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

Charles A. Coleman, Ph.D.
Senior Managing Director, SAS Institute
Higher Education and Academic Medical Center Practice, SAS Institute
Evidence Based Healthcare Initiative, SAS Institute

John G. Bartlett, M.D.
Distinguished Professor and Chief of Infectious Diseases (HIV AIDS)
Bloomberg School of Public Health, Johns Hopkins University

David D. Hadden, CEO
TheraSim, Inc.
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?
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?
"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."
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?

Clinical Performance Dashboards
- Protocols & Guidelines
- Published Best Practices
- Agencies & Organizations
- Evidence based Healthcare
- Systematic Reviews
- Published Research Results
- Research Topics

Protocols Guidelines & Order Sets embedded in EMR or CPOE
- CPM & Clinical Simulations
- Traditional In-Service Training
- Published Research Results
- Evidence based Healthcare
- Systematic Reviews
- Published Best Practices
- Agencies & Organizations

FDA
- JCAHO
- AHRQ
- CMS

Traditional Conferences & Lecture
- Traditional CME

AMA
- ADA
- IHI
- NIH
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
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
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)**

### Databases

#### Patients
- Patient#
- Birth Date
- Gender
- Admission Data
- Discharge Data

#### Medicines
- Patient#
- Medicine
- Date
- Order Information

#### Diagnoses
- ICD-9
- Patient#
- Diagnosis
- Date
- Admit/Discharge

#### Procedures
- ICD-9
- Patient#
- Procedure
- Date

### ETL
- **Data Quality**
- **Data Integration**

### RAPID CARDIOCARD
- SAS BI Server
- Staging Platform
- Metadata

### Data Marts

### OLAP
- SAS Health Metrics Dashboard Data
- Architecture / ASP
- Databases

<table>
<thead>
<tr>
<th>Name</th>
<th>Q2 - 2004</th>
<th>Q3 - 2004</th>
<th>Q4 - 2004</th>
<th>Q1 - 2005</th>
<th>Q2 - 2005</th>
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<td></td>
<td></td>
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<td>Aspirin Prescribed at Discharge</td>
<td>94.915</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>95.349</td>
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<tr>
<td>Aspirin Within 24 Hours of Arrival</td>
<td>98.413</td>
<td>100</td>
<td>100</td>
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<td>100</td>
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<tr>
<td>PTCA Times-Percent Within 90 Minutes of Arrival</td>
<td>64.7</td>
<td>64.2857</td>
<td>73.333</td>
<td>66.7</td>
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<td>Ace Inhibitor for LVSD</td>
<td>90.919</td>
<td>100</td>
<td>100</td>
<td>87.5</td>
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<td>Smoking Cessation Advice/Counseling</td>
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<tr>
<td>Beta Blocker Prescribed at Discharge</td>
<td>96.491</td>
<td>100</td>
<td>97.917</td>
<td>95.349</td>
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<tr>
<td>Inpatient Mortality</td>
<td>8.571</td>
<td>6.78</td>
<td>1.754</td>
<td>5.769</td>
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</tbody>
</table>
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
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.
For the negative trends, how can I take action?
JCAHO MEASURES Heart Attack (AMI)

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

Trend Line Influenced In Q4
Imagine if aviation used the measure mistakes rather than prevent mistakes approach.

- **Aviation Accidents per Million Departures**
  - 11.5 accidents/M
  - 263.8 deaths/M

- **Medical Errors per 100,000 Admissions**
  - By 2020 $896B
  - #6 COD
  - (44% factor)
  - (98,000 deaths/yr 268/day)
  - #9 COD

- **Medical Errors per 100,000 Admissions**
  - $10B /year/1990
  - 0.9 accidents/M
  - 23.3 deaths/M
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

Baseline Behavior
- Gap against Measures
- Predict errors not experienced in your practice yet

FILL SKILL GAPS
- Case simulation
- Change behavior

Analysis of Clinical Performance Metrics and Predictive Modeling

START HERE
Clinical Data Systems →

CIMS feeds clinical data to data repository for analysis

Clinical Outcome Repository. Quality of care is measured
QUALITY GAP ANALYSIS

CDS
Training (Simulation) Baseline Behavior

TS
Clinicians (Physicians, NPs, PAs)

PATIENT CARE

Clinical Outcomes

Data Repository

SAS

Patient Data

CIMS (EMR, CPOE, Practice Mgmt, Billing)

DSS
Sources of Medication Error

Error introduced after the physician's treatment decisions

1. Initial Order
   - Error originating directly from the physician due to lack of knowledge or skill.
2. Error Due to Knowledge/Skill Deficit
   - Predictable through simulation
   - Preventable through training and simulation

- Performance Knowledge: 44%
- Dosage: 19%
- Miscommunication: 33%
- Other: 2%
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

The TheraSim Clinical Composer translates the information into clinical rules for the TheraSim Knowledgebase.
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. . .
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.
### Demographic Data
- **Name:** Jenny S.
- **Gender:** Female
- **Age:** 31
- **Height:** 167 cm
- **ID:** IDSA-01

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

### Drug Allergies or Intolerance
- **Date:** 17 Sep 07
- **Drug:** No known allergies

### Physicians Notes and Condition Assessments
- **17 Sep 07**
  - **Condition:** AIDS
  - **Condition:** HIV Infection
  - The patient is sexually active with several partners and refuses to consider using contraceptives at this time.
- **16 Sep 07**
  - **Condition:** AIDS
  - **Condition:** Pneumocystis jiroveci pneumonia (PCP)
  - **Condition:** Candidal Esophagitis
  - **Condition:** HIV Infection
- **15 Sep 07**
  - **Condition:** AIDS
  - **Condition:** Pneumocystis jiroveci pneumonia (PCP)
  - **Condition:** Candidal Esophagitis
  - **Condition:** HIV Infection
- **10 Sep 07**
  - **Condition:** AIDS
  - **Condition:** Pneumocystis jiroveci pneumonia (PCP)
  - **Condition:** Candidal Esophagitis
  - **Condition:** HIV Infection
- **06 Sep 07**
  - **Condition:** AIDS
  - **Condition:** Pneumocystis jiroveci pneumonia (PCP)
  - **Condition:** Candidal Esophagitis
  - **Condition:** HIV Infection
  - Discharged from the hospital on oral medications. Follow-up appointment with HIV provider in about 10 days.
- **03 Sep 07**
  - **Condition:** AIDS
  - **Condition:** Pneumocystis jiroveci pneumonia (PCP)
  - **Condition:** Candidal Esophagitis
  - **Condition:** HIV Infection
- **01 Sep 07**
  - **Condition:** AIDS
  - **Condition:** Pneumocystis jiroveci pneumonia (PCP)
  - **Condition:** Candidal Esophagitis
  - **Condition:** HIV Infection

### Current and Previous Therapies by Office Visit
<table>
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<tr>
<th>Visit Date</th>
<th>Therapy</th>
<th>Dose</th>
<th>Freq.</th>
<th>End Date</th>
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<tr>
<td>16 Sep 07</td>
<td>predniSONE</td>
<td>20 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
</tr>
<tr>
<td></td>
<td>trimethoprim-sulfamethoxazole</td>
<td>2 mg</td>
<td>tid</td>
<td>17 Sep 07</td>
</tr>
<tr>
<td></td>
<td>flunazolene</td>
<td>200 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
</tr>
<tr>
<td>15 Sep 07</td>
<td>predniSONE</td>
<td>20 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
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<td>trimethoprim-sulfamethoxazole</td>
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<td>17 Sep 07</td>
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<td>flunazolene</td>
<td>200 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
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<tr>
<td>10 Sep 07</td>
<td>predniSONE</td>
<td>20 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
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<tr>
<td></td>
<td>trimethoprim-sulfamethoxazole</td>
<td>2 mg</td>
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<td>17 Sep 07</td>
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<tr>
<td></td>
<td>flunazolene</td>
<td>200 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
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<td>06 Sep 07</td>
<td>predniSONE</td>
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<td></td>
<td>trimethoprim-sulfamethoxazole</td>
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<tr>
<td></td>
<td>flunazolene</td>
<td>200 mg</td>
<td>qd</td>
<td>17 Sep 07</td>
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<tr>
<td>03 Sep 07</td>
<td>trimethoprim-sulfamethoxazole</td>
<td>2 mg</td>
<td>tid</td>
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<tr>
<td></td>
<td>predniSONE</td>
<td>40 mg</td>
<td>qd</td>
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<td></td>
<td>flunazolene</td>
<td>200 mg</td>
<td>qd</td>
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<td>01 Sep 07</td>
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<td></td>
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<td>06 Sep 07</td>
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<td>trimethoprim-sulfamethoxazole</td>
<td>2 mg</td>
<td>q8h</td>
<td>03 Sep 07</td>
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**Reverse Transcriptase Mutations:** M41L, M184V, T215Y; (V245V -- no mutation at this site)

**RTI Implications for Resistance**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>BRAND</th>
<th>GENERIC</th>
<th>RESISTANCE</th>
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<tr>
<td>3TC</td>
<td>Epivir</td>
<td>lamivudine</td>
<td>Resistant</td>
</tr>
<tr>
<td>ABC</td>
<td>Ziagen</td>
<td>abacavir</td>
<td>Sensitive</td>
</tr>
<tr>
<td>AZT</td>
<td>Retrovir</td>
<td>zidovudine</td>
<td>Sensitive</td>
</tr>
<tr>
<td>d4T</td>
<td>Zerit</td>
<td>stavudine</td>
<td>Sensitive</td>
</tr>
<tr>
<td>ddI</td>
<td>Videx</td>
<td>didanosine</td>
<td>Resistant</td>
</tr>
<tr>
<td>FTC</td>
<td>Emtriva</td>
<td>emtricitabine</td>
<td>Resistant</td>
</tr>
<tr>
<td>TDF</td>
<td>Viread</td>
<td>tenofovir</td>
<td>Sensitive</td>
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**NNRT Mutations:** K103N

**NNRTI Implications for Resistance**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>BRAND</th>
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<tr>
<td>DLV</td>
<td>Rescriptor</td>
<td>delavirdine</td>
<td>Resistant</td>
</tr>
<tr>
<td>EFV</td>
<td>Sustiva</td>
<td>efavirenz</td>
<td>Resistant</td>
</tr>
<tr>
<td>NVP</td>
<td>Viramune</td>
<td>nevirapine</td>
<td>Resistant</td>
</tr>
</tbody>
</table>

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

**PI Implications for Resistance**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>BRAND</th>
<th>GENERIC</th>
<th>RESISTANCE</th>
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<tbody>
<tr>
<td>ATV</td>
<td>Reyataz</td>
<td>atazanavir</td>
<td>Sensitive</td>
</tr>
<tr>
<td>DRV</td>
<td>Prezista</td>
<td>darunavir</td>
<td>Sensitive</td>
</tr>
<tr>
<td>FPV</td>
<td>Lexiva</td>
<td>fosamprenavir</td>
<td>Sensitive</td>
</tr>
<tr>
<td>IDV</td>
<td>Crixivan</td>
<td>indinavir</td>
<td>Resistant</td>
</tr>
<tr>
<td>SQV</td>
<td>Fortovase/Invirase</td>
<td>saquinavir</td>
<td>Resistant</td>
</tr>
<tr>
<td>LPV/r</td>
<td>Kaletra</td>
<td>lopinavir-ritonavir</td>
<td>Resistant</td>
</tr>
<tr>
<td>NFV</td>
<td>Viracept</td>
<td>nelfinavir</td>
<td>Resistant</td>
</tr>
<tr>
<td>RTV</td>
<td>Norvir</td>
<td>ritonavir</td>
<td>Resistant</td>
</tr>
<tr>
<td>TPV</td>
<td>Aptivus</td>
<td>tipranavir</td>
<td>Sensitive</td>
</tr>
</tbody>
</table>
Tests Available to Order or View

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

Lab Tests Already On File

- 24 Feb 06 CBC with Differential
- 24 Feb 06 CD4 Test
- 24 Feb 06 HIV Diagnostic Panel
- 24 Feb 06 Syphilis Serologies
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.

OSO 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 HIV 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)
**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
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
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]

**Missed test**: Chem Screen

- Most clinicians order a chem screen to screen for azotemia, hepatotoxicity, hyperglycemia and various other substances. It is not a toxicology screen.
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 Tuberculosis 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

- Recommendations To Help Patients Avoid Exposure to Infection from Opportunistic Pathogens, June 11, 2002 (NEW WINDOW)
<table>
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<th>African Participants (internet)</th>
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AIDS Case-based Simulated 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 competencies 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
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


7. **Computerized HIV Teaching System: Monitoring and Improving Skills** - IDSA--October 2006--Toronto (Blevins, Hadden and Bartlett)