

| Торіс   | Speakers  | Time                  |
|---|---|-----------------------|
| Introduction and course objectives  | All   | 1:30 p.m. – 1:35 p.m. |
| 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.   | Dr. Peter<br>Pronovost                              | 1:35 p.m. – 2:20 p.m. |
| How do you begin to think about clinical data transactions<br>like financial data transactions and governance: a quick<br>overview of COSO, due diligence and ERM. How to begin<br>to applying these concepts to clinical data quality and<br>reporting integrity | Aloha McBride/<br>Marc Schulman/<br>Tamil Chellaiah | 2:20 p.m. – 3:15 p.m. |
| Break   | -   | 3:15 p.m. – 3:30 p.m. |
| Leveraging data mining/analytics to improve quality of care through the automated generation and distribution of actionable exception reports   | David Hoffman                                       | 3:30 p.m. – 4:30 p.m. |

# 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.

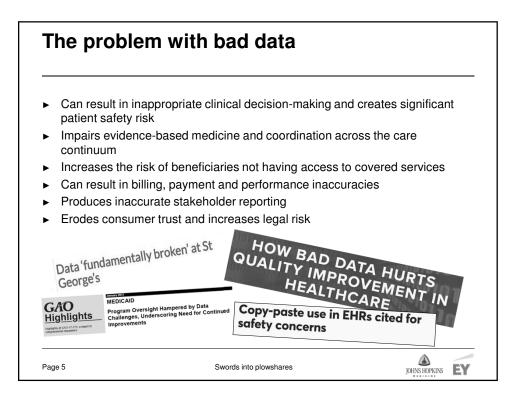
Instead of using PSIs, there is an enormous need for valid and reliable measures that can be tested, controlled and audited, similar to financial transactions and measures.

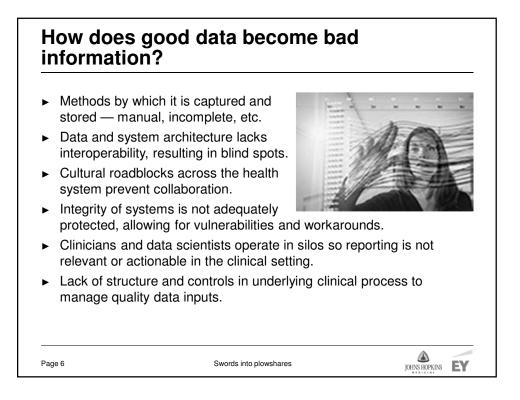
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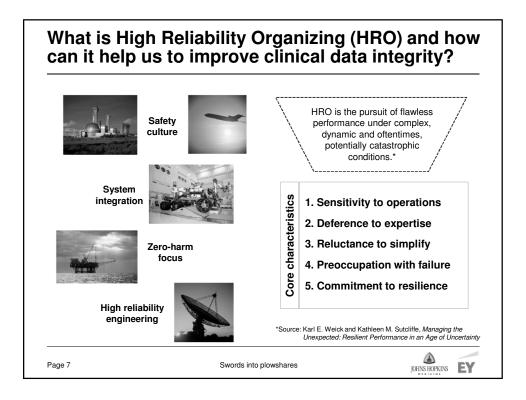
Swords into plowshares

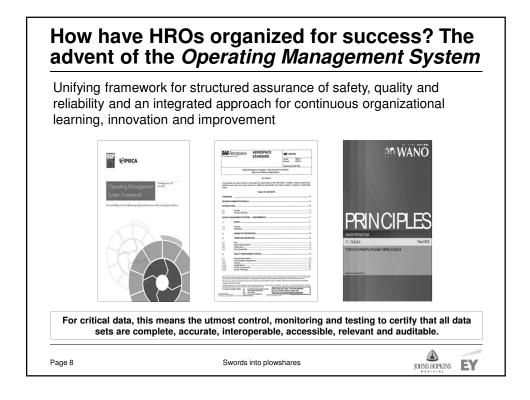
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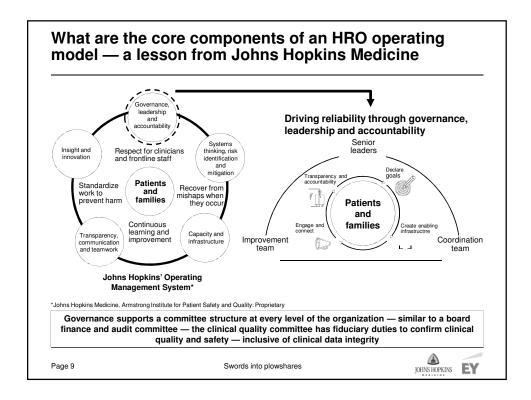
#### Medical errors – why they occur and the role of clinical data integrity Why do errors occur? **MEDICAL ERRORS NATION'S** Commonly, errors are caused by systemic **THIRD BIGGEST KILLER IN 2013** problems, including a lack of integrated Heart disease 611,000 process, technologies and governance that drive unwarranted variation. Cancer 585,000 What is at stake when clinical data 251,000 Medical error contains errors? COPD 149,000 A patient's life and livelihood ► Misdiagnosis/delayed diagnosis Suicide **41,000** ► Medication errors ► Firearm 34,000 Performance measurement calculation ► Motor vehicle 34,000 errors Reimbursement errors Source: Martin Makary, Michael Daniel study at Johns Hopkins University School of Medicine ► Trust in your organization's ability to Jim Sergent, USA TODAY provide safe care Page 4 Swords into plowshares JOHNS HOPKINS EY











## 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

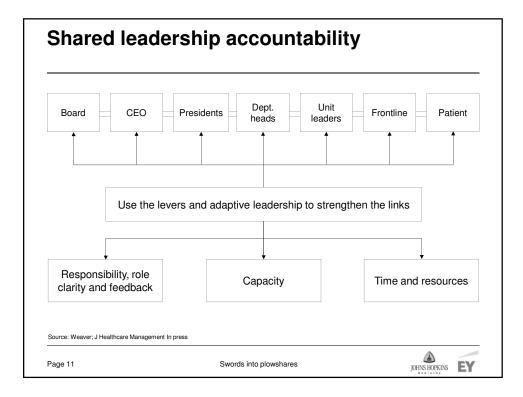


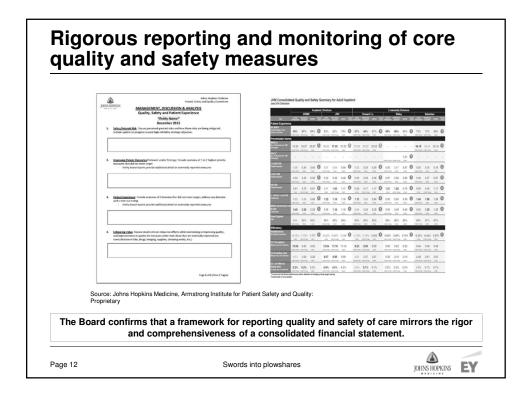
- Each clinical area is accountable for performance in four standard domains (patient safety, experience, value and external reporting)
- Leaders create shared accountability that cascades from Board to bedside

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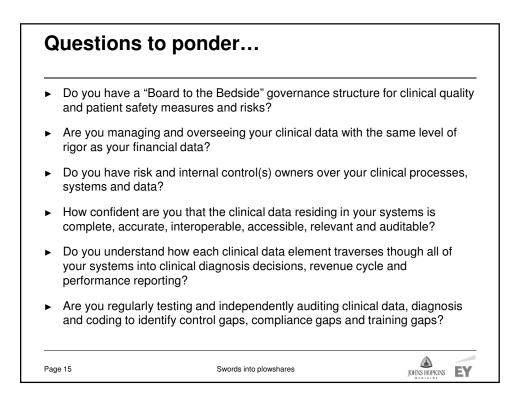
## So – why are we concerned with clinical data quality and controls?

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.

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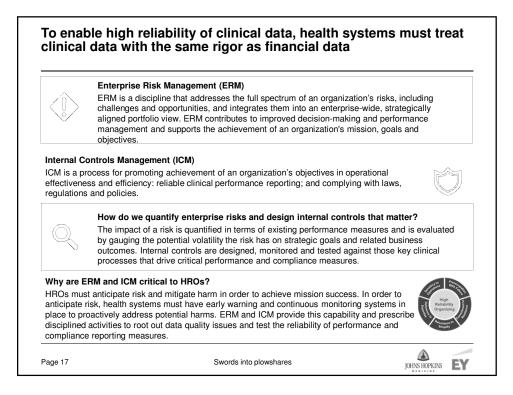
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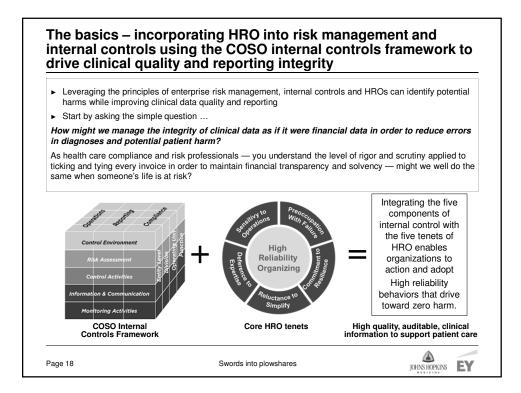
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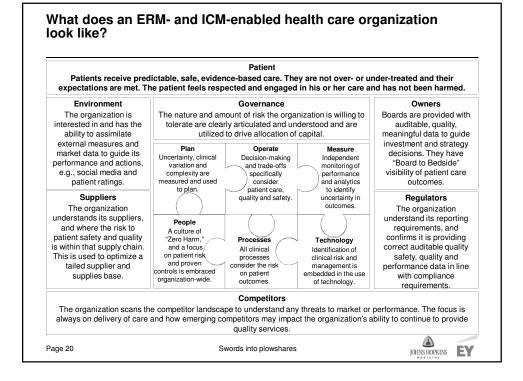
## Health systems must proactively *identify, understand* and *manage* clinical risks ... robust effective internal controls, monitoring and governance activities are crucial

| Health care risk themes   |  |  |  |   |  |
|---|--|--|--|---|--|
| Significant cost pressures  | Increased regulatory<br>requirements   | Patient safety and<br>quality concerns         | Competitive market –<br>new business models  | Growth of health<br>insurance exchanges   | Digital health/access to<br>performance data   |
|   |  |  |  |   |  |
| Health care emerging risks  |  |  |  |   |  |
| <ul> <li>Increasing move tow<br/>related reimburseme</li> <li>The need to demons<br/>improvement</li> <li>Emerging market-dr</li> </ul> | strate efficiency, leading practiven delivery models (ACOs)<br>ns, government intervention a | ents and protocols and<br>stice and continuous | <ul> <li>quality and patient ca</li> <li>Increasing vertical intracross traditional bou</li> <li>Increased demand on reporting</li> <li>Heightened focus on and digital platforms</li> </ul> | egration throughout the hea<br>ndaries to deliver integrated<br>IT systems for analytics, b<br>privacy and security lapses<br>hand for performance inform | Ith care value chain<br>d care models<br>usiness intelligence and<br>with the advent of mobile |
|   |  | Health care                                    | e top issues   |   |  |
| Quality   | Health data/accuracy,<br>security and use  | CMS compliance                                 | Regulatory adherence   | Maximize revenue from<br>activity   | Meaningful use   |
| Safety  | Clinical innovation/<br>evidence-based care  | Cost management and<br>efficiency              | Technology<br>Investments and value  | Resource<br>capacity/capability   | Health insurance<br>exchanges  |
|   |  |  |  |   |  |
|   | _  | Health care e                                  | xternal forces   |   |  |
| Economic  | Regulatory   | Demographic                                    | Political  | Societal  | Technology   |
|   |  |  |  |   |  |

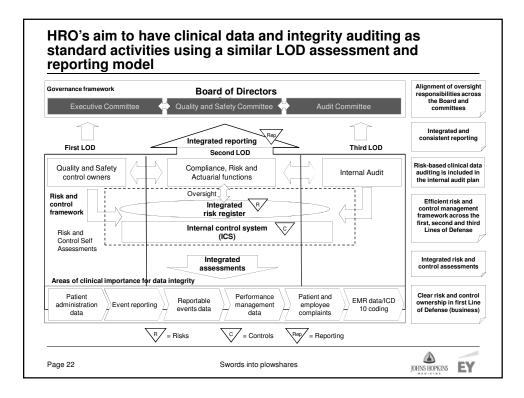




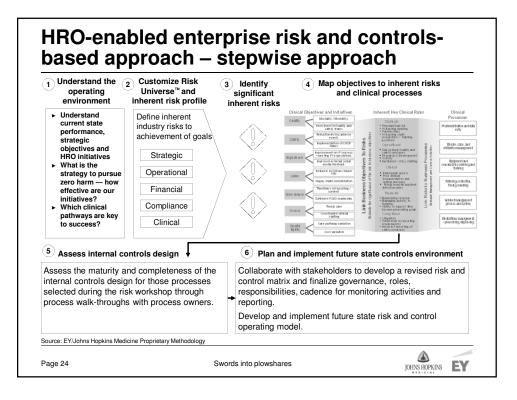
| <ol> <li>Demonstrates commitment to integrity and ethical values</li> <li>Board of Directors demonstrates independence from management and<br/>exercises oversight responsibility</li> <li>Management, with board oversight, establishes structure, authority<br/>and responsibility</li> <li>The organization demonstrates commitment to competence</li> <li>The organization establishes and enforces accountability</li> </ol> | Commitment to resilience<br>Preoccupation with failure<br>Deference to expertise<br>Reluctance to simplify<br>Sensitivity to operations  |
|---|--|
| <ol> <li>Specifies objectives with sufficient clarity to enable identification of risks</li> <li>Identifies and assesses risk</li> <li>Considers the potential for fraud in assessing risk</li> <li>Identifies/assesses significant change that could impact system of<br/>internal control</li> </ol>  | Preoccupation with failure<br>Sensitivity to operations<br>Reluctance to simplify  |
| 10. Selects and develops control activities<br>11. Selects and develops general controls over technology<br>12. Deploys through policies and procedures   | Preoccupation with failure<br>Sensitivity to operations<br>Deference to expertise  |
| 13. Obtains or generates relevant, quality information<br>14. Communicates internally<br>15. Communicates externally  | Preoccupation with failure<br>Commitment to resilience<br>Reluctance to simplify   |
| <ol> <li>Selects, develops and performs ongoing and separate evaluations</li> <li>Evaluates and communicates deficiencies</li> </ol>  | Preoccupation with failure<br>Deference to expertise<br>Commitment to resilience   |
|   | <ul> <li>exercises oversight responsibility</li> <li>Management, with board oversight, establishes structure, authority<br/>and responsibility</li> <li>The organization demonstrates commitment to competence</li> <li>The organization establishes and enforces accountability</li> <li>Specifies objectives with sufficient clarity to enable identification of risks</li> <li>Identifies/assesses risk</li> <li>Considers the potential for fraud in assessing risk</li> <li>Identifies/assesses significant change that could impact system of<br/>internal control</li> <li>Selects and develops control activities</li> <li>Selects and develops general controls over technology</li> <li>Deploys through policies and procedures</li> <li>Obtains or generates relevant, quality information</li> <li>Communicates internally</li> <li>Scommunicates externally</li> <li>Selects, develops and performs ongoing and separate evaluations</li> </ul> |

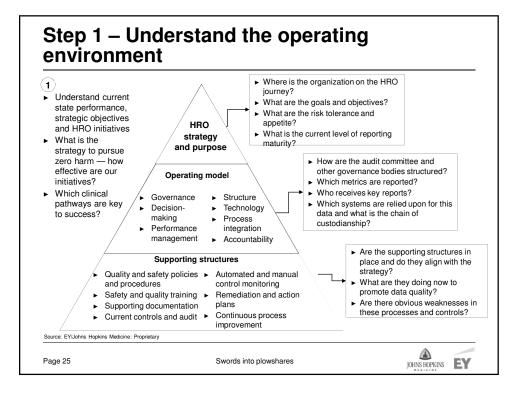


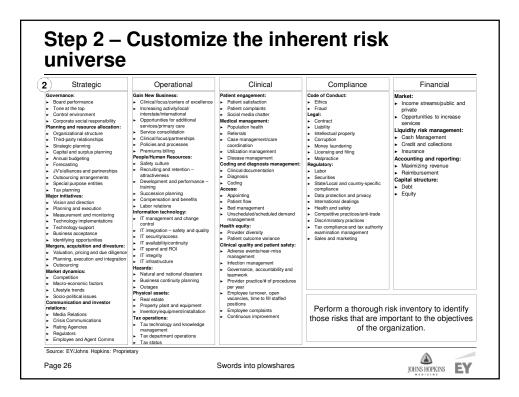
|   | e model confirms there is segregation b<br>rrsight and independent assurance on th<br>ocesses.  |  |
|---|---|--|
|   | Sets the strategy and risk appetite of the  | organization   |
| First line<br>risk ownership  | Second line<br>oversight and monitoring   | Third line<br>independent assurance and validatio  |
| Risk taking business ur   | its Compliance and risk functions   | s Internal audit function  |
| <ul> <li>Are responsible for owning a managing risks in the busine</li> <li>Develop and implement th strategy</li> <li>Measure business performance</li> <li>Implement internal contror risk management framewith</li> <li>Confirm that the business managed within the agree appetite</li> </ul> | <ul> <li>management of risks by the business:</li> <li>Design and deploy the overall risk management framework across the organization</li> <li>Monitor adherence of the business to risk framework policies and procedures</li> <li>Support and aballance the</li> </ul> | <ul> <li>Independently assess and<br/>report on effectiveness of<br/>design and operation of the risk<br/>management framework</li> <li>Carry out testing of key<br/>controls</li> <li>Review activities performed by<br/>first and second LOD so that<br/>they are appropriately meeting</li> </ul> |











## Step 3 – Identify areas of significant clinical quality and safety risk — sample risk areas and categorize across a threat matrix

3 Review the risk assessment to review and validate supporting and relevant data. Assess the key risk indicators and variance to compile a qualitative and quantitative assessment of the key risk areas.

Safety and Quality

in repeat issues

handover and communication

reporting

errors

Governance

#### Clinical

- Variations in service delivery related to demographic
   Incident database incomplete, inaccurate potential for
- underreporting of eventsEMR incomplete, incorrect: misdiagnosis or incorrect
- treatment Errors in receipt of medications
- Delayed identification of service quality errors i.e.,
- undetected shifts in mortality/morbidity
- Systems disparate: linkages are unstable
- Data entry predominately manual and by low-skilled teams
- Lack of clarity concerning the underlying analytics
- ► Insufficient cybersecurity measures potential for safety Workforce
- and security breaches
   Underdeveloped business continuity planning for system shutdown
   Signature

#### Compliance

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- Risk of non-compliance with mandatory reporting resulting from poor data control
- Delayed action in addressing undiscovered issues

EY/Johns Hopkins Medicine Proprietary

### Swords into plowshares

limited predictive value
 Unclear reporting and accountability structures in key areas

► Errors to patient laboratory data — slow/inaccurate

Primary care referral database out of date affecting patient

► Incident reporting lag — three month turnaround; May result

Medical record process manual — increased opportunity for

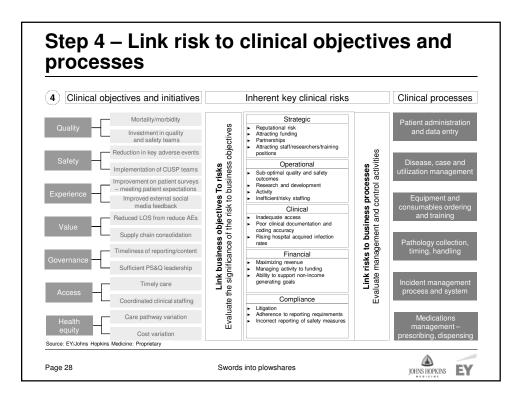
▶ Performance reporting is static: consolidate three month -

- Rostering occurs separately from planned activity
- Significant churn in the administrative department resulting in operational disruption

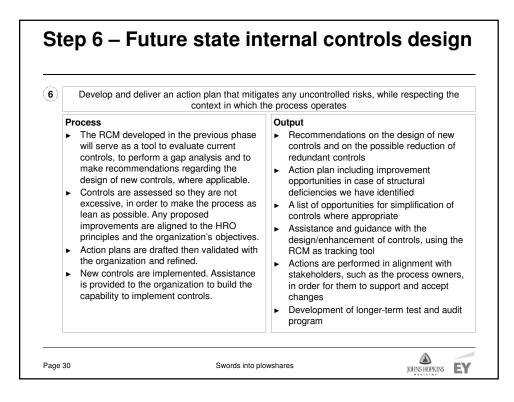
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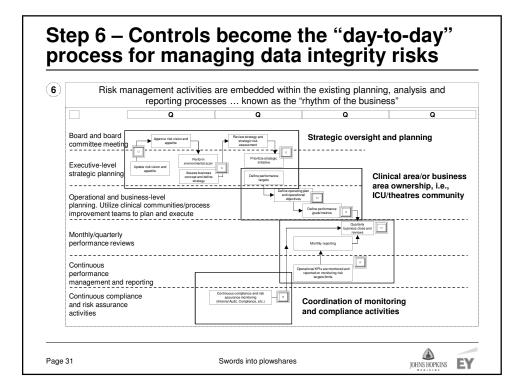
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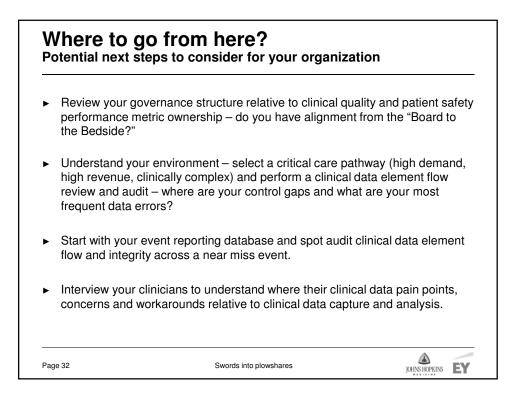
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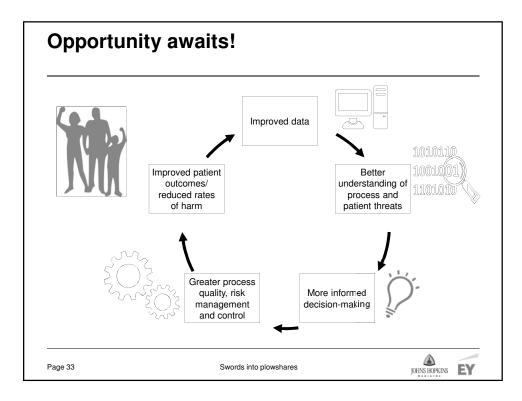


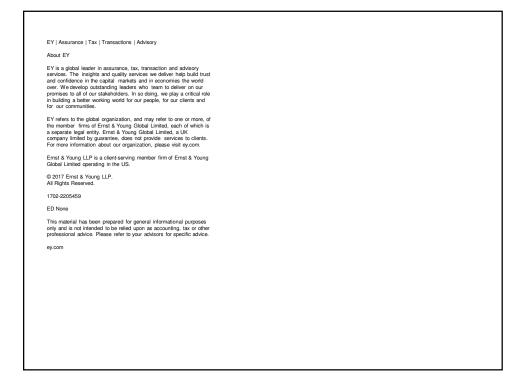
#### Step 5 – Assessment of internal controls design (5) Clinical process and control documentation Process Conduct risk-based process understanding interviews ► and walk-throughs for in-scope clinical processes Document process flows to Document clinical process risks, controls, gaps and ► visualize a process entirely. relevant control information (owner, frequency, Aim to fully understand the evidence, IT systems, etc.) in narratives, flowcharts process and pinpoint where and the Risk and Control Matrix (RCM) Develop remediation plans to address control gaps risks, controls and gaps ► and other process and control design exist. recommendations This also enables greater Output coordination with the Process narratives and/or flowcharts ► process owners when Risk and Control Matrix - i.e., controls to be • validating understanding, implemented to address the identified risks Summary report of finding themes and and agreement. ► recommendations, including organizational maturity in managing risk Page 29 Swords into plowshares EY JOHNS HOPKINS



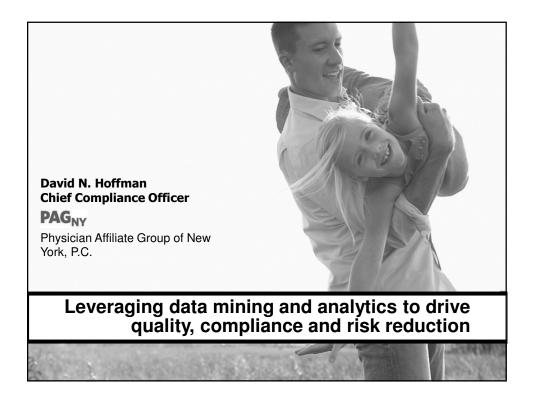


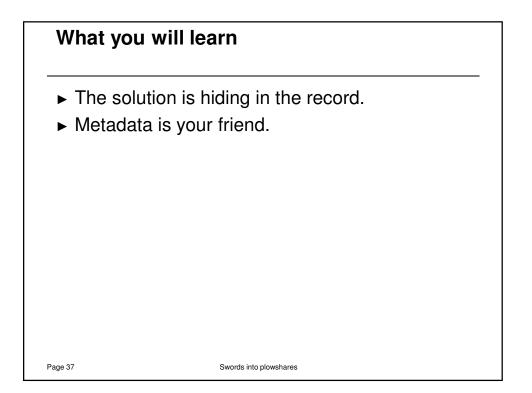


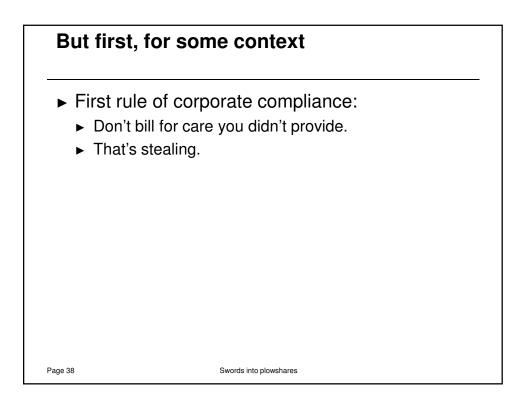


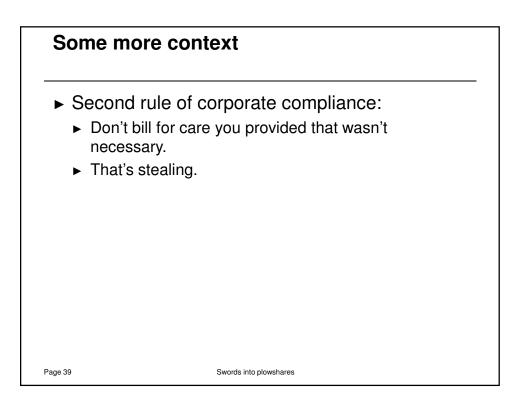


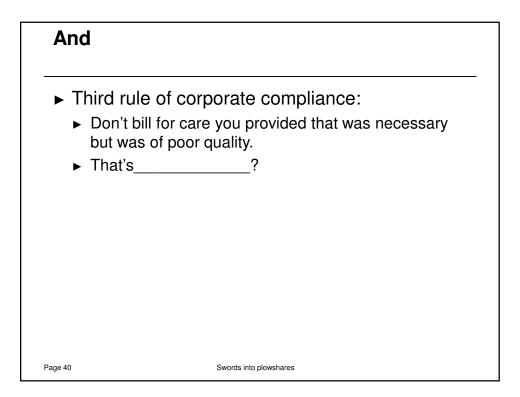


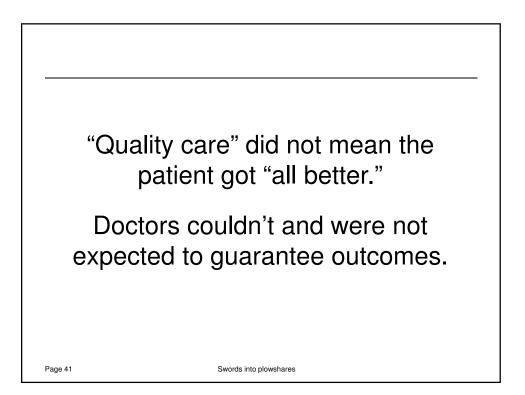


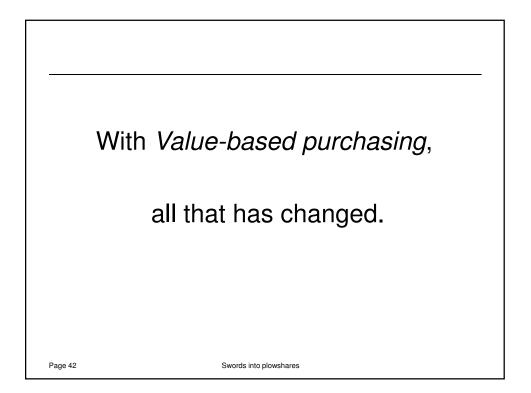


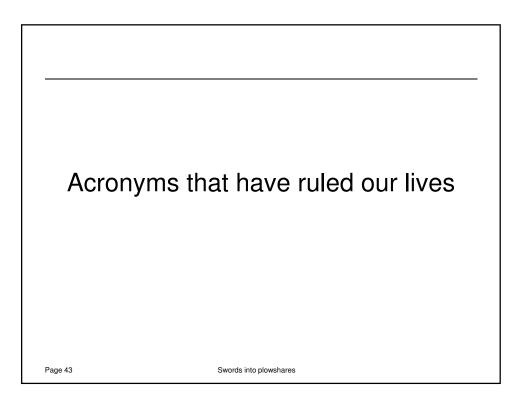


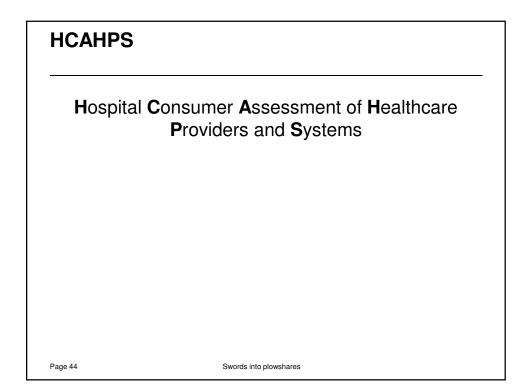


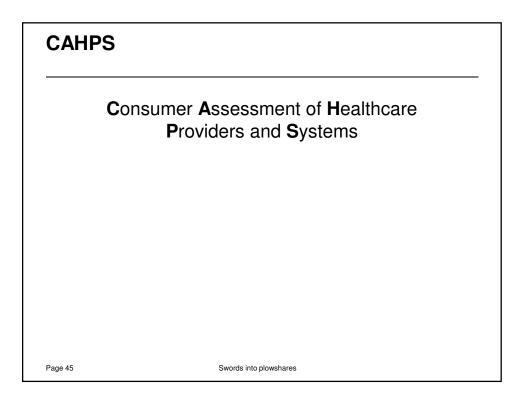


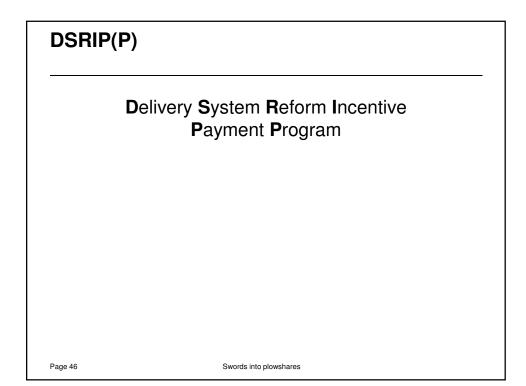


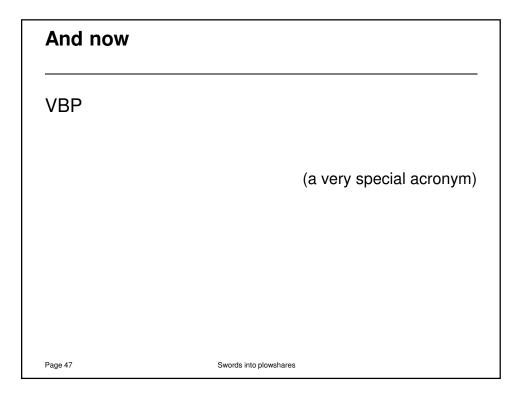


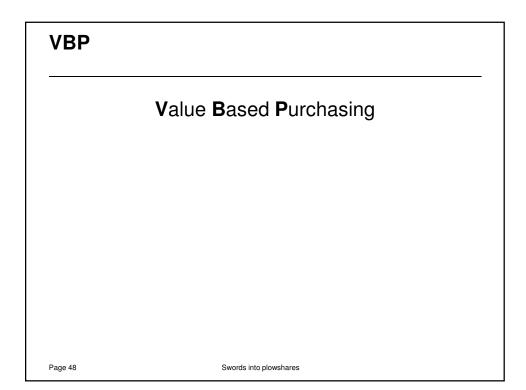


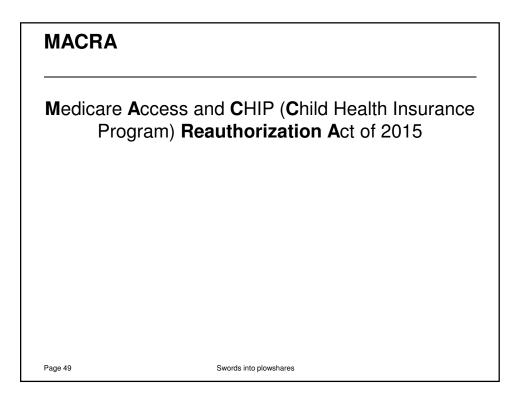


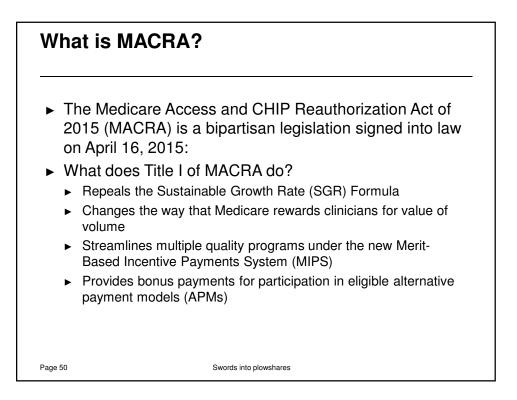


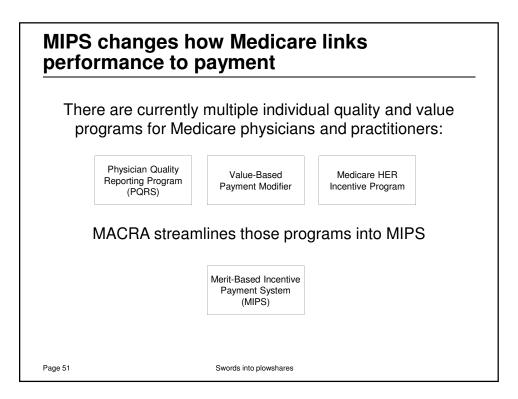


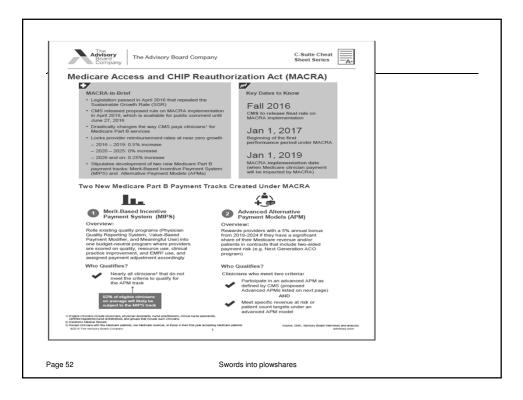


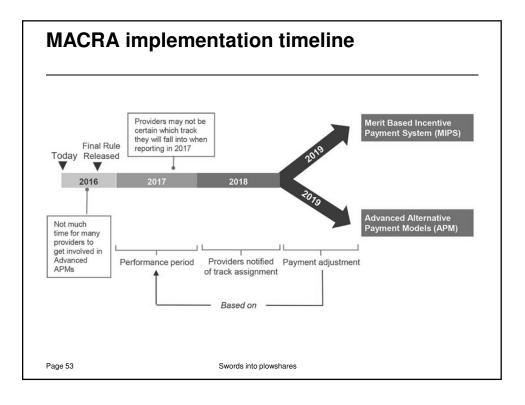


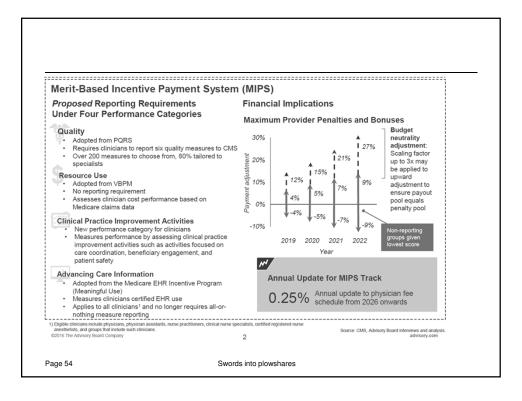






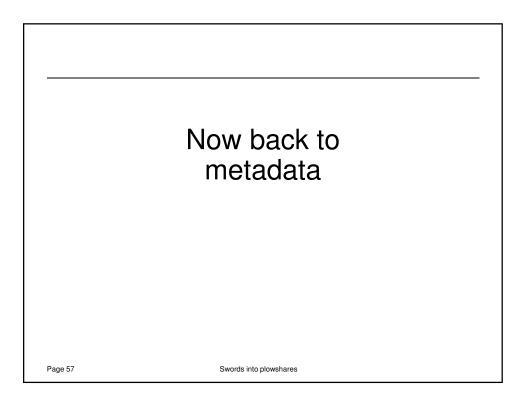


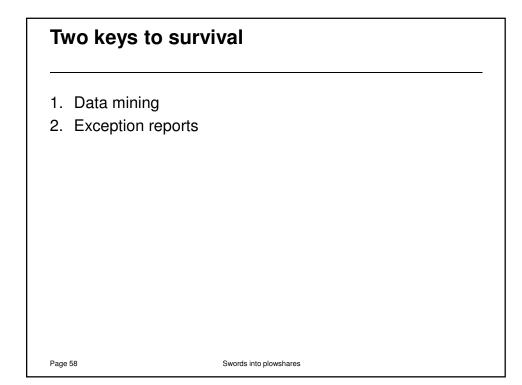


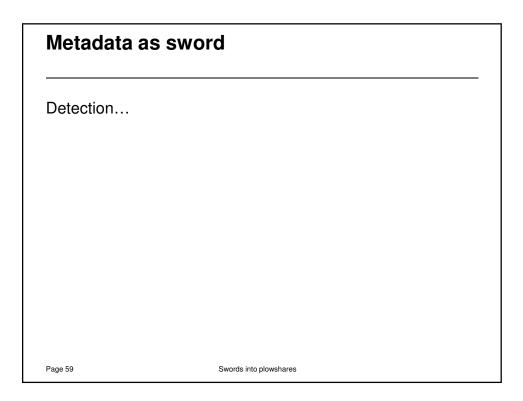


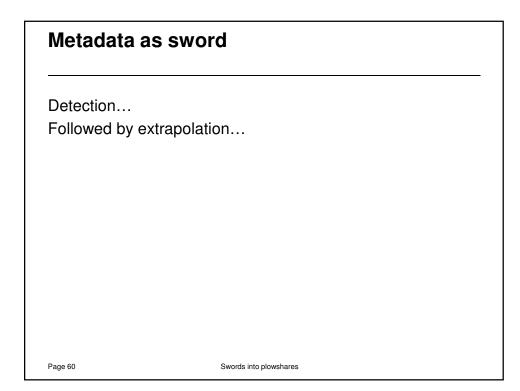
| AMA ST                         | PRACTICE SUPPOR<br>HOME   MOD   | RT RESOURCE LIBRARY CONTACT US SHARE +<br>ULES + LIVE EVENTS HOW IT WORKS |
|--------------------------------|---|---|
| CATEGORIES                     |   |   |
| 🕑 All (43)                     | Listening with empathy<br>Save time, communicate more effect<br>and provider satisfaction                                 | •   |
| Patient Care (13)              |   |   |
| Workflow and<br>Process (12)   |   |   |
| Leading Change (6)             | Preventing Physician D<br>Suicide   | istress and CME AVAILABLE   |
| Professional<br>Well-Being (4) | Recognize and respond to physician of   | distress and suicidal behavior  |
| Technology and<br>Finance (8)  | Quality Reporting and th<br>Qualified Clinical Data H<br>in maximizing your suc<br>Ensure your practice's quality reporti |   |

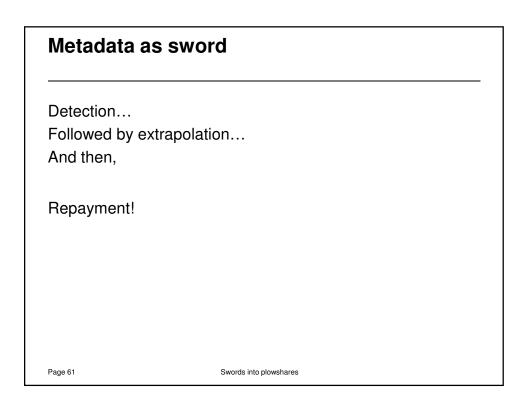
| AMA     | Payment Model<br>Evaluator                           |
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| Page 56 | Swords into plowshares                               |

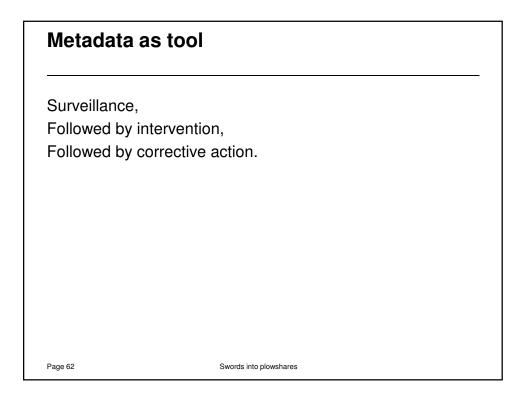


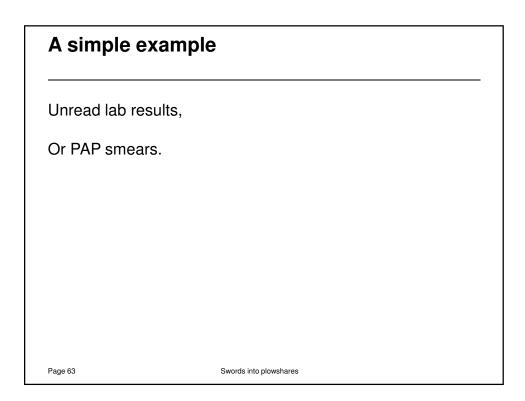








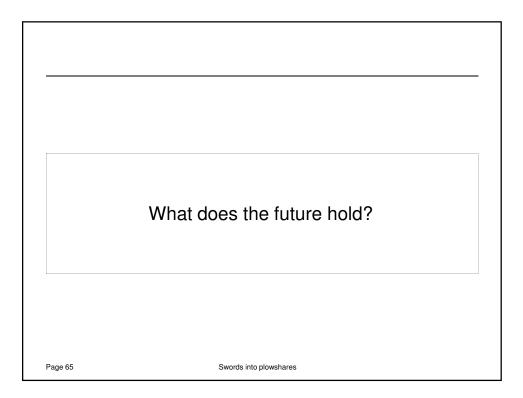




| A not-so-simple example |  |  |  |
|-------------------------|--|--|--|
| DVT prophylaxis         |  |  |  |
|                         |  |  |  |
|                         |  |  |  |
|                         |  |  |  |
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|                         |  |  |  |

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Swords into plowshares



| Electronic medical records (EMR) |                        |  |  |
|----------------------------------|------------------------|--|--|
| Friend or Foe?                   |                        |  |  |
|                                  |                        |  |  |
|                                  |                        |  |  |
|                                  |                        |  |  |
|                                  |                        |  |  |
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