Advancements in Interoperability: Achieving Anatomic Pathology Reports That Adhere to International Standards and Are Both Human-Readable and Readily Computable

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ABSTRACT

PURPOSE Over the past 50 years, multiple pathology organizations worldwide have evolved in cancer histopathology reporting from subjective, narrative assessments to structured, synoptic formats using controlled vocabulary. These reporting protocols include the required data elements that represent the minimum set of evidence-based, clinically actionable parameters necessary to convey the diagnostic, prognostic, and predictive information essential for patient care. Despite these advances, the synoptic reporting protocols were not harmonized across the various pathology organizations. Cancer pathology continues to be widely reported and stored in free-text format, or without encoded data such that it is neither computable nor interoperable across organizations.

METHODS In 2020, SNOMED International created the Cancer Synoptic Reporting Working Group (CSRWG). This resulted in international collaboration across multiple pathology organizations. CCRWG's mission was to use SNOMED Clinical Terms (CT) concepts to represent the required content within the College of American Pathologists (CAP) and International Collaboration on Cancer Reporting (ICCR) published pathology reporting protocols.

RESULTS In late 2023, the CSRWG published over 1,300 new or revised SNOMED CT concepts to represent all required pathology cancer data elements for adult and pediatric solid tumors in both CAP and ICCR using the semantic principles of the SNOMED-CT concept model. Thus, computability and interoperability would be broadly established.

CONCLUSION This work brings to fruition the longstanding desire for an international, interoperable, human- and machine-readable cancer pathology report for use in patient care, health care quality improvement, population health, public health surveillance, and translational and clinical trial research. The following report describes the project, its methods, and applications in the stated use cases.

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BACKGROUND

Pathology cancer reporting has been in evolution since the 1950s when the WHO announced that it would begin to establish standards for cancer classification. Numerous efforts to standardize the representation of the data contained within the pathology report were attempted including efforts by the College of American Pathologists (CAP) to establish a systemized terminology for anatomic pathology reporting, first as the Systemized Nomenclature for Pathology in 1965 and beginning in 1975 its transition to the SNOMED. By the 1980s, the CAP began to publish best practice guidelines for pathology cancer reporting to ensure completeness of clinically actionable findings. In 2007, the CAP issued its first electronic Cancer Protocols (eCPs). In 2010, the International Collaboration on Cancer Reporting (ICCR) was created to standardize cancer reporting on an international scale with the publication of the first reporting data sets in 2013. Despite the progress in establishing international guidelines for reporting on cancer, and despite the fact that CAP planned to use SNOMED Clinical Terms (CT) to encode the cancer protocols with the first release of eCPs,

TABLE 1. SNOMED CT Concepts by SNOMED CT Top-Level Hierarchy

SNOMED CT Hierarchy	New or Edited Concepts Developed	New or Edited Concepts Mapped to CAP Cancer Protocols	Mapped SNOMED CT Concepts to CAP Cancer Protocols
Observable entity	1,010	585	664
Morphologic abnormality	76	54	430
Qualifier value	73	37	175
Disorder	53	0	38
Substance	42	0	1
Staging scale	12	0	0
Situation	3	0	1
Procedure	1	1	166
Specimen	1	0	10
Total	1,326	698	2,013

NOTE. Column 1 represents new and/or edits SNOMED CT concepts developed in this project by top-level hierarchy. Column 2 indicates the number of new and/or edited concepts mapped to CAP cancer protocol data elements. Column 3 represents the total number of mapped SNOMED CT concepts to CAP cancer protocol data elements.
Abbreviations: CAP, College of American Pathologists; CT, Clinical Terms.

computable and interoperable representation of data contained in the reports remained elusive. The US Centers for Disease Control and Prevention (CDC) commissioned Reporting Pathology Protocol studies in 2005 and 2009 and determined that the two prevalent data standards available for pathology, Logical Observation Identifiers Names and Codes and SNOMED CT, were insufficient to represent pathology data in the CDC cancer registry. Of primary concern was the lack of content available in either terminology for use in cancer reporting and the paucity of concept definitions to render encoded data unambiguous for ongoing data analytics.

Data contained within cancer pathology reports are critical to providing the diagnostic, prognostic, and predictive information essential for health care teams. The information within pathology reports is further used for public health surveillance, health system planning, hospital quality measures, clinical trials, and translational research. However, the historically prevalent narrative style of pathology reports renders data difficult to find within a sea of prose, sometimes ambiguous, incomplete, and not computable.[1-5] Efforts to standardize and structure pathology reports by the CAP,[6] the Royal Colleges of Pathology in the United Kingdom (RCPath)[7] and Australasia (RCPA),[8] and the ICCR[9] have been successful on an international scale. The widespread adoption of standardized cancer pathology data sets and synoptic reporting styles by pathologists in which evidence-based core (required) and noncore (recommended) data elements are enumerated and expressed in a parameter/response (question/answer) fashion has improved the completeness[10-13] and quality of pathology reports[14,15] along with the realization of increased levels of satisfaction by those consuming the reports.[16] Furthermore, the use of synoptic reporting has driven best practice policy decisions in prostatectomy approaches[17] and has been associated with improved outcomes in colon cancer.[18] Despite the evidence supporting structured pathology reports, most pathologists continue to create cancer reports in free-text format using narrative text; thus, they are not inherently computer-readable nor are they interoperable. At least one underlying cause is the absence of a suitable international data standard.[19,20]

In the seminal paper by Ellis and Srigley et al[15] of Cancer Care Ontario,[21] the authors present a progression of structure and utility for cancer pathology reporting. This reporting evolution is described as six levels, with each level adding structural aspects to a pathology report ranging from complete narrative to fully structured text AND discrete, machine-readable representation of the structured text. Finally, the most advanced level of reporting (level 6) is realized when the structured text and machine-readable content use semantically interoperable computable terminology.

The demonstrated benefits of synoptic cancer pathology reports can only be extended internationally through agreed-upon data elements and computable terminology. The United States and Canada share common data elements via CAP protocols. In a complementary effort, the work of the ICCR supported by the CAP, RCPath, RCPA, and other international organizations has aligned evidence-based cancer pathology reporting requirements on the international level.[22] The remaining component to realize level 6 reporting is use of a single underlying computable medical terminology to represent each data element in the reporting protocols from both sources.[23] The SNOMED International Cancer Synoptic Reporting Working Group (CSRWG) was established in 2020 to fill this terminology gap.

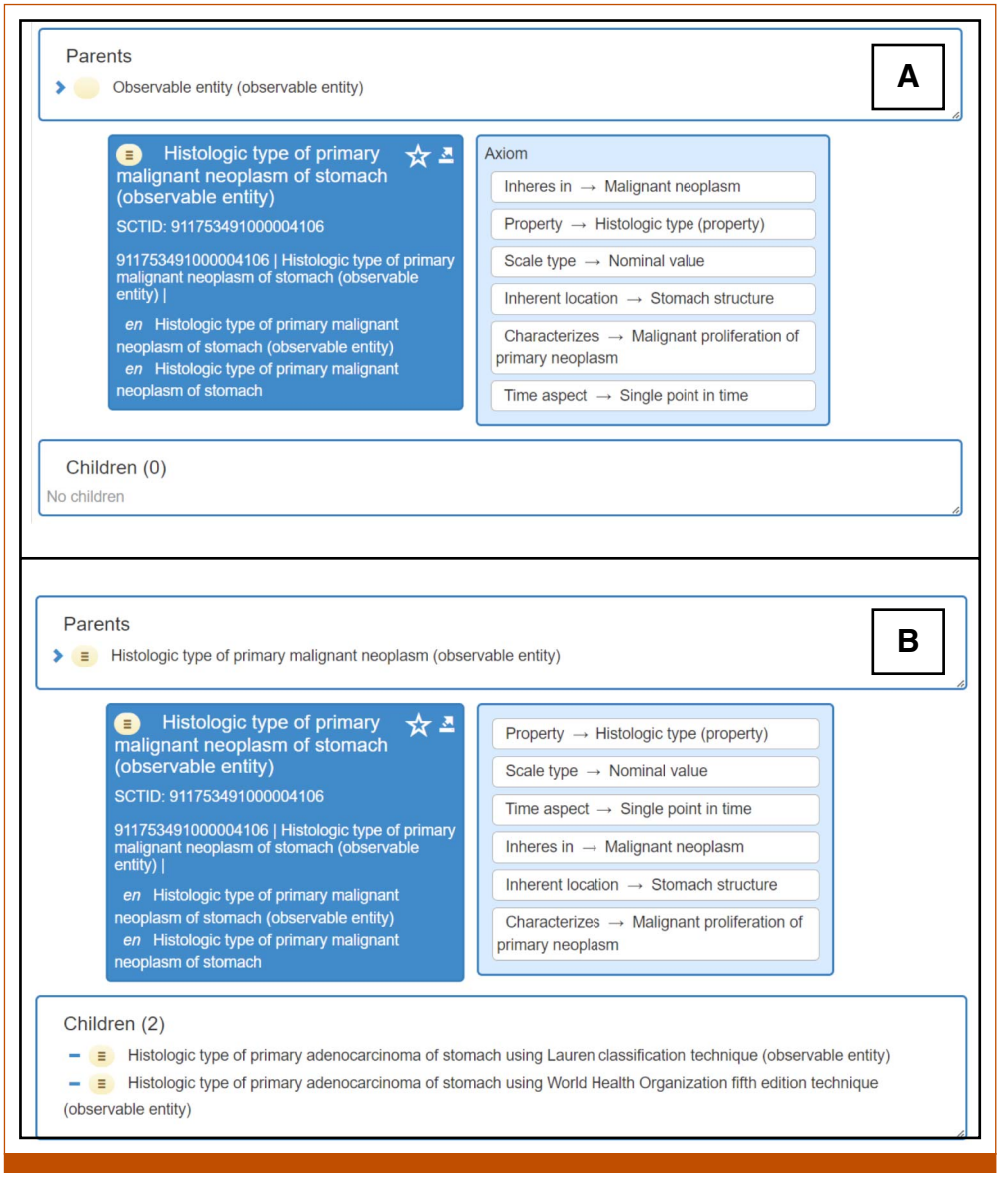

FIG 1. (A) The stated definition of Histologic type of primary malignant neoplasm of stomach. The concept is defined as a type of Observable entity with defining characteristics enumerated. The concept has no stated child concepts. (B) The computed or inferred definition of the concept. Although the defining characteristics are the same, the concept's logical relationships to other SNOMED CT concepts are enumerated. The concept is logically a subtype of Histologic type of primary malignant neoplasm with two child concepts that define two separate methods of describing histologic type. CAP, College of American Pathologists; CT, Clinical Terms.

METHODS

Investigators at the University of Nebraska Medical Center (UNMC), in response to researcher needs for access to pathology cancer report data in support of clinical trials and other translational research, began to expand SNOMED CT to create unambiguous human- and machine-readable report output in 2014 as a pilot project. It is important to note that SNOMED CT content available at the outset of this project is the same content deemed unfit for use by the aforementioned CDC Reporting Pathology Protocol studies. Examples of these concepts can be found in the SNOMED CT browser as subtypes of <<250537006 |Histopathology finding (finding)|, <<395557000 |Tumor finding (finding)|, <<384740007 |Finding of grade (finding)|, and <<373369003 |Finding of histologic grading differentiation AND/OR behavior (finding)|. They are simply concept identifiers with word string definitions. As such, they do not have sufficiently computable concept definitions to unambiguously and accurately represent pathology cancer data elements, and the CSRWG chose not to use them.

TABLE 2. SNOMED CT Attributes Used in Concept Definitions

Attribute	Description
|Property|	This attribute is used to assert the property, or feature, being assessed by the pathologist. Target values for this attribute include <<410668003 |Length property (qualifier value)|; <<30001000004102 |Histologic feature (property) (qualifier value)|; <<1300001000004107 |Location property (qualifier value)|; <<705057003 |Presence (property) (qualifier value)|; <<118582008 |Percent (property) (qualifier value)|; <<758637006 |Anatomic location (property) (qualifier value)|
|Inheres in|	This attribute is used to assert the entity that carries the property being measured. In most cases, the target values are <<108369006 |Neoplasm (morphologic abnormality)|
|Inherent location|	The inherent location attribute is used to describe the anatomical location of the entity that carries the property being assessed. In most cases, the inherent location indicates the anatomical location of the primary malignant neoplasm, that is the primary organ affected by the malignancy
|Component|	This attribute is used to indicate an entity that is being assessed for presence such as necrosis within a neoplasm. It is also used to represent the numerator in a person observation
|Relative to|	This attribute is used for the denominator in a percent or number fraction observable
|Direct site|	Direct site is specifically used to define the specimen in which the observation is being made
|Technique|	Technique is used to define the method by which the observation is being made. This attribute is used to specify methods of tumor staging, histologic grading methods, direct vision (gross) evaluation, microscopy, and immunohistochemistry methods
|Time aspect|	The tie aspect for all cancer pathology observable entities is 123029007 |Single point in time (qualifier value)|
|Scale type|	This attribute is used to describe the evaluation scale used for the observation. 117362005 |Nominal value (qualifier value)| is used to describe observable entities assessing morphologies, body structures, and procedures. 117363000 |Ordinal value (qualifier value)| is used in histologic grade observation and observations indicating the presence, absence, or degree of presence. 30766002 |Quantitative (qualifier value)| is used for numerical observations
|Characterizes|	Characterizes is used to represent the underlying processes of the neoplasm. These include <<1204295007 |Malignant proliferation of neoplasm (qualifier value)| and <<1255587009 |Regression of neoplasm (qualifier value)|
|Process extends to|	This attribute is used to define the end point of the process indicated by the characterizes attribute/value pair. In most concepts, the associated value of this attribute is <<123037004 |Body structure (body structure)| to indicate where the neoplasm has grown or metastasized

The pilot project involved SNOMED CT–certified UNMC faculty working in conjunction with pathologists to identify, modify, or create a SNOMED term for each required data element enumerated in the CAP protocols specific to colorectal cancer, breast cancer, and melanoma. These synoptic-style reports conform to the SNOMED CT observable entity construct. SNOMED CT observable entities represent concepts that describe a thing, process, or other phenomenon that can be measured or assessed with sufficient context to unambiguously interpret the measurement recorded. Using this model, initial content was authored in the UNMC SNOMED CT extension namespace (100004) for the pilot project [24] and subsequently donated to SNOMED International in 2020.

Due to the shared, international need for improved cancer pathology content in SNOMED International and the success of the UNMC pilot project, the member nations approved the creation of the CSRWG in 2020. Their task was to develop all the necessary SNOMED CT content to bind to the required data elements for the CAP cancer protocols and the ICCR published data sets for all published adult and pediatric solid tumors, building on the pilot work begun at UNMC. The CAP data elements were defined as the starting point for a primary source of truth. This decision was based on (1) accessibility of robust documentation, (2) longevity of content availability, (3) maturity of content management and management tooling, (4) large user community, and (5) substantial (>95%) overlap with ICCR protocol content. The CSRWG comprises multiple pathologists, informaticists, and cancer registrars from member nations, along with members of SNOMED International authoring staff. The project leader maintained relationships with CAP Informatics and Pathology Electronic Reporting Tools committees and membership on ICCR's Dataset Steering Committee, facilitating access to a large, international network of pathologists all committed to the development of standardized, international, and interoperable cancer reporting.

Weekly meetings across the collaborating teams were maintained throughout the project. Extensive input from pathologists was used to establish the precise meaning of the SNOMED CT concepts being authored. SNOMED CT authors met regularly to ensure that these concepts unambiguously represented the pathologist's observations. Template, or pattern-based, authoring was used for concept classes shared across numerous protocols to ensure consistency in the modeling and naming of new concepts with iterative model refinement as needed. Concept authoring followed SNOMED CT practices. Upon concordance between pathologists and concept authors, concepts were reviewed by the Chief Terminologist for SNOMED International. When approved, these concepts were promoted to the international version of SNOMED CT.

RESULTS

In total, over 1,300 SNOMED CT concepts were authored or revised, with the majority comprising newly authored entries. SNOMED CT content spans all 60+ protocols for solid tumors in adult and pediatric patients including content for prognostic and predictive immunohistochemistry observations. The majority of new and revised concepts are found in the Observable Entity (question) hierarchy of SNOMED CT. Hematolymphoid and CNS neoplasms were excluded in this initial release as synoptic reporting is not universally used to

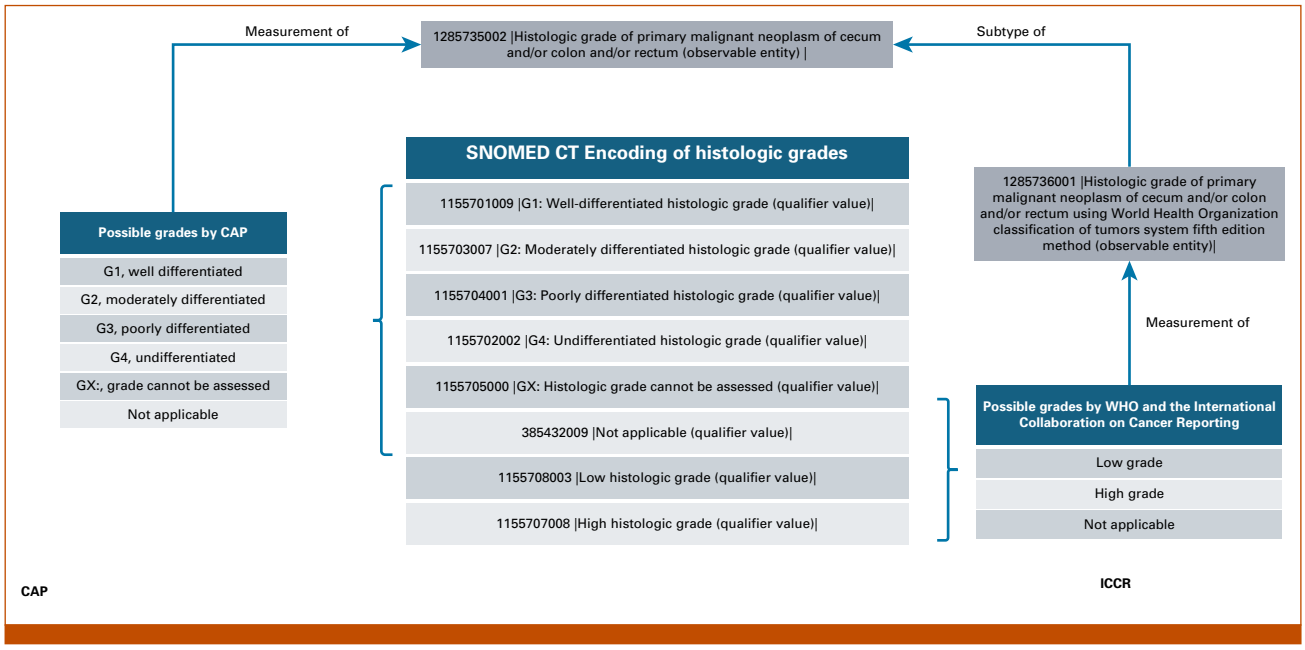

FIG 2. Example of SNOMED CT terminology bindings to histologic grade for colorectal cancer data sets as published by the CAP and the ICCR. Histologic grade is measured from G1 to G4 by the CAP and as low grade or high grade by the ICCR and the WHO. The question for the CAP and the ICCR differs by naming the technique used to assess grade. The CAP uses a general (historical) method, and the ICCR uses a specialization (subtype) method as specified by the WHO. This allows specificity of encoding by the method used and ensures context-specific comparison of measurements (answers) reported. CAP, College of American Pathologists; CT, Clinical Terms; G, grade; ICCR, International Collaboration on Cancer Reporting.

report pathology assessment for these tumor types. Table 1 enumerates the number of new and/or edited SNOMED CT concepts developed in this project by SNOMED CT top-level hierarchy. All content is found in the International Release of SNOMED CT and available for international review through their browser.[25]

The SNOMED CT concept model for observable entities allowed the CSRWG to author observable entity content with high levels of specificity and render unambiguous data element representation. Furthermore, the polyhierarchical and subsumptive nature of SNOMED CT supports logical concept aggregation. Figure 1 provides an example using histologic type of primary malignant neoplasm of stomach. The concept is stated to be an observable entity with defining attributes that assert that the concept is an assessment of (ie, property) histologic type that is inherent in a malignant neoplasm located in the stomach. In addition, the malignant neoplasm is characterized by primary growth (ie, this is a primary malignancy versus metastatic malignancy). After classification, the concept is found to be a subtype of an assessment (measurement) of the histologic type of a primary malignant neoplasm; in the case of gastric tumors, there are two subtypes that define the classification systems used to assess the neoplasm (ie, the Lauren system and the WHO Classification of Tumors Fifth Edition method). Table 2 provides a synopsis of defining attributes used to model observable entity concepts in this project.

New content was developed in the qualifier hierarchy that was necessary to achieve full definition of observable entities. For example, concepts defining grading techniques and scales such as Gleason, International Society of Urological Pathology, and the WHO Classification of Tumors fifth edition grading techniques were introduced along with additional qualifier values for grading value sets, as well. Although sufficient SNOMED CT concepts existed for most anatomic locations and morphologies in the body structure hierarchy, new concepts had to be created in the acquired body structure hierarchy to represent surgical margins.

The consistent use of similar data elements across CAP and ICCR protocols allowed the modelers to develop full concept semantics for the data elements in both the CAP and ICCR publications. Differences between CAP and ICCR content varied only slightly. ICCR content reflects international practice patterns, whereas the CAP represents North American pathology practices. For example, the ICCR reflects WHO practice parameters for grading tumors, whereas the CAP reflects a more generic parameter. Both methods were easily accommodated (Fig 2) while simultaneously showing the relationship between the two methods. ICCR protocols solicit premicroscopic examination information from the pathologist such as type of antineoplastic treatment before resection (neoadjuvant therapy), whereas CAP does not request this type of information. The ICCR staging parameters generally reflect Union for International Cancer Control

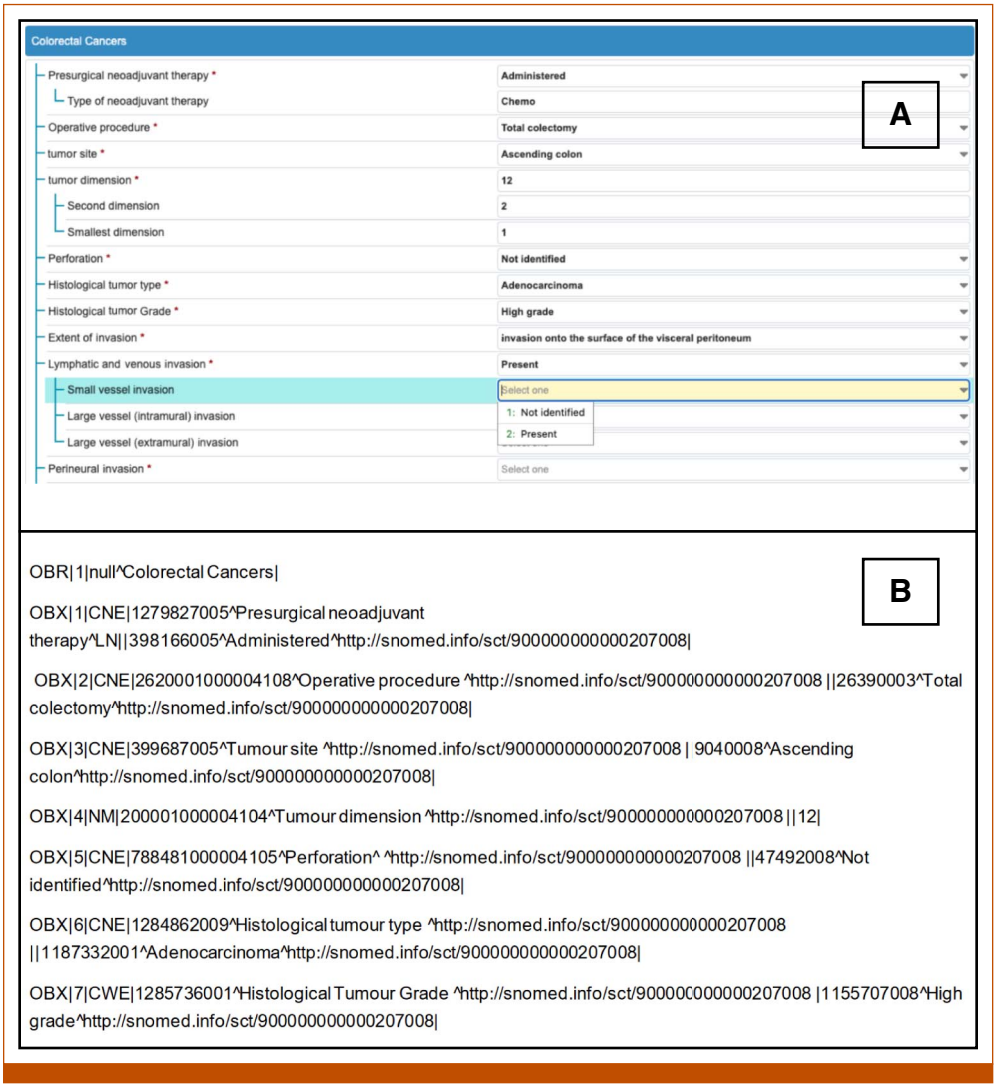

FIG 3. Sample pathology report. (A) Sample FHIR-based structured data capture[26] pathology form. (B) Corresponding HL7 version 2, SNOMED CT encoded pathology report. CT, Clinical Terms; FHIR, Fast Healthcare Interoperability Resources.

content, whereas the United States and Canada use American Joint Committee on Cancer staging guidelines. Despite the noted differences, there was no issue developing SNOMED CT content for ICCR- or CAP-published content that was not conducive for use by either organization and remained fully interoperable.

A data element inventory system created by the CAP was used to index each SNOMED CT observable entity and observation (measurement) concept that was bound to the eCPs required and many nonrequired, observable/observation combination. The data element concept inventory consists of over 12,000 concept binding combinations. These bindings have been given to the CAP and ICCR for incorporation into future pathology cancer reporting. Table 1 illustrates the numbers of unique SNOMED CT concepts directly used in the CAP eCPs.

Authors noted that SNOMED CT content reflected historical nomenclature, in particular for neuroendocrine neoplasms. Previously, SNOMED CT had labeled all tumors of neuroendocrine histology as neuroendocrine carcinomas (NECs), thereby conflating well-differentiated neuroendocrine tumors (NETs) with poorly differentiated NECs. Although NETs are considered malignant and their behavior ranges from indolent to somewhat aggressive, even the grade 3 well-differentiated NET will present with a well-differentiated cytomorphology. Necrosis and mitotic activity are limited compared with the poorly differentiated NECs that are recognized by the presence of extensive apoptosis, very high mitotic activity, and poorly differentiated cytomorphology. Thus, the WHO Classification of Tumors fifth Edition reserves the term NEC for poorly differentiated high-grade tumors and NET for those with well-differentiated cytomorphology. The CSRWG remodeled this content in

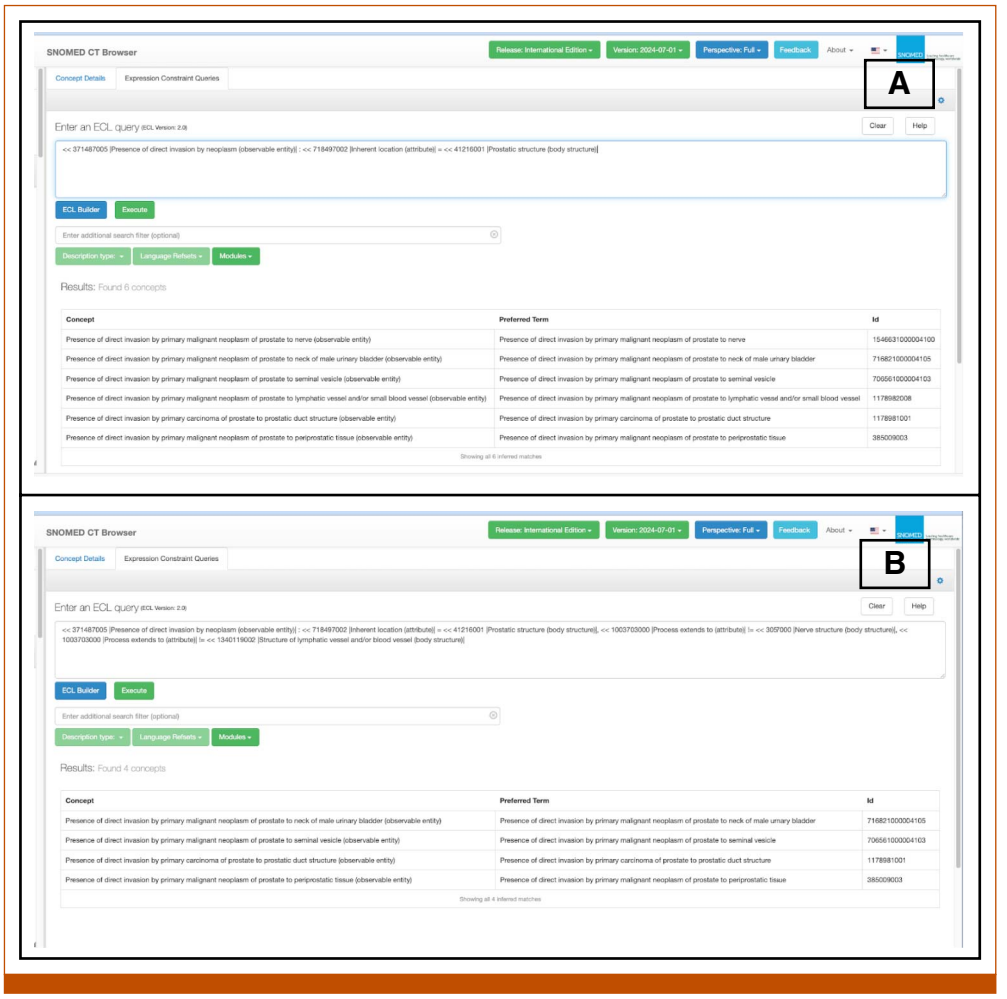

FIG 4. Prostate invasion query. (A) SNOMED CT expression constraint language query identifying all SNOMED CT concepts for the presence of direct invasion by prostate tumors. (B) SNOMED CT expression constraint language query identifying all SNOMED CT concepts for the presence of direct invasion by prostate tumors excluding perineural and lymph-vascular invasion. CT, Clinical Terms.

SNOMED CT and it will also be reflected in the upcoming release of International Classification of Diseases-O-4.

DISCUSSION

With the development and release of SNOMED CT content specific to pathology cancer reporting, the international community finally has a uniform method to capture, communicate, and use cancer pathology data on a large scale. This project specifically addressed the deficiencies in existing controlled medical terminologies to achieve a fully computable, standardized method to represent cancer pathology data in a precise, unambiguous fashion for use throughout the data lifecycle from patient care to public health to translational research.[2,26,27] The choice to use SNOMED CT was not random as it is the largest international health data terminology, used in over 48 nations. It has been rooted in pathology since inception and is used in the International Patient Summary and in the United States Core Data for Interoperability (USCDI). CAP, Canada Infoway, the United Kingdom, and Sweden specified that SNOMED CT be the unifying coding system for this project. The North American Association of Central Cancer Registries has expressed interest in using it.

Binding SNOMED CT to CAP and ICCR cancer data sets has immediate effect on patient care and data interoperability. Many North American EHR and LIS software vendors are able to display CAP eCPs in human-readable form published for clinician use and also ingest SNOMED CT encoded data elements. SNOMED CT encoded data elements can then be used within the context of the EHR to support computations for best practice advisory alerts, staging calculations, and tumor characteristics needed for clinical trial identification/eligibility as well as population surveillance. Use of SNOMED CT to represent synoptic data elements renders the pathology cancer report data available for electronic and interoperable data transfer between health care institutions to

facilitate patient care and to cancer registries for population surveillance without manual data extraction. Figure 3 represents a cancer pathology report and a portion of the corresponding HL7 message of the encoded data in HL7 version 2.x. and Fast Healthcare Interoperability Resources (FHIR; partial) formats.

SNOMED CT encoded cancer pathology reports also enable secondary use of pathology data. The underlying concept model used to author SNOMED CT concepts conveys precisely what a concept *means* (ie, how it is defined) and is not simply a unique code. Furthermore, after concept creation, SNOMED CT concept classification generates all logically valid relationships between all other concepts. As such, they are an integral element of common data models such as Observational Medical Outcomes Partnership. Queries to aggregate data across multiple layers of content with varying degrees of granularity are now possible. Figure 4 provides an example data request to identify all cases of prostate cancer with invasion. The SNOMED CT concepts returned represent invasion by the tumor to seminal vesicles, bladder neck, prostatic duct, periprostatic tissue (ie, extraprostatic extension), lymph-vascular spaces, and perineurium. Refinement of the query to omit lymph-vascular and perineural invasion provides the set of concepts that can identify cases with local extraprostatic invasion to adjacent structures. The ability to identify unique patient populations on the basis of complex data is critical for the assessment of clinical care quality, operational effectiveness by health care delivery systems, improving the health care disparities, supporting clinical trial operations, and achieving public health objectives.

The efforts invested into the development of controlled medical terminology for pathology cancer reporting is complementary to and supportive of the development of artificial intelligent– and machine learning–based solutions. Structured data capture and subsequent representation in a common data model provides a high level of trust that such data are fit for purpose. These data can be used as training sets for large language models for future applications, given that these technologies are not sufficiently mature or medically validated at this point in time to guarantee a complete pathology report. A pathway to interoperable, structured, synoptic reporting exists now, can be widely adopted, is complete according to international guidelines, and can be implemented broadly regardless of economic status of any particular nation.

National and international mechanisms are in place to support the broad adoption of these encoded protocols. The EHR and LIS software vendors in the United States and Canada already support the use of the CAP eCP product, and the inclusion of SNOMED CT binding profiles in the regularly updated eCP distribution files for incorporation into the medical record is straightforward. In other nations such as the Netherlands, the national pathology databank, PALGA, uses a dedicated application, the PALGA Protocol Module (PPM), that is linked to the LIS platforms and used by pathologists to complete the synoptic report. The PPM transmits a full synoptic report with pTNM staging to the LIS/EHR, and the data are entered into the national registries using the national infrastructure of PALGA. (This is a use case for SMART on FHIR implementation.[28]) The recent Office of the National Coordinator, National Institutes of Health, CDC, and US Food and Drug Administration cancer data summit to develop recommendations for the USCDI+ Cancer Program identified encoded, structured pathology reports as the most readily available and reliable data for cancer reporting that should be acted on immediately for cancer data capture.

Both a common terminology and data structure (ie, information model) are necessary to achieve true semantic interoperability. The efforts of the CAP, ICCR, and supporting pathology societies achieved high levels of information model agreement for cancer reporting. The remaining differences in their data element content are greatly narrowed by the use of SNOMED CT to fill the gaps and realize interoperability. The SNOMED CT content referenced in this manuscript provides a comprehensive, computable terminology fit for use in pathology cancer reports. Although improvements and changes to cancer data sets and the underlying SNOMED CT terminology will continue, this collaborative effort has made level 6 pathology reporting and its associated patient benefits tractable and achievable on a global scale today. Together, these international efforts bring worldwide cancer pathology data interoperability much closer to fruition.

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