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I. Executive Summary/Purpose Statement

Background
The HIMSS CNO-CNIO Vendor Roundtable was formed to optimize health engagement and care outcomes through IT by leveraging the thought leadership of health IT supplier nurse executive leaders. This pioneer partnership led by HIMSS and including the nursing health IT suppliers depends largely on our ability to move beyond the cultural norms of each partner’s organization in the service of innovation to advance outcomes for nursing and clinical practice.

Key objectives are to:

- Serve as an advocate and leader for the nursing community;
- Provide guidance on informatics competencies for nursing; and
- Provide guidance on EHR related topics including analytics, interoperability, usability, terminology, workflow, quality and outcomes.

In response to recommendations by the HIMSS CNO-CNIO Vendor Roundtable, the Big Data Principles Workgroup was established. The Workgroup was tasked with developing a paper to: identify big data principles, barriers and challenges; develop a framework for universal requirements; identify differences in the context of nursing outcomes; address the impact of health IT system versions/configurations; analyze the variation in quality measures; and discuss implementation challenges. This paper will also provide the foundation for future discussions with the broader nursing community including nurse executives in hospitals, healthcare systems and other key stakeholder groups to explore and advance shared objectives.

Dr. Ellen Harper and Joyce Sensmeier were selected to co-lead the broad and diverse group of individuals who represent the nursing leadership perspective of health IT suppliers around the world.

Members of the Workgroup are:

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<thead>
<tr>
<th>Big Data Principles Workgroup</th>
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Purpose of the Paper

The Triple Aim challenges the US healthcare marketplace to improve the patient experience and overall health while reducing costs (Berwick, Nolan, and Whittington, 2008). Historically, concentration has been on data input and storage thus creating silos of data; however the Triple Aim requires big database management and interoperability to simultaneously improve population health, improve the patient experience of care, and reduce per capita cost. The current focus is on managing data to assess the following: What are the risks in patients and populations? Who is predicted to be compliant with treatment? How can we realize personalized care? How are we achieving patient outcomes? Who needs home care or other community resources? The shift is toward quality, economics, and safety as well as the correct care pathway for the patient and population.

The economic value of health and care data is exploding, and the ability to store, aggregate, and combine such data to perform analyses has become ever more important. Several forces are triggering an increase in the digitization of health and care data and will continue to fuel exponential growth: technology, healthcare reform, and the movement toward patient-centered care (Harper, 2013). Each force is exerting pressure to capture, manage, and share health information as a series of ongoing data elements, producing a holistic longitudinal person-centered framework that is appropriate for the patient and the healthcare ecosystem. The potential exists for big data to produce system-wide improvement at a scale that enables healthcare system stakeholders to realize the full potential. “Big data,” large pools of data that can be captured, communicated, aggregated, stored, and analyzed, are now part of every sector and function of the global economy (Versel, 2009). While most research into big data to date has focused on the question of volume, there is evidence that the business and economic possibilities of big data are also important for consideration (McKinsey Global Institute, 2011).

The need for sharable, comparable information in healthcare is evident. There has been more than a decade of progress in digitizing medical records, as pharmaceutical companies and other organizations aggregate years of research and development data in electronic databases. For example, large healthcare delivery systems like the Cleveland Clinic are using their vast databases of similar cases and studies to predict probable outcomes depending on the treatment a patient chooses (Landro, 2014). The federal government and public stakeholders have also accelerated the move toward transparency by making data usable, searchable, and actionable by the healthcare sector as a whole (Kayyali, Knott, and Van Kuiken, 2013). Together, these increases in data liquidity have brought the industry to a critical point. Healthcare stakeholders now have access to promising new threads of knowledge, yet there are still barriers to making this possible. If nursing fails to process nursing care data in an electronic format, healthcare decisions will be made without nursing input, despite the findings that ignoring nursing data results in inaccurate reimbursements (Welton et al., 2006). Today, nursing care data, beyond basic compliance data, is seldom stored electronically, despite studies demonstrating that including nursing problems improves the accuracy of costing healthcare and predicting outcomes (Welton, Halloran, and Zone-Smith, 2006). If electronic healthcare documentation contains little data about the decisions nurses make, such as decisions about nursing problems, independent intervention actions, and the resulting outcomes, nursing data will not be used in healthcare planning and priority selections. Therefore, nursing’s role in healthcare will remain invisible, and nursing’s potential contribution will not be considered in healthcare policy (Thede, 2008).

An important expanded role for nurses and especially nurse leaders is needed in the strategic planning and implementation of health IT. Capturing health and care data in a structured way is a critical building block in the foundation to accomplish the vision of accurate, reliable, clinically meaningful measurement across systems and settings of care. Using data elements consistently and reliably will allow for information to be collected once and reused for multiple purposes, including outcomes measurement, practice level improvements, surveillance, population health, research and decision support (Office of the National Coordinator for Health IT (ONC), 2014). Many nurses and nurse leaders already have stepped into these roles, but many more will be required in future years.
This “Guiding Principles for Big Data in Nursing” paper represents a welcome opportunity for nurses to lead and diffuse collaborative health IT efforts to achieve improved health and healthcare quality, safety, and communication among all members of the care team. This paper is organized into sections that address the following:

1. **Define big data principles.** This section will address the key principles and components of big data and how they interrelate to form the structure that will improve the usefulness of big data in nursing practice. There are four key principles that underscore big data: Privacy and security of health information, data standards, interoperability and immutability.

2. **Describe the need for alignment of industry standards and scales/tools.** A significant challenge is lack of standardization of disparate health data from various healthcare organizations and providers. There are national initiatives underway to advance the ubiquitous exchange, sharing, and reuse of operational clinical data stored in EHRs leveraging the necessary standards (Rea et al., 2012).

3. **Identify barriers and challenges.** The Workgroup compiled a list of barriers and challenges to achieving true interoperability of clinical data, e.g., multiple nursing terminologies, need for licensure of copyright tools, no de facto standard of evidence-based scales or instruments.

4. **Consider the need to formalize data relationships to enhance knowledge.** There is a call to develop a framework for appropriate universal requirements and to map it consistently. A single, universal framework is required to overcome these barriers to allow clinical data to be universally collected and incorporated into analytics for quality improvement efforts in all areas of patient care. According to the University of Washington (2014), clinical data is either collected during the course of ongoing patient care or as part of a formal clinical trial program and falls into six major types:
   - Electronic health records
   - Administrative data
   - Claims data
   - Disease registries
   - Health surveys
   - Clinical trials data

5. **Identify critical differences in documentation that are relevant in the context of nursing outcomes.** Many EHRs include a documentation system or component but during the implementation process, the healthcare organization may undertake extensive localized customization or configuration, which creates further disparity of standardization. While the clinical assessment and care planning process and its basic content areas are widely accepted and acknowledged, there still remains considerable variation in what is collected and documented.

6. **Consider the implications of health IT system versions/upgrades.** The Workgroup identified that management and alignment of health IT system upgrades are increasingly complex. Interdependencies and aggressive timelines create challenges for organizations, health IT suppliers, and the many industry partners involved with implementing health IT.

7. **Identify policies and analytics that enhance workflow and create incentives for clinicians to adhere to recommendations.** There is a need to identify teams of analytics experts who can provide the knowledge to merge, standardize and analyze data, while providing feedback within the clinician's workflow.

8. **Engaging nurses in health IT.** Nursing Informatics was recognized in 1992 as a specialty by the American Nurses Association (ANA, 1992), yet nurse informaticists have not been widely utilized or maximized to their fullest potential. Nurse informaticists are needed to support the cognitive interaction between the nurse, the nursing process, nursing data, patients and technology. Evidence suggests it would be wise to leverage their skills, esteem, and front-line involvement with patients as we proceed toward a more connected, IT enabled healthcare system (Rein, 2011).
The authors used their collective knowledge and experience as nurse leaders within health IT supplier organizations to envision this Guiding Principles for Big Data call to action. This paper will offer recommendations for removing barriers and advancing big data to accelerate the creation of new knowledge while considering strategies for implementation.

II. Defining Big Data Principles

Understanding big data is a top priority for nurses as they aim to provide the best possible care to patients. Working in healthcare organizations with complex information technology landscapes, and networks with multiple clinical, financial, and claims systems that must be integrated is merely the tip of the iceberg of the big data challenge. The ability to integrate and analyze disparate data and make sense of them with speed and accuracy in order to positively impact outcomes is no small feat. Having access to the right information at the right time to support clinical decisions is essential in planning and providing the right care for patients. Nurses need real-time information to make timely, critical, clinical decisions. The use of big data technologies can help nurses and other healthcare providers improve care quality, optimize outcomes and reduce the cost of healthcare.

While the data that comprise the elements of health information continue to expand in volume and complexity, the crux of “big data” is within the ability to analyze and use it in a meaningful way for continual improvements. So what exactly is big data? The McKinsey Global Institute defines “big data” as “datasets whose size are beyond the ability of typical database software tools to capture, store, manage, and analyze (McKinsey Global Institute, 2011).” While there are many general and technical definitions of big data, it has most frequently been described in terms of volume, variety, velocity, and veracity (Gaffney and Huckabee, 2014).

Volume
The volume of data being created today is growing exponentially with the increase in EHRs, medical device and monitoring data, genomic data and so on. The volume of data being created and the ability to distinguish its value from noise is critical and the power to do so resides with big data analytics, knowledge-generation and related tools. The volume of data can range from terabytes to petabytes and beyond.

Variety
The variety of data elements requires standardization and normalization in order for any meaningful comparisons or integration to occur. This variation in data can be structured or unstructured as in the example of clinical notes. The ability to analyze the wide variety of data and integrate it in a meaningful way to improve costs, outcomes and quality is a critical success factor.

Velocity
Our ability to use data is challenged by the rapid speed at which data are being created (velocity) and the need for analysis to occur in near to real time. Complex analytics capabilities and tools are required.

Veracity
The veracity of data is an important factor as well, in terms of the need for data integrity, accuracy and trustworthiness. Veracity is a key element when using big data to make decisions impacting patient care.

When considering the role of big data in healthcare, especially big data in nursing, the rich potential for advances in care and health improvements easily come to mind. For this potential to become a reality, however, one must understand the underlying principles and establish a clear route toward these outcomes. This section will address the key principles and components of big data and how they interrelate to form the structure to improve the usefulness of big data in nursing practice.
Four Key Principles
There are four key principles that underscore big data: privacy and security of health information, data standards, interoperability and immutability.

Privacy and security of health information. While much is written about the data privacy and security of health records, the potential to breach this trust with EHRs remains greater than desired. Safeguarding personal data and health information is imperative to maintain trust. The use of big data in healthcare must ensure appropriate data privacy and protection measures. Big data can be viewed as a double-edged sword, carrying the potential for great opportunities as well as key responsibilities. The accurate identification, de-identification and re-identification of data and data sources are also critical. There are standards and protocols that can be used for each of these processes.

Data standards. In healthcare, standards provide a common language and set of expectations that enable interoperability between systems and/or devices. Ideally, data exchange schema and standards should permit data and information to be shared between clinicians, labs, hospitals, pharmacies, and the patient or their designees regardless of application or health IT system in order to improve healthcare delivery (HIMSS, 2014).

Standards are established by professional groups and are generally accepted through consensus or mandate. However, individual institutions are at liberty to establish their own standards and taxonomies to meet their internal needs. When data are shared across institutions, having different meanings and using different standards make it impossible to compare data in a meaningful way. Standards are critical so that data can be shared to create the necessary scale that enables analytics to realize value (McKinsey, 2011).

Interoperability. Interoperability, or the ability to exchange data in a comparable and meaningful way, is provided through the use of standard sets of languages and tools. In healthcare, interoperability is the ability of different information technology systems and health IT system applications to communicate, exchange data, and use the information that has been exchanged.

According to HIMSS (2013) there are three levels of health IT interoperability:

1. “Foundational” interoperability allows data exchange from one IT system to be received by another and does not require the ability for the receiving information technology system to interpret the data.

2. “Structural” interoperability is an intermediate level that defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of health data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.

3. “Semantic” interoperability provides interoperability at the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged.

Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that the receiving information technology systems can interpret the data. This level of interoperability supports the electronic exchange of health-related financial data, patient-created wellness data, and patient summary information among caregivers and other authorized parties. This level of interoperability is possible via potentially disparate EHR systems, business-related information systems, medical devices, mobile technologies, and other systems to improve wellness, as well as the quality, safety, cost-effectiveness, and access to healthcare delivery.
Interoperable data contain data elements that are defined, measured, and retrievable in the exact same format. (Keenan, 2014). Continuity in the patient care process requires harmonizing concepts across disparate health IT systems and the growing mobile health solutions. In order for data to be sharable and comparable, they must be structured in standard ways that enable the data to be used interoperably.

The extensive tailoring and configuring of health IT systems to meet the unique needs of organizations can reduce comparability between institutions. As a result, much of the data entered into EHRs by nurses is not standardized which impacts interoperability (Staggers, 2013). Consistent approaches and the use of standards in data measurement are critical components. According to Staggers (2013), “the accuracy, precision, data values, verification, and validity of data are essential for any meaningful analysis of data.” Simply put, interoperability is not just about the ability to compare apples to apples, but the ability to compare red delicious apples to red delicious apples. Even so, the granularity with which data are utilized and for what purpose must be considered.

Currently, the healthcare infrastructure is fragmented, contributing to inefficiencies and uncoordinated care. Gaps exist between entities, organizations, and settings, which need to be bridged to enable information sharing with stakeholders such as patients, clinicians, end users, and payers. The value of sharable, comparable, consistent and accurate data can be realized through interoperable systems, advances in EHRs and broader implementation of meaningful use (Sensmeier, 2014).

**Immutability.** The immutability of health data is the fourth key principle underlying the use of big data for nursing. Health data records are unique in that they are immortal and cannot be changed. To maintain immutability, you can add data to the record or system, but recorded data should not be altered or erased (Berman, 2013). The historical perspective of a patient’s care and treatment are relevant in the context of health and healthcare. Data managers must employ the functionality of identifiers and time stamps tied to event data so that the data can be modified without altering the original content. Time stamps enable temporal events to be documented using a standard measurement for time in which the event occurred. This time-stamp must be accurate, persistent and immutable.

When new events occur, they can subsequently be added to a data object containing this related event data such that the old data is not replaced with the new data. The data object contains the information to distinguish one event from another, enabling the selection of the appropriate event data for analysis. Data integrity assures the accuracy, correctness and validity of data, using a set of validation criteria against which data are compared or screened. The protection of data integrity from compromise or alteration is essential.

When dealing with legacy data in healthcare, immutability (as well as any legal implications) must be taken into consideration when correcting and updating data and records through data-merging operations, reconciling data object identifiers across big data resources, and merging data between resources (Berman, 2013).

With these key principles in mind, nursing must look next toward the essential components of big data. These components include data sources, data types, data attributes, data location, and data movement.

**Data Sources**
The source of various types of data is a foundational component of big data. Due to the variety of sources, overlap, the associated variety of formats, purposes and ownership, capturing the source of data presents many challenges. The number of available data sources is expanding at a rapid pace. While nurses may traditionally think of data as evolving from health records held by providers, and claims data captured by insurance companies, emerging data sources include social media, monitoring devices and other evolving technologies.

For example, the terms Patient Generated Health Data, Genomic Data, and Clinical Trial Data are now being used to differentiate such sources of data. While the facility to monitor and track data elements such as vital signs, weight, and caloric intake has been around for a long time, the interest and ability of individuals to digitally monitor and track these and other data points is of growing interest. Health IT will continue to enable individuals to be active participants in managing their care as an important contributor of information to the health record (e.g., patient experience, self-rated health, and self-generated data) (ONC, 2014).
Data Type
In this section, the various types of data are described according to where the data is generated – from providers, payers, patients, and educational systems, denoting areas of overlap as applicable.

According to the McKinsey Global Institute analysis (2011), data can be described according to the following data types:

A. Clinical data
B. Pharmaceutical R&D data
C. Activity (claims) and cost data
D. Patient behavior and sentiment data

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<tr>
<th>Data Type</th>
<th>Description</th>
<th>Owner</th>
<th>Sources and Examples</th>
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<tr>
<td><strong>Clinical data</strong></td>
<td>Clinical data captured in information systems</td>
<td>Providers, school systems, employers, home health, long-term care, community resources</td>
<td>EHRs, medical images, clinical data warehouses, genomic data, registry data, school health and immunization records, occupational health record data</td>
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<tr>
<td><strong>Pharmaceutical and medical health IT systems R&amp;D data</strong></td>
<td>Therapeutic mechanism of action, target behavior in the body and side effects and toxicity of drugs, including clinical trial data</td>
<td>Pharmaceutical companies, academia</td>
<td>Clinical trials, high throughput screening libraries, genomic data, registry data</td>
</tr>
<tr>
<td><strong>Claims and cost data</strong></td>
<td>Services provided and how they were reimbursed</td>
<td>Payers, providers</td>
<td>Utilization of care, cost estimates, Administrative/financial Data, claims data, registry data</td>
</tr>
<tr>
<td><strong>Patient behavior and sentiment data</strong></td>
<td>Patient activities and preferences, both within healthcare and as consumers. Compliance with diagnostic and treatment care plans in all care settings.</td>
<td>Various including consumer and stakeholders outside healthcare (e.g., retail, apparel)</td>
<td>Patient behaviors and preferences, retail purchase history, exercise data captured in apparel and athletic shoes, devices, and personal sensors</td>
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Figure 1. Examples of common data types and their sources. (Adapted from the McKinsey Global Institute, 2011)

Clinical data comprise an extensive array of digitized patient, financial and administrative data that include accounting and patient information. The digitization and aggregation of clinical data, such as data pertaining to progress toward goals or treatment outcomes, remain in the early stages. Even when clinical data are digitized, they are not often shared beyond healthcare systems and organizations. Data may even be in the form of real time monitor feeds or videos not currently stored. Frequently, data remain within the health IT system, and do not follow the patient or impact outcomes across care settings.

Clinical data include information that is related to the health and healthcare of an individual, collected while receiving healthcare services, or through monitoring of personal health activities. These data include all relevant clinical, pharmacological, socioeconomic information disclosed by the patient and others, as well as assessments, observations, findings, therapeutic interventions, and prognostic statements generated by members of the healthcare team (HIMSS, 2010).

Assessment data include findings from clinical evaluations such as physical exams, patient interviews, observations, clinical findings, and interpretations of diagnostic testing or other clinical reports such as labs, diagnostic imaging or EKGs.
Care plan and treatment data include the listing of health problems, goals, interventions and evaluation of outcomes that document the process of care. Based on the assessment data, the patient’s plan of care is a roadmap that guides and directs healthcare services for a patient. It includes goals and expected outcomes related to health problems as well as interventions and actions related to treatment options. Care plans include a nursing assessment or problem list and contain goals or outcomes, specific plans and interventions as well as implementation and evaluation of care delivered consistent with the nursing process (HIMSS, 2010). Treatment plans are based on diagnoses associated with codes that are tied to billing and reimbursement. Progress notes include descriptive documentation summarizing an assessment of the patient status, treatment plan and interventions outcomes, evaluation, and plan.

Encounter data describe an interaction that occurs when a patient presents for the delivery of healthcare. These data generally include the visit type, level of urgency, reason for visit, demographic data, location, diagnosis and treatment information, disposition, payment information and associated coding. Demographic data include vital statistics such as name, address, date of birth, gender, marital status, race, identification numbers, and so on. These data can be generated by both providers and payers in order to identify and link patients and their associated case records and data sets, as well as their financial identification numbers or member numbers for billing information. While this is basic information, the variety of formats, codes, and terms remains challenging for many entities.

Enrollment data represent a type of payer data that denote membership or coverage within a particular group and define parameters for eligibility for certain benefits. These data also include demographic data, as well as relationship data, group data and coverage timeframe/eligibility dates.

Utilization data are concerned with healthcare services and benefits for individuals and groups of patients as previously described. In addition to using utilization data for coverage and benefit determinations, payers are interested in utilization data from the perspective of comparing providers and facilities, and services utilized by members and groups, making comparisons against benchmarks, and the assessment of access to care and network provider coverage.

The scope of discussion of payer data will be limited to that which includes enrollment, utilization and claims data. Claims data are rich sources of clinical data that can be used to better understand the cost and quality of care and to identify patients at risk of developing or who have certain conditions. Claims provide a vast amount of information regarding utilization of care services, patterns of illness, care, and treatment as well as provider entity characteristics. Claims data include billing codes used by physicians and other healthcare providers to submit to payers. Health insurance claims are essentially bills that a provider submits to a payer for payment of healthcare services provided. The process, coding, and format for submitting claims is relatively consistent and complete across health IT systems as providers must generate a claim in order to receive payment for services provided.

A limitation of payer data is that it obviously only pertains to covered patients. Data regarding uninsured patients, unreimbursed care and other health disparities have critical implications for nursing, public health, and society as a whole.

A medical device, application, or wearable personal monitoring device such as a pedometer or a personal health tracker generates personal data. Personal data may also be captured as part of the health record or as patient generated data, depending on the type and location of the device. For example, data from an EKG monitor used in the hospital are captured as part of the patient’s health record, whereas data from a home blood pressure machine are considered patient generated data.

Educational data include information from the school system relevant to public health and safety. These data generally include immunization records, communicable disease records and health and injury records from occurrences while the child is in school. Increasingly, children are dealing with chronic illnesses, such as asthma and diabetes, and require care during the school day from a school nurse. The longitudinal records on a child throughout their education can provide unique insights into their health and its impact on learning. Coordination with school nurses, social workers and others on the health team plays a key role in effective management of care across settings. Student health records provide important information contributing to a holistic picture of the patient status.
Use of Big Data for Personalized Healthcare

The movement from basic biology to genetics in healthcare applications provides the capability of determining who will respond to personalized healthcare. The volume requirement to match phenotype (who the patient is and their current conditions), with genotype (what genes they possess and what the genome structure is of their clinical condition) is beyond big data analytics used for measuring quality, costs, and effectiveness. The genetic analysis of one patient can produce up to one terabyte of data in a single encounter (Savage, 2014).

Patient care pathways requiring diagnosis and treatment based upon their genomes, multiplies the data needs by the number of times the genomes are measured to determine if the patient is improved, stabilizing, or deteriorating. Additional data included in the pathway analysis may include imaging data (X-ray, MRI, CT Scan), tissue biopsy data, staging of disease, laboratory data, clinical observations of signs and symptoms of improvement, toxicities to treatments, or rejections of transplant tissue. When multiplied by the number of patients with a certain condition (in the case of cancer, 1.7 million people diagnosed in 2013), the data growth becomes massive.

The power of computers is essential to sift through these massive amounts of data using data mining analytics to determine what genes are important to target for the patient’s disease. Cloud-based, open-source platforms for sharing and analyzing genomic data are now available. Translation of findings and recommendations for treatment will be available to clinical practice in the near future. Research in large database analytics can predict which patients will succeed in treatment, and those at risk for complications and toxicities (McCarthy, et al, 2013).

Informatics has become the essential component to bring personalized healthcare to the point of care, provide decision support for clinicians, and support EHR data, storage, retrieval, and management for tracking quality metrics that impact health outcomes (Garraway, 2013). Big data analysis of newborn screening is one of the key public health databases to help determine if evidence from screening improves health outcomes (McCormick and Calzone, 2015). Now that the cost of conducting genome sequencing has decreased to $1000 or less, the linkage of health, financial and genomic data can demonstrate the value of personalized healthcare.

Data Attributes

Timeframes describe the temporal aspects of data and denote the relative place in time the data characterize such as retrospective, real time or predictive. The timeframe of data has utility for purposes of analysis, understanding and value.

Transparency makes data available and accessible to stakeholders, creating value to consumers, providers and payers alike. Incentives for various groups to share data and capture the inherent potential of shared data must be aligned. Transparency of data can highlight and enable process improvements, decision making and cost comparisons.

Location of Data

Data location describes where the data reside. With the need to use a data element in multiple forms, and places, data may be accessed from their location via a relational database, for example. Data may reside on-site or “in the cloud” and can be located within a health system, a provider-based location or network, on a patient portal, in a patient’s home, in the community, workplace or school. Of course, data privacy and security elements are of great importance when addressing data location.

Data Movement

Data movement deals with the transmission of data. The security and protection of data is paramount when data is in motion as well as at rest. Data flow attributes describe the movement of data and include the data source, the data recorder, setting, and health record field. The ability of data to be communicated in a clear and useful manner, such as in a transfer to another facility or in consult with another provider, depends upon standards and key elements of concern, ideally using a shared format and common terms. In addition, data privacy and protection are critical elements in terms of appropriate protection, encryption, decryption and re-identification of data, depending on the purpose and use of the data. Standards for protection of data at rest as well as data in motion are beyond the scope of this paper, but are well documented. Data quality and consistency are important and rely upon appropriate data storage and the ability to extract data in a relational manner from large data repositories, data warehouses, on clouds, or platforms of health information exchange systems.
Legal Issues

Beyond clinical care and payment, big data has utility in supporting research, and in developing a greater understanding of trends and impacts of policy initiatives. However, there are myriad legal issues and challenges in bringing together data from disparate sources and leveraging electronic clinical data for purposes beyond treatment and payment. Among the challenges are legal, ethical and policy issues regarding the access, use, and disclosure of EHR data to improve healthcare quality, safety, effectiveness and efficiency (McGraw and Leiter, 2011).

There is a lack of clarity related to regulation of secondary uses of EHR data for research purposes, further complicated by reuse of de-identified data from groups of patients at multiple scales. Reliance on Internal Review Boards (IRB) presents challenges, as each adopts its own internal policies, especially in cases of multi-site research studies. Maintaining organizational control or stewardship over data, while at the same time making them available for secondary purposes, is challenging for researchers. Differences in state health information laws add to the complexity of the regulatory landscape.

The major categories of legal issues in health information as described in a Robert Wood Johnson Foundation project (Rosenbaum and Painter, 2005) are understood to exist regardless of whether health information is stored, disclosed, or transmitted in electronic form. These categories include the following:

1. Under what circumstances is it lawful to collect, store, use, and disclose information about the racial and ethnic characteristics of health plan members and healthcare patients?
2. Who owns health information: the consumer, provider, clinic or hospital? When must the owner of the health information provide access to others?
3. When is it proper to disclose patient information to third parties, particularly in the case of sensitive information such as psychiatric treatment notes?
4. Under what circumstances can or should the government compel the collection and reporting of personal health information?
5. Under what circumstances should health insurers and payers have the power to compel the collection and disclosure of health information as a condition of payment or performance measurement?
6. Should liability exist when payers and providers fail to use information to improve quality or reduce disparities, and under what circumstances should private litigants have legal access to data?
7. Should government have access to stored health information for law enforcement purposes, ranging from criminal prosecution under state and federal law to enforcement of civil rights laws barring discrimination?
8. Under what circumstances can health information be used for biomedical, behavioral, and health services research; and what types of conflict of interest notices must healthcare systems provide when personal information is to be used in research?
9. How should the law change to both encourage and accommodate the growth and rapid diffusion of new market technology and what conditions should be placed on this growth and diffusion?

While further exploration of these and other legal questions and issues pertaining to big data are beyond the scope of this paper, it is important to consider their impact when making recommendations for nursing.
Over several decades, the profession of nursing has worked to standardize nursing language, beginning with the introduction of the North American Nursing Diagnosis Association (NANDA) terminology in 1973. Several goals driving standardization of nursing language include: to facilitate accurate communication among nurses and other healthcare providers; to increase visibility of nursing interventions; to improve patient care; and, to enhance data collection to evaluate nursing care outcomes (Rutherford, 2008). As of this writing, there are 12 standard terminologies that support nursing practice as recognized by the American Nurses Association (ANA, 2012):

- NANDA International (NANDA-I)
- Nursing Interventions Classification (NIC)
- Nursing Outcomes Classification (NOC)
- Clinical Care Classification System (CCC)
- The Omaha System
- Perioperative Nursing Data (PNDS)
- International Classification for Nursing Practice (ICNP)
- Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT)
- Logical Observation Identifiers Names and Codes (LOINC)
- Nursing Minimum Data Sets (NMDS)
- Nursing Management Minimum Data Sets (NMMDS)
- ABC Codes

While these standard terminologies are in varying degrees of use in nursing practice, several barriers and challenges prevent widespread adoption. The multiplicity of standard nursing terminologies has resulted in limited adoption of any single standard. In a recent survey of nurses’ perceptions of the ANA’s recognized terminologies, respondents reported being most familiar with NANDA, NIC and NOC. However, of those participants who were familiar with a terminology, only NANDA was reported as being in use by more than 50% of respondents (Thede and Schwirian, 2013). Thede and Schwirian’s survey also suggested that the comfort level of respondents in using the standard nursing terminologies is low, and their opinions of their colleagues’ comfort in using a terminology is even lower. This may be attributed to a lack of education on the terminologies, or perhaps a lack of synonyms provided by the terminology. For example, a nurse documenting care to prevent venous thromboembolism in an EHR might want to chart “sequential compression device applied,” or “leg compression device initiated,” while the nursing terminology might present “apply compression therapy modalities.”

Compounding the issue of the disparate use of nursing terminologies is the availability of multiple research-based assessment scales and instruments across the United States and internationally. For example, several research-based falls risk assessment tools are in widespread clinical use, with no de facto standard identified; this inconsistency in use of instruments is sometimes present in different facilities, often within the same parent organization. The burden of cost for copyright permissions and/ or licensing of such instruments can also factor into the decision about which scale to use in an organization or in a health IT product. This lack of standardization makes comparison of assessment/instrument data very challenging, if not impossible.

Another area of concern with the current state of nursing terminologies is the difficulty in communicating with partner clinician stakeholders within and across care settings. Current practices to support Value-Based Purchasing and Accountable Care necessitate the need for interdisciplinary care teams, and clear communications among all clinicians caring for the patient (Flareau et al, 2011). While many organizations intend to implement an interdisciplinary documentation framework for assessments and care planning, many struggle to implement nursing specific terminologies within that framework, as the disciplines outside of nursing may find the language awkward and not relevant to their professions.
Challenges also exist with attempts to integrate multiple discipline-specific terminologies (e.g., Nutrition Care Process Terminology [eNCPT], NANDA, NIC, NOC, etc.) in a common documentation framework. The professions of physical, occupational and speech therapy lack their own standard terminologies. When forced by their organizations to use standard nursing terminologies in an interdisciplinary framework, therapists may find that the nursing terminologies are not normal clinical expressions for their discipline and are not sufficient to meet regulatory compliance standards or billing requirements for their scope of practice and the care provided. Specificity may also be lacking and additional annotations or other textual documentation may be needed in order to satisfy audit requirements.

One additional barrier to validating nursing’s contribution to care is the use of different measurement criteria for ‘at risk’ or various definitions for ‘within defined limits’ (WDL) to represent discrete values within the EHR. Today, the community lacks a universal, agreed upon, standard definition of the discrete data elements that constitute WDL. Each hospital or organization typically defines their own policy when documenting WDL. And, when that policy changes, there is no practical way to reference the meaning of WDL, for example in 1999 versus 2014 if the only data element stored is “WDL”. Further, use of WDL without storing the discrete data elements when recording assessment parameters negates the ability to see patient trends over time. Population health and big data are the future of value-based practice and comparative effectiveness research. Building validity is dependent on a full and complete set of data.

IV. Formalizing Clinical Data Relationships to Enhance Knowledge

The barriers and challenges of big data integration are not unique to industry or the nursing community and neither are the solutions to address them. The Scope and Standards of Practice for Nursing Informatics include a description of the data, information, knowledge, and wisdom continuum as a framework that can be applied to the specialty of nursing informatics (ANA, 2015). Matney, et al, provide additional insight into this framework by expounding on the philosophical foundations and implications for nursing practice (2011). A review of this framework allows for the definition of the barriers and challenges above as a gap in the knowledge layer. According to Matney, “Knowledge is derived by discovering patterns and relationships between types of information.” (Matney et al, 2011). The Workgroup supports efforts to promote standardization in the capture of data as well as standardization of the relationships between data. The Workgroup also supports research that promotes definition of tacit knowledge in order to expand our ability to formally capture and share expertise.

The plan to overcome the barriers noted above must allow clinical data to be universally collected and shared at the knowledge level in order to improve the wisdom and result in actions that will improve the quality of all areas of patient care. The key factors that must be taken into account when creating and enhancing the current knowledge layer include: authority, universality, usability, and funding.

In 2013, nurse thought leaders gathered at the University of Minnesota to discuss big data issues in nursing. One of the goals of this effort is to “work with information technology designers to include standardized nursing terminologies in their health IT systems, eliminating the need for each health system to map local codes to standards.” Industry is willing to leverage standardized terminologies, despite early evidence to the contrary (Giannangelo and Fenton, 2008), but struggles with a lack of clarity about which data sets should be incorporated into health IT systems. Knowledge transfer of clinical data among and across health IT systems is dependent on communally accepted standards for data capture, storage and transmission.

In addition to the ongoing work to adopt terminologies, additional efforts are needed to grow and map content-specific terminology sets. Current mappings between terminology sets are not complete or comprehensive. For example Kim, Hardiker, and Coenen recently examined mappings between ICNP® and SNOMED CT and found differences in content coverage leading them to suggest further enhancement to both terminology sets (2014). Health IT systems require comprehensive knowledge transfer; terminologies must support all types of documentation in every care domain area. Where additional subject specific terminologies have been developed, they should be mapped back to recognized terminology sets described above. The recognized terminology sets should be expanded to include subject specific terminology sets when feasible. This expansion will support knowledge transfer and secondary use of data for healthcare analytics.
Adoption of standardized terminology sets will also enhance usability for the wide variety of nurses who interact with health IT systems for data entry, as well as for secondary data use. Standardization at the knowledge layer through mapping to recognized terminology sets also promotes data interoperability, information search and retrieval, automated inference, natural language processing, and local mappings to meet colloquial language needs. The recognized terminologies should be made available to international standards organizations for translation and further mapping.

V. Identify Critical Differences in Documentation Relevant in the Context of Nursing Outcomes

To capture the value of nursing practice and demonstrate the impact on clinical outcomes, it is important to consider the differences in electronic documentation systems and approaches. The information derived from the process of clinical documentation defines the practice along with the care and treatment provided as part of the care delivery process. This information is used as a means to analyze practice patterns, identify trends and support the monitoring of clinical performance which is more critical than ever in today’s healthcare environment.

While electronic documentation systems have been in use for many years there remains wide variation in the specific documentation systems that clinicians use. This variation may be attributed to the needs of different specialties or settings resulting in the subsequent challenge for information exchange from one system to another. Systems may still rely on free text, or narrative documentation which limits the ability to use analytics and capitalize on big data for research and knowledge generation. Many health IT systems include a documentation system or module but, during the implementation process, the healthcare system may undertake extensive localized customization; this creates further disparity in terms and standardization.

While the clinical assessment and care planning process and its basic content areas are widely accepted and acknowledged there still remains considerable variation in what is collected and documented. While this may be done to address gaps in product content or to meet the practice needs of the organization, it is also influenced by the interpretation of regulatory and accreditation requirements. Additionally, there are multiple instruments and scales in use (i.e., fall risk, skin assessments), which make it challenging to align and standardize documentation. Within each organization it is important to manage the overall governance of documentation to facilitate adherence to as much standardization as possible.

Collaboration across healthcare organizations promotes coordinated care and improved outcomes for patients. However clinical disciplines may document in different ways, in different systems, using different terminologies. Systems must account for an interdisciplinary approach to documentation that supports data that can be standardized, shared and reused, facilitating the communication of the same information across disciplines and settings. The Workgroup promotes the use of standardized and accepted terminologies that can address the documentation needs of the entire care team regardless of care setting. Health IT systems must also address the need for alignment on standardized terminologies that can be mapped to industry standards for purposes of providing comparable data that can be shared across systems to support the evaluation of clinical outcomes. This alignment also requires addressing usability challenges related to what clinicians find acceptable in their documentation practice versus the need for reference terminologies that support interoperability and reporting.

As health IT continues to advance and evolve the complexity of quality measures and quality reporting also continues. The pace of these requirements and the timeframes in which organizations must adopt, measure, and report on them is extremely challenging. The documentation performed by nurses and other members of the care team enables the ability to measure and monitor the defined eMeasures across quality and performance programs. It is important to consider the data necessary to support the measure and its impact on clinician workflow – is it part of acceptable clinical practice? Measurement of quality data including meaningful use clinical quality measures and nursing sensitive performance indicators is a complex process. And data needed to populate these measures come from multiple sources—some of which are not included in the EHR today. Therefore, alignment on the data to be collected, the way in which they are structured, the supporting terminologies and the ability to share data across settings and organizations is critical.
Managing the alignment of health IT system updates to support new enhancements, versions and upgrades is increasingly complex. Interdependencies and aggressive timeframes make this extremely challenging for organizations, health IT suppliers and the many industry partners involved in implementing health IT. To effectively and successfully implement a system update it is important to step back and consider the process from end to end. Industry must address all aspects of the standard product development life cycle to ensure that the health IT system meets defined requirements, is stable and works as designed. Quality management systems guide and oversee the development life cycle process to maintain quality controls. As the product update or version is rolled out health IT suppliers install the health IT system across their customer base, assisting customers with workflow process and redesign, implementation and deployment. Healthcare systems are also part of the systems life cycle. They must address the evaluation and analysis of the updates and their impact to clinical workflow and patient safety, create a project plan for the update, complete a technical assessment, perform education and execute on the deployment of the health IT system.

Following the systems life cycle can help to ensure that the implemented system supports clinical practice and addresses key aspects of the Triple Aim - improving the patient experience of care, improving the health of the population and reducing the per capita cost of healthcare. Current industry requirements and timeframes have created a complexity that presents challenging impacts from both a cost and resource perspective for all involved. Health IT suppliers and their customers must work together to manage, support and align multiple software versions and health IT systems. Competing projects and business objectives make it increasingly difficult to manage all of this activity without facing the potential of negative consequences. Balancing industry requirements with a realistic approach to the development, implementation and deployment of health IT will provide the most effective and efficient path forward.

As national programs continue to evolve it is important to learn from the experiences of initiatives such as Meaningful Use and clinical quality measures efforts. Determining best practices for advancing this work while considering the impact to the clinicians’ workflow as well as practical considerations will yield new approaches offering untapped potential in meeting clinical quality outcomes.

One additional challenge to leveraging big data for nursing is the incongruence of taxonomies and ontologies used in quality eMeasure reporting. Quality eMeasure specifications for hospitals were introduced as part of the American Recovery and Reinvestment Act of 2009 (ARRA, 2009). Hospitals began collecting data using these initial quality measure electronic specifications as required by ARRA, even though these e-specifications contained errors in value sets and measure logic, and had not been piloted or field tested. Since that time, the Centers for Medicare & Medicaid Services (CMS) and ONC have introduced improvements to align quality programs and to improve the development of eMeasures specifications. Some of these improvements include creation of a Quality Data Model; Value Set Authority Center; and Measures Authoring Tool. Despite these efforts quality eMeasures continue to include value set inconsistencies, logic errors and timing issues. These inconsistencies result in challenges with data collection within normal clinician workflows, not to mention frustration for clinicians.

Standardized measurement and reporting of clinical data enables the identification and implementation of best practices that contribute to high quality, safe, and cost-effective patient care (McCormick, et.al, 2015). Health IT systems that generate structured coded data as a byproduct of patient care are needed to populate eMeasures (Dykes and Collins, 2013). The advent of EHRs facilitates standardized reporting and aggregation of clinical quality measures (CQMs). Beginning in 2014, the United States government will require electronic submission of CQMs (CQM, 2013) for quality reporting. In July of 2012 the ANA convened the 2nd Tipping Point for EHR (TP-EHR) meeting. This meeting brought together experienced leaders in standards development, policy development, and quality measurement to explore this topic, and the TP-EHR working group was launched.
The nursing information model developed by two healthcare organizations with complete health IT systems, Kaiser and the Veterans Administration (Kaiser-VA), was studied as a model for nursing. The initial Kaiser-VA work on Pressure Ulcer assessment and prevention was created to share data across different EHRs (KP-VA Nursing Collaborative, 2011). While Kaiser-VA had previously completed much of the work, eSubmission of quality measures had not been considered; thus began the organized TP-EHR working group including representation from the ANA, National Database of Nursing Quality Indicators (NDNQI®) researchers at the University of Kansas, School of Nursing, the Cerner Corporation and other professional societies.

In order to report CQMs from an EHR, e-specifications must be developed for each CQM. The e-specifications include the data elements, logic and definitions for that measure in the form of a Health Level Seven (HL7) standard known as the Health Quality Measures Format (HQMF). This standard represents a clinical quality measure that can be recorded in the EHR so that the data can be sent or shared electronically (Warren, 2013). Clinical quality measures were designed as tools to help measure and track the quality of healthcare provided. They are considered the foundation of quality improvement programs and include much of the public reporting seen in healthcare today. eMeasures provide the opportunity to improve the capture and reporting of clinical quality and leverage the information collected in EHRs. However, these efforts have highlighted many challenges in making the shift from traditional chart extraction to deriving eMeasures through health IT systems.

Many organizations have multiple electronic systems and must manage a multitude of IT requirements, upgrades, maintenance and support on an ongoing basis. This is a complex environment with many interdependencies and Meaningful Use eMeasure requirements have added complexity that remains challenging for the industry at large. Learning gained from the ONC Meaningful Use program has informed many discussions as the program evolves; this specifically includes advancements with eMeasures.

Several factors must be considered in the development of eMeasures - what data need to be collected, where they are collected, who collects them, and are they available electronically or from some other source. Clinical quality eMeasures must support evidence-based, cost effective care that follows clinical practice and minimizes the impact on clinicians at the front-line. Considerations must take into account whether or not the information is already part of the normal workflow of the clinician and if the eMeasure logic works.

The TP-EHR working group developed a model for converting paper-based quality measures into eMeasures, providing validity, reliability, and feasibility for each measure and formatting the extracts to support eSubmission for recognition by the National Quality Forum (NQF). Accurate, interpretable data efficiently gathered and communicated without subjective human interpretation was foundational to the eMeasure development. In 2013 the NQF commissioned feasibility studies to be conducted in hospitals using three different health IT systems (Warren, 2013). The feasibility studies quickly demonstrated that the ability to capture data does not necessarily equal data quality. Structured placeholders in EHRs do not always ensure population of the fields, even when the data are present. The data are not consistently recorded in the specific format or field the eMeasure expects (Kennedy, Watt, and Hamlin, 2012).

The TP-EHR working group used models and standards already commissioned by the NQF to harmonize quality measures and facilitate their evolution into eMeasures. The Quality Data Model, based on the HL7 HQMF provides a standard way to clearly and consistently describe clinical concepts in quality measures and for sharing information across EHRs and other clinical systems. The Quality Reporting Document Architecture and the Measure Authoring Tool supported documentation and submission of measures for recognition. Each of these initiatives required significant time to learn the standard and/or process and then to translate into the work of the NDNQI measure set for pressure ulcer data extraction.

The industry continues to provide input and feedback to the programs focused on clinical quality eMeasures and has consistently voiced the need for alignment of measures, their data elements and value sets to improve consistency in design and to alleviate complex and challenging reporting requirements. As eMeasures evolve, the program must ensure their feasibility and value with well-defined field testing prior to rollout and inclusion in regulation. Changes in program requirements reduce expected development timelines--often requiring health IT suppliers to repeatedly reassess development plans. Timelines should be evaluated and adjusted to support consumption by health IT suppliers and clinicians in an approach that positions all parties to get the most out of the information gathered and to have a meaningful impact on quality outcomes. Additionally the Workgroup supports alignment across industry groups to drive practical guidance relative to clinical quality eMeasures so that the objectives of these programs are met with success.
As nurses consider the advancement of nursing sensitive eMeasures, lessons learned and approaches of the Meaningful Use program clinical quality eMeasures should be carefully evaluated. The ability to gain from these experiences and leverage knowledge gained will positively position new eMeasures with direct nursing impact.

The use of big data offers tremendous potential for healthcare, and its opportunity to accelerate the growth and adoption of new knowledge to make a real impact on health and care outcomes is limitless. Clinical quality eMeasures are integral to these efforts and as they evolve they will become essential as analytics and big data initiatives rely on the information they provide. Nursing is well positioned to play a major role in these efforts to shift from a focus on collecting data, to understanding what the data mean and determining new practices based on evidence that will have a profound impact on the quality of care nurses deliver as well as patient outcomes.

VIII. Recommendations

Promote Standards and Interoperability
The ability for nurses to make optimal clinical decisions is dependent upon having access to accurate, real-time information regardless of care setting. Data must also be structured in standard ways to enable sharable, comparable information. The value of consistent and accurate data can be realized through interoperable systems, advances in EHRs and alignment on standards and terminologies. Knowledge transfer of clinical data among and across health IT systems is dependent on communally accepted standards for data capture, storage and transmission.

1. Nurses should promote the use of standardized and accepted terminologies that address the documentation needs of the entire care team regardless of care setting. All care delivery settings should create a plan for implementing an ANA-recognized nursing terminology that is mapped to national standards i.e. SNOMED CT or LOINC.

2. Nurses should recommend consistent use of research-based assessment scales and instruments that are standardized through an international consensus body. The lack of standardization makes comparison of data challenging and adds to the burden of cost for copyright permissions and/or licensing of such instruments.

3. The ANA-recognized nursing terminologies should be consistently updated and made available to international standards organizations for translation and complete, comprehensive mapping.

4. Minimize use of free text documentation. When ‘within defined limits’ is used, discrete data elements should be stored within the EHR to enable decision support, research, analytics and knowledge generation.

Advance Quality eMeasures
Measurement of quality data, including Meaningful Use clinical quality measures and nursing sensitive performance indicators is a complex process. The data needed to populate these measures come from multiple sources, some of which are not available in the EHR today. Therefore, alignment on the data to be collected, how they are collected, and the terminologies needed to support them is critical to the ability to share data across settings and organizations. As nurses consider the advancement of nursing sensitive eMeasures, the lessons learned from the Meaningful Use program on clinical quality eMeasures should be carefully evaluated. The ability to gain from these experiences will positively position new eMeasures with direct nursing impact. Clinical quality eMeasures are integral to these efforts and, as they evolve, will become essential for enabling analytics and big data initiatives to generate new evidence and knowledge.

1. Efforts to develop and design quality eMeasures must ensure the data to be collected, and measured are aligned with the clinician’s workflow, not as additional documentation.

2. To advance nursing sensitive quality eMeasures, paper measure sets must be evaluated for appropriateness, and expectations set for which data should be collected, how the data are collected and the required terminologies to be used.

3. Initiatives and programs that define and promote new quality eMeasures and their requirements should allow time for testing and piloting with defined timeframes that consider all stakeholders.

4. Clinical quality eMeasures must support evidence-based, cost effective care that follows clinical practice guidelines and minimizes the negative impact on clinicians’ workflow.
Leverage Nursing Informatics Experts

Nursing informatics (NI) is a specialty that integrates nursing science with multiple information management and analytical sciences to identify, define, manage, and communicate data, information, knowledge, and wisdom in nursing practice (ANA, 2015). NI supports nurses, consumers, patients, the interprofessional healthcare team, and other stakeholders in their decision-making in all roles and settings to achieve desired outcomes. This support is accomplished through the use of information structures, information processes, and information technology (ANA, 2015). The application of nursing informatics knowledge is essential to enable capturing health and care data in a structured way to accomplish the vision of accurate, reliable, clinically meaningful measurement across systems and settings of care.

1. Healthcare organizations should utilize nurse informaticists who will provide valuable insight into concept representation, design, implementation, and optimization of health IT to support evidence-based practice, research, and education.
2. To achieve the desired outcomes, nurse informaticists should have formal informatics training, education and certification.

IX. Conclusion

Healthcare organizations anticipate that big data and the use of analytics will reduce escalating healthcare costs and improve the quality of care. The opportunity to capitalize on the vast amount of health and care data that are captured and stored is now a reality. Healthcare organizations are taking on more risk for managing their patient populations and to do so they need more data on how well they are performing including the ability to identify patterns and determine which treatments are most effective for which patients. Cloud computing capabilities have made big data accessible to many organizations. As they consider how to better use this information they will have an eye on new research and evidence-based treatments, including the potential for personalized healthcare.

Big data offers tremendous opportunity to accelerate the growth and synthesis of new knowledge to make a positive impact on nurses and the individuals and populations they serve. Understanding the principles, barriers, challenges and implications of big data in nursing will help us more rapidly reach the Triple Aim of improving the patient experience of care, improving the health of the population and reducing the per capita cost of healthcare.

X. References


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XI. Acknowledgement

The authors would like to thank Nick Hardiker, RN, Ph.D., and Kathleen A. McCormick, Ph.D., RN, FAAN, FACMI, FHIMSS for their invaluable contributions to this paper.