
- ✂ 2003-4 Refined modules, piloted faculty development and new modules



Sample Data from Michigan State University Experience

- ✂ Residents and students in month-long rotations with groups of 2-6
 - Interview with convenience sample of 6 residents, pharmacy & medical students
 - Took rotation 6, 8, 9, 10, 12, and 22 months previous to interview
 - 2 residents and 2 PharmD students now practitioners. 2 were now residents
- ✂ Results
 - 6 (all) remembered the patient safety lecture and class exercises, but not to any level of detail
 - 5 said that the change in attitude about system design had persisted.
 - Most vivid memory for 4 was their new understanding about the lack of user-centered design, and how this deficiency led to hard-to-use systems and errors.



Nursing Students at West Mich Univ

- ✂ 4 hours of required nursing informatics course
- ✂ Approx 400 students in 16 sessions over 5 yrs
- ✂ Written evaluations very good
- ✂ Qualitative finding: quotes by other nursing instructors:
 - "we can tell that the nursing students have been taught about HFE, they ask so many irritating questions on clinical rotations!"



NCPS HFE and Safety Training

- ✘ For nurses, physicians, & other healthcare personnel
 - Learning to lead activities like RCA or HFMEA
 - Approx 1800 learners at 25-plus training sessions
- ✘ Changing mindset, HRO, new look at old problems
- ✘ 10 of 20 hours were generic to all patient safety
- ✘ Highly rated, anecdotal comments great, but...
 - Stubborn old mindset or fragile new mindset
 - RCAs and other work products still improving (outcome)



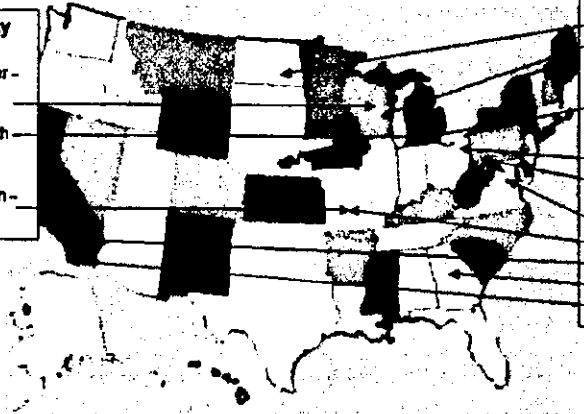
Modules for 2002-3 Pilot

1. Patient safety overview (interactive presentation - IP)
2. Human factors engineering and patient safety (IP)
3. Effective patient safety interventions (IP)
4. Root Cause Analysis – RCA (exercise)
5. Usability testing group project (exercise)
6. Journal club (interactive – group discussion)

Patient Safety Curriculum Pioneers

Patient Safety Managers

- Craig Renner - Madison, WI
- JoElyn Smith - Ann Arbor, MI
- Tim Anderson - Columbia, MO



Physician Teachers

- Kim Krohn - Univ of North Dak
- Jerry VanRuiswyk - Milwaukee
- Greg Ogrinc - White River Junx VA (VT) and Dartmouth
- Allen Kachalia & Raj Mangru - Univ of Michigan
- Mark Graber - Northport VA, NY
- Anne Tomolo - Cleveland VA
- Luke Chelluri & Richard Bjerke - Pittsburgh VA and Univ Pittsburg
- Gerry Hayes - Washington DC
- Wendy Medigoosky - Univ of M
- Ana Dvoredsky - Long Beach
- John Bonner - Atlanta VA
- Matt Weinger - San Diego VA

Physician Pioneers

- ✧ Matt Weinger - San Diego VA and UC-San Diego
- ✧ Jerry Van Ruiswyk - Milwaukee VA and Med College of WI
- ✧ Greg Ogrinc - White River Junx VA, VT and Dartmouth
- ✧ Allen Kachalia & Raj Mangrulkar - Univ of Michigan
- ✧ Mark Graber - Northport VA, NY
- ✧ John Bonner - Atlanta VA and Emory University
- ✧ Luke Chelluri & Richard Bjerke - Pittsburgh VA and Univ Pittsburgh
- ✧ Gerry Hayes - Washington DC VA
- ✧ Anne Tomolo - Cleveland VA and Case Western Reserve
- ✧ Barbara Temeck - Hines VA, Chicago
- ✧ Ana Dvoredsky - Long Beach VA, California
- ✧ Kim Krohn - Family Practice Residency - Univ of North Dakota



Patient Safety Manager Pioneers at VA Hospitals

- ✂ Craig Renner – Madison, WI
- ✂ JoEllyn Smith – Ann Arbor, MI
- ✂ Tim Anderson – Columbia, MO



Packets of Material

- ✂ Initial and one update of Powerpoint and MS word via e-mail
 - Modules I-V
 - Overview of all Modules
 - Surveys (assessments) for each
- ✂ Support Material via Mail
 - New employee orientation video & Beyond Blame video for Mod I
 - Video of Mod IV exercise on CD-ROM
 - Event investigation book by Dekker for all Modules, especially V
 - CD-ROM and Triage Cards for Mod V



Overview of Activities

- ✧ Initial and “ad hoc” one-on-one phone interviews
- ✧ Monthly teleconferences
- ✧ Packets of electronic, video, and print support
- ✧ Site visits and team teaching:
 - Milwaukee
 - Madison
 - Columbia (MO)
 - Pittsburgh
 - Cleveland



Quick Summary of Module Activities

- ✧ Lots of Module I and V by volunteers
- ✧ Some Module III, III, and IV by John during site visits
- ✧ Two sites using their previously developed lectures and exercises similar to Module I and V

Overall Summary

	Mod I	Mod II	Mod III	Mod IV	Mod V	Unique
Med Students	149	130	5	20	24	170
Residents	31	5	49	6	30	120
Fellows/ Attendings		20		20	8	40
Nursing Students		47		47		
Other Learners	20		10		10	40
CME	62					62
Sub-total	262	202	64	93	72	430

New Totals When Adding Similar Modules...

	Mod I	Mod II	Mod III	Mod IV	Mod V	Uniques
Sub-total	262	202	64	93	72	430
Estimate of "similar" modules	140	11	3		60	214
Total (approx)	402	213	67	93	132	644

Assessment

✘ Instructors

- Monthly conference calls

✘ Learners (after each teaching session)

- Written surveys for each module
- Group discussion as time allows (what worked, surprises)

Response Comparisons Between Modules

Overall, this teaching session was worthwhile

Categories: 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree

	Module 1	Module 2	Module 3	Module 4	P-value
N	95	148	42	75	
Mean	3.76	4.00	4.10	4.29	0.00 *
Range	1 - 5	1 - 5	2 - 5	2 - 5	

* Statistically significant difference between Module 1 and Modules 2 3 4 responses.

Response Comparisons Between Modules

Average response of questions Q6-Q12

Categories: 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree

	Module 1	Module 2	Module 3	Module 4	P-value
N	95	148	43	75	
Mean	3.68	3.91	3.92	4.16	0.00 *
Range of avg	1.4 - 5	1.4 - 5	2.4 - 5	2.9 - 5	

* Statistically significant difference between **Module 1** and **Modules 2 3 4** responses.

Comparisons Between Participant Type By Module

How well were teaching objectives met?

Categories: 1=Very Inadequate, 2=Inadequate, 3=Neutral, 4=Adequate, 5=Very Adequate

	Med Students	Residents	Nursing + Other	P-value
	(N) Mean	(N) Mean	(N) Mean	
Module 1	(82) 4.00	(7) 3.67	(6) 3.83	0.35
Module 2	(82) 4.06	(8) 3.88	(56) 4.11	0.61
Module 3	(3) 4.67	(21) 4.16	(19) 3.86	0.23
Module 4	(9) 4.11	(9) 4.37	(56) 4.32	0.61

Response Comparisons Between Participant Type By Module

I would recommend this teaching module to a colleague

Categories: 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree

	Med Students (N) Mean	Residents (N) Mean	Nursing + Other (N) Mean	P-value
Module 1	(82) 3.70	(7) 3.29	(6) 3.83	0.55
Module 2	(82) 3.70	(8) 4.00	(56) 4.25	0.00 *
Module 3	(3) 4.33	(19) 3.95	(19) 4.21	0.60
Module 4	(9) 4.00	(9) 3.89	(55) 4.29	0.20

* Statistically different responses between Med Students & Nursing+Other

April 2003 Three-Day Symposium

✂ 80% of volunteers attended (most with own \$)

✂ Attendance by key stakeholders

- ACGME and AHRQ
- Two university dean's office



✂ Common themes

- Liked doing some modules, but need more integration
- Need more faculty development
- "Homework" and case analysis (M&M) need more emphasis

Major Changes to Modules

Old

- I. Patient Safety Overview
- II. Human Factors Engineering
- III. Patient Safety Interventions
- IV. Usability Testing Exercise
- V. RCA Exercise

New

- A. Hazard Analysis and Assessment (I)
- B. Problem-Solving Approaches (e.g., II, human factors engineering)
- C. Safety Interventions (III)
- D. Case Analysis – Class Exercise (V)
- E. Swift and Long-Term Trust (part of I & V)
- F. Case Analysis (modified M&M)
- G. Modulettes: Just-in-Time and Integrated into Existing Curriculum (G1, G2, G3, ...)
- H. Outcomes Card
- I. Patient Safety Journal Club

New Module Formats Piloted

- ✂ Case Analysis with patient safety focus
- ✂ Modulettes to fit into existing teaching/work rounds
- ✂ Patient safety consult service
- ✂ Human factors demos → Friday VA grand rounds