

It's my pleasure to be here this afternoon to kind of take the next steps. So we had a very interesting and lively discussion about what happens with a patient with low back pain who is very commonly on opioids so what other options do we have and that's kind of what we'll focus on today. So as was mentioned I'm a physiatrist by training and my practice is split, I spend about half my time doing research and the other half seeing patients in the outpatient setting about 90% of which with spinal conditions. So this is basically the bread and butter of my practice.

So this is something I'm speaking to the choir here, you all see this in your practices as do I, but just to really reiterate the problem at hand, at any given time if you ask the general population if they've had back pain in the last 3 months about 50% will answer affirmatively. So this is a huge problem and about 20% of those people with back pain will report that they cannot work. So in addition to the burden on their quality of life there is also societal burden, financial burdens, etc. that go along with this. The costs associated with low back pain now are nearing \$100 billion annually all costs considered, so this is an enormous problem, an enormous strain on our healthcare system. The lifetime incidence approaches 90%, so pretty much everyone is going to be touched by this problem at some time in their lives and so we really need to get a handle on how we should be approaching the treatment.

So here is part of the problem. So this is what has happened over the previous decade with what we have done with the patients presenting to us with low back pain. So this is what happened to lumbar spine MRI imaging, it skyrocketed, similarly the use of opioids as we just heard also skyrocketed, and the use of epidural steroid injections for pain went up precipitously as did lumbar fusion rates.

What's interesting if you look at this you can argue well maybe more people are presenting, more people are coming to the doctor, but the number of office visits over that same period of time with a complaint of low back pain stayed the same. So we are doing more. What's problematic there is we are not doing better.

So this is data over that same period of time looking at musculoskeletal disability, which actually increased over that same period of time where we are ordering more scans, prescribing more meds, doing more injections, doing more fusions the disability rate went up precipitously. Interestingly enough for low pain specifically self-reported functional limitations actually increased over that same period of time. So we are spending a lot more money, and we are doing worse. So we are really at a crisis in terms of what we need to do with low back pain.

Even more concerning is that we are not consistent in the care that we are providing. So this is data looking at surgical volumes for laminectomies and discectomies across the country. And what you can see is perhaps what is joked about in the spine community which is really not all that funny is your biggest predictor of whether or not you get a laminectomy is where you live, okay. Kind of a concerning comment on the way we are practicing medicine in this arena, but not to put all the blame on the surgeons because if you look at the same type of data for the rates of epidural steroid injections you see a similar pattern. It is very much driven by geographic variations in the standard of care. So we are spending more money, we are doing a poorer job and we are all doing something very, very different for our patients. So this brings us to the idea of a pathway.

So what is a pathway? And I bring this up because as the committee started looking at this we had to define these. It's somewhat semantics but we really had to define what we are doing, so it is distinct from a guideline which is a consensus statement based on the evidence based literature. What a pathway really is is a multidisciplinary plan of care but it is the purpose of a pathway is to actually translate the evidence based practice guidelines into a local structure. So take that best evidence and figure out how we can apply it in our everyday practice.

So the treatment has to have a plan algorithm, etc. that you can follow along quickly, and has to have timeframes or criteria based progression which you can move through the pathway to figure out the best treatment for your patient. And obviously aim toward a specific clinical problem with the goal of trying to improve the standardization of care.

So this was the process that we used, we have developed a pathway and many of you may have seen this, it actually rolled out on October 4th, so the timing of this, of this symposium is very interesting because it just did roll out. Has anyone seen the pathway in the EpicCare build yet? No one, that's interesting because Dr. Starz just pointed out to me today that although it's supposed to flag for a pathway that you can click into it seems that that functionality in EpicCare is not yet working so that's an interesting thing I need to take back to our committee. But nevertheless I'll show you the process, I'll introduce you to, to what it actually will look like when you are able to open it in your EpicCare system.

So we had a multidisciplinary group of content experts so brought people together that were taking care of patients with low back pain, surgical and nonsurgical, administrators, health members of the health plan and members of E-Record. I'll mention to you later it would have been helpful to us to actually bring the E-Record, electronic medical record, people into the discussion sooner than we did, we would have learned a lot from that process. But we did bring them in toward the end of the development.

We had a very iterative approach, so there were many, many, many versions of this pathway. We modified this based on multiple stakeholder input and feasibility, probably the most important input we had was from primary care physicians helping us to figure out the feasibility of this. And the sources that we used were obviously we went to the primary literature, we went to Cochrane and systematic reviews, and we used consensus guidelines. This was particularly important because as we are entering this era of meaningful use in a time in which we are going to be required to present patient reported outcomes what we felt was really important was to kill two birds with one stone if you will with the pathway, and that is develop a pathway to help standardize care and be a tool for a primary care physician or others taking care of low back pain but also to start to satisfy some of the meaningful use in patient reported outcomes requirements.

So we paid careful attention to National Quality Forum endorsed metrics because all things are starting to point toward the fact that CMS is likely to adopt some of the NQF, National Quality Forum, endorsed metrics. So if we incorporated those into our pathway it's hopeful that when that comes down the pike that we'll be ready and it's already setup in the system.

So interestingly enough defining – so the first pathway we set out to develop was for acute axial low back pain. Interestingly enough coming to consensus on the definition of that one simple entity was the hardest part. It took us many, many rounds and many iterations to all agree that what we were defining – the reason this is important is it defines who is going to then flow into that pathway. So the definition that we eventually came up with was that it was nonradicular pain, this was very important, muscle tension or stiffness primarily to the low back because of course we all know that our patients describe things somewhat diffusely at times, below the costal margin, above the inferior gluteal fold with or without referred pain without neurologic symptoms. So that wording was chosen very carefully because we know a lot of our patients will have referred pain particularly from facet mediated pain for example and other things that are not radicular and less than 12 weeks, again staying with that acute. Importantly patients with a true radiculopathy were excluded from this pathway, however as of this morning actually in our committee meeting we've started to develop an analogous parallel pathway for the use in patients with radiculopathy, so that's coming down the pike. But for this first path that was eliminated from the pathway.

So I put this up not so that you can really appreciate the nuances of everything that is involved here but yet you can see how complex our initial pathway was. Each of these decision nodes was based in best practices, in evidence based medicine. We went from identifying red flags to determining if imaging was indicated to examining patients for a stepoff suggestive of spondylolisthesis, discussion about evidence based medication usage, etc., etc. And like I said all of these decision nodes had backup information. So we finally completed this, we all sat back, we patted ourselves on the back

and we said what a great job we did. We rolled it out to the electronic medical record team, we rolled it out to the primary care physicians who are advisors on this and they looked at us and said are you nuts? No one is going to be able to incorporate this into their daily practice, in to a 15 minute office visit where the patient also has 3 other complaints by the way besides their low back pain. So we said ah, we should have brought you in earlier on this process. So that was lesson 1 that was learned. But the feedback that we got was invaluable and it really has resulted in us making a lot of changes.

So what we learned from this first pass was the usability of the pathway was paramount. So in addition to it being evidence based and complete it also had to be usable; and also the definition as I mentioned how difficult it was to get to that definition of low back pain but how we actually implement the pathway was of critical importance. It's clear that the scheduler who is called – who is taking the call and putting that patient on the schedule cannot kickoff the pathway because they are not going to be able to make that determination. So we had to do some backwards working thinking okay how can the MA who is rooming the patient actually get this started so that the physician doesn't have to go through a series of questions once they get into the room because all – I can relate to the fact that the last thing any of us want in our busy practices is more things to click on during a patient encounter. So we had to really figure out how we would start to implement this and the final decision was that in fact it would be that MA that would be guided through a series of questions that would help us identify the appropriate patient.

So as we streamlined this we looked for the big wins to go after. And how did we identify those big wins? Well our primary care advisors told us the things that would help the most in the clinic flow would be red flags. What those red flags are, how to identify those red flags and what's the appropriate order set to go with those red flags, something really simple and clickable there for the red flags would be user usable and also to streamline only the most important pertinent outcome measures. And so initially we had a lot of different information that we were collecting from that patient, things like physical activity, physical activity stages of change, where were they in terms of their readiness to participate in an exercise or physical therapy program? We collected a lot of other different information about that patient and realized that again we needed to boil that down because if that meant the patient was sitting in a waiting room taking extra time to fill out their paperwork they were missing their appointment.

So we needed to boil that down to what was most important. And what we determined that we would keep is two questions that I'll show you from a physical activity standpoint that is a red flag for someone who is unlikely to do well without a structured program and the Oswestry Disability Index, and that is a patient report set of questions where they go in, answer how does their pain impact their functional abilities to do different activities of daily living and instrumental activities of daily living.

The reason we kept the Oswestry in was again because all signs are pointing to the fact that this is going to be one of the metrics that we are going to be held accountable to in terms of quality when we look at low back pain. So how is functional disability as measured by the Oswestry improved after your encounter with that patient? So if our predictions are correct that the Oswestry is what is

adopted for that metric then we'll be ahead of the curve by implementing this and that was really the goal here.

So here are some of the recommendations that we came to, and again I am not meaning for you to go through all of this right now, this is really here for your reference if you are interested in where we came up with all of the recommendations that we made about medications. The references are listed here and in the slide set as well that are in your packet. But nonsteroidal antiinflammatories if the GI, cardiovascular and renal side effects are appropriate and acceptable, otherwise start with Tylenol. No evidence for one NSAID over the other though in terms of going back into the literature for low back pain. Muscle relaxants, there is strong evidence for nonbenzodiazepine, so not Valium and other benzos within the first week only. So for acute low back pain it's really only in that very acute timeframe that muscle relaxant is appropriate. Maybe for the first few days, obviously the side effects should be considered. That is most of these are on Beers list for the geriatric population as you are probably aware of. Soma as was mentioned in our case is metabolized to a metabolite that has a risk for abuse and overdose so Soma is one that is relatively contraindicated and should be used with caution. And sometimes combining with NSAIDs can add some synergy again during that first week. For beyond that first week there is no evidence to suggest that a muscle relaxant is beneficial. Ultram is a potential option for patients, really not a lot of data to support this however. There is a single randomized placebo controlled trial showing some benefit in acute low back pain, but it is an option that's out there for you outside of the opioid pain medications.

So what is not recommended? So for acute onset of low back pain opioids are not recommended, there is insufficient evidence to support their use. If used at all it should be limited to less than 2 weeks for an acute episode of low back pain and there is really no good evidence to suggest one over another. We all use these occasionally but you know the consensus at this point is the rare use of opioids really for those patients who the pain is so disabling and can't be controlled with the other lists in the hierarchy.

Other things that are not recommended for acute axial low back pain are oral steroids, tricyclic antidepressants, SSRIs, SNRIs and Gabapentin and other antiepileptics. Now keep in mind that this is, we have not included radiculopathy in this subset, so we are talking about nonradicular acute low back pain. So these medications have not shown sufficient evidence to be recommended. This doesn't mean that they are not available to you, it just means they are not recommended in the pathway as you get your Smart Sets to come out of the pathway. These are the references if you are interested.

So how do we do with – so that's kind of the body of existing recommendations, how do we do with that? So interestingly enough in a study that came out in 2010 in the emergency department opioids were the most commonly prescribed medication for acute low back pain, 62% of patients presenting to the emergency department received an opioid. So despite the recommendations against that 62% were prescribing opioid. PCPs same thing, discordance with the recommendation about 40% discordant with the recommendation of opioids and 91% were discordant with the use of muscle relaxants in an acute episode of low back pain. So again this was 2010 data.

So we think okay well we certainly do better than that here in a more academic setting. This is old data now but we actually reviewed some data, some early data from the pathway this morning and I can tell you the patterns are not dissimilar. This is data from our own health plan that came out in 2001 and 55% had for low back pain had analgesic claims, a total of \$1.4 million in costs and 68% of those that were prescribed a medication were given an opioid. So again we are not following, we are not following best practices, 58% were receiving an NSAID. In terms of the total health plan expenditures for pain including cancer pain, low back pain was almost 50% of the utilization of opioid medication, again going against the current recommendations here. So there is some work to do, there is some things that we can build into this pathway to help us. It's interesting what has been seen in all of the meaningful use, the good things if you will that have been seen in many of the meaningful use initiatives that have been done is I think we all think we are practicing in a certain pattern and when we go back I know when I've gone back and look at my own utilization I'm surprised by what I see. The way I think I practice is often distinct from what you actually see, and when you aggregate all of the data together. It's an interesting exercise and one which we are all going to be forced to do here very soon.

So what about other guidelines? There was 35% discordance again in a study in 2010 in regards to recommending diagnostic imaging for acute low back pain which are pretty strong recommendations that we should not be imaging the noncomplicated patient without red flags in the first couple of weeks. Other components that could potentially have an impact that perhaps we can improve upon by the use of our pathway, so 9% were still recommending acute bed rest after an episode of back

pain and we've known that now for 10 years, at least 10 years, probably more going on 20 that the sooner we reactivate the patient the sooner we get them moving the better their long term outcome. So a recommendation of bed rest is not something that we should be providing our patients. Instead we should actually be giving them information about how to remain active and this is something that we've built into the pathway to actually give tools to the referring physician that are printable on the after visit summary and deliverable right to the patient.

About 42% fail to give any advice or education regarding the management of low back pain and what we do know is that the more the patient understands about their back pain and they are not fearful about movement, they are not fearful that they are going to injure themselves further the better that they do. So that little bit of education is a very important piece here and it's something that we are missing in our clinical practice and again building this into the pathway where it's as simple as click it, it goes into the after visit summary, it prints out for the patient is something we are hoping we can improve upon those numbers.

So almost one year later this is what the pathway currently looks like and this is what was built into EpicCare, those of you that are using EpicCare. So the patient presents with a chief complaint of low back pain, so the chief complaint lists it as low back pain, back pain or acute low back pain. The MA will then enter that and it will prompt the MA to answer a couple of questions. One is have they been to physical therapy before and two other questions about their fear of movement. These two questions that I'll show you have good diagnostic sensitivity and specificity for predicting

people that are not going to do well, that are not going to do well without a structured exercise program. And obviously we collect information specifically about their pain as well.

If time is permitting at this stage the patient completes the Oswestry Disability Index, if not they see the physician and they complete that at the end of the visit before they leave ideally. The physician then enters the room and they get a pathway prompt. The patient is presenting with low back pain, go to the pathway please. And there the first set of information is evaluating the patient for the red flags. Again this is the advice that we got from our primary care advisors that this was one of the most useful things and so there are toggle buttons that are listed there. So evidence of malignancy, infection, spondylolisthesis, cauda equina, fracture, inflammatory disease, progressive weakness or non-musculoskeletal causes, if you click on any one of those it takes you to a suggested Smart Set for orders that then you can place to further workup that red flag diagnosis.

If any of those red flags are negative the physician – so all you can click, you can just click none. If you click none it takes you to a screen – it takes you to a screen that will say no imaging is indicated.

Okay, so in the absence of red flags in acute presentation of low back pain no reason to refer for an MRI. Okay, and we felt again this was one of the big wins here that we would be able to have an impact on.

The physician is then given the answers that the patient already answered to the fear avoidance as well as the description of their pain, so again hoping to try to streamline the visit a little bit, they are already given those answers. And these are the decision nodes here, so again we've very much

simplified this. So the three decisions are one would be a home exercise program and that's recommended if the patient has a history of a similar prior episode, a history of being compliant with a home exercise program in the past and their pain is identical to what they had experienced before and they had done well with a home exercise program. We all know that we have patients who for various reasons financial issues included don't want to attend physical therapy and so we built this into the pathway so that there is a way to give them some exercise guidance if they are not interested in attending physical therapy.

The physical therapy referral is strongly recommended if they agree with any of the fear avoidance beliefs questionnaires. And again these questions if they answer yes to suggest that they are going to have so much fear of movement that they are unlikely to engage on their own. And then a physician referral if the pain is so severe that the patient can't participate in physical therapy, so that can be clicked on. Obviously that will also take in addition to taking you to a list of potential referrals it will also take you to a list of potential medications if you are comfortable managing that on your own. It will give some recommended medications or you can just click to the referral. And then the follow-up will occur after that.

So this is kind of what it looks like in the EpicCare build, again the pathway triggered by a chief complaint of low back pain, acute low back pain or just garden variety back pain. Here is the patient presents with back pain, please click the low back pain intake. And this is the click, Dr. Starz, that is supposed to be active. Is that the one that you tried to click on? It is not active. So that's very important. That would explain our utilization over the last week of 20, so we had 20 people that

actually opened the pathway and we thought maybe they just didn't like it, but it turns out that maybe the link is inactivated in some offices. So they will be asked how long have you had it and have you been to physical therapy in the past? And this is what the MA fills out okay. So again this was streamlined from what was originally proposed believe it or not. It still looks like a lot but what we found is that this can occur in pretty much less than a minute, unless the patient is really kind of thinking a lot about what they want to answer.

These are the two questions that I mentioned. These two questions are the questions, so I should not do physical activity which might make my pain worse? Or I should not do my normal work with my present pain? If the patient answers yes to either one of those that is what we consider a yellow flag, so that's a good indication that this patient is unlikely to do well on their own and need some structure to what they are doing. And then talk – get some specifics about the pain itself and then this is where the Oswestry Disability form is filled out.

The provider then enters the room, the provider is prompted with this link to click on the pathway and here is those toggle forms for the red flags. If you click on any of these red flags it takes you to a Smart Set. If the red flags are negative you see this screen that says no imaging is indicated according to the UPMC pathway. Please be aware of concurrence of depression in low back pain and proceed with placing orders from the Smart Set. If patient agrees with either FABQ which you are reminded of here, strongly recommend a PT referral. And then it just repeats the definition here for you. It also gives you the Oswestry so when you see them back in follow-up you can see if

you've implemented a change in their disability. Obviously it gives you their back score and the location of their pain as well.

And then this is an example of the Smart Set that comes up. So it will come up pre-checked based on what has been entered by the patient so this one is pre-checked with home exercises which since the patient disagreed with FABQ they have been to physical therapy in the past, maybe you can try a home exercise program. What that will do is it will provide information about what that home exercise program structure could be that will printout on the after visit summary. So again it gives you the patient information that you can just hand to the patient. And all of this was designed with efficiency in mind. The PT referral, the consult here is listed if they have agreed with the fear avoidance questionnaires and then referrals if needed.

So that's where we are now. I can't help but take an opportunity to just give you a snippet of where we would like this to go. So obviously we need to make this – so this is working on making things more standardized but how do we go back to making things more personalized? Clearly the way we've done it in the past hasn't been working because we haven't been getting better results. So the research that we are doing in our own laboratory is really looking at how can we understand the biology of what's going on in back pain better and use that to guide our treatment paradigms? So we have in vitro model systems where we can actually take the cells and expose them to stretch for example. And what we've seen is that with certain magnitudes and durations of mechanical loading we can actually have an antiinflammatory response so the exercise in and of itself can be antiinflammatory. So the more we understand the biology of that the more we can rationally design

the treatment program for that individual patient. We have ex vivo model systems where we can also look at what's happening at the whole tissue level and put the entire functional spine unit while it's still bioactive through an exercise regimen and understand what happens to the biology, look at the changes in gene expression, look at the breakdown of the matrix if that's occurring. And then lastly we have in vivo model systems where we are actually starting to look for some of these markers in human serum to help guide us. So the pie in the sky goal with all of this is then to understand what is appropriate for that specific patient, not just from an exercise protocol but for other things as well.

And hopefully that will allow us to design exercise based protocols with improved outcomes whereas much of what we are doing right now is based on the empiric evidence that we've had in the past.

So this is just to really hit this idea home that the MRI is not helping us a lot, this, this has been in the literature for quite some time. This is data from our own laboratory where we looked at adults 65 and older with axial low back pain. We compared their pain score here shown on the X axis with their MRI index which is a computer generated assessment of the health of the intervertebral disc. We also compared their pain score against two clinical radiologist readings and what you can see was there was absolutely no correlation between the patient's pain and their findings on MRI. This probably doesn't come to a surprise to anyone that has taken care of a particularly older adult population. Importantly as well the MRI findings as read by our radiologists did not have any correlation to function, so SPPB is Short Performance Physical Battery, it's a test of patients'

function, it tests walking speed, ability to rise from a seat, these sorts of functional endeavors and really there was no correlation there as well.

What we did see was some small to moderate correlations however were some of the blood based biomarkers. And in fact as you start to link some of those biomarkers these biomarkers all have some biochemical rationale to them so they all have come out of the in vitro and in vivo model systems that we've used so that we know they have some relevance to the low back pain problem. As you start to combine those into little small panels you start to see some moderate correlations between things like their pain, their depression, etc., again still moderate but certainly better than what we were seeing on the MRI. So we are hopeful that this is going to be helpful as we move forward.

And some hot off the press data that is way too early for me to be sharing but I'm going to share it anyhow because I find it so exciting is we are currently doing a study where we are looking at blood based biomarkers as predictors for who will and will not respond to an epidural injection. So what we know is that there is a subset of patients – so the literature right now for epidurals as you are probably aware is all over the board. There is no good evidence to suggest who we should be injecting, when we should be injecting and as you can see what has happened with the injections is they've just skyrocketed because they are reimbursed very well frankly, and speaking somewhat cynically. However what we know is that if we can predict the subset of patients who are more likely to respond we don't put the patients who are unlikely to respond at unnecessary risk, we save the health system money by not doing procedures when they are likely to be futile and we effect

better outcomes by only treating those patients with that injection whereas the other patients we would treat with a different treatment paradigm. And this is just some of that early data that in our patient population this is only 40 subjects, so the study is underpowered at 100 and we are only at 40 right now, but the patients that responded, so got a beneficial response to an epidural steroid injection had a significant correlation with an R of .79 between the change in their pain score and the level of an inflammatory marker RANTES that was present in their blood before the injection. So it's really exciting, really early preliminary data but I'm hopeful that this is going to help us further refine things down the road. Maybe someday we can think about a pie in the sky idea where we can think about a blood based biomarker much like we do for many other conditions for back pain and have that to help guide our treatment.

So through going through this whole exercise of developing this pathway what are the lessons learned and the keys to success? So what we found it is necessary but not sufficient is efficiency, medical records support as I mentioned early on, and overlap with meaningful use and patient reported outcome requirements. So again as we are all going to be required to submit these the more we can do to kill two birds with one stone and implement these patient reported outcomes into our pathway systems the better off we are going to be prepared for when that comes down the pike.

What is mandatory is multidisciplinary buy in, so getting everyone to agree to this process which is no small task, really this is what makes us go back to the evidence, go back to the evidence based practice. We all have different styles of practice and going back to the evidence is really important in getting everyone to come to consensus and a spirit of collaboration. So again with the idea that

we are kind of all in this to improve the patients' functional outcomes, checking the turf battles at the door before coming into the committee meeting was a very, very important thing to make this, to make this flow. And so I really see this as a particular opportunity in low back pain. So as we enter this new healthcare era I see this as the glass half full as we think about low back pain. So as opposed to thinking about rationing care what we are really talking about is doing less for the patient and by doing that maybe actually doing more. This is different from doing nothing, okay. But we can have the opportunity to do here is do less of the inappropriate things and streamline our care so that we are providing more appropriate care not necessarily imaging that patient every time they come in, not necessarily doing an injection for every patient but really looking at what's going to be appropriate at that level of care so as we have a time where we are faced with what's going to be quality based reimbursement, not quantity based reimbursement the disincentives are going to start to be removed, we are going to need to increase our use of collaboration using each other's strengths in all of our different fields to then result in improved health and quality of life for our patients. So I really think there is a unique opportunity, a particular opportunity in low back pain that we can accomplish this and I think the time is right for us to do that.

So I'd just like to thank the people that worked so hard on this. As you can see a very multidisciplinary group of committee members, we had a lot of support from the EpicCare team and we had a lot of support from our primary care reviewers early on in the process. And as I mentioned this has been rolled out, it's rolled out as of October 4th, I'd be very interested at this stage in your suggestions and questions because this remains an iterative work in progress. So it's something that we plan to continue to revise, continue to change to make this more useful to everybody so it

shouldn't be an added burden but it should actually be something that helps in the flow of the patient clinic encounter, but also continue to improve things for the quality of life of the patient. So thank you very much, I'd be interested in your comments.