ontada®

Oncology Real-world Data and Research:

Generating Evidence 12 Oncology Research Studies

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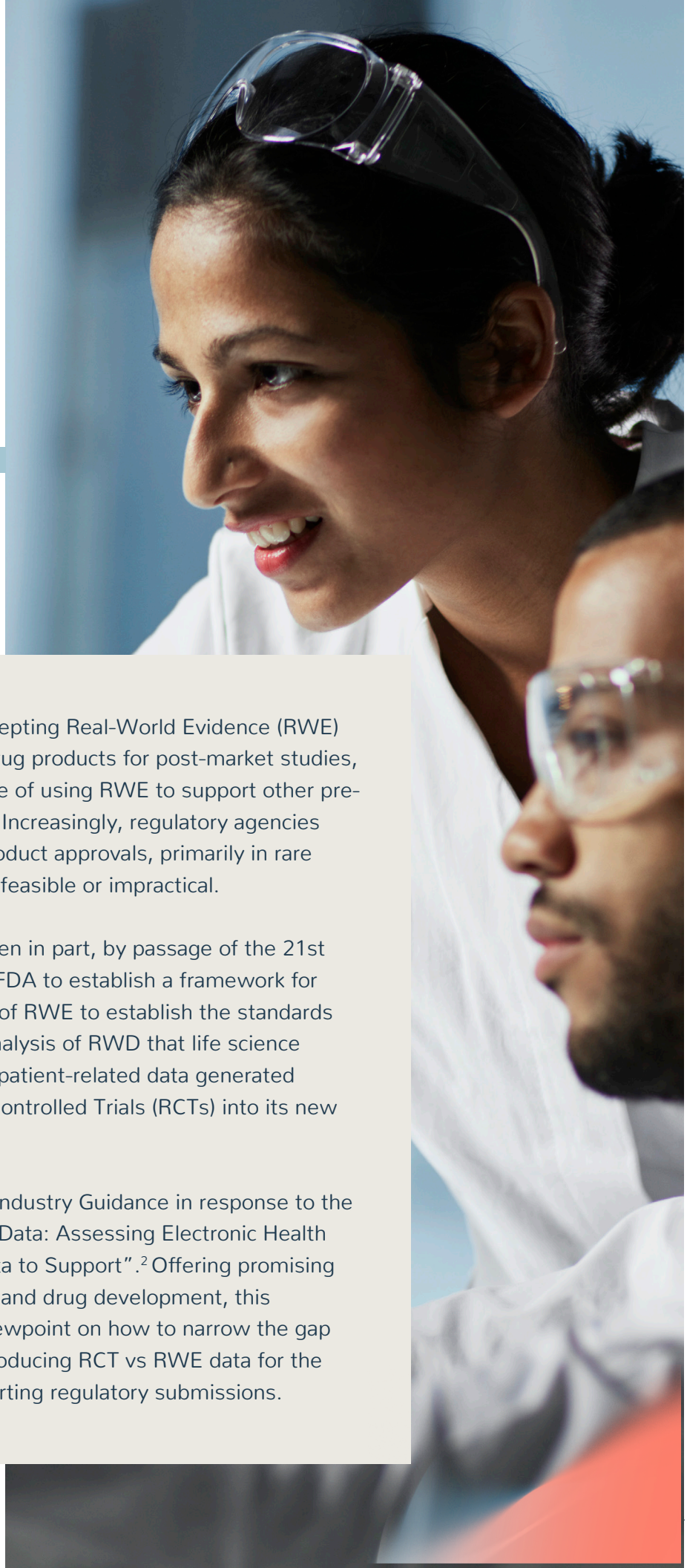

While the FDA has a long history of accepting Real-World Evidence (RWE) to monitor and evaluate the safety of drug products for post-market studies, there is growing acceptance of the value of using RWE to support other pre- and post-approval regulatory decisions. Increasingly, regulatory agencies have accepted RWE to support drug product approvals, primarily in rare diseases where randomized trials are infeasible or impractical.

This growing acceptance has been, driven in part, by passage of the 21st Century Cures Act, which required the FDA to establish a framework for a program that would leverage the use of RWE to establish the standards and methodologies for collection and analysis of RWD that life science companies could rely on to incorporate patient-related data generated outside of the context of Randomized Controlled Trials (RCTs) into its new drug applications.[1]

The FDA recently published the fourth Industry Guidance in response to the Cures Act mandate, titled "Real-World Data: Assessing Electronic Health Records (EHRs) and Medical Claims Data to Support".[2] Offering promising guidance for innovation in study design and drug development, this document reflects the FDA's current viewpoint on how to narrow the gap between the methodological rigor of producing RCT vs RWE data for the purposes of presenting evidence supporting regulatory submissions.

What is Real-World Evidence?

According to the U.S. Food & Drug Administration (FDA), Real-World Data (RWD) is information about patient health status or the delivery of healthcare collected from a variety of sources, including electronic health records (EHR), billing and claims databases, and disease registries. Real-World Evidence (RWE) is the clinical evidence regarding the usage and potential benefits or risks of a drug treatment based on the analysis of RWD.

RWE Use Cases

Ontada is committed to working with our biopharma partners to gather critical insights designed to accelerate the development of new drugs and treatment strategies in oncology. Our work continues to support science in oncology and improve cancer care through real-world data and research.

Following are highlights of recent publications as well as pivotal research presented at ISPOR. For more details, click on the links to the individual abstracts or papers, or download the full research summaries.

Actionable Insights into Oncology Treatments

RWE complements clinical trials by capturing data on the day-to-day usefulness of drugs that can be used to support both regulatory and policy decisions. While RCTs remain the gold standard for evaluating drug safety and efficacy, they can be expensive, time-consuming, and often conducted among relatively homogenous patient populations, limiting their generalizability to broader patient populations.

With the ability to track more patients over a longer period of time, real-world studies complement clinical trials by providing actionable insight into how treatments perform in clinical practice. The FDA is predicting that greater use of RWE will result in safety and efficacy information becoming available sooner and helping to further inform regulatory decisions.[3]

Feasibility of Using Oncology-Specific Electronic Health Record (EHR) Data to Emulate Clinical Trial Eligibility Criteria

Pharmacoepidemiology. 2023; 2(2):140-147. https://doi.org/10.3390/pharma2020013

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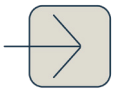
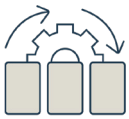


Approach

Eligibility criteria from recent oncology clinical trials was examined to assess the degree to which RWD from an oncology specific EHR in a community setting could be used for the emulation of inclusion/exclusion (I/E) eligibility criteria for external control arms in oncology clinical trials. Using trials for oncology drugs approved by the FDA in 2020, verbatim text from trial inclusion and exclusion criteria was qualitatively assessed to determine if criteria could be ascertained from structured and unstructured EHR data. Identified criteria were categorized (cancer-related, comorbidity-related, demographic, functional status, and trial operations) and subcategorized.

Results

Among 53 identified trials, 20 met the requirements for study inclusion, which included 463 eligibility criteria. Percentages of criteria by category were as follows: cancer-related factors (46%), comorbidities (20%), functional status (18%), trial operations (14%), and demographics (2%). For 18 of the 20 trials, 80% of the eligibility criteria could be ascertained with RWD; while 4 of 20 trials met the 100% threshold when all criteria were considered. When trial operation-specific criteria were excluded, all 20 met the 100% threshold.



Conclusion

Results indicate that both structured and unstructured data from community-based oncology-specific EHRs can be used for determining patient eligibility for external control arms for clinical trials. Restrictive clinical trial eligibility criteria have been cited as one of the major barriers to the participation of a more diverse population in trials. The use of RWD to construct external control arms can aid in improving inclusivity and generalizability.

Assessing the quality of real-world data and real-world evidence in oncology research: A Cohesive Framework for Researchers

ISPOR 2023 Poster - top 5% finalist for the ISPOR Research Presentation Awards

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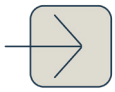
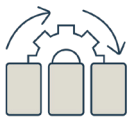


Approach

Established methods for evaluating the quality of Real-World Data (RWD) and Real-World Evidence (RWE) were evaluated through a literature review, focusing on understanding what oncology research questions can be answered with the RWD available. Based on the results, Ontada researchers developed a new method for assessing the quality of RWD and RWE for oncology studies. The new tool organizes RWD into nine domains to evaluate the quality of RWD and RWE tailored to oncology: conformance, completeness, consistency, accuracy, scalability, timeliness, generalizability, validity, and transparency. Categories of quality were then defined as high, moderate, and low.

Results

Multiple methods for determining the quality of RWD and RWE were identified through the literature review. The new tool will help aid researchers understand RWD and RWE quality more broadly and for specific domains. Additional details on the methods and results from applying this tool to data from practices in The US Oncology Network will be presented at future peer-reviewed research forums.



Conclusion

The new tool will provide a more comprehensive understanding of RWD and RWE quality. Data quality is often defined as being fit-for-purpose, meaning that the data are relevant, reliable and can adequately answer the research question under consideration. Results suggest that existing methods are available for identifying fit-for-purpose RWD, which has important implications for generating RWE to understand the natural history of disease and the effectiveness of treatment.

The Utility of "Single Exposure" versus Causal Architecture Approaches in Real-World Research

ISPOR 2023 Poster

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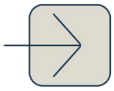


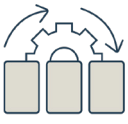
Approach

Epidemiologic methodology has evolved substantially to encompass a variety of techniques for focusing on the most unbiased effect estimate of a single exposure (e.g., a treatment effect). Less attention has been paid to the refinement of study designs and analysis to evaluate clinical, environmental, and social determinants that interactively influence disease risk or outcomes. In this conceptual paper, researchers defined single exposure and causal architecture approaches and delineated key considerations related to assessing which approach would be fit-for-purpose based on the overarching research question.

Results

Drawing upon examples from Real-World (RW) research types, such as use of external control groups, comparative effectiveness, and prediction of likely responders to treatment, both approaches were evaluated using three case studies related to regulatory and/or payer decision-making:

- In one case study based on a single exposure approach, historical, observational outcomes for patients with Merkel cell carcinoma (MCC) were compared to the outcomes from a single-arm clinical trial which suggested that immune checkpoint inhibitors improve treatment outcomes. Results helped establish FDA approval of avelumab in 1L MCC.
- One case study using a casual architecture approach evaluated the prevalence of Triple-negative breast cancer (TNBC). The study found that the prevalence of TNBC was more prevalent in predominantly Black vs. White neighborhoods, driven by modifiable metabolic exposures. Results can inform local cancer control and prevention efforts.



Conclusion

Both single exposure and causal architecture approaches to study design and analysis have a place in Real-World research. A single exposure approach enables hypothesis testing in specific populations and a causal architecture approach can identify multi-level, multi-factorial relationships to inform risk stratification approaches. A careful examination of when each approach is fit-for-purpose can lead to the application of innovative strategies to the design and conduct of RW studies.

Comparisons of Real-World Time-to-Event End Points in Oncology Research

JCO Clinical Cancer Informatics 2021 :5, 45-46

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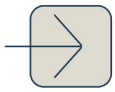


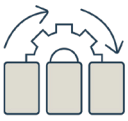
Approach

Progression-free survival (PFS) is a common end point for anticancer treatment assessments and is often assessed using RECIST criteria in clinical trials. Real-world PFS (rwPFS) is based on clinician-assessed response and is often used for real-world studies. Other surrogate end points, such as time-to-treatment discontinuation (TTD) and time-to-next treatment (TTNT), measure treatment durations that may correlate with clinical benefit.

The potential for TTD and TTNT to serve as proxies for rwPFS was evaluated through a literature review. Data for patients with metastatic solid tumors treated in The US Oncology Network were captured from the iKnowMed electronic heath record (EHR) system. All end points were measured from the administration dates for infused therapies and prescription dates for oral oncolytics. TTD spanned until discontinuation of initial treatment; TTNT spanned until initiation of subsequent treatment or death; and rwPFS spanned until earliest date of clinician-assessed progression or date of death.

Results

Based on pooled study data, median TTD durations were shorter than median rwPFS and TTNT durations, with 95% CIs overlapping just once among the measures. The 95% CIs for TTNT and rwPFS overlapped for three of the five studies, but the 95% CIs for TTNT were greater than rwPFS in the remaining two studies. When expressed as point estimate ratios between surrogate measures and rwPFS, TTD or rwPFS ranged from 0.22 to 0.70 while TTNT or rwPFS ranged from 0.88 to 2.43.



Conclusion

TTD appears to be a lower-bound surrogate outcome for rwPFS among these studies. TTNT, by contrast, was similar to or exceeded rwPFS. These differences highlight the importance of clinical context in selecting appropriate surrogate end points. Assessment of rwPFS itself can also appear to be greater than or less than that reported in clinical trials depending on the timing of follow-up visits. While sample sizes for rwPFS were limited to study populations that underwent chart abstraction, use of study end points that do not require chart abstraction such as TTD and TTNT can increase the study sample size, potentially increasing power, lowering study costs, and expediting study completion.

Considerations for Common Exclusion Criteria in Real-World (RW) Retrospective Observational Studies in Oncology

ISPOR 2023 Poster

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Approach

A key strength of well-designed Real-World (RW) research studies is the potential to include larger and more representative populations than randomized-controlled trials (RCTs). Two commonly applied exclusion criteria across RW oncology studies involve: 1. Patients from clinical trials and 2. Patients with other primary cancers. These criteria are often specified to maximize a study's internal validity (minimize bias), which is prioritized against external validity (generalizability and transportability). In this study, researchers examined the necessity and operational definitions of exclusion criteria when designing fit-for-purpose research.

Results

Patterns in the disqualification rates and differences in the verbiage applied were observed in the study. Based on these results, key dimensions across which these two exclusion criteria have been differently defined were identified and examined for their impact on patient disqualification. Recognizing a trade-off between sample size, bias reduction, and operational efficiency related to the implementation of these criteria, Ontada researchers proposed a conceptual framework for the application of these criteria in future studies.

Conclusion

Exclusion of patients from clinical trials and/or patients with other primary cancers was common and the application of these criteria may have a substantial impact on the internal and external validity of RW studies. Therefore, these criteria should be thoroughly and systematically assessed for each study to ensure selection of the appropriate patient population for the research question being addressed. Customization of exclusion criteria to reduce bias while maximizing sample size and representativeness is crucially important for RW study design.

Understanding the Value of Chart Abstraction for Assessing Oral Treatment History in the Oncology Outpatient Setting

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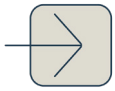
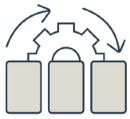


Approach

Completeness rate of data describing oral oncolytic start and stop dates from charts was evaluated, focused on understanding the value of chart abstraction for complete oral treatment histories. However, it is common for structured data from electronic health records (EHR) to lack accurate treatment histories on actual fulfilment and how patients are taking oral therapies at home. Thirty-six completed retrospective observational chart review studies within The US Oncology Network between January 2019 - December 2021 that included oral oncolytics as treatment options for solid tumors were identified. Chart abstraction data were reviewed to identify the number of patients who initiated oral oncolytics and to identify the number of total oral oncolytics among these patients. Known start and stop dates were captured, and if a start or stop date was not available, the date was documented as unknown.

Results

Researchers identified 9,886 oral oncolytics initiated among 4,814 patients across the 36 studies in 11 cancer types. Overall, approximately 81% of these therapies had a known start and stop date. Completeness rates by disease ranged from 82% to 100%.



Conclusion

High completion rates of start and stop dates were observed through chart abstraction. Integrating structured data with unstructured chart abstraction data can help provide a more comprehensive treatment history to better understand oral oncolytic treatment patterns in the real world. Capturing precise start and stop dates for oral oncolytics through chart abstraction is critical to understanding the impact of duration of therapy and compliance on patient outcomes and adverse events.

Lack of standardization in quantitative evaluations of the efficacy-effectiveness gap (EEG) for cancer therapies: a targeted literature review

ISPOR Poster

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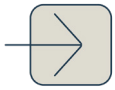
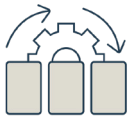


Approach

The efficacy-effectiveness gap, (EEG) is the difference between Randomized Clinical Trial (RCT)-based efficacy and Real World Evidence (RWE)-based effectiveness estimates for different cancer therapeutics. Quantification of EEGs improves understanding of how clinical trial results may apply to RW patient populations and what methodological improvements can be made to RCT and RWE studies. Yet few studies formally quantify the magnitude and underlying reasons for EEGs. In this targeted literature review, researchers used four databases to examine studies published between 01/2017–12/2021 to quantify the magnitude of and investigate factors contributing to the EEG for cancer therapeutics.

Results

The targeted literature review identified 10 studies involving more than 25 cancers and more than 45 treatments (systemic, targeted, and immunotherapy). Trial eligibility criteria was identified as the most common EEG explanatory factor, but treatment duration/completion and key confounders were also considered. Poorer performance status and early treatment discontinuation (e.g., due to toxicities) were highlighted as important differences between RCT and RW populations that partly accounted for EEG in some studies. Stratification among trial-eligible subsets of RW populations was a common strategy for investigating influence of eligibility criteria on the EEG.



Conclusion

Results suggest that better understanding of the scope and drivers of the EEG may lead to innovations in study design and methodology for both clinical trials and RW studies. This may result in more inclusive clinical trials.

Application of medication history for comorbidity assessment in cancer patients

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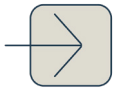
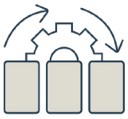


Approach

Cancer patients, at the time of diagnosis, often possess multiple comorbid conditions that may or may not contribute to their ability to initiate and continue treatments, manage adverse events and achieve desired outcomes. In retrospective, observational real-world research studies where access to medical history may be incomplete, comorbidity assessment that leverages the patient's current medication profile may be of value. In this comprehensive literature review, researchers identified studies of comorbidity assessment among patients with cancer treated in real-world settings published within the last 10 years.

Results

The targeted literature review identified 30 studies and a keyword search using terms associated with cancer, real-world settings and comorbidity assessment instruments was performed. Most studies captured comorbidities using standardized instruments, particularly the Charlson Comorbidity Index. Other approaches included targeted comorbidity searches, patient-reported information, as well as linkage of electronic health records and claims data. None of the included publications described use of patients' medication histories to derive chronic conditions.



Conclusion

Assessment of comorbidity is important in cancer research, as it may influence treatment selection, confound patient outcomes and preclude clinical trial eligibility. In the real-world setting, patients' medication history may be readily available and there is an opportunity to explore how this information could be used to measure comorbidities through validated approaches. Such techniques would need to consider how to differentiate off-label, acute and non-specific use among cancer populations. Results suggest that a valid and reliable comorbidity assessment derived from baseline medication profiles could provide meaningful insights for cancer populations.

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Biomarker testing and tissue journey among patients with metastatic non-small cell lung cancer receiving first-line therapy in The US Oncology Network

Lung Cancer, 2022 Apr;166:197-204. Epub 2022 Mar 10.

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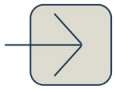

Approach

As the molecular drivers of non-small cell lung cancer (NSCLC) are identified and new targeted therapies are developed, this has led to rapid changes in the field of precision oncology and biomarker testing guidelines. The MYLUNG (Molecularly Informed Lung Cancer Treatment in a Community Cancer Network) ConsortiumTM is designed to optimize timely and appropriate comprehensive biomarker testing at the point of diagnosis.

The first phase of MYLUNG, a retrospective observational chart review study, utilized the iKnowMed™ oncology specific electronic heath record (EHR) system to identify patients with metastatic (mNSCLC) initiating first-line systemic therapy between April 2018 - March 2020. Biomarker testing rates and timing relative to first-line therapy for epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) gene rearrangements, c-ros oncogene 1 (ROS1) gene rearrangements, proto-oncogene B-Raf (BRAF) mutations, and Programmed Death-Ligand 1 (PD-L1) were assessed, including use of next-generation sequencing (NGS).

Results

The study included 3474 patients: 90% (n=3123) of patients in the overall study population had at least one biomarker test result available, while results for all 5 biomarkers were available in 46% (n=1602) of patients. 79.2% (n=2752) had at least 1 biomarker test result before initiating first-line therapy and only 35% (n=1230) had testing for all 5 biomarkers prior to first-line therapy initiation. 10.7% (n=371) had their first test result only after initiating first-line therapy, and 10.1% (n=351) had no test results documented. Changes in testing rates from 2018 to 2020 were 42% to 49% for all 5 biomarkers and NGS testing increased from 33% to 45%. Median time from mNSCLC diagnosis to first-line therapy was 35 days. Median turnaround times from biomarker testing orders to results ranged from 10 to 15 days for the individual biomarkers and 18 days for NGS.

Conclusion

Results showed that while most patients received at least one biomarker test prior to first-line therapy, less than 50% received all 5 tests. NGS testing also occurred in less than 50% of patients but appeared to increase over time. Decreasing the time from diagnosis of mNSCLC to first-line therapy initiation and including upfront comprehensive testing for all biomarkers may help ensure appropriate and timely treatment decision making.

Clinical outcomes and resource utilization after surgical resection with curative intent among patients with non-small cell lung cancer treated with adjuvant therapies in a community oncology setting: A real-world retrospective observational study

Thorac Cancer 2021 Jul;12(14):2055-2064. doi: 10.1111/1759-7714.14007. Epub 2021 May 24.

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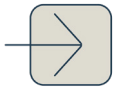


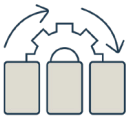
Approach

Approximately 87% of lung cancers are classified as non-small cell lung cancer (NSCLC).[4] Patients diagnosed with early-stage NSCLC who are eligible for surgical resection can achieve 5-year survival rates of 63% for stage I disease but only 35% for stage IIIA disease[4]. Adjuvant chemotherapy has been shown to improve survival in patients with completely resected early-stage NSCLC. This real-world retrospective observational study evaluated real-world relapse rates and healthcare resource utilization in patients with stage II-IIIB NSCLC receiving adjuvant therapy in a community oncology setting after complete resection.

Researchers utilized the iKnowMed™ oncology specific electronic heath record (EHR) system to identify patients with stage II-IIIB NSCLC and complete resection receiving any adjuvant therapy during June 2008 - April 2017 at US Oncology Network clinics, with follow-up through April 2019. Primary endpoints were rate of relapse, time to relapse (TTR), disease-free survival (DFS), overall survival (OS), and monthly emergency department (ED) visits and hospitalizations before and after relapse.

Results

The study identified 456 patients with a median age of 66 years and equally distributed between male and female. In patients with relapse (45.2% n=206), median follow-up was 31.7 months and median TTR was 13.7 months. Median OS was 82.4 months in the overall population and shorter in patients with relapse than without relapse (41.6 months vs. not reached). Among study patients with relapse during the follow-up period, the proportion of patients with at least one hospitalization was higher after relapse (59.5%) than before relapse (36.4%). Patients with relapse also had significantly more ED visits.



Conclusion

Patients with stage II-IIIB NSCLC treated with adjuvant therapy after complete resection had high relapse rates, reduced survival, and significantly increased healthcare resource use when relapse occurred. New therapeutic options to reduce relapse rates in patients with early-stage NSCLC could reduce healthcare utilization and costs.

Real-World Outpatient Cost of Care among Patients with Non-small Cell Lung Cancer (NSCLC) Treated in the US Community

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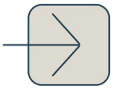
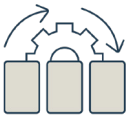


Approach

Retrospective study to evaluate cost of care and changes in cost over time among patients with Non-small Cell Lung Cancer (NSCLC). Electronic health records (EHR) and claims data for adult patients diagnosed with diagnosed with NSCLC in The US Oncology Network from March 2015 through June 2022 and treated with chemotherapy, were sourced from the iKnowMed™ oncology specific EHR. All costs were paid amount for outpatient services and analyzed as cost per patient per month (PPPM) longitudinally since 2015.

Results

The study included 26,615 patients across all four US census regions and the median age was 68 years. The median total outpatient medical care costs were $5,219 for all patients. The majority of total costs were for chemotherapy at a median PPPM of $2,957. There were significant changes in overall costs over the past 5 years, increasing from $3,476 in 2016 to $6,848 in 2021.



Conclusion

This large retrospective study of patients with NSCLC assessed the cost of care in community oncology settings in the US and shows that the cost of treating NSCLC has increased significantly over time. Results may provide oncology stakeholders with insights into how advancements in NSCLC care influences costs.

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Mapping the flow of biomarker testing information, from test order through impact on treatment decision-making: a case study in Metastatic NSCLC

ISPOR 2023 Poster

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Approach

The growth of biomarker-specific treatments in oncology requires providers to navigate an increasingly complex range of testing choices and results. The effectiveness of clinical decision support (CDS) tools for selecting therapies in precision oncology is dependent on the flow of biomarker testing information through the electronic health record (EHR).

More than 3,100 (n=3,126) patients initiating treatment for metastatic Non-Small Cell Lung Cancer (mNSCLC) between January 2020 and April 2022 were identified using structured data in iKnowMed™, an oncology-specific EHR. Events and characteristics of biomarker testing, including test orders, method of result documentation, utilization of the CDS tool, and use of biomarker status for treatment recommendations were captured and analyzed using both structured data and unstructured data collected through chart abstraction.

Results

Ninety percent of patients (n=2,816) had at least one test result among 13 biomarkers and 91 percent (n = 2,849) of these patients had test results saved in structured EHR fields. The CDS tool was used to select treatment for 65 percent (n = 2,027) of patients, with 3,669 treatment recommendations within the study period. Immunotherapy was a recommended treatment, per NCCN guidelines, for 51% (n = 1,600) of patients.

Conclusion

CDS tools can assist providers to identify precision oncology treatment options with access to biomarker results. This study illustrates the flow of testing information and measures the degree to which CDS tools use structured data to support treatment decisions in a community oncology setting. Results suggest that identifying gaps in the flow of biomarker information can improve treatment decision making and reduce burden on providers

Resources

[1] Hills B, Zegarelli B. 21st Century Cures Act Requires FDA to Expand the Role of Real World Evidence. Dec. 19, 2016. https://www.healthlawpolicymatters.com/2016/12/19/21st-century-cures-act-requires-fda-to-expand-the-role-of-rwe/

[2] United States Food and Drug Administration. The Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products, Guidance for Industry, September 2021

[3] Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new strategic framework to advance use of real-world evidence to support development of drugs and biologics, December 06, 2018

[4] SEER Cancer Statistics Review, 1975-2017, National Cancer Institute, Bethesda, MD [Internet]. [updated April 15, 2020; cited September 17, 2020]. https://seer.cancer.gov/csr/1975_2017/

Summary

Ontada's real-world research (RWR) Team, comprised of experienced outcomes researchers, oncologists, data abstractors, epidemiologists and biostatisticians have deep roots in oncology. We leverage our in-depth clinical data to help life sciences companies generate real-world evidence (RWE) for multiple use cases, including product value demonstration, and to support value-based care, inform clinical development lifecycle, understand standard of care, and more.

Ontada researchers have published 250+ peer reviewed studies. From descriptive retrospective studies to complex longitudinal study designs with custom data curation, our researchers, oncologists, data abstractors, and biostatisticians help generate the insights and evidence needed to support a product's value in competitive treatment landscapes.

Ontada's unique partnership with The US Oncology Network, one of the largest networks of community oncology providers in the U.S., allows us to leverage interconnected technology and real-world insights. It's our goal to accelerate drug development and commercialization, connect community oncology providers to treatment educational programs, and advance precise, evidence-driven patient care through practice technologies in the community setting.

To learn how Ontada can support your real-world data and research needs, contact one of our experts for an introductory call.

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Ontada is an oncology technology and insights business dedicated to transforming the fight against cancer. Part of McKesson Corporation, Ontada was founded on the core belief that precise insights – delivered exactly at the point of need – can save more patients' lives. We connect the full patient journey by combining technologies used by The US Oncology Network and other community oncology providers with real-world data and research relied on by all top 15 global life sciences companies. Our work helps accelerate innovation and powers the future of cancer care. For more information, visit ontada.com.