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Development, implementation, and initial evaluation of a foundational open interoperability standard for oncology treatment planning and summarization

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ABSTRACT

Objective Develop and evaluate a foundational oncology-specific standard for the communication and coordination of care throughout the cancer journey, with early-stage breast cancer as the use case.

Materials and Methods Owing to broad uptake of the Health Level Seven (HL7) Consolidated Clinical Document Architecture (C-CDA) by health information exchanges and large provider organizations, we developed an implementation guide in congruence with C-CDA. The resultant product was balloted through the HL7 process and subsequently implemented by two groups: the Health Story Project (Health Story) and the Athena Breast Health Network (Athena).

Results The *HL7 Implementation Guide for CDA, Release 2: Clinical Oncology Treatment Plan and Summary, DSTU Release 1* (eCOTPS) was successfully balloted and published as a Draft Standard for Trial Use (DSTU) in October 2013. Health Story successfully implemented the eCOTPS the 2014 meeting of the Healthcare Information and Management Systems Society (HIMSS) in a clinical vignette. During the evaluation and implementation of eCOPS, Athena identified two practical concerns: (1) the need for additional CDA templates specific to their use case; (2) the many-to-many mapping of Athena-defined data elements to eCOTPS.

Discussion Early implementation of eCOTPS has demonstrated successful vendor-agnostic transmission of oncology-specific data. The modularity enabled by the C-CDA framework ensures the relatively straightforward expansion of the eCOTPS to include other cancer subtypes. Lessons learned during the process will strengthen future versions of the standard.

Conclusion eCOTPS is the first oncology-specific CDA standard to achieve HL7 DSTU status. Oncology standards will improve care throughout the cancer journey by allowing the efficient transmission of reliable, meaningful, and current clinical data between the many involved stakeholders.

Key words: Medical Oncology, Breast Neoplasms, Health Information Management, Electronic Health Records, Continuity of Patient Care, Information Science

RESEARCH AND APPLICATIONS

BACKGROUND AND SIGNIFICANCE

Cancer care is data-intensive, multidisciplinary, lifelong, and increasingly dependent on the seamless electronic transmission of clinical data. As an example, consider a postmenopausal, diabetic woman who has just been diagnosed with early-stage invasive breast cancer. This woman lives 150 km from a National Accreditation Program for Breast Centers (NAPBC) Center of Excellence.[1] Results from surgery at the NAPBC center have determined that she will require adjuvant (postoperative) chemotherapy, radiation treatment, and hormonal therapy. She has an established relationship with a local primary care physician (PCP) and an endocrinologist, both of whom encourage her to receive adjuvant chemotherapy at a network affiliate 50 km away and daily radiation therapy near her home. None of her providers share an interoperable electronic health record (EHR). The patient and her caregivers are faced with accessing multiple portals, each with only a slice of the pertinent medical information. As shown in Figure 1, the resultant paths of communication are often incomplete and susceptible to errors. This problem will only grow worse as she enters the survivorship phase of her treatment, which will extend for years to decades.[2]

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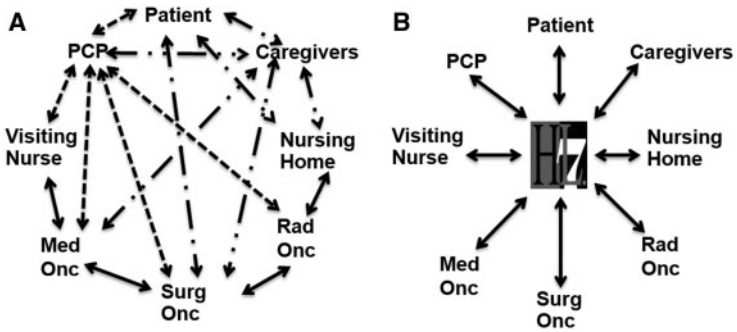
Figure 1. Illustration of some of the potential stakeholders in a routine cancer care scenario. Without standards (**A**), communication pathways may be haphazard, incomplete, and nonsynchronous. Standards (**B**), illustrated by the HL7 logo, enable reliable, complete, and replicable communication—with or without a central source of truth, such as a health information exchange.



This vignette illustrates the norm for many cancer patients today, including those obtaining most of their care in urban settings, because competing hospital systems often do not interoperate. This is one of the many reasons that the Institute of Medicine (IOM) considers our cancer care system to be a "system in crisis" with disjointed, fractured, and often error-prone care—a situation that has not changed appreciably between their critiques in 1999 and 2013.[3,4] In addition to the practical implications for individual patients, the secondary use of clinical information for regional or national cancer analyses, including quality reporting, is impeded by a chronic lack of interoperability.[5–9] The IOM also criticized the cancer establishment for not adequately engaging patients regarding their treatment values and concerns, not providing suitable educational materials, and not communicating information about patients' cancer for their own and their future clinicians' use. Accurate electronic health information encompassing a complete and interpretable record is critical for engaged patients and coordination of care across all phases of the cancer journey, from diagnosis through end of life.[10,11]

National standards for the exchange of clinical data, including narrative elements, have existed since 2000, when the Clinical Document Architecture (CDA, currently in release 2) was first described.[12–14] CDA-R2 is an Extensible Markup Language-based documentation model that represents health concepts using the Reference Information Model (RIM) distributed by Health Level Seven International (HL7).[15] CDA-R2 has been demonstrated to be an effective medium for the exchange of structured clinical data between both systems and providers.[16,17]

The Health Information Technology for Economic and Clinical Health Act, which was part of the American Recovery and Reinvestment Act of 2009, enacted the Meaningful Use (MU) EHR Incentive Program. MU Stage One cites the Continuity of Care Document (a constraint on CDA-R2) as the format for clinical document exchange between EHRs and related systems.[18] However, sharing data electronically across multiple clinical practices remains difficult owing to lack of harmonization of data, inadequate use of structured data capture, lack of standards for specialty care, the proprietary nature and general incompatibility of current EHRs, and lack of consensus on the role of unstructured or semi-structured narrative notes. At the same time, recognition is growing that structured data alone, although it may have importance for billing and compliance documentation, leaves much of the record unavailable.[19] Unambiguous events such as services rendered and laboratory tests are amenable to structure, but the nature of illness and the cancer journey are not.[20] This challenge was stated eloquently by Dr. Robert S. Foote:

> "The medical record is not data. It contains data, as do many forms of writing, but it is not data, nor is it simply a repository into which data are poured. Although its raw material is information—some of which, importantly, can only be expressed with words and not with numbers—a finished medical record is information that has been transformed by the knowledge, skill, and experience of the physician, motivated by the healing impulse, into an understanding of human experience that makes the care of the patient possible."[21]

Although the Centers for Disease Control and Prevention has previously developed the *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012*,[22] this profile was not balloted through an American National Standards Institute (ANSI)-certified Standards Development Organization (SDO), and is meant for cancer case reporting rather than clinical care. Recently, an oncology-specific implementation of the normative HL7 version 3 (v3) Care Record message was described for the continuity of nursing care for oncology patients transitioning from inpatient to home settings.[23] To our knowledge, an oncology-specific standard for the electronic transmission of data required for the overall coordination of clinical care has not previously been described.

OBJECTIVE

In 2012, the Health Information Technology Work Group of American Society of Clinical Oncology (ASCO), comprised of

volunteer cancer clinicians, created the Data Standards and Interoperability Taskforce (DSIT) for the development of oncology interoperability standards. The primary objective was to develop interoperable oncology-specific standards through an ANSI-certified SDO, to enable a reliable source of truth that can be used to untangle the complex web of interprovider and provider–patient communication (Figure 1). The DSIT selected HL7 for its focus on healthcare and broad market penetration; its aspirational goal of attaining interoperability at the application level of the Open Systems Interconnection model for health information exchange;[24] and the rigor imposed by the consensus methods used in balloting, reconciliation, and standard approval. A secondary objective was to evaluate the resultant electronic Clinical Oncology Treatment Plan and Summary (eCOTPS) product in artificial and clinical settings. This paper reports the development of the first oncology-specific HL7 CDA-R2 standard and the insights gained from its early implementation.

MATERIALS AND METHODS

Source material: ASCO chemotherapy treatment plan and summary templates

In 2007, ASCO developed a suite of treatment plan and summary (TPS) templates for cancer care, motivated, in part, by the shortcomings clarified by the aforementioned IOM reports, the seminal IOM report "*From Cancer Patient to Cancer Survivor: Lost in Transition*,"[25] and the loss of continuity and paper health records caused by the catastrophic Hurricane Katrina in 2005.[26,27] Oncologists and advanced nurse practitioners with clinical subject matter expertise participated in focused task forces to develop generic and histology-specific TPS templates. The templates are brief by design, comprising only the most critical data needed for basic coordination and continuity of care. They are paper-based documents that can be used during the cancer work-up and treatment planning phase, during actual treatment, and as a summary after treatment is complete. The summary may be provided to the patient, caregivers, and PCPs (who may often be unaware of the signs of recurrence or potential long-term side-effects of chemotherapy, radiation, and other methods used during cancer care[28–30]). The templates vary, but generally contain several common data elements (Table 1). Because the treatment of curable breast cancer is a common but fairly complex scenario, ASCO's DSIT selected the Breast Cancer Adjuvant TPS (BCTPS) as the source material for the foundational HL7 oncology standard (Figure 2).

Table 1: Data elements in the ASCO TPS templates

Diagnosis, site, and staging
Family history and major comorbidities
Eastern Cooperative Oncology Group performance status[31]
Surgical procedures and notable findings and complications
Biopsy results
Tumor markers and genomic data
Radiation and chemotherapy treatment data and potential and actual side effects
Survivorship plan and follow-up monitoring
Contact information for all significant providers of cancer care

These elements are rather generic across the multiple TPS templates, but are also site- and histology-specific.

Consolidated CDA as a reference standard

Consolidated CDA (C-CDA) uses Extensible Markup Language to transmit patient-specific medical data in structured and unstructured formats.[32] It builds upon HL7's CDA-R2[14] and the HL7 v3 RIM,[33] a consensus view of the way clinical information can be abstractly represented. The CDA constrains the v3 RIM by applying principles for the representation of information in clinical documents. The C-CDA implementation guide (IG) provides building blocks, known as templates, to create specific document types, such as "Discharge Summary" or "History and Physical." Each document type may contain a combination of sections (e.g., problems, results) and entries (e.g., diagnosis of cancer, result of genetic testing). As building blocks, these templates, both sections and entries, may be reorganized into different document types while maintaining the semantic accuracy of the clinical information. MU Stage 2 specified C-CDA Release 1.1 as the standard for the exchange of clinical summaries and transfer documentation between EHR systems.[34] Because of this citation of C-CDA and its fostering by large programs such as the Mid-South Clinical Data Research Network[35] and ONC's Query Health,[36] the DSIT intentionally developed the oncology HL7 standard to be congruent with C-CDA principles.

Creation of the eCOTPS HL7 CDA-R2 IG

To begin translating ASCO's BCTPS into a CDA-R2 standard, the data were defined and disambiguated to map concepts to standard terminologies, vocabularies, and nomenclatures or modeled to the HL7 RIM. This process required extensive input from medical and surgical oncologists in the DSIT, ASCO staff, external oncology and interoperability stakeholders, and developers from the Lantana Consulting Group. The development included review and analysis of previously successfully balloted clinical exchange standards and published IGs for existing templates relevant to cancer treatment, such as the *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, Release 1.0*,[37] the *HL7 Implementation Guide for CDA R2: Quality Reporting Document Architecture—Category I (QRDA) DSTU Release 2 (US Realm)*,[38] and the *HL7 Implementation Guide for CDA Release 2, IHE Health Story Consolidation, Release 1.1—US Realm*.[32]

Each concept in the BCTPS was analyzed to determine whether it comprised a distinct data element within C–CDA.

Figure 2. Page One of the ASCO Breast Cancer Adjuvant Treatment Plan and Summary template, available at http://www.asco.org/quality-guidelines/breast-cancer-treatment-plan-and-summary-resources. This form is available as a modifiable Microsoft Word document, a Microsoft Word form, or a Microsoft Excel spreadsheet. In all cases, the product is intended to be a paper artifact that is printed for the patient, limiting the possibility of interoperability. Page Two has several additional elements (data not shown).

The Treatment Plan and Summary provide a brief record of major aspects of breast cancer adjuvant treatment. This is not a complete patient history or comprehensive record of intended therapies.

Patient name:		**Patient DOB:** (__/__/__)
Practice site:		**Medical record number:**
Patient phone:	**Patient cell:**	**Patient email:**
Hem-onc provider name:		**Hem-onc phone:**
Support contact name:		**Support contact phone:**

BACKGROUND INFORMATION

Age at diagnosis:	**Breast cancer site:** □ Left breast □ Right breast □ Bilateral	
Family history: □ None □ 2nd degree relative □ 1st degree relative □ Multiple relatives		
Definitive breast surgery: Date:(__/__/__) **Type:** □ Lumpectomy □ Mastectomy □ Mastectomy/immediate recon		
# lymph nodes removed (total – sentinel node + dissection):		**# lymph nodes positive:**
Axillary dissection: □ Yes (__/__/__) □ No	**Sentinel node biopsy:** □ Yes (__/__/__) □ No	
Notable surgical findings/comments:		
Tumor type: □ Infiltrating ductal □ Infiltrating lobular □Mixed lobular/ductal □ Other:		
T stage: □T1 □T2 □T3 □T4a □T4b □T4c □T4d	**N stage:** □ N0 □ N1 □ N2 □ N3	
Stage: □ 0 □ I □ II □ III	**Oncotype DX recurrence score (if applicable):**	
ER status: □ Positive □ Negative	**PR status:** □ Positive □ Negative	**HER2 status:** □ Positive □ Negative
Major comorbid conditions:		
Echocardiogram or MUGA result prior to chemotherapy (if obtained): EF= %		

ADJUVANT TREATMENT PLAN	**ADJUVANT TREATMENT SUMMARY**
White sections to be completed prior to chemotherapy administration, shaded sections following chemotherapy	
Height: in/cm **Pre-treatment weight:** lb/kg	**Post-treatment weight:** lb/kg
Pre-Treatment BSA: **Date last menstrual period:**(__/__/__)	**Date last menstrual period:** (__/__/__)
Name of regimen:	
Treatment on clinical trial: □ Yes □ No **Pre-operative chemo administered:** □ Yes □ No	
Start Date: (__/__/__)	**End Date:** (__/__/__)

Chemotherapy drug name	Route	Dose	Schedule	Dose reduction needed	Number of cycles administered
				□ No □ Yes Reasons/comments	
				□ No □ Yes Reasons/comments	
				□ No □ Yes Reasons/comments	
				□ No □ Yes Reasons/comments	

Concepts were then mapped to a template that modeled the semantics of that particular concept. The IG consists of three categories of templates: (1) existing; (2) modified; and (3) new. Existing templates consist of constraints that are unchanged from the original CDA-R2 template. Design aimed to reuse existing templates wherever possible. Modified templates further define and restrain cardinality and vocabulary sets for coded elements to represent BCTPS-specific content. When no template existed or could be further constrained, a new template was designed to represent the relevant concept. Examples are listed in Table 2.

Because the family history C-CDA template is brief and inadequate for pedigree drawing, transmission of genetic test results, and other functions critical to an oncology patient, the DSIT used the convention of CDA-R2 classes targeted at external information objects. Thus, a pointer to *HL7 Version 3 Standard: Clinical Genomics Family Health History Pedigree Model* was included.[39] This practice allows implementers to use either the C–CDA-based family history template for the transmission of minimal family history elements or the pedigree model for risk evaluation, clinical decision support, genetic testing results, and other advanced functions.

Table 2: Examples of existing, modified, and new templates used in the eCOTPS

Category	CDA-R2 Template Name	eCOTPS Template Name	Explanation
Existing	**Allergies Section**	**Allergies Section**	Existing CDA-R2 allergies section was reused in the eCOTPS document.
Modified	**Medications Section**	**Medications Section BCTPS**	CDA-R2 medication section was modified to contain therapies administered to the patient during cancer treatment. Entry templates were added to this section to represent BCTPS-specific content such as chemotherapy activity and lifetime dose of anthracyclines.
	Included entry: Medication Activity	Included entries: Anthracycline Lifetime Dose Chemotherapeutic Drug Therapy Discontinued Chemotherapy Medication Activity Medication Activity	
New	Not applicable	**Anthracycline Lifetime Dose**	Because the use of anthracycline is specific to oncology, a new template was designed to represent the total cumulative dose of drugs in the anthracycline drug class that a patient has received in his or her lifetime.

Balloting of eCOTPS through HL7

HL7 operates under the consensus rules of an ANSI-certified SDO. The HL7 ballot facilitates widespread collaboration in the development of technical specifications. Participation is free and open to HL7 members, and nonmembers must register and pay an administrative fee. Interested parties register prior to the release of the ballot packages. Once per cycle, registered participants have at least 1 month to review the draft standard and submit a vote and comments.

HL7 has four types of ballots to which proposed standards can be submitted:

- Normative—meets the highest threshold for consensus under ANSI process, and is stable and implementation-ready.
- Informative—provides detailed information regarding the interpretation or implementation of an HL7 specification.
- Draft Standard for Trial Use (DSTU)—meets ANSI requirements for trial implementation; may not be forward-compatible with later, normative edition.
- Comment—gathers input on the viability and clarity of a proposed document; no votes are taken, but all comments are considered.

Votes, if applicable, may be submitted as affirmative, abstain, or negative. Negative votes must include comments that document the reason for the negative vote. Comments as part of an affirmative vote are encouraged and can improve the content or clarity of standards. DSTU standards that meet quorum for approval must still address and reconcile all comments during the reconciliation process, with the intent of improving the quality and clarity of the proposed draft standard. After all comments have been resolved, the balloted document is resubmitted for either publication or re-ballot.

RESULTS

Development of the draft standard

The initial draft of the IG was developed over the course of 6 months, during which weekly conference calls were held between the developers and cancer clinicians. Several new CDA-R2 templates were developed to represent BCTPS-specific concepts, specifically data for family history of breast cancer, the American Joint Committee on Cancer's Tumor, Node, and Metastasis Staging System breast cancer codes, breast cancer chemotherapy and hormonal therapy, surgical findings, and potential adverse effects of breast cancer treatment. Several Tumor, Node, and Metastasis codes were not represented by extant Systematized Nomenclature of Medicine, Clinical Terms codes; new codes were added in cooperation with the National Library of Medicine.

Balloting and approval as a DSTU

The draft standard, IG, and artifacts were submitted to HL7's Structured Documents Work Group in the spring of 2013 for open balloting. The standard met quorum for approval and all comments were resolved per the usual HL7 process. In November 2013, the revised standard was approved and published as *HL7 Implementation Guide for CDA, Release 2: Clinical Oncology Treatment Plan and Summary, DSTU Release 1*.[40]

Implementation in the Health Story Project

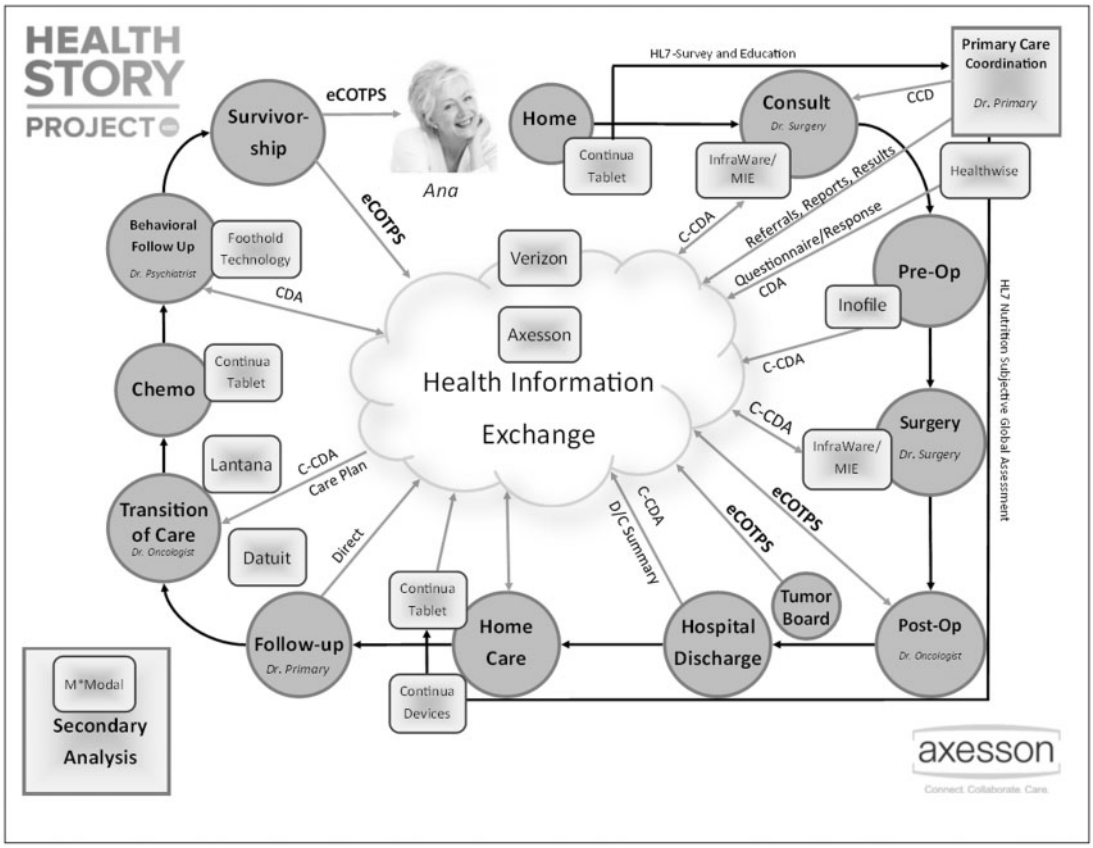
In 2014, the eCOTPS was successfully implemented in the demonstration by Health Story Project (Health Story) at the Healthcare Information and Management Systems Society

(HIMSS) Interoperability Showcase. Health Story began in 2006 as a not-for-profit alliance of healthcare vendors, providers, and associations. As part of its mission, Health Story coordinates an annual presentation at the HIMSS Interoperability Showcase. A clinical vignette (Figure 3) similar to that described above was used to iteratively transmit accumulative eCOTPS data through real-time interactions with various EHRs and other electronic data applications. This realistic scenario demonstrated modular use of the eCOTPS; coordination of care for a cancer patient with multiple comorbidities; incorporation of patient preferences into the clinician workflow; electronic linkage of an interdisciplinary care plan manager and a Health Information Exchange; multiple data capture methods directly from devices; and patient-reported symptom and preference information. The demonstration was well received by more than 800 HIMSS attendees.

Implementation and evaluation through Athena

The Athena Breast Health Network (Athena) is a collaboration among the five University of California (UC) medical/cancer centers (UC Davis, UC Irvine, UC Los Angeles, UC San Diego, and UC San Francisco), the Graduate School of Public Health at UC Berkeley, and a number of public and private partners.[41] Athena's mission is to prototype new approaches to the screening and treatment of breast cancer. Members of the Athena team engaged in a comprehensive clinical workflow analysis to identify opportunities for improving data capture at the point of care. The analysis at four Athena sites involved 45 key informant interviews with clinicians, practice managers, cancer registrars, and other stakeholders. Specifically, the project team focused on hand-offs and interfaces between clinical workflows, as well as data capture, validation, and utilization through existing health information exchange mechanisms. From this emerged a subset of data that is critical for decision making, clinical trials, and registry reporting. These data elements were reviewed by over 50 clinicians across the five UC academic medical centers, with a primary focus on key clinical and research data. The project team compared their data elements against existing relevant data standards, including the eCOTPS, the College of American Pathologists electronic

Figure 3. The Health Story Project clinical vignette. The patient, "Ana," is diagnosed with breast cancer and goes through a series of health care interactions on her journey through treatment to survivorship. "Actors" in the vignette are labeled in italics; vendors or organizations with a primary role in a given clinical interaction are shown adjacent to that interaction. All information is passed by using established standards for structured and/or unstructured data, as shown. In particular, the eCOTPS is passed to the Health Information Exchange during treatment planning and to Ana herself at the conclusion of primary treatment. D/C: discharge; MIE: medical informatics engineering.



Cancer Checklists, the California Cancer Registry, and the National Cancer Institute Cancer Therapy Evaluation Program Common Data Elements for clinical trials. Athena's data elements were selected based on their perceived importance in comprehensive care coordination, point-of-care data capture, clinical registration, and quality improvement. Athena's data aligned well with ASCO's BCTPS elements, making the eCOTPS an ideal data exchange standard for the project. However, because the eCOTPS is, by design, a brief planning and summary document, certain data required for certain aspects of care delivery were not represented; examples are measurements of specific lesions and exact radiation treatment dosages (when applicable).

A web-based Athena application with dynamic data entry forms ("data entry checklists") was mapped to the eCOTPS, essentially ensuring semantic correctness when converting question/answer pairs to HL7 observations. This was managed by a team that included an HL7 expert, a breast cancer informatics analyst, and a software engineer. Although the Athena checklists have data element groupings similar to the ASCO TPS data elements (Table 1), they are more comprehensive and certain concepts are more granular than those in the eCOTPS. Additionally, mapping from the checklist format to the eCOTPS document format was more complex because some of Athena's checklists contained data elements that mapped to multiple eCOTPS document sections. It was then necessary to perform many-to-many mapping of certain checklist data elements to eCOTPS document sections (i.e., document sections containing data elements from more than one checklist). For example, the Athena checklist *Initial Diagnosis and Treatment* has detailed information about the individual lesions discovered by one or more imaging techniques, including their identity, location, size, invasive grade, and whether molecular or genetic testing was performed. Representing these data in the eCOTPS required the creation of additional CDA-R2 templates including new vocabulary bindings.

DISCUSSION

In the mid-2000s, ASCO recognized that a standardized summary of cancer care was necessary. This recognition was fortuitously driven by an improved outlook for many cancer patients that has increasingly created the need for summarization and survivorship programs.[42] With many cancer patients now outliving their disease by years or decades, major life events such as geographic relocation or changes in employment status are common.[43,44] Likewise, with an expanding survivor population, medical oncologists have increasingly relied on resumption of care by PCPs after completion of primary therapy. Despite ASCO's successful creation of a suite of TPS templates, uptake was unimpressive, partly because these templates remained paper-based, tedious, and time-consuming to complete.[45,46] According to one large recent survey, only one-third of cancer survivors are currently receiving treatment summaries.[47]

The DSIT embarked on the process of translating and modifying the paper TPS templates to an interoperability standard with three goals in mind: (1) to create a rigorously vetted standard through an ANSI-accredited SDO; (2) to approach this standard creation process in a manner enabling modularity; and (3) to provide the resultant products for open consumption by the healthcare market in accordance with ASCO's not-for-profit approach.

Although healthcare-specific standards have been in development for decades, uptake has been frustratingly slow. The many reasons for this include competing standards at the national and international levels, loss of enthusiasm at early implementation, lack of monetary reimbursement for implementation, perceived or actual lack of backward compatibility, proprietariness, and conformance concerns.[48] Fortunately, the landscape is changing, largely driven by the widespread uptake of EHRs necessitated by MU.[49] MU Stage 2 cites many specific standards (including C-CDA), and is hoped to accelerate the dissemination and implementation of healthcare standards.[50] Where the information needs of eCOTPS and MU certification criteria overlap—as in medication and problem lists—adoption is easier and reuse of data collected during clinical care is supported. Standards risk becoming obsolete if they are not used; thus, it was a goal to implement the eCOTPS soon after DSTU designation was achieved. ASCO was fortunate to identify two enthusiastic early adopters: Health Story and Athena. Each of these experiences was informative and will help guide and refine the eCOTPS so that it may eventually reach HL7 normative status. Although the Health Story demonstration was constructed around a synthetic patient scenario, it is realistic in that it brought together multiple for-profit and not-for-profit organizations who had to interoperate to succeed. Athena is a very large network that cares for almost 45% of the breast cancer patients diagnosed in California. In their evaluation, Athena found that using CDA-based data exchange for the eCOTPS is likely to require additional CDA-R2 templates and vocabulary bindings, which invokes nontrivial efforts. One possible solution is the open source "greenCDA" implementation toolset (http://www.openmapsw.com/index.htm), which was found to significantly reduce the time and resources needed for the implementation of the eCOTPS. After new templates were added, the creation of the complete Athena CDA and the simplified greenCDA with the tools was simplified for both designers and implementers. Tools like this are an essential part of efficiently and correctly implementing CDA-R2 specification.

There is an alternative oncology-specific nursing standard for continuity of care, the HL7 v3 Care Record,[23,51] and like eCOTPS, it supports electronic information exchange among cancer providers and patients. The use case for the HL7 v3 Care Record was to provide summary information to inform nursing home care. This leaves an unmet need for a standard to serve as a form of ongoing communication to augment the overall coordination of care for an oncology patient, during and after treatment. The C-CDA framework was chosen instead of v3 messages because the eCOTPS requires a canonical human-readable format, which can be displayed on ubiquitous tools, given a single style sheet. V3 messages (e.g., Care Record) require a custom style sheet that is not reusable across message or document types, increasing the level of effort to

implement for clinical end users. Thus, successful implementation of the v3 Care Record message implies the existence of a relatively sophisticated infrastructure. The eCOTPS use case suggests that it can be deployed across a range of applications, from sophisticated EHRs to any browser-enabled device. Pragmatically, CDA is much more widely implemented than v3 messages in the United States and most countries with a national health information technology initiative. Wide implementation is one sign that the specification offers practical advantages and that it will be easier to recruit vendors to adopt the specification. In terms of modularity, the HL7 v3 RIM framework is ideal. Specifically, many elements are common across cancer (which is not a distinct disease, but rather 100+ site- and histology-specific subtypes[52]). Other elements are quite specific to subtypes of cancer, such as estrogen receptor status in breast cancer. A template-driven extensible standard provides significant flexibility as more cancer subtype-specific TPSs and other cancer-specific areas, such as survivorship, are standardized in future work.

Whereas these initial implementations are mostly positive, the ultimate success of the eCOTPS will be dependent on three critical factors: (1) widespread uptake by EHR vendors with oncology-focused solutions; (2) auto-population of data elements to eliminate redundant data entry; and (3) the willingness of large practices and hospital systems to fully embrace seamless interoperability. Although policy levers such as MU play their part, a culture change toward sharing and transparency, while simultaneously respecting patient privacy and autonomy, is still needed. It remains to be seen whether disruptive standards such as HL7's Fast Healthcare Interoperability Resource (FHIR)[53] will change the general calculus of interoperability, as well as the future of eCOTPS; fortunately, there are encouraging signs of cooperation between the FHIR and CDA communities (http://www.hl7.org/implement/standards/fhir/comparison-cda.html). Thus, if FHIR becomes a successful and widely used standard, implementation of eCOTPS using FHIR will be feasible.

As Athena goes live with the eCOTPS, transmitting breast cancer data throughout the UC Healthcare System, ASCO's DSIT is already expanding the eCOTPS, adding data from the Colon Cancer Adjuvant TPS. At the same time, the DSIT is undertaking improvements to the existing eCOTPS based on Athena's experiences. The DSIT plans to iteratively expand the eCOTPS so that over the next few years, it will include disease-specific data for the most prevalent cancers, critical survivorship information, and patient-reported data.

CONCLUSION

The eCOTPS is the first oncology-specific CDA-R2 standard to achieve DSTU status through the HL7 balloting process. Early implementers have demonstrated that the standard is functional and adaptable to different needs. Having the flexibility to create additional CDA-R2 templates is essential for supporting real-world patient care. Continuing experience gained through trial implementation will inform the DSIT's future work. Oncology interoperability standards will improve the quality of cancer care by allowing the efficient transmission of reliable, meaningful, and up-to-date clinical data between all stakeholders involved in the cancer journey.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

CONTRIBUTORSHIP

J.L.W., S.E.M., K.S.H., J.C.K., P.P.Y., L.N.S., D.K.M., L.A., Z.G., and E.P.A. participated in the design and creation of the eCOTPS HL7 standard; J.L.W., L.A., G.A.K., Z.G., and E.P.A. participated in the implementation of eCOTPS in the Health Story Project; M.H., M.S., A.S.F., S.E.D., and L.E. participated in the implementation of eCOTPS in the Athena Breast Health Network; J.L.W. and S.E.M. wrote the initial draft manuscript; all authors contributed to the manuscript revisions and approved the final manuscript.

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