

Smarter, Accessible Data Means Learning from Every Patient

by Dr. Brian Anderson, Andre Quina, and Dr. Jay Schnitzer

COGNOSCENTI | 1



A Snapshot of the mCODE™ Initiative

It only makes all the sense in the world:

With one query across data pulled from thousands of electronic health records, a doctor discovers which treatment has been most successful for 53-year-old Asian women with stage 2 lung cancer based on what hundreds of clinicians have previously tried in similar cases. The collection, exchange, and analysis of patient data enables the clinician and patient to have an informed discussion about treatment options.

So why hasn't it become a reality?

For more than 10 years, the healthcare community has dedicated tremendous effort and investments to developing standards and achieving interoperability. Despite these efforts, the promise of a *Learning Health System*, one in which each interaction between a clinician and patient provides high-quality data leading to safer care, improved outcomes, and lower costs for everyone, remains unfulfilled. These lofty goals were built on the expectations that big data, captured in electronic health records (EHRs), would enable evidence-based decisions.

Today, however, more than 90% of U.S. doctors use one of the hundreds of proprietary and customized EHR systems available to capture patient data (demographics, biomarkers, details of disease) and treatment (chemotherapy, surgery, radiation). In addition, clinicians, providers, and vendors use different terms to describe the same type of data and/or collect data in different, incompatible formats, making it difficult to exchange and analyze data across organizations.

Accordingly, we continue to learn from what did and did not work in our quest for interoperability. For example, one of the successes was the development and implementation of FHIR (Fast Healthcare Interoperability Resources), now a widely accepted standard. FHIR enables *structural* interoperability – but that is only part of the solution.

A more complete solution would include *semantic* interoperability, which would lead to broad-scale information sharing and analysis, data harmonization, and a common language for healthcare. We, as a community, need to adopt the same data language to provide patients the best possible treatment options.

Coordinating a Solution Focused on Cancer

A group of researchers and clinicians from American Society of Clinical Oncology (ASCO), CancerLinQ, and MITRE decided to explore new, efficient ways to collect the right data and express that information consistently to support interoperability. Our remit is to evaluate different approaches for creating and demonstrating the benefits of structured data entry, capture, and display for sharing information, leading to improved care.

Developing a coordinated data strategy takes collaboration across a large ecosystem of stakeholders – patients, doctors, providers, payers, vendors, government, and researchers. As a starting point, our cross-organization team

agreed to the following guiding principles for patient health data:

- ◆ Standardized and collected in a computable manner so it can be aggregated with data from many other patients and analyzed for best practices
- ◆ Exchanged through EHR systems that are interoperable
- ◆ Collected in a streamlined way that doesn't burden the clinicians
- ◆ Secure and protective of patient privacy

We, as a cross-organization team, discussed (and continue to refine) our ideas with our stakeholders with a goal of finding consensus approaches. The team asked them many questions, e.g., “What technology must be developed along the way?” “What would incentivize stakeholders to participate?”

“Today, however, more than 90% of U.S. doctors use one of the hundreds of proprietary and customized EHR systems available to capture patient data (demographics, biomarkers, details of disease) and treatment (chemotherapy, surgery, radiation)”

After gathering and analyzing their input on needs and requirements, we developed a vision, strategy, and roadmap. As a team, we decided to start small, test ideas, and build on lessons learned from the past decade in health data, as well as experience in treating patients and participating in clinical trials.

Executing the Strategy

Today, novel cancer therapies are being created for sub-populations, and these treatments depend on large amounts of data. The lack of data available for research and development of these therapies is another reason we began with a focus on cancer.

Most of the high-quality data that leads to new cancer treatments comes from clinical

trials. However, these trials involve only about 3% of U.S. cancer patients – thus providing limited information about what treatments work for which patients. Traditionally, these trials have been homogeneous, excluding many types of patients, such as certain age groups, people who do not live near the organizations conducting trials, and patients with multiple health issues. This means that clinicians and researchers don't have ready access to data from the other 97% of cancer patients – data that could potentially tell them what treatments have worked for, say, 67-year-old Latino men who suffer from diabetes as well as cancer.

In fact, these clinical data do exist, contained in thousands of EHRs, as well as in databases. A great deal of data about treatments and results, however, is locked in the unstructured free text of clinical notes. Unfortunately, the recorded data is inconsistent – e.g., using different terms to describe the same thing or not capturing critical information (was the treatment safe and effective?). Data that are incompatible and cannot be easily searched and analyzed cannot support improved patient outcomes or contribute to a learning health system.

First Milestone: mCODE™

To address this need, we are building mCODE (Minimal Common Oncology Data Elements), a new data standard intended to facilitate breakthrough insights into high-quality data across multiple use cases. The approach of mCODE is to standardize the health record and health data itself, rather than focusing on exchange standards. The initial data standard, published at mCODEinitiative.org, covers six domains: patient, lab/visits, disease, genomics, treatment, and outcomes, with 73 distinct data elements. We use common medical terminology and build on existing standards. mCODE provides both a common data language and an open source, nonproprietary data model for interconnectivity across systems (available on GitHub).

We have identified the minimal cancer data elements that are essential for analyzing treatments across patients (via their EHRs) and cancer practices to drive the best possible cancer research and treatment. The insights, generated by capturing the right data at the right time, have the potential to improve patient care quality, empower shared decision making, drive innovation, and set the foundation for a national cancer health learning system. A team of ASCO clinicians worked on prioritizing the elements in mCODE for testing and socializing across the ecosystem for validation. ▶

Use Cases

Clinical trials use a complex, detailed system to collect data, including documenting whether the treatment was safe (were there any adverse effects?) and effective (did the treatment work?). These are the end points we set out to collect in a less complex, higher level manner that fits into the clinicians' existing workflow and does not add burden. The goal is to demonstrate that, yes, we could arrive at the same end points using our lightweight approach as we could through a clinical trial approach. This gives clinicians more options for gathering and using data in conjunction with clinical trials.

Pilot Project 1. Breast Cancer

The team chose to focus first on breast cancer because this cancer has many available therapies. Multiple therapies can be used in sequence – and it can be difficult to execute trials to account for many possible sequences and combinations. Treatment decisions are multifaceted and having more real-world data from similar cases would be very valuable.

The mCODE team is collaborating with a clinical trial team that is testing a new indication of an existing drug to treat breast cancer to validate our lightweight data collection. Initial results indicate that the accuracy of our results match those of the clinical trials 95% of the time. We are continuing to expand the scope of the evaluation in new trials to evaluate the accuracy against a broader set of clinical events.

Pilot Project 2. Integrating Clinical Trials and Real-world Endpoints (ICARE) Data Study

Building on our first trials, we're moving to look at other types of cancer and extend the data we need to collect to enable better treatments. The team is continuing to partner with stakeholders to define representation of outcomes and use trials to evaluate the outcome elements for mCODE, including disease status and changes in treatment.

We are working with multiple partners in the Integrating Clinical Trials and Real-World Endpoints (ICARE, <http://icaredata.org/>),

a study focused on EHR-based clinical trials endpoints collection. The goal of the ICARE data study is to enable clinical oncology research by gathering high-quality, real-world data with a focus on safety and efficacy.

Our team began with the idea of collecting detailed information about adverse events patients suffer during clinical trials. There are 800 different events (e.g., vomiting, dizziness) tracked during trials, and each is graded on a 1-5 scale. Working with doctors, we discovered this was too much data for them to efficiently collect in EHRs. Based on this feedback, we changed direction and decided to try

mCODE data in EHRs through the SMART (Substitutable Medical Applications and Reusable Technologies) on FHIR framework. Our solution introduces lightweight tags into the doctor's notes. These hashtags have a fixed vocabulary and make it simple to pull data from the notes and capture the subtleties of each patient's story.

Pilot Project 4. Compass (see <https://www.youtube.com/watch?v=jl5ddxDFWol>)

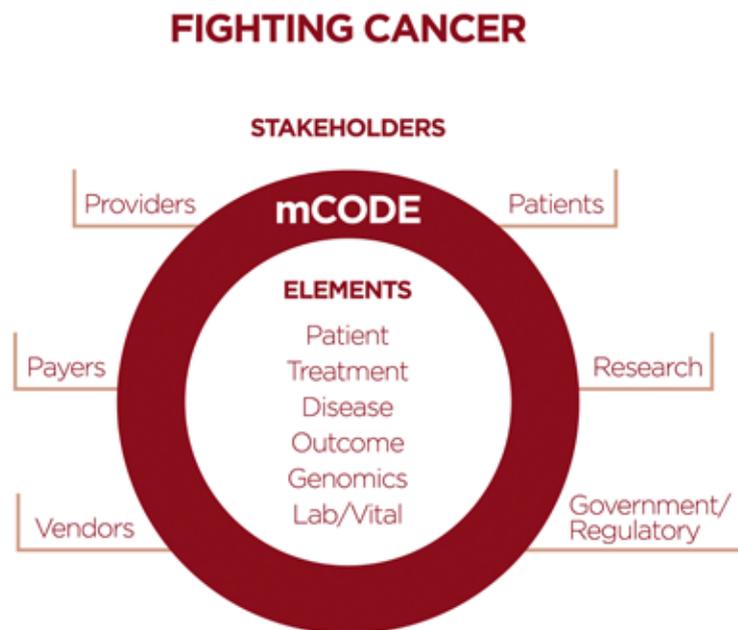
To support mCODE data sharing, we looked at ways to extract mCODE data so that providers and patients could make informed, data-driven decisions and provide data back to generate new knowledge. To accomplish this, we developed Compass, a SMART on FHIR application, to allow its integration into the EHR system and clinical workflow.

For this pilot, Compass is used to filter a patient's data against the CancerLinQ patient database to determine those who fit a profile most common to the patient. Compass extracts mCODE data from EHRs and organizes it into reports for doctors and researchers, and to inform patients about real-world treatment options, side effects, and outcomes. This data can enhance the discussion between patients and healthcare providers about possible diagnoses and steps forward.

As a result of the mCODE process of collection, sharing, and analysis, Compass has the potential to empower better diagnosis, improved care planning, and shared decision making at the point of care. The mCODE team is testing the use of Compass now with several partners, including Intermountain Healthcare.

Other Use Cases

Our plan is to develop a stable core for mCODE and evolve it carefully, working with organizations across the ecosystem to determine other high-priority needs. As we assess results and explore new use cases, we will either add new common elements to mCODE or develop extensions. We are already



documenting when changes in treatment occur for each patient. A change in treatment provides an opportunity to document the rationale associated with the change. In the case where the change is safety related (e.g., the patient couldn't tolerate the treatment), we can document that change and safety event.

Pilot Project 3. Collection Methods

We've been seeking collection approaches that are effective, capture critical information, and align with clinical workflows – without adding burdens on clinicians. Working with partners to test various data collection processes led to the development of a prototype, named Flux Notes. This tool can be used to collect

looking at many other possibilities brought to us by stakeholders.

For example, the team is investigating whether an mCODE-based authoring tool could improve the functionality and interoperability of clinical pathways. These flowcharts of standard care for treatment are meant to drive down variability in care by presenting treatment options based on efficacy, quality, and cost effectiveness. Despite the growing use of pathways in oncology, the lack of standardization¹ and issues with obtaining data from EHRs continue to be a burden to oncologists. We are investigating the use of mCODE to document in EHRs where patients are on the pathway and to improve doctors' decisions about next steps.

“Most of the high-quality data that leads to new cancer treatments comes from clinical trials. However, these trials involve only about 3% of U.S. cancer patients – thus providing limited information about what treatments work for which patient”

Another possible use is applying mCODE data to help providers reduce the resources needed to process Prior Authorization requests from insurance companies. Today, a disproportionate effort is needed to gather the appropriate patient information and manage the process necessary to decide whether to approve reimbursement of a proposed cancer treatment. What if the required information was already captured in patients' EHRs? Potentially, that data could be made available to insurance companies to fulfill preauthorization requests, thereby saving staff time and ensuring complete and accurate information is provided. Additionally, this could be tied together with pathways to enable a more automated, pathway-based Prior Authorization process.

Conclusion

mCODE still has a long way to go on its roadmap. We believe, however, that the team has developed a solution that can be adapted to many needs in the healthcare community – including needs beyond cancer – from patients, who want to access their own records, to doctors, who want to make the best decision possible for each patient, to payers, who will benefit from increases in safety and efficacy.

We also believe the timing is right – the technology is at hand to address frustrations with “Big Data” and lagging returns on EHR investments. For example, today, cancer researchers must spend time curating existing patient records, scanning texts and notes – reams of paper and online documents from different organizations – to find what worked for which cohort. Progress could proceed faster if curation were such that we could access and search data in EHRs.

We have established the mCODE Executive Committee to drive the program forward and steward mCODE as it matures. ASCO, CancerLinQ, and MITRE, all nonprofit organizations, are committed to working with the entire ecosystem to meet the overall goal of making data smarter and more useful. Likewise, organizations are encouraged to collaborate with the team, through the mCODE Council, representing all the stakeholder groups, and the HL7 FHIR Accelerator, known as CodeX, to develop and expand mCODE with targeted extensions. ^{1,2,3,4}

In part 2 of this article, we'll describe these activities in more detail and share results from our ongoing pilots and trials.



Dr. Brian Anderson is a Harvard trained physician-scientist, innovator, and digital health expert. Dr. Anderson's focus is on the use of information technology in support of emerging clinical decision support (CDS) models and the provision of safe, effective, patient-centered care. Dr. Anderson is the co-leader of MITRE's Oncology Standard Health Record research program and sits on

the mCODE Council's Executive Committee. He also leads the Digital Health Engineering Group within MITRE's Health Technical Center. Previously, while at athenahealth, he led the Informatics Department and launched a new model of CDS leveraging artificial intelligence. Dr. Anderson has served on several national health information technology committees in partnership with the Office of the National Coordinator.



Andre Quina specializes in creating and managing teams to develop open source tools for healthcare. He is the co-lead for the Oncology Standard Health Record program, an initiative defining a U.S. national standard for the logical content for electronic health records for cancer. Previously, he led the development of a MITRE research initiative called Crucible, which is a comprehensive

Fast Healthcare Interoperability Resources (FHIR) testing infrastructure and test catalog designed to evaluate the accurate implementation and interoperability characteristics of an FHIR server. He has previously done significant work in the development of tools to support electronic clinical quality measurement, including MITRE's Tacoma project, a federally sponsored initiative to enhance the clinical quality improvement framework. The project is championed by the Centers for Medicare & Medicaid Services and the Office of the National Coordinator for Health Information Technology. The goal is to unify clinical quality measurement and CDS standards and technology to simplify integration and reporting for providers and improve healthcare delivery.



Dr. Jay J. Schnitzer is Vice President and Chief Technology Officer at The MITRE Corporation. He oversees MITRE's internal research and development (R&D) program to 1) ensure a world-class internal R&D effort, 2) deliver transformational capabilities that drive mission success and global leadership, 3) meet the needs of MITRE's federal sponsors through innovation, R&D, and

transitioning technology directly to government, and 4) return value to the nation by transferring innovations to industry. Before joining MITRE, Dr. Schnitzer was the Director of the Defense Sciences Office at the Defense Advanced Research Projects Agency (DARPA). Prior to DARPA, he was at Boston Scientific Corporation as Chief Medical Officer and Senior Vice President. Earlier, Dr. Schnitzer held a staff appointment at the Massachusetts General Hospital (MGH) as an attending pediatric surgeon, with a joint appointment at the Shriners Burns Hospital, and was a faculty member at Harvard Medical School. Dr. Schnitzer remained at the MGH for 15 years having attained the rank of visiting surgeon and associate professor of surgery. He was the principle investigator on multiple peer reviewed research grants (NIH and others), and authored and co-authored numerous publications.

mCODE is a trademark of the American Society of Clinical Oncology. Used with permission.

Reference

1. “How Oncology Care Decision-Makers Define Clinical Pathway Programs: Conceptual vs Reported Definitions,” *Journal of Clinical Pathways*, June 2018. <https://www.journalofclinicalpathways.com/article/how-oncology-care-decision-makers-define-clinical-pathway-programs-conceptual-vs-reported>