eMeasure Development Process Exemplar

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PURPOSE

This report identifies the process used when developing a quality eMeasure. An example is provided using a measure from the National Database of Nursing Quality Indicators (NDNQI) while under the auspices of the American Nurses Association (ANA).[1*] The national emphasis on electronic health records (EHRs), the Learning Health System and the health informatics discipline have had a dramatic impact on the skill set a measure developer must possess. ANA considers the process that was applied to the hospital-acquired pressure ulcer to be an exemplar that can be used to support the development of other eMeasures.

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eMeasure Development Process for NQF: Recognition to be used by NDNQI®

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eMeasure Development Requirements

Overview

In August 2010, the first Tipping Point collaboration met. This was a self-organized group that came together to determine how to influence public policy to highlight the contributions nurses make to patient outcomes and safety. Members had complementary skill sets and connections to succeed in this task — standards development experience, lobbying experience, policy development experience and quality measure experience. The major outcome of the meeting was the decision to use the model developed by a Kaiser-VA collaboration to drive policy influencing and development with patient data, especially the regulations around Meaningful Use. Their initial work on pressure ulcer assessment and prevention was used to test the feasibility of this approach. While Kaiser-VA had completed much of the work, quality measures had not been considered. Participants decided to test the methodology by using it on the NDNQI Pressure Ulcer Indicator.

Subsequently, another group of nurses began to work with Health Level Seven International (HL7) to develop a Domain Analysis Model (DAM) of pressure ulcers. Many of the nurses in this group worked on the Kaiser-VA project. This group contacted the International Health Terminology Standards Development Organization Nursing Special Interest Group to assist with mapping SNOMED CT, the global language of healthcare, to the terminology used in the DAM. The group also approached Logical Observation Identifiers Names and Codes (LOINC) to add the Braden Scale. Later, NDNQI approached LOINC to add the Norton Scale, as it is one of the scales needed for the eMeasure. The other pressure ulcer risk scales were already in LOINC.

As this project evolved, more complexity was added. The National Quality Forum (NQF) was asked to harmonize quality measures and facilitate its evolution into eMeasures. Thus, NQF developed the Quality Data Model (QDM), based on HL7 standards for Health Quality Message Format (HQMF), Quality Reporting Document Architecture (QRDA) and Virtual Medical Record (vMR) for Clinical Decision Support, and the Measure Authoring Tool (MAT) to document and submit measures for recognition. The MAT is now managed by the Centers for Medicare and Medicaid Services (CMS). The Office of the National Coordinator for Health Information Technology (ONC) developed, in conjunction with CMS, regulations on how eMeasures were to be used in data interoperability and care reimbursement strategies. ONC and the National Committee on Vital and Health Statistics designated the standard terminologies to be used in the measures. The National Library of Medicine (NLM) opened the U.S. SNOMED CT extension service so that new concepts could be submitted for inclusion in SNOMED CT. Other terminologies have their own updating services. Each of these initiatives required significant time to learn the standard and/or process and then to translate into the work of NDNQI.

Steps to develop an eMeasure

2.1 • Overview

The following description of developing an eMeasure can serve as an exemplar for future eMeasure development. The process is based on lessons learned from working with ANA, the Wound Ostomy and Continence Nurses Society (www.wocn.org), the National Pressure Ulcer Advisory Panel (www.npuap.org), the National Quality Forum (NQF) (www.qualityforum.org), HL7 (www.hl7.org) and the NLM (http://nlm.nih.gov).

2.2 • Select the quality indicator for conversion to eMeasure

The first step is to select an existing indicator for conversion or to identify a new indicator for development. Criteria to use in this decision are:

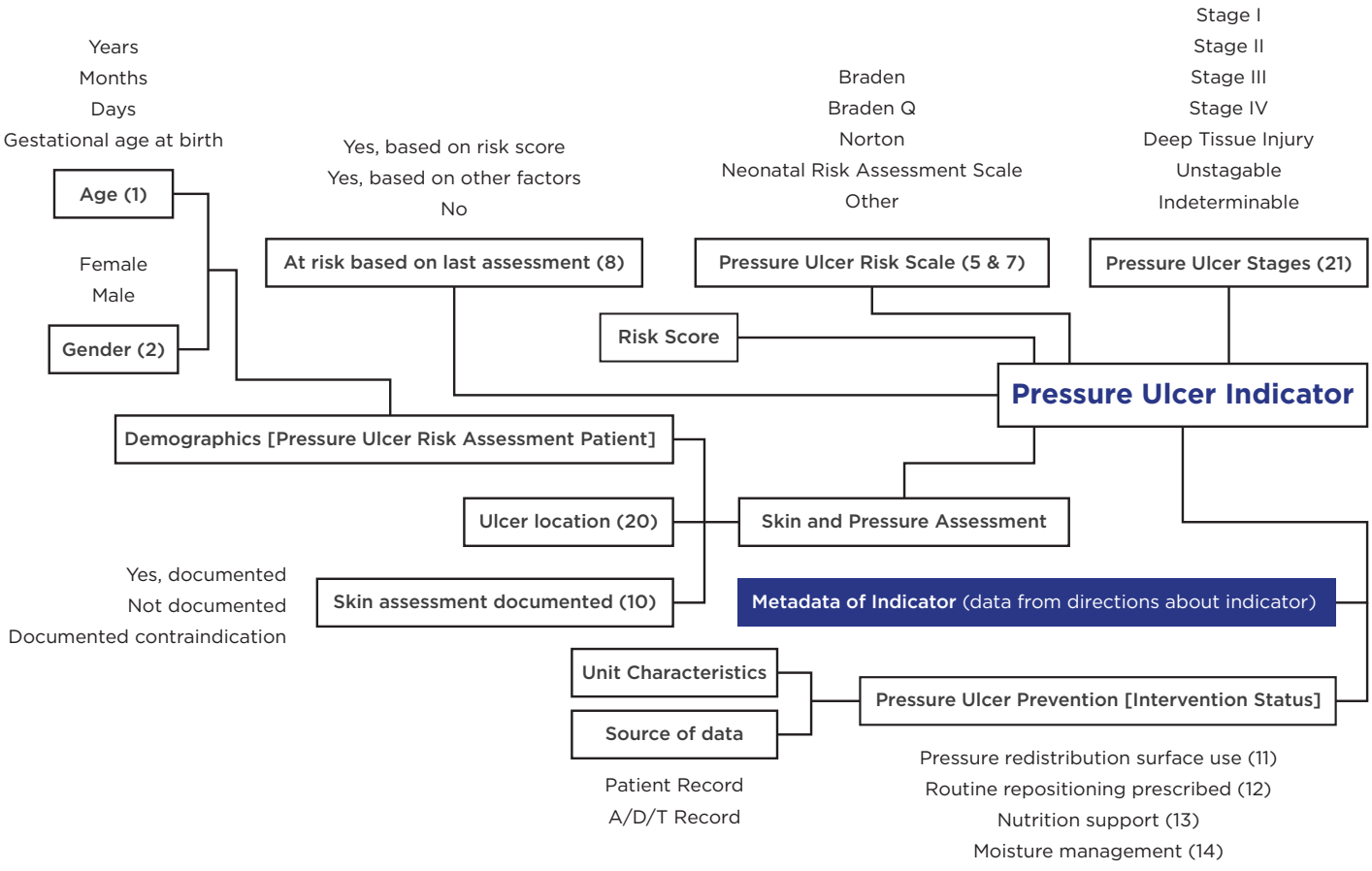
- Sufficient body of knowledge and research/evidence within the domain.
- Funding for a new indicator.
- Alignment with national quality and reimbursement priorities.
- A well-qualified measure development team:
  - A team leader with research skills to conduct the reliability, validity and feasibility studies.
  - IT personnel for the design of the submission containers and update of the submission website.
  - Analysts to ensure that a data dictionary is designed to meet analysis needs.
  - Informaticists to design a data dictionary and interpret evolving health information technology standards.
  - Informaticists to map terminology and submit requests for new terminology to the various required terminology developers.
- Identified clinical experts in the field may include a professional nursing society (the {specify the clinical areas} Advisory Committee).
- Identified technical experts (the Technical Expert Panel).
- Member hospitals willing to participate in the reliability, validity and feasibility studies.
- Vendors willing to participate in the reliability, validity and feasibility studies.

2.3 • Review content domain for the eMeasure

2.3.1 • Evaluate the manually extracted indicator

This step is taken when an existing indicator is selected for eMeasure development (if a new eMeasure is being developed, skip this step). This step focuses only on the data and not the directions for collecting the data (managing the complexity of the indicator).

- Review the data collection form.
- Identify the data to be collected.
- Develop a mind map of the data elements to be collected plus the value set for each data element.



2.3.2 • Evaluate any new clinical and research evidence

Conduct a literature review to look for relevant research and expert opinions. Professional nursing organizations should be consulted, as well as any advisory panels. Update the data collection form and the mind map with the obtained information.

2.3.3 • Evaluate what is being collected to calculate the metric for the indicator

Determine what is being measured and whether it can be extracted (queried) from an electronic database such as the EHR, a discharge/transfer/admissions database or other such database used in health care. This new data element may not be what was measured in the manual extraction. For example, manually you may check that something was done or not done, or was done within the past 24 hours — this takes human judgment to determine. Electronically you may query for the date/time stamp of the data documented or other data elements resulting from a transaction (charting). For example, the date/time stamp demonstrates that it was done and then you can calculate the time frame in which it was done. Then determine if the new data element still facilitates the calculation of the metric and national benchmarking.

Focus on indicator data that comes from a database and not what is currently being manually extracted.

2.4 • Review all relevant health care informatics standards

The standards space is evolving at light speed and takes knowledgeable, committed individuals to monitor the activity. These individuals must understand nursing data representation, how to influence the standards process to support nursing data, and how to apply the standards to eMeasure development. This requires participating in the various standard development organizations (SDOs).

2.4.1 • SDOs and their roles in eMeasure development

The following is a list of SDOs to be monitored:

- HL7 (www.hl7.org). While you don't need to be a member to participate in the development of standards, you do need to be a member to vote on the standards. NDNQI is a member and has two part-time consultants participating in standards development. CMS and ONC require all eMeasures developed to qualify for Meaningful Use be in compliance with the relevant HL7 standards. There are several projects of interest to eMeasure development, plus the harmonization effort between them (since the QRDA, HQMF and vMR were developed in isolation of each other).
    - QRDA (www.hl7.org/implement/standards/product_brief.cfm?product_id=35). This "document describes constraints on the Clinical Document Architecture (CDA) header and body elements for QRDA documents. QRDA is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data." The CDA is an XML structure.

- HQMF (www.hl7.org/implement/standards/product_brief.cfm?product_id=97). This is "a standard for representing a health quality measure as an electronic document. A quality measure is a quantitative tool that provides an indication of an individual or organization's performance in relation to a specified process or outcome via the measurement of an action, process or outcome of clinical care. Quality measures are often derived from clinical guidelines and are designed to determine whether the appropriate care has been provided given a set of clinical criteria and an evidence base. Quality measures encoded in the HQMF format are referred to as 'eMeasures.'"
- vMR (www.hl7.org/implement/standards/product_brief.cfm?product_id=338). The vMR is "a data model for representing the data that are analyzed and/or produced by CDS [clinical decision support] engines. The term vMR is used in the CDS community to refer to a simplified representation of the clinical record that is suitable and safe for a CDS knowledge engineer to directly manipulate in order to derive patient-specific assessments and recommendations." Collection of quality indicator data can be seen as CDS.
- Fast Health Interoperable Resources (FHIR) (www.hl7.org/implement/standards/fhir). This is a new project and not much is known. HL7 describes it as follows: "FHIR solutions are built from a set of modular components called 'Resources.' These resources can easily be assembled into working systems that solve real-world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts — mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional health care providers and much more." It is the EHR sharing component that puts it on the watch list for eMeasure development.

- Standards and Interoperability (S&I) Framework (www.siframework.org). The S&I Framework is a collaborative community of participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information. The S&I Framework uses a set of integrated functions, processes and tools that enable execution of specific value-creating initiatives.
  - Clinical Quality Framework Initiative (http://wiki.siframework.org/Clinical+Quality+Framework+Initiative). The scope of this group is to identify, define and harmonize electronic standards that promote integration between CDS and electronic clinical quality measurement (eCQM) in the areas of:
    - Metadata: Identify common metadata across the two domains and harmonize the representation of that metadata.
    - Quality information data model: Develop a common quality information data model that supports the requirements of both eCQM and CDS.
    - Logical expression language: Develop a common expression language that can be used to define both CDS and eCQM logical expressions.

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2.4.2 • National regulations and requirements for eMeasures

CMS

- Quality Data Model (QDM) (www.healthit.gov/quality-data-model). The QDM describes clinical concepts in a standardized format to enable electronic quality performance measurement. The model is the backbone for representing criteria used in quality measures that are currently used by stakeholders involved in electronic quality measurement development and reporting. There is a user group for the public to participate in the evolution of the QDM. It is necessary that NDNQI participate, as the QDM is the foundation for all eMeasure work and supports submission for recognition of the eMeasure.
- MAT (www.emeasuretool.cms.gov). The MAT is "a web-based tool that allows measure developers to author eCQMs using the QDM. The tool provides the capability to express complex measure logic and export measures in several formats, including a human-readable document that can be viewed in a web browser, the fundamental green eCQM XML syntax and an eCQM HQMF XML document for integration with EHRs. The data expressed in the tool by users serves as the input for the 'transform' process [that] ultimately supports the defined export files." Note the standards used in the MAT come from HL7. Comments can be sent to the MAT help desk and may influence the evolution of this tool.
- BONNIE (https://bonnie.healthit.gov/users/sign_in). This is a new tool developed by CMS and may be of use to NDNQI, though it has not been used yet. BONNIE is "a testing tool for eCQMs designed to support streamlined and efficient pretesting of eCQMs used in the Meaningful Use program. This tool is designed for use by measure developers as part of their development processes to provide specific feedback on the behavior of the CQM logic."

NLM

- Value Set Authority Center (VSAC) (https://vsac.nlm.nih.gov). The VSAC provides downloadable access to all official versions of vocabulary value sets contained in the 2014 Clinical Quality Measures and from indicators developed in the MAT. The tool constrains the use of terminology for the value sets of each eMeasure to conform to the federal requirements: SNOMED CT, LOINC, RxNORM, ICD-9-CM and Current Procedural Terminology (CPT). At some point in the future, ICD-10-CM will replace ICD-9-CM.
  - Access to the VSAC requires a free Unified Medical Language System® (UMLS) Metathesaurus License (available at https://uts.nlm.nih.gov/license.html).
  - It is expected that any use of value sets is consistent with these licensing requirements and copyright protections.
  - 2014 Clinical Quality eMeasures (eCQMs) downloads are available at https://vsac.nlm.nih.gov/#.
- RxNORM is maintained by the NLM. This is a drug terminology system.
- The U.S. extension of SNOMED CT is maintained by the NLM. New concepts can be requested at the U.S. SNOMED CT content Request System, https://uscrs.nlm.nih.gov/main.xhtml.
  - Access requires a free UMLS Metathesaurus License (available at https://uts.nlm.nih.gov/license.html).

- LOINC (http://loinc.org) manages the terminology for laboratory and assessment tools. Requests can be made for the addition of content.
- ICD-9-CM is managed by the National Center for Health Statistics (NCHS) (www.cdc.gov/nchs/index.htm). ICD-9 and ICD-10 are developed by the World Health Organization (WHO). NCHS modifies the ICD terminology to meet U.S. needs. Addition of terms and codes must be done through the WHO process.
- CPT is developed by the American Medical Association and has processes for adding new terms and codes (www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page).
- ONC (www.healthit.gov) is the principal federal entity charged with the coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.
- NQF (www.qualityforum.org). CMS has engaged NQF to provide a recognition process for eMeasure developers to use. Once a measure has been recognized, CMS is willing to consider it for Meaningful Use. This is the goal of eMeasure developers.
    - Several conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards.
        - The measure is in the public domain or a measure steward agreement is signed.
        - The measure owner/steward verifies there is an identified responsible entity and a process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least as often as every three years.
        - The intended use of the measure includes both accountability applications (including public reporting) and performance improvement to achieve high-quality, efficient health care.
        - The measure is fully specified and tested for reliability and validity.
        - The measure developer/steward attests that harmonization with related measures and issues with competing measures have been considered and addressed, as appropriate.
        - The requested measure submission information is complete and responsive to the questions so that all the information needed to evaluate all criteria is provided.
- If all conditions for consideration are met, measures are evaluated for their suitability based on standardized criteria in the following order:
    - Importance to measure and report.
    - Scientific acceptability of measure properties.
    - Feasibility.
    - Usability and use.
    - Related and competing measures.

Develop the eMeasure and data dictionary

Once the manually extracted data collection tool review, the evidence update, and the review of new standards and regulations have been completed, a data dictionary needs to be developed. Two pilot hospitals and one EHR vendor need to be recruited to determine whether the data elements in the dictionary can be extracted from their EHRs. The data dictionary provides guidance to the measure team and the pilot hospitals for the development of queries of the EHRs. The hospitals need to have the resources for this pilot, as queries may have to be developed and run numerous times before the data dictionary is refined. Depending on the results of the pilot, the dictionary may need to be revised.

3.1 • Data dictionary format

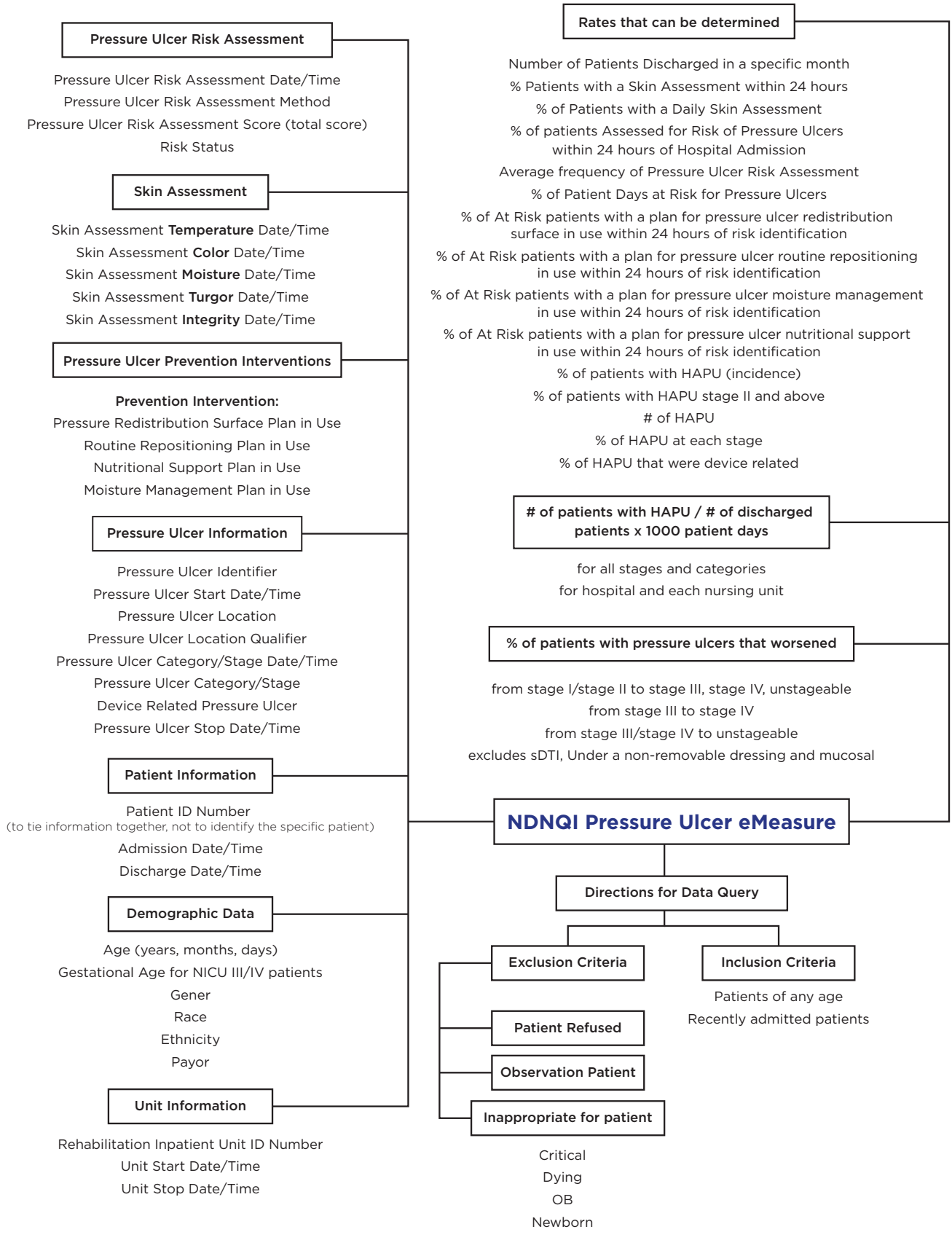
The data dictionary is developed using a form created in Excel.

Data Element Name	Field Name	Description	Data Type	Value Set	Additional Type Information	Mandatory

3.2 • Revise the previous mind map

Once the data dictionary is finalized, a new mind map needs to be developed. The purpose of this map is to focus on the data elements and their value sets. Again, the purpose is to hide the complexity of the measure and just look at the data to ensure that it is what you want. The following is an example of this type of revision from the figure in 2.2.1. (See page 11.)

Once the data dictionary is finalized, a new mind map needs to be developed. The purpose of this map is to focus on the data elements and their value sets.


Pressure Ulcer Risk Assessment
Pressure Ulcer Risk Assessment Date/Time
Pressure Ulcer Risk Assessment Method
Pressure Ulcer Risk Assessment Score (total score)
Risk Status
Skin Assessment
Skin Assessment Temperature Date/Time
Skin Assessment Color Date/Time
Skin Assessment Moisture Date/Time
Skin Assessment Turgor Date/Time
Skin Assessment Integrity Date/Time
Pressure Ulcer Prevention Interventions
Prevention Intervention:
Pressure Redistribution Surface Plan in Use
Routine Repositioning Plan in Use
Nutritional Support Plan in Use
Moisture Management Plan in Use
Pressure Ulcer Information
Pressure Ulcer Identifier
Pressure Ulcer Start Date/Time
Pressure Ulcer Location
Pressure Ulcer Location Qualifier
Pressure Ulcer Category/Stage Date/Time
Pressure Ulcer Category/Stage
Device Related Pressure Ulcer
Pressure Ulcer Stop Date/Time
Patient Information
Patient ID Number
(to tie information together, not to identify the specific patient)
Admission Date/Time
Discharge Date/Time
Demographic Data
Age (years, months, days)
Gestational Age for NICU III/IV patients
Gener
Race
Ethnicity
Payor
Unit Information
Rehabilitation Inpatient Unit ID Number
Unit Start Date/Time
Unit Stop Date/Time
Rates that can be determined
Number of Patients Discharged in a specific month
% Patients with a Skin Assessment within 24 hours
% of Patients with a Daily Skin Assessment
% of patients Assessed for Risk of Pressure Ulcers within 24 hours of Hospital Admission
Average frequency of Pressure Ulcer Risk Assessment
% of Patient Days at Risk for Pressure Ulcers
% of At Risk patients with a plan for pressure ulcer redistribution surface in use within 24 hours of risk identification
% of At Risk patients with a plan for pressure ulcer routine repositioning in use within 24 hours of risk identification
% of At Risk patients with a plan for pressure ulcer moisture management in use within 24 hours of risk identification
% of At Risk patients with a plan for pressure ulcer nutritional support in use within 24 hours of risk identification
% of patients with HAPU (incidence)
% of patients with HAPU stage II and above
# of HAPU
% of HAPU at each stage
% of HAPU that were device related
# of patients with HAPU / # of discharged patients x 1000 patient days
for all stages and categories
for hospital and each nursing unit
% of patients with pressure ulcers that worsened
from stage I/stage II to stage III, stage IV, unstageable
from stage III to stage IV
from stage III/stage IV to unstageable
excludes sDTI, Under a non-removable dressing and mucosal
NDNQI Pressure Ulcer eMeasure
Directions for Data Query
Exclusion Criteria
Patient Refused
Observation Patient
Inappropriate for patient
Critical
Dying
OB
Newborn
Inclusion Criteria
Patients of any age
Recently admitted patients

Determination of the logic and metrics for the eMeasure

4.1 • Determine the value set(s)

For each element in the data dictionary that requires a value set, a terminology map needs to be developed. The QDM specifies the federally mandated terminology to use for the value set. The most common terminologies for nursing are SNOMED CT and LOINC. The following online browsers can help find the official terminology and its code: http://browser.ihtsdotools.org and http://search.loinc.org. If the concepts are not in the terminologies, contact the developers and request their addition (see 2.3.2 for how to do this). A sample map* is given below:

NDNQI Term	Fully Specified Concept Name in SNOMED CT	SNOMED CT Code
Hospital-acquired pressure ulcer present	Hospital-acquired pressure ulcer (disorder)	446261004
Pressure ulcer stage	Pressure ulcer stage (observable entity)	420592002
Pressure ulcer stage I	Pressure ulcer stage 1 (disorder)	421076008
Pressure ulcer stage II	Pressure ulcer stage 2 (disorder)	420324007
Pressure ulcer stage III	Pressure ulcer stage 3 (disorder)	421927004
Pressure ulcer stage IV	Pressure ulcer stage 4 (disorder)	420597008
Pressure ulcer unstageable	Unstageable pressure ulcer (disorder)	421594008

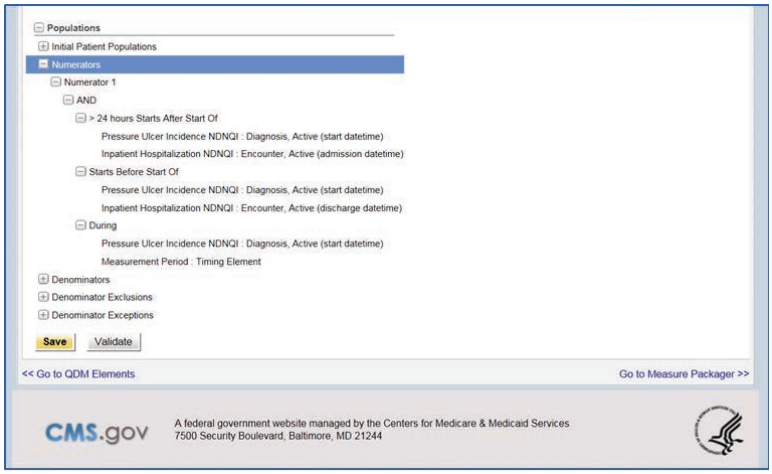
**Used with permission of Press Ganey.*

The mind map becomes invaluable in determining the terminology/concepts needed.

For each element in the data dictionary that requires a value set, a terminology map needs to be developed.

4.2 • Develop the logic statements

The team collaborates with the measure analysts and statisticians to specify the logic of calculating the eMeasure. This activity may identify the need for more terminology to populate the numerator and denominator of the metrics. The following shows a numerator specification:



4.3 • MAT and the VSAC

4.3.1 • MAT components

The next step is to enter the eMeasure into the MAT (www.emeasuretool.cms.gov). The information needed to complete this process is:

eMeasure title:
Abbreviated name:
Measure scoring:
eMeasure identifier:
GUID:
NQF number:
Measurement period: 01/01/20xx through 12/31/20xx
Measure steward: ANA
Measure developer: NDNQI
Code system:
Code system version:
Endorsed by NQF:
General description:
Copyright: ANA
Disclaimer:
Measure type:
Stratification:
Risk adjustment:
Rate aggregation: One
Rationale:
References:
Guidance:
Transmission format:
Initial patient population:
Denominator:
Denominator exclusions:
Numerator:
Supplemental data sets:

- "ONC Administrative Sex" using "ONC Administrative Sex Value Set (2.16.840.1.113762.1.4.1)"
- "Patient Characteristic: Race" using "Race CDC Value Set (2.16.840.1.114222.4.11.836)"
- "Patient Characteristic: Ethnicity" using "Ethnicity CDC Value Set (2.16.840.1.114222.4.11.837)"
- "Patient Characteristic: Payer" using "Payer Source of Payment Typology Value Set (2.16.840.1.114222.4.11.3591)"
- "Patient Characteristic: Birth date" using "Birth Date LOINC Value Set (2.16.840.1.113883.3.560.100.4)"
- Measure set: (this includes the logic statements)

Current policy is to test the eMeasure with three vendors and three hospitals using each vendor, for a total of nine hospitals.

4.3.2 • Creating value sets

Value sets are created in the VSAC (https://vsac.nlm.nih.gov). The MAT links automatically to the VSAC. There is an import spreadsheet to populate so that more than one concept at a time can be entered. As this tool evolves, this spreadsheet changes (but shouldn't be too different from the sample above). The current one is on the website.

Conduct reliability, validity and feasibility studies

The NQF requires these studies to qualify for recognition. The criteria are listed at www.qualityforum.org/docs/measure_evaluation_criteria.aspx. Current policy is to test the eMeasure with three vendors and three hospitals using each vendor, for a total of nine hospitals.

5.1 • Reliability and validity studies

First the studies should define the extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Because of the nature of these studies, additional institutional review board approval for human subjects needs to be gained. Depending on the hospital processes and the existence of a human subject office, this process can be lengthy.

The methodology for this type of study is well-known. When the pressure ulcer eMeasure was studied, the reliability and validity were established by comparing data gathered through a query of the EHR and the data gathered during a traditional prevalence and incidence study. A prevalence and incidence study is completed by pressure ulcer experts who directly examine all patients at a facility to determine whether pressure ulcers exist.

NQF provides guidance for performing the reliability and validity studies and the process used to evaluate their quality as it applies to endorsement/recognition decisions (www.qualityforum.org/Publications/2013/10/Review_and_Update_of_Guidance_for_Evaluating_Evidence_and_Measure_Testing_-_Technical_Report.aspx).

5.2 • Feasibility study

Feasibility studies address the extent to which the specifications, including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement. For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure check, lab test, diagnosis, medication order). The required data elements are available in EHRs or other electronic sources. It is necessary to demonstrate that the data-collection strategy can be implemented. For eMeasures, a feasibility assessment addresses the data elements and measure logic, and demonstrates that the eMeasure can be implemented.

NQF provides guidance for performing the feasibility studies and the process used to evaluate their quality as it applies to endorsement/recognition decisions (www.qualityforum.org/Publications/2013/04/eMeasure_Feasibility_Assessment.aspx).

Guidance documents

6.1 • Guidance for hospitals submitting eMeasures

The measure development team needs to develop a guidance document for each eMeasure. This document describes the purpose and rationale of eMeasures. It contains the following sections:

- Overview of the specific measure.
- Description of the hospital team needed to collect the data.
- Information about each data element:
  - The data dictionary.
  - Suggestions for structuring the EHR or other electronic query.
- Description of the container for submitting the results of the query.
- Process for submitting data to the database.
- Appendices containing useful information about HL7, NQF, the mind map, the terminology map(s) and other clinical resources.

6.2 • Container and ETL development

The IT team needs to develop a container for submission.

Submission of an eMeasure to NQF

To submit an eMeasure, a steward must complete and electronically submit the online measure submission form for each measure the steward wishes to submit to NQF for consideration. The online submission form is found at www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx. There is an FAQ guidance document that assists with the submission process (www.qualityforum.org/Docs/Measure_Submission_Form_Help.aspx). Furthermore, there is a recorded webinar describing this process (http://commpart.vo.llnwd.net/o28/NQF/NQFPM/index.html).

Periodic reevaluation of the eMeasure

Each eMeasure will be reevaluated for its currency, relevance and scientific evidence.

[*] Following the development of the eMeasure process described in this report, ANA transferred ownership of NDNQI to Press Ganey.

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