October 19, 2020

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-8013

Submitted electronically: RadiationTherapy@cms.hhs.gov

Innovation for High-Value Radiotherapy: An Informal Request for Information on Radiation Oncology Model Clinical Data Elements (CDEs) from the Center for Medicare and Medicaid Innovation

Dear Administrator Verma:

The American Society for Radiation Oncology (ASTRO) is writing to provide comments on the "Innovation for High-Value Radiotherapy: An Informal Request for Information on Radiation Oncology Model Clinical Data Elements (CDEs) from the Center for Medicare and Medicaid Innovation," published for comment on September 18, 2020. We are disappointed and dismayed that the Agency has issued an RFI that does not recognize the challenges associated with collecting this type of data nor the low value of data with little to no specificity. Over the last several years, ASTRO has worked diligently to collaborate with the Agency to address these issues and assist with the determination of appropriate data elements and collection methods. Unfortunately, the issued RFI does not reflect our good faith efforts from this collaboration.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the world. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare reporting requirements and oncology-related interoperability.

The Center for Medicare & Medicaid Services' (CMS') Innovation Center finalized the Radiation Oncology (RO) Model to test whether prospective episode-based payments for radiation therapy episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care. In addition to collecting quality measures data, CMS also plans to collect clinical information on Medicare beneficiaries treated for five cancer diagnoses: prostate cancer, breast cancer, lung cancer, bone metastases, and brain metastases. Clinical data element (CDE) collection is a pay-for-reporting requirement applied to Professional and Dual participants

and is tied to the Aggregate Quality Score and the two percent quality withhold under the RO Model payment methodology (See Appendix). CMS intends to create new outcome quality measures based on the CDEs collected.

ASTRO values the importance of developing measures and has committed countless resources to measure and guideline development over the years. We agree with the Agency that the number and quality of measures for radiation oncology are limited; however, the CMMI approach is flawed and will only result in burden, frustration and wasted resources for both clinicians and CMS without reaching the intended goal. We are alarmed that all of the time and effort put into educating CMMI officials on the appropriate types of data collection activities that could be feasible under the RO Model have clearly been dismissed, as evidenced by this RFI. ASTRO's efforts to engage with CMMI over the last several years have involved numerous meetings with ASTRO leadership as well as a tour of a radiation oncology practice. ASTRO's efforts were initiated in an effort to educate the Agency and to collaborate on the development of measures that are necessary for the field. We have grave concerns about the breadth of the draft CDE list and the lack of specifics in the proposed data elements. **Given our concerns about both the Agency's unrealistic expectations for CDE collection and the lack of standardization for data elements as detailed below, we urge CMS to significantly limit the number of data elements to those currently standardized CDEs and delay CDE collection until at least 2022.**

Unrealistic Expectations for CDE Collection

As mentioned multiple times in conversations with Agency officials, ASTRO has experience both with data collection from electronic health systems for registry use as well as quality measure development. In 2010, ASTRO established a pilot for the National Radiation Oncology Registry (NROR) in prostate cancer. (See attached abstract.) The NROR attempted to collect patient-specific radiation therapy data electronically to allow for rapid comparison of the effectiveness of competing treatment approaches and account for outcomes, quality and safety. It was intended to provide benchmark data and quality improvement tools for individual practitioners. The goals of NROR aligned well with those proposed by CMS for CDE collection.

For NROR, prostate cancer subject matter experts first determined the data elements thought to be helpful in characterizing disease and management. The final data dictionary had to be pared back due to the recognized realities of data availability and burden of manual data entry. After a significant amount of data was collected, experts in prostate cancer and measure development attempted to create quality measures from the available information but were ultimately unsuccessful. Even though countless hours were invested into specifying the data elements and creating data quality reports, concepts thought to be relatively simple, such as radiation dose, were inconsistently interpreted and reported because of a lack of data standardization. The wide scope of the project and data collected resulted in excessive reporting burden and largely unusable data that did not meet the purpose and goal of the registry. After investing more than $2 million and hundreds of hours of staff and volunteer time over several years, the NROR was discontinued.

Despite our efforts to educate the Agency, CMS is repeating these same mistakes and unfortunately will very likely experience the same unsatisfactory outcome, only on a larger scale with much more at stake. Clear metrics must be in place prior to the collection of clinical data, not the other way around. Starting with the identification of quality measures and then designing the simplest data dictionary necessary to assess those measures reduces data collection burden, enables focus on data quality and helps meet the project goals. CMS should follow its own *CMS Measures Management System Blueprint*, version 16.0 released in September 2020, that describes in the detail the stages in the "Measure Lifecycle," which first begins with measure conceptualization and then specification, including data element determination, and measure testing. **Collecting potentially interesting but unspecified data points on patients with the intention of retrospectively creating outcome measures is irresponsible and goes against the industry standard.**

We applaud the leadership of the Veterans Affairs for their thoughtful approach to quality in radiation oncology measure development. ASTRO had the honor of supporting the VA across two projects in establishing a set of quality measures for five disease sites (lung, prostate, breast, rectal and head and neck cancers) to be utilized in the VA-Radiation Oncology Quality Surveillance Program. (See attached abstract.) Only after the quality measure specifications were finalized by disease site experts did the measure developers, in combination with VA informaticists, start working on identification and collection of the relevant data elements. Even with this proven approach, testing and implementation of developed quality measures results in data element and measure refinement. **ASTRO strongly urges CMS to follow its own policy and the example of the VA by first identifying measures before collecting the focused set of data elements related to those measures.** Further, we would support alignment between the VA and CMS on quality metrics and encourage CMMI officials to learn from colleagues at the VA and consider prioritizing harmonization with metrics that have been created by the VA.

Lack of Standardization for Data Elements

The Agency states that the proposed data elements are not readily found in claims or other sources; however, several of the requested data points can be determined by claims information, such as number of delivered fractions and treatment timing. Additionally, more of the proposed CDEs are available in the National Institute of Health's Surveillance, Epidemiology, and End Results Program (SEER) database, including stage, histology and grade. SEER also provides key demographic, rurality and socioeconomic data that are critical in identifying true disparities and gaps in care within cancer care. ASTRO recommends that the Agency utilize data in existing repositories instead of requiring additional reporting by RO Model participants. As the Department of Health and Human Services houses both CMS and SEER, it would be more cost-effective and efficient for CMS to utilize practices participating in the RO Model and SEER as a pilot for the model. This would also reduce reporting burden for practices and provide CMS with a control group to learn of unintended consequences of the RO Model.

Other physician groups and specialties rely on common data elements that are already standardized and used by information systems. While radiation oncology does utilize some of these common data types, the vast majority is unique and has not been standardized by such

recognized bodies as Health Level 7 (HL7) using SNOMED and other coding systems. ASTRO's focus on radiation oncology specific data was furthered in 2019 by the publication of the Minimum Data Elements for Radiation Oncology and participation on the Executive Committee of the Minimal Common Oncology Data Elements (mCODE) initiative, which started under the leadership of the American Society of Clinical Oncology (ASCO) and the MITRE Corporation. The goals of mCODE and its sister initiative, Common Oncology Data Elements Extensions (CodeX), are to build a strong foundation of standardized oncology-specific data elements that can improve data availability and transfer, for physicians as well as the patients they serve. This requires starting with a core set of data elements and expanding once implementation and adoption are established. mCODE recently took this standardization a step further and requested that a small set be incorporated within the US Core Data for Interoperability (See attached letter). ASTRO recommends the same approach be applied for the CDE collection related to the RO Model. Starting with a small number of standardized data points will result in increased reporting compliance, comparability and the Agency's ability to identify areas of potential growth. **Unstandardized data will, conversely, increase the burden of data collection, exasperate issues with data transfer and result in a repository of data that is of little use to CMS.** Only five of the proposed data elements are currently codified within the HL7 international standards: beneficiary ID, performance status, AJCC stage, treatment intent and laterality. Beyond this, even though AJCC stage is codified, it does little good to require stage without thinking through the complexities of which data elements within stage to require, for example the important distinction between clinical versus pathologic stage and how to stage patients who receive neoadjuvant systemic therapy.

ASTRO originally expressed concern in our comment letter on the RO Model proposed rule regarding the additional reporting requirement, particularly given that so little information was shared on the proposed CDE. The vast majority of the proposed CDEs are not standardized and are extremely underspecified. For example, a proposed CDE for breast cancer is "dose constraints to the heart". While this conceptually may be reasonable, it is ultimately meaningless without detailed parameters. Within the VA contract, ASTRO created 12 metrics related to this topic. Dose constraints are part of a complicated series of treatment plan objectives that are obtained from dose volume histograms. It may be specified as the mean dose, maximum dose, dose to a certain percentage of the organ or volume of an organ that received a certain dose, and this exact specification of how the dose is measured and at what point on the dose spectrum is important. It also varies depending on the delivery site, fractionation regimen, technique, and prescribed dose. This information is found in software related to treatment planning and is not often shared with patients as it is not meaningful without rigorous training and experience in radiation oncology and radiobiology. Dose metrics within commercially available treatment planning systems are further not readily exportable nor easily linked with clinical or delivered dose information. Additionally, the art and science of radiation therapy often requires tradeoffs in dosing between the tumor and normal tissues specific to each patients' tumor characteristics (e.g., location in that patient's anatomy, prognosis) and must be accounted for when treating the cancer and sparing healthy tissue.

The collection of clinical information requires detailed testing, and therefore, the Agency should delay CDE collection while it learns from the implementation and vetting of VA measures and

metrics. CMS's own *Measures Blueprint* warns that a common error is "[i]nadequate evidence of scientific acceptability for commonly used data elements. Data elements (e.g., diagnosis codes, EHR fields) that are in common use still require testing or evidence of reliability and validity within the context of the new measure specifications (e.g., new population, new setting)." Trying to sidestep critical steps and speed through established processes is reckless and will not benefit patient care.

Vendor and Physician Readiness

Additionally, we continue to be concerned that the addition of new reporting requirements would require vendors to develop new software, which will take time to modify and install, the cost of which will most likely be borne by radiation oncology practices. In the RO Model final rule, CMS finalized the proposal to collect CDEs as previously described; however, the Agency still did not provide any additional information on the CDE to be collected in the RFI. Vendors are willing to build or alter what is necessary for their customers' compliance to reporting programs; however, the list of elements presented in the RFI are vague and, as stated, may have multiple interpretations. This continued lack of detail leaves vendors in a holding pattern and physicians unsure what to request from their vendors. There is not enough information to know what to modify in their systems nor how the data will be reported.

CMS states that they are committed to working with vendors to facilitate data collection for quality measures and CDE, but based on ASTRO's experience, the responsibility will fall solely on providers to collect and report this information—so much for "patients over paperwork." Vendors and clinicians need far more than the 60 days stated in the RO Model final rule to provide "time to facilitate medical record software updates to include appropriate fields to comply with the data submission and monitoring requirements of the model." The slate of CDE identified in the RFI is contrary to the Office of the National Coordinators' (ONC) recommendation to "waive documentation requirements as may be necessary for purposes of testing or administering APMs" wherever possible and to "reduce overall regulatory burden around documentation" as published in the *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.*

As mentioned in the *ONC Burden Report* "there are significant challenges in accessing, extracting, and integrating data from one or more health IT sources. The widespread use of a large number of vendors, and an absence of standardized elements and transfer protocols, promotes a fragmented system containing many data silos that cannot always effectively exchange data. Additionally, many health care providers report difficulties in retrieving or extracting data from their existing health IT systems, with many health care organizations forced to commission custom data reports or extractions in order to access data necessary for quality and health IT program reporting." This paints a very clear picture of data within the field of radiation oncology in which data exists in disparate systems.

These systems often include a broad electronic health record (EHR), an oncology information system (OIS), and treatment planning system(s). Many radiation oncology practices utilize an EHR like those developed by Epic or Cerner to collect basic patient information that is shared

with various healthcare providers overseeing the overall health and management of the patient. Many hospital-based radiation oncology centers have relied on these EHRs for Medicare reporting programs. The hospital manages the cost of the system as well as the necessary upgrades, benefiting those hospital-based practices. However, broad EHRs do not have the necessary radiation oncology data. The radiation oncology team also utilizes an FDA-approved OIS from companies such as Varian or Elekta to manage radiation-related cancer care and document radiation dose delivered. These systems, in many cases, have not received the same consistency of upgrade, including the 2015 Base CEHRT edition software. Conversely, small and rural practices have long had an option for a hardship in EHR reporting programs under the Medicare Incentive Payment System (MIPS) and have not needed to upgrade their systems to meet the 2015 CEHRT requirements. Both these scenarios leave radiation oncology practices with the need to complete a costly and time-consuming upgrade in a matter of weeks to meet the requirements of the RO Model, per the CMMI mandate. Additionally, radiation oncology practices use a third system that complicates data aggregation. All radiation oncology practices must utilize one or more treatment planning systems where specific radiation dosing and delivery specifications are determined. This software is developed by various vendors, including Accuray, Philips, Varian, and MIM and are sometimes specific to a delivery technique or type of equipment.

As is apparent, radiation oncology practices are often working with software from two, three, even four or more different vendors. ASTRO honors the importance of interoperability given this unique technical environment. Since 2005 ASTRO, along with the American Association of Physicists in Medicine (AAPM), has worked to address the unique data collection and sharing issues related to radiation therapy treatment by sponsoring the Integrating Healthcare Enterprise - Radiation Oncology (IHE-RO) initiative which brings together relevant vendors to work to transfer data between systems. Nevertheless, there are still many situations that create siloed data points that cannot be exported into a complete patient report. Expecting all this information to effortlessly transfer and collate into a simple compendium of information is unrealistic.

In addition to the time needed for system upgrades, financial cost to the practice, increased staff hours and likely need for additional hiring, the Model is scheduled to begin ten months into a worldwide pandemic that has stretched health care resources to the limit in many practices and health care facilities. If practices are unable to sustain these additional stresses, there may be grave consequences for patients needing cancer treatment including, but not limited to, closure of some rural practices, and limited or delayed access to other centers if staffing levels are unable to be maintained.

ASTRO's Proposal

In our comment letter on the RO Model proposed rule, ASTRO recommended a delay in the implementation of the CDE requirement until 2022 to allow for a collaborative effort between ASTRO, vendors and CMS officials to establish a well thought out approach. Based on the current scenario of radiation oncology data as laid out in this letter, ASTRO continues to recommend a phased approach. Collection, starting in 2022, should begin with the five standardized data elements itemized below. Four of these five elements are currently codified

within the HL7 international standards. Additionally, CMS is already requiring three of these elements (performance status, stage and intent) to be collected in the medical record for each patient as a separate monitoring requirement finalized for the RO Model. By starting with a concentrated set of information, it allows time for standards to be formalized, vendors to complete the necessary upgrades and physicians to change workflows to capture the required data. The only CDEs collected for the five cancers should be:

- **Beneficiary ID.** This standard patient-specific information will help track and link patients across available data sets.
- **Performance Status**. This would be collected utilizing the Eastern Cooperative Oncology Group (ECOG) scale. Practices utilizing the Karnofsky scale would be required to transcribe to ECOG, which is burdensome, but implementation can be consistently done.
- **Stage**. Stage would be specified with the staging system developed by the American Joint Committee on Cancer (AJCC) utilizing the TNM methodology. CMS would need to provide the specific version of AJCC related to associated disease sites as these change and adoption can lag. Specific instructions regarding type of stage collected (clinical vs. pathologic) and rules regarding which to report and when to report both are absolutely needed.
- **Treatment Intent**. CMS provided a binary option of either curative or palliative treatment intent. While this is sufficient for now, breakthroughs on how to treat and think about oligometastatic disease are rapidly occurring. Patients who were previously thought to be palliative may be cured, and this paradigm shift is blurring what has been a binary choice. Further, if the model expands, there are other scenarios where radiation is given for benign disease or prophylaxis of disease states, and these indications also need to be considered within the concept of treatment intent.
- **Prior Radiation**. We would also like to recommend an amended version of a proposed data element for bone metastases. Prior radiation to an overlapping area for bone metastases can influence treatment plans; however, prior radiation in general is broadly applicable to all disease sites and should be captured systematically for the safety of patients. Therefore, ASTRO recommends capturing prior radiation for all five disease sites specified for CDE collection.

Additionally, the timing of data capture for each data element was not included in the RFI and may occur numerous times during a course of radiation treatment. ASTRO recommends that all five of our recommended data elements be captured by the time of patient simulation.

We remain apprehensive about the CDE collection that establishes another layer of reporting burden on practices participating in the mandatory RO Model, but believe our proposal addresses stakeholders concerns and goals. Still, we worry that this comprehensive assessment of the RFI will fall on deaf ears. The interactions between ASTRO and CMS over the past few years and the final RO Model have resulted in a fracture of trust and a strong belief in the radiation oncology community that CMS is not listening to our concerns. We hope that CMS will finally listen to the radiation oncology community and engage in a meaningful collaborative effort to get this right. Should you have any questions on the items addressed in this comment letter, please contact

Randi Kudner, Senior Quality Improvement Manager at 703-286-1664 or
Randi.Kudner@ASTRO.org.

Respectfully,

Laura I. Thevenot
Chief Executive Officer

Attachments
- Abstract: Developing a National Radiation Oncology Registry (NROR): A Radiation Oncology Institute (ROI) Initiative
- Abstract: VA-Radiation Oncology Quality Surveillance Program
- mCODE Letter to ONC re: US Core Data for Interoperability

Attachments

Developing a National Radiation Oncology Registry (NROR): A Radiation Oncology Institute (ROI) Initiative
C. M. Rose, C. A. Lawton, J. A. Efstathiou, J. E. Bekelman, S. Mutic, C. R. Bogardus, T. R. McNutt, A. L. Zietman, J. R. Palta

Published October 1, 2011 https://doi.org/10.1016/j.ijrobp.2011.06.1324

Purpose/Objective(s): IMRT, IGRT and proton therapy may improve local control/survival with less morbidity but with increased cost. Use in real world settings may not be as beneficial as initial testing suggests. The NROR will improve care by capturing population-based treatment and health outcome data. We will establish a framework for Radiation Oncology (RO) Proceedings of the 53rd Annual ASTRO Meeting S693 comparative effectiveness research (CER) and pilot this approach in prostate cancer. We will determine feasibility of electronic data capture to provide stakeholders with critical decision making information. Competing treatment option controversies and adoption of emerging technologies can be addressed by capturing descriptive data and CER studies. RO process measures associated with improved outcomes that can be used as surrogates for outcomes will be identified.

Materials/Methods: 1) Create a common taxonomy/data dictionary for collection of data on demographics, patient/diagnostic/ tumor characteristics, radiation treatment details, disease as well as clinician- and patient-reported toxicity/quality-of-life (CRand PR-QOL) outcomes. 2) Deploy a centralized electronic infrastructure to support collection of CR-radiotherapy treatment and outcome data and PR-QOL assessments securely and anonymously. 3) Integrate a pilot network of participating centers using interoperable prospective electronic data collection methods and pilot this integration to assess the feasibility of systematically collecting treatment and outcome data in patients with localized prostate cancer. 4) Develop financially sustainable observational study infrastructure through a multi-stakeholder engagement model.

Results: 1) Data Dictionary Committee is rationalizing data elements utilized by the three commercial EMRs used by . 90% of the RT centers in the USA, to be submitted for endorsement to the NIH Common Data Element browser 2) IT Infrastructure Committee is creating an end-user data specification for aggregation of data from EMRs and treatment planning systems into a central registry 3) Major RO organizations, patients, payers, and government stakeholders are participating in a series of conferences to build acceptance for widespread voluntary registry participation and to develop a plan for financial sustainability.

Conclusions: We have established an innovative partnership for a scalable prospective registry to improve our understanding of existing and emerging cancer therapies to generate relevant, reliable, and timely information across the entire cancer spectrum. Acknowledgment: The project is supported by the ROI and Federal Share of program income earned by Massachusetts General Hospital on C06 CA059267.

VA-Radiation Oncology Quality Surveillance Program

Michael Hagan, MD, PhD Rishabh Kapoor, MS, Jeff Michalski, MD, Howard Sandler, MD, Benjamin Movsas, MD, Indrin Chetty, PhD, Brian Lally, MD, Ramesh Rengan, MD, PhD, Cliff Robinson, MD, Andreas Rimner, MD, Charles Simone, MD, Robert Timmerman, MD, Michael Zelefsky, MD, John DeMarco, PhD, Daniel Hamstra, MD, PhD, Colleen Lawton, MD, Louis Potters, MD, Richard Valicenti, MD, Sasa Mutic, PhD, Walter Bosch, PhD, Christopher Abraham, MD, Douglas Caruthers, MS, Ryan Brame, PhD, Jatinder R. Palta, PhD, William Sleeman, IV, MS, Joseph Nalluri, PhD

Purpose

We sought to develop a quality surveillance program for approximately 15,000 US veterans treated at the 40 radiation oncology facilities at the Veterans Affairs (VA) hospitals each year.

Methods and Materials

State-of-the-art technologies were used with the goal to improve clinical outcomes while providing the best possible care to veterans. To measure quality of care and service rendered to veterans, the Veterans Health Administration established the VA Radiation Oncology Quality Surveillance program. The program carries forward the American College of Radiology Quality Research in Radiation Oncology project methodology of assessing the wide variation in practice pattern and quality of care in radiation therapy by developing clinical quality measures (QM) used as quality indices. These QM data provide feedback to physicians by identifying areas for improvement in the process of care and identifying the adoption of evidence-based recommendations for radiation therapy.

Results

Disease-site expert panels organized by the American Society for Radiation Oncology (ASTRO) defined quality measures and established scoring criteria for prostate cancer (intermediate and high risk), non-small cell lung cancer (IIIA/B stage), and small cell lung cancer (limited stage) case presentations. Data elements for 1567 patients from the 40 VA radiation oncology practices were abstracted from the electronic medical records and treatment management and planning systems. Overall, the 1567 assessed cases passed 82.4% of all QM. Pass rates for QM for the 773 lung and 794 prostate cases were 78.0% and 87.2%, respectively. Marked variations, however, were noted in the pass rates for QM when tumor site, clinical pathway, or performing centers were separately examined.

Conclusions

The peer-review protected VA-Radiation Oncology Surveillance program based on clinical quality measures allows providers to compare their clinical practice to peers and to make meaningful adjustments in their personal patterns of care unobtrusively.

October 19, 2020

Mr. Steven Posnack, MS, MHS, Deputy National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Submitted electronically via e-mail

Dear Mr. Posnack,

The American Society of Clinical Oncology (ASCO), MITRE, and the mCODE™ Initiative Collaborators[1] are pleased to submit a proposal for new data elements to be added to the US Core Data for Interoperability (USCDI). While we have utilized the USCDI ONC New Data Element and Class (ONDEC) submission system as required, we wished to also highlight our submission to you and provide additional information regarding the breadth of our membership, and current pilot activities. We feel it is important to begin this discussion as CMS is already considering data elements in oncology, as evidenced by the recent Radiation Oncology RFI released by the Center for Medicare and Medicaid Innovation.

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mCODE™ Initiative Collaborators

The mCODE ("Minimal Common Oncology Data Elements" - a focused set of data elements selected based on their broad applicability to cancer patients and survivors) Initiative is governed by the mCODE Executive Committee, a group of public and private entities who have voluntarily come together to further mCODE adoption. Members include The Alliance for Clinical Trials in Oncology Foundation; the American Society of Clinical Oncology (ASCO) and its nonprofit subsidary, CancerLinQ LLC; The MITRE Corporation; The American Society for Radiation Oncology (ASTRO); and the Society of Surgical Oncology. A larger standing group, the mCODE Council, provides thought leadership for mCODE, advises the Executive Committee, sponsors use cases, and promotes mCODE adoption. The Council also consults on new and amended data elements and use cases for the mCODE core data specification and its extensions. The Council currently consists of over 20 groups and includes medical societies such as the American Society of Hematology (ASH) and the College of American Pathology (CAP), health information technology developers such as Varian and Epic, and health system and government entities such as Intermountain Healthcare, Mount Sinai Health System, and the National Cancer Institute (NCI).

Ongoing Implementation Pilots to Test mCODE

Many organizations are collaborating on pilots to enable, test, and advance mCODE use. Several of these activities are being coordinated through the CodeX HL7 FHIR Accelerator:

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[1] Available at https://mcodeinitiative.org/collaborators/

- ICAREdata™ study: The mCODE team is working with the Alliance for Clinical Trials in Oncology on the Integrating Clinical Trials and Real-World Endpoints (ICARE) data project. ICAREdata aims to demonstrate that mCODE-based real-world data can drive more efficient clinical research by incorporating the data for a broader population of patients while maintaining the same quality as traditional clinical trials.
- Integrated Trial Matching for Cancer Patients and Providers: The American Cancer Society Cancer Action Network (ACS CAN), The MITRE Corporation, TrialScope, Cancer Insights, and Breastcancertrials.org are working to leverage mCODE to improve capability for patients to find clinical trials for which they may be eligible. The goal is to demonstrate the ability of a trial matching service to receive an mCODE record, analyze the record to make matches, and then present the matches back to the patient or provider.
- Cancer Registry Reporting: Several CodeX members are working to enable low-burden, mCODE-centered reporting of cancer data from cancer centers to registries that are aggregating data for different reasons. The goal is to demonstrate that information can be reported from the clinical site to the designated cancer registry, in a low-burden and semantically interoperable way, allowing a patient's status and outcomes to be tracked as that patient's therapy progresses.

mCODE Data Elements Selected for Submission to USCDI

In the US, an estimated 16.9 million individuals with a history of cancer were alive on January 1, 2019; by January 1, 2030, it is estimated that the population of cancer survivors will increase to more than 22.1 million due to the growth and aging of the population alone.[2] In 2020 there will be an estimated 1.8 million new cancer cases diagnosed and 606,520 cancer deaths in the United States.[3] For this population of patients and survivors it is critical that their medical records reflect at least the minimum amount of data required to enhance care coordination and to highlight previous diagnoses of cancer and, given long-term treatment effects, therapies received.

mCODE is a focused set of data elements selected based on their broad applicability to cancer patients and survivors and to support a variety of cancer care and research applications across a variety of cancer types. mCODE elements were developed by a collaboration of oncology experts. As a Health Level 7 (HL7) Standard for Trial Use these elements were refined with broad input and review through the ballot. Finally, the mCODE elements are currently being tested through a variety of implementation use cases managed through the CodeX HL7 FHIR Accelerator. For this initial submission to the ONDEC, the Collaboration is submitting elements that have both reached consensus within the oncology and HL7 communities and are also applicable to disease areas beyond oncology.

Data Classes and elements submitted include:
- Patient
  - Date of Death/Deceased - Indicates if the individual is deceased or not at the time the data is reported
- Problem

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[2] https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/cancer-treatment-and-survivorship-facts-and-figures-2019-2021.pdf
[3] https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2020.html

- o Disease Trend - clinician's overall judgment on the current trend of a condition, e.g., whether it is stable, worsening (progressing), or improving (responding)
  - o Disease Stage / Staging System – A disease-specific set of categories, based on etiology, pathophysiology and severity used to cluster clinically homogeneous patients to inform treatment options
- Assessment and Plan of Treatment
  - o Functional Status (examples include ECOG and Karnofsky) - Tools used to measure a patient's functional status and used to compare the effectiveness of or patient's ability to tolerate different therapies.
  - o Treatment Change - Documents the reason for changes to the plan of treatment plan
- Procedures/Medications
  - o Treatment Intent - The purpose of a treatment, or the desired effect or outcome resulting from the treatment (i.e. curative vs. palliative).

Radiation Oncology Model Clinical Data Elements and mCODE

Adoption of mCode into USCDI could help to support CMS priorities such as the Center for Medicare and Medicaid Innovation's (CMMI) Radiation Oncology (RO) mandatory payment model. CMMI is requiring the collection of certain specific "clinical data elements" (CDEs) from participants in the RO model scheduled to begin in January, 2021. Incorporation of standard cancer data classes and elements into the USCDI and certified EHRs by ONC could ultimately help CMS to standardize data collection and decrease reporting burden, benefiting both patients and providers.

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ASCO thanks ONC for the opportunity to submit to ONC these data elements for consideration for use in the USCDI and thanks the agency for its time and attention. If you have any questions or need further information, please contact Andre C. Quina at MITRE (aquina@mitre.org) or Karen Hagerty at ASCO (karen.hagerty@asco.org).

Sincerely,

Monica Bertagnolli, American Society of Clinical Oncology
Jay Schnitzer, The MITRE Corporation
Jim Hayman, American Society for Radiation Oncology
Ken Cardona, Society of Surgical Oncology
Tarun Kumar, Cancer Insights
Nikhil Wagle, Count Me In
John Halamka, Mayo Clinic
Amy Lin, University of California – San Francisco
Lawrence Shulman, University of Pennsylvania

cc: Don Rucker, MD, National Coordinator for Health Information Technology
        Thomas Mason, MD, Chief Medical Officer
        Mr. Brett Andriesen, Health IT Program Analyst, ONC

Mr. Albert Taylor, Medical Informatics Officer, OTECH
Mary Greene, MD, Director, Office of Burden Reduction and Health Informatics (OBRHI), CMS