

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 Pronovost	1:35 p.m. – 2:20 p.m.
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	Aloha McBride/ Marc Schulman/ 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.
- ${\bf Patient\ safety\ indicators\ are\ frequently\ inaccurate-missing\ many\ harms}$ 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 clinicalcare. 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

# MEDICAL ERRORS NATION'S THIRD BIGGEST KILLER IN 2013 Heart disease 611,000 Cancer 585,000 Medical error 251,000 COPD 149,000 Suicide **41,000** Firearm 34,000 Motor vehicle 34,000 USATODAY

## Why do errors occur?

Commonly, errors are caused by systemic problems, including a lack of integrated process, 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

Page 4

Swords into plowshares

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# 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
- Increases the risk of beneficiaries not having access to covered services
- Can result in billing, payment and performance inaccuracies
- Produces inaccurate stakeholder reporting



# How does good data become bad information?

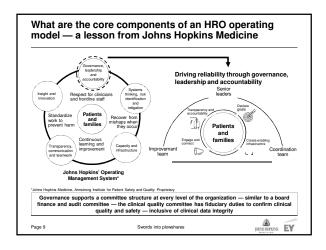
- ► Methods by which it is captured and stored — manual, incomplete, etc.
- Data and system architecture lacks interoperability, resulting in blind spots.
- Cultural roadblocks across the health system prevent collaboration.
- ► Integrity of systems is not adequately protected, allowing for vulnerabilities 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.



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# 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 oftentimes, potentially catastrophic conditions.\* 1. Sensitivity to operations 2. Deference to expertise 3. Reluctance to simplify 4. Preoccupation with failure 5. Commitment to resilience Page 7 Swords into plowshares

# 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 WANO SACArcopace ASSOCIACE M ----**PRINCIPLES** 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. INS EY



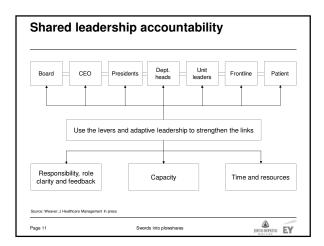
# Johns Hopkins Medicine - governance, leadership and accountability

- ► Board of Trustees (Board) confirms oversight for quality and safety
- Applies the same rigor as applied to
- ▶ 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

Page	10	

Swords into plowshares





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Performance below target for one month or one performance period (ex: one quarter)	Local champions to form performance improvement team     Review data and investigate defects     Identify barriers and implement targeted interventions
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
Performance below target for three months	Department Director/MD champion present to local hospital Quality and Safety Board (trustee chair and President sign Ol plan)     President presents to JHM Quality Safety Board Committee     Al conducts peer-to-peer review

# 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.

Page 14 Swords into plowshares PARS HERN EY

# 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,
- 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?

Swords into plowshares



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 requirements	Patient safety and quality concerns	Competitive market – new business models	Growth of health insurance exchanges	Digital health/access to performance data
			<b>₩</b>	⇧	⇧
		Mantel anna			

		Health care	top issues		
Quality	Health data/accuracy, security and use	CMS compliance	Regulatory adherence	Maximize revenue from activity	Meaningful use
Safety	Clinical innovation/ evidence-based care	Cost management and efficiency	Technology Investments and value	Resource capacity/capability	Health insurance exchanges
,	-				-

Swords into plowshares



To enable high reliability of clinical data, health systems must treat clinical data with the same rigor as financial data



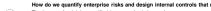
Enterprise Risk Management (ERM)
ERM is a discipline that addresses the full spectrum of an organization's risks, including
challenges and opportunities, and integrates them into an enterprise-wide, strategically
aligned portfolio view. ERM contributes to improved decision-making and performance
management and supports the achievement of an organization's mission, goals and

## Internal Controls Management (ICM)

internal controls wanagement (Lwn)

ICM is a process for promoting achievement of an organization's objectives in operational
effectiveness and efficiency: reliable clinical performance reporting; and complying with laws,
regulations and policies.





How do we quantify enterprise risks and design internal controls that matter?

The impact of a risk is quantified in terms of devisting performance measures and is evaluated by gauging the potential votatility the risk has on strategic goals and related business outcomes, internal controls are designed, monitored and tested against those key clinical processes that drive critical performance and compliance measures.

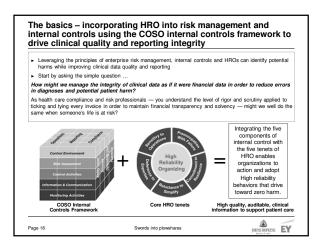
Why are ERM and ICM critical to HROs?

HROs must anticipate risk and mitigate harm in order to achieve mission success. In order to anticipate risk, health systems must have early warning and continuous monitoring systems in place to proactively address potential harms. ERM and ICM provide this capability and prescrib disciplined activities to root out data quality issues and test the reliability of performance and compliance recording measures. compliance reporting measures.



Swords into plowshares

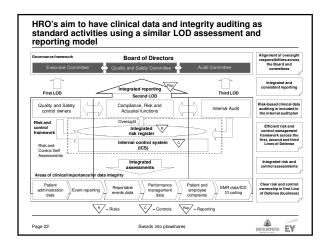




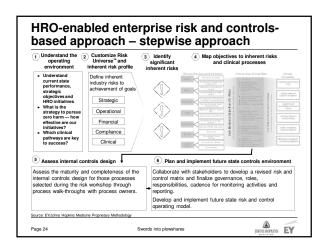
Components of internal control	Principles of internal control	Alignment to high reliabilit tenets
Control environment	Benostrates commitment to integrity and ethical values     Board of Directors demonstrates independence from management and exercises overnight responsibility     Management, with board oversight, establishes structure, authority and responsibility     The organization demonstrates commitment to competence     The organization stabilishes and enforces accountability	Commitment to resilience Preoccupation with failure Deference to expertise Reluctance to simplify Sensitivity to operations
2. Risk assessment	Specifies objectives with sufficient clarity to enable identification of risks     I. Identifies and assesses risk     Considers the potential for fraud in assessing risk     Udentifies/assesses significant change that could impact system of internal control	Preoccupation with failure Sensitivity to operations Reluctance to simplify
3. Control activities	Selects and develops control activities     Selects and develops general controls over technology     Deploys through policies and procedures	Preoccupation with failure Sensitivity to operations Deference to expertise
4. Information and communication	Obtains or generates relevant, quality information     Communicates internally     Communicates externally	Preoccupation with failure Commitment to resilience Reluctance to simplify
5. Monitoring	Selects, develops and performs ongoing and separate evaluations     Evaluates and communicates deficiencies	Preoccupation with failure Deference to expertise Commitment to resilience

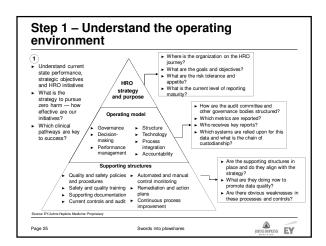
				nder-treated and their nd has not been harmed.
Environment The organization is interested in and has the ability to assimilate	tolerate are clea	Governance nount of risk the organ rly articulated and un to drive allocation of	derstood and are	Owners  Boards are provided with auditable, quality, meaningful data to guide
external measures and market data to guide its performance and actions, e.g., social media and patient ratings.	Plan Uncertainty, clinical variation and complexity are measured and used	Operate Decision-making and trade-offs specifically consider	Measure Independent monitoring of performance and analytics	investment and strategy decisions. They have "Board to Bedside" visibility of patient care outcomes.
Suppliers The organization Inderstands its suppliers, and where the risk to patient safety and quality s within that supply chain. This is used to optimize a tailed supplier and supplies base.	People A culture of Zero Harm, and a focus on patient risk and proven controls is embraced organization-wide.	patient care, quality and safety.  Processes All clinical processes consider the risk on patient outcomes.	to identify uncertainty in outcomes.  Technology identification of clinical risk and management is embedded in the use of technology.	Regulators The organization understand its reporting requirements, and confirms it is providing correct auditable quality safety, quality and performance data in line with compliance requirements.

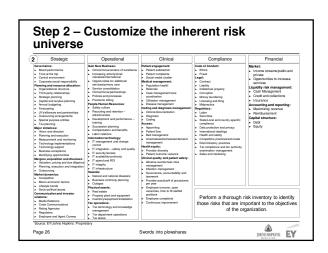
	Board	
	Sets the strategy and risk appetite of the	organization
First line risk ownership	Second line oversight and monitoring	Third line independent assurance and validati
Risk taking business un	its Compliance and risk functions	Internal audit function
Are responsible for owning a managing risks in the busine  • Develop and implement the  strategy • Measure business performance • Implement internal control  risk management framew. • Confirm that the business  managed within the agree  appetite	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 policies and procedures	Provides independent assurance:  Independently assess and report on effectiveness of design and operation of the rist management framework.  Carry out testing of key controls.  Review activities performed by first and second LOD so that they are appropriately meeting their responsibilities.



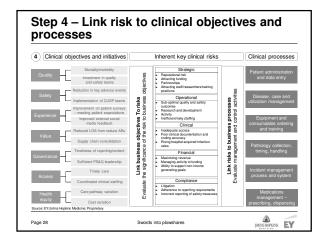


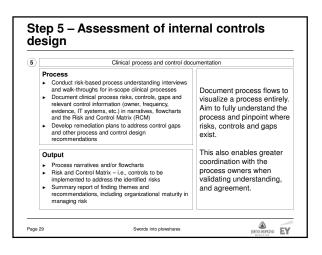






# Step 3 — Identify areas of significant clinical quality and safety risk — sample risk areas and categorize across a threat matrix (3) Review the risk assessment to review and validate supporting and relevant data. Assess the key risk indicators and variance to compile a qualitative and quantitative assessment of the key risk areas. Clinical • Variations is service delivery related to demographic incorrect materials in incorrect insidiagnosis or incorrect teamment • EMR incomplete, incorrect — periodial for incorrect meanment • Emror incorrect or indications • Incorrect or incorrect meanment • Errors in confident above account of a dealercting patient hardward and communication on incident reporting lag—three morth unaround; May result in the control of the dealer reporting in a dealercting patient hardward and communication on incident reporting lag—three morth unaround; May result in the control of the dealer reporting in a discount process manual — increased opportunity for energy in the process of the control of the dealer reporting in a discount static consolidate three morth—initial delivery in the security periodinated by a discount of the control of the dealer reporting in a discountation of the process manual — increased opportunity for energy in the security process. • Performance reporting is static consolidate three morth—initial deferrable value. • Proformance reporting is a static consolidate three morth—initial deferrable value. • Proformance reporting is a district consolidate three morth—initial predictive value. • Proformance reporting is a district consolidate three morth—initial predictive value. • Proformance reporting is a district consolidate three morth—initial predictive value. • Proformance reporting is a district consolidate three morth—initial predictive value. • Proformance reporting is a district consolidate three morth—initial predictive value. • Proformance reporting is a district consolidate three morth—initial predictive value. • Proformance reporting is a distri

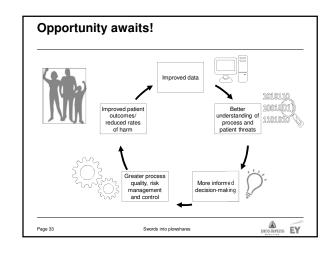




# 6 Develop and deliver an action plan that mitigates any uncontrolled risks, while respecting the context in which the process operates Process • The RCM developed in the previous phase will serve as a tool to evaluate current controls, to perform a gap analysis and to make recommendations regarding 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 HRO principles and the organization so 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. \*\*Swords into plowehares\*\* \*\*Swords into plowehares\*\* Development of longer-term test and audit program

# Step 6 — Controls become the "day-to-day" process for managing data integrity risks (a) Risk management activities are embedded within the existing planning, analysis and reporting processes ... known as the "rhythm of the business" and board processes ... known as the "rhythm of the business are strategic planning. Utilized incide communities/process planning and compliance activities. Page 31 Swords into plowshares

	o go from here? xt steps to consider for your organization	on
	ur governance structure relative to clinical qualice metric ownership – do you have alignment fre?"	
high reven	d your environment – select a critical care path ue, clinically complex) and perform a clinical da l audit – where are your control gaps and what a tata errors?	ita element flow
	our event reporting database and spot audit cli tegrity across a near miss event.	nical data element
	our clinicians to understand where their clinical and workarounds relative to clinical data capture	
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David N. Hoffman Chief Compliance Officer PAGNY Physician Affiliate Group of New York, P.C.	
Leveraging data min quality, com	ning and analytics to drive pliance and risk reduction
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- ▶ The solution is hiding in the record.
- ► Metadata is your friend.

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Swords into plowshares

# But first, for some context

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

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Swords into plowshares

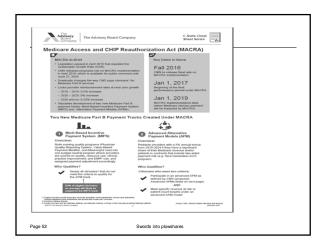
Some more context	
<ul> <li>Second rule of corporate compliance:</li> <li>Don't bill for care you provided that wasn't necessary.</li> </ul>	
➤ That's stealing.	
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And	
<ul> <li>► Third rule of corporate compliance:</li> <li>► Don't bill for care you provided that was necessary but was of poor quality.</li> <li>► That's</li> </ul>	
F mats:	
Page 40 Swords into plowshares	
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"Quality care" did not moan the	
"Quality care" did not mean the patient got "all better."	
Doctors couldn't and were not	
expected to guarantee outcomes.	-
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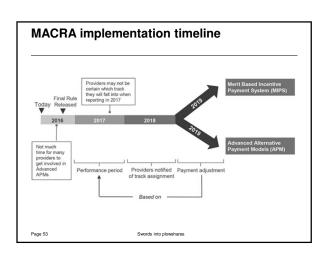
With Value-based purchasing,	
all that has changed.	
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Acronyms that have ruled our lives	
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HCAHPS	1
Hospital Consumer Assessment of Healthcare Providers and Systems	
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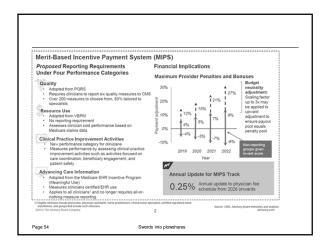
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Consumer Assessment of Healthcare		
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DSRIP(P)		
Delivery System Reform Incentive Payment Program		
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VBP	
Value Based Purchasing	
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MACRA	7
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Medicare Access and CHIP (Child Health Insurance Program) Reauthorization Act of 2015	
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Page 49 Swords into plowshares	
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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?	
<ul> <li>Repeals the Sustainable Growth Rate (SGR) Formula</li> </ul>	
<ul> <li>Changes the way that Medicare rewards clinicians for value of volume</li> </ul>	
<ul> <li>Streamlines multiple quality programs under the new Merit- Based Incentive Payments System (MIPS)</li> </ul>	
<ul> <li>Provides bonus payments for participation in eligible alternative</li> </ul>	
payment models (APMs)	
	_
Page 50 Swords into plowshares	

# 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 (PORS) Value-Based Payment Modifier Medicare HER Incentive Program MACRA streamlines those programs into MIPS Merit-Based Incentive Payment System (MIPS) Swords into plowethaires











Now back to metadata	
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Two keys to survival	
Data mining     Exception reports	
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Metadata as sword	
Detection	
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Metadata as sword	]
Detection	
Followed by extrapolation	
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Metadata as sword	
Detection Followed by extrapolation	
And then,	
Repayment!	
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Metadata as tool	1
Surveillance, Followed by intervention, Followed by corrective action.	
Pollowed by corrective action.	
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	<b>-</b>
A simple example	
Unread lab results,	
Or PAP smears.	
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A mad an aimmle assessed	٦
A not-so-simple example	
DVT prophylaxis	
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What does the future hold?	
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Electronic medical records (EMR)	
Friend or Foe?	
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Electronic medical records (EMR)	
<ul><li>Friend or Foe?</li><li>It doesn't matter.</li></ul>	
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EMR as a term paper	]
► Citation, not Plagiarism.	
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EMR as a term paper	
► "Copy and Paste"	
▶ Is a dangerous tool we actually don't need	
Page 69 Swords into plowehares	
A wonderful challenge	]
Changing a flat tire on a bus	
while the bus is moving.	
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Thank you!	1
► (Please complete your evaluation)	
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