To the ONC:

Thank you for the opportunity to comment on the measures framework, and to offer simultaneously an apology for what is a long and rambling comment. I would like to propose additions to the interoperability measurement framework to address the barriers faced by post acute care, home and community based service providers, and individuals with their immediate caregivers. Their collective needs for interoperability, benefits they might derive from it, and the challenges they face to achieve it are very different from the barriers and benefits of hospitals and physician groups. Individuals and these “non-eligible” service providers have the potential to contribute interoperable data that is unavailable anywhere else in the system and critical to achieving good outcomes. We face the challenge of expanding the foundation for interoperability to include the care-team members needed for individuals with the most complex mix of medical, behavioral, functional and social/environmental issues: a challenge which includes developing a standards-based vocabulary that meets their needs while reducing barriers to interoperability.

By way of background, NQF completed an Environmental Scan as part of its Interoperability Measurement Framework that included several important observations:

1. Interoperability requires a complex set of interactions and prior conditions before it can occur.
2. Interoperability is a local, not a global phenomenon. The details of achieving interoperability are different depending on the trading partners, the population of individuals under care, the complexity of their needs, the size of the team required to meet them and the specific information needs of each party.
3. Multiple studies demonstrate that interoperability rests on one fundamental common component, a shared vocabulary between the parties exchanging data. These studies also demonstrate that there is no single shared vocabulary that applies to all participants.
4. Interoperability appears to grow incrementally as semantic standards and transport standards are adopted by both trading partners.

There is a new interoperability use case in health care which is not driven by Meaningful Use attestation. It is driven by changes in reimbursement under emerging value based payment models which provides incentives for at-risk entities to manage the total health care spend of the populations for which they are responsible. This presents both challenges and opportunities for the current healthcare system because healthcare spending is not distributed evenly within a population. The highest utilizing 1% of the population accounts for 23% of total health care costs while 5% accounts for 50% of all spending. (<https://www.nihcm.org/categories/concentration-of-us-health-care-spending> ).

The highest spending 5% is made up of three populations: those individuals with costly, unanticipated new conditions (~50%), those at end of life (~15%), and those with a mix of heavy burdens of chronic medical and behavioral health conditions, functional impairment, and adverse social determinants of health (~35%). It is the latter two groups that provide the opportunity for the at-risk providers to reduce spending while improving care and outcomes. The way care must be organized for these groups will push the current limits of interoperability.

For individuals at the end of life, the opportunity exists to provide care that is more consistent with the individual’s goals, priorities and preferences. Given the ability to make an informed choice, individuals overwhelmingly opt for less intensive care. Communicating these priorities and preferences is important for achieving optimal outcomes. (<http://wiki.hl7.org/images/d/d1/Industry_Team_Mtg_20151020.pdf> )

For individuals with serious chronic behavioral health issues, functional impairment, and a significant burden of complex chronic medical conditions, the opportunity to manage cost and improve care requires improved coordination of large teams of service providers. It also requires new and different service providers who deliver support services to address issues of unemployment, isolation, need for assistance with personal care as well as inadequate housing and transportation. Through the application of these services, at-risk entities can substitute lower cost (and more effective) non-medical interventions to avoid the use of expensive “medical” interventions such as hospitalization and emergency room to address “social” issues. This strategy of substituting lower cost interventions extends to using post acute care services in lieu of hospital based care where the interventions are a mix of clinical, functional and social.

The new interoperability use case is complex. Large teams of health care and support service providers are required to address the complex issues that threaten the health of these populations. These teams might include home and community based service providers, housing advocates, transportation providers and public services such as first responders in addition to the usual hospital, outpatient office and post acute care based providers. The size of the teams alone adds complexity. But in addition to size, these teams are composed of individuals and organizations with widely varying levels of clinical and HIT sophistication, as well as different data needs.

All team members have information that is of value to other team members; however the value of that information is not equally shared by all members of the team. The value derived from moving data from LTSS/HCBS providers, the individuals and their immediate caregivers accrues primarily to the at risk entities, largely physician groups, hospitals and networks. Specific examples of this information include the voice of the individual (priorities, goals and preferences) as well as real time, in-person observations of function, cognition, fall risk, nutrition and medication management. The value of this information increases as it becomes standards-based and electronically exchanged; however it has value even if non-standards based and sent on paper.

There is less value gained by LTSS/HCBS providers by moving hospital/office data to them except for limited datasets, which if standardized, could provide a benefit by improving efficiency of data acquisition. Examples include patient identification, lists of care team members and event notification. The lack of a common, shared standards-based vocabulary limits options for data reuse. Also missing for most team members is a compelling business case to acquire the capability to move or access information electronically. From the perspective of complex team care, one of the challenges for interoperability is to connect these disparate services providers so that information is available where and when it is needed. This will require new standards-based vocabularies and possibly a new way of thinking about standards and how they apply to “non-medical” providers. Currently, the care needs of individuals with complex conditions appear to extend beyond the reach of the standards.

Despite these significant challenges, there is opportunity to lay the foundation for interoperability by building the capability of non medical providers to create standards-based information using standards-based data sets even if this information is not shared in an electronic format. If standardized, this information is still useful, and can be reused once it is converted by the receiver to an electronic format. This approach to achieving interoperability rests on building a small number of standards-based data sets (modules) that can be recombined to create more complex information exchange.

I would like to propose four concepts for consideration as additions to the measure framework:

1. Gall’s Law
2. “Pre-electronic” data standardization
3. Acquisition of “Pre-interoperability” capabilities:
4. Measurement framework based on capabilities

**1. Gall’s Law**

Gall’s Law states: “*A complex system that works is invariably found to have evolved from a simple system that worked. A complex system designed from scratch never works and cannot be patched up to make it work. You have to start over with a working simple system.”* (Systemantics: How Systems Really Work and How They Fail. 1975). His observation applies to the complex system of interoperability. The clear implication of Gall’s Law is to emphasize the basic, simple, reproducible requirements of interoperability, the “modules” if you will, from which interoperability is built. The supposition is that if we identify the basic modules and make them reliable, the new care organizations will re-use them to create more complex and reliable systems of information exchange.

Interoperability will grow organically, opportunistically, and unpredictably in a modular way. This is a complementary approach to the use of standards in the proposed measure framework. The goal here is to create “light and tight” content standards for use in the basic business processes that are common across all types of service providers. By building interoperability from the ground up, using standards to tightly define content and meaning, and linking them to essential business practices we have an opportunity to create simple, highly reliable building blocks for interoperability that have value for support service providers. Clinical data and standards have less value to support service providers because they use relatively little clinical data. However, consistency of basic “administrative” data

Is an attractive introduction to interoperability for these providers because of efficiencies of data acquisition.

Candidate modules include the basic business processes of service providers such as:

Identify the recipient of services

Receive a request for services

Request and receive additional information needed to provide the service

Receive permission to share information with other providers and payers

Establish the payment source

Convey the details of the an agreement to provide services

Establish the goals of the intervention

Report outcomes of an intervention

Terminate a service agreement

The data sets required in these processes could be tightly constrained and use standards-based vocabulary. This would establish the foundation for interoperability by establishing highly reliable modules that can be used in the course of normal business activities and provide efficiencies of data acquisition. This would entail developing standards-based data sets for:

Data elements to identify the individual

Data elements to identify the service provider

Standard set of potential issues to be addressed

Standard set of services to be provided

Taxonomy of potential outcomes

List of payment sources

Standard consent to share information (will be highly dependent on local laws and regulations)

Statement of the individual regarding information he/she wants the service providers to know

**2. Pre-electronic data standardization:**

Although the goal of interoperability is to make re-usable information available electronically wherever it is needed, the necessary first step is to make re-usable information available in any format. By standardizing the data needed for basic business processes, we can set the foundation of interoperability by collecting standardized data. For some service providers this may be as simple as identifying a specific service need, identifying an eligible community based service provider, establishing availability, scheduling the service and monitoring the outcome. One approach to standardization could be to provide a library of modules that meet the business needs of these service providers. The first step of electronic data exchange is not the acquisition of HIT; rather, it is the creation of a shared vocabulary that builds the foundation for semantic interoperability. Especially since this group of service providers may never acquire sophisticated HIT. This is the “pre-electronic” standardization of data that might be considered for addition to the framework.

The business processes are a reasonable place to start because all HCBS providers currently use them. Changing the data that is currently collected to make it consistent with a set of shared standards is a relatively low bar to hurdle. A higher hurdle would be to extend this approach to include a broader set of standardized data elements that have greater value for at risk providers because they are more, but not exclusively, clinical. Potential candidates for these data sets listed in order of clinical content from low to high include:

1. Demographics
2. Contact information of sender
3. Patient preferences, priorities, advance directive, statement of what matters most
4. Social determinants of health
5. Team members
6. Master problem list (all issues that affect the health and well being of the individual)
7. Function
8. Cognition
9. Medications
10. Allergies
11. Condition specific data sets (e.g. Congestive Heart Failure: type, ejection fraction, goal weight, goal blood pressure, medications, if not on evidence based medications- why not, contact information of responsible clinician)
12. Medication specific data sets (e.g. Opiates: indication, duration, medication, dose, number of doses provided, plan for continuation, next appointment)
13. Anticoagulation specific data sets (e.g. for Warfarin: indication, duration, target INR, contact information for party responsible for management, last doses, last INRs, doses until next INR)

Standardization of “pre-electronic” data makes the step to electronic exchange easier because the data are already standardized. The next step requires acquisition of a suitable electronic platform and not the simultaneous acquisition of electronic exchange and transition to standardized data. This is one approach to extend interoperability to service providers who have new and previously unavailable information. Home based service providers (including family and immediate caregivers) make daily observations of the individual at home regarding function, cognition, nutrition, fall risk, and medication management. They are the first to identify changes which could result in a hospitalization. Were these data made available in standardized, machine readable format they would enable real time decision support with the potential to prevent hospitalizations, improve care and lower overall costs.

Use of these few standardized elements by the care team members would support queries to identify all service providers engaged with one individual, all issues currently addressed for that individual, and all outcomes achieved. These queries provide the basis for identifying gaps in services for the individual, a provider list to share event notifications and care plan updates. Because the data are “standardized” and used by all service providers, it would be possible to aggregate the data of each individual from each service provider to created pictures of populations, their service needs and active providers: information that is difficult to obtain otherwise. In this way population health data could be derived from the care of each individual.

**3. Acquisition of “Pre-interoperability” capabilities**

Entities must acquire a sufficient number of capabilities in order to participate in an interoperable exchange. The more capabilities acquired, the more complex and extensive their participation. There are some entities that may acquire only the most basic capabilities because that is all that their trading partners require. Others will acquire the full range because of the benefits that interoperability brings to transitions of care, shared care plans and data reuse.

The following capabilities are among the requirements for interoperability:

1. A shared, standardized vocabulary (semantic interoperability) used by trading partners
2. A mutually agreed upon process for identifying the individual for whom care is provided
3. A standard process for obtaining consent from the individual to share data
4. A mutually agreed upon transport process that preserves the degree of data detail required by each party
5. A shared process to identify and correct system failures
6. Shared governance of standards

These capabilities are independent of any specific vocabulary, transport standard or processes for identification and problem resolution. These decisions would be made by the local trading partners to identify the specific components that best meet their needs. The fact that there are well established standards and standardized processes for each of these components makes the selection easier

We could take advantage of some high value exchanges which are currently driving the adoption of some of these capabilities. For example the ability to create, send and receive an ADT message is being adopted by many systems as a standard way to communicate the change in location or services provided to an individual. This has growing clinical value as systems of care seek to improve care coordination and resource use. There several separate requirements, sub-capabilities if you will, that underlie this exchange: capabilities that may be acquired one at a time, and which lead down the path of increasing interoperability.

From the most simple to the most complex, some of the necessary sub-capabilities are:

1. The capability to receive an ADT message: this requires a “connection”, a standardized transport mechanism and a process to identify and use the message once received.
2. The capability to create an ADT message: this requires a process to create messages according to agreed upon standards (note that there are many different “flavors” of ADT messages and they are not necessarily exchangeable beyond a small group of trading partners. To address this disparity and move towards a more widely accepted ADT standard, perhaps the ONC HIE Admission, Discharge, and Transfer (ADT) Community of Practice (CoP) can propose a more tightly constrained ADT format as a new standard.
3. The capability to send an ADT message: a “connection” and shared transport standard.
4. A process to resolve issues of content, syntax and transport, and to measure performance.
5. Participation in governance of the system.

These capabilities are the same for the exchange of other standardized documents such as care summaries and shared care plans. As electronic documents get more extensive, interoperability will rest on increasingly precise vocabularies. To extend interoperable exchange beyond just a few trading partners, additional components may be required:

1. A Master Patient Index of individuals who have given consent to share their health information
2. A Master Provider Index of entities who provide services to this population with unique identifiers and rules on data sharing
3. A Relationship Listing Service to identify those patients and providers with existing relationships in order to route messages appropriately
4. An Event Notification Service to enable the delivery of specific messages to specific recipients for specific reasons
5. A list of specified documents that trigger this service
6. An oversight process to continually improve function of this network

This is a complex and multi-tiered set of requirements. There is an analogy that can be made between building the capabilities needed to engage in interoperable exchange and the adoption of an electronic medical record. We might want to consider an approach similar to the HIMMS EMRAM, Electronic Medical Record Adoption Model, which has seven stages. The following is a “straw man” Interoperability Adoption draft. Trading partners could designate the Stage they require of other trading partners.

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| --- | --- |
| Stage  | Cumulative Capabilities  |
| Stage 7 | Participate in governance process for bidirectional information exchange |
| Stage 6 | Contribute to and use Master Patient Index, Master Provider Index and Relationship Listing Service |
| Stage 5 | Send standardized electronic documents |
| Stage 4 | Create standardized electronic documents |
| Stage 3 | Receive standardized electronic documents (Business processes, ADT, CCDA) with consent to share |
| Stage 2 | Use a standard patient identification algorithm |
| Stage 1 | Implement standards-based data sets needed by other trading partners |
| Stage 0 | Exchange non-standardized data by fax, phone, secure email |

Entities need only to get to the level required of them by their trading partners. Not everyone needs to achieve Level 7. The actual level required by any entity is the level of interoperability specified by what the trading partners need (“I need you to be at Level 3 to participate in my network.”) There will be very powerful market forces at work to direct entities to the level of adoption required by their local system. And as the local system evolves, so will the business cases that support more robust interoperability such as those being considered by LTPAC CoP (Community of Practice) which has identified ADT notifications, the ability to query and submit to an immunization registry, as well as specific data at transitions, (<https://basecamp.com/2847230/projects/11321286>); and the eLTSS Work group (Electronic Long Term Services and Supports) within the S&I Framework is developing a common vocabulary for exchange an LTSS care plan. These work groups could be asked to submit high value use cases for inclusion in the measurement framework as a way to push interoperability to a wider group of service providers.

**4.Measurement Framework Based on Capabilities**

These three capabilities-based measures are proposed for consideration for addition to the framework:

1. Those capabilities which reduce semantic imprecision
2. Those needed to query the individual regarding the impact of interoperability
3. Those required to achieve different levels of interoperability

**Semantic imprecision**

The degree of semantic imprecision in the system (the extent to which vocabularies are not constrained or precise) degrades the value of interoperability. This imprecision even extends to “standardized” documents such as ADT, which exists in multiple variations which cannot be interoperably exchanged. We might want to consider a measure of semantic precision within the process of information exchange to address this issue. This is another way to ask which standards are being used. Such a measure might encourage interventions to eliminate imprecision. Effortlessly exchanging imprecise information is not an improvement. Along the same lines, with any deviation from the transport standards there is a decrease in the reliability of the data exchange. We might want to consider measures that look at these two foundations of interoperability.

**Impact of Interoperability on the Individual**

A recently published peer reviewed study (Ziniel SI, Rosenberg HN, Bach AM, Singer SJ, Antonelli RC. Validation of a Parent-Reported Experience Measure of Integrated Care. Pediatrics. 2016 Dec; 138(6)) demonstrates the reliability of measuring parents’ perception of “care integration” received by their children. This may be an approach we could expand to measure the impact of interoperability on all individuals, specifically their perception of care integration. Another (untested) measure based what matters most to the individual is a universal outcome measure: “All of the issues that matter to me have been addressed in a manner acceptable to me to achieve outcomes that I value”. Although not a direct measure of interoperability, it is unlikely that this statement would be possible without interoperability. Ultimately, assessment of the value of interoperability should include the individual’s experience.

**Capabilities to Achieve Interoperability**

A more refined hierarchy of capabilities similar to those presented in Section 3 could serve as a guideline and benchmark for enabling interoperability. More granular measures could include the % of shared care partners (providing services to a shared patient) that receive information from you in a manner that is acceptable to them. Conversely, what % of information do you receive from shared care partners in a manner that is acceptable to you (e.g. timely, complete, easily reused, concise, standards-based). This approach recognizes the local, bi-lateral relationships that exist within care teams and which form the basis of interoperability.

**Thank you.**

**Submitted by,**

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