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Proem 00:53

Why my fascination with chronic pain? So many people have it? Pain is often silent, hidden, personal, universal, misunderstood, devastating, mysterious, sapping, infuriating, inexplicable, unique, varied. Wow, just scratching the surface and piercing the heart. Managing pain draws on almost everything we know about managing life well at a time when we can't manage a thing. On the other hand, when successful, pain management to live life, can be most satisfying. Poetic, isn't it? My series on pain management collects personal stories, mine and others – people with pain, clinicians, partners, academics, activists, device makers, and more.

Introducing Jessica DeFrank 02:07

Today I'm joined by Jessica DeFrank. Dr. DeFrank conducts behavioral and health services research for various studies funded by the US Food and Drug Administration, National Institutes of Health, Patient Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ), and American Cancer Society. Her areas of interest include health decision making, measurement of patient-reported outcomes and attitudes, and evaluation of health promotion programs, with a focus on cancer, screening, prescription drugs, and vaccination. Dr. DeFrank has also worked extensively in the area of communicating scientific information to lay audiences and leads an experimental study testing recommended practices for communicating uncertainty about prescription drug risks. In addition to her

work in prescription drugs, Dr. DeFrank has extensive experience working in cancer-related decision-making, psycho-oncology and survivorship issues.

Health Hats: Jessica DeFrank. Thanks for joining me today. I think we met at an RTI gig. You work for RTI. I'm a consultant on the gig. We've had some communication around how a patient-facing pain app looks and about usability, and I think we both said, 'so what.' We might have used different words. Please introduce yourself.

Jessica DeFrank: My name is Jessica DeFrank, and I work at [RTI International at the Center for Communication Science](#). We are a large nonprofit organization with a mission to improve the human condition. So, I am a behavioral scientist at RTI. In brief, I study how patients make decisions about their health.

Health Hats: When I was looking to get more information about you before this call, the first thing I saw that you are working on an INSPIRE trial.

Pragmatic study explained 04:19

Jessica DeFrank: [INSPIRE](#) is a clinical trial, a [pragmatic clinical trial](#) that RTI leads.

Health Hats: You're going to define pragmatic clinical trials because I bet most people won't know.

Jessica DeFrank: That's a good idea. So, I'll describe first what a regular randomized clinical trial is? Then that will help give some context to what a pragmatic trial looks like. So, in a randomized clinical trial for whatever intervention or drug that you may be studying, patients are randomized to two or more different studies conditions. The study assesses their outcomes and tightly controls conditions. That means that we don't want to see a lot of outside influences if we can. We make sure that everybody randomized to that condition gets the same thing to the extent we can control it, the exact same conditions. That way, we keep everything as similar and equal as we can so that we know if we see any differences between these two conditions, it was, in fact, due to what's being tested rather than something else. So that's how a randomized controlled trial work. It has the word controlled in it. In contrast, a pragmatic trial wants to know how these different interventions work in real-world conditions. So, we're not trying to control all these other outside source forces, et cetera. We just want to know what happens in the real world. It's more challenging in some ways to run this type of trial, but I think the information you get is potentially more valuable from an implementation standpoint.

Health Hats: Okay. Thank you. So, you were describing INSPIRE as a pragmatic study?

Jessica DeFrank: Yep. It's a pragmatic study, and it's conducted at three different clinical sites, at the University of North Carolina, Vanderbilt University and, Duke Medical Center in real-world scenarios.

Health Hats: And it's studying what?

INSPIRE study for management of chronic pain 06:46

Jessica DeFrank: It's testing two different strategies to help patients manage their chronic pain. These are patients who are already on a high dose of opioids, and it's testing two different strategies to help them better manage their pain with the ultimate hope that they may want to consider tapering or reducing their reliance on their opioids.

Health Hats: Okay. So this issue of managing chronic pain, it seems in the patient-caregiver circles that I travel in whenever people talk about opioids and managing opioids use, what's clear, it's really about managing chronic pain and that opioids are one method. Opioids are often a focus because opioids are considered such high risk and problematic. But starting with opioids rather than with chronic pain doesn't work so well for patients. There are so many factors in managing chronic pain in a person's life and the limitations on their life. There's the clinician - the relationship with the clinician and the skill of the clinician, access to non-medication solutions, or medication solutions other than narcotics. When you're thinking about the decision-making process, how do other factors work into your study?

Jessica DeFrank: That's a wonderful question. Like you said, decisions around medication are multifaceted. There are a lot of pieces that go into that decision. One of the conditions, the study arms that we're testing as part of the INSPIRE trial, is called shared decision making. Shared decision making is simply a two-way conversation between clinicians and patients where they're exchanging information about how to manage the pain best. And it goes deeper than just facts about the risks and benefits of opioids versus another technique. But what they want to know, and potentially, more importantly, are what are the patient's preferences and their values and their concerns and their goals. And so, this is a much more in-depth conversation. For example, a patient may say, I value my family. I value my time with my grandchildren and being able to see them and lift them and put them in my lap. And with this pain, I'm no longer able to do that. So, my goal is to be able to lift my grandchildren and have them in my arms. It just allows the clinician and the patient to have a better exchange about what their goals are and what they really want to get out of this. And then they may say, for example, I have tried this medication, but my preference is to not be on medication. I would rather try another approach. So, then they start talking about these types of preferences. So, it's this exchange of information between the clinician and patient that goes beyond just simple facts.

Technology pre- and post-Covid 10:15

Health Hats: So, when you're doing this study, is technology included, or is this is about the relationship and the conversation. How does that come into play?

Jessica DeFrank: I have two answers to that question. I'll answer it first before COVID and then post COVID if that makes sense? The intent with shared decision making is to, aside from this conversation that patients and clinicians are having, it's good to somehow prepare the patient for these conversations so that they can come in prepared and educated and with a list of questions. As part of this intervention, patients would receive a packet of information either through email or hard copy of a packet to study. Included in one of the packets that we give patients electronically is a link to a video called the [Car with Four Flat Tires](#). And it's a video, released by the [American Chronic Pain Association](#) that talks about strategies to pain management and how there's usually no one single strategy. So, it's similar to a car with four tires; you need to work on all four. So anyway, so technology comes into play. There is the way we share information and educate our patients. To answer the other question

What about educating clinicians? 11:40

Health Hats: Before you go to Covid it's always interesting to me that often the conversation is about educating patients. And I think a relationship is two people or more than two people. And so it's

interesting to me that it's not often the conversation about educating the other part of the relationship, which is the clinician. How does that work its way into this?

Jessica DeFrank: Yeah, that's a great question. From our study's perspective, physicians who are part of this INSPIRE study have trained to engage in shared decision making. So, this is a shared decision you're making, clearly goes outside of our research. And this is a technique that several clinicians have trained in. So, there is an education component to learn how to have those conversations, how to probe and what it looks like. And I remember at one point in the early stages of the study, someone spoke up and said, isn't this what clinicians do anyway? And don't they just naturally have these conversations? And that may not always be the case that sometimes these conversations could be a little more one-sided or prescriptive. But these are tested techniques to exchanged information so that it genuinely feels like more of a shared decision-making model.

Health Hats: Okay. Part of the physician end of it is learning about the life and the situation of the patient that they're working with. I had a conversation with Dr. David Edwards recently, and - these are not his exact words - but that he thinks about people in different buckets. People who say, 'look, just tell me what to do, you're the expert. Tell me what to do.' Then people who say, 'I know what I want, and your job is to help me get what I want.' Then people who are not necessarily comfortable being in this relationship. And I think there were more buckets, but - now my words - I think there's as much variation in clinicians as there are in patients and in various permutations of the two. We'll talk about caregivers later, another permutation on the dilemma. You are going to talk about now COVID.

Technology and COVID 14:18

Jessica DeFrank: You had asked about technology and what came to mind is how healthcare had to pivot during COVID to an online platform. That affected our study as well. For example, with INSPIRE these shared decision-making visits were happening in a clinical context, the patient would go in for their normal visit and engage in this conversation with their clinician. But then as clinics were pivoting to telehealth, INSPIRE had to do the same. Our concern: can a clinician and patients still have these sensitive conversations about their pain and their preference, and their values? Can they be done effectively over the phone or the internet, or are we going to lose something in that transition? Are these conversations best reserved or best done in person? Fortunately, we found that the conversations went just fine. They felt that telehealth was an asset, and they are absolutely able to maintain rapport with their patients and have these types of conversations. That doesn't mean telehealth can replace in-person medicine, but it was an acceptable option, and we don't feel like it harmed the study in any way. The second arm of our research is group therapy: group cognitive behavioral therapy. These are group sessions led by a moderator where they share techniques for managing pain. One of our largest challenges with the INSPIRE study had to do with these group sessions. Some people didn't want to enroll in the study because they knew they couldn't come to these group sessions every week for eight weeks. So that was the requirement you come for eight sessions. Because of distance or transportation, or time, they could not make that commitment. But with the transition to telehealth, we had to put these sessions on a virtual platform. Again, we had the same concerns. Will everyone have internet access? Will they even want to do a group session online? Will they feel comfortable having their face on a screen? Will they be engaged, or will they be checked out? I don't have data to offer but we're finding that a lot of patients prefer this telemedicine model for the group sessions because they can now

be there, whereas before they had a lot of difficulties making these sessions. So, it can reach some patients who are maybe more geographically isolated or have other transportation barriers.

Barriers 17:14

What we don't know is who these technologies leave out. Are there individual patients that have been left out? We don't have an answer to that yet, but it's certainly something we want to look at, and of course, the concern is that we already know that there are there's a disparity in the type of access to health care. We don't know if telehealth is widening that disparity gap or closing it or both.

Health Hats: Yeah, depending on who. I know when I worked at Boston Children's Hospital when I had spare minutes, I would go in the lobby and sit myself on the floor, off to the side and watch the kids go by. I saw parents with several kids. One child needed treatment, but they're going with all their kids or all their kids that aren't in school. I thought, oh my goodness, here's an access challenge. Now, these are the ones that could make it and drag their kids along. I'm assuming that for the most part, they're there were for multiple visits. This wasn't a one-off. They had to do this often. It seems like barriers are so varied, and technology probably helps with some barriers and creates others. But technology isn't just the video or the phone. It's also about CBT, cognitive behavioral therapy. Do apps support CBT? Is that part of what you're doing, or is yours more live? Whether it's virtual or not?

Jessica DeFrank: For the INSPIRE study, this is live, intentionally set up as a group setting, because there's some benefit to being in a group and sharing experiences and stories. Again, this did not rely on an app. But I am aware of some apps for people that want a more individual setting.

Health Hats: Yes. Okay. What other kinds of technology have you found people using as they're managing their chronic pain?

INSPIRE and technology 19:54

Jessica DeFrank: I'll speak first about the technologies we're using in the INSPIRE study. Then I can shift to pain as I think about that a little bit more. In INSPIRE, we collect information from patients in surveys about their pain intensity and its interference with their lives. It's important for us to know how these two different strategies are working, and if there's one that seems to outperform another. So anyway, back in the day, we would administer these surveys using a paper survey. Participants fill in those bubbles and mail them back. Sometimes we get them back, sometimes we don't, sometimes you're not sure what bubble they filled in - all kinds of limitations. With technology, data collection has become so much easier. For example, when patients enrolled in our study, they would enroll in person at the clinic. We would hand them a tablet with the survey loaded. We said, 'okay, take 15 minutes and click your responses. then it's automatically uploaded into our database. So that streamlined a lot of effort for us. The other nice thing is now that most patients have access to email, I want to say over 80%, maybe even close to 90% of the participants in INSPIRE gave us a working email address. We can administer these surveys online and send them a link. Then they have that link that's meant for them individually. It's linked to their email address, so it cannot be forwarded to somebody else. They can fill out these surveys for us right there. We've had very few problems as far as technology or glitches with those. It helps us increase our data collection numbers, and then patients can come back and do their next survey because they know it's not a heavy lift.

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Medication-free solutions 22:40

Health Hats: Okay. Now step aside from the study. And so corollary learning that you've observed in the process? Do you see that there are other technologies that people are using as they're trying to manage their pain? I had mentioned the portal. Some people I've heard say they use a meditation app.

Jessica DeFrank: I haven't heard too much about that, but I do know that in the CBT arm, they're trying to teach patients strategies for managing their pain that are not reliant on opioids, like sleep strategies or meditation strategies or breathing strategies. I don't know if the therapists recommend specific apps for them, but that is one place a lot of patients turn to. A large number of apps can be used for either low cost or free that can guide patients through some of these activities. They may not necessarily market it for pain, but they're for several different conditions.

Results in action (implementation) 23:54

Health Hats: If you're wildly successful with INSPIRE and not only is A more likely than B to be effective for this population under these circumstances, but there's a large group of people that's true for. Nothing is ever everybody. How do you, as a scientist, think about what happens after this study?

Jessica DeFrank: No, that is an excellent question and something I think we all struggle with a little bit in science. I have a few answers to that. First, when we are designing a research study and thinking about our proposal, we do design it thinking with future dissemination in mind. So, we try to use that lens. We would not want to recommend a study that could not, in any way, be disseminated in any form later that would not be practical or feasible.

Health Hats: Dissemination means that you do a study, you write a report, you have some results, and you share those results widely. Sharing narrowly would be in academic journals and conferences and widely would be beyond that but for our purposes. So that's what you mean by dissemination, or is it also you're thinking about implementation so that people are using it and doing it?

Jessica DeFrank: Right. So absolutely implementation. So that's probably a better word for that. Yes, we want it to be implemented, and those strategies to also be disseminated. So we want to be sure, not only can the study be implemented here in this condition at RTI and Duke and UNC and Vanderbilt where we're doing it, but it could also be packaged in a way that could be taken off the shelf and use somewhere else.

Health Hats: Yeah. Like rural West Virginia or

Jessica DeFrank: Exactly

Health Hats: Someplace that's not an academic medical center. So that must be some of the art of designing a study because you want to go where the expertise and the patients are in some volume where you can have a significant sample size, and often where it's implemented there's much less of a volume. I've never been in that position of trying to think about how is it going to be used in rural West Virginia? And I say rural West Virginia because I lived in rural West Virginia, and sometimes I read these funding applications, and I think, oh my goodness, we could never do this.

Jessica DeFrank: I'm from rural West Virginia as well.

Health Hats: Are you really? What a riot?

Jessica DeFrank: Yes,

Health Hats: I lived in Weston, West Virginia.

Jessica DeFrank: Weston. Wow. Okay. Coal mining?

Health Hats: Gas and wood. Near Clarksburg.

Jessica DeFrank: Gosh, I can't say I've been to Weston. No, absolutely. That's a consideration. I can't say that the results of this study can be implemented without change in a more rural environment. Clearly, things would have to be adapted, but if we learn, for example, from INSPIRE that shared decision making is a very powerful tool. It was successful in helping patients taper, then there's no reason why clinicians who treat pain patients in West Virginia, in rural areas, can't learn shared decision making, especially since there are now- we're getting back to technology - a lot of online training in courses for physicians.

Risk Tolerance – risky business 27:48

Health Hats: When I'm wearing my preventative and chronic health management hat, I think that people have varying tolerance for risk. That's acute now with COVID because people come to me often, and they want my advice about something. And I feel like, who the hell am I to give them advice? Usually, the conversation I have with them is about their risk tolerance. I feel well able to have those kinds of conversations because as both as a nurse and as a person with chronic illness myself, I am continually thinking about relative risk. An example for me is that my most significant risk is falling. But another risk is not to walk. So, those are risks that are in constant tension because the more I walk, the more likely I am to fall, but if I don't walk, I won't keep up my strength, which is an important thing. So when people are in chronic pain, and they're involved in this relationship with their clinicians of the shared dismay decision making, informed decision, making, whatever there's this understanding of relative risk. And it's not just the relative risk of the patient, but it's the relative risk of the clinician. And so for the clinician, it may be how much time do they want to spend, or can they spend given their productivity pressures or the scrutiny that they might have of their prescribing habits. For patients, it's as you were saying, I want to hang out with my grandkids and do whatever with my grandkids. But what does it take to be able to do that with the amount of pain I have or my foggiess from having that pain or treating that pain? How does this risk tolerance fit into this or not? If yes, how?

Jessica DeFrank: Absolutely. So, we know that patient's perceptions of risk are very strong drivers of the decisions they ultimately make. And that's been shown in the literature time and again. But how do patients weigh risk is a good question. So, I think you're speaking about risk of, for example, risk of

action and inaction. So, if I act, here's the risk. If I do exercise, there's a risk of falling or injury, but there's also a risk of inaction. So, if I don't exercise, there are certain benefits that I'm losing so that loss of a benefit is in itself a risk. Patients are weighing these benefits and risk. Some other ways they think about two things and they're not always aware that they're thinking about these things, but what typically goes through their minds is it's first the likelihood of that risk. So how likely is it would I be to fall versus how likely it would be for me to experience something negative from not exercising. Okay. So, you're looking at the likelihood of each outcome and then the seriousness or severity of that outcome. If I were to fall, how bad would that be? What's the level of badness? If I fall, am I going to break a hip and, or are we talking about just an uncomfortable fall versus the severity of not exercising? So if a patient says, if I don't exercise, I know that's bad for my heart, and I have a heart condition. I need to be sure to get physical activity. It could be a serious risk not to exercise and get that cardiovascular benefits. So this is the type of weighing that's going on in patients' minds. I don't think patients always sit down and write down the pros and cons of this decision, but it's an unconscious calculation.

Health Hats: A collaborative relationship is trying to ferret that out with the clinician. I know, for me with my primary care doc and my neurologist, I do not want to risk my pathological optimism. I don't want to do something that's going to mess with that. That's a risk too far. So if they're going to prescribe something for me that might affect that, I'm more likely to say no, and they know that about me. So that's part of the conversation in terms of the pros and cons. I was reading about you to prepare, and it seems like that your work was in cancer care before, right? Okay. My wife had breast cancer, and we thought a lot about these percentages of risk. It seems like on the one hand, all that seems really similar, this idea of risk. Cancer care or, for me, I have MS, or if it's chronic pain, the conversations are similar. But in your experience, as you've moved along from studying cancer care to studying chronic pain to life, are there unique risk thinking depending on the domain you're in, or are they are just common threads?

Jessica DeFrank: That's a great question. I'm going to answer this from my gut rather than a scientific perspective, but I think the ways patients think about risks. Some ways they think about risks apply across any context. Then, of course, some contexts are more emotionally charged than others. The way you would think about cancer diagnosis and the numbers around that have a lot more emotion than something about the risk of something milder, right? That would not be life-threatening. But to answer your question, as a whole, there are some best practices and communicating risks that apply across the board.

Health Hats: Okay. So, tell us about two of them.

Jessica DeFrank: Yeah, sure. First, you mentioned cancer. That brings to mind some of the earlier work I had done. The first place where patients have some difficulty understanding, and we have difficulty communicating to patients is what that number means. If someone tells you that you have a 5% chance of cancer recurring, that does not mean that you, as a patient, your chance is 5%. Five percent is a population level number. Because of your personal history, age, or other factors, your actual number could be well above that or below that. But again, there's some difficulty in communicating with patients. This is the population level chance of this recurring. It doesn't mean we know your percentage.

Health Hats: And 5% could freak me out and not bother my wife at all.

Jessica DeFrank: Exactly, people interpret the same number in different ways. I found in a study if you say this cancer has a 5% chance of recurring and you ask them how large that feels, some patients will say that feels very small, and I'm not worried. And some will say that it feels very large and I'm very worried. So there are varied interpretation in those numbers. The same applies if you give the patient a range. If you say, your chances are between five and 10 percent, patients don't know where they are going to fall on that range. We tend to be optimistic as human beings. It's called optimism bias. We want to say, those things happen to other people, but not to me personally. So, I'm probably closer to 5% and not 10%. And it's just a natural bias we have.

Health Hats: What a fraught conversation! Today, with COVID, we have risk on steroids. Some people feel like this will never happen to me; I don't know anybody who's gotten it; I'm not worried. Then somebody's mother died, and they're freaked out. So the sense of risk can be based on personal experience, right? My mom had cancer, so that's a little more real to me. God, none of it is simple.

[Informed decisions and family caregivers 37:06](#)

Let's shift a little bit for a minute. We've been talking about shared decision making as a dyad of a patient and clinician. In many people's lives, there are way more people involved in that. There can be a designated care partner or a whole family. In my experience as a nurse, you are never just treating the patient. Never, almost never. In a way, it was sad if you were just treating the patient because that felt so lonely. But then you're adding this dimension of family. I have questions about that. How does that figure into the study? This added dimension of more people with influence?

Jessica DeFrank: That's a great question. Unfortunately, that's not something that we've been able to address with the INSPIRE study. But, certainly, something that we acknowledged early on that pain and management, or whether it be another condition or cancer or whatever, it is often not involving one person. It involves the entire family. So the wellbeing of the patient can influence the wellbeing of the caregiver and vice versa. So it truly is a dyad. Literature in the pain world suggests that having that social support from a caregiver, whether it be a spouse or somebody else, can greatly enhance their ability to manage pain. Having that person help take you to an appointment or stay on top of your medicines or remind you to do exercises that you haven't done or to motivate you to do them can be beneficial. But unfortunately, it's not a component we can look at with INSPIRE, but it's certainly essential.

Health Hats: And then probably the flip side of that is maybe having my wife be my care partner helps me out, but it could also be very wearing to her. And so then she's more at risk for other things because she's putting so much energy into the best life for me.

Jessica DeFrank: Absolutely. The cancer literature has documented that caregivers have been a neglected population in healthcare for a while. But we do know that the caregivers suffer enormous distress. They're carrying the burden of their loved one, but they also need to take care of themselves. So, that's something that we're now addressing, and there are different types of support now for caregivers and a recognition that they need some extra help.

[King for a day – equal access 40:05](#)

Health Hats: You've been researching all these different things. When I sent you a question, I said, if you could be King for a day, and I said something about changing a policy or practice. I don't want to limit

that. You're a thoughtful scientist, and you're a family person. As you're learning in this shared decision-making communication and health sphere, if you could wave your magic wand and change something, what would it be that you think would have an impact on the wellbeing of either patients or clinicians or caregivers? So, I'm asking you a very subjective question.

Jessica DeFrank: That's fine. Yes, I would love a magic wand for a day. The thing that bothers me the most and that I think our magic wand could address would be disparities in access to the types of care that we're talking about. For example, we just talked about how INSPIRE's done at a large academic institution. Now, those patients in rural West Virginia that don't have access to these large medical centers that are relying more on small underfunded community centers that may not have access to technology or not be aware of these apps. I'm concerned we leave many segments of the population behind on the advances in science that we generate. That's a difficult question to know how you address that? And technology can come into play here, but, yeah, I would love to see a lot more energy placed on how we can make sure these disparity gaps are lessening rather than widening as we learn more in the research world.

Health Hats: Thank you for that answer. So, what should I be asking you that I'm not?

After INSPIRE 42:03

Jessica DeFrank: Oh, my goodness. How about what's next after INSPIRE? So, what did we do plan to do with that? The INSPIRE trial still has several years to go, but we hope we'll find that one or both of these strategies turns out to be effective for helping patients manage their pain. So, the next step - we already talked a little bit about this - what do we do with that information? How can we get it into practice? One thing that we've talked about is, because of COVID, we had to pivot to these online virtual group sessions for the CBT, the cognitive-behavioral therapy. And from what we can tell, patients have been very receptive. The therapists running the sessions have been receptive to it. We were not planning to offer this online at the outset of the study. So, you could say, this has been a natural experience, and all of a sudden, we're looking at how technology can enhance this type of intervention. I would love, if you are on the PCORI board and deciding what grants got out, what got through and what didn't. I think I would love to have an opportunity to take these findings and adapt them for a virtual or online setting so that they can reach more patients. There has been a growing body of research, but at least in CBT for pain management, we have not seen anything like this done yet. So that would be really cool, I think, is to see what happens if we take this to telehealth.

Health Hats: Wonderful. Thank you, Jessica.

Jessica DeFrank: You have a good weekend. Okay. Bye.

Reflection 43:55

We talked about the difference between a randomized control and pragmatic study, studying strategies for tapering off high doses of opioids, technology pre- and post-Covid, turning research into action, risk tolerance, and informed decision-making and families. Turning research into action and risk tolerance feel most important to me. Research without action is ink on paper – worthless to non-academics (patients, caregivers, communities, and clinicians). Risk tolerance provides context for informed choices. In COVID-world, people living paycheck to paycheck with few income-generating options, in general,

tolerate more infection risk than people with many options and money in the bank. I didn't ask Jessica about patient-caregiver engagement in the INSPIRE research strategy, operations, analysis, and dissemination processes. I should have. Thanks for reading or listening. Onward!