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# PQI IN ACTION



**CLONOSEQ® NEXT GENERATION  
SEQUENCING FOR MINIMAL RESIDUAL  
DISEASE TESTING IN MULTIPLE MYELOMA**



**NCODA'S POSITIVE QUALITY  
INTERVENTION IN ACTION**

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# INTRODUCTION

In an effort to promote higher quality patient care, NCODA created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients. This article will explore the PQI in patients who are monitored with minimal residual disease (MRD) testing. This PQI in Action is a follow up to the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** and explores how the medically integrated teams at Florida Cancer Specialists & Research Institute (FCS) and Rocky Mountain Cancer Centers incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** elevates patient care.

FCS is the largest independent medical oncology/hematology practice in the United States. With over 100 locations, FCS serves patients throughout the state of Florida with the intention of bringing world-class cancer care closer to home. FCS's medical team is substantial, comprising almost 500 healthcare providers, including physicians, advanced practice providers, and physician assistants who bring their expertise from prestigious universities and research institutions across the country. The institute's national reputation for excellence stems from its personalized treatment plans, innovative clinical research, and cutting edge technologies. FCS's state-of-the-art clinical labs are equipped with the most advanced technologies, including the ability to perform flow cytometry and next generation sequencing (NGS).

Rocky Mountain Cancer Centers (RMCC) is an independent, physician-owned, multidisciplinary practice with 19 community-based clinic sites across the state of Colorado. They offer patient-centered, state-of-the-art treatments closer to home. RMCC is part of The US Oncology Network, a network of physicians that form a community of shared expertise and resources dedicated to advancing cancer care and improving outcomes. RMCC also participates in clinical trials through the Sarah Cannon Research Institute, offering patients access to cutting edge treatments in a community-based setting. RMCC offers fully accredited laboratory services at many of their locations, including state-of-the-art, in-house flow cytometry technology to ensure maximum accuracy and rapid turnaround time.

## THE PARTICIPANTS

### **Florida Cancer Specialists & Research Institute (FCS)** **Fort Myers, FL**



**Maen Hussein, MD**

*Medical Oncologist & Hematologist*



**Austin Cox, PharmD**

*Senior Director of Trade Relations*



**Carlos Perez**

*Lab Technician*



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**James Mann, BS, MLS (ASCP)**

*Area Laboratory Manager*



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*Clinical Lab Coordinator of Quality  
Compliance and Training*



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# THE MEDICALLY INTEGRATED TEAM, THE PQI, AND CLONOSEQ: NEW TECHNOLOGIES TO DETECT DEEPER RESPONSES

The treatment of multiple myeloma (MM) has changed drastically in the last decade with the introduction of new therapies and combinations, which has led to significant survival improvements. These improvements have included deeper and more sustained responses, with nearly all patients achieving some sort of treatment response and more than half achieving a complete response.<sup>1</sup>

Various methods have been developed to detect these responses. In 2006, stringent complete response (sCR) criteria were introduced. This criteria used normalization of the kappa and lambda serum free light chain (sFLC) ratio and absence of clonal plasma cells in bone marrow by immunohistochemistry (IHC) or immunofluorescence to detect response.<sup>2</sup> However, multiple myeloma is still considered an incurable disease and most patients will eventually relapse.<sup>1</sup> It's become evident that new methods with greater specificity are needed to detect minimal residual disease (MRD) in patients experiencing these deeper responses.<sup>3</sup>

Robert Rifkin, MD, FACP, Medical Oncologist/Hematologist and RMCC Central Laboratory Medical Director muses on the history of monitoring treatment response in MM and how it has evolved. "Over time in myeloma, the bar has been consistently raised. Many years ago, if you got rid of 75% of the plasma cells in Southwest Oncology Group (SWOG), that was considered a complete response. And now, as you all know, we have even a complete response. It's MRD negative at  $10^{-5}$  or  $10^{-6}$ ."

MRD refers to the number of cancer cells that are still present during and after treatment.<sup>4</sup> MRD negativity correlates with improved progression-free survival and overall survival (OS).<sup>5</sup> In 2016, the International Myeloma Working Group (IMWG) established new criteria for defining MM disease response, including MRD assessment.<sup>3</sup> New techniques intended to detect deeper responses include flow cytometry (including multiparametric flow cytometry and next-generation flow cytometry), allele-specific, oligonucleotide-dependent, real-time quantitative PCR (ASO-PCR), and next-generation sequencing (NGS).<sup>1</sup> Each has their own advantages and disadvantages. NGS or next-generation flow are recommended by the IMWG and NCCN guidelines due to their ability to detect one multiple myeloma cell in  $10^5$  or  $10^6$  cells (with  $10^5$

being the minimum sensitivity).<sup>3,6</sup> Outside of clinical trials, the decision to use MRD testing is dependent on the physician, practice, and patient scenario.<sup>7</sup> Widespread adoption of MRD testing depends on the availability of reliable and accurate assays.<sup>4</sup> clonoSEQ is the only FDA-cleared test to detect MRD in patients with multiple myeloma.<sup>8</sup> It is an NGS-based assay that measures MRD in the bone marrow and the blood. It is a two-part test that requires an initial (or "ID") sample to identify a unique disease-associated sequence arrangement (clonotype) that can later be used to track the presence and frequency of these clonotypes in follow-up samples in order to detect the presence or absence of MRD.<sup>4</sup>

Megan Blakely, MLS (ASCP), Clinical Lab Coordinator of Quality Compliance and Training at RMCC briefly explains the MRD testing process. She says, "clonoSEQ uses MRD testing to look for that specific gene sequence that they identify in that first specimen, that high disease-burden specimen. And then they can use that to track the patient's response to treatments. It can go down to one cell in a million. We can see those results quicker than we can in some of the traditional testing in myeloma patients, where we would be using things like immunoglobulins, free light chains. MRD testing can see that one cell faster than we can see a change in something like an immunoglobulin or an SPEP."

The clonoSEQ assay can be managed by the Medically Integrated Team, and thus offers patients more comprehensive care. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.<sup>9</sup> This model has historically included medications, but can be extended to relevant lab testing. The MID model can improve management of patients being monitored with the clonoSEQ assay in several ways including improved communication issues, managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste.<sup>10</sup>

Denise Hart, Southern Colorado Laboratory Supervisor at RMCC expands on how both patients and staff benefit from

collaboration between team members for coordination of care and testing services. In terms of staff benefits, she says, “I think that whenever various disciplines work in collaboration with one another, it creates a better environment for everyone involved. If it’s done well, I’ve seen that it helps to reduce stress, increase efficiencies, and therefore, fewer errors.” Regarding patient benefits, she says, “it promotes good teamwork, good communication, and that across the board helps to be able to

deliver the best patient care.”

NCODA offers multiple tools to aid the medically integrated practice in managing MRD testing. This toolbox contains a Patient Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance database, Treatment Support Kits, and of course the Positive Quality Intervention clinical resource.

## THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

**B**lakely comments on the value of the PQI. “We know healthcare is driving in the fast lane. We’re always busy. I think having the clonoSEQ PQI has the capacity to help you follow best recommended practices in making everyone more successful in getting patients those answers.”

[CLICK HERE  
TO VIEW PQI](#)

Maen Hussein, MD, Medical Oncologist & Hematologist at FCS agrees that the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** is a useful resource for both providers and patients. He says, “it is a good summary of the test, where to use it and how to use it. It is precise and concise instead of a monograph that is pages and pages. It takes you five minutes to read, and you understand it. I use this sometimes just to explain to the patient certain things, like the sampling information. I do explain to the patient how they do it, for example they have to get a signature of the clone, and then they look for it in the blood. I feel that is the important part to understand.”

This article will explore the benefits of PQI utilization as a core standard of the Medically Integrated Team and how adoption can benefit any practice. FCS and Rocky Mountain Cancer

Centers have each found successful ways to incorporate the PQI clinical resource. These practices position their Medically Integrated Teams in a way to ensure appropriate treatment, increased tolerability, and optimized clinical outcomes. We will explore their practice settings, how implementing the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** benefits their staff and patients, and how they advance patient care on a daily basis.

“WE KNOW HEALTHCARE IS DRIVING IN THE FAST LANE. WE’RE ALWAYS BUSY. SO I THINK HAVING THE CLONOSEQ PQI HAS THE CAPACITY TO HELP YOU FOLLOW BEST RECOMMENDED PRACTICES IN MAKING EVERYONE MORE SUCCESSFUL IN GETTING PATIENTS THOSE ANSWERS.”

Megan Blakely, MLS (ASCP)

## THE MEDICALLY INTEGRATED TEAM: ELEVATING CARE

**A**s cancer treatment continually grows in complexity containing IV, oral, combination regimens, and now biomarker testing, the Medically Integrated Team continues to offer an invaluable option for patient care. The Medically Integrated Team and multidisciplinary staff has unparalleled access to patient information and

means of direct communication with other members of the team. This model greatly reduces fragmentation of care.

Austin Cox, PharmD, Senior Director of Trade Relations at FCS notes that offering NGS in-house is a unique benefit of interdisciplinary collaboration at FCS. “I think it takes a village when it comes to cancer care. And really, the ultimate goal is

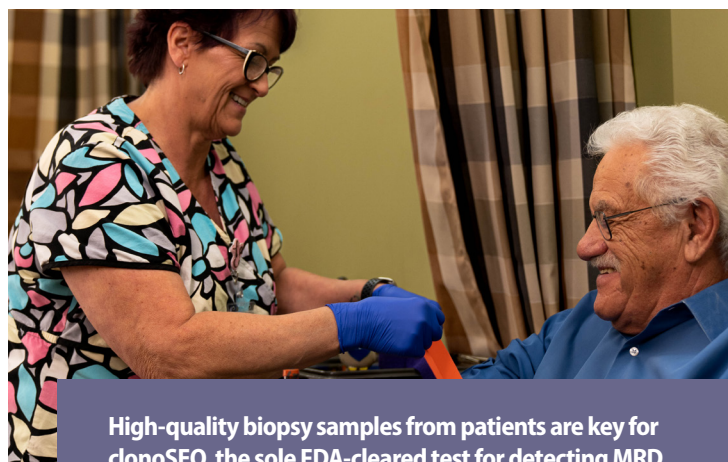
all of these teams pulling together in the same direction to ultimately reduce turnaround time. It takes from not only getting test results that could determine a treatment choice and really shortening the curve, to where we can actually get the patients on the most appropriate therapy the soonest that we possibly can.” Regarding turnaround time, he goes on to say, “we were at about two weeks of receiving a mutational test by outsourcing it. And we’ve reduced that to less than a week now. We are really encouraged by the progress we have made.”

**“I THINK IT TAKES A VILLAGE WHEN IT COMES TO CANCER CARE. AND REALLY, THE ULTIMATE GOAL IS ALL OF THESE TEAMS PULLING TOGETHER IN THE SAME DIRECTION TO ULTIMATELY REDUCE TURN-AROUND TIME. IT TAKES FROM NOT ONLY GETTING TEST RESULTS THAT COULD DETERMINE A TREATMENT CHOICE AND REALLY SHORTENING THE CURVE, TO WHERE WE CAN ACTUALLY GET THE PATIENTS ON THE MOST APPROPRIATE THERAPY THE SOONEST THAT WE POSSIBLY CAN.”**

Austin Cox, PharmD

He goes on to explain the role of pharmacy as one of the initial steps in streamlining the MRD testing process. “It takes the pharmacy team really building out that vision from the EMR work flow perspective to make these tests readily available for our physicians. Making it top of mind for our physicians that have that resource at their fingertips. Then they will order the test and then push that to our lab. And then they streamline the process because kind of we’re all connected, and we can all communicate in a time loop.”

Hart emphasizes the importance of building order sets to assist with ease of ordering MRD tests. “Multiple systems, manual workflows. Those are all very hard to manage. So having order sets is an easy order entry option for providers that helps them in decision making. Lab integration ensures that the flow of orders and results is seamless across systems. I would say order sets, optimized workflows, and lab integration helps providers spend less time on administrative tasks and helps to ensure that



**High-quality biopsy samples from patients are key for clonoSEQ, the sole FDA-cleared test for detecting MRD in multiple myeloma patients.**

they follow best practice.”

James Mann, Area Laboratory Manager at RMCC mentions communication as one of the most important factors for ensuring a timely and successful MRD test. “When physicians know they are going to want the test, we want them to come in and communicate with the lab. Because we really won’t know about it until it’s basically dropped in our lap. We can actually do the legwork. I would rather have the lab do the legwork for the ordering and processing and timely shipping out of the sample than putting it on the clinician, because they have so much more to do.” He also mentions that RMCC has laboratory technicians assist with the bone marrow aspiration procedure to further decrease turn around time. “We are in there with the doctor, we help. The lab tech is right there with them, so they know ahead of time. They know what to prepare. They know how to get it out for testing.”

Blakely agrees that communication with the providers is key to decreasing turn around time for MRD test results. She says, “we utilize a messaging system in our EMR. It really helps us communicate with that team. We’re often not always in the same building as them, so we can’t always walk down the hall and chat with them. That has made us really successful.”

One goal of integration is to make the MRD ordering process so easy that providers do not even have to think about it. Dr. Hussein notes, “It feels like a smooth process. Honestly, it’s one of the things I don’t worry about.” But he acknowledges the work it takes to get there. “There is an army that works behind the scenes to make this happen, and I appreciate that.”

Another important aspect of streamlining the MRD ordering process is ensuring that everyone is fully educated on what the clonoSEQ assay is and how it gets ordered. Both FCS and RMCC have methods for educating their staff. Dr. Rifkin says, “the best part about using this is educating all of the stake-

holders. And that is why, when we bring a new drug or a new test, we try to do an in-service, even if it's the scheduler or back office person or front office person. So when they see an order for clonoSEQ, they know what it is and what to do with it. There is nothing worse than walking up to someone and saying, 'I need the clonoSEQ,' and they say, 'What's that? Never heard of it.' So really our goal is to minimize that kind of confusion. We do it through a lot of education."

At RMCC, education can also happen at monthly provider

meetings. Hart notes, "I think that the information provided on the clonoSEQ or Adaptive Biotech website is very easy to navigate, easy to read. And I think just getting that information out, and that education out to providers and clinics is really important. So we utilize this test option more often."

At FCS, they use their formulary navigator in addition to internal provider communications. The formulary navigator is a clinical support tool that provides guidance for MRD testing with initial diagnosis and routine monitoring thereafter.

## PUTTING THE CLONOSEQ® NEXT GENERATION SEQUENCING FOR MINIMAL RESIDUAL DISEASE TESTING IN MULTIPLE MYELOMA PQI INTO ACTION

**T**he PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The Medically Integrated Team is in a unique position to ensure appropriate treatment, improve tolerability, and maximize clinical outcomes. Positive Quality Interventions (PQIs), an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes. The **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** is written in sections, beginning with a Description and ending with Patient-Centered Activities and References.

Following the Description, the Background section gives pertinent historical data and information, clinical trial experience, and the main focus of the intervention. Regarding clonoSEQ, the Background discusses guideline recommendations, literature, and FDA approvals supporting the use of MRD testing in MM.

Both FCS and RMCC find that MRD's greatest utility is during the maintenance phase of treatment. Cox says, "Providers are using it mainly in that maintenance space where maybe they want to give that patient a break, or maybe the patient wants a break. They have been on therapy a long time. It's really nice to have that peace of mind and say, 'Okay, you are MRD negative and I feel comfortable and confident about giving you a break in this therapy. So I think that is where it has the strongest foothold within our practice today.'"

Dr. Rifkin agrees. "The most important thing in myeloma is to get the deepest response possible out of the starting gate. If you can show where clonoSEQ is useful at getting to that MRD

negative state, that is where it makes an impact. Maybe then I can back off therapy and come up with an easier maintenance program. People really don't want bone marrow transplants or stem cell transplants if they can avoid it. I think it's really going to help in designing the best maintenance regimen, because myeloma is by and large a continuous therapy disease. And that is difficult to explain to patients. But if you can make their maintenance, or whatever deepest response therapy, safe, effective, and non-toxic, that's important."

**"IF YOU CAN SHOW WHERE CLONOSEQ IS USEFUL AT GETTING TO THAT MRD NEGATIVE STATE, THAT IS WHERE IT MAKES AN IMPACT. MAYBE THEN I CAN BACK OFF THERAPY AND COME UP WITH AN EASIER MAINTENANCE PROGRAM. PEOPLE REALLY DON'T WANT BONE MARROW TRANSPLANTS OR STEM CELL TRANSPLANTS IF THEY CAN AVOID IT. I THINK IT'S REALLY GOING TO HELP IN DESIGNING THE BEST MAINTENANCE REGIMEN, BECAUSE MYELOMA IS BY AND LARGE A CONTINUOUS THERAPY DISEASE."**

Robert Rifkin, MD

# THE PQI PROCESS: A TEAM EFFORT

The next section of the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** is the PQI Process. This section lays out the intervention in step by step points, contains clinician directed guidance, and critical clinical criteria that can benefit the entire team.

The first step of the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** mentions the need for a clonality ID sample in order to identify a patient's unique myeloma rearrangement.

Blakely explains that “You want to be able to get that ID off a high burden specimen. So usually, that is when the patients are first getting diagnosed, or if they have a relapse.”

Carlos Perez, Lab Technician at FCS mentions that all acceptable specimens now automatically get sent for an ID at their lab. He says, “any bone marrow biopsy that gets to our lab in Fort Myers, they are reflexing to IDs for acceptable specimens. Obviously, if they do a bone marrow biopsy and there is nothing, they're not going to send for ID.”

The next step details best practices for obtaining a clonality ID and what to do if the clonality ID was not collected on the initial bone marrow aspirate or smear slide that was used to determine initial MM diagnosis.

Hart says, “most patients are going to have a bone marrow biopsy done at the time of diagnosis, and those are the primary specimens we send. The medical assistants that assist with the bone marrow biopsies, if they are performed in our facility, are responsible for making sure that samples are placed in the correct preservative, labeled appropriately, and the order requisition is complete. If they are not done in our facility, the medical assistant team is responsible for recovering that archive specimen, and they have a procedure they follow. That is definitely important in reducing that lengthy turnaround time for patients, so that providers can make personalized treatment decisions for the patient and get the ball rolling quicker.”

Perez mentions another way to streamline the MRD testing process. “If a patient had a bone marrow biopsy years ago, they'll put in the ID and MRD order together and we will go through that process of ordering through the Adaptive portal. The path report, the one that they were diagnosed off of that showed cancer. So it's just as simple as that. The physician orders it. The patient will come to me after they've seen the physician to get the blood drawn for the MRD. That way we send the MRD in conjunction with the order for the ID.



The expertise and unwavering dedication of lab team members are pivotal in maintaining a seamless workflow for clonoSEQ.

Once the ID is done, we can do the MRD immediately and set up our schedule for MRDs after that.” He also mentions that “The assistance from Adaptive on their side in the portal is awesome. You never have to do much in the way of helping with specimen retrieval. They handle all of it.”

The last step in the PQI process details appropriate timing for follow-up MRD testing to assess treatment response. Cox is a huge advocate for PQIs. He mentions that they are also helpful for assisting with building order sets within the electronic medical record (EMR). “I like how the PQI has the transplant eligible, transplant ineligible patient broken down. And I love the fact of the intervals that the PQI has laid out, that really helps us build that order set as far as prompts and reminders to when we need to retest these patients.”

[CLICK HERE TO VIEW PQI](#)

The PQI also includes a sample order set from the clonoSEQ Next Generation Sequencing for Minimum Residual Disease Testing in Chronic Lymphocytic Leukemia PQI that can be modified for each practice's needs.

Mann feels that the biggest value from team collaboration from a lab perspective is, “a quality outcome, quality visit for the patient. I don't want them to complain. Time is of the essence. Their time is valuable. Let's get them in, get their services done, and get them home and healthy. I also like to bring to light what the lab does, because an analogy I use a lot for my team is, imagine a football team. Doctors, clinicians are the quarter back, running back. The lab is the right guard. Name a right guard on any football team. We're important, but they're not going to know who you are and what you do. So I like to bring to light what the lab does. We all work together.”

## SAMPLE ORDER SETS FOR EMR:

- *clonoSEQ Clonality ID, archived specimen*

>>**Specimen:** Upon request within the clonoSEQ\_ordering portal, Adaptive can assist in retrieving an archived pathology specimen; this should be a high disease burden specimen representative of the patient's malignancy

>>**Action:** If utilizing the pathology retrieval service through Adaptive, place Clonality ID Test order in Adaptive portal, then fax clonoSEQ\_requisition form and a copy of the patient's diagnostic pathology report to Adaptive (866) 623-4408 or email the materials to [clinicalservices@adaptivebiotech.com](mailto:clinicalservices@adaptivebiotech.com)

- *clonoSEQ Clonality ID, fresh bone marrow aspirate*

>>**Specimen:** fresh bone marrow aspirate, 1 mL in an EDTA tube; this should be a high disease burden specimen representative of the patient's malignancy\*

>>**Action:** prepare 1 mL fresh bone marrow aspirate in an EDTA tube

- Patient navigators will place a Clonality ID order via the clonoSEQ\_diagnostic Portal and upload a copy of the requisition to the patient chart
- Medical assistants will include specimen and a printed copy of the clonoSEQ test requisition in Adaptive kit for send out

- *clonoSEQ MRD tracking, fresh bone marrow*

>>**Specimen:** fresh bone marrow aspirate, 1 mL in an EDTA tube

>>**Action:** prepare 1 mL fresh bone marrow aspirate in an EDTA tube

- Patient navigators will place an MRD Tracking order via the clonoSEQ\_Diagnostic portal and upload a copy of the requisition to the patient chart
- Medical assistants will include specimen and a printed copy of the clonoSEQ test requisition in Adaptive kit for send out

- *clonoSEQ MRD tracking, fresh peripheral blood*

>>**Specimen:** fresh peripheral blood, 2 mL in an EDTA tube\*

>>**Action:** Prepare 2 mL fresh peripheral blood in an EDTA tube

- Patient navigators will place an MRD tracking order via the clonoSEQ diagnostic portal and upload a copy of the requisition to the patient chart
- Medical assistants will include specimen and a printed copy of the clonoSEQ test requisition in adaptive kit for send out



Scan the QR code or [click here](#) to learn more about what Maen Hussein, MD from FCS has to say about the benefits of MRD testing and the positive impact it has on patients.



# PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

**T**he clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team.

In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.<sup>11</sup> Standard 1.2 of the ASCO/NCODA Standards reads:

*Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.<sup>11</sup>*

These standards also extend to MRD testing where many of the components of medical integration can assist the patient in better understanding the rationale for MRD testing.

Perez feels that patients are able to easily understand the MRD testing process if the content is explained appropriately. He says, “we like to compare it a lot to your standard cancer markers, but we are detecting it at a much smaller level. We are looking for just the smallest bits in the blood stream. Once you really break it down for them, they understand it pretty easily. I can’t think of anybody that left without understanding.”

Dr. Rifkin mentions that patients are already asking questions about MRD testing. He uses the clonoSEQ reports to discuss MRD testing with patients. He says, “I think the clonoSEQ report is a really good communication tool for the patients and for the referring clinicians, because we have sent flow cytometry to other places where I get a page that comes out. It says it’s X percent of this positive, X percent of that positive, with no interpretation. I mean, we might as well not have done that. That is crazy. So I think the reports here are very helpful, both for clinicians, patients, and even to show the lab the sample they drew.”

Dr. Hussein notes that it’s important to explain MM monitoring as a whole to patients. In terms of MRD testing, he says, “it’s a learning curve. I try to simplify as much as possible to them, that this is looking at the lowest clone possible to see if it’s coming back or not. I do explain that it is a piece of the puzzle. It’s not everything.”

Hart emphasizes that the PQI itself can be utilized as a resource for patient education. “I feel like the patient-centered activities portion is really important for people that are qualified to communicate what MRD testing is to patients. It really provides insight and valuable ways to communicate the testing to the patient. Those questions are posed to us when the patients first arrive, and of course, ultimately the explanation lies on the physician and the nurse. But having this understanding is helpful. I think the document is very clear and concise, and to the point with each of these topics.”

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## FINANCIAL ASSISTANCE: A BENEFIT OF THE MULTIDISCIPLINARY TEAM

**I**n addition to close follow up and detailed education, medical integration of MRD testing renders the practice able to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford MRD testing.

Dr. Hussein says that the seamless integration of MRD testing in their workflow gives him peace of mind that patients

will not have to pay out of pocket for the test. “I feel like the support that the team [Adaptive] provides is amazing. It really makes things easy, especially when it comes to reimbursement. So far, I haven’t had any complaint from patients that they got a bill, or they have to cover it, because I know these tests can be expensive. So I think that definitely gives the peace of mind that I can test the patients that I feel it’s appropriate. That they

need the test when it's indicated and not to worry about the logistics."

Mann mentions that Adaptive's in person training sessions were instrumental in educating the lab staff on the utility of MRD testing. "The MRD testing was relatively new to my staff. Once they started to learn about it and for the biggest part, some of my techs said, 'so someone could get off their treatment regimen a year earlier if they do this testing?' That all fascinated us, and how it could cut down costs, and give the patient back more time. Especially in this field, time is precious."

Dr. Rifkin hopes that implementing MRD testing will save money in the long run. Regarding cost he says, "I think over time, integrating Adaptive technologies and other MRD platforms, if used judiciously, it's my hope that we can save money because at the end of the day, everyone benefits. Then we can spend the rest of the dollars on therapy as well."

[CLICK HERE  
TO VIEW FINANCIAL  
ASSISTANCE TOOL](#)

If patients do happen to have high copays or concerns about test coverage, the PQI includes a Financial Assistance Tool that guides providers to clonoSEQ's patient assistance resources.

"I FEEL LIKE THE SUPPORT THAT THE TEAM [ADAPTIVE] PROVIDES IS AMAZING. IT REALLY MAKES THINGS EASY, ESPECIALLY WHEN IT COMES TO REIMBURSEMENT. SO FAR, I HAVEN'T HAD ANY COMPLAINT FROM PATIENTS THAT THEY GOT A BILL, OR THEY HAVE TO COVER IT, BECAUSE I KNOW THESE TESTS CAN BE EXPENSIVE. SO I THINK THAT DEFINITELY GIVES THE PEACE OF MIND THAT I CAN TEST THE PATIENTS THAT I FEEL IT'S APPROPRIATE. THAT THEY NEED THE TEST WHEN IT'S INDICATED AND NOT TO WORRY ABOUT THE LOGISTICS."

Maen Hussein, MD

## CONCLUSION: NCODA, THE MEDICALLY INTEGRATED TEAM AND THE PQI: OPTIMIZING PATIENT OUTCOMES

All team members agree that the Medically Integrated Team model and the PQI Clinical Resource are valuable to the team and to patients. Every day the Medically Integrated Team can make a difference in the life of patients.

Cox sums up the process for streamlining integration of MRD testing into clinical workflows by saying, "I think any practice is capable. It is about working in their team to understand the resources and all the steps that go into this. But the way I look at it is, pharmacy team makes it top of mind for a physician. A physician has to then utilize that, identify the appropriate patient they want to use it in. But after that, it is on the lab team to really pull that through and get those results back. And so they are a crucial part of this process."

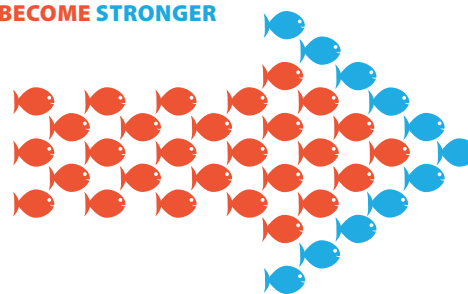
The team can continually learn something new or can begin a process that optimizes care. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization and by impro-

ving strategies to enhance tolerability for the patient and their Medically Integrated Teams.

Dr. Rifkin believes that Adaptive's centralized database is a model for future testing platforms. "The beauty of what Adaptive does right now is, I can test a patient and my colleagues across the street, or across the country, could have done the initial clone ID. And you can couple all the reports together. That's probably the biggest advantage. I don't know that anybody else can do it quite with the precision that they do. It is all in the Adaptive database. And we need to do a lot more of that, because it is very powerful, especially in myeloma." He goes on to say, "MRD negativity should at least improve progression-free, if not overall survival. And that is really the goal at the end of the day, to use it so that our patients do better and live longer and hopefully are free of disease. I don't know that anyone has announced the cure for myeloma. But that is what we all strive for, and this will be one tool that will be useful."

The PQI provides the Medically Integrated Team with an easy to use, compact clinical resource guide when discovering the right patient and using MRD testing to guide treatment decisions. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing medical integration with the **clonoSEQ® Next Generation Sequencing for Minimal Residual Disease Testing in Multiple Myeloma PQI** meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,  
WE BECOME STRONGER**



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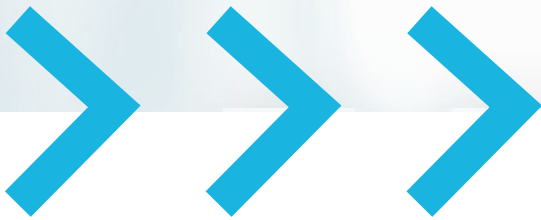
### ON THE COVER:

- The clonoSEQ assay heralds a new era in precision medicine, providing unparalleled insights for personalized treatment strategies.



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

Important notice: NCODA has developed this Positive Quality Intervention in Action platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



## **NCODA'S POSITIVE QUALITY INTERVENTION IN ACTION**

March 2024

