NASH: Take Action! Podcast Series

EPISODE 6. Working Together

TRANSCRIPT

The NASH Take Action Podcast Series is a CME program brought to you by the American Gastroenterological Association. NASH is the most advanced form of nonalcoholic fatty liver disease. This six-episode podcast series is ACCME accredited. The series is sponsored by a medical education grant from Novo Nordisk. You can find all six episodes and collect your CME credits at NASH.Gastro.org.

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Jay Shubrook [JS]: Welcome to the NASH Take Action Podcast. I'm Dr. Jay Shubrook, a family physician and diabetologist. I'm also a professor at Touro University of California and I have an active clinical practice in a F2HC and a diabetes center.

In this podcast, I and my colleague Fasiha Kanwal will talk to global leaders in gastroenterology, hepatology, endocrinology, and primary care about the real-world practical implications of screening, diagnosing, and managing people with NAFLD and NASH.

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In this episode, we're talking about how primary care providers and specialists can better collaborate to meet the needs of patients with NAFLD and NASH. The two main topics we'll cover today are when patient referral to a gastroenterology is

appropriate and timely, and the roles of a gastroenterologist, endocrinologist, and primary care providers in the screening, diagnosis, and management of NAFLD and NASH.

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I'm here today with my co-host, Dr. Fasiha Kanwal, specializing in hepatology and the Chair of the AGA NASH Initiative. Fasiha, thanks for joining us today.

Fasiha Kanwal [FK]: Thank you very much Jay for having me. I'm Fasiha Kanwal, I'm a gastroenterologist, hepatologist, based at Baylor College of Medicine, Houston, Texas, and a great pleasure to work with Jay and several other colleagues on the AGA NASH clinical care pathway.

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JS: Yeah, we had a lot of fun, and we certainly have learned a lot.

When I think about diabetes, I've always called that diabetes is a team sport. And I said, think of NAFLD and NASH – it's part of that continuum of kind of that cardiometabolic condition. I feel like its very much the same.

So today we're going to be talking about how healthcare providers can work together for our patients with NAFLD and NASH. What's your take on this? How do we improve the team-based sport that managing NAFLD and NASH should be?

0:02:32FK: Important question, Jay, and I like the analogy that you used for a team-based sport, because that's really what this is.

As you know, most of the patients with NAFLD and NASH are going to be seen a primary care clinics. That's where most of these patients are. And there are data and

studies showing that there is under-recognition of this condition; there are very few people who get the explicit diagnosis and management plans are instituted. So clearly there is a need for more awareness at the primary care end. But at the same time, there are really no clear-cut guidance or recommendations on which patients need to be referred to a specialist – and when I say specialist, it is gastroenterology, hepatology, and endocrinology – even cardiology.

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When should that happen? For what subset of patients? And how frequent would that be? If the patient is screened today, is that it? Or do we come back to that patient in a few years and reassess and rescreen.

So there are lots of points of clarification. It's not very surprising that the care is not very structured because there has not been any effort to put those guidance or those structures around. And that is why this pathway, the clinical care pathway, I believe, is important, because it describes those points in the care continuum, where that handoff needs to happen. And it tries to put a structure and a process around it.

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It is a _____ and dilemma for primary care providers, but also it is an issue for specialty clinics, because there are patients that are seen that might not need to be seen. And clearly we do miss patients that need to be seen. So I think this dilemma occurs at both ends, and hopefully with this pathway and its implementation, some of these issues and nuance hopefully would be sorted out.

And clearly there is more work that needs to be done, and I think we will learn as time elapses, and hopefully could even potentially refine the clinical care pathway to make it easier to manage and implement. But I have to say, this is a good place to start. It highlights different aspects that were previously unaddressed.

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KC: Yeah, and I think, you know, what I love about the clinical care pathway is it provides the lattice, or the structure for us to kind of know what steps to take next. The thing that I would highlight – and we certainly highlighted in our podcast – is the need for communication, so that we can have bidirectional understanding about who's doing the next step. Because, of course, we want the best for our patients, we want to make sure that we're identifying things in a timely way, and we certainly don't want to overburden the patient or the healthcare system, so that we make our referrals targeted, effective, and certainly with the patient in the center of the decision-making process.

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FK: Absolutely, absolutely.

KC: So, today I have the opportunity to talk to Dr. Hashem El Serag, the Chair of the Department of Medicine at Baylor College, and the past president of the AGA. This is what he had to say regarding team-based care.

So, today we're going to talk a bit more about nonalcoholic fatty liver disease, and really share some exciting updates that are coming as part of a paper that's going to be in *Gastroenterology,* really focusing on some updated recommendations regarding the diagnosis, evaluation, and treatment. And Dr. El-Serag, I really would like to know a little

bit about, in your practice, how does non-alcoholic fatty liver disease present, and who are the patients that you're typically seeing?

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El-Serag [ES]: Yes, thank you. So, NAFLD, non-alcoholic fatty liver disease, has become the dominant disorder that patients get referred to my clinic, and I would say all of my colleagues' clinics in the year 2021. With the successful treatment for hepatitis C, and the low number for hepatitis B, NAFLD has become the most common liver disorder.

It is estimated that a third of all adults in the U.S. have some sort of affliction with NAFLD, and if you take it to people with risk factors, like people with diabetes, it's estimated that two-thirds of patients with type-2 diabetes have NAFLD.

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So, it's a common disorder affecting primary care, endocrinology, and certainly it is now the dominant disorder that we see in liver clinic, both on the mild end, like those with non-alcoholic steatohepatitis, but also on the complicated end, patients with cirrhosis and with the unfortunate complications related to that, like hepatocellular carcinoma.

INT: And you've brought up some really important points. Many patients with NAFLD actually have other diseases. And so, in the primary care space, we often – and I'll speak for myself – often put a little less emphasis on NAFLD because we're overwhelmed with the other conditions that the person might be experiencing.

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So, when you see a patient with NAFLD, of course they have other conditions as well. What are some things that are unique to your practice in terms of the evaluation and treatment of NAFLD?

ES: Yes. So, I tend to think of the other conditions with NAFLD to fall into one of three big buckets. One of them is the risk factors for NAFLD. And these are conditions that are thought to predispose to NAFLD, and in some corners of the argument, NAFLD may even predispose to these risk factors.

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And by that I talk about obesity, diabetes, hypertriglyceridemia, low HDL, and hypertension. So those buckets I call risk factors, comorbid risk factors. They travel in packages, and NAFLD tend to travel in one or more of these metabolic disorders. So that's one bucket.

The second bucket, and that's the reason why most people get referred to me, is the liver-related disorders. So, NAFLD has a spectrum of affliction – and it could be different diseases, even – that affect the liver. On one end of the spectrum is the relatively benign accumulation of fat called steatosis. The next level is non-alcoholic steatohepatitis, where the steatosis or liver fat now is accompanied by cellular injury and by deposition of fat or scar tissue – and that's NASH.

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Within NASH, there is a spectrum of fibrosis, or scarring, and one common numeric system extends from 1 to 4, 4 being the worst. And when you get to fibrosis level 4, that's what's clinically defined as cirrhosis of the liver. And, as I mentioned

earlier, cirrhosis of the liver tends to be regarded as the precursor condition for developing hepatocellular carcinoma, or primary liver cancer, and therefore HCC is part of that spectrum. So, this is the second bucket, which is liver-related disorders.

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But there is also a third bucket, and that bucket, despite the name of non-alcoholic fatty liver disease, where liver features prominently in the name, the most common reason for demise, for morbidity and mortality among patients with NAFLD is really cardiovascular-related disease. So, the third set of disorders are ischemia, silent CAD, heart failure, and cerebrovascular disease, both in the realm of primary, secondary, and tertiary prevention.

To summarize, there's the comorbid risk factors, there is the liver disease, and there is the cardiovascular disease.

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INT: And I really love the way that you've just set that up. Because as a primary care provider, I'm always trying to figure out who's on a certain team. And, you know, on a very narrow level I talk about the diabetes team. But we've learned, right? Most people with diabetes die from cardiovascular disease.

And it started to feel overwhelmed, like who's on the asthma team, who's on this? But quite honestly, as we think about NAFLD, we really should be grouping, not separating, into a cardiometabolic team, right? A team that really addresses all those.

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So, as a primary care, I guess I'd like to know, if you had a wish list, how do I set someone up to send them to you? And let's start maybe with the risk-factor category. What would be the things that you'd like to see us do before we send a referral over?

ES: Yeah, that's a great point. First, I want to say that I sympathize with the primary care teams. I actually sympathize with all teams that take care of NAFLD. Because when you deal with a bulk disorder, it becomes sort of a big deal to start thinking about what one, every third patient, what do I do with them – especially in the absence of clear data and clear guidance.

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But, having said that, I think there are two issues at the primary care level. One is the detection. Most patients with NAFLD are asymptomatic. So, it's rare, if ever, that someone is going to come and complain to you of their fatty liver. So that means you have to have a high index of suspicion, and I would argue, for a condition that affects a third of your population, people need to have a high index of suspicion.

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Well, how to translate this high index of suspicion into actions, steps that a busy primary care doctor can do? Focusing on the metabolic risk factor would be a good start. So, obesity, diabetes, high triglycerides, low HDL are conditions that predispose to the increase in the risk of NAFLD. That's one bucket.

The other bucket are people with abnormal liver enzymes, particularly elevated ALT.

The third bucket, people coming to you with incidental ultrasounds which may show fatty liver.

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So, now you have the screening part. In other words, you're detecting, trying to detect those with non-alcoholic fatty liver disease. You would do your liver enzymes, you would do your ultrasound, to assess that first level.

After you're done with the screening – the screening meaning, do they have, or are they likely to have fatty liver disease or not? – if you actually pass every person that you diagnose with NAFLD to the second level of referral, you're likely to create several bottlenecks. You're going to clog the system with so many patients that you're referring.

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So, your next big task – and it's really big – is to try to stratify, among the masses that you're going to diagnose with NAFLD, who are at a high risk of complications. For that, it happens to be relatively simple to at least state. The degree of liver fibrosis seems to be the major determining factor for complications, be it at the liver end or at the heart end, which makes it somewhat easy to figure out.

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So now, you need to know, or automate in your practice, how to risk-stratify hepatic fibrosis. For that, there are automated calculators – FIB-4, NAFLD fibrosis scores that depend upon easily obtainable and commonly obtainable measures. So, you'll have age and ALT and platelets and PT – things that almost every practice has available at their disposal. And you'll have a calculator, and the calculator would spew

out numbers, with cutoffs, and those who belong to the intermediate and high category could be and should be referred to the next level of referral, which is hepatology.

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I think if this somehow gets streamlined and translated into a pathway that a busy practitioner can either look at it, or automated into the flow of their clinical practice in the electronic medical record, that would be my wish list. So, sorry for the long-winded answer, but that's my answer to my wish list at the primary care level.

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I would be remiss to say that my wish list also should include the receptive hand, or should I say hands, that would take over after you refer someone. And the hands, in an ideal setting, needs to have people involved in weight loss, people who are endocrinologists and hepatologists. Because without that, we're leaving you, in the primary care, at a complete loss by having the responsibility of diagnosing a large number of people with a disease entity, even stratifying them and finding those with a high-risk disease entity, and very little to do with them.

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So, the complementary wish list is to have a system in which the multidisciplinary practice involved in the optimal management of patients with NAFLD are available.

KC: I love that, and I'm going to take that even just a step further.

In our previous primary care podcast, we talked a little bit about those tests. And for those that not familiar, any medical calculator can do a FIB-4 score. You just need transaminases and age and platelets. And so, you can very quickly do a FIB-4 score.

And I'll tell you from my personal experience, I'm quite surprised. I now know the variables and how they affect, but all those factors are important. And I would say that if you have a person with either biochemical transaminitis or evidence of steatosis, please do yourself a favor and calculate that FIB-4 score. And that's really going to help you to sort it out.

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And I would say, I also think the second point you made is quite important, that most of these patients are going to benefit from the treatments we're putting on for the corollary conditions – diabetes, hypertension, obesity – but, the benefit of an early referral for someone that is of intermediate to high risk is that we can potentially prevent, or at least address, those who are at highest risk for cirrhosis or hepatocellular cancer. And yes, we all know that you can't see everyone. And, we already know what to do for the low-risk people because we should be doing it for their diabetes and other conditions.

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So, when I do send a patient your way, I'm going to do that FIB-4 score. I'm going to send you a note. But it sounds like I should expect that, quite honestly, they're going to come back my way with some suggestions for treatment. And many of those treatments could be used even by primary care, some may not be. Is that correct?

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ES: That is correct, that is current. Let me delve a little bit more in depth here. So, I love the way you explained the FIB-4 and the calculators. And I would double-down on

what you said. Someone might argue, hey, there's a calculator or two or five for every entity, and if I download all of them, I'll be spending my day just on calculators – and that's a true statement.

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But there's an exception here. I would be sort of – I don't know of any other conditions that would affect a third of your practice. So, I think it deserves its calculator, because it's going to be a commonly used calculator, worthwhile the effort into downloading it and understanding it. You're going to generate a lot of people with an abnormal FIB-4 that belongs to the intermediate and the high risk.

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So, the next step, which we can argue, where would that next step best take place, is to further stratify them into the actual measurement of fibrosis. And the most common modality to do that is not invasive. So, I think that's an important message, because if somehow people switched off for the past 10 years or so on the practice of liver disease, everything was going livery-biopsy way, and it wouldn't be practical or useful to offer that.

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So, non-invasive measures of hepatic fibrosis include FibroScan. It's an ultrasound-based technique that noninvasively, very short, and very accurate, actually for measurements of the degree of hepatic fibrosis. There are more sophisticated measures that are related to MR, so there's MR elastography.

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So again, we could debate. Some primary care practices might purchase their own FibroScan and learn how to do it. They might find someone in the neighborhood or in the region or in the network with a FibroScan machine and do that after the FIB-4, or they can refer it to the hepatologist, and the hepatologist would take care of the FibroScan and the noninvasive measurements.

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So, I'm going to take what you've given me, with an elevated FIB-4, and I'm going to slice out a segment of those where the FibroScan wouldn't show advanced fibrosis. And by advanced fibrosis, many people refer to it as fibrosis grade 2, 3, or 4. Some people say 3 or 4, but more or less that's what it is.

So, now I'm going to take this group and recommend management. If I find fibrosis 4, which is cirrhosis, it's not likely that I'm going to return this to you. But admittedly, we're talking about 5 to 10 percent of the big pie. I'm going to keep those cirrhosis in our practice, and follow them closely.

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The vast majority, however, as you alluded, will come back to you saying, "This person has NAFLD indeed. They have NASH, their fibrosis is F-2. We recommend treatment. The mainstay of treatment is weight loss."

Now, depending on the practice of the guideline, you might hear 10 percent body weight, 15 percent body weight. We will have related measures, Mediterranean diet, increasing physical activity. We might be prescribing medications in non-diabetics such as vitamin E. But there are no other really approved medications yet.

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So, we will come back and say, “Optimize their diabetes management. Consider referring them to endocrinologists for use of pioglitazone, optimize weight-loss management, optimize exercise.” That is the likely outcome. And that’s why, when you asked me about my wish list, I hope my wish list will include that I refer them back to you, and to someone who actually knows how to do those things – not that you don’t – because they do them full time. So, weight loss experts, nutritionists, endocrinologists. That becomes a more palatable return back to you with the recommendations of how to manage that.

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KC: Yeah, and I think that’s still of great value. So, I think often we will refer, and we think okay, well, they’re going to take over management, and I think it’s absolutely important to know which patients will need continued ongoing specialty care versus episodic care. And I do think that it is, as again, with other chronic diseases, develop your team. And your often will need to be a nutritionist, often might need to be a diabetes educator, might be a diabetologist or endocrinologist. Might be a nephrologist.

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And so, the more that you can communicate with the team, the better it’s going to be for the person. And so, how do you communicate back with the primary care team when you send the patient back?

ES: I’m going to give you the best-case scenario, where I deal with a primary care physician who’s in my network, and therefore is on my same electronic medical record.

Then our notes has the diagnosis, the criteria for the diagnosis, and a management plan laid out, and a linkage to the recent guideline, and recommended names of people on our network, be it a dietitian, endocrinologist.

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However, I wish I could tell you this happens a lot, because as you know, the healthcare system in the U.S. is quite open, so many people come to me who are not in our network, and the primary care receives somewhere close of a note like the one I described to you, but their hands would be tied in the sense that they cannot use the nutritionist in my system, they may not be able to use the endocrinologist, etc., and I go back to the wish list. You've got to assemble your team, because with a common condition like this, there's simply not enough time for you to stop and think, Who do I refer this person to, as opposed to referring them to the multidisciplinary team.

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And it's a worthwhile effort to invest upfront in, because you reap the rewards later in terms of efficiency and improved outcomes.

KC: And I think that's so important. And you know, it is true that every provider will have a different potential team. I have a network of dieticians and diabetes educators and nurse educators that I can utilize. And I think more and more, primary care healthcare systems do have those kind of additional providers. And if you have expertise within your umbrella, where you can get, let's say, access to a medication that someone may not have access to – or, if you're comfortable, you certainly can do it yourself. But I think that communication is so important.

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And sometimes – and I'll utilize this example – sometimes I'll utilize my partnership with a nephrologist to get additional access to tools, because sometimes my nephrologist partner will have additional tools. I assume the same is true within some hepatology practices, where if I don't have access, if they can help with access, that will make it better.

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ES: Yes, yes. That is correct. And if I may follow up – and it may not have come very clear from our previous discussion – there are really new things that we both are talking about, other than the refer, refer back, do your thing.

There was a true sense of nihilism about, is this a real disease or not, just 10 years ago. The other level of nihilism is Hey, all we tell them is to lose weight. Why do I bother referring? Third, even if I refer them to the specialist, they'll just return them to me and say, "Lose weight."

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So, let me sort of debunk all three myths. It is very common. A lot of people may not have harm, at least in the foreseeable future, but now we know that a good portion of people progress. It's becoming a dominant reason for cirrhosis, and it is forecasted to be the leading cause of liver cancer in the next 15-20 years.

Second, is there treatment? Yes, weight loss remains central, but referral to the specialist opens your patients to be enrolled in – tons is sort of a generic number, but

many trials that are currently active, that treat different – or target different mechanisms of non-alcoholic steatohepatitis with fibrosis. And the field is now rife with new agents.

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So, there is actually something that you can do for your patients, at least 10-15 percent of them who would have meaningful fibrosis, that they would not be offered this opportunity should they just remain languishing, of you will, in a usual practice with not much emphasis. So, I think it's important to drum up the highs here, in addition to the process improvement issues that we're talking about.

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KC: Yeah, and that's actually something I wanted to highlight, is that for those patients who are at higher risk, we would want to offer any treatment we can as early as we can. And some of these are things we already do, but this is, I think, a potentially exciting time in NAFLD, where I expect, in the next five years, there's going to be some newer agents, and there's going to be agents that may even be specifically approved for NAFLD.

And so, because this is such a silent and serious condition, it is important that we give our patients who are at highest risk access. And so I think that that's – I really appreciate that point.

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ES: I completely agree with that. And I'll just mentioned an example of unanticipated benefits. I mean, the medications that people are excited about now for weight loss and for diabetes, like the GLP-1 RAs – well, there's really good evidence that they help also

in NASH-NAFLD. And had we not started that virtuous cycle of referring patients, stratifying them, enrolling them in trials, we wouldn't know that.

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KC: And we have much more that we're going to continue to learn.

So, today we summarized. We talked a bit about how common NAFLD is. We're going to all see it; we're going to see it regularly.

We've learned more information about NAFLD, and we have learned how to stratify those who are at highest risk. And so, if we have simple screening and risk factor assessments that we could do in our practice, we can then take those who have intermediate or high risk and refer them for targeted recommendations and further evaluation.

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Whether we do the FIB-4 score, which is really the recommendation, and the FibroScan, if we have it available, that would be ideal, but then that really arms our team to give us the best advice and the best resources for our patients – knowing that many of them will come back for continued intermittent episodic evaluation, while we continue to work on risk factor management.

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And because we have a wealth of knowledge now, and we have the ability of having interdisciplinary teams, we really should utilize those opportunities for our patients so that they have the opportunity to get the best care available. And that continues to evolve.

Any closing comments, Dr. El-Serag?

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ES: First, I echo and agree with everything you've mentioned. And let me sort of end where you started. A plug in for this, I think, a wonderful paper that is going to come soon in *Gastroenterology* that is focused on the issues that we just talked about – how to create a path and a pathway that starts in primary care, ends with the specialist, and then comes back to primary care, and how to create that multidisciplinary team. So, I encourage your viewers to read it.

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And I think we all took care that this is an implementable and a testable pathway. So, try to do it, try to measure it. See what works, see what doesn't work. It's a much-needed step in the right direction, so congratulations to you and your co-authors and coworkers.

KC: And thanks for being part of the committee to contribute such value information to make that happen.

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FK: Thank you, Fasiha, and special thanks to my guest, Hasim El Serag. Thank you all for joining us for this episode on team-based care. You can find the other five episodes in this series, the NASH Clinical Care Pathway, and more resources at the program's website, NASH.Gastro.Org.

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Announcer: Visit NASH.Gastro.org to get your CME credits, and find clinical pearls and a full transcript of this episode. Be sure to listen to the other five podcasts in this series on NAFLD and NASH, covering important topics like diagnosis, management, and team-based care.

Also at NASH.Gastro.org, you can download our NASH app to help you apply what you've learned in clinical practice.

Thanks also to our sponsor, the American Gastroenterological Association, and for the medical education grant from Novo Nordisk.

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