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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Tailored to Fit: Precision Medicine in Metastatic CRC

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Dr. Turck:
Strides continue to be made in the fight against metastatic colorectal cancer, or mCRC for short. There are more than 1,300 oncology medicines and vaccines in development, including biomarker-driven therapies. But many patients still face barriers in access to care.[1] Biomarker testing can help identify an mCRC tumor's genomic subtype, which in turn can inform personalized treatment decision-making. By adopting biomarker testing into routine practice, clinicians can improve patients' access to appropriate treatment options available to combat this life-threatening disease.

This is *Project Oncology* on ReachMD and I'm Dr. Charles Turck. In this program, we'll share best practices in overcoming barriers to biomarker testing in mCRC.

Joining me to share their perspectives are Dr. Mark Lewis and Dr. Kristen Ciombor.

Dr. Lewis is the Director of Gastrointestinal Oncology at Intermountain Health in Salt Lake City, Utah. Dr. Lewis, welcome to the program.

Dr. Lewis:
Thanks for having me.

Dr. Turck:
Also with us is Dr. Kristen Ciombor, Associate Professor of Medicine at the Vanderbilt-Ingram Cancer Center in Nashville, Tennessee. Dr. Ciombor, thank you for being with us today.

Dr. Ciombor:
Happy to be here.

Dr. Turck:
Diving right in, Dr. Ciombor, can you give us some background on the role of biomarker testing in mCRC?

Dr. Ciombor:
Yes. We can use biomarker testing to identify actionable tumor targets to personalize treatment options for our mCRC patients and consider appropriate biomarker-driven therapy options in their fight against the disease or offer a clinical trial.[2]

And biomarkers are becoming increasingly important in precision oncology not only to personalize treatment with approved biomarker-

driven therapy as appropriate, but also to help with understanding the diagnosis, management, and overall prognosis.[3]

But the truth is that even though the guidelines recommend biomarker testing at diagnosis with advanced or metastatic CRC, current rates of testing in clinical practice remain inadequate.[4,5]

Dr. Turck:
Now turning to you, Dr. Lewis, why do you think testing rates remain low? What challenges do clinicians face in adopting biomarker testing in their clinical practice?

Dr. Lewis:
That's an important question, and we know that many different barriers may come into play.

For one, building general awareness is important. Clinicians who treat across a variety of disease states may not be aware of the latest in the ever-growing list of actionable biomarkers or have low awareness of the rarer subtypes.[6] Next, delays in test turnaround time are a common issue. And so, rather than waiting for test results to return, clinicians may start patients on a few rounds of standard of care therapy that may disregard potentially actionable targets in the meantime.[6] And in some instances, this may be detrimental. There are other potential challenges with testing, such as inadequate tissue quality or insufficient tissue quantity.[6] And the reporting of results lack standardization,[6] which can lead to inaccurate interpretation and confusion. Integration of the test results into practice may also cause documentation and EMR issues. And of course, there's the question of testing cost – whether to outsource testing or perform them in-house.[7] And lastly, there's the concern of performing the biomarker testing, but implementing the results insufficiently.[8] And so overall, there are several different areas we need to be doing better to break down healthcare inequities in biomarker testing.

Dr. Turck:
Dr. Lewis, you bring up some important considerations across the clinical encounter. So, turning to you now, Dr. Ciombor, I want to talk about how we can address these challenges in biomarker testing for mCRC. Let's start with staffing and infrastructure. What are some practical suggestions here?

Dr. Ciombor:
Understandably, each institution or practice is resourced differently. But in terms of optimal staffing solutions, there are a few ways we can ensure we have adequate resources to deliver quality precision oncology with biomarker testing.[9]

Consider your practice's ability to staff with adequate personnel and services – if possible, with oncology nurse navigators, genetic counselors, financial counselors, and billing personnel – interdisciplinary professionals who can help patients navigate the complexities of the testing and treatment process.[9]

Clinical research coordinators can also help identify treatment pathways and clinical trials that might be appropriate for your mCRC patients.[9] The goal of these staffing recommendations is not only to create a culture of consistent and thorough interdisciplinary communication, but to embed that culture into everyday practice.[9]

Now when we look at infrastructure, we want to make sure that there are effective training protocols for clinicians, lab personnel, and pathologists. And these should include protocols for test ordering, result reporting and interpretation, and most importantly, reflex testing.[9]

Dr. Turck:
For those just tuning in, you're listening to *Project Oncology* on ReachMD.

I'm Dr. Charles Turck, and today I'm speaking with Dr. Mark Lewis and Dr. Kristen Ciombor about barriers to implementing biomarker testing for metastatic colorectal cancer or mCRC for short.

Dr. Ciombor, you mentioned the importance of interdisciplinary communication and some key players in the patient care team. So, getting back to you, Dr. Lewis, which multidisciplinary teams or team members do you find clinicians should engage with to be successful in adopting guideline-recommended biomarker testing?

Dr. Lewis:
Well, one option here is a molecular tumor board, or MTB for short. If you have one available, join one. If not, create one or consider joining a virtual MTB. MTBs are valuable in that they can teach clinicians how to read their biomarker testing reports, interpret the results, and ensure that you're using the most up-to-date testing strategies.[9] And the MTB teams often also include nurse practitioners, nurse navigators, pharmacists, and other allied HCPs who can be great multidisciplinary collaborators, especially if you don't already

have access to these types of providers in your own practice.

Another key member of the care team is the pathologist. For example, if you need to get a lab done urgently, you'll want to contact and discuss it with them. They can help you interpret your biomarker testing report and figure out which components of the report will be the most vital to your patient.[10,11]

So don't discount the importance of communicating your needs, and your patient's needs, to the pathologist. They'll not only ensure you're performing the right test sooner, but they can also help you create a standardized order protocol, and they can help you stay up-to-date on the latest biomarker developments.[10,11]

Dr. Turck:
And keeping these biomarker developments in mind, Dr. Ciombor, with so many biomarkers to test for, how can we perform these tests and preserve tissue effectively?

Dr. Ciombor:
In some institutions, one option may be using immunohistochemistry tests for some biomarkers, including mismatch repair testing and HER2 amplification. But there has been a recent trend towards switching to NGS, short for next generation sequencing, which is a comprehensive, cost-effective, and potentially tissue-effective method that allows us to test multiple biomarkers at once, including rare ones.[6]

Another potential option includes liquid biopsies for circulating tumor DNA (ctDNA) analysis, particularly if tumor tissue is scarce. This is a convenient and minimally invasive way to overcome insufficient tissue sampling and may even be considered as a complement to tissue biopsy or as an initial test, with negative results reflexing to tissue NGS testing.[6]

Dr. Turck:
It is important to note that certain approved treatments for mCRC have specific approved companion diagnostics, which may not include NGS. Please be sure to refer to approved product labeling and www.fda.gov/CompanionDiagnostics for information on FDA-approved companion diagnostics.

Now, I'd like to take a step back and take a broad view of our topic, so Dr. Lewis, let's talk about health care disparities. How can we ensure that *all* of our patients have equal access to biomarker-driven therapies and biomarker-driven clinical trials?

Dr. Lewis:
That's a critical issue that a lot of us in precision oncology are working on. In order to improve access to care, we need to improve patient diversity in clinical trials.

If the treatment trial data only includes certain populations, how can we ensure the treatment will work equally well in all populations?

We need to include community practice patients, who make up the vast majority of the patient population, in clinical trials.[5] We also need to find strategies for expanding clinical trial access, as well as broader healthcare and treatment access to other patient groups with historical healthcare disparities including age, race, and geographic location.

To do this, academic clinicians can create research networks to help expand and diversify the patient populations recruited for these clinical trials. That way, community clinicians can ensure their patients will be eligible for clinical trial recruitment if they have certain biomarkers on testing.[6] Additional strategies to improve trial participation diversity and representation may include: trial site location selection in underrepresented areas, recruitment of diverse investigators, translation and transportation services, and simplification of protocols to minimize patient visits.[12] Another potential approach is to standardize eligibility criteria to simplify and expand patient access.[13]

Dr. Turck:
And as we bring our program to a close, Dr. Ciombor, are there clinical decision-support tools or educational resources that clinicians can use to help them adopt biomarker testing into their clinical practice?

Dr. Ciombor:
Yes, there are a number of resources available; I'll take just a moment to highlight a few. There are several online and institutional resources that are widely available and diverse in their offerings.

These include general toolkits for implementing and improving biomarker testing in clinical practice.[9] Other groups focus on providing clinics with free adaptable educational and support tools, such as patient handouts and access barriers worksheets.[1,4] Expansive

knowledge bases on known cancer genomic alterations gather and update this data in one place for reference.[1,5] And some organizations have developed clinical decision support tools that contain information on certain cancers and associated biomarkers as well as approved biomarker-driven therapies.[16] Finally, clinical trials are not only ongoing for biomarker-driven therapies on potential actionable targets, but also are validating new use cases for existing targeted anticancer drugs for similar genomic alterations.[17]

Dr. Turck:
Thank you, those are some great practical takeaways to consider as we end today's program. I want to thank my guests, Dr. Mark Lewis and Dr. Kristen Ciombor, for sharing their insights on implementing biomarker testing for patients with metastatic colorectal cancer.

Dr. Lewis, Dr. Ciombor, it was great speaking with you today.

Announcer:
This program was sponsored by Pfizer Oncology Medical Affairs. If you missed any part of this series, visit ReachMD.com/ProjectOncology. This is ReachMD. Be Part of the Knowledge.

References:

1. Sherak J. Community oncology practices build more equitable access and outcomes. *Oncologistics*. 2022;21(1):6-11. Accessed February 14, 2023. https://www.iononline.com/-/media/assets/ion/pdf/publications/2022/sps-os-oncologistics-april22-final.pdf
2. National Cancer Institute. Accessed February 14, 2023. https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment
3. National Cancer Institute. Accessed February 14, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine
4. Sepulveda AR, Hamilton SR, Allegra CJ, et al. Molecular biomarkers for the evaluation of colorectal cancer: guideline summary from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology. *J Oncol Pract.* 2017;13(5):333-337. doi:10.1200/JOP.2017.022152
5. Iyer P, Deng M, Handorf EA, et al. Assessing Oncologists' Adoption of Biomarker Testing in Metastatic Colorectal Cancer Using Real-World Data. *JNCI Cancer Spectr*. 2022;6(6):pkac065. doi:10.1093/jncics/pkac065
6. Quinn E, Rangaraju S, Nagle A, et al. The Promise of Precision Medicine: Why Equitable Access in the Treatment of Cancer Depends on Comprehensive Genomic Profiling. *J Precis Med*. 2022;8(3):6-17. Accessed February 14, 2023. https://www.thejournalofprecisionmedicine.com/wp-content/uploads/equitable-access-treatment-cancer.pdf
7. Patel K, Clinton N, Mukhi H, Patel M. The Role of In-Office Next Generation Sequencing to Advance Precision Medicine in Community Oncology. *Targ Ther Onc*. 2021;10(7):23. Accessed February 14, 2023. https://www.targetedonc.com/view/the-role-of-in-office-next-generation-sequencing-to-advance-precision-medicine-in-community-oncology
8. Sadik H, Pritchard D, Keeling DM, et al. Impact of Clinical Practice Gaps on the Implementation of Personalized Medicine in Advanced Non-Small-Cell Lung Cancer. *JCO Precis Oncol*. 2022;6:e2200246. doi:10.1200/PO.22.00246
9. Association of Community Cancer Centers (ACCC). BiomarkerLIVE: Biomarker Testing in Practice: Process Improvement Toolkit. 2021. Accessed February 14, 2023. https://www.accc-cancer.org/docs/projects/biomarker-live/biomarkerlive-toolkit.pdf
10. Lewis D. Overcoming Barriers to Genomic Testing in Community Care Settings. *Targ Ther Onc*. 2021;1(1). Accessed February 14, 2023. https://www.targetedonc.com/view/overcoming-barriers-to-genomic-testing-in-community-care-settings
11. Oxnard G, Ritterhouse L. Best Practices in Incorporating Biomarker Testing to Deliver Precision Therapy in Cancer. *JONS*. Accessed February 14, 2023. https://www.jons-online.com/best-practices/1916-precision-therapy-in-cancer. Published August 7, 2018.
12. Ahluwalia, M. Diversity In Clinical Trials: 10 Strategies To Increase Minority Enrollment In Oncology Trials. Clinical Leader. Accessed March 3, 2023. https://www.clinicalleader.com/doc/diversity-in-clinical-trials-strategies-to-increase-minority-enrollment-in-oncology-trials-0001. Published July 20, 2021.
13. Gerber DE, Singh H, Larkins E, et al. A New Approach to Simplifying and Harmonizing Cancer Clinical Trials-Standardizing Eligibility Criteria. *JAMA Oncol*. 2022;8(9):1333-1339. doi:10.1001/jamaoncol.2022.1664
14. From Testing to Targeted Treatments. Biomarker Testing for Cancer Treatment. Accessed March 3, 2023. https://www.fromtestingtotargetedtreatments.org/biomarker-resource/
15. Chakravarty D, Gao J, Phillips SM, et al. OncoKB: A Precision Oncology Knowledge Base. *JCO Precis Oncol*. 2017;2017:PO.17.00011. doi:10.1200/PO.17.00011
16. Oncology Nurses Society. Genomics and Precision Oncology Learning Library. Accessed March 3, 2023.

https://www.ons.org/learning-libraries/precision-oncology
17. Mangat PK, Halabi S, Bruinooge SS, et al. Rationale and Design of the Targeted Agent and Profiling Utilization Registry (TAPUR) Study. *JCO Precis Oncol*. 2018;2018:10.1200/PO.18.00122. doi:10.1200/PO.18.00122