Revisiting Information Governance

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Revisiting Information Governance

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In 2017, the International Federation of Health Information Management Associations (IFHIMA) published a whitepaper with case studies - Advancing Health Information Governance: A Global Imperative. The paper offered details regarding the pressing need for information governance (IG) with consideration for transformation in the delivery of health services brought on by the digitization of data, new regulations and more.

Then in 2020 COVID-19 shook the world, especially the world of healthcare. The disease spread so quickly that even the experts seemed to be at a loss and overwhelmed. This crisis forced the use of technologies that were formerly on the fringe. Healthcare at a distance, telehealth, became routine. Reliance on artificial intelligence and consumer driven tools, i.e., smartphone and apps proliferated in professional and personal settings. At many institutions, health information management professionals (HIMs) moved to remote settings to continue their work while taking on new roles and responsibilities. These conditions and the continuation of transformation of health service in nations around the world, have made IG even more challenging and important. That’s why IFHIMA is revisiting this important and timely topic.

Information is a strategic asset, much like physical assets – buildings, equipment, and technology – and is the essential tool for transformation.

Local and national health services, irrespective of the maturity of their systems and data use, are redesigning care delivery and public and private health services by embracing 21st century solutions. Redesign is supporting the shift from illness-based care to wellness. These priorities involve greater engagement and inclusion by patients, families, and communities and have refined approaches to information access, information sharing, funding, and reimbursement. Layered on these trends is the evolving information demands resulting from the COVID-19 pandemic.

Information is a strategic asset, much like physical assets – buildings, equipment, and technology – and is the essential tool for transformation. “Organizations that encourage staff to think about information and data as a strategic asset can extract more value from their systems.” Systems mean both technology and operational processes. Every healthcare organization needs to optimize its systems – in other words, optimize its information and data created or used from its various systems.

In all circumstances, information must be trustworthy to meet the demands and strategic transformational goals of healthcare organizations, their consumers/patients, and governmental and non-governmental agencies.

Health providers continue to transition from paper-based to digital health systems. Developing nations are especially focusing on this transition through an initial launch of digital systems or when they are using a hybrid approach to meet their goals. The hybrid approach may be a combination of electronic, imaged, and paper records. A myriad of approaches is evident in both mature health environments and developing nations. These systems support personal wellness and care; care delivery systems; local, national, and global public health disease prevention, identification, and tracking; and information policy development and improvement initiatives. The COVID-19 pandemic further demonstrates the need to create, link, and share data supporting individual, national and global health.

Digital health information requires focused management and governance – stewardship – to address new challenges and risks. Thus, stewardship through governance requires data quality and integrity, data access, reporting, data integration, confidentiality and security, patient and provider identity management and lifecycle management. (Stewardship is explored in IFHIMA’s 2020 whitepaper, Privacy of Health Information, an IFHIMA Global Perspective.)

Regardless of where organizations or nations reside on the technology adoption and data standardization spectrum, it is never too soon for a ministry of health, a health department, a large healthcare enterprise, a small ambulatory...
Information governance (IG) provides the authority mechanism that sets forth principles and policies and approves procedures and technology for how an organization will exercise its stewardship responsibilities.

**The Importance of Information Governance**

The importance and goal of healthcare transformation is well summarized in this statement that describes the role of the World Health Organization (WHO): “To improve equity in health, reduce health risks, promote healthy lifestyles and settings, and respond to the underlying determinants of health.”

The building blocks supporting these goals are health records - records of patients' health status, treatment, and social determinants of health (SDOH); and vital records - birth and death records.

Health care organizations are learning that they need to formalize IG. According to Health IT Analytics, “In a survey released by AHIMA at the 89th Annual Exhibit & Convention, 53 percent of respondents said they have information governance programs in place or recognize the need for one. A scant 14 percent have initiated organization-wide IG programs, but 18 percent have some form of governance activity underway.”

The importance of information in transforming healthcare cannot be overstated. From electronic health records to smart phone apps to patient portals to telehealth, information is driving healthcare decisions at all levels as never before. For example, the use of telehealth as a viable care delivery and management option has grown exponentially during the COVID-19 pandemic. “During the first quarter of 2020, the number of telehealth visits increased by 50%, compared with the same period in 2019, with a 154% increase in visits noted in Surveillance Week 13 in 2020, compared with the same period in 2019.” With that rapid deployment, often without advance planning or adequate risk assessments, came the challenges of network infrastructure, documentation requirements, data sharing, and privacy and security. In the IFHIMA article, Managing Health Information Privacy During the COVID-19 Pandemic: Considerations and Perspectives from Around the Globe, released September 24, 2020, we discussed how the COVID-19 pandemic has heightened the need for managing the privacy of information and the urgency for governance around it.

**Data explosion as a driver for IG**

Electronic/digital transformation in healthcare means that the volume of data is growing exponentially. “IDC (International Data Corporation) predicts that our global datasphere – the digital data we create, capture, replicate and consume – will grow from approximately 40 zettabytes of data in 2019 to 175 zettabytes in 2025 (with one zettabyte equaling one trillion gigabytes).” Further, “human and machine-generated data is experiencing an overall 10x faster growth rate than traditional business data, and machine data is increasing even more rapidly at 50x the growth rate.” This growth is due to the growing number of devices, sensors, and the increasing use of artificial intelligence (AI) and machine learning (ML). As cloud computing becomes mainstream, data lakes and data warehouses are being created to accommodate the data explosion. Precision medicine in some countries is defining exact treatments and drugs through intelligence derived from genomics and the research and analysis of vast stores of structured and unstructured data. With this uptick in data growth comes the need to harness it for its business value, and, likewise, to determine what is redundant, obsolete, or trivial (ROT) data, and ultimately, information.
Data Governance: a key IG component

While healthcare may be lagging other industries in establishing formalized IG programs, some organizations have elected to focus first on data governance (DG). DG is an essential dimension of a comprehensive IG program due to the increasing data volume and diverse use. DG is focused on the data used across key applications and processes (i.e., master data and metadata), as well as tools used in managing data (i.e., data dictionaries, data glossaries, data integration and data mapping). DG activities may include addressing patient or provider identifiers, master data and metadata management, data mapping, data dictionaries, and data standardization. DG efforts identify data that is useful and data that is redundant, obsolete, or trivial and work to address the appropriate disposition of ROT data. Creating high quality, trusted data across an organization is the goal of DG and is a critical dimension of IG. Data governance is like information governance in that it requires formalization around its activities. A DG program should report to IG and take strategic direction from the IG program. It is critical that the goals of DG and IG are aligned and support an organization’s strategic objectives.

By contrast, the whole patient record, including narrative content, and the policies that drive its use, retention and privacy are all within the purview of IG. It is reasonable for healthcare organizations to focus first on getting the data right through DG, because error is costly, and trust may be jeopardized. The emergence of electronic health record (EHR) related errors results in data being lost or incorrectly entered, displayed, or transmitted, leading to loss of information integrity. Without solid DG, one cannot have information integrity.

Information Governance as Stewardship

Effective stewardship of health information is an important obligation for all who create, use, or manage information. “Stewardship is an ethic relating to the responsible handling of information; and governance sets forth the ground rules for execution of this responsibility.”

Preserving confidentiality is an indisputable stewardship obligation when the subject of the information is identifiable. This obligation remains true when patient or provider identifiers have been removed from a data set for research and other purposes. (See whitepaper, Privacy of Health Information, an IFHIMA Global Perspective.)

Stewardship Foundations

The Principles of Fair Information Practice (FIPPs) and the Caldicott Principles offer policy makers around the world guidance in crafting stewardship frameworks for governing health and other sensitive information in physical or digital form. Several of the FIPPs principles are highlighted in Figure 1 by the Organization for Economic Co-operation and Development (OECD) that represents the cooperation of 35 member nations. These nations have adapted their own laws covering health information with consideration to local values; they are generally legislative expression of the FIPPs principles.

The Caldicott Principles adopted by UK’s National Health Service (NHS) include eight key principles shown in Figure 2 that are the foundation for stewardship practice and can serve as another important framework in developing an IG program.

---

**Principles of Fair Information Practice (OECD, 1988)**

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection Limitation</td>
<td>Limits the collection of personal data; obtained by lawful and fair means, and where appropriate, with knowledge and consent of subject.</td>
</tr>
<tr>
<td>Data Quality</td>
<td>Data relevant to the purposes for which it is used and be accurate, complete, and kept updated for those purposes.</td>
</tr>
<tr>
<td>Purpose Specification</td>
<td>The purposes specified not later than at the time of data collection, and subsequent use limited to the purposes.</td>
</tr>
<tr>
<td>Use Limitation</td>
<td>Disclosed or made available only for specified purposes except a) with the consent of the data subject, or b) by the authority of law.</td>
</tr>
<tr>
<td>Security Safeguards</td>
<td>Protected by reasonable safeguards against loss or unauthorized access, destruction, use, modification, or disclosure of data.</td>
</tr>
<tr>
<td>Openness and Transparency</td>
<td>A general policy of openness about developments, practices, and policies with respect to personal data.</td>
</tr>
<tr>
<td>Individual Participation</td>
<td>Individuals have right to know who has their data, to obtain a copy within reasonable time in a usable form, and to challenge if request for access is denied.</td>
</tr>
<tr>
<td>Accountability</td>
<td>A data controller should be accountable for complying with measures, which give effect to the principles stated above.</td>
</tr>
</tbody>
</table>

*Figure 1*
### Caldicott Principles, 2020 Update

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justify the purpose(s)</td>
<td>Every single proposed use or transfer of patient identifiable information within or from an organization should be clearly defined and scrutinized, with continuing uses regularly reviewed, by an appropriate guardian.</td>
</tr>
<tr>
<td>Don't use patient identifiable information unless it is necessary</td>
<td>Patient identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).</td>
</tr>
<tr>
<td>Use the minimum necessary patient-identifiable information</td>
<td>Where use of patient identifiable information is essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.</td>
</tr>
<tr>
<td>Access to patient identifiable information should be on a strict need-to-know basis</td>
<td>Only those individuals who need access to patient identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.</td>
</tr>
<tr>
<td>Everyone with access to patient identifiable information should be aware of their responsibilities</td>
<td>Action should be taken to ensure that those handling patient identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.</td>
</tr>
<tr>
<td>Understand and comply with the law</td>
<td>Lead the evaluation of data quality with focus on ICD-11 coded data and develop appropriate queries to resolve discrepancies.</td>
</tr>
</tbody>
</table>

The principles are fully operationalized through roles and functions outlined in the 2020 Caldicott Guardians Manual.13

With stewardship foundations in place, IG can function to establish principles and policies, to assess and measure how well they are working,
and to identify when they need to be improved upon based on new learning or new advances. Illustrating the accepted global importance of IG, Gartner defines IG as the specification of decision rights and an accountability framework to ensure appropriate behavior in the valuation, creation, storage, use, archiving and deletion of information. It includes the processes, roles and policies, standards and metrics that ensure the effective and efficient use of information in enabling an organization to achieve its goals.  

Governance as Ground Rules and Guardrails

IG provides the authority mechanism that sets forth principles and policies and approves procedures and technology for how an organization will exercise its stewardship responsibilities. Healthcare organizations set the scope of governance by determining the types of information that will be governed and who has the authority to set policies and oversee their execution. Health information management (HIM) plays a key role in IG by participating in policy formulation and/or subsequent execution.

From a practical perspective, IG considers the lifecycle of the information from its creation and integration through archiving or destruction. Illustrating the importance and practical application, the Canadian Health Information Management Association (CHIMA) has a special workgroup focused on IG and managing the lifecycle of data. IG considers the range of functions including:

- Information design and collection
- Records and content management
- Access
- Quality and integrity of information.

IG requires a multi-stakeholder approach supported by senior leaders and anchored in a formal framework.

IG Framework to Ensure Success

There is no one-size-fits-all framework. The framework should be established to fit within the culture of the organization. However, the key components of a framework that should be considered are executive sponsorship, strategic committee structure with key stakeholder membership and designated leadership, program charter, organization-wide education plan, policies and procedures, and metrics and accountabilities. A key requirement for a successful IG program is the formalized infrastructure around it. A formalized framework ensures that:

- The right stakeholders are involved;
- There is a reporting and support hierarchy;
- There are documented goals that are aligned with the organization’s strategic plan; and
- Metrics are in place to show results of the program and its activities.

Lastly, an organization must create a culture that supports a multi-disciplinary approach to establishing information policy and managing information as a key asset.

IG and Health Information Management Practice

Health Information Management (HIM), a nearly century old profession, has its roots in monitoring and improving the content of the health record. HIM focuses on managing the lifecycle of the record, particularly its protection, storage, retrieval, and disposition. Information curation is an important HIM skill with curation defined as “the act of individuals chartered with the responsibility to find, contextualize, and organize information, providing a reliable context and architecture for the content they discover and organize.” The ability to preserve information availability, sustain its credibility, apply the appropriate compliance, and uphold its integrity are all vital and integral HIM skills.
The changing landscape of health information capture and distribution channels is providing new opportunities in the healthcare ecosystem to maximize information curation and improve information value. The HIM profession faces many challenges in managing the quality and integrity, lifecycle management and confidentiality and security of digital information. While grounded in traditional practices, the scope, tools, and complexities of HIM practice in a digital health environment require new skills, competencies, and changes in how HIM services are staffed and organized. HIM professionals are recognized as well-established resources for clinical recordkeeping with aptitudes that continue to be sharpened, expanded, and called upon to institute and execute IG. Their critical knowledge and skills can be shared across the entire organization in managing all types of information – clinical, financial, human resources, contractual, legal, and other business information. HIM professionals possess the requisite information management knowledge and skills to positively impact the management of information across the entire healthcare setting.

To realize the full value of digital information in transforming healthcare, HIM professionals worldwide must engage in and lead the charge to improve information. HIM professionals must:

• Lead efforts to advance IG and information management practices,
• Ensure governance policies and best practices are applied, and
• Ensure all types of critical information assets are included as the information lifecycle is rolled out.

### Trigger Events

Perhaps the most difficult part of developing and executing an IG program is finding the trigger event that catapults IG to the forefront. Thus, it’s critical to identify current day triggers and build the IG program around those, using them to align with the organization’s strategic goals. The ability to quickly address current day triggers in an expeditious and formalized way will prove the worth of an IG program.

Clearly the COVID-19 pandemic should be seen a trigger. The need to move quickly in times of uncertainty is paramount.

Technology adoption and implementation such as a new electronic record, a data lake, a data warehouse, or using artificial intelligence or machine learning might also be seen as trigger events.

An IG program that is built with stewardship to deliver accurate health information will enable health care organizations to respond in both ordinary and challenging times.
one other important lesson. Advancing IG requires a keen awareness of what is happening throughout the organization.

It’s Time to Start

Information Governance is critical to ensuring the trustworthiness of a healthcare organization’s information for patient care and other business needs. Health information management has traditionally demonstrated excellence through cost effective, consistent practices carried out by trained HIM professionals. The time is now to ensure that your organization has an IG program to meet both operational and strategic priorities. But, where to start? Below are recommended actions to move governance forward:

- Learn as much as possible about information governance and data governance concepts and practices in healthcare. This white paper is an excellent start.
- Network with HIM peers to discuss best practices, top priorities, and lessons learned.
- Share your IG and DG knowledge and expertise with senior leaders and peers,
- Demonstrate how governance practices can reduce costs, risks, and can increase compliance.
- Evaluate how your organization manages its information and data. Is it managed in individual departments, business units, and/or entities? Is it managed with a narrow scope in mind? Determine if governance practices are in place, even if in an immature stage.
- Bring forth ideas for where your organization can begin in evolving current or immature practices, to mature, optimized procedures and systems. Look at current processes around areas such as record retention, storage, and destruction, seeking opportunities to improve processes and reduce costs and risks. Further, identify areas of inefficiency – areas where there is redundancy and rework.
- Volunteer to lead the charge! HIM professionals are fully equipped to be the expert and take the lead role.

Conclusion

Healthcare always requires trusted information and with the many factors impacting healthcare transformation – from transitioning from illness-based care to wellness care, advances in the delivery of healthcare, the digitization of health records, the exponential growth of data, to the proper sharing of information for the improvement of health on a global scale – information governance is needed now more than ever.

These factors, along with a crisis, such as a global pandemic, are driving the need to accelerate the adoption of an IG framework. One that begins with a commitment from diverse stakeholders and disciplines across a healthcare organization.

HIM professionals, are natural stewards of health information. They have an important contribution to make in the development and execution of an IG framework. They possess the requisite knowledge and skills in management of information across the entire healthcare setting.

Through this whitepaper and the other topics and articles cited within, IFHIMA encourages the practice of information governance to realize its vision of “a healthy world enabled by quality health information.”
References and Endnotes

1. Advancing Health Information Governance: A Global Imperative, IFHIMA October 2017  

2. Privacy of Health Information, an IFHIMA Global Perspective, IFHIMA November 2019, updated September 2020  

3. Managing Health Information Privacy During the COVID-19 Pandemic: Considerations and Perspectives from Around the Globe, IFHIMA September 2020  


   http://www.who.int/healthpromotion/about/goals/en/

6. Health IT Analytics, xtelligent HEALTHCARE MEDIA, Information Governance Gaining Ground in Healthcare Organizations, Jennifer Bresnick, October 12, 2017,  
   Information Governance Gaining Ground in Healthcare Organizations (healthitanalytics.com)


9. The Exponential Growth of Data. The Exponential Growth of Data (insidebigdata.com)

10. Impact of Electronic Health Record Systems on Information Integrity: Quality and Safety Implications:  
    https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797550/


12. OECDprivacy.org, is © Ben Gerber 2009, 2010 and is licensed under a Creative Commons Attribution 3.0 Unported License.  
    http://oecdprivacy.org/

13. Justice and Laws Website, Canada, date modified: 2021-08-06  
    http://laws-lois.justice.gc.ca/eng/acts/P-21/index.html

14. Eur-Lex, Access to European Union Law, April 27, 2016,  

15. Health Insurance Portability and Accountability Act of 1996, U.S. Dept. of HHS,  

    TheEightCaldicottPrinciples — The UK Caldicott Guardian Council (ukcgc.uk)


18. Top 5 Librarian Skills: #1 Information Curation”  
    LiBSource, an LAC Company.  
    https://libsource.com/top-5-librarian-skills-information-curation/, accessed 7/21/17

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Information Governance Assessment Helps Grande Ronde Hospital and Clinics Develop an IG Roadmap

Debi Primeau, MA, RHIA, FAHIMA
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Summary/Introduction

In the spring of 2020, the Grande Ronde Hospital and Clinics (GRH) Data Governance Committee held its first meeting to begin its development of a data governance program. The Committee members quickly realized that they needed some help getting started. Although the GRH stakeholders valued information, they soon realized that developing an Information Governance (IG) culture and aligning their IG initiatives with their strategic goals was an important, yet daunting project. Members determined the need for some structure, support and guidance to develop an IG Road Map, but didn’t know where to begin. Although initially the IG assessment was scheduled to be onsite, with the COVID pandemic unfolding, the assessment was determined to be better conducted remotely. The IG assessment was determined to be a critical, strategic project that could not be delayed due to the pandemic.

Background

Grande Ronde Hospitals and Clinics is located in La Grande, Union County, Oregon USA and is a 25-bed Critical Access Hospital with 12 Clinics. Since 1907, Grande Ronde Hospital has led this region in efforts to stabilize and secure rural health care services for the communities it serves, while also working to improve the quality of life for all area residents. The service area has over 25,000 residents.

Grande Ronde is an award winning, State and nationally recognized organization that is not-for-profit and is privately held. Today it employs more than 700 people, all dedicated to providing quality health care services to patients. The Hospital offers a broad range of diagnostic, surgical and therapeutic outpatient services, a Level IV Trauma Emergency Services Department, a Family Birthing Center, Rehabilitation Therapy Services, Home Health and Hospice care. GRH also operates 12 primary and specialty care clinics.

Problem Statement

To launch an Information Governance Program, like many organizations, GRH needed to determine where to begin. Although GRH had begun a data governance program with a formal committee and a charter, it was limited and had only met once. “We’ve always recognized the importance of data and information. However, we did not understand the formal process required to assess what would be necessary to get our IG Program off to a good start,” says Karli Wright, GRH’s Director of Business Services. Wright knew that it would not be easy to raise awareness of Information Governance without a plan. “When we started diving into the world of Information Governance, it was overwhelming,” recalls Wright. “We didn’t know which initiatives to include or where we would get the best results. We also needed to educate ourselves and our leadership team on Information Governance to break down the silos and optimize our effectiveness.”
GRH identified its overall goals as:

- Align information governance with organizational strategies
- Provide trustworthy, reliable information
- Decrease silos of information
- Create a culture that values information governance
- Develop a Roadmap to begin the IG efforts

GRH’s team members determined help was needed and engaged a consulting organization to assist them in achieving their goals. A kick-off meeting was scheduled to provide the necessary education to help the GRH team understand the importance of information governance and what was needed to begin the journey. The next step was an IG Assessment. This Assessment was done virtually due to the COVID-19 pandemic. The IG Assessment consisted of questions about GRH’s current IG situation. The teams discussed each question as the consulting company’s experts provided guidance to reach consensus on the answer to each question. Having these discussions with all the stakeholders enriched the understanding of governance and helped the organization focus its effort. Multiple telephone interviews were scheduled with key stakeholders.

Stakeholder groups

Key stakeholders included the following roles: Chief Information & Security Officer, who served as the Executive Sponsor of GRH’s IG initiative, Chief Medical Informatics Officer, who served as the IG Lead, other stakeholders included Director of Analytics, Director of Informatics within the IS Division, Director Business Services/Revenue Cycle, Compliance & Privacy Officer, Director of Health Information Management.

Findings

Information Governance Assessment

GRH decided to partner with the consulting firm to assess its Information Governance (IG) Program. Initially, the assessment was planned to be held onsite, but with the pandemic impacting travel and face to face meetings, the assessment was conducted remotely. The consulting firm’s interactive online IG Assessment tool has seven sections, each with a comprehensive set of questions. Every question was reviewed, the stakeholders discussed, collaborated and reached consensus on their response. The questions can be answered with a yes, no or partial response with comments entered to summarize the discussion. Each section’s score is generated based on the number of yes, no or partial responses. Upon the completion of the seven sections and a tabulation of all the responses, an overall score was determined for the IG Assessment. The IG Assessment generated an action plan used to develop a road map to help GRH prioritize its initiatives.

Based on the IG Assessment, GRH identified key accomplishments, the importance of information governance in the organization, as well as strong leadership and expertise in privacy, security and analytics. The IG Assessment also identified GRH’s areas of focus including IG structure, policy and procedure management, Legal Health Record best practices and Role Based Access enhancement.
## Sample Questions

<table>
<thead>
<tr>
<th>#</th>
<th>Topic</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Organizational IG</td>
<td>Is the Information Governance (IG) Program a recognized information strategy within the organization?</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Organizational IG</td>
<td>Is there a charter for IG Program activities within the organization?</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Organizational IG</td>
<td>Is there an established IG Committee made up of key stakeholders?</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Organizational IG</td>
<td>Have other IG roles, such as workforce stewards, been identified, defined and expectations established?</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>Organizational IG</td>
<td>Is there a list of IG-relate activities/projects?</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>Organizational IG</td>
<td>Are ongoing IG activities and initiatives as robust as the IG stakeholders would like?</td>
<td>No</td>
</tr>
<tr>
<td>10</td>
<td>Organizational IG</td>
<td>Has the IG Program been undertaken across all business units and departments of the organization?</td>
<td>No</td>
</tr>
</tbody>
</table>

### IG Assessment Results

It showed that there was, however, strong support for the Information Governance Program and some early stages of adoption had already begun. Privacy and security, analytics, and information technology are highlighted as areas that indicated excellent progress being made prior to the assessment.

### Key Observation Examples

#### Privacy and security

- The organization has implemented a set of documented policies and procedures to apply reasonable and appropriate privacy safeguards to records and systems with PHI that comply with the HIPAA Privacy and Breach Rules
- The organization maintains standard locations for all privacy and security related materials and records
- Workforce members have access to policies and procedures relevant to their job role
Analytics

- The organization has a formalized Analytics Team
- The Analytics Team is under the oversight of the Information Management Oversight Committee (IMOC) and aligned with key stakeholders

Information technology

- The organization has an active, documented security governance committee
- The organization’s IT governance includes all stakeholders, including fiscal, clinical and administrative staff in making decisions about technology solutions
- The organization ensures workforce training includes protection from and reporting of malicious software, phishing, hacking, ransomware, insider threats, log-on attempts monitored, reviewed, sanctions and password security
- The organization has implemented a documented policy/procedure that governs the removal of hardware, devices and electronic media that contain electronic protected health information (ePHI) and other sensitive or confidential information.

Areas of Opportunity Examples

- IG Structure and Management
  › Holistic view of Information Governance
  › Review/Develop IG Charter
  › Reporting to the Board of Directors
- Policies and Procedures
  › Inventory
  › Gap Analysis
  › Development
- IG Legal Health Record
  › Identify and document the Designated Record Set (DRS)
  › Identify and document the Legal Health Record (LHR)
  › Vet the DRS and LHR by Legal Counsel
- Privacy and Security
  › Develop role-based access
### Grande Ronde Assessment Score by Section and Response Breakdown

<table>
<thead>
<tr>
<th>Section</th>
<th>Questions</th>
<th>Possible Points</th>
<th>Points Earned</th>
<th>Total</th>
<th>Yes responses</th>
<th>No responses</th>
<th>Partial Responses</th>
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<tr>
<td>A – Organizational Information Governance</td>
<td>17</td>
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<td>36.5</td>
<td>51</td>
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<td>7</td>
<td>4</td>
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<td>B - Managing Organization Information*</td>
<td>30</td>
<td>94</td>
<td>37</td>
<td>39</td>
<td>6</td>
<td>12</td>
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<td>C – IG &amp; Related Policies &amp; Procedures*</td>
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<td>D – IG Legal Health Records*</td>
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<td>1.5</td>
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<td>72</td>
<td>69</td>
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<td>*Focus Areas of Opportunity</td>
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<td>50</td>
<td>48</td>
<td>50</td>
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### Assessment Becomes Key Compliance Step

The IG Assessment provided GRH with a baseline score and specific action items to develop an IG Road Map, focusing on key initiatives for success. Use of the IG Assessment findings and recommendations helped drive GRH to establish policies, manage accountability, protect its information and prioritize its strategic goals. Wright said, “although we were disheartened with our overall initial score, we were reminded by the consulting team that our IG efforts had only just begun. Most importantly, we now had a Road Map to take us to future success. Additionally, we now have the tools and guidance to continue our journey in developing our information Governance Program and we better recognize and value information as an organizational strategic asset.”
**Recommendations/Solution**

**Results Summary**
Based on the findings at GRH and industry leading practices, the following areas were considered as priorities for initial information governance efforts.

- Recognize current organizational IG best practices
- Reduce IG silos through improved communication and collaboration
- Identify opportunities for IG improvement
- Develop an IG Action Plan
- Ensure organization's information will be trustworthy, reliable, compliant, meets regulatory requirements and supports business decisions

**Detailed IG Assessment Findings and Recommendations Examples**

**Organizational IG Structure and Management**
IG Oversight Committee: This group should provide oversight and management of all information decisions across the organization. It should define and approve the IG charter. This group should also review the baseline Assessment results and develop an IG Road Map, prioritizing IG-related projects and initiatives. Having a formalized oversight group should not only drive decisions around information governance, but should also define staff roles, responsibilities, education and accountabilities across the entire organization. Currently, the Information Management Oversight Committee (IMOC) serves loosely in this role. Formalizing and transitioning IMOC to the Information Governance Committee would allow Grande Ronde to have a bi-directional reporting relationship with Data Governance, Analytics, and other designated workgroups report to the IG Committee. The IG Committee should report workgroup goals, metrics, and summaries to the Governing Board and other executive groups within the organization.

Business Process Data Ownership: Another critical requirement for a successful Information Governance Program is to break down barriers caused by compartmentalized data decisions exhibited in the various business units of the organization. This is a cultural change but must be addressed early on to ensure data ownership is appropriately defined and delegated and that the Data Governance Program ultimately drives and oversees data decisions.
Additional Recommendations Examples

Formalize executive IG structure
- Prioritize projects based on the organization’s strategic initiatives with consideration for those that are mission critical, possible quick wins, risk reduction, cost avoidance and return on investment
- Develop role-specific IG education in annual, refresher and department-specific training
- Integrate IG principles and competencies into the culture of the organization through updates on IG-related projects and successes

Legal health record
- Conduct an inventory of all electronic health record systems
- Conduct an inventory of all paper records
- Vet by Legal Counsel

Privacy and security
- Update job descriptions
- Assign access based upon job roles/need to know

Lessons Learned

Tapping into ongoing support
Wright says, “The consulting firm’s services reflect our intention to create a culture of compliance and one that values information. Information Governance is an ongoing priority for us and it requires collaboration, communication, education and accountability,” Wright adds, “The IG Assessment has allowed us to focus our efforts on the right initiatives and stay on track with Information Governance—which in turn supports our organization and our patients.”

Conclusion
GRH learned many things from the remote IG Assessment and its collaborative process. Not only did the online assessment tool provide GRH with the IG assessment results, it also helped develop and prioritize initiatives to ensure its IG Program is on the right track for success. The team benefited by having support from Senior leadership to drive the IG Program and ensure it is aligned with the organization’s strategic goals. While effective IG takes time, GRH achieved good progress in its initial efforts and now has a roadmap to move forward.
How Data Recovery in the Wake of a Major Health Information System Failure Reinforced the Need for Information Governance

Executive Summary/Introduction:

On July 11, 2012, the province of Alberta experienced one of the largest information technology (IT) down times in its history. A transformer failed inside a third-party communication and data centre in Calgary, Alberta, Canada, setting off the sprinkler system and causing damage to several major communication servers. The centre hosted many government, healthcare, and private industry IT infrastructures. As a result, access to and flow of information was compromised and critical communication services were interrupted.

The transformer failure caused widespread Alberta Health Services (AHS) IT network system disruption. The systems were inaccessible for more than 36 hours. Radio stations were off the air, internet and telephone service was down, and many city and provincial government computer networks were affected. The Calgary Zone was the hardest hit with approximately 200 non-functioning applications. Calgary city officials activated a municipal emergency plan and AHS activated their zone emergency operation centre. Using information governance and information management principles, ingenuity, and a spirit of cooperation, staff were able to respond to the situation in a controlled manner and implement recovery procedures once the system was back online.

Background/Statement of Problem:

The province of Alberta (AB) has a single health authority responsible for providing health services to over 3 million Albertans. Alberta Health Services (AHS) has almost 100,000 employees with an additional 16,800 volunteers and 8,020 physicians. Programs and services are offered at over 400 facilities throughout the province, including hospitals, clinics, continuing care facilities, mental health facilities, and community health sites. There are approximately 8,100 acute care beds, 21,700 continuing care beds/spaces, plus equity partnership in 40 primary care networks.

When the sprinkler system was triggered during the July 12th fire, major government and healthcare applications automatically shut down.

The main AB government and AHS information applications or operations affected included:

- AB government Person Directory that issues Unique Lifetime Identifiers (ULIs). ULIs are the primary provincial identifier to link person specific information across the health system including health information exchange (HIE);
- Registry offices including services around person identification and vital statistics (e.g., person identity, birth and death registries);
- Admission, Discharge, and Transfer (ADT) System (i.e., the software application that locates and tracks patients/clients throughout the Calgary Zone);
- Laboratory, Diagnostic Imaging (DI), Pharmacy, Triage, Operating Room Manager, Public Health, Emergency Medical Services (EMS), Regional on Call Application for Physicians, and staff scheduling.

As an organization that embraces information governance principles for healthcare, AHS had downtime and recovery procedures in place for all affected systems.
**Stakeholder Group:**

The team leading the downtime and reconciliation process involved individuals from diverse backgrounds. Clinical staff, HIM, IT, and senior executives from AHS, Foothills Medical Center, Calgary Zone, Southern AB and Health Link, worked together to ensure ongoing service. Supporting staff included Application and Interface Specialists from IT, and clinical operational staff from Lab, DI, Pharmacy, and Clinical Operations.

As a key stakeholder and the business owner of the ADT system (foundational and critical to other affected applications), HIM co-led the reconciliation strategy and was a crucial participant and fundamental contributor in all meetings.

**Findings:**

The first step towards mitigating the situation was to set up a command centre and a means of communication. A major incident teleconference line was set up and a zone emergency operation centre launched. AHS HIM initiated regular conference calls with representatives participating in the major incident and the emergency call centre. A command centre was established at Foothills Medical Centre, one of the largest hospitals in the Calgary Zone. Text messaging was still available as was access to some Gmail accounts, so these applications became the means of communicating non-confidential information.

HIM service challenges during the event included moving to manual processes during a time of restricted communication which resulted in:

- Limited accessibility of up-to-date reference information (e.g., procedures, shared drives, contact information),
- Inconsistency in the manual tracking of patients affecting accuracy of patient census
- Limited ability to validate status of patients with Bed Management service.

Mitigation of patient safety concerns was a priority. Due to the large number of systems and interfaces affected, the Calgary Zone clinical information system (CIS) was taken off-line as many of the connecting systems were not operational. Patient identification labels were unable to be printed. Some duplicate health record numbers were assigned by mistake and some clinical requisitions were missing the health record number.

After functioning in a paper environment for more than 36 hours, AHS servers were restored and permission was granted to begin the reconciliation process (i.e., data entry and validation). Clinical informatics and HIM Services developed a reconciliation strategy to ensure appropriate sequencing for the restart of clinical applications, to reduce the potential impact to patient safety and care delivery. The challenges post-event centred on the retrospective entry and validation of data, and complexity of the business reconciliation processes.

The ADT system is foundational to all the other clinical applications and the data had to be accurate before any other application could begin their recovery process. Patients admitted, transferred, and discharged during the system downtime had to be retrospectively entered into the ADT system in a sequential time and date order and validated.

HIM Services facilitated the process with cross-site teams working in close partnership with IT and clinical program areas. Back entry and validation of patient and clinical information took several days for some of the affected applications.
Staff involved in the reconciliation process had to have the necessary experience and training to understand the implications and reasoning behind the process, and had to have the proper information system access. Training requirements and appropriate system access limited the ability to bring in additional staff. Clinical staff experienced frustration with perceived delays in action because they did not understand the complexity of the reconciliation process.

**Recommendation/Solution:**

The CIS reconciliation process started with the creation of three main overarching principles:

1. Accuracy and integrity of ADT data is foundational for accurate information in all other clinical information systems.

2. Sequencing and coordination of the reconciliation processes must be controlled and managed to ensure the integrity of clinical data in all applications.

3. Only individuals proficient in the CIS application and with the appropriate level of system access can perform the reconciliation process. Professional licensing regulations may apply to some applications.

Due to the number of applications involved and the extended downtime, the scope of reconciliation was significant and unique. End user access to any applications reliant on an ADT interface followed an identified sequence of recovery post-reconciliation. For example, AHS used the following reconciliation priority rankings in the ADT system:

- **Priority 1:**
  - Inpatients
  - Patients presently in the Emergency Departments
  - Patients presently in the Day Surgery Units

- **Priority 2:**
  - Emergency patients seen and discharged from the ED during the downtime
  - Day Surgery patients treated and discharged during the downtime

- **Priority 3:**
  - Ambulatory care patients seen in outpatient clinics during the downtime

End user access to secondary applications that did not rely on an ADT feed could occur at any time as long as the resources required did not detract from the priority application recovery.

Communication and monitoring remained strong throughout the reconciliation process. The clinical conference call line was used to monitor the reconciliation phases, which ensured appropriate sequencing of system recovery and allowed for the provision of clinical system updates. Hourly ADT reconciliation status updates were provided to the technical bridge teams to coordinate the recovery of applications according to the approved sequence priority.

Collaboration throughout the crisis was instrumental in maintaining services.
Lessons Learned:

Many opportunities for improvement and lessons learned emerged from this incident. The following descriptions are some, but certainly not all, of the lessons learned.

1. Communication is key. The downtime process for bed management identified several challenges including confusion over the ‘owner’ of the census, how to consistently track patients in a manual system, and how to communicate updated patient location lists. It is imperative that appropriate and accurate fax contact fan-out lists are available and accessible. Consistent messaging is necessary to support who can and who cannot be using the system, and when they can be using the system. A priority listing of what systems come back online and in what order is imperative to ensure data integrity.

2. A validation plan for person identification is needed, especially for newborns. A downtime process for the Unique Lifetime Identifiers should be considered.

3. Standardized documentation and processes must be in place to support back entry of data and the organization of paperwork for revalidation. Staff must be able to access the procedures so that second-guessing of manual processes does not occur. For example, critical passwords should not be stored in email systems as these may not be accessible when needed.

Conclusion:

IG provides an opportunity to build a framework for practice that would engender trust in the Canadian healthcare system and its information management practices. An IG practice framework would provide the checks and balances essential for accountability and ongoing improvement in information management practices, particularly important during unexpected technological downtime (CHIMA, Iron Mountain, 2017). Healthcare jurisdictions should embrace information governance/information management principles and leading practices to ensure healthcare data is managed throughout its lifecycle (Abrams, Learmonth, Gibson, 2017). Policies and procedures must be in place to ensure the integrity and quality of information and data.

Orientation and ongoing refreshers of downtime procedures and processes are important for all staff and clinicians. Downtime procedures must be stored so as to be accessible when needed most. The scenarios used in downtime orientation and training should be based on a worst-case scenario, as no two downtimes are the same. Cross training of staff on key reconciliation processes should be considered.

Above all, be prepared. This could happen to you!

References:


Executive Summary / Introduction:

In an increasingly complex and competitive Australian health care environment, where huge amounts of data both structured and unstructured are being created, the need to “manage and use” this information, rather than just collect and store it, is vitally important for strategic planning, privacy and security, and many other reasons vital to the management of a hospital.

Cabrini Health is a five-site acute and sub-acute hospital organization with approximately 720 beds with most clinical specialties being treated by largely Visiting Medical Officer / Consultant medical staff. Cabrini also currently has an aged care facility, medical imaging and pathology businesses, as well as the Cabrini Linen Service and Cabrini Technology which incorporates a number of business lines.

Background / Statement of Problem:

In general, health can lag other industries in IG but the amount of data within health organizations and the importance of being able to understand the data is paramount. This is particularly pertinent with regard to patient experience, strategic planning, predictive analytics and staff satisfaction all of which can be impacted heavily by IG.

The complexity and breadth of Cabrini’s services supports the need to establish Information Governance (IG) principles across all facets of the business wherever possible. Recognizing the problems was a necessary first step for IG.

- An externally appointed consultant review of the Human Resources (HR), also known as people and culture function, identified several issues within HR, as well as downstream problems in areas like Business Intelligence (BI) where reporting accuracy and consistency was compromised.
- Different parts of the business have different definitions for similar aspects of the business and some variation is needed due to the variety of businesses. However, different definitions need greater visibility.
- There was a general lack of corporate knowledge about IG with a need to educate all staff from the chief executive on down.
- The IG role is part time making it difficult to be pro-active and strategic.

Stakeholder Group:

Cabrini key stakeholders included the Executive Director, Commercial Services and Business Systems, Performance Monitoring and Improvement, and the director of Health Information Services, who subsequently took the lead for Information Governance.

Findings:

The core group that included members from HR, BI, IT, payroll, along with an external consultant, became our IG team. Beginning with HR data, numerous issues were identified and prioritized. Slowly the list was worked through. Many of the issues were resolved and monitoring tools were put into place so as to minimize reoccurrences.
Cabrini has no fewer than twenty High Value Data Systems. Data quality issues were identified throughout by working system by system. A data quality tool was deployed to analyze and report on data quality problems regarding patient demographic data including address, email and mobile (“cell”) number. Double UR numbers (unique patient identifying numbers) were also tackled including user education.

**Recommendation / Solution:**

Apart from the remediation and prevention type of work there was the requirement to improve and build more of an IG culture within the Hospital. This is a work in progress and one that is an ongoing challenge.

- Despite a great deal of communication, the capacity and appetite for such initiatives can quickly wane, especially when “life gets in the way” and these types of initiatives can lose visibility.

- There was also the requirement for a number of foundation stones of IG to be put in place. The first of these was the IG Policy that addresses the requirements for executing, maintaining and improving the organization’s information governance capacity and staff member’s roles and responsibilities.

- A Data Governance, Information Technology Executive Committee was convened which was chaired by the chief executive with all executives attending as well as a number of other key staff. Our research had informed us that without C-Suite buy-in, our work would flounder; this was something we obviously did not wish to occur. A Data Governance Working group was also convened which contained more operational staff.

- The High Value Data Systems data stewards and owners for each of our information systems was also agreed to at this point, as were data definitions of two of our significant data sets – finance and human resources.

- The data definitions were particularly problematic and this probably shines a light on why IG is so important. The lack of consistency continually meant that reports were being stated as “wrong” when in effect the figure was not wrong but the application and different uses of the term FTE was wrong. This lead to a mistrust of data that was routinely displayed in our Business Intelligence tool. Once definitions are established, the subsequent challenge is to ensure that the reader of the report knows which definition is being used.

- A data governance framework was also established to provide the principles, guidelines, standards and processes to ensure ongoing improvement of data quality so that information relied upon for decision making has integrity with the vision being simply “right data at the right time.”
Lessons Learned:

It is safe to say that the lessons learnt were many and they continue to be learnt. There is no doubt that many of the principles of IG are absolutely borne out in day to day operational issues and these include:

- The need for C-Suite involvement;
- Dealing with bite-sized issues initially to get runs on the board and building momentum;
- Use the expertise of others where possible;
- And prioritize the implementation of data definitions.

The scope and challenge of IG requires full time focus. It is difficult to do when one has an already challenging position. Although there have been some good achievements along the way and reasonable levels of support from senior leaders, it takes application and the time to develop the new skills required to advance IG across a complex organization.

References:

- AHIMA – 2014 Information Governance in Healthcare
- Data Governance – A Team Game, K. Moysey, Deloitte 2013
Executive Summary/Introduction

The Hospital Corporation of America (HCA) has over 160 hospitals across 20 US states. HCA has a corporate office in Nashville, TN. The corporate office has organizational units that are responsible for setting company standards. This includes the centralized Information Technology & Services model and the Clinical Services Group (CSG) that established clinical best practices. Within CSG is the Clinical Informatics Systems Governance and Operations Department (CI-SGO) responsible for electronic health record (EHR) maintenance, usage, and governance.

CI-SGO governance is accountable to uphold information integrity, which includes authorship of documentation, namely, electronic signatures. In this case, such authorship involves attributing the origination or creation of a particular unit of information (or an entry) to a specific individual or entity acting at a particular time. HCA had adopted a historical approach that required detailed “due diligence” to determine the validity of electronic signature capabilities from an external organization’s system before endorsing those entries through an interface. These practices were first applied at a corporate level and then were rolled out to the hospital divisions; division offices, in turn, rolled out the practices to the hospitals.

Background

Clinical information interfaces containing EHR entries were evaluated using established criteria. External systems were required to meet this criteria in order to transmit authenticated entries to HCA HISs. If the findings of the evaluation were negative, the entry—and its accompanying signature—could still be transmitted and populate the HIS. However, the HIS’s technical mechanics would not mark the entry as final; therefore indicating it as an incomplete (or unauthenticated/unsigned) entry per the HIS’s definition of a finalized entry.

As a result, the organization had a large volume of entries that did not have a “final” entry status in the HIS which dated back slightly more than 10 years. However, these entries did reflect an electronic signature when viewed, printed, or otherwise produced pursuant to information release requests. Therefore, complying with reproducibility standards and customary industry recordkeeping practices. It was then determined that the external organization signature validity evaluation criteria had not been updated for at least a decade. When the initial criteria was developed it was felt that the organization had an obligation to perform a stringent level of evaluation on its inherent systems and hold other entities to the same signature integrity requirements.

Statement of Problem

Documenting and imposing such stringent criteria for the generation of electronic signatures in foreign systems jeopardized the organization’s recordkeeping credibility. This was evidenced by the voluminous number of non-finalized entries and the organization’s inability to uniformly govern the evaluation and processes for accepting entries attributed with externally generated electronic signatures. Audit trails and HIS indicators did not reflect authenticated entries, which had a potential for detection during electronic legal discovery. A challenge was also posed with regard to system downtime and recovery. This being that unsigned entries constituted an active account. Automated system redundancy and restorative
processes were required to cycle through all active accounts in order to back up or restore the system.

Guaranteeing data integrity is complex, this case exemplifies that data systems needed reengineering and accompanying process improvements. A cross-domain deliberation was required to produce outcomes that address system and process design and uphold patient safety, quality care, regulatory compliance, privacy/security standards adherence, applicable medical-legal considerations and mitigation of institutional risks. Resulting outcomes were to be recorded in an open and verifiable manner. Memorialization documentation evidenced the organization’s “due diligence” and provided transparency to the organization’s leadership, workforce members, and other appropriate interested parties in accordance with legal obligations. Because of the varying parties involved and the widespread impact, an organized governance effort was needed to evaluate an approach according to HCA’s strategic visions.

Stakeholder Groups:

These challenges affected various roles within the organization. Information Technology & Services (IT&S) had the responsibility to (1) evaluate and certify interfaces carrying electronic signatures, (2) configure the system to mark the incoming transmitted entries accordingly, and (3) to restore the system when an outage occurred. Health Information Management (HIM) was responsible for ensuring the permanent record reflected final signed entries using system indicators. Quality/Patient Safety and Legal were invested to ensure that any remediation efforts were well vetted and the right “due diligence” was applied to uphold any patient-risk or legal consideration.

Findings:

Internal legal counsel engaged external advisement regarding the organization’s responsibility to accept electronic signatures from external entities. It was determined that “unless an apparent abnormality could be deduced from a customary level of ‘due diligence,’ neither federal nor state laws prohibited the organization from presuming that electronic signatures were otherwise invalid.” A review of the current organization’s requirements for accepting external signatures determined that it was outdated as many of the regulations and accrediting bodies now hold all healthcare entities to higher electronic signature veracity standards (i.e. Uniform Electronic Transactions Act2 and 21 CFR Part 113).

It was determined that accreditation and auditing agencies have the right to inquire about the methods in place to ensure the integrity of an electronic authentication (signature) within the medical record. It was felt that this could be met in one of two ways. Either: (1) performing “due diligence” during the initial integration activities to ensure the source system (vendor) meets compliance requirements set forth by the facility that outline signature integrity; or (2) developing a company Ethics and Compliance Policy that outlines proper authentication integrity safeguards, with vendors entering into an organizational contract that designates adherence to signature integrity.
**Recommendation/Solution:**

The topic was presented to the company’s Clinical Information Governance Committee. A subcommittee was commissioned to perform further investigation and recommend a proposed solution. This subcommittee was made up of representatives from Clinical Quality Standards, IT&S, HIM, Legal, Information Protection, Architecture Security, and CI-SGO.

It was determined the best approach for remediation would be to revise the current certification process as well compose a Risk Assessment Toolkit that could be used by a division or individual facility to assess the external system/vendor capability for electronic signature integrity. A three-year monitoring cycle was incorporated. Some of the items were standardized and required across the company, while other components were left to the interpretation of division/facility approving bodies. This allowance supported a governance structure that could be realistically enforced at the division or facility levels instead of at the company level. If requirements were not met, the toolkit included a provision for exceptions. In such instances, the division/facility approving body could determine to accept the signatures, however, would document the justifications using a Risk Acceptance Protocol (RAP) and Risk Acceptance Form (RAF). The RAF is signed by division/facility executives to evidence the justification as formally acknowledged and documented. The signed RAF is retained to support decisions that were made should there be a need to produce evidentiary documentation in response to future inquiry.

**Lessons Learned:**

Once the new evaluation and certification standard was developed, insufficient time and effort were expended on strategizing a plan and performing subsequent execution, socialization, and implementation. It was determined that further harnessing of existing communication channels to effectively cascade messaging would have led to increased adoption and success. It was found that many of the companies’ divisions/facilities continued to operate under the previous guidelines and, therefore, continued to generate incomplete entries.

**Conclusion:**

Approaching the problem with well-established governance principles that provided a systematic approach in which evidentiary documentation could be produced, and allowed for autonomy and flexibility at the division/facility level, proved to work best in this situation. Mitigation challenges to information integrity in today’s healthcare environment should be considered part of an information ecosystem rather than at an individual organization level. As interoperability of information becomes more and more integrated, a solid approach should be applied that recognizes information integrity, credibility, and an overall responsibility to accountable recordkeeping.

**References**