A Novel Clinical Pathways Approach to Delivering Regional-Based Clinical Trials and Patient Care in a Hybrid Academic-Community-Based System

Kathryn E Patronik, MHA; Edward S Kim, MD, FACP

AFFILIATION:
Levine Cancer Institute, Atrium Health, Charlotte, NC

ADDRESS CORRESPONDENCE TO:
Edward S Kim, MD, FACP
1021 Morehead Medical Drive, Suite 3100
Charlotte, NC 28204
Phone: (980) 442-3130
Email: edward.kim@atriumhealth.org

ABSTRACT: The health care landscape is becoming constantly more complex with new drug treatments and molecular testing. In order to achieve consistent, up-to-date patient care, clinical pathways are becoming increasingly utilized. There are numerous types of guidelines and clinical pathways that providers and systems use. Since 2015, the Levine Cancer Institute (LCI), Atrium Health, has created and utilized the Electronically Accessible Pathways (EAPathways), which has helped drive standardization and enhance provider and patient diagnostic and treatment knowledge across its regional network. The EAPathways offers providers access to clinical services, therapies, genomic testing, and clinical trials information. This article describes LCI's experience of utilizing the EAPathways thus far, including their origin, aims, and implementation.

KEY WORDS: clinical pathways, oncology, care coordination, guidelines

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Patient care is changing as providers and health systems increasingly place value on standardized yet individualized care. In order to deliver this type of care to patients consistently and efficiently across regional health networks, clinical pathways are becoming increasingly useful and necessary in everyday practice. This is especially true in oncology where there are rapidly changing standards of care with new approvals of therapeutics and diagnostics.[1-3] Treating patients efficiently also requires increased access to supportive care services, genetic counseling, survivorship, and clinical trials, which are essential for individual patient care management. By implementing and using clinical pathways, all users are empowered to make evidence-based treatment decisions and deliver consistent, high-quality, individualized care in an expedited, efficient manner.

LEVINE CANCER INSTITUTE

In 2012, Atrium Health (previously Carolinas HealthCare System), established the Levine Cancer Institute (LCI), an academic-community-based hybrid oncology center with a mission to provide patients with cancer care closer to where they live. LCI consists of 21 regional care locations across North and South Carolina with its largest facility and headquarters in Charlotte, NC (Derek Raghavan, MD, PhD, President). Patients treated at any of these locations have access to expertise and services including medical, hematologic, surgical, radiation, and supportive oncology services (eg, palliative care, integrative medicine, behavioral health, patient navigation, etc). Additionally, patients

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have access to over 400 clinical trials, a 220-chair infusion center, a phase I clinical trials unit, bone marrow transplant unit, and the opportunity to receive treatment from the first Planetree-designated outpatient cancer network in the world, highlighting the highest achievement and excellence in person-centered care.[4] With various locations and 1194 employees (over 100 providers), LCI strives to treat all of its patients closer to their homes while implementing cutting-edge medicine.

Generally, guidelines are systemically developed statements that help drive provider decision-making through an appropriate sequence of events for care management.[2] Alternatively, clinical pathways are locally agreed-upon, multidisciplinary, evidence-based plans that help drive specific treatment decisions in a particular clinical setting or patient type.[2] There are national platforms such as those provided by the National Comprehensive Cancer Network (NCCN) and other commercial programs embedded within electronic medical record (EMR) systems that exist for the same purpose of helping to drive treatment decisions, deliver recommendations, and order testing for patients.[2] This type of technology can be a valuable tool for regional networks; however, these systems are limited to the features included by the organization or commercial developer.

THE EAPATHWAYS

In 2015, LCI created an electronic clinical pathways tool, Electronically Accessible Pathways (EAPathways), with the purpose of providing standardized, evidence-based, continually updated clinical pathways for all LCI network providers. The goal was to standardize care, provide access to patient services and clinical trials, promote specialized care by local providers, and deliver care in a similar manner across a regional network. The EAPathways is a stand-alone software program first imbedded within the Atrium Health intranet in 2015 and consequently imbedded within the Atrium Health EMR system in 2017. With a network login and password, users at 16 of 21 LCI regional and affiliate locations who use the same EMR can access the EAPathways clinical pathways content through the EMR. The remaining sites that do not operate on the same EMR can access the same content from the intranet version.

The EAPathways tool provides a way for the physicians, advanced care practitioners, pharmacists, and nurses across a regional network to obtain access to treatment approaches, diagnostic and molecular testing, clinical trials, and patient resources. The clinical pathways, attached documents, and clinical trials can be updated in "near-real-time" based on the urgency of information. For instance, when atezolizumab was Food and Drug Administration approved for use in patients with urothelial cancer,[5] our genitourinary disease section discussed the indication immediately and recommended placing atezolizumab on the appropriate page within the EAPathways. The section communicated this with the EAPathways administrative team that same day and by the following morning, atezolizumab, the first immunotherapy treatment for urothelial cancer, was included in the treatment options on the EAPathways. This is one example among many others in which therapies were efficiently reviewed and updates expedited for provider utilization. Other immunotherapies have subsequently been listed for treatment of urothelial cancers on the EAPathways.

In addition to clinical updates, the EAPathways includes custom features that allow effortless communication between departments and provides supportive resources for clinical teams and patients. Users have easy access to updated clinical trials information, clinical notifications, patient and provider teaching documents, program information (eg, tobacco cessation, supportive care, early diagnosis), and other clinical resources that did not exist within one place previously. The tool continues to evolve based on provider feedback as well—existing features are enhanced, and new features are added. As a result, LCI providers see value in using the tool and are increasingly enrolling patients on clinical trials, participating in genomic and molecular testing, and referring patients to programs for services such as tobacco cessation, behavioral health, and cancer screening.

Developing Content

Content within the EAPathways is developed by disease-site sections (eg, breast cancer, thoracic cancer, genitourinary cancer, gastrointestinal cancer, neuro/brain cancer, cutaneous malignancies, and hematology) consisting of multidisciplinary teams of providers and pharmacists as well as research and administrative staff. Sections meet monthly and on an as-needed basis to discuss, review, and suggest proposed clinical pathways content, research protocols, etc. The clinical pathways content regarding treatment recommendations comes directly from these sections and are made based on peer-reviewed literature, clinical best practice, and other national guidelines or clinical pathways. As new articles or information regarding patient treatment, diagnostics, or other therapeutics become available, this information is reviewed and discussed by the members of the corresponding section, and the EAPathways are revised if needed.

After the section members approve the content, the section leader creates or edits the content which is then given to and approved by the department chair. After this final approval, a local team of EAPathways administrative users edits and publishes the updated content within the EAPathways. The EAPathways administrative team receives notifications from appropriate departments or providers to maintain regular updates to all content within the EAPathways.

By regularly addressing updates and changes, the EAPathways remains current and provides users with therapeutic, diagnostic, genomic testing information, clinical trials, and clinical pathways. The EAPathways currently houses approximately 40 LCI solid tumor and hematologic clinical pathways, 16 supportive care clinical pathways, and 12 additional LCI and Atrium Health clinical pathways for chronic obstructive pulmonary disorder, management of heart failure, pulmonary embolism management, concussion, cancer screening, etc.

Notable Features

A notable feature of the EAPathways is the ability to capture and report data. By creating functionalities for providers to enroll patients on treatment regimens, inquire about clinical trials, enroll patients in opt-outs, and inquire or refer to other relevant programs or diagnostic and molecular testing, the EAPathways has streamlined these processes. Each enrollment, inquiry, and referral is recorded within the tool. EAPathways administrative users can access these data and generate reports regarding when the clinical pathways are created or edited, total users, total enrollments within treatment regimens, total number of opt-out utilization, clinical trial inquiries, genomic test referrals, in addition to numerous other customizable reports.

While regional-based care is attractive, the challenges of delivering high-quality, consistent care with access to crucial patient programs is difficult yet important to implement.[6] Interpretation of guidelines and clinical pathways can be broad and not specific to each patient and patient situation. LCI sought to create a tool that would not only create local clinical pathways but also create access to important information and services not readily available outside of the main center and to consistently engage all network providers in the creation and use of the clinical pathways. Engaging all pathway users in the development process is a crucial criterion for the creation of high quality clinical pathways.[1]

LCI has over 400 clinical trials available for patients with cancer across the entire system. In regional networks with this number of clinical trials, it is crucial that patients across all sites have access to the same trials regardless of where they live and receive treatment. The EAPathways created an opportunity to improve provider knowledge and patient access to available clinical trials. It also offered the opportunity to create a more efficient mechanism for communication between referring providers and clinical trials staff. In each monthly disease site section meeting, providers discuss clinical trials and coordinate with the EAPathways administrative users to add clinical trials icons to their clinical pathways where they are relevant for patients. The EAPathways administrative users attach protocols, informed consents, investigator, and study coordinator information to each trial icon. Additionally, they manage updates and changes to trial statuses daily. The clinical trial accrual status (eg, pending, open to accrual, closed to accrual) is indicated by the color of the clinical trials icon (yellow, green, red, respectively). When the status of a trial is updated in the EAPathways, the icon color changes to reflect its current status. These "near-real-time" updates allow for providers to know exactly which trials are open for their patients while connecting them with all of the information about each trial. Trials can be placed on any of the 68-individual clinical pathway sets within the EAPathways.

ONGOING EFFORTS

The EAPathways tool was implemented in 2015, and we have compiled utilization metrics and preliminary data from 2016 and 2017. Adoption has increased since initiation (70% compliance in 2017 among providers), especially with regards to clinical trial enrollments. Despite having a similar number of studies open yearly from 2015 to 2017, clinical trial enrollments have steadily increased, especially at our regional sites. Additionally, there have also been more referrals to patient clinical services (eg, medical genetics, tobacco cessation program, etc.)

In 2016, the American Society of Clinical Oncology (ASCO) released the "ASCO Policy Statement on Clinical Pathways in Oncology" to address the fact that there were no current standards to measure the integrity and quality of clinical pathways. Subsequently, a newly developed ASCO Task Force created a set of criteria for the development and implementation of clinical pathways that focused on 3 main areas: pathway development, implementation and use, and analytics.[3,6] The EAPathways currently meets 12 of 15 criteria stated in the ASCO Criteria for High-Quality Clinical Pathways in Oncology.[6] However, the EAPathways does not yet meet the following 3 criteria: (1) efficient and public reporting of performance metrics—the EAPathways does not publicly report metrics or utilize analytics to move from compliance-based to outcome-based results yet, as it is too early and we need to collect more data first; (2) outcome-driven results—the EAPathways does not have analytics yet in place to measure outcome-driven results through the EAPathways; and (3) promotes research and continuous quality improvement—we do promote research, but we are still in the process of measuring quality improvement. In the future, LCI hopes to use data captured within the EAPathways to report on patient outcomes and also contribute to research and process improvement projects, if applicable.

Since 2015, LCI has created 68 individual clinical pathways that have been published in the tool for all LCI providers to utilize. These efforts continue as oncology care evolves and new approaches to care are developed. The ability to add new therapeutics or diagnostics in less

than 24 hours has enhanced the ability of LCI providers to deliver cutting-edge care. As genomic testing has become mainstream, the EAPathways has helped standardize this process across LCI's 21 regional locations. Additionally, clinical trials accrual has increased dramatically since implementation of the EAPathways in 2015.

CONCLUSION

The practice of oncology is an exciting, yet challenging area. The number of new drug and diagnostic indications in the past 5 years is unprecedented. Tools, such as the EAPathways, help empower providers to deliver the very best services and most up-to-date care for patients, especially in regional-based networks. ◆

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