4th International Conference of Evidence-Based Health Care Teachers & Developers

Better Evidence for Better Health Care

Taormina (Italy), 31st October - 4th November, 2007

Using Evidence Based Best Practices and Clinical Performance Scorecards to Improve QUALITY AND SAFETY through CLINICAL SIMULATIONS as part of a CRITICAL APPRAISAL SKILLS PROGRAM

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EBM Conference, Oxford, 2006

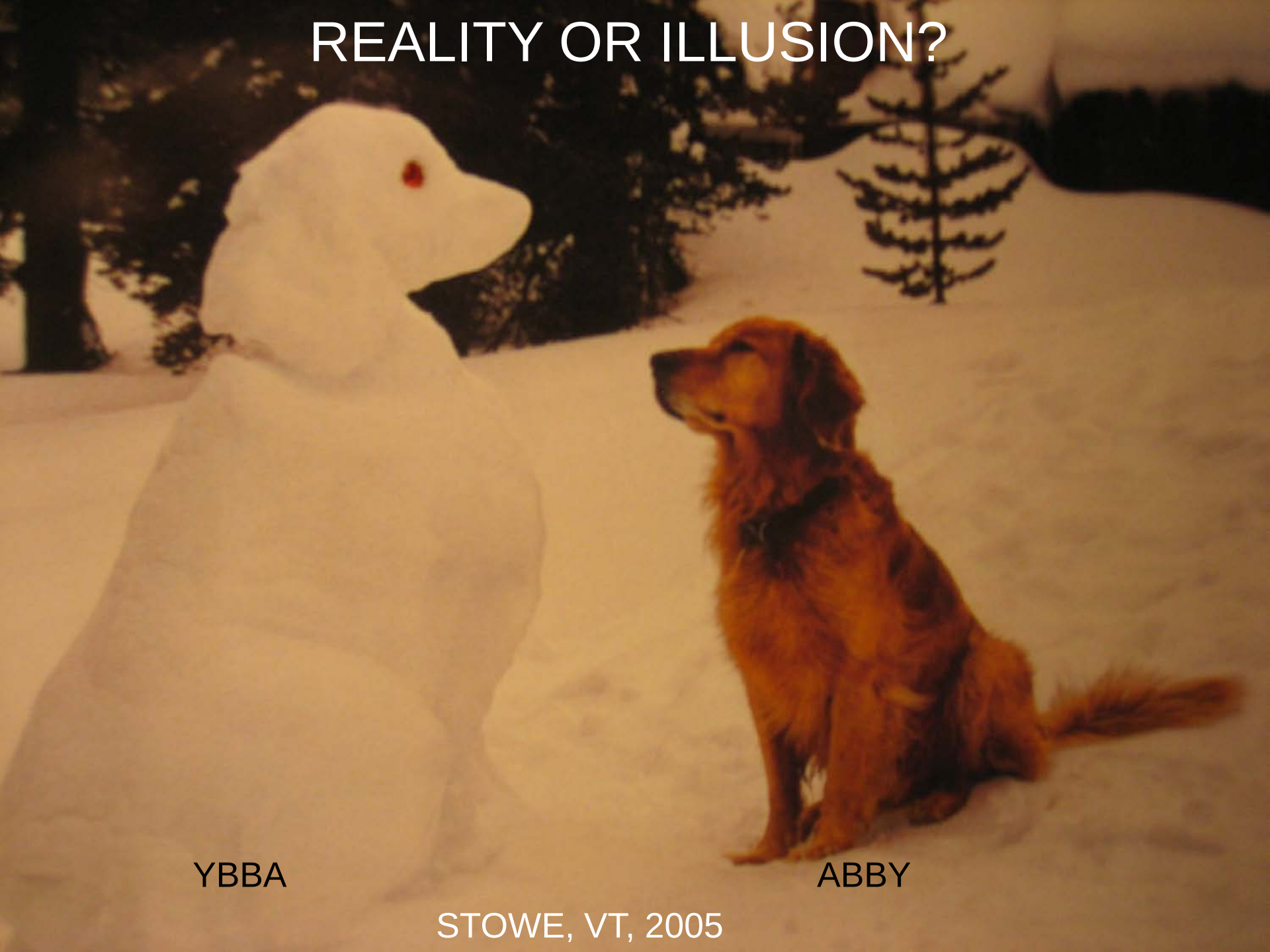
These are the 5 Physical and Metaphysical Forces of the Universe

- Fate and Chance
- Risk and Reward
- Time and Space
- Life and Death
- Quality and Quantity

Today, we are going to explore all of these, starting with an analysis into the last force: Quality vs. Quantity . . .

But is this a magic show? Can you believe what you are about to see . . . ?

REALITY OR ILLUSION?



YBBA

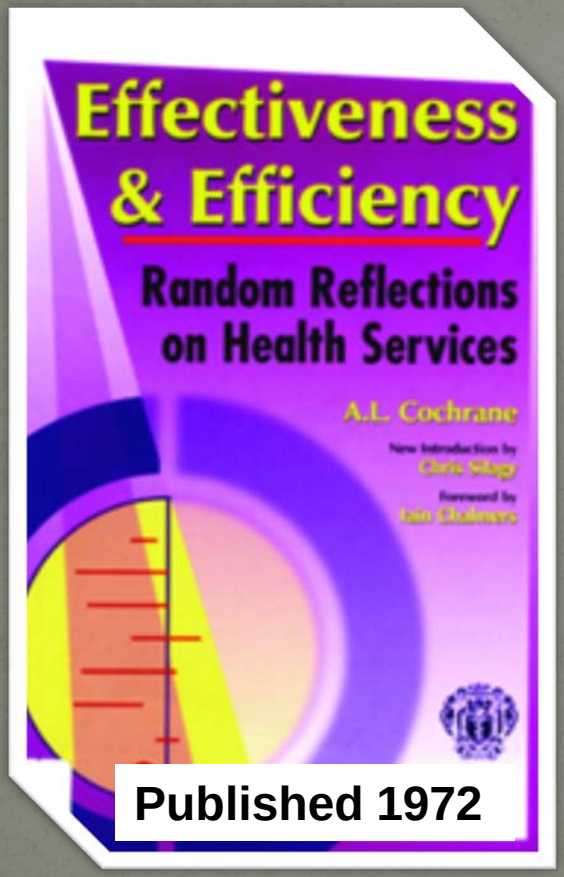
ABBY

STOWE, VT, 2005

Attempt to Answer These 5 Questions

- How can you **quantify** the **quality** of healthcare administered to the patient?
- Where do "**best practices**" come from?
- How do **research results** and evidence-based medicine find their way into clinical practice? (USA: "Bench-to-Bed")
- How can I—as a healthcare professional—**know** that I am improving the quality of care in my hospital, unit, clinic, or doctor's office?
- How can I leverage best practices and state-of-the-art **tools—such as clinical simulations—to measure** and **change** clinical behavior for the better?

The Father of EBM—Archie Cochrane



"I had considerable freedom of clinical choice of therapy: **my trouble was that I did not know which to use and when**. I would gladly have sacrificed my freedom for a little knowledge. I had never heard then of 'randomised controlled trials', but I knew there was **no real evidence that anything we had to offer had any effect on tuberculosis**, and I was afraid that **I shortened the lives of some of my friends by unnecessary intervention**."

Click button for sound.

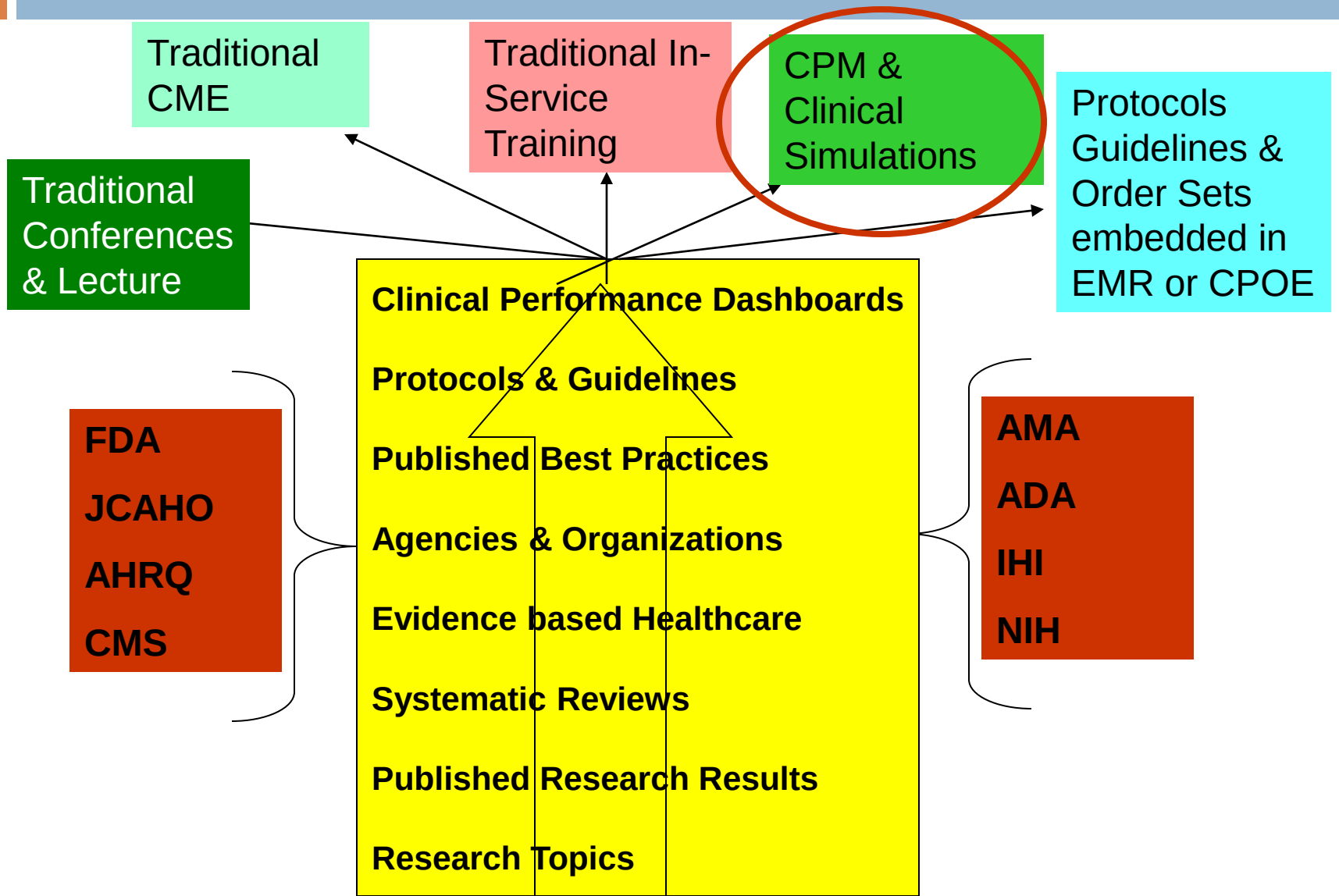
Institutionalizing the Results of Evidence Based Medicine in Data Outcomes

Evidence-based guidelines / Standards-based metrics

Evidence-based guidelines (EBG) is the practice of evidence-based medicine at the organizational or institutional level. This includes the production and incorporation of

1. continuously updated guidelines & protocols
2. clinical metrics and clinical performance scorecards/dashboards
3. the use of clinical data polling, data mining, and data monitoring tools
4. clinical performance outcomes reporting
5. incorporation of order sets and protocols into EMRs (Electronic Medical Records) and CPOE (Computerized Physician Order Entry)
6. policy and regulations: the role of the (IRB) Institutional Research Board
7. metrics and standards based on internal and external healthcare agencies' recommended or required measures (e.g. JCAHO, AHRQ, NQF, ADA)

So how do Clinical Guidelines and Best Practices Find their way into Clinical Practice?



Introducing Clinical Analytics and "**in simulo**" Case-Based Simulations for Improving Quality of Care

in vivo (circa ?): experiments done within the living organism—from the Latin, literally "in life"

in vitro (circa ?): experiments done outside of the living organism—from the Latin, literally "in glass" (test tubes)

in silico (circa AD 1989): complex biological experiments performed completely in a computerized simulation—not from the Latin. . . term was made up by mathematician Pedro Miramontes

in simulo (circa AD 2006): from the Old Italian, "modello" through the Middle French, "modelle" (AD 1575) meaning "to make like a copy or pretend a thing is so," as in "clinical medical diagnoses and patient treatment simulations"

Phase One

1. Establish Your Metrics: What Do I Want to Measure? Why is it important or valuable? What specific data points do I need? Apply the outcomes from my systematic review.

2. Develop Statistically Valid Algorithms and Scorecards based on Best Practices ("Clinical Intelligence")—Identify sources of data

3. Begin data mining from your clinical databases or medical records (manual abstraction if necessary)

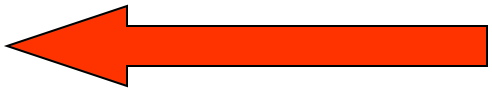
4. Begin Measuring Your Clinical Performance: Set your goals and be Transparent

5. Publish Your Outcomes—Internally at first

AN EXAMPLE . . .

Joint Commission on Accreditation of Healthcare Organizations--JCAHO

5 Core Measures

1. Heart Attack Care 
2. Heart Failure Care
3. Pneumonia Care
4. Pregnancy Care
5. Surgical Infection Prevention

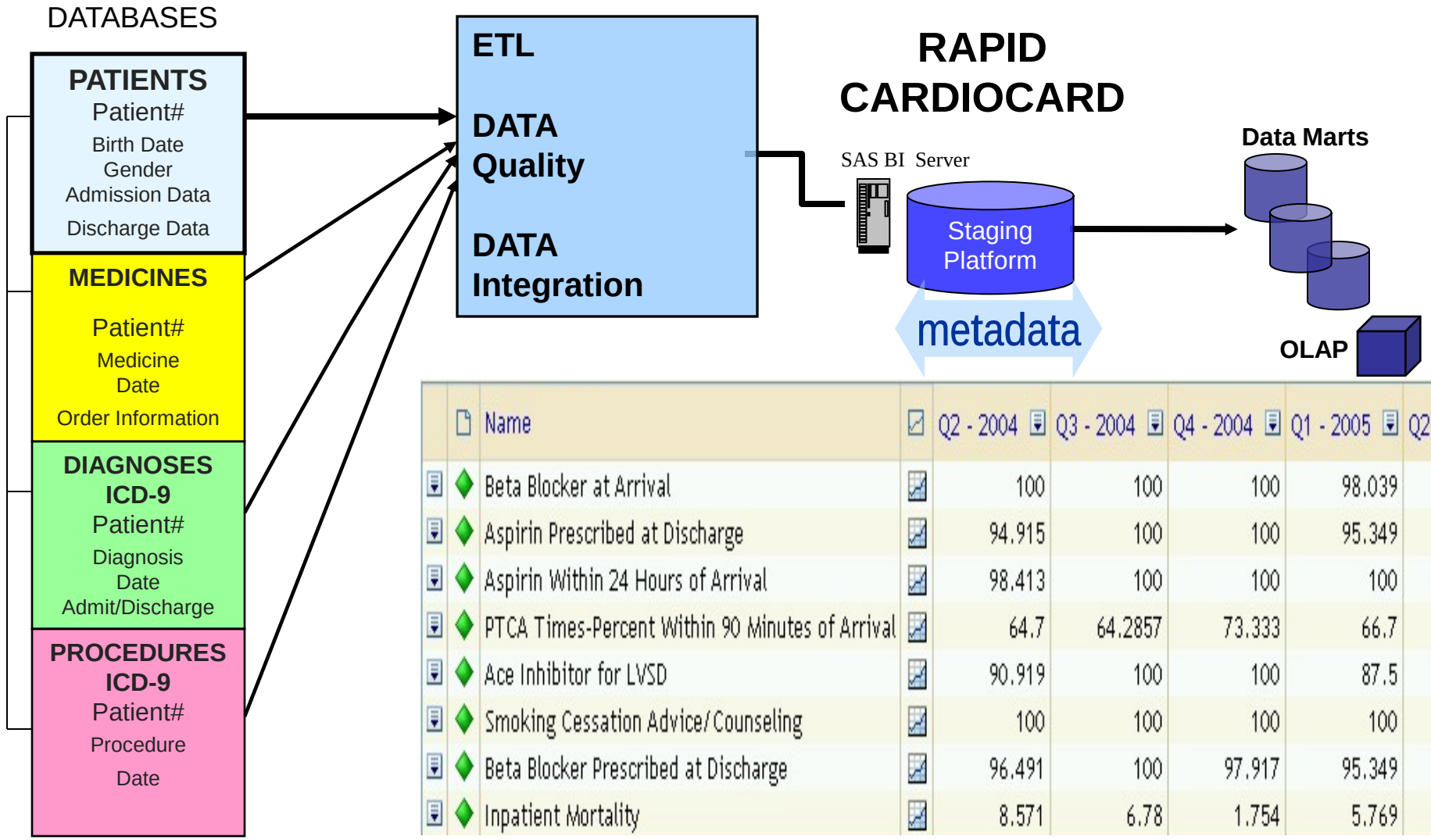
JCAHO Heart Attack (AMI) Quality Measures CardioCard # 1

ACUTE MYOCARDIAL INFARCTION NATIONAL QUALITY MEASURES (9 Primary measures 2 sub-measures)

- **Measures—8 are time-sensitive**

- **AMI-1** Aspirin at Arrival
- **AMI-2** Aspirin Prescribed at Discharge
- **AMI-3** ACEI or ARB for LVSD
- **AMI-4** Adult Smoking Cessation Advice/Counseling
- **AMI-5** Beta Blocker Prescribed at Discharge
- **AMI-6** Beta Blocker at Arrival
- **AMI-7** Median Time to Fibrinolysis
- **AMI-7a** Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
- **AMI-8** Median Time to Primary PCI
- **AMI-8a** Primary PCI Received Within 90 Minutes of Hospital Arrival
- **AMI-9** Inpatient Mortality

SAS Health Metrics Dashboard Data Architecture / ASP (Application Service Provider)



Name	Q2 - 2004	Q3 - 2004	Q4 - 2004	Q1 - 2005	Q2 - 2
Beta Blocker at Arrival	100	100	100	98.039	
Aspirin Prescribed at Discharge	94.915	100	100	95.349	
Aspirin Within 24 Hours of Arrival	98.413	100	100	100	
PTCA Times-Percent Within 90 Minutes of Arrival	64.7	64.2857	73.333	66.7	
Ace Inhibitor for LVSD	90.919	100	100	87.5	
Smoking Cessation Advice/Counseling	100	100	100	100	
Beta Blocker Prescribed at Discharge	96.491	100	97.917	95.349	
Inpatient Mortality	8.571	6.78	1.754	5.769	

Phase Two

1. Focus in on Metrics derived from known Medical Errors
2. Based on your Clinical Performance Management Outcomes, create intervention plans to improve skills
3. Implement In-Service evidence-based Simulations to continuously educate your Clinical Staff
4. Measure Effectiveness of Training and Publish Outcomes on an ongoing, iterative basis

SEARCH citation or a

NEWS FLASH!

The NEW ENGLAND JOURNAL of MEDICINE

Volume 357:1573-1575 October 18, 2007 Number 16

WHAT?

Next

Nonpayment for Performance? Medicare's New Reimbursement Rule

Recently, the Centers for Medicare and Medicaid Services (CMS) announced its decision to **cease paying hospitals** for some of the care made necessary by **"preventable complications" — conditions that result from medical errors or improper care and that can reasonably be expected to be averted**. This rule, which implements a congressionally mandated change in hospital reimbursement, is the latest in a series of steps that have rendered Medicare's payment policy far less passive than it once was.

SAS Web Report Viewer · AMI Drill Down Report

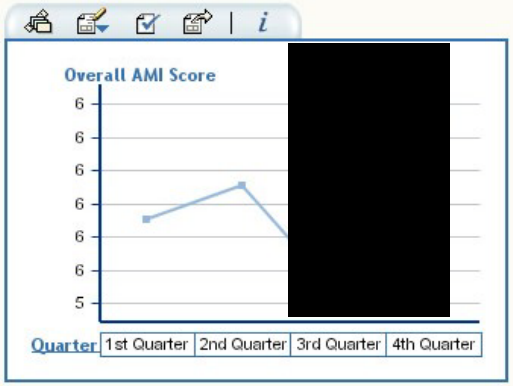
Report ▾ How Do I

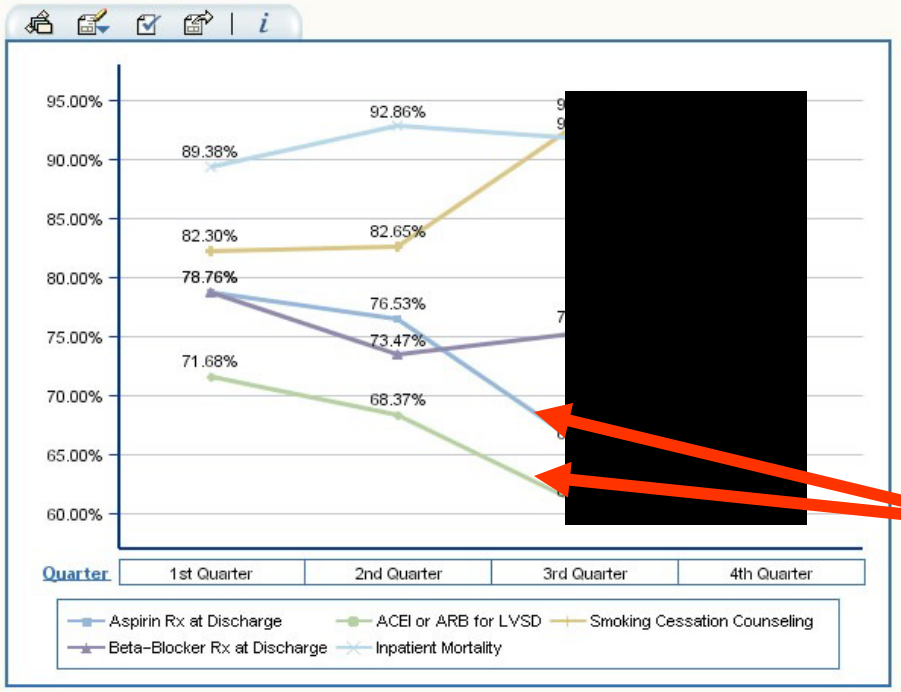
Refresh

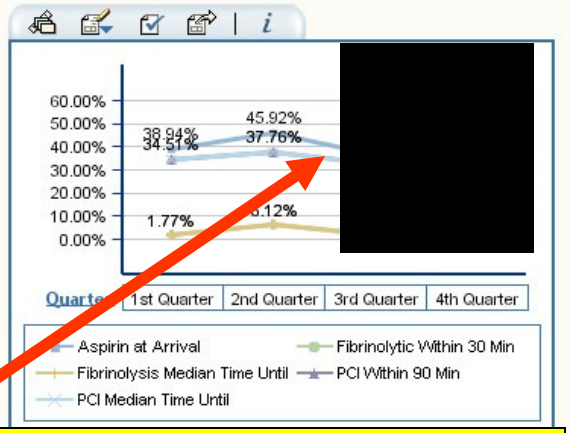
Data selected from: *AMI_DRILL*

JCAHO MEASURES Heart Attack (AMI)

	Inpatient Mortality	PCI Within 90 Min	PCI Median Time Until	Fibrinolytic Within 30 Min	Fibrinolysis Median Time Until	Beta-Blocker at Arrival	Beta-Blocker Rx at Discharge	Smoking Cessation Counseling	ACEI or ARB for LVSD	Aspirin Rx at Discharge	Aspirin at Arrival
Quarter											
1st Quarter	89.38%	34.51%	34.51%	1.77%	1.77%	53.10%	78.76%	82.30%	71.68%	78.76%	38.94%
2nd Quarter	92.86%	37.76%	37.76%	6.12%	6.12%	47.96%	73.47%	82.65%	68.37%	76.53%	45.92%
3rd Quarter	91.80%	32.79%	32.79%	1.64%	1.64%	50.82%	75.41%	93.44%	60.66%	65.57%	36.07%
4th Quarter											







For the negative trends, how can I take action?

SAS Web Report Viewer · AMI Drill Down Report

Report ▾ How Do I

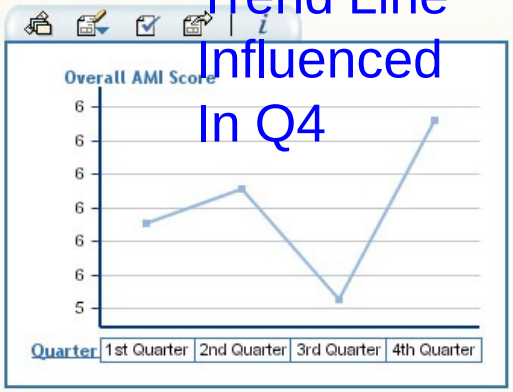
Refresh

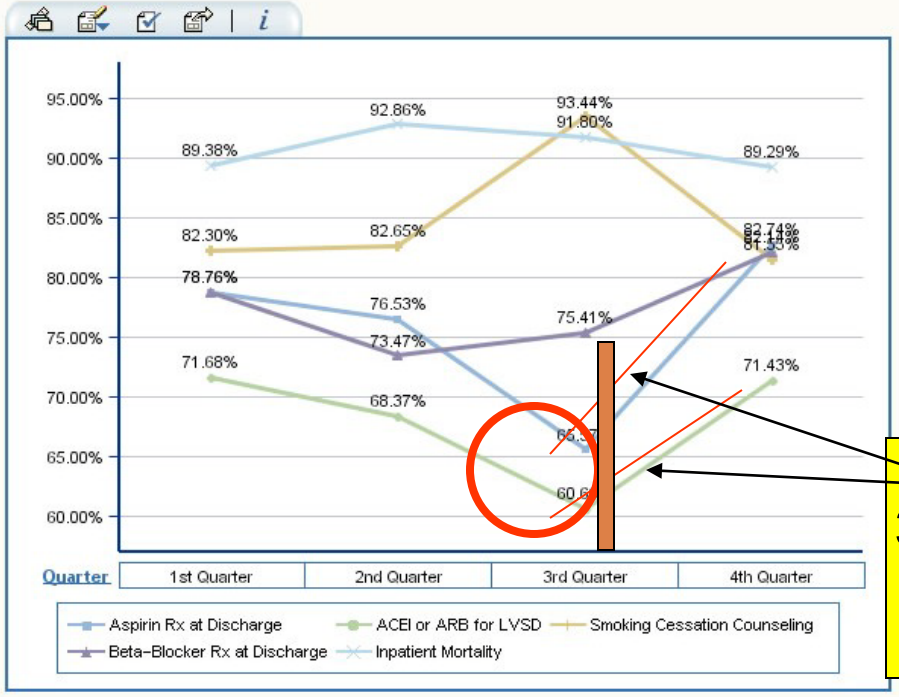
Data selected from: AMI_DRILL

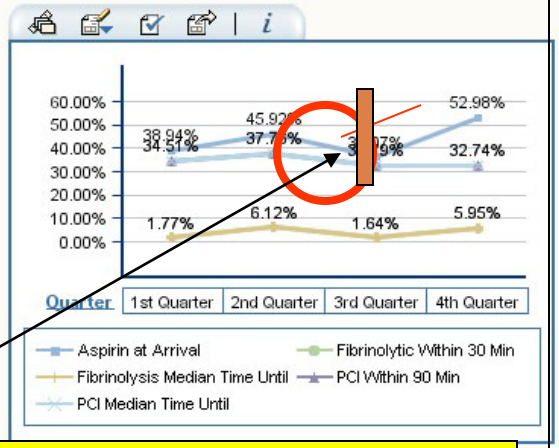
JCAHO MEASURES Heart Attack (AMI)

Quarter	Inpatient Mortality	PCI Within 90 Min	PCI Median Time Until	Fibrinolytic Within 30 Min	Fibrinolysis Median Time Until	Beta-Blocker at Arrival	Beta-Blocker Rx at Discharge	Smoking Cessation Counseling	ACEI or ARB for LVSD	Aspirin Rx at Discharge	Aspirin at Arrival
1st Quarter	89.38%	34.51%	34.51%	1.77%	1.77%	53.10%	78.76%	82.30%	71.68%	78.76%	38.94%
2nd Quarter	92.86%	37.76%	37.76%	6.12%	6.12%	47.96%	73.47%	82.65%	68.37%	76.53%	45.92%
3rd Quarter	91.80%	32.79%	32.79%	1.64%	1.64%	50.82%	75.41%	93.44%	60.66%	65.57%	36.07%
4th Quarter	89.29%	32.74%	32.74%	5.95%	5.95%	58.33%	82.14%	81.55%	71.43%	82.74%	52.98%

Trend Line Influenced In Q4



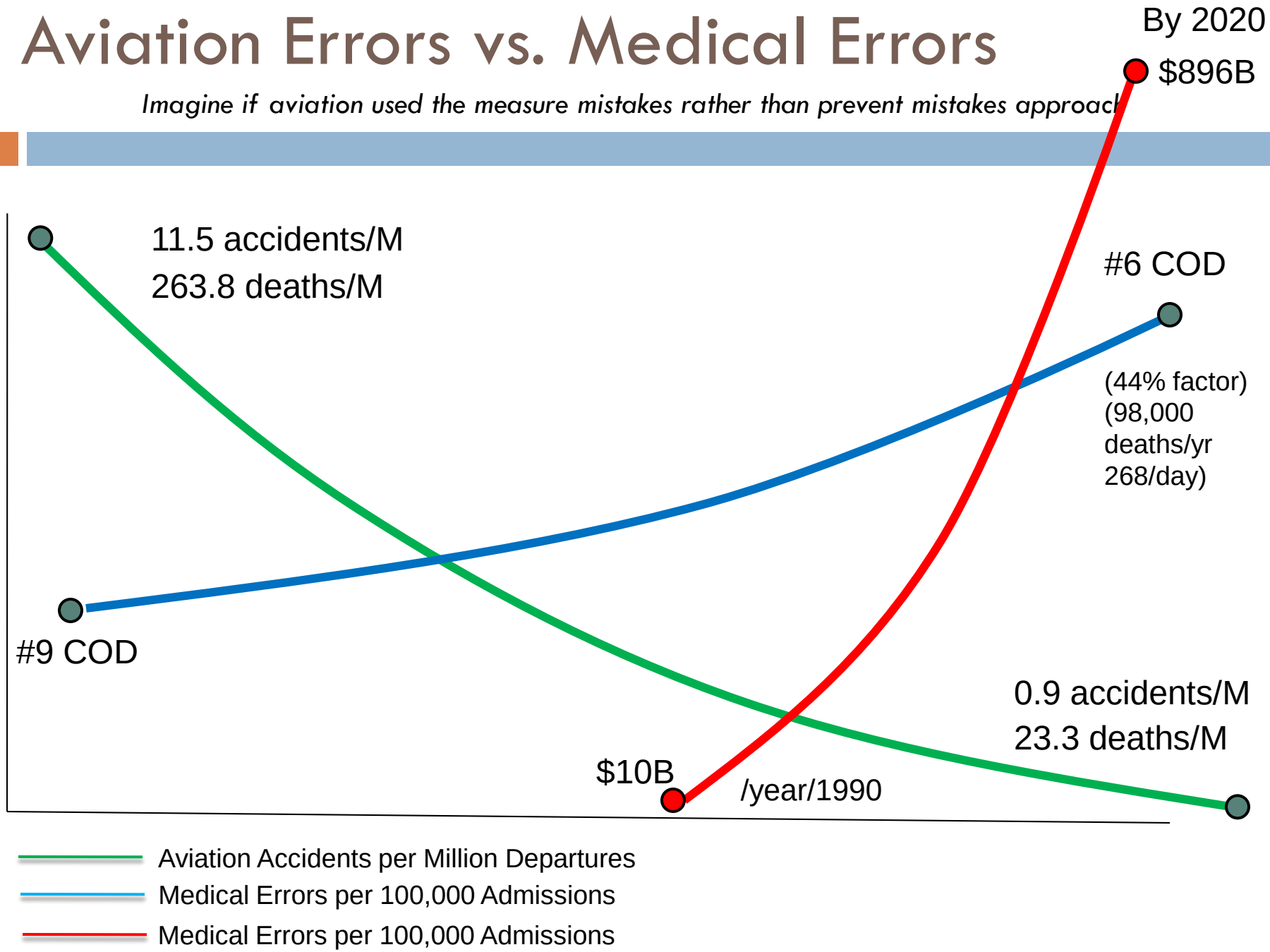




3 Measures Targeted for In-Service Training Simulations at end of Q3

Aviation Errors vs. Medical Errors

Imagine if aviation used the measure mistakes rather than prevent mistakes approach



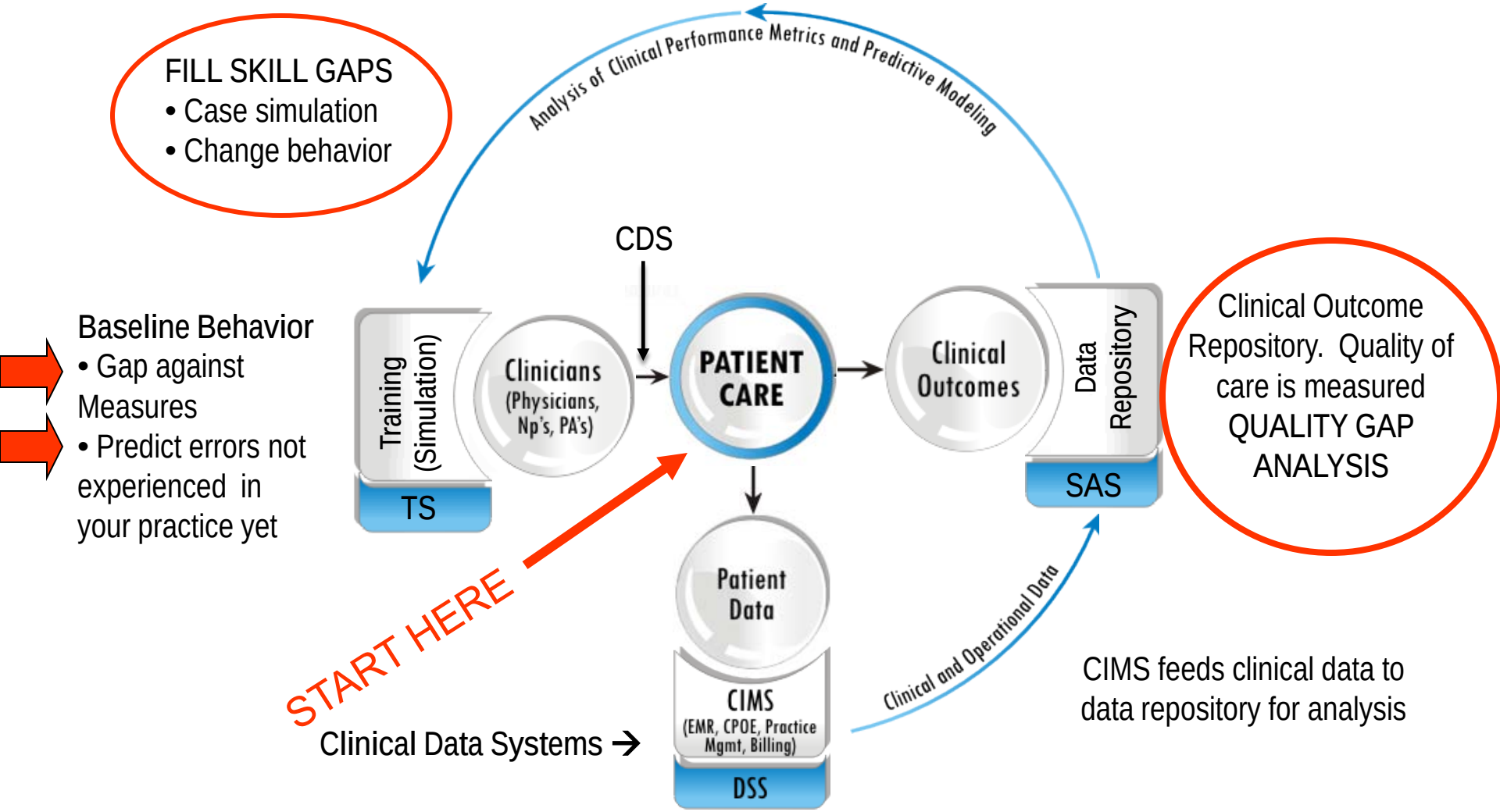
Copy aviation in reducing errors, crashes, deaths and financial loss

- How to achieve Continuous Process Clinical Improvement?

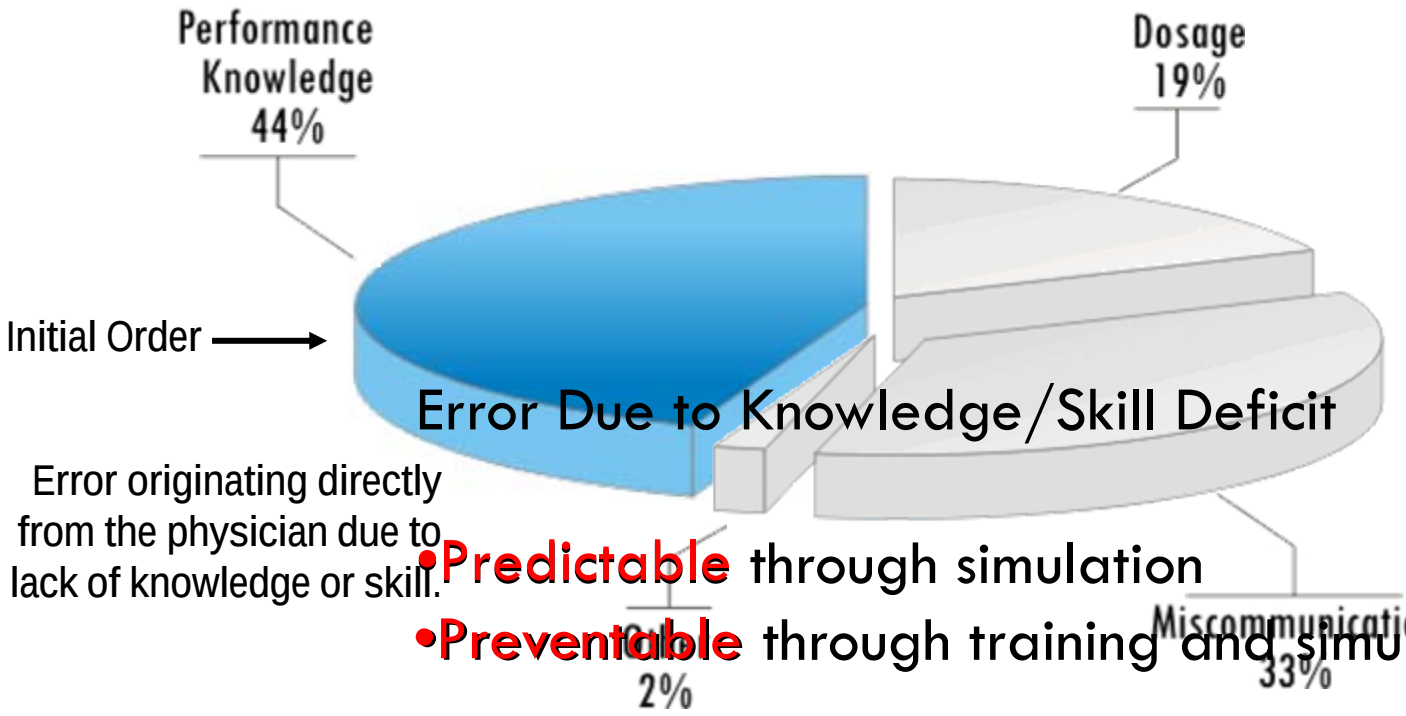
1. Create rigorous standards (**benchmarking scorecards**)
2. Provide learning support (**in-flight trainers**)
3. Measure behavior in order to predict, improve, prevent error (**flight simulations**)
4. Provide a rapid and adaptive training mechanism (**flight simulators**)
5. Score and evaluate clinical skills (**statistical analytics)**

- That's why all airlines today require on-going training that is measurable, quantifiable, and instructional "*in simulo*" mode

Closed-loop Iterative Improvement Model for Clinical Care & Care Givers



Sources of Medication Error



- Predictable through simulation
- Preventable through training and simulation

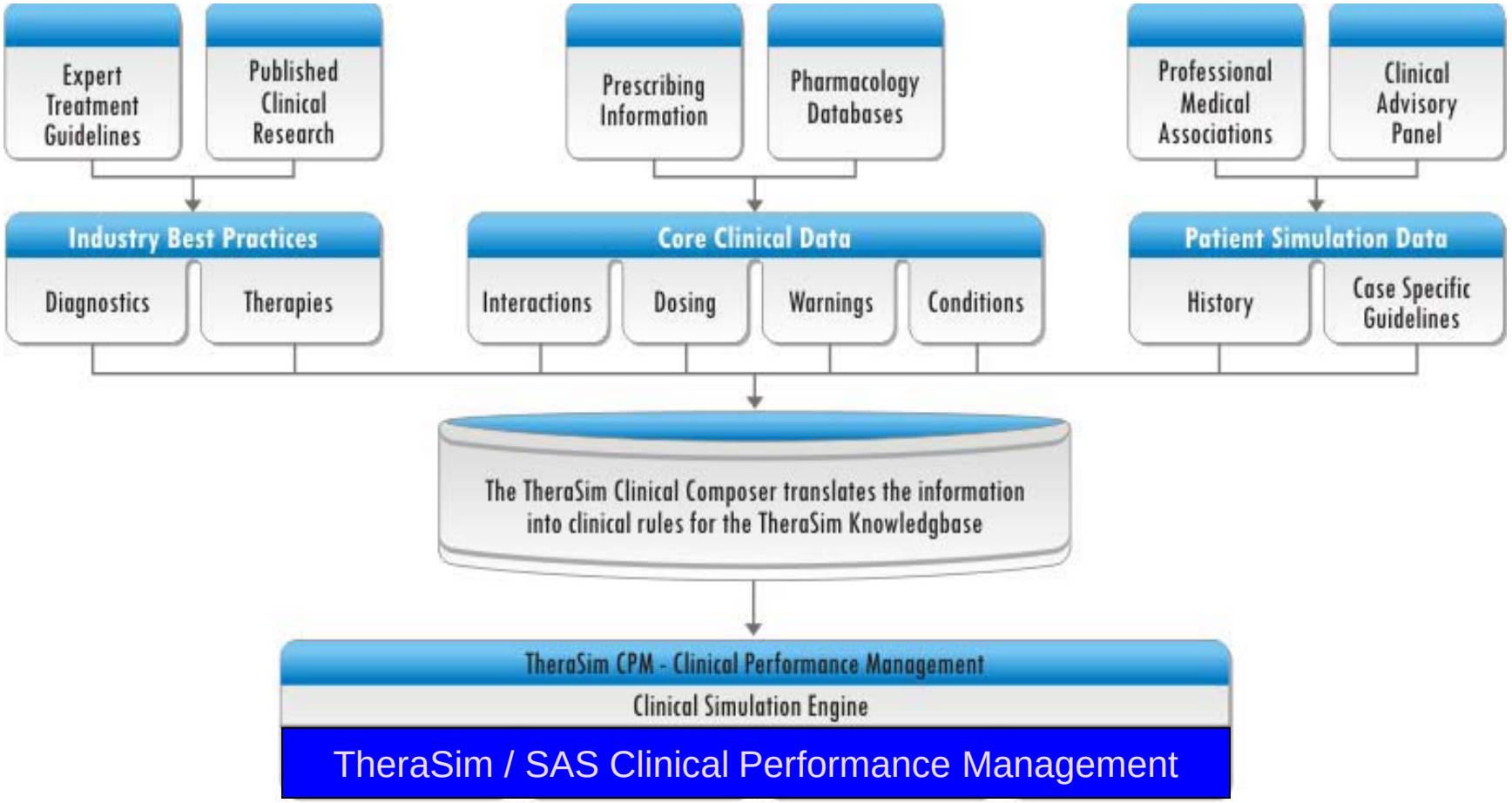
Clinical Healthcare Analytics Can Tell You . . .

- How well are we doing based on our clinical improvement goals?
- Where are our immediate greatest risks and greatest opportunity based on the most reliable and timely evidence?
- What's the best way to implement actionable training and skills enhancement programs based on our clinical outcomes?
- When can our clinical analytics help us to **prevent** medical errors in the future?
- How can we leverage statistical modeling and leading edge indicators to **predict** our next worst clinical nightmare or our best clinical success in an "if-then" simulated environment?
- How do we get everyone on the same page?

Through Clinical Simulations: A Virtual EMR

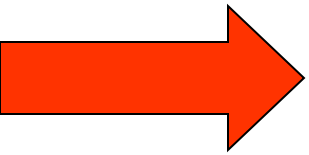
- Interactive EMR interface--Simulations
- Drug database and individually crafted alerts provide real-time clinical guidance *in simulo*
- Users read histories, order tests (results are immediate), make diagnoses (from 100's), and order therapies (from 100's)—No, this isn't your grandfather's multiple choice test!
- Guidelines (written and backed by DHHS, WHO, CDC, and BMJ, etc.) and evidence-based, with instant feedback

How the *In-Simulo* Simulator Works



Case-Based Simulations . . .

- Based on real patient cases specifically selected
- Digitally text & image-mined and abstracted into TheraSim clinical AI engine
- Cases aggregated based on clinical skills being stressed and peer-reviewed by experts
- Cases reviewed and compared with evidence-based best practices
- Presentation layer and GUI auto-generated
- Statistical analysis running on every move the clinician makes while in the training simulator
- Test scores are weighted based on severity of decision



Jenny Smith is in your exam room now. Open the door and begin your encounter. . .

Jenny S. (IDSA-01) | 1. Intro | 2. History | 3. Order Tests | 4. Test History | 5. Diagnosis | 6. Orders | 7. End Session

Medscape from WebMD

CME

Meet the Patient

Next Tab >>

This 31 year-old woman with a history of HIV infection developed generalized fatigue, dysphagia and mild cough 1 months ago following a treatment for thrush. CXR showed pneumonia, and she was started on azithromycin, but later that day she experienced increasing SOB, fever with cough and pleuritic pain which became worse over 48 hours. She was urgently admitted with PCP, and esophagoscopy revealed candida esophagitis. Today she is being seen for her first hospital follow-up visit by an HIV provider after completing 3 weeks of therapeutic doses of trimethoprim-sulfamethoxazole, prednisone and fluconazole.

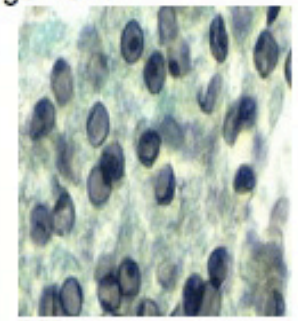
She has been known to be HIV test positive for 6 years, denies risk factors, rarely seeks medical care, and has not been treated with ART. She has now come to your clinic after a 2-week hospital stay for follow-up and further management. History of moderate alcohol use in past; no substance use. Admitted inconsistent use of condoms and does not want to use contraceptive medications or an IUD. Tolerated tmp/sulfa and denies rash, dyspnea, cough, or pain with swallowing but continues to have some mild fatigue. A recent pO2 was up to 88 mm Hg. Physical exam is unremarkable.

Images

Click on Image to see enlargement

UGI endoscopy
27 Aug 07 - Consistent with candida esophagitis

CXR
27 Aug 07 - Bilateral infiltrates and hypoxia.



PCP
27 Aug 07 - GMS stain from BAL specimen.

Go to the next tab (2. History, above) to continue.

"CLOSED BOOK"
Clinical Guidance Turned Off

Jenny S. (IDSA-01) | 1. Intro | 2. History | 3. Order Tests | 4. Test History | 5. Diagnosis | 6. Orders | 7. End Session

<< Previous Tab

Review Patient History

Next Tab >>

Demographic Data

Name:	Jenny S.
Gender:	Female
Age:	31
Height:	167(cm)
Id:	IDSA-01

Vital Signs

Date	Kg	BMI	RR	HR	Temp	BP
17 Sep 07	69	24.7	16	82	96.8	108/84
06 Sep 07	67	24	16	70	97.6	110/70
27 Aug 07	64	22.9	20	90	99.1	105/65
08 Aug 05	67	24	16	66	97.6	110/66
12 Jul 01	67	24	18	72	98	108/68

Drug Allergies or Intolerance

Date	Drug	Notes
	No known allergies	

Current and Previous Therapies by Office Visit

Visit Date	Therapy	Dose	Freq.	End Date
16 Sep 07	predniSONE	20 mg	qd	17 Sep 07
	trimethoprim-sulfamethoxazole	2	tid	17 Sep 07
	fluconazole	200 mg	qd	17 Sep 07
15 Sep 07	predniSONE	20 mg	qd	17 Sep 07
	trimethoprim-sulfamethoxazole	2	tid	17 Sep 07
	fluconazole	200 mg	qd	17 Sep 07
10 Sep 07	predniSONE	20 mg	qd	17 Sep 07
	trimethoprim-sulfamethoxazole	2	tid	17 Sep 07
	fluconazole	200 mg	qd	17 Sep 07
06 Sep 07	predniSONE	20 mg	qd	17 Sep 07
	trimethoprim-sulfamethoxazole	2	tid	17 Sep 07
	fluconazole	200 mg	qd	17 Sep 07
03 Sep 07	trimethoprim-sulfamethoxazole	2	tid	17 Sep 07
	predniSONE	40 mg	qd	06 Sep 07
	fluconazole	200 mg	qd	17 Sep 07
01 Sep 07	predniSONE	40 mg	qd	06 Sep 07
	fluconazole	200 mg	qd	17 Sep 07
	trimethoprim-sulfamethoxazole	2	q8h	03 Sep 07
27 Aug 07	fluconazole	200 mg	qd	17 Sep 07
	predniSONE	40 mg	bid	01 Sep 07
	trimethoprim-sulfamethoxazole	2	q8h	03 Sep 07

Physicians Notes and Condition Assessments

17 Sep 07
AIDS
HIV Infection
The patient is sexually active with several partners and refuses to consider using contraceptives at this time.

16 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

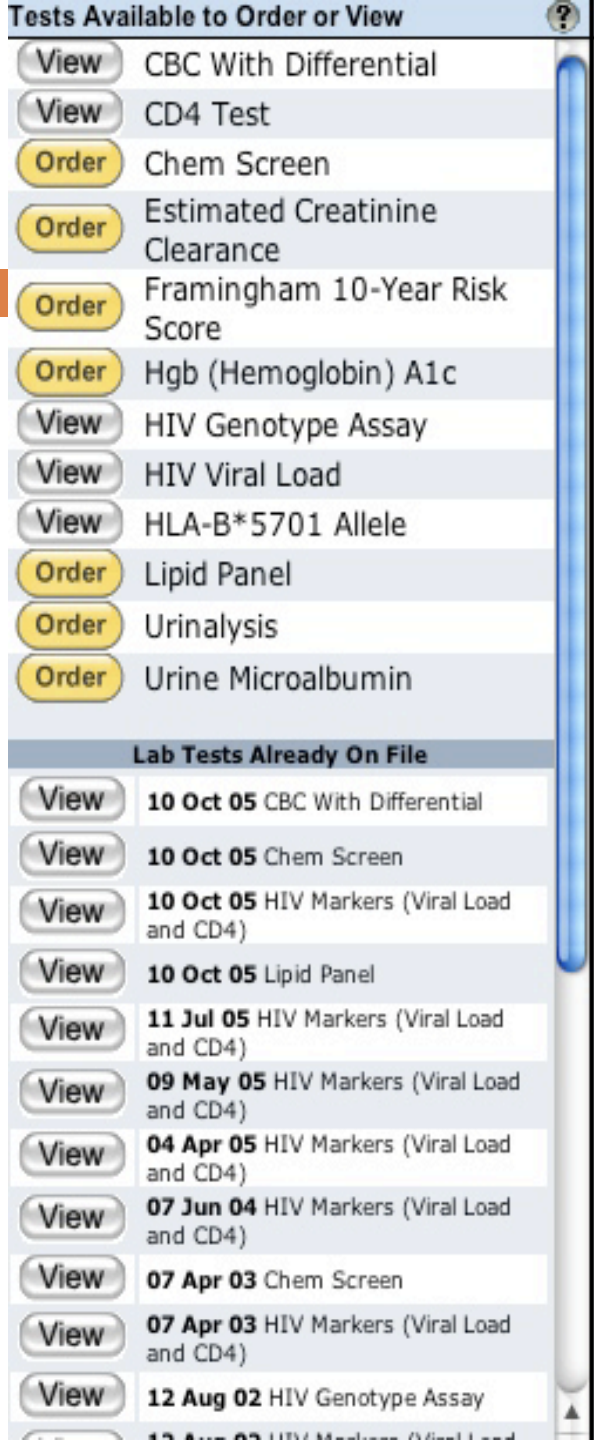
15 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

10 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

06 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection
Discharged from the hospital on oral medications. Follow-up appointment with HIV provider in about 10 days.

03 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

01 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection



Test Results

Reverse Transcriptase Mutations: M41L, M184V, T215Y; (V245V -- no mutation at this site)

RTI Implications for Resistance

DRUG	BRAND	GENERIC	RESISTANCE
3TC	Epivir	lamivudine	Resistant
ABC	Ziagen	abacavir	Sensitive
AZT	Retrovir	zidovudine	Sensitive
d4T	Zerit	stavudine	Sensitive
ddI	Videx	didanosine	Resistant
FTC	Emtriva	emtricitabine	Resistant
TDF	Viread	tenofovir	Sensitive

NNRT Mutations: K103N

NNRTI Implications for Resistance

DRUG	BRAND	GENERIC	RESISTANCE
DLV	Rescriptor	delavirdine	Resistant
EFV	Sustiva	efavirenz	Resistant
NVP	Viramune	nevirapine	Resistant

PI Mutations: L10I, K20M, L24I, L33F, M36I, M46L, F53L, I54V, L63P, A71V

PI Implications for Resistance

DRUG	BRAND	GENERIC	RESISTANCE
ATV	Reyataz	atazanavir	Sensitive
DRV	Prezista	darunavir	Sensitive
FPV	Lexiva	fosamprenavir	Sensitive
IDV	Crixivan	indinavir	Resistant
SQV	Fortovase/Invirase	saquinavir	Resistant
LPV/r	Kaletra	lopinavir-ritonavir	Resistant
NFV	Viracept	nelfinavir	Resistant
RTV	Norvir	ritonavir	Resistant
TPV	Aptivus	tipranavir	Sensitive

TheraSim

Welcome Dr. Blevins on 25 May 2006 Logout

Feedback | Resources | Help

Clinical Simulator V4.0 | 1. Intro | 2. History | 3. Order Tests | 4. Test History | 5. Diagnosis | 6. Orders | 7. End Session

Order/View Tests

Save Session | Enable Help Bubbles

Tests Available to Order or View

- Order — CBC with Differential
- Order — CD4 Test
- Order — Chem Screen
- View — Chest X-ray Images

Lab Tests Already On File

- View — **24 Feb 06** CBC with Differential
- View — **24 Feb 06** CD4 Test
- View — **24 Feb 06** HIV Diagnostic Panel
- View — **24 Feb 06** Syphilis Serologies

Test Results

« Previous Tab

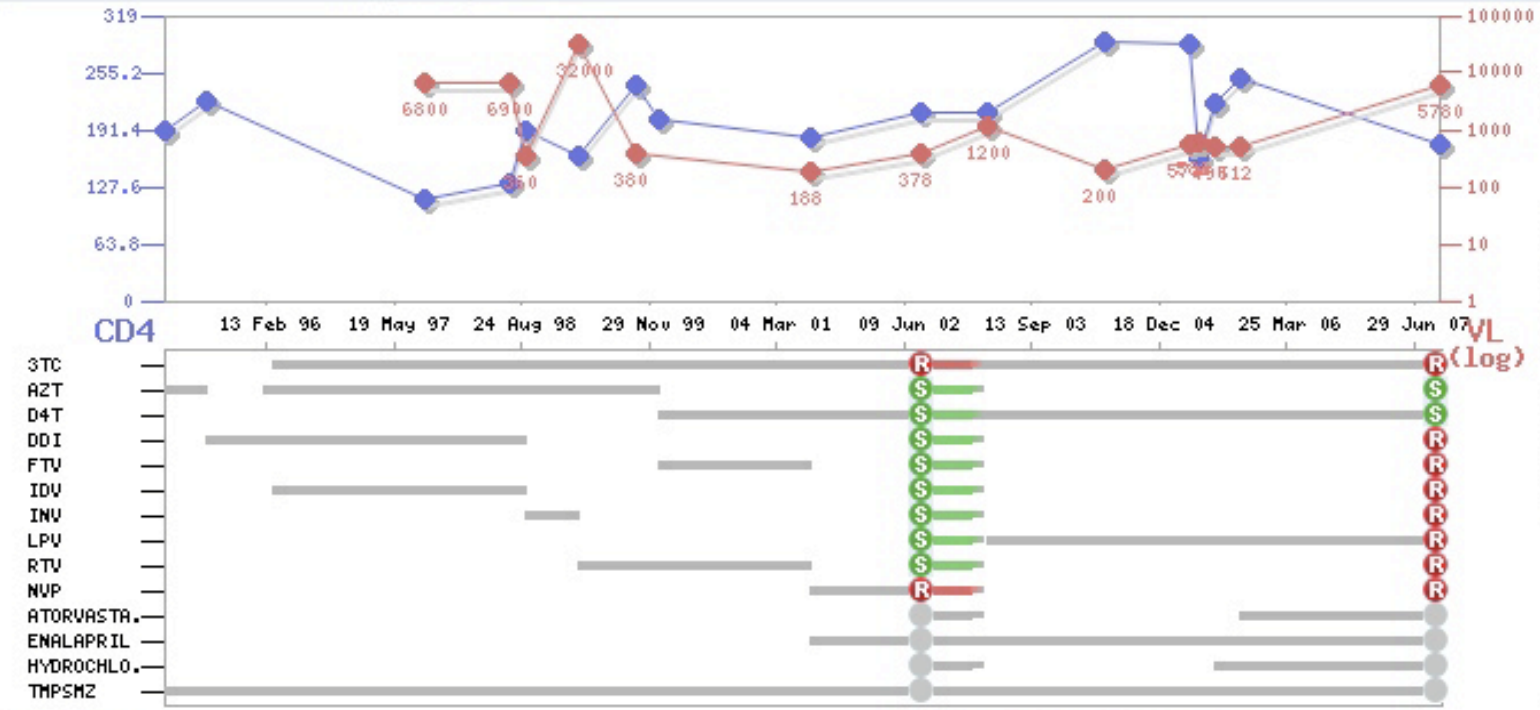
Review Test History

Next Tab »

CD4 / VL Graph

Select graph to view: Temp/Kg | CD4/VL | HgbA1c/FPG | LDL/HDL

Hide: CD4 VL



Lab Results

Visit Date	Lab	Results	Range
27 Sep 07	**--- CBC With Differential ---**		
	HCT (Hematocrit)	42 %	40 - 54
	Platelet Count	224 1000/mm^3	50 - 350
	WBC (White Blood Cell Count)	5.5 1000/mm^3	4.0 - 10.8
27 Sep 07	**--- HLA-B*5701 Allele ---**		
	Comments	HLA-B*5701: not present (negative)	
27 Sep 07	**--- CD4 Test ---**		
	CD4	176 cells/mm^3	513 - 2,325
27 Sep 07	**--- HIV Viral Load ---**		
	HIV-RNA	5,780 copies/mL (RNA)	0 - 51
10 Oct 05	**--- HIV Markers (Viral Load and CD4) ---**		
	HIV-RNA	512 copies/mL (RNA)	0 - 51

Click here to order additional tests

Drug Resistance Reports

Drug name	Geno	Pheno	Gen/Phen
3TC	R		
ABC	S		
AZT	S		
d4T	S		
ddI	R		
FTC	R		
TDF	S		
ATP			

Drug name	Geno	Pheno	Gen/Phen
DLV	R		
EFV	R		
NVP	R		

Drug name	Geno	Pheno	Gen/Phen
ATV	S		
DRV			
FPV	S		
FTV	R		
IDV	R		
INV	R		
LPV/r	R		
NFV	R		
RTV	R		
TPV			

Drug name	Geno	Pheno	Gen/Phen
T20			
MVC			

"OPEN BOOK"
GUIDANCE TURNED ON

Jenny S. (IDSA-01) | 1. Intro | 2. History | 3. Order Tests | 4. Test History | 5. Diagnosis | 6. Orders | 7. End Session

Diagnose New Conditions

Next Tab >>

Condition:

Add Condition | No New Diagnoses

Physicians Notes and Condition Assessments

17 Sep 07
AIDS
HIV Infection
The patient is sexually active with several partners and refuses to consider using contraceptives at this time.

16 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

15 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

10 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

06 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection
Discharged from the hospital on oral medications. Follow-up appointment with HIV provider in about 10 days.

03 Sep 07
AIDS
Pneumocystis jiroveci pneumonia (PCP)
Candidal Esophagitis
HIV Infection

Clinical Guidance

To Make a Diagnosis:
In the field on the left:

- Start typing the name of the condition in the box -- a drop down list of conditions that contain those letters will appear;
- Select the desired condition from the drop down list;
- Click the *Add Condition* button.

To indicate that you do not wish to declare any new diagnoses, click the *No New Diagnoses* button.

040 Diagnosis_Help

Order Detail

HIV Viral Load: You appropriately ordered the HIV Viral Load for this patient.

- Baseline HIV-RNA (viral load) is necessary to determine virologic control. Patients ideally need to be started on ART prior to CD4 counts declining below 200 cells/mm3. Much debate continues about the time to initiate ART, however. (502)

CD4 Test: You appropriately ordered the CD4 Test for this patient.

- Baseline CD4 lymphocyte count is necessary to determine the need for antiretroviral therapy (ART), follow the progress of HIV, help define AIDS (CD4 <200) and determine virologic and immunologic status and control. Patients ideally need to be started on ART prior to CD4 counts declining below 200 cells/mm3. Much debate continues about the time to initiate ART, however. (502)

any resistance: You appropriately ordered the any resistance for this patient.

- The May 2006 DHHS HIV Treatment Guidelines recommends genotypic resistance testing before starting antiretroviral therapy in patients with acute or chronic HIV infection due to a prevalence of antiretroviral resistance in treatment-naive patients approaching 16%. Initiation of therapy with a drug to which the virus is resistant may result in suboptimal viral suppression. Using genotypic testing to guide selection of initial therapy also appears to be cost effective. (502)

« Previous Tab

Prescribe All Therapies

End Session >>

Add a Therapy

Step 1: Choose a Therapy. **Step 2:** Choose a product, dose, etc.

Therapy: Start typing the name of a drug here

Weight: 69 Kg
ECC: N/A mL/min

Dose Form: ---(enter drug above, then this will show the dosing forms)---

Quantity: dose **Dose frequency:** qd (daily)

Titrate up: Add Therapy

This Visit

17 Sep 07	Therapy	Dose	Freq.	Titr.
Remove	EFV (efavirenz 600 mg oral tablet)	600	qd (daily)	n
Remove	TDF (tenofovir 300 mg oral tablet)	300	qd (daily)	n
Remove	sulfamethoxazole-trimethoprim 800 mg-160 mg oral tablet	1	qd (daily)	n

Continue All Therapies

SU Buttons: All Allowed Drugs Auto Pass

Add Other Orders and Consults

Add Orders: ----------select---------- Add Order

Add Consults: ----------select---------- Add Consult

Other Orders | Consults

Clinical Guidance

You Have Significant Alerts -- Scroll down to see alerts

No Diagnosis Made: You have not offered any diagnosis for this patient. If this is intentional, please click the *No New Diagnoses* button on the Diagnosis tab.

Therapy Combination

DHHS Guidelines on Initial Therapy Combination: DHHS Guidelines on therapy initiation are available at this link: Table 6a. (502)

Drug Alerts

EFV Alert:

- Efavirenz-containing regimens should be avoided in pregnancy (particularly during the first trimester) because significant teratogenic effects were seen in primate studies at drug exposures similar to those achieved during human exposure. Use of efavirenz should also be avoided when adequate contraception cannot be assured.

Drug Interactions

EFV and Pregnancy Testing: Use of efavirenz should be avoided in the first trimester, and *women of childbearing potential must be counseled regarding risks and avoidance of pregnancy*. Use after the second trimester of pregnancy can be considered if other alternatives are not available and if adequate contraception can be assured postpartum. **Consider recommending a pregnancy test.** Table 29. (502)

sulfamethoxazole + HIV Infection (*Caution Only - No Deduction*): The use of sulfonamides is associated with large increases in the risk of Steven ...More Info 700

Some Antiretroviral Dosage Options

TDF (tenofovir): 300mg, q24h,
Notes: (512)
EFV (efavirenz): 600mg, q24h,
Notes: (Preferable to take at bedtime), (525)

Standard Dosing Ranges with Commentary

0.5-1 ea of sulfamethoxazole-trimethoprim 800 mg-160 mg oral tablet daily

Review Closing Case Remarks

Session Details

Patient Case ID: IDSA-01
Patient Case Summary: Antiretroviral treatment-naive 31 year-old patient with HIV infection is being seen today after 3 weeks of treatment for PCP and candida esophagitis.
Module: Treat ART-naive patient; provide secondary prophylaxis. 31.1, 21.0, 21.2, 23.0, 23.1

Decision Points

- Baseline Labs
- Resistance Testing
- ART Initiation
- Efavirenz and Women
- PCP Secondary Prophylaxis

Closing Case Remarks

This patient has AIDS. The diagnosis is confirmed by a CD4 <200 and the +HIV antibody. However, even if the CD4 had been above 200, PCP in an HIV+ individual still defines AIDS. (502) Baseline lab studies, CXR and ppd, syphilis and other STI and hepatitis screening, CBC and a chem panel are all indicated (563), as is counseling about the disease and prevention of transmission. This is the time to establish a good relationship with the patient -- to demonstrate patience and compassion -- and to pay attention to the psychosocial issues that may be arising. (502)

Secondary prophylaxis against PCP should start immediately after the 3-week treatment course regardless of CD4 count. Trimethoprim-sulfa 160/800 (one double-strength tablet) daily also offers some protection against CNS toxoplasmosis, occasionally seen in patients with CD4 <100 and positive toxo-IgG assays. Daily dapsone is another reasonably inexpensive prophylactic agent for the sulfa-allergic patient, while atovaquone offers an expensive alternative. (503)

When to Start
Had this patient not developed PCP -- an AIDS-defining condition and qualifier for ART -- baseline CD4 lymphocyte count and HIV-RNA (viral load) would still be necessary to:

- determine the need for antiretroviral therapy (ART);
- follow the progress of HIV;
- help define AIDS (CD4 <200); and
- determine virologic and immunologic status and control.

Much debate continues about the time to initiate ART. (502) Patients ideally need to be started on ART prior to CD4 counts declining below 200 cells/mm3 with consideration once the CD4 count is below 350 cells/mm3 according to patient readiness.

HIV TREATMENT

Initial Antiretroviral Treatment (ART) Recommendations

October 2006 DHHS recommendations for initial ART regimens (3648) for the treatment-naive patient include:

1 NNRTI + 2 NRTIs

- The preferred NNRTI is efavirenz, but this patient cannot assure use 1 (much less 2 forms of) of reliable contraception

Review Session Results

Alert Summary		
✗	Rejected / Contraindicated:	0
⛔	Severe Alerts:	1
⚠	Warnings:	4
✓	Appropriate Action/Met Learning Objective:	0

See below for detailed descriptions of these alerts.

Session Deductions by Category	
Category	**Deduction**
Diagnosis	0
Orders	-14
Therapy Initiation	-21
Therapy Combination	-15
Alerts	0
Drug Alerts	-21
Drug Interactions	0
Dosing	0
Lab Assessments	0
Drug Resistance	0
Prevention & Prophylaxis	0
Treatment	0
Warnings and Precautions	0

ZERO is a perfect score

Click on the links in the table above, or scroll down for a detailed description of these deductions.

Order Detail

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Missed test: Chem Screen

- Most clinicians order a chem screen to screen for azotemia, hepatotoxicity, hyperglycemia and various

Resources -- Click Any Tab Above to Return to End Session

Drug Monographs	HIV / Aids	Hepatitis	Endocrinology	Cardiology	Oncology	Vaccination	Rheumatology	Asthma / Allergy

Guidelines

Educational Materials

1

Guidelines

- US DHHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents - October 10, 2006 (NEW WINDOW)
- Indian National Guidelines For Implementation of Antiretroviral Therapy (ART) (Draft, August 2004) (NEW WINDOW)
- Namibian Guidelines for Anti-Retroviral Therapy, April 2003 (NEW WINDOW)
- South African National Antiretroviral Treatment Programme Guidelines, 2004 (NEW WINDOW)
- Ugandan National Antiretroviral Treatment and Care Guidelines for Adults and Children, November 2003 (NEW WINDOW)
- WHO HIV Treatment Guidelines for a Public Health Approach 2006 revision (NEW WINDOW)

Pediatric Guidelines

- Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection - November 3, 2005 (NEW WINDOW)
- Supplement I: Pediatric Antiretroviral Drug Information - November 3, 2005 (NEW WINDOW)
- Supplement II: Managing Complications of HIV Infection in HIV-Infected Children on Antiretroviral Therapy - November 3, 2005 (NEW WINDOW)
- Supplement III: Adverse Drug Effects - November 3, 2005 (NEW WINDOW)

Management of HIV Complications

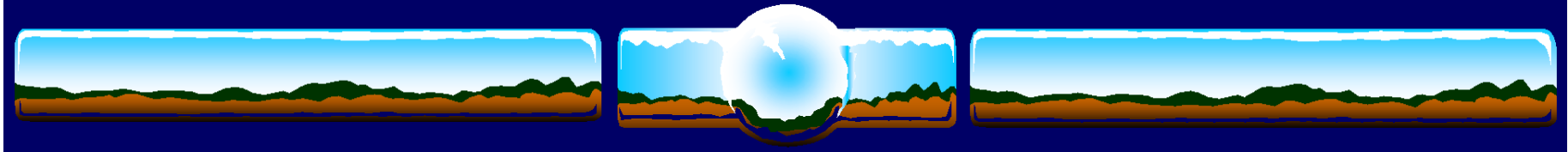
- Treatment of Tuberculosis - June 20, 2003 (NEW WINDOW)
- Indian NACO: Guidelines for Management of HIV-TB Co-infection (NEW WINDOW)

Supplements

- Updated Guidelines for the Use of Rifamycins for the Treatment of Tuberculosis Among HIV-Infected Patients Taking Protease Inhibitors or Nonnucleoside Reverse Transcriptase Inhibitors - January 20, 2004 (NEW WINDOW)
- CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection - August 08, 2003 (NEW WINDOW)
- Acquired Rifamycin Resistance in Persons with Advanced HIV Disease Being Treated for Active Tuberculosis with Intermittent Rifamycin-Based Regimens - March 15, 2002 (NEW WINDOW)
- Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection - June 09, 2000 (NEW WINDOW)
- US CDC Sexually Transmitted Diseases Treatment Guidelines 2006 (as updated Sept. 8, 2006) (NEW WINDOW)
- Indian NACO: Guidelines for the Prevention of Mother to Child Transmission of HIV (NEW WINDOW)

Prevention and Treatment of Opportunistic Infections Guidelines

- 2001 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with HIV - November 28, 2001 (NEW WINDOW)
- Recommendations To Help Patients Avoid Exposure to or Infection from Opportunistic Pathogens - June 14, 2002 (NEW WINDOW)



AFRICAN PARTICIPANTS (internet)

Angola	Bhutan	Botswana
Congo (DRC, Zaire)	Ethiopia	Gambia
Ghana	Kenya	Libya
Malawi	Mauritius	Mozambique
Namibia	Nigeria	Rwanda
Sierra Leone	Somalia	South Africa
Sudan	Tanzania	Tunisia
Uganda	Zambia	Zimbabwe

AIDS Case-based Simualted Patient Encounters: Results of Immersion Usage

- 4,669 clinicians
- Representing 120 countries
- Completed 13,365 sessions
- Averaging 25 interactive browser page views /session
- Averaging 15 minutes/session
- Average score of 72
- 54% failure rate in the "closed book" mode of testing competencies (range: 25-69%)

OUTCOMES (DHHS)--2006

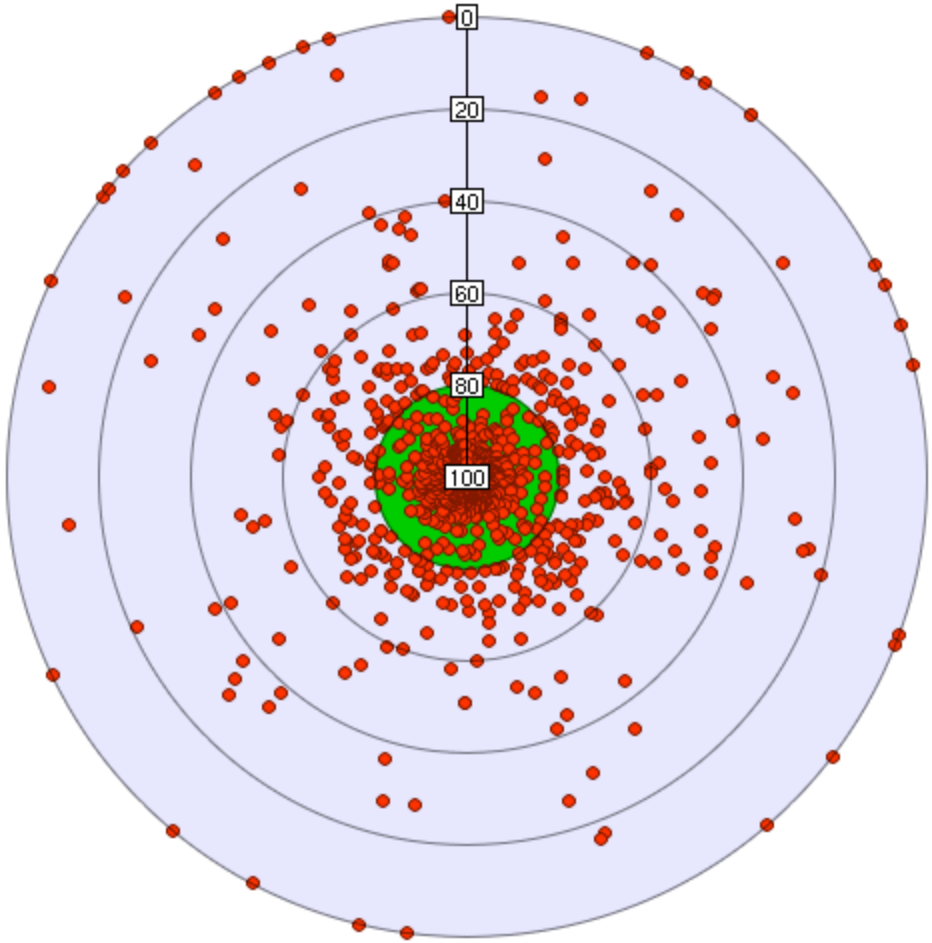
- 6 HIV simulation cases (3 pre- and 3 post-test)
- User initial pass-rate was 11% pre-tests without clinical guidance
- Clinical guidance turned on: users went through additional simulations
- Clinical guidance turned off: Final re-test pass rate: 72%
- Overall scores increased 32 points

OUTCOMES (WHO)—2006-2007

- 5 training programs in 3 African countries
- 2,780 pre-/post-tests
- 4,465 sessions
- Users passed 71% of pre-tests with clinical guidance turned off
- Clinical feedback turned on and multiple case-based simulations availed
- Clinical feedback turned off: Post-test scores increased by an average of 35 points
- Final pass rate 93%

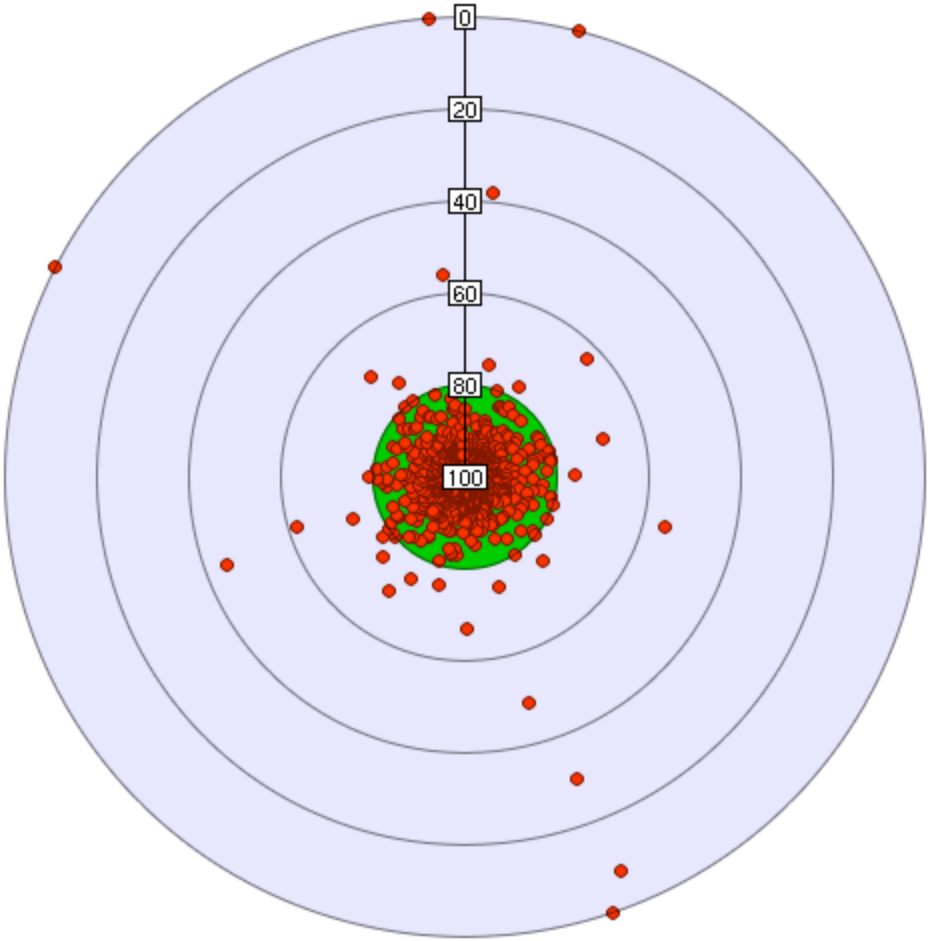
Measuring Behavior--BEFORE

Scatter-Plot rendering of **Pre-Simulation** Clinical Test Performance Measurement Results -- Variance from Best-Practices Protocols



Measuring Behavior--AFTER

Scatter-Plot rendering of **Post-Simulation** Clinical Test Performance Measurement Results -- Variance from Best-Practices Protocols



SUMMARY: USED TOGETHER . . .

Clinical Case Simulation and Clinical Scorecards

- Tracks performance of individuals and groups
- Targets deficiencies while improving clinical skills in a consequence-free "virtual" environment
- Provides "hands on" self-paced education with instantaneous "best practices" feedback
- Serves as a framework for developing compentencies and clinical performance management

Would You Like to Sign Up. . . ?

For a proof-of-concept in your own hospital or clinic? No hardware, software, or professional staff required.

- SAS Institute will provide one Quality Template hosted as an ASP (Application Service provider) for your facility at no cost to you for six months.
- TheraSim will provide you with a series of clinical case simulations in one disease or quality domain at no charge for six months
- **You'll need** to help us to **access and de-identify** the patient/clinical data supplied to us
- **You'll need** to incorporate the clinical scorecards outcomes and the TheraSim simulations as part of your existing in-service and or CME training program
- It costs you nothing: but could mean the world to your quality initiative
- There is no obligation on any parties: its an *in simulo* experiment!

Contact Us . . . .

- **Charles A. Coleman, Ph.D.**
- Senior Managing Director, SAS Institute
  - charles.coleman@sas.com

- **David D. Hadden, CEO**
- TheraSim, Inc.
  - www.therasim.com/html/contact/index.htm

Thank You . . . Questions

Only 50 days!

RUDOLPH?

ABBY

Novel Clinical Performance Management System: HIV, HBV, HCV and Adolescent Vaccines

Abstract:

Background: Traditional clinical training methods are expensive, take physicians out of the practice setting, and the impact is difficult to measure. We report on physician performance using an interactive computer-based simulation and data analysis program for practitioners to manage virtual HIV, HBV, HCV, and adolescent vaccination patients with various infectious and metabolic abnormalities.

Methods: Using an interactive virtual medical records interface, clinicians can review histories, order tests, make diagnoses, and start treatments for 76 patient simulation modules (3-20 cases/program) targeting >100 competencies in nine web-based and two African (CD-based) program sites. The simulation provides expert system, guidelines-based feedback on the appropriateness of choices, including a summary of medical errors, warnings, and deviations from guidelines at completion. Electronic mentoring occurs at the point of care.

Novel Clinical Performance Management System: HIV, HBV, HCV and Adolescent Vaccines

Results:

Usage*:* 4,669 clinicians representing 115 countries completed 9,893 sessions, averaging 27 pages in 18 minutes/session and an average score of 71 (42% failure). *Errors:* Users failed to: order required viral and metabolic tests in 25%, make secondary diagnoses in 40%, treat viral illness appropriately in 32%, manage co-morbidities (herpes, candida, DM and lipids) in 41%, use PCP prophylaxis in 21%, and order appropriate vaccines in 86% of sessions. In vaccine, lipid and arthritis programs, 44% of clinicians failed to order HIV screening. *Outcomes:* In two African training trials using WHO guidelines (1,319 pre-test/post-test modules), 32% of 164 users failed initially, but after activating clinical feedback, average scores increased by 34 points and failures declined to 4%.

Conclusion: These simulations show significant discordance between guidelines and clinical choices in therapy selection, preservation, and change. This tool can augment global HIV, HBV, HCV and vaccine mentoring and training, track performance of individuals and groups, target deficiencies, and provide a framework for certification of competencies.

References

1. CDC National Diabetes Fact Sheet 2003. Accessed November 20, 2006 at www.cdc.gov .
2. Hellman R, *et al*. Provider error is an important cause of poor outcomes in diabetes care. *Diabetes*. 48:A67, 1999
3. J Phillips, *et al*. Retrospective analysis of mortalities associated with medication errors. *Am J Health-Syst Pharm* 58(19):, 2001.
4. Dutta P, *et al*. Using an automated care simulation tool to assess physician errors in diabetes care. *Diabetes* Jun; 53 (Suppl 1):519, 2004.
5. **HIV Education Using Clinical Case Simulation -** IDSA Oct.2005 San Francisco - Blevins, Hadden (TheraSim), Brewer(Harvard)
6. **Novel Computerized System for Monitoring and Improving Clinician Skills** – USAID/PEPFAR--June 2006—Durban, SA - Blevins, Hadden, Firnhaber, Bartlett
7. **Computerized HIV Teaching System: Monitoring and Improving Skills** - IDSA--October 2006--Toronto (Blevins, Hadden and Bartlett)