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Advancing Health Information Governance: a Global Imperative



International Federation of
Health Information Management Associations

Health services are undergoing transformation in virtually every nation around the world. Local and national health services are redesigning care delivery and public and private health services by embracing 21st century solutions. They are facilitating greater engagement and inclusion by patients, families, and communities and refining approaches to funding and payment.

Information is the essential tool for transformation. Health providers, therefore, are evolving from paper-based to digital health systems. These systems support personal wellness and care; care delivery systems; and local, national, and global public health policy and improvement initiatives.

Digital health information requires focused management and governance to address new challenges and risks to data quality and integrity, data integration, confidentiality and security, and lifecycle management. Information governance (IG) provides the authority mechanism that set forth principles and policies and approves procedures and technology for how an organization will exercise its stewardship responsibilities. Most importantly, a strong information governance program serves the needs of the consumer, patient and citizen.

To realize the full value of digital information in transforming healthcare, health information management professionals worldwide must lead the charge to improve information governance.

The International Federation of Health Information Management Associations (IFHIMA) is a non-governmental organization (NGO) in official relations with the World Health Organization (WHO). The Federation, founded in 1968, acts as the global voice of the health information management profession to support delivery of healthcare services and activities and to share best practices. IFHIMA is committed to the advancement of health information management practices and the development of its members for the purpose of improving health data and health outcomes.

The Global Information Imperative

The global goals of healthcare transformation are well summed up in this quote from 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.”¹

Key building blocks supporting these global goals are health records - records of patients’ health status and treatment - and vital records - birth and death records. Some countries have evolved to longitudinal patient records using second or even third generation electronic records. Other countries are just beginning their journey from paper health records to electronic records or have a combination electronic and paper records. Still, others have largely skipped the paper step and are adopting electronic solutions as their first care record. Vital records across the globe also vary in their rigor and accuracy. Some countries have highly standard and established vital records; others grapple with variation in how vital records are handled.

Regardless of whether it is a ministry of health, a large enterprise, or a small medical clinic – and no matter where they reside on the technology adoption and data standardization spectrum - it is never too soon to incorporate governance and stewardship practices.

The importance of information in transforming healthcare cannot be overstated. From electronic health records to smart phone apps, information is driving healthcare decisions at all levels as never before. Rapid technological advances have generally outpaced our capabilities to safeguard and govern the expanding volumes of health information and its range of uses.

The data explosion that is accompanying the electronic/digital transformation means healthcare data volume is doubling every two years. “The volume and variety of information in all forms requiring retention and management are also increasing dramatically. In fact, 90 percent of unstructured information will require formal governance and management by 2020.”² 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.

Health system improvement requires information that is accurate, available, understandable and trusted. As the data reflects highly sensitive and confidential health matters, it must be appropriately safeguarded. These requirements were difficult to achieve even in what was historically perceived as a tightly controlled paper-based system. Digital information demands greater formalization of information governance (IG) to ensure that information resources fully support safe and effective care and efficient health delivery systems. HIM professionals must:

- Lead efforts to advance IG and information management practices and
- Ensure governance policies and best practices are applied to all types of critical information assets across the information lifecycle.

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Information Governance as Stewardship

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Effective stewardship of health information is an important obligation for all who create, use and manage information. Preserving confidentiality is an indisputable stewardship obligation when the subject of the information is readily identifiable. This obligation remains true when patient or provider identifiers have been removed from a data set for research and other purposes. “Stewardship is an ethic relating to the responsible handling of information; and governance sets forth the ground rules for execution of this responsibility.”³

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)⁴ 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 FIPP principles.^{5,6,7}

Principles of Fair Information Practices (OECD 1980)	
Collection Limitation	Limits on the collection of personal data; obtained by lawful and fair means and, where appropriate, with knowledge and consent of the subject.
Data Quality	Data relevant to the purposes and for the use and be accurate, complete and kept updated for those purposes
Purpose Specification	The purposes specified not later than at the time of data collection, and subsequent use limited to the purposes.
Use Limitation	Disclosed or made available only for specified purposes except a) with the consent of the data subject, or b) by the authority of law.
Security Safeguards	Protected by reasonable safeguards against loss or unauthorized access, destruction, use, modification or disclosure of data.
Openness and Transparency	A general policy of openness about developments, practices, and policies with respect to personal data.
Individual Participation	Individuals have the right to know who has their data, to obtain a copy within reasonable time, in an intelligible form, and to challenge if request for access is denied.
Accountability	A data controller should be accountable for complying with measures, which give effect to the principles stated above.

The Caldicott Principles adopted by UK's National Health Service (NHS) include seven 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.

Caldicott Principles, 2012 Update	
Justify the purpose(s)	Every single proposed use or transfer of patient identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.
Don't use patient identifiable information unless it is necessary	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).
Use the minimum necessary patient-identifiable information	Where use of patient identifiable information is considered to be 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.
Access to patient identifiable information should be on a strict need-to-know basis	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.
Everyone with access to patient identifiable information should be aware of their responsibilities	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.
Understand and comply with the law	Every use of patient identifiable information must be lawful. Someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements.
The duty to share information can be as important as the duty to protect patient confidentiality	Professionals should in the patient's interest share information within this framework. Official policies should support them doing so.

The Principles are fully operationalized through roles and functions outlined in the 2017 Caldicott Guardians Manual.⁸

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. HIM plays a key role in IG by participating in policy formulation and/or subsequent execution. HIM has traditionally demonstrated excellence of information management through cost effective, consistent practices carried out by trained HIM professionals.

Illustrating the 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.⁹

IG requires a multi-stakeholder approach anchored in a formally supported program by senior leaders.

From a practical perspective, IG considers the lifecycle of the information from its creation and integration through archiving or destruction. IG considers the range of functions including information design and collection; records and content management; access, disclosure and use; privacy and security; and the quality and integrity of information. IG requires a multi-stakeholder approach anchored in a formally supported program by senior leaders.

Data Governance to Advance IG

Most health care organizations are just now learning that they need to formalize IG, and some have elected to focus first on data governance (DG).

Most health care organizations are just now learning that they need to formalize IG. According a 2014 study performed in North America by Cohasset Associates in conjunction with AHIMA, only two-thirds (65%) of respondents from participating healthcare organizations recognize the need to formalize information governance practices to align how information is managed across functional areas. Of these, 43% have actually initiated an IG program.¹⁰ Most health care organizations are just now learning that they need to formalize IG, and some have elected to focus first on data governance (DG). DG is an essential dimension of comprehensive IG. DG is focused on the data used most often across key applications and processes (i.e., master data), as well as data quality, data glossaries, data integration and data mapping. The DG activities may include addressing patient or provider identifiers, metadata, data mapping, data glossaries, and data standardization. Creating high quality, trusted data across an organization is the goal of DG, and is critical dimension of IG.

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, because error is costly. The emergence of EHR-related errors results in data being lost or incorrectly entered, displayed, or transmitted, leading to loss of information integrity.¹¹

IG should 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.

IG sets the ground rules across the lifecycle of information and it considers the way information is handled throughout the healthcare organization, whether that be a ministry of health, large healthcare enterprise, or a small group of physicians. IG builds consistent practices that help break down costly information silos. For example, all parts of the organization should handle access to and requests for patient information in a manner that is in compliance with organizational policy, laws and regulations.

Finally, IG establishes the metrics and measures to ensure that the ground rules are being followed. IG should 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.

Information Governance and Health Information Management Practice

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.”¹² 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.

Applying IG principles to healthcare systems in developing nations may in fact be easier than retrofitting mature healthcare systems and their practices to conform to IG principles.

Information Governance in Developing Nations

Applying IG principles to healthcare systems in developing nations may in fact be easier than retrofitting mature healthcare systems and their practices to conform to IG principles. “Emerging markets are undergoing (often rapid) modernization of national and local regulatory regimes, resulting in completely new information governance and records management requirements for companies doing business there. These regulations require organizations to identify and retain entirely new records.”¹³ Developing nations have the opportunity to:

- Establish clear lines of authority for information management and governance decision making at strategic and operational planning
- Incorporate information governance and sound information management practices in budgets and planning so they are considered in design of policies and processes and acquisition of technology

Most importantly, a strong IG program serves the needs of the consumer, patient and citizen through strengthening their associated data.

- Establish consistent policy and standardize processes at the inception of digital or paper systems
- Create a culture that supports a multi-disciplinary approach to establishing information policy and managing information as a key asset
- Define data governance and the associated disciplines such as standardized data dictionaries, data integration, metadata and master data before data is create
- Institute data quality standards and the associated measurements that will substantiate success or drive change

Building trusted, consistent data must be part of the design and implementation of a paper based or digital system be it at the level of the ministry of health, or at the hospitals or care delivery sites in the public or private sector. Applying governance principles and practices at initial, strategic points or when new systems are being funded and designed can create a unique opportunity to align the strategic goals and metrics with the needs of the multi-stakeholder community. Most importantly, a strong IG program serves the needs of the consumer, patient and citizen through strengthening their associated data.

Learning from IG Experiences around the World

IFHIMA is a powerful network of HIM professionals from around the world, sharing best practices for IG and the day-to-day challenges of managing patient information and other important health information resources. In the face of health system change and transformation, this network has never been more important. Learning from one another is the surest way to advance at the pace that change is required today. To support the translation of HIM practice and knowledge, three international case summaries have been included as an appendix in this paper to demonstrate the need for and value of IG.

The Case Summaries describe the IG journeys of Alberta Health Services (AHS) in Canada, Cabrini Health (Cabrini) in Melbourne Australia and the Hospital Corporation of America (HCA) headquartered in Nashville Tennessee, USA. They are dynamic stories of change and learning and these 2017 snapshots convey a number of important lessons that can be adapted and adopted by other organizations. The lessons fall into three general categories: Purposeful Organizing for IG, Careful Priority Setting, and Adaptation.

Purposeful Organizing for IG

Establishing information policy requires a range of expertise and IG requires a multi-specialty group to function as a steering committee. Convening a stakeholder group is an essential and first step for successful IG. Several stakeholders are listed within the case summaries including clinical, operations management, business, technology, information management, legal and compliance and quality improvement. The composition of the stakeholder group will depend on the organization. It must include a range of specialists and executive level decision makers.

The case summaries reveal the importance of gaining support from the highest levels of the organization. For Cabrini Health, senior leadership comes from the Executive Director who is personally involved. Senior leadership is essential in conveying the importance of IG for the organization and to asset authority in ensuring that adopted information policies are carried out.

Convening a stakeholder group across disciplines – that includes a range of specialists and executive level decision makers – is an essential and first step for successful IG.

Careful Priority Setting

The Case Summaries focus on specific issues reflecting high priorities for each organization. Priorities include electronic signatures, downtime recovery protocols and getting the organization's information policy house in order. Cabrini Health notes that the best approach is "dealing with bite-sized issues initially to get runs on the board and building momentum."

This sound advice is reinforced by many other organizations. Steering committees will have no trouble identifying complex, priority information challenges that benefit from improved governance. Particularly in the early years, it is wise to choose projects to work on that will have tangible return on the time and effort invested or that represent a real risk to the organization.

Measuring and Adapting

In the AHS case summary, the critical importance of accurate demographic information in the ADT system played a key role in prioritization. Critical thinking is key to measuring the before and after impact of change. In the HCA case summary, standardization and the ability to monitor conformance drove the solution.

Today's solution may change tomorrow as new technology becomes available and as experience shows better practices. IG is not linear and it is never complete. It is a circular process whereby improvements are quantified and celebrated at the same time the organization looks for ways to improve further.

As with all transformative change, there is usually a trigger that is both a threat and an opportunity. The Case Summaries make clear one other important lesson. Advancing IG requires a keen awareness of what is happening throughout the organization so that HIM professionals are recognizing and responding to trigger opportunities to advance IG. For example, the Alberta and US experiences show that different sized triggers can actually help to leverage and demonstrate the importance of IG. The realization that stronger protections are needed to ensure data integrity and authentication can be a powerful motivator. In the Australian case, the need for IG was emphasized due to growing organizational complexity and the variations in practice such growth brings to light. So too can be growing organizational complexity and the variation in practices it brings to light as described by the Australian Case Study.

The first and most important first step in advancing IG is to leverage the triggers—triggers that exist in every health care organization-- to begin educating and engaging the organization in the need for IG.

Advancing IG requires a keen awareness of what is happening throughout the organization.

IG is not linear and it is never complete.

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IFHIMA 2019
D U B A I

The IFHIMA 19th International Congress and 50th Anniversary Celebration will be held in Dubai, UAE.

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Appendix

CASE SUMMARY CANADA

How Data Recovery in the Wake of a Major Health Information System Failure Reinforced the Need for Information Governance

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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!

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CASE SUMMARY AUSTRALIA

Australian Private Hospital enters a new frontier of Information Governance

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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 led 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.

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CASE SUMMARY USA

Electronically Transmitted Signature Integrity

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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 time¹. 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 success⁴. 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.

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