PQI IN ACTION

Positive Quality Intervention

NCODA

Fruquintinib (Fruzaqla®)

INTRODUCTION

NCODA developed the peer-reviewed Positive Quality Intervention (PQI) as an easy-to-use and relatable clinical guidance resource for healthcare providers. By consolidating quality standards, real-life effective practices, clinical trial results, and package insert and other guidance, PQIs equip the entire multidisciplinary care team with a comprehensive yet concise resource for managing patients receiving oral or IV oncolytics.

This PQI in Action is a follow up to the Fruquintinib (Fruzaqla®) PQI and explores how the medically integrated teams at Florida Cancer Specialists & Research Institute (FCS) and AtlantiCare Cancer Care Institute (AtlantiCare) collaborate and utilize the information found in the PQI as part of their daily practice. This PQI in Action focuses on the use of fruquintinib to optimize the treatment of patients with previously treated metastatic colorectal cancer (CRC).

Fruquintinib (Fruzaqla®)

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FRUQUINTINIB (FRUZAQLA®) FOR METASTATIC COLORECTAL CANCER

STANDARD chemotherapy for metastatic colorectal cancer (mCRC) in the earlier lines of treatment typically includes fluorouracil and leucovorin combined with either irinotecan (FOLFIRI) or oxaliplatin (FOLFOX). For select patients with good performance status, a more intensive regimen such as FOLFIRINOX may be considered.[1,2] Targeted therapies—including VEGF inhibitors (bevacizumab, aflibercept) or EGFR inhibitors (cetuximab, panitumumab)—are frequently added to these chemotherapy backbones based on tumor molecular features, such as RAS mutation status.[1,3]

Although many patients retain good performance status following two lines of therapy, third-line treatment options remain limited. Recommended therapies in this setting include regorafenib, trifluridine/tipiracil (with or without bevacizumab), and most recently, fruquintinib.[1]

Approved in November 2023, fruquintinib (Fruzaqla®) is a selective oral inhibitor of VEGFR-1, -2, and -3, designed to block angiogenesis and suppress tumor growth.[6] It is indicated for adult patients with mCRC who have previously received:

- Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
- An anti-VEGF therapy
- And, when clinically appropriate, an anti-EGFR therapy for RAS wild-type tumors

Fruquintinib's efficacy was demonstrated in two phase 3, randomized, double-blind, placebo-controlled trials:

- FRESCO-2: A global study involving 691 patients with mCRC who had progressed following standard chemotherapy, an anti-VEGF agent, and, when appropriate, an anti-EGFR agent, as well as trifluridine/tipiracil or regorafenib.[7]
- FRESCO: Conducted in China with 416 patients who had disease progression after standard chemotherapy.[8]

In both trials, patients were randomized 2:1 to receive fruquintinib 5 mg orally once daily for 21 days of a 28-day cycle, or placebo, in combination with best supportive care. Treatment continued until disease progression or unacceptable toxicity.

Overall survival (OS) was the primary endpoint in both studies:

- FRESCO-2: median OS was 7.4 months with fruquintinib vs. 4.8 months with placebo (HR 0.66; $p < 0.001$)
- FRESCO: median OS was 9.3 months vs. 6.6 months (HR 0.65; $p < 0.001$)[7,8]

The most frequently reported adverse events (≥20%) associated with fruquintinib included hypertension, hand-foot syndrome, proteinuria, dysphonia, abdominal pain, diarrhea, and fatigue.

HEALTHCARE PROVIDER INSIGHTS

The decision to initiate fruquintinib involves a thoughtful and collaborative evaluation process grounded in clinical appropriateness, patient-specific factors, and team-based confirmation of eligibility. Syed Zafar, MD, a medical oncologist with FCS, emphasized how evolving data has shaped treatment sequencing in mCRC. He shared that fruquintinib has become a valuable option in the third- or fourth-line setting, offering survival benefit over placebo with a manageable toxicity profile. "We use it after progression on earlier lines of therapy, and in many ways, it's better tolerated than other agents in this space," he noted, highlighting the standard 5 mg dosing schedule taken three weeks on and one week off.

Neha Chawla, MD., of AtlantiCare further emphasized appropriate patient selection, particularly the need for measurable disease and prior use of EGFR and other targeted agents. Her team closely monitors for common toxicities associated with VEGF inhibitors, including hypertension, GI side effects, hand-foot syndrome, and cytopenias. "It's relatively new, but in the right setting, it's a good option," she said.

Nicole Bentivegna, PharmD, BCOP, FCS Clinical Pharmacy Services Manager, shared that pharmacists play a key role early in the workflow by confirming the patient's diagnosis and therapeutic history. "We follow the providers' notes to confirm the clinical context—looking for documentation of the required prior therapies, ECOG status, and any

Fruquintinib (Fruzaqla®) for Metastatic Colorectal Cancer - continued

pathology or biomarker data that support appropriate use," she said. This eligibility check is not only essential for aligning with NCCN Guidelines® but also for ensuring payer authorization.

David Borrone, RPh, AtlantiCare Oral Oncology Specialty Pharmacist, echoed the importance of this front-end review, noting that "it's a matter of reviewing the patient's chart to make sure they have completed all the prior therapies that are required for prior authorization approval, and to make sure that we are within guidelines."

ELEVATING PATIENT CARE THROUGH MEDICALLY INTEGRATED PHARMACY (MIP)

ONCE a treatment decision is made, the multidisciplinary team, including pharmacists, providers, nurses, and technicians, works in sync to support the patient journey. The availability of a medically integrated pharmacy (MIP) model within oncology clinics has meaningfully elevated the standard of care by improving medication access, enhancing toxicity monitoring, and streamlining care coordination. Having pharmacy services embedded in the clinic setting has proven especially valuable with oral oncolytics like fruquintinib, where close monitoring, timely education, and proactive communication are essential. Bentivegna explained that "we can follow patients more closely, intervene faster, and create individualized care goals that traditional specialty pharmacies may not offer." She added that the pharmacy team can reach out to providers directly if issues arise and provides 24/7 pharmacist access to patients for urgent questions or side effect concerns.

Dr. Chawla emphasized how the collaborative structure strengthens both access and continuity of care. "We involve our pharmacists right from the start, introducing them to the patient, walking through drug education and consent, and reviewing toxicities. Then they follow up after the drug is received, reinforce education, monitor for side effects, and run drug interaction checks.". She also highlighted the pharmacy's role in helping patients access high-cost medications. "Before we had medically integrated dispensing, many patients couldn't receive prescribed medications due to cost. Now our pharmacy staff helps with insurance coordination and access programs to ensure the patient actually gets the drug."

From a nursing perspective, Rosa Speirs, BSN, RN, OCN, described the MIP team as essential across the entire care continuum. "It takes a village to get

BENEFITS OF MEDICALLY INTEGRATED PHARMACY IN DISPENSING FRUQUINTINIB

01	Faster access
02	Closer follow-up for side effect management
03	24/7 care team support
04	Insurance coordination and copay assistance
05	Personalized care goals and toxicity monitoring
06	Drug interaction checks and proactive education

Elevating Patient Care Through Medically Integrated Pharmacy (MIP) - continued

patients through this difficult journey, whether they're headed toward survivorship or end-of-life care. Every discipline in our department works together to make the process as seamless and supportive as possible." Specialty Pharmacy Technician Kristen Shockey, CPhT sees the consistency and communication made possible by MIP as game-changing. "It helps with accuracy in patient care plans and ensures everyone is on the same page, from the office to the home. Sometimes patients forget to mention things during appointments, but they will bring it up when talking to me on the phone. That closes the loop on care."

MULTIDISCIPLINARY TEAM HIGHLIGHTS

PHYSICIAN

Leads clinical decision-making

Leads diagnosis, treatment decisions, and monitoring

PHARMACIST

Ensures safe, effective medication use

Educates patients, verifies therapy, supports access, manages AEs

NURSE

Patient education and follow-up care

Coordinates care, educates patients, tracks adherence

PHARMACY TECHNICIAN

Access, affordability, and documentation

Supports workflow, refills, patient check-ins

DOSING AND DRUG INTERACTION MANAGEMENT

ONCE eligibility is confirmed, the next step in initiating fruquintinib involves accurate dosing and a thorough review of the patient's current medications. As outlined in the PQI, the standard starting dose for fruquintinib is 5 mg taken orally once daily for 21 consecutive days, followed by 7 days off in a 28-day cycle. Providers determine the appropriate starting dose, taking into consideration any hepatic impairment. While no adjustment is needed for mild hepatic impairment, the medication is not recommended in cases of severe impairment due to limited safety data.

Dr. Zafar noted that by the time patients are prescribed fruquintinib, they are often experienced with oral therapies and familiar with treatment cycles. "It is not very difficult to lay out the plan for the patient. They take it once a day for 21 days each month, and we mark the start of the cycle so they can easily keep track. Typically, we will see them monthly in the beginning." Before dispensing fruquintinib, the care team conducts a thorough review of the patient's current medications to identify any potential drug interactions. Pharmacists complete a comprehensive medication reconciliation with a focus on interactions involving CYP3A4 and enzymes such as CYP1A2, CYP2C19, CYP2C8, and CYP2C9. Pharmacy technicians assist by flagging high-risk interactions and alerting the pharmacist for further assessment.

Shockey described her process using Lexi-Drug during patient calls. "I enter everything the patient tells me, including supplements and over-the-counter medications, and the system flags interactions as minor, moderate, or severe. If anything comes up at all, even if it's not marked severe, I let the pharmacist know right away." Bentivegna emphasized how MIP streamlines this process by giving the pharmacy team access to the patient's medical record. "One of the biggest advantages is being able to proactively screen the patient's medication list in the EMR when the new order comes in. If we see something that might interact, we can message the provider right away and suggest an intervention." She also noted that the pharmacy continues monitoring throughout the treatment journey. "Sometimes the interaction surfaces during our initial counseling, or the patient may call during a refill or after starting a new medication. No matter when it comes up, we are always evaluating for potential issues."

PRESCRIPTION REVIEW AND DISPENSING

FOLLOWING dosage determination and interaction checks, the care team transitions to prescription review and dispensing. The PQI outlines that providers should electronically prescribe fruquintinib with the correct dose, cycle, and any necessary modifications. Pharmacists are then responsible for validating the prescription against clinical standards, confirming alignment with the treatment plan and ensuring that all documentation is complete. Bentivegna explained how this step fits into their standardized pharmacy workflow. "The pharmacist reviews the prescription based on the chart, guidelines, and package insert to ensure everything is appropriate," she said. "Every month, we do a dispense assessment to see if a dose adjustment might be needed. We triage accordingly. It's something we look at closely each cycle."

Pharmacy technicians also play an important role in dispensing. Shockey ensures the medication is dispensed in its original stock bottle, with all auxiliary labels applied. "We include a patient information sheet, which helps patients remember the key points including taking it at the same time daily, with or without food, and the importance of monitoring blood pressure." FCS Specialty Pharmacy Nursing Manager Jessica Caraway, RN added further detail about the layered structure of support her team provides. "We follow standardized protocols that begin with initial counseling and welcome kits. With each fill, we complete clinical assessments that include dose verification, medication reconciliation, patient education, and routine monitoring. Any adverse events are documented, and if concerns are identified, we reach out to the provider and the office directly to ensure those concerns are addressed on all fronts."

LAB MONITORING AND FOLLOW-UP SCHEDULING

LAB monitoring and follow-up scheduling allow the team to stay one step ahead, proactively identifying toxicities, adjusting therapy if needed, and keeping the patient safe and supported throughout their treatment journey. In the AtlantiCare clinic, patients are brought in for lab checks as early as one to two weeks after starting fruquintinib. Weekly labs are ordered initially to monitor white blood cell counts, liver function, and other metabolic indicators. As stability is established, the team often extends those lab intervals while maintaining consistent contact. "A regular assessment and schedule is really important while they're on this medication," M.J. Redmond, APN shared.

Dr. Chawla also sees the value of this proactive structure. After the first two-week follow-up, patients are typically seen monthly, then every two to three months depending on tolerance and disease course. Imaging is scheduled around the two-month mark to evaluate therapeutic response, allowing adjustments if the drug is not having the desired effect.

Pharmacists play a key role in reinforcing adherence and early intervention. The AtlantiCare pharmacy team conducts a two-week follow-up call after treatment begins to confirm the patient is taking fruquintinib correctly, to screen for any adverse reactions, and to update the medication list. With every refill, they contact the patient to check for new medications, supplements, or ER visits, and they document any findings in the system.

At FCS, patient management programs contain built in, structured touchpoints, typically a seven-day post-start check-in and monthly dispense assessments. During these, pharmacists and nurses review lab values and vitals in the EMR, ask about side effects, and collaborate on next steps. If any red flags are identified, the pharmacy team connects with the provider to discuss dose adjustments or supportive measures.

ADVERSE EVENT MANAGEMENT AND ESCALATION

TOXICITY management is a key element of fruquintinib therapy and a defining strength of the MIP model. Fruquintinib, like other VEGF-targeted therapies, is associated with a known set of class-effect toxicities. Dr. Zafar noted that most oncologists are familiar with these risks, especially in metastatic colorectal cancer, where patients have often received previous VEGF inhibitors. Still, early and ongoing monitoring remains essential, particularly for hypertension, hand-foot syndrome, gastrointestinal issues, and lab abnormalities such as elevated liver enzymes.

Dr. Chawla described her team's approach to preparing patients, which includes blood pressure monitors, skincare kits, and treatment calendars to reinforce dosing schedules. "We are setting the patient up for success. We bring them back about two weeks after starting treatment to assess tolerability and adjust if needed."

Pharmacists are central to toxicity education and follow-up. They reinforce what to expect, when to report symptoms, and how to manage common side effects. During follow-up calls, pharmacists assess patient-reported issues and labs and recommend interventions or dose adjustments to providers when appropriate. Technicians support the process by tracking and documenting symptoms, ensuring continuity and visibility across the care team.

Caraway highlighted the importance of symptom tracking tools. "We encourage patients to use symptom logs and report any new or worsening side effects during follow-up calls. We assess symptoms, adjust strategies, and collaborate with the oncologist and pharmacist to recommend changes or supportive interventions." The following sections highlight common adverse events associated with fruquintinib and outline effective strategies for monitoring and management.

HYPERTENSION MANAGEMENT

Hypertension is a commonly observed adverse event associated with fruquintinib and other VEGF inhibitors. While often manageable, early detection and intervention are critical to avoid treatment interruptions or dose reductions. From the outset, the care team prioritizes patient education and preparation. At AtlantiCare, patients are proactively equipped with tools to support hypertension monitoring, including a blood pressure cuff and a logbook to track daily readings. "We check to see if the patient has a blood pressure monitor at home. If they don't, we provide one, along with a logbook," said Borrone. Redmond added, "Patients are asked to record their blood pressure, and if hypertension develops, we often start a low-dose antihypertensive. If side effects become concerning, we consider dose reduction." Patients are encouraged to bring their logs to follow-up visits, where trends can be reviewed and therapy adjusted as needed.

Consistent communication with both oncology and primary care providers is emphasized. Speirs spoke of the benefit of involving primary care. "It's a team effort." Patients are advised to inform their primary care physician that they have started fruquintinib, in case elevated blood pressure is observed during unrelated visits. Dr. Chawla reinforced the importance of follow-through. "If the patient's blood pressure is elevated, we take the necessary steps to adjust medications. Consistent communication and re-education are key," she said. This includes educating patients on what to monitor, how often to log, and when to contact their care team.

HAND-FOOT SYNDROME (HFS) MANAGEMENT

Hand-foot syndrome (HFS), or palmar-plantar erythrodysesthesia, is a dermatologic toxicity associated with fruquintinib that can significantly impact patient comfort and adherence if not proactively managed. Education and prevention start before treatment begins. Redmond shared that patients are thoroughly counseled on skin care basics, saying, "Patients are very well educated on taking care of their skin, making sure they're provided with lotions, and understanding the importance of monitoring for any changes."

The AtlantiCare MIP provides patients with large jars of emollient cream, such as Udderly Smooth®, at no charge. "Daily application to the palms and soles has helped us either prevent or significantly minimize HFS," Borrone said. Patients are encouraged to request more cream as needed to maintain continuous protection. Caraway described the comprehensive education her team provides to patients on prevention and symptom management. "We teach patients to exfoliate gently, keep hands and feet moisturized, avoid hot showers or excessive heat, and minimize pressure on sensitive areas by wearing comfortable shoes and avoiding tight socks," she explained. Throughout therapy, nurses, pharmacists, and technicians maintain close communication with patients to identify early signs of HFS. Adjustments to therapy, supportive measures such as topical steroids, and additional educa-

Adverse Event Management and Escalation - continued

tion are implemented promptly when symptoms develop.

Photosensitivity can increase the risk of skin reactions with sun exposure. According to Borrone, AtlantiCare uses innovative strategies such as providing patients with wristbands that change color in UV light, offering a visual reminder of sun intensity. “When they see the band turn bright purple, it’s a signal to seek shade,” he explained. Patients are counseled on minimizing midday sun, wearing protective clothing, and using sunscreen consistently. Caraway reinforced the need to adjust outdoor activities to avoid extended periods in direct sunlight, especially during peak hours. For patients engaging in outdoor chores or hobbies, education includes recommendations to wear gloves when gardening or working outside to reduce friction on hands—which can simultaneously help prevent hand-foot syndrome and protect against sunburn.

OTHER POTENTIAL ADVERSE EVENTS

LFT elevations are uncommon but important to monitor closely during the early cycles of therapy. Liver enzyme elevations typically occur during the first or second cycle if they appear at all according to Dr. Zafar. “We just follow protocol. If LFTs trigger a dose reduction or hold, we make those adjustments early, and it’s unusual to see problems after that,” he explained. Regular lab checks ensure early detection and intervention.

Fatigue is another side effect that, if not addressed, can significantly impact daily living. Borrone educates patients on recognizing fatigue not as simple drowsiness, but as a need to rest and recharge: “When fatigue sets in, it’s important to listen to your body rather than pushing through, take 15 to 20 minutes to relax, and try to schedule important activities earlier in the day.”

PATIENT EDUCATION AND COUNSELING

Pharmacists, nurses, and providers collaborate to ensure patients fully understand their fruqintinib treatment plan, including the 21-day on/7-day off dosing cycle, administration instructions, such as swallowing tablets whole with or without food, and how to recognize and report side effects. Patients receive clear guidance on what to do if they miss a dose, taking it if less than 12 hours late but avoiding doubling up, and are advised not to retake a dose if vomiting occurs.

Initial counseling sessions provide a comprehensive review of dosing, administration, side effects, storage, and when to seek medical help. Bentivegna shared, “All of our patients receive initial counseling with a pharmacist covering the medication details, and they get kits with handouts and supportive care items to help prevent side effects.” Caraway added the FCS team provides both written education materials and frequent verbal counseling, including follow-up calls to reinforce key points, ensure understanding, and check for side effects. “Our nursing team focuses on helping patients recognize symptoms early and feel confident managing their treatment,” she explained.

Patients are given one of NCODA’s Patient Education Sheets. This sheet details fruquintinib’s purpose, dosing schedule, potential side effects, and important safety tips. Counseling also includes advice on avoiding significant drug interactions by notifying the care team of any new medications, over-the-counter products, or supplements, as well as counseling on reproductive risks and the need for effective contraception for patients of child-bearing potential. Borrone says his role often includes translating clinical rationales into patient-friendly language to improve adherence. For example, rather than using technical terminology like "VEGF inhibitor," he tells the patient that the medication “blocks a protein that helps cancer cells grow and spread.” He uses this strategy to help patients understand why they are taking the drug and to encourage compliance.

A key tool highlighted by clinicians is the use of treatment calendars to support adherence. Redmond emphasized, “A calendar is really key because they can see and monitor their dosage and check it off... patients find it very helpful to

Sustainability and Future Expansion - continued

stay on track." Borrone noted the benefit of starting treatment cycles on a Monday, simplifying tracking and minimizing confusion about restart dates. Dr. Chawla added that pharmacists or nurses often print and highlight calendars for patients, especially elderly individuals or those using pill boxes, to clearly indicate dosing days and scheduled breaks. These calendars help patients confidently manage their cycles, avoid missed or early doses, and ensure they remain engaged in their treatment.

NCODA TREATMENT SUPPORT KITS: SUPPORTING PATIENTS AND CLINICS

Beyond improving adherence, NCODA's Treatment Support Kits (TSKs) play a vital role in elevating cancer care. By providing clear, accessible education and practical tools for managing side effects, TSKs help patients feel more confident and supported, leading to higher satisfaction and better outcomes. Kits empower providers as well by streamlining counseling, saving time during clinic visits, and fostering focused discussions about adverse event management, allowing care teams to offer personalized, efficient support.

Specifically for fruquintinib, the NCODA TSK includes **a treatment booklet with a Patient Education sheet, a treatment calendar, a daily pill container, and a water bottle**, all provided complimentary for NCODA member practices. Borrone emphasized the real-world impact of these kits: "We give the fruquintinib support kits to our patients. They include the water bottle, pill box, medication information sheet, and an 11-month dosing calendar. Patients can document their start date and track cycles to stay on schedule."

CONCLUSION

THE Fruquintinib (Fruzaqla®) PQI highlights how a cohesive, patient-centered approach enhances care quality, optimizes treatment adherence, and empowers the entire oncology team. Pharmacists, nurses, technicians, and providers each play a vital role, working together to ensure that patients feel supported and confident throughout their therapy.

The structured format of the PQI was universally praised by participants. Borrone felt that its clear breakdown of responsibilities fosters accountability: "Anytime you have it broken down like this, it gives opportunities for improvement. You can see what your responsibility is or confirm what others are doing." Speirs appreciated that the PQI is "detailed and concise without overwhelming the reader," making it approachable for all team members.

Bentivegna described the PQI as an excellent step-by-step guide for pharmacists, ensuring no critical aspect of prescribing, counseling, or monitoring is overlooked. Caraway emphasized its value for nurses and pharmacy staff as a shared reference to streamline patient counseling, enhance communication, and maintain high-quality care. Shockey found the PQI perfectly aligned with technician workflows, especially when coordinating remotely with pharmacists and providers: "It shows a cohesive look at what it looks like to work as a team, even if you're not in the same location."

The PQI not only improves internal processes but also directly benefits patients by standardizing practices around dosing, adverse event management, and education. With tools like treatment calendars, NCODA Treatment Support Kits, and a dedicated multidisciplinary team, patients are better equipped to navigate their therapy confidently.

Ultimately, this PQI exemplifies how a well-structured, collaborative model—rooted in clear communication, proactive monitoring, and comprehensive education—can elevate patient-centered care and support positive outcomes for those receiving fruquintinib.

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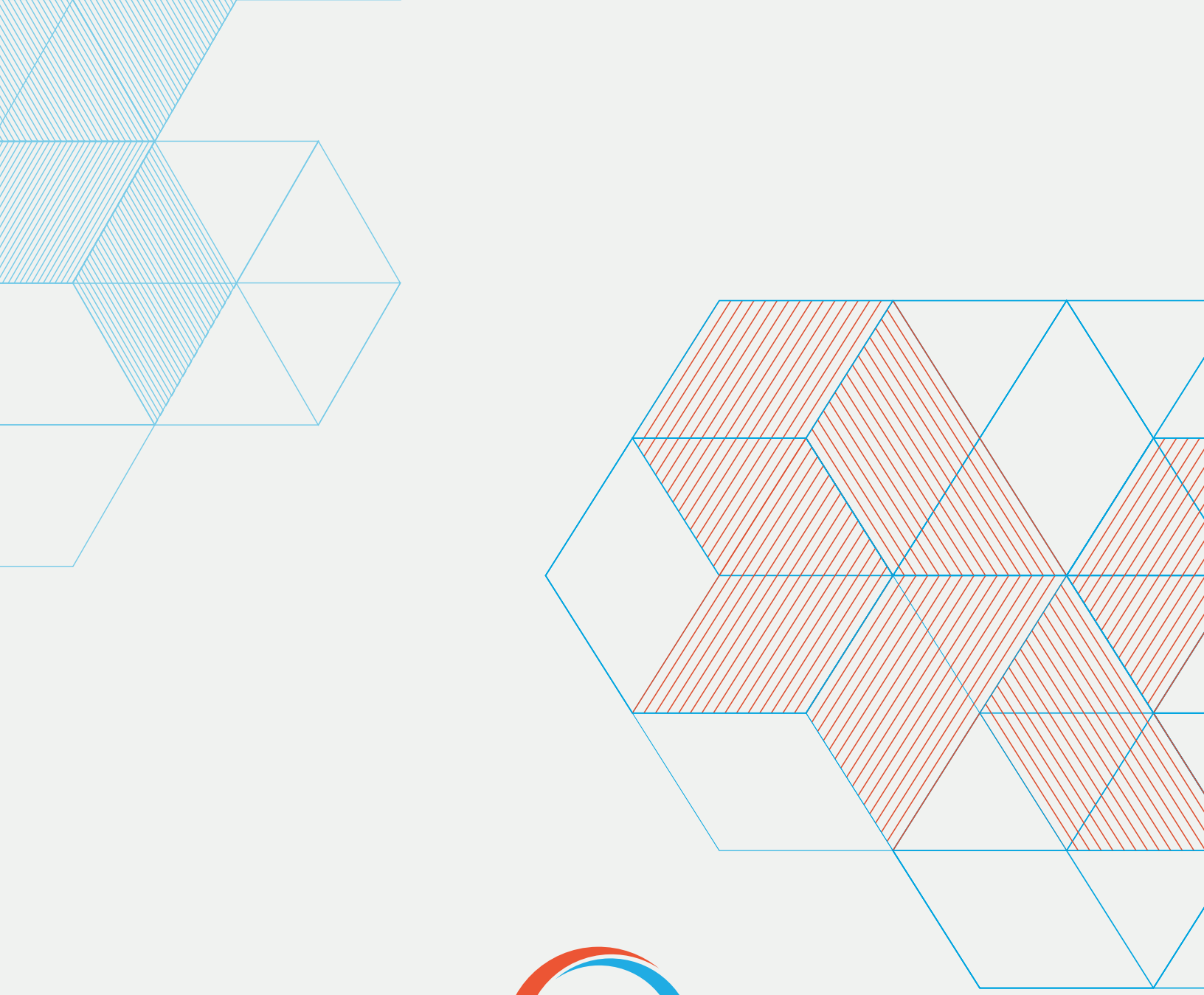

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.