# Swords into plowshares

Leveraging clinical data quality excellence and data mining tools for promoting quality of care

Dr. Peter Pronovost, Sr. Vice President – Patient Safety and Quality, Johns Hopkins Hospital
Aloha McBride, Principal, Ernst & Young LLP
Marc Schulman, Executive Director, Ernst & Young LLP
David N. Hoffman, Chief Compliance Officer, Physician Affiliate Group of New York, P.C.

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## Course agenda and session topics

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speakers</th>
<th>Time</th>
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<tbody>
<tr>
<td>Introduction and course objectives</td>
<td>All</td>
<td>1:30 p.m. – 1:35 p.m.</td>
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<tr>
<td>Why we need to start treating clinical data like financial data. A case study from Johns Hopkins, the value of data. Leveraging high reliability principles and financial management concept.</td>
<td>Dr. Peter Pronovost</td>
<td>1:35 p.m. – 2:20 p.m.</td>
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<tr>
<td>How do you begin to think about clinical data transactions like financial data transactions and governance: a quick overview of COSO, due diligence and ERM. How to begin to applying these concepts to clinical data quality and reporting integrity</td>
<td>Aloha McBride/ Marc Schulman/ Tamil Chelliah</td>
<td>2:20 p.m. – 3:15 p.m.</td>
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<td>Break</td>
<td>–</td>
<td>3:15 p.m. – 3:30 p.m.</td>
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<td>Leveraging data mining/analytics to improve quality of care through the automated generation and distribution of actionable exception reports</td>
<td>David Hoffman</td>
<td>3:30 p.m. – 4:30 p.m.</td>
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Setting the stage on data — the never-ending struggle to determine the signal through noise

- Patient safety indicators are derived from administrative codes in billing and are broadly used in hospital ranking programs and pay-for-quality programs.
- Patient safety indicators are frequently inaccurate — missing many harms while also reporting false positives.
- Too often, hospital ratings and rankings reflect how well a hospital codes rather than how a hospital provides care.
- For instance, Johns Hopkins reduced the number of patient safety indicator (PSI) incidents it reported to CMS by 75%, thereby reducing its penalties.
- However — only 10% of the improvement resulted from changes in clinical care. The other 90% resulted from documentation and coding that was more thorough and accurate.

Instead of using PSIs, there is an enormous need for valid and reliable measures that can be tested, controlled and audited, similar to financial transactions and measures.

Medical errors — why they occur and the role of clinical data integrity

Why do errors occur?
Commonly, errors are caused by systemic problems, including a lack of integrated processes, technologies and governance that drive unwarranted variation.

What is at stake when clinical data contains errors?
- A patient's life and livelihood
- Misdiagnosis/delayed diagnosis
- Medication errors
- Performance measurement calculation errors
- Reimbursement errors
- Trust in your organization's ability to provide safe care

The problem with bad data

- Can result in inappropriate clinical decision-making and creates significant patient safety risk
- Impairs evidence-based medicine and coordination across the care continuum
- Increases the risk of beneficiaries not having access to covered services
- Can result in billing, payment and performance inaccuracies
- Produces inaccurate stakeholder reporting
- Erodes consumer trust and increases legal risk
How does good data become bad information?

- Methods by which it is captured and stored — manual, incomplete, etc.
- Data and system architecture lacks interoperability, resulting in blind spots.
- Cultural roadblocks across the health system prevent collaboration.
- Integrity of systems is not adequately protected, allowing for vulnerabilities and workarounds.
- Clinicians and data scientists operate in silos so reporting is not relevant or actionable in the clinical setting.
- Lack of structure and controls in underlying clinical process to manage quality data inputs.

What is High Reliability Organizing (HRO) and how can it help us to improve clinical data integrity?

HRO is the pursuit of flawless performance under complex, dynamic and sometimes, potentially catastrophic conditions.*

1. Sensitivity to operations
2. Deference to expertise
3. Reluctance to simplify
4. Preoccupation with failure
5. Commitment to resilience

Core characteristics

*Source: Karl E. Weick and Kathleen M. Sutcliffe, Managing the Unexpected: Resilient Performance in an Age of Uncertainty

How have HROs organized for success? The advent of the Operating Management System

Unifying framework for structured assurance of safety, quality and reliability and an integrated approach for continuous organizational learning, innovation and improvement

For critical data, this means the utmost control, monitoring and testing to certify that all data sets are complete, accurate, interoperable, accessible, relevant and auditable.
**What are the core components of an HRO operating model — a lesson from Johns Hopkins Medicine**

![Diagram showing the core components of an HRO operating model](image)

- **Governance** supports a committee structure at every level of the organization — similar to a board finance and audit committee — the clinical quality committee has fiduciary duties to confirm clinical quality and safety — inclusive of clinical data integrity.

- **Driving reliability through governance, leadership and accountability**

- **Transparency, communication and teamwork**

- **Capacity and infrastructure**

- **Respect for clinicians and frontline staff**

- **Standardize work to prevent harm**

- **Recover from mishaps when they occur**

- **Continuous learning and improvement**

- **Patients and families**

- **Senior leaders**

- **Executive teams**

- **Coordination team**

- **Patients and families**

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**Johns Hopkins Medicine – governance, leadership and accountability**

- Board of Trustees (Board) confirms oversight for quality and safety
- Applies the same rigor as applied to finance
- High reliability is a specific strategic objective
- Strategic objectives flow consistently throughout the health system
- Quality, safety and service are key components of strategic objectives
- Each clinical area is accountable for performance in four standard domains (patient safety, experience, value and external reporting)
- Leaders create shared accountability that cascades from Board to bedside

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**Shared leadership accountability**

![Diagram showing shared leadership accountability](image)

- Board — CEO — Presidents — Dept. heads — Unit leaders — Frontline — Patient

- Use the levers and adaptive leadership to strengthen the links

- Responsibility, role clarity and feedback

- Capacity

- Time and resources

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*Source: Weaver; J Healthcare Management In press*
Rigorous reporting and monitoring of core quality and safety measures

The Board confirms that a framework for reporting quality and safety of care mirrors the rigor and comprehensiveness of a consolidated financial statement.

Driving accountability through proactive monthly and quarterly reporting and oversight

1. Performance below target for one month or one performance period (ie: one quarter)
   - Local champions to form performance improvement team
   - Review data and investigate defects
   - Identify barriers and implement targeted interventions

2. Performance below target for two months or two performance periods
   - PI team presents to local Hospital Quality Council and President/CEO
   - President meets with appropriate clinical director and PI team
   - President presents plan with timelines to JHM QSS executive committee

3. Performance below target for three months
   - Department Director/MD champion present to local hospital Quality and Safety Board (trustee chair and President sign QI plan)
   - President presents to JHM Quality Safety Board Committee
   - AI conducts peer-to-peer review

By monitoring clinical quality and safety, any small change in clinical pathway performance is noted, investigated and remediated thoughtfully and quickly — individuals are rewarded for anticipating, identifying and remediating clinical risks.

So – why are we concerned with clinical data quality and controls?

Health care organizations require complete, accurate, relevant and reliable patient safety, quality and performance data in order to make sound clinical decisions, support reimbursement documentation and meet their internal and external reporting requirements.
Questions to ponder…

- Do you have a "Board to the Bedside" governance structure for clinical quality and patient safety measures and risks?
- Are you managing and overseeing your clinical data with the same level of rigor as your financial data?
- Do you have risk and internal control(s) owners over your clinical processes, systems and data?
- How confident are you that the clinical data residing in your systems is complete, accurate, interoperable, accessible, relevant and auditable?
- Do you understand how each clinical data element traverses though all of your systems into clinical diagnosis decisions, revenue cycle and performance reporting?
- Are you regularly testing and independently auditing clinical data, diagnosis and coding to identify control gaps, compliance gaps and training gaps?

Health systems must proactively identify, understand and manage clinical risks … robust effective internal controls, monitoring and governance activities are crucial

To enable high reliability of clinical data, health systems must treat clinical data with the same rigor as financial data
The basics – incorporating HRO into risk management and internal controls using the COSO internal controls framework to drive clinical quality and reporting integrity

- Leveraging the principles of enterprise risk management, internal controls and HROs can identify potential harms while improving risk management and reporting.
- Start by answering the simple question: How might we manage the integrity of clinical data as if it were financial data in order to reduce errors and ensure timely and accurate reporting?

As healthcare compliance and risk professionals—you understand the level of rigor and scrutiny applied to auditing and tying every invoice in order to maintain financial transparency and solvency—might we well do the same when reviewing data at risk?

Integrating the five components of internal control with the five levels of HRO enable organizations to action and adopt high reliability behaviors that drive toward zero harm.

High quality, scalable clinical information to support patient care.

COSO and HRO aligned – COSO provides a structured framework to assess the internal controls environment to identify potential risk which clearly is aligned to HRO

<table>
<thead>
<tr>
<th>Component of internal control</th>
<th>Principles of internal control</th>
<th>Segments to high reliability behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controls environment</td>
<td>1. Environments necessitate integrity and ethical values</td>
<td>Internal controls is embraced organization-wide.</td>
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<tr>
<td></td>
<td>2. Board of Directors demonstrates independence from management and operates effectively</td>
<td>Middle management and collaborative structure actively and responsibly.</td>
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<td></td>
<td>3. The organization demonstrates commitment to competence</td>
<td>Functions to simplify complexity to operations.</td>
</tr>
<tr>
<td>Risk assessment</td>
<td>4. The organization demonstrates commitment to independence</td>
<td>Functions to simplify complexity to operations.</td>
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<tr>
<td></td>
<td>5. Identifies and assesses risk</td>
<td>Functions to simplify complexity to operations.</td>
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<td></td>
<td>6. The organization demonstrates significant change that could impact system of internal control</td>
<td>Functions to simplify complexity to operations.</td>
</tr>
<tr>
<td>Control activities</td>
<td>7. Scales and manages controls to detect</td>
<td>Functions to simplify complexity to operations.</td>
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<td></td>
<td>8. Monitors and develops general controls over technology and processes through policies and procedures</td>
<td>Functions to simplify complexity to operations.</td>
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<tr>
<td>Information and communication</td>
<td>9. Coordinates, evaluates, and documents relevant, quality information</td>
<td>Functions to simplify complexity to operations.</td>
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<td></td>
<td>10. Communicates externally</td>
<td>Functions to simplify complexity to operations.</td>
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<tr>
<td>Marketing</td>
<td>11. Monitors, develops, and performs ongoing and separate evaluations</td>
<td>Functions to simplify complexity to operations.</td>
</tr>
<tr>
<td></td>
<td>12. Evaluates and communicates objectives</td>
<td>Functions to simplify complexity to operations.</td>
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What does an ERM- and ICM-enabled healthcare organization look like?

<table>
<thead>
<tr>
<th>Patient</th>
<th>Patient receives predictable, safe, evidence-based care. They are not over- or under-treated and their expectations are met. The patient feels respected and engaged in his or her care and has not been harmed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boards</td>
<td>Boards are provided with available, quality meaningful data to guide its investment and strategic decisions. They have high levels of leadership and accountability.</td>
</tr>
<tr>
<td>Owners</td>
<td>The organization owns the competitor landscape to understand any threats to market or performance. The focus is always on delivery of care and how emerging competitors may impact the organization’s ability to continue to provide quality services.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operations</th>
<th>Operations perform the required activities and measure performance against defined key business metrics.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regimes</td>
<td>The organization understands the reporting requirements, and complies in providing correct, auditable, quality data, quality and timeliness. It ensures the internal controls are in compliance with control requirements.</td>
</tr>
<tr>
<td>Compliance</td>
<td>The organization scores the competitor landscape to understand any threats to market or performance. The focus is always on delivery of care and how emerging competitors may impact the organization’s ability to continue to provide quality services.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Structures</th>
<th>Structures aligns the required strategic, functional, and operational components with the organization’s current and desired future state.</th>
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<tbody>
<tr>
<td>Governance</td>
<td>Governance oversees the alignment and ensures the risk to patient safety and quality is within the expected range. It is used to escalate or de-escalate the provided care.</td>
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<tr>
<td>Diagnosis</td>
<td>Diagnosis identifies and analyzes relevant and significant clinical and non-clinical data to identify risks and opportunities.</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Monitoring identifies and analyzes relevant and significant clinical and non-clinical data to identify risks and opportunities.</td>
</tr>
<tr>
<td>Prevention</td>
<td>Prevention implements strategies that can prevent, contain, or mitigate identified risks that can impact the organization.</td>
</tr>
<tr>
<td>Assessments</td>
<td>Assessments measure, validate, and analyze data to drive decision to action.</td>
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The Three Lines of Defense Model for clinical data

The Three Lines of Defense model confirms there is segregation between direct accountability for risk decisions, independent oversight and independent assurance on the effectiveness of risk management, control and governance processes.

**First Line (Direct Accountability):**
- **Risk taking business units:** Are responsible for owning and managing risks in the business.
  - Develop and implement the strategy.
  - Measure business performance.
  - Implement internal control and risk management frameworks.
  - Confirm that the business is managed within the agreed risk appetite.

**Second Line (Internal Control):**
- **Compliance and risk functions:** Provide objective oversight of the management of risks by the business.
  - Design and deploy the overall risk management framework across the organization.
  - Monitor adherence of the business to risk framework and performance.
  - Support and challenge the first line on management of risks and controls.

**Third Line (Independent Assurance):**
- **Internal audit function:** Provides independent assurance on the effectiveness of risk management.
  - Independently assess and report on effectiveness of design and operation of the risk management framework.
  - Carry out testing of key controls.
  - Review activities performed by first and second LOD so that they are appropriately meeting their responsibilities.

HRO’s aim to have clinical data and integrity auditing as standard activities using a similar LOD assessment and reporting model

Leveraging an HRO-enabled risk and controls approach to drive clinical data integrity
**Step 1 – Understand the operating environment**

1. Understand current state performance, strategic objectives and outcomes.
   - What are the key performance indicators in the operating environment?
   - What is the strategy to pursue zero harm?
   - What are the key performance indicators and outcomes?
   - How do the key performance indicators align with the strategy?

**Operating model**

- Governance
- Decision making
- Performance management
- Technology
- Process integration
- Accountability

**Supporting structures**

- Quality and safety policies and procedures
- Safety and quality training
- Supporting documentation
- Current control and audit

- How are the key performance indicators and outcomes aligned with the strategy?
- What is the current level of reporting and control?
- How do the key performance indicators align with the strategy?
- What are the key performance indicators and outcomes?
- How are the supporting structures in place and do they align with the strategy?
- Are there obvious weaknesses in these processes and controls?

**Step 2 – Customize the inherent risk universe**

**Strategic**

- Mission and vision
- Business strategy
- Key performance indicators
- Strategic objectives
- Strategic initiatives

**Operational**

- Processes and procedures
- Key performance indicators
- Strategic objectives
- Strategic initiatives

**Clinical**

- Processes and procedures
- Key performance indicators
- Strategic objectives
- Strategic initiatives

**Compliance**

- Processes and procedures
- Key performance indicators
- Strategic objectives
- Strategic initiatives

**Financial**

- Processes and procedures
- Key performance indicators
- Strategic objectives
- Strategic initiatives

- How are the key performance indicators and outcomes aligned with the strategy?
- What are the key performance indicators and outcomes?
- How do the key performance indicators align with the strategy?
- Are there obvious weaknesses in these processes and controls?
Step 3 – Identify areas of significant clinical quality and safety risk — sample risk areas and categorize across a threat matrix

- Variations in service delivery related to demographics
- Inconsistent database entries, inaccurate — potential for underestimating of events
- Incorrect, incomplete, incorrect, uncalculated, or incorrect feedback
- Delayed identification of serious quality errors — i.e., unreported deaths in inpatient and outpatient
- Systems disparate — linkages are unavailable
- Delayed patient safety events, wrong patient, wrong
- Lack of clarity concerning the underlying analytics
- Inadequate process, business continuity planning for system shutdown
- Compliance
- Inadequate compliance with mandatory reporting resulting from poor data entry
- Delays seen in addressing underserved issues

Step 4 – Link risk to clinical objectives and processes

<table>
<thead>
<tr>
<th>Clinical objectives and initiatives</th>
<th>Inherent key clinical risks</th>
<th>Clinical processes</th>
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<tr>
<td>Safety and Quality</td>
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<td>Safety</td>
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<td>Compliance</td>
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<td>Safety</td>
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<tr>
<td>Clinical process and control design</td>
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Step 5 – Assessment of internal controls design

- Conduct risk-based process understanding interviews and walk-through for in-scope clinical processes
- Document clinical process risks, controls, gaps and relevant control information (owner, frequency, evidence, IT systems, etc.) in narratives, flowcharts and the Risk and Control Matrix (RCM)
- Develop remediation plans to address control gaps and other process and control design recommendations

Document process flows to visualize a process entirely. Aim to fully understand the process and pinpoint where risks, controls and gaps exist.

This also enables greater coordination with the process owners when validating understanding, and agreement.
Step 6 – Future state internal controls design

Process
- The RCM developed in the previous phase will serve as a tool to evaluate current controls, to perform a gap analysis, and to make recommendations regarding the design of new controls, where applicable.
- Controls are assessed so they are not excessive, in order to make the process as lean as possible. Any proposed improvements are aligned to the HPO principles and the organization's objectives.
- Action plans are drafted then validated with the organization and refined.
- New controls are implemented. Assistance is provided to the organization to build the capability to implement controls.

Output
- Recommendations on the design of new controls and on the possible reduction of redundant controls.
- Action plan including improvement opportunities in case of structural deficiencies we have identified.
- A list of opportunities for amplification of controls where appropriate.
- Assistance and guidance with the design/enhancement of controls, using the RCM as tracking tool.
- Actions are performed in alignment with stakeholders, such as the process owners, in order for them to support and accept changes.
- Development of longer-term test and audit program.

Step 6 – Controls become the “day-to-day” process for managing data integrity risks

<table>
<thead>
<tr>
<th>Risk management activities are embedded within the existing planning, analysis and reporting processes – known as the “rhythm of the business”</th>
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<td>Board and leaders</td>
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<td>Strategic oversight and planning</td>
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<td>Clinical area to business area ownership, i.e., ICU/theatres community</td>
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<td>Coordination of monitoring and compliance activities</td>
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<td>Multi-factorial performance measurement and reporting</td>
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Where to go from here?
Potential next steps to consider for your organization

- Review your governance structure relative to clinical quality and patient safety performance metric ownership – do you have alignment from the “Board to the Bedside”?
- Understand your environment – select a critical care pathway (high demand, high revenue, clinically complex) and perform a clinical data element flow review and audit – where are your control gaps and what are your most frequent data errors?
- Start with your event reporting database and spot audit clinical data element flow and integrity across a near miss event.
- Interview your clinicians to understand where their clinical data pain points, concerns and workarounds relative to clinical data capture and analysis.
Opportunity awaits!

- Improved data
- Better understanding of process and patient threats
- More informed decision-making
- Greater process quality, risk management and control
- Improved patient outcomes, reduced rates of harm

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Leveraging data mining and analytics to drive quality, compliance and risk reduction

What you will learn

► The solution is hiding in the record.
► Metadata is your friend.

But first, for some context

► First rule of corporate compliance:
  ► Don't bill for care you didn't provide.
  ► That's stealing.
Some more context

- Second rule of corporate compliance:
  - Don’t bill for care you provided that wasn’t necessary.
  - That’s stealing.

And

- Third rule of corporate compliance:
  - Don’t bill for care you provided that was necessary but was of poor quality.
  - That’s__________?

“Quality care” did not mean the patient got “all better.”

Doctors couldn’t and were not expected to guarantee outcomes.
With *Value-based purchasing*,
all that has changed.

Acronyms that have ruled our lives

HCAHPS

_Hospital Consumer Assessment of Healthcare Providers and Systems_
CAHPS

Consumer Assessment of Healthcare Providers and Systems

DSRIP(P)

Delivery System Reform Incentive Payment Program

And now

VBP

(a very special acronym)
VBP

Value Based Purchasing

MACRA

Medicare Access and CHIP (Child Health Insurance Program) Reauthorization Act of 2015

What is MACRA?

► The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is a bipartisan legislation signed into law on April 16, 2015:
► What does Title I of MACRA do?
  ► Repeals the Sustainable Growth Rate (SGR) Formula
  ► Changes the way that Medicare rewards clinicians for value of volume
  ► Streamlines multiple quality programs under the new Merit-Based Incentive Payments System (MIPS)
  ► Provides bonus payments for participation in eligible alternative payment models (APMs)
MIPS changes how Medicare links performance to payment

There are currently multiple individual quality and value programs for Medicare physicians and practitioners:

- Physician Quality Reporting Program (PQRS)
- Value-Based Payment Modifier
- Medicare HER Incentive Program

MACRA streamlines those programs into MIPS

MACRA implementation timeline

- Final Rule Release
- Not much time for many providers to get involved in APMs
- Providers notified of link assignment
- Payment adjustment based on performance
- Advanced Alternative Payment Models (APMs)
- Merit-based Incentive Payment System (MIPS)
Now back to metadata

Two keys to survival

1. Data mining
2. Exception reports

Metadata as sword

Detection...
Metadata as sword

Detection...
Followed by extrapolation...

And then,

Repayment!

Metadata as tool

Surveillance,
Followed by intervention,
Followed by corrective action.
A simple example

Unread lab results,
Or PAP smears.

A not-so-simple example

DVT prophylaxis

What does the future hold?
Electronic medical records (EMR)

Friend or Foe?

► Friend or Foe?
► It doesn't matter.

EMR as a term paper

► Citation, not Plagiarism.
EMR as a term paper

- “Copy and Paste”
- Is a dangerous tool we actually don’t need

A wonderful challenge

Changing a flat tire on a bus …

… while the bus is moving.

Thank you!

- (Please complete your evaluation)