STANDARDIZED CARE PLAN DOCUMENT EXCHANGE

PROOF OF CONCEPT PROJECT REPORT

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education and the advancement of HL7 Consolidated Clinical Document Architecture (C-CDA).
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Introduction

The Standardized Care Plan Document Exchange Proof of Concept Project was the third step in a series of initiatives undertaken to address requirements for exchanging care plan information. It was needed because the HL7 Consolidated-CDA (C-CDA) Care Plan Document Template is a draft standard for trial use (DTSU). Early use of the standard exposed some gaps in the specification that was released in C-CDA R2.0 and R2.1. Additional analysis was done to review Care Management and Disease Management Care Plan requirements and recommend adjustments to the C-CDA Care Plan Document template to meet those requirements. The proof of concept project was initiated to confirm the usefulness and feasibility of those recommendations.

The goal in vetting the recommendations from the prior requirements analysis project was to further clarify the Care Plan Document template gaps and potential resolutions so these issues could be reported as DSTU Comments against C-CDA R2.1 and used by HL7 to improve this draft standard.

The primary objective was to engage implementers in trial use of the C-CDA Care Plan Document in order to contribute careful, reality-based evaluation that would lead to clear and specific refinements to help mature this emerging interoperability specification.

A secondary objective was to initiate industry collaboration needed to establish value sets for encoding the different kinds and types of care plans, the patient enrollment statuses in a care plan, and other structured data that does not yet have industry-accepted code lists to convey machine processable information needed in care plans.

A team representing payer, provider and vendor stakeholders came together to gain hands-on experience with this new standard, and to assess the utility of the new Care Plan document template when used with the adjustments recommended from the Care Plan Requirements Assessment project. The experience showed the adjustments did address many of the previously identified gaps.

The Care Plan Proof of Concept Project accomplished the following:

- Revealed implementation strategies that lowered the technical challenges for implementing CDA document exchange.
- Identified high value approaches to improve sharing care plan information.
- Helped to prioritize the list of issues to report as DSTU Comments against the C-CDA R2.1 Care Plan Document template and to clarify the recommendations to propose as the needed resolution.

The project garnered interest from several active care plan implementation projects. It informed the industry of shortcomings in the current Care Plan standard and suggested feasible ways to address the gaps. The additional awareness and knowledge sharing inspired by the project is expected to accelerate successful use of C-CDA Care Plan Documents in larger scale implementations.

The project showed positive results with recommended C-CDA Care Plan Document template revisions. This progress could be leveraged by other implementers who are exploring the use of the C-CDA Care Plan standard. It also generated recommendations regarding how to approach the challenge of structured data representation in a way that supports progress for information exchange and fosters the collaboration needed to achieve greater care plan content standardization.
Project Description

The purpose of the Proof of Concept Project was to gain experience exchanging digital care plan information while testing the feasibility and usefulness of the recommended “containerized” Care Plan Document template design modifications.

The project focused on creating and consuming Care Plan Document content. The goal was to gain “implementer” experience using and generating feedback on needed refinements for the HL7 C-CDA Care Plan Document template. Transport of data between systems was out of scope. This allowed participants to focus fully on content creation and consumption.

A story board from the HL7 Care Plan Domain Analysis Model was used to inform the flow of information. The story board shows the role of case management and disease management from a payer’s perspective. In the scenario, Adam Everyman has multiple chronic conditions and is seen by a variety of providers. His care manager is helping him improve the outcome of his care. The story board provides the longitudinal and clinical details of the care and care management that Adam receives. It established the basis for validating the timing of care events and the clinical details shared in the CDA documents.

Figure 1 provides an overview of the proof of concept project undertaken to exchange care plan information for Adam Everyman in the context of the guiding story board.

Figure 1 – Project Overview

About the Care Plan Proof of Concept Project

• Focus on Care Plan document content
• Generate feedback on needed refinements
• Transport mechanisms out of scope

Information Flow Over Time

Participants from BCBSA and Healthwise, provided overall project leadership and management. Lantana Consulting Group provided technical management and support. ZeOmega, Edifecs, and GSI Health used the adjusted Care Plan Document template to fulfill the proof-of-concept testing.
Edifecs implemented OpenEHR technology to simulate the creation of CDA documents used across the continuum of care and over time. They simulated an EMR used by Adam’s primary care physician (PCP) and created a C-CDA Continuity of Care Document (CCD) to share information gathered during Adam’s annual exam. They also simulated an EMR used by the Emergency Department where Adam went to address an Asthma attack. They created a C-CDA Discharge Summary to share information gathered during that ED visit.

ZeOmega consumed the available CCD and Discharge Summary CDA documents to update the patient’s care plan in the ZeOmega system used by the health plan’s care manager. The information was used to establish the concerns, goals, and planned interventions in the care plan. Additionally, the discharge diagnosis in the Discharge Summary document was used to identify relevant patient education materials available in the Healthwise system. This integration with the Healthwise system permitted the selected patient education interventions to automatically populate the care plan in the ZeOmega system. The ZeOmega system shared the updated care plan information by creating a C-CDA Care Plan Document with the recommended design enhancements.

GSI Health consumed the C-CDA Care Plan Document produced by ZeOmega. The document was imported into the GSI Health system. The Care Plan Document was then available to be viewed by a clinician involved in managing the patient’s care.

Edifecs also consumed the C-CDA Care Plan Document into a document repository solution which showed how consumed documents can be organized to provide a longitudinal view of the shared information available for the patient.

A recorded presentation showing the results of project is available for review at:
Approach

The project was run as a short, 8 week sprint. It was highly focused on content creation and consumption of the design-enhanced Care Plan Document. A highly detailed story board was used to guide the content expectations for the project. Specific vendors agreed to play the needed technical roles. This included roles to establish the information exchange artifacts that set-up the context for the experiment, as well as the actual creation and consumption of the Care Plan Document. A strong element of vendor education was mixed in with the implementation instructions to make sure vendors clearly understood the correct way to populate the CDA Care Plan. Technical support was also provided to develop technically acceptable workarounds when implementation challenges were experienced.

The project included the following steps:

1. Review of C-CDA Care Plan header expectations then creation and confirmation of header content.
2. Review of C-CDA Care Plan section expectation then creation and confirmation of section structure.
3. Review of C-CDA Care Plan section content expectations then creation and confirmation of the “structured narrative”. This step involved detailed analysis of the ZeOmega system content in order to clarify its “mapping” to the corresponding concepts defined within the section and entry templates used by the C-CDA Care Plan Document template.
4. Review of the C-CDA Care Plan design modifications and standard entry level templates in order to instruct on how to add corresponding machine readable entries for the C-CDA Care Plan Document produced in step 3.

The “Level Two before Level Three” Methodology

One of the primary goals of the HL7 Clinical Document Architecture, Release 2 (CDA R2) standard is to support exchange of human-readable documents between users, including those with different levels of technical sophistication. To accomplish this goal, the CDA standard establishes a single CDA xml Schema. The CDA Schema establishes the architecture that can be present in any CDA document. The full architectural possibilities are then constrained by applying one or more of a hierarchical set of templates to constrain the richness and flexibility of CDA.

There are many kinds of HL7 templates. Among them, two are particularly relevant for clinical documents: (1) those that constrain the document sections based on the type of document (section-level templates); (2) those that constrain the entries within document sections (entry-level templates). The practice of creating CDA documents that are constrained by HL7 templates has given rise to terms that describes this characteristic. Table X summarizes the “Level” characteristic of a CDA Document.
When a CDA document is a Level Two CDA, all the information in the body of the document is contained within well-defined section level templates. When a CDA document is Level Three CDA, some or all of the information contained in a section of the document may be available as machine-encoded data. There remains some debate about the exact relationship between the human readable information in the section and the data in the associated machine readable entries. However, in the majority of cases, the following principles are true:

- If the information in a section is generated from a set of machine readable entries, then all clinically relevant machine encoded data will be represented in the human readable information in the section.
- If the machine encoded data is generated from the human readable information in the section, then the machine encoded data will be represented in the human readable information in the section, but there may be additional human readable information in the section that is not also present as machine encoded data.

The “Level Two before Level Three” methodology is being recommended as a way of creating CDA documents from the top-down. Use of this methodology may seem counter intuitive given the current push toward sharing structured data. However, this methodology stems from a belief that the fastest way to achieve high quality structured data is to first achieve high quality “structured narrative”. This step is essential to the evolution from today’s paper documents to the more powerful, efficient digital documents we aim to use. If the step to “structured narrative” is skipped, the right foundation for structured data is not built, and the end goal can’t be attained with the same level of success. Simply put, the Level Two before Level Three recommendation is a “crawl, walk, run” strategy where the value of each developmental phase is recognized as essential in the evolutionary process. Each level of capability should be mastered successfully before moving to the next level.

Our data processing systems require this type of formative evolution to make sense of the information before transforming it into interoperable machine readable data. When you agree first on what you mean to say, it is then possible to agree on how to convey that information in a coded form. Approaching the problem from the bottom-up where focus is first on representing machine encoded data creates a recipe for failure. It makes it unclear what the intended human meaning of the information actually is. Starting with the end in mind is always the best approach. For CDA, the end that must be kept in mind is the human readability of the information.

The Level Two before Level Three methodology is a recommendation based on the principle that effective clinical data exchange is best accomplished when systems evolve first from sharing non-digital information to sharing structured narrative before evolving to share machine-encoded data that represents the information. The methodology is unique in that it seeks first to preserve and perfect the fidelity of the information then seeks to mature the terminology systems emerging to facilitate computerized data processing.
Results

The Edifecs team produced a C-CDA Continuity of Care Document (CCD) to record information from the patient’s annual exam. They also produced a C-CDA Discharge Summary to record information from an emergency department visit.

Both of these documents were consumed by the ZeOmega care management system. Availability of the CDA documents triggered activity to occur in the ZeOmega system. Data from the headers were used to identify the care plan in the ZeOmega system for the corresponding patient. Users of the ZeOmega system were able to view the information available in the earlier CDA documents and make appropriate updates to the information in the ZeOmega System.

The Care Manager used the discharge diagnosis information to query the Healthwise system for relevant patient education materials. The ZeOmega system did not automate processing of the machine readable discharge diagnosis information because it was out of scope for the project. However, participants reviewed how this could be done in the future. Agreement was reached that this represented a potentially valuable data interface, but real benefit was gained by enabling the care manager to immediately know that the patient had been discharged from the ED and to easily see what the discharge diagnosis was. It was a significant incremental improvement in workflow.

Information supplied from the Healthwise system was used to automate addition of the planned patient education interventions into the care plan. This included data that makes it possible to automate the way the intervention is tracked and confirmed, and to automate updates to the care plan when the intervention is completed.

The ZeOmega system created a C-CDA Care Plan Document using the recommended containerized design. The document was implemented as a Level Two CDA (see Table 1, on page 9). It included a machine processable header and a machine processable structured body with sections that included the care planning information as structured narrative. The Care Plan Document did not include the associated machine readable entries to further encode the content of the structured narrative. Use of the “containerized” design enabled the patient’s multiple care plans (or various condition-specific care plans) to be communicated as distinct plans within one physical Care Plan Document.

Figure 2 shows a compressed representation of some of the content in the Care Plan Document created by ZeOmega. It shows a small portion of the CDA header information in blue and purple. It also shows there were two care plan containers, one for an Asthma disease management plan and another for a Diabetes disease management plan. It shows the data elements included in the metadata for the container holding the Diabetes care plan. The metadata includes the care plan manager who authored the plan. It also includes the kind of care plan, the type of care plan program, the acuity level, patient enrollment date, patient enrollment status, referral source, reason for the plan, date when the plan was last updated, and to whom the plan’s management is assigned.
The Care Plan Document was consumed by the GSI Health system. It used the header information to associate the document with the correct patient’s chart. Users of the GSI Health system were able to view the information available in the Care Plan Document.

The Care Plan Document was also consumed by the Edifees system to show how external documents can be managed and organized to optimize viewing of the information as a longitudinal record of the patient’s care. It used the header information to associate the document with the correct patient.
Findings and Lessons Learned

All issues identified while using the VSAC Collaboration Tool are noted in the sections below. Discussion includes assessment of issues which seem related to our discoveries during the pilot experience.

Finding #1: Containerized design adds value
The “containerized” design adjustments made it possible to share multiple distinct care plans for the same patient in a single C-CDA Care Plan Document. If the containerized design had not been used, it would not have been possible for content consumers to easily tell which problems, goals and interventions belonged with the Asthma Care Plan and which belonged with the Diabetes Care Plan.

Figure 3 illustrates the proposed containerized design recommended to address gaps in the current C-CDA Care Plan Document template specification.

Figure 3 – Representation of the proposed containerized design

Some internal adjustments and workarounds were needed to output the care plan information within the context of distinct care plans. The ZeOmega system presented the information as two distinct care plans to users, but needed to make some system adjustments to output the information organized in this way.

Lesson Learned
Once ZeOmega system engineers understood the “containerized” design, they were able to quickly make adjustments to allow their system to produce the C-CDA in the needed exchange format. These engineers thought the design was so useful they invited other product management personnel to participate in an educational session about the “containerized” care plan concept so that their
product planning could leverage this useful mechanism for organizing multiple care plans for a single person.

**Finding #2: Guidance on use of id elements is insufficient**
Implementing the id elements needed by the C-CDA Care Plan Document was challenging for content creators. Within CDA, the information components—the document instance itself, the entity participants, the sections, and the clinical statement entries—need to be coded with globally unique identifiers. This is often a completely new requirement which systems likely have not anticipated needing. It can represent a fairly significant hurdle to clear. C-CDA does not provide any guidance on how to develop an id creation and management strategy.

C-CDA uses id elements to represent four different types of information:

1. Id’s that provide identity information, in which case the root of the id is an external assigning authority that is not the system making this document.
2. Id’s that link the human readable content with the associated machine readable entries.
3. Id’s that provide internal reference within the context of the document. These allow linking between related information. The system that makes these ids is the assigning authority.
4. Ids that are an external reference (like a medical record number or a master patient ID) to information generated from and identified by another systems.

Systems that have been developed without functional requirements associated with exchanging interoperable data using CDA documents often do not have robust id creation and management capabilities built-in. Adding an id “indexing engine” often represent a major revision. Although this may represent a major change, id creation and management is a foundational capability for a FHIR server. All systems that develop the capability to support the indexing needed for CDA creation will find the investment supports movement toward the use of FHIR based information exchange too.

**Lesson Learned**
While it is understandable that the C-CDA standard does not want to dictate or limit the id strategy developed by various implementers, it would be helpful for C-CDA to at least identify one approach that could easily be used by any vendor who didn’t already have an id strategy in place. The guidance could clearly state that the specification allows for other approaches to be used.

Remaining silent and providing no guidance about how to deal with id elements leaves a big gap that impedes implementers who don’t have a developed strategy for this requirement. The risk of developing an incorrect or inefficient strategy is high with no guidance to follow. It can be a complete deterrent and prevent systems from generating valid C-CDA Care Plan documents at all.

There are many facets to the creation and use of id elements. They do more than just uniquely identify particular pieces of information in a CDA document. Id elements are vital to data processing and they may play a key role in data processing capabilities that support reference linking, reconciliation, data provenance, and consent. They may even play a role in the evolution toward the use of FHIR resources. This is an area where more implementer guidance clearly would be valuable.

**Finding #3: Value sets for container-related metadata need further definition**
The containerized design modifications include metadata data elements that record the kind of care plan represented in the container and a machine readable enrollment observation entry to encode specific enrollment information for each care plan. This entry includes information such as the type
of care plan (a sub-classification under care plan kind), the patient’s enrollment status, and potentially other metadata relevant to a specific care plan. Figure 2 shows the set of concepts included by ZeOmega based on the information maintained in their system for each care plan.

The exact set of metadata data elements needed to describe and categorize each care plan is not yet well defined. While it is clear and agreed that metadata per care plan is needed, the specific set of data elements and their precise meaning has not been clarified enough to be specified in a standard that is expected to support exchange of all care plans generated by a variety of different systems.

Further, value sets defining the set of allowable concepts for each of the metadata data elements, and the definitions for each of the allowable concepts also do not yet exist. This represents a major gap for standardizing care plan information in a way that supports interoperability. It is not enough for data structures to be defined. The semantic meaning of the information that can be contained in the structures also must be defined and constrained to a specific set of concepts with agreed upon meaning.

**Lesson Learned**
Mapping of internal concepts to an agreed upon set of concepts for external exchange of care plan information was the most difficult aspect of the project. It was a challenge for two reasons. First, the set of concepts for data exchange was not available. Second, it is inherently challenging to map internal meaning to a set of externally defined concepts. This problem is best addressed when an industry first defines the set of concepts to represent a particular data element, and then develops individual systems with content that corresponds to the standard. Unfortunately this is rarely the way systems get developed.

The best approach at this point would be a two-step process. First, gather the full set of existing terms used by implementers of care plan management systems. Each vendor would contribute their system’s set of concepts used to represent the data to be exchanged. Next, work collaboratively to clarify, sort, and harmonize those concepts so value sets can be created that support information exchange. This approach maximizes the reuse of as many as possible of the concepts currently in use and minimizes the amount of change needed to achieve standardized interoperability.

**Finding #4: Machine readable entry creation is a major barrier for implementers**
The level of effort required to move from a pdf care plan output to a Level Two CDA (machine readable header plus a structured body with sections containing structured narrative) was a reasonable expectation of implementers. The goal was attainable and the resulting output document significantly improved the possibilities for care plan information to be shared across disparate systems. However, the level of effort, required to understand how to encode all the exchanged information as individual machine readable entries was exorbitant and the expected near-term value-add was minimal. This largely was attributed to a lack of complete and specific data representation requirements in the CDA standard to indicate how the machine readable data would be achieved.

**Lesson Learned**
In the near-term, creation and consumption of Level Two CDAs appears to be a “low-effort/high-value” strategy while aiming for Level Three CDA’s appears to be a “high-effort/low-value” strategy. There also seems to be greater risk associated with forcing implementers into creating coded machine readable data when there isn’t proven quality in the human readable data being shared. Focusing first on sharing the right information, as confirmed by human intelligence and human use, appears to be a wiser path forward. It’s an easier and more immediately valuable
solution and it provides a better foundation for adding quality machine encoding in the future. Simply put, until the industry is clear on what information actually needs to be shared in a document, it is impossible to produce machine processable information that is of clear and certain value. It does not make sense to invest in making information sharing more efficient before establishing what information is needed to be shared for effective communication.

Until the industry gains more experience with what detailed information is available and needed at the clinical statement level representation of entry-level structured data will continue to be a challenge. Alignment between the models established by the standards and the actual content being gathered must be achieved to support structured data standardization.

During the project, we realized the ZeOmega system included several pieces of information that were not represented in the model. For example, their intervention information included additional date information for an expected completion date which was different than the actual completion date. This expected completion date was used to trigger additional system functionality. Should it become part of the standard model, or remain a local extension of the model within the ZeOmega system. Will there be problems if this additional concept is not shared when a care plan created by ZeOmega is exchanged with another system? If so, perhaps the model needs to be revised so that all systems will understand this additional expected completion date information. The data cannot become more standardized until the information itself becomes more standardized. Again, this points to the need for greater focus on refining the expectations and clarity of the human readable information. Increased understanding of all the information used by the humans is the key to improving the structured data available to be processed by the machines.

In the future, all piloting of the Care Plan Document standard should follow the “Level Two before Level Three” methodology. It proved to be a valuable step that fostered the needed conversations and collaboration to establish common understanding and agreement among implementers where present standards are underdeveloped or require further refinement.

**Finding #5: Implementers benefit from more instruction and greater guidance**

Implementers benefit from more education and interactive guidance on the use and application of standards within their products. They often do not have the time to learn about the standards and successfully apply them within their products.

**Lesson Learned**

Implementers are busy and focused on many other critical issues and development pressures. Integration of standards into their product lines is a multifaceted issue. It requires technical insight into how to apply the standards. It requires business insight to see the value proposition for the use of standards. It takes product planning and financial investment to put projects in place to make standards adoption a part of production versions of shipping systems.

Standards developers and those who support the use of standards for data exchange may need to do more to “bring the mountain to Mohamed” rather than expecting “Mohamed to come to the mountain”. To a large extent, the Proof of Concept Project was more about making it easier and more valuable for implementers to use the standards than it was about getting implementers to try using the standard. The additional education and technical support was found to bridge the standards knowledge gap in an efficient and effective way.
Finding #6: Pathways for incremental improvement in machine readability are needed
A wide chasm exists today between the current system capacities to represent digital care plan information and the levels of interoperable care planning data desired to support sophisticated reconciliation, clinical decision support, quality measurement, population health and the myriad of other possibilities envisioned once care plan information is machine processable. Current expectations are set higher than what implementers can possibly attain, and so progress is frustratingly delayed and advancement thwarted. In this proof of concept project, efforts to move from a Level Two CDA to a Level Three CDA were not successful. Even with additional instruction about how to add machine readable entries and guidance on how to navigate the C-CDA Implementation Guide, the chance of realistically outputting a CDA Care Plan Document with was deemed unattainable within the scope of the project. Furthermore, the value for adding machine readable entries in every area of the document was questionable, so it was difficult to get implementers to commit resources needed to take on such a large step.

Lesson Learned
It seems we have created too vast a chasm between where implementers are today and where we want them to be tomorrow. As a result the barrier to progress is too great. If guidance could be provided on how to gradually build up the capacity of systems to generate structure data, implementers may be more likely to schedule resources to begin the journey. Product roadmaps could illustrate a plan composed of incremental steps that add value at each level of improvement along the way. We’ve established a path that is too steep and set the bar too high without designing in an incremental progress plan that implementers can feasibly follow. New techniques and guidance are both needed that can help implementers successfully bridge the structure data chasm that presently exists.

Finding #7: Patient matching continues to be a challenge
While content to be exchanged between systems is becoming more standardized, the processes for using the content in similar operations remains unique to each application. The set of fields used to identify the patient and the logic used to determine a match between the incoming information and a patient in the receiving system has not been established as a standard. Patient matching continues to be a challenge for all information exchange, even when standard content is supplied.

Lesson Learned
Methods for doing patient matching need to be standardized to eliminate inconsistency and improve matching accuracy. This is not a new need. An effort to establish a standard way, or a set of standard ways to do patient matching would bring significant gains for information exchange across disparate systems.

Finding #8: Data quality is low, inconsistency is high, and validation techniques are not used in practice
Systems are just beginning to generate CDA documents. From system to system, the quality of CDA documents produced varies widely. The degree of inconsistence across CDA documents causes a challenge for systems attempting to consume the information being exchanged. Each system consuming information from CDA documents is making different decisions about how to address the inconsistencies. The divergent approaches may magnify the inconsistencies and compound the
problem. It can even lead to incorrect processing of the information if the correction applied to fix the inconsistent CDA data introduces an error.

**Lesson Learned**
CDA validation tools exist. In fact, there are many CDA Validators. The validators don’t all produce the same results when validating a CDA document. HL7 has started a project to address this issue. Resolving this source of inconsistent validation will be an improvement. However, it won’t address the whole challenge. CDA validators tend to be used to validate system performance at a point in time like testing, development or revisions. Implementers currently don’t have validation techniques baked into their run-time CDA document processing procedures. Each vendor is making their own decisions about how to use the information received in a CDA document, even if the document isn’t a valid document. Although implementers fear that too many standards or standards that are too strict may create barriers to information exchange, the lack of standard validation processes and the lack of data processing policies to govern the way invalid or poor quality CDA documents will be handled also creates barriers for interoperability.

This project didn’t include any governance tasks where participants discussed and agreed on the validation requirements for incoming and outgoing CDA documents. Nor did participants establish processing workflows to address what actions would be taken to reject or correct incoming CDA Documents that were invalid or inconsistent.

In the future, data sharing agreements could become more standardized so that issues like these could be spelled out between data sharing partners. This would be a way to establish expectations without burdening technical specifications to address this business issue.
Recommendations

Based on experience gained from the Proof of Concept experience, the following recommendations are made to build upon and clarify recommendations resulting from the initial Case Management/Disease Management Care Plan Requirements Review and Recommendations report.

Summary of Prior Recommendations

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<th>Description</th>
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<tr>
<td>5.1</td>
<td>Form a Technical Implementation Team to Address Use Issues for C-CDA R2 Templates to Meet the Emerging/Evolving Needs of Care Plan Documentation</td>
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<tr>
<td>5.2</td>
<td>Establish Coded Concepts and Value Sets to Clarify Expected Care Plan Content and Support Machine Readable Entries</td>
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<td>5.3</td>
<td>Create a Detailed Implementation Guide for Creating and Processing Care Plan Documents to Record Progress as It Happens</td>
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<tr>
<td>5.4</td>
<td>Explore and Develop Content Representation That Makes Sense in Clinical Use</td>
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Updated Recommendations

1. **Categorize Issues to Focus Efforts Toward Resolution**

   Use prior requirements analysis report findings and proof of concept experience to identify a specific set of issues that need to be addressed in the C-CDA R2.1 Care Plan Document template and the templates it uses. Express the issues as a set of potential DSTU Comments to clearly express the current situation as well as the recommended change to address the issue.

   Organize the issues according to the following criteria:
   a. Changes requiring new templates to be created
   b. Changes requiring existing templates to be changed
   c. Additional implementation guidance needed which does not require changes or new templates to be made, but would require additional clarification or examples to be created to show how to use CDA and C-CDA to address the issue

2. **Establish a Technical Implementation Team to Support Tasks Needed to Reach Resolution**

   For all new templates to be added, convene a group of vendors with systems that create care plans to confirm the metadata data elements needed for each care plan container. Include representatives from the Patient Care Work Group (PC) and Structure Document Work Group (SDWG). Work with this group to identify and define the value sets that would be needed for data elements being proposed in new templates.
1. Identify an initial set of concepts for each value set needed in new template designs while also establishing value set definitions and bindings that would easily permit revisions and additional concepts to be added and experience with the Care Plan Document standard matures.

This recommendation is consistent with prior recommendations 5.1 and 5.2.

3. **Fund CDA Subject Matter Experts to Support the Technical Implementation Team**

Work with CDA subject matter experts to develop material to provide additional implementer guidance where needed. The material should include explanatory descriptions of how to apply the CDA and C-CDA standard. It also should include examples and sample documents that demonstrate how to apply the guidance. The CDA subject matter experts can also educate and guide the efforts of the technical implementation team which likely would be comprised of volunteers engaged in the effort to gain knowledge and share requirements for their respective products. The volunteers may have care plan management experience, but likely will not have sufficient CDA expertise to craft resolutions, document guidance, and create accurate examples on their own. Engaging committed CDA expert resources to support the team would not only ensure attainment of the desired deliverables, but also would ensure the necessary transfer of knowledge between standards developers and standards implementers that accelerates standards adoption. The combination of implementation experience and standards knowledge working together may also shed light on ways to incrementally work toward the goal of machine readable data that is feasible and adds value as it is achieved.

This recommendation is consistent with prior recommendation 5.3, as well as 5.1 and 5.2.

4. **Utilize HL7 Governance Processes**

Engage HL7 SDWG by reviewing the results of steps 2 through 4 above. Work within the governance processes established by HL7 and SDWG to clarify the right steps to use to address each issue. Use the DSTU Comment process, where appropriate, and follow other processes as required to affect the needed changes.

The work associated with determining how to make functional improvements to the C-CDA Care Plan Document template may be more difficult than it seems. The current governance processes with HL7 SDWG do not clearly address how to incrementally improve portions of the C-CDA standard without bringing the whole body of work through a new ballot cycle to release a new version. Further complicating matters, releasing a new version of C-CDA has interdependencies with federal regulations. Presently, the continuous improvement process to support maturation of this Draft Standard for Trial Use faces many uncertainties. See the blog article titled, “Consolidated CDA: Pursuing Continuous Improvement” for additional information: [https://www.lantanagroup.com/2016/02/17/consolidated-cda-pursuing-continuous-improvement/](https://www.lantanagroup.com/2016/02/17/consolidated-cda-pursuing-continuous-improvement/)
5. **Foster Continued Trial Use of the C-CDA Care Plan Document**

Continue to support implemeniter activities to pilot and explore trial uses of the Care Plan Document for exchanging care planning information between disparate systems. Allow real implementation experience to guide decisions about what makes sense to require and define in the Care Plan Document standard. Establish and maintain visibility for Trail Use of the C-CDA R2.1 Care Plan Document template and request support from HL7 to assist where SDWG work processes don’t meet requirements for improving the C-CDA Care Plan template as needed.

This recommendation is consistent with prior recommendation 5.4.