

ACTION-APS
Pain Taxonomy Meeting

July 19, 2014

A Matter of Record
(301) 890-4188

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6 **ACTION-APS PAIN TAXONOMY MEETING**
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10 **Saturday, July 19, 2014**
11 **1:05 p.m. to 3:57 p.m.**
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14 **Westin Annapolis**
15 **Annapolis, Maryland**
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1 **PROCEEDINGS**
2 **(1:05 p.m.)**
3 **DR. BRUEHL: Let's go on and get started.**
4 **We're on a little bit of a tight time schedule this**
5 **afternoon because obviously a number of people are**
6 **leaving. And unlike what is on the agenda, we're**
7 **going to try to shut things down by 4:00,**
8 **regardless of whether we've finished or not.**
9 **Now, just keep in mind here to keep on**
10 **schedule because the number of groups we've**
11 **got -- Bob had this all worked out. So we've got**
12 **about 15 minutes total for each working group to**
13 **handle what they need to handle. So what we would**
14 **like to do is have discussion that is no more than**
15 **10 minutes. And then the remainder of that time,**
16 **up to the 15-minute mark, is discussion and**
17 **questions and that kind of thing.**
18 **I'm going to be actually timing just to keep**
19 **us on track. And I think if we have questions that**
20 **are urgent that we need to get addressed, why don't**
21 **we write them down. And then maybe after the**
22 **meeting is over, we can discuss them more, those of**

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1 us that are still around, kind of come back to
2 those.
3 Presumably, every working group has a
4 presentation of some kind, maybe PowerPoint or some
5 other program. The computer up here is ready.
6 Has everybody loaded what they want to
7 display during their talks? No? Okay. If you
8 want to get a thumb drive, you can just put it
9 directly on there, and we'll be okay.
10 So when you were up here -- the way it was
11 written was that there were going to be multiple
12 people. So like the working group co-chairs would
13 be presenting this potentially. Because there
14 might be more than one person, we had it set up so
15 that you could just sit up here. Whoever is going
16 to be doing this can talk. Please use the
17 microphones so this can get on the transcript.
18 We've got the clicker up here for advancing the
19 slides, and you can see the slides from the front.
20 So this should work okay.
21 Now, we're going to start -- the questions
22 about -- thank you. Say your names, please, when

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1 you start -- if you bring up questions of anything
2 when you start talking. I'll try to introduce each
3 group so that gets on the record who it is that's
4 presenting.
5 The first group is going to be the
6 Neuropathic Pain working group, and this is -- Roy
7 Freeman and Rob Edwards were the co-chairs. And
8 it's for the central pain. So we've got peripheral
9 and central are two separate issues.
10 Presentation - Roy Freeman
11 DR. FREEMAN: My name's Roy Freeman. We
12 decided that we would combine the central and
13 peripheral group, and the entire group had some
14 heavy hitters. Stephen was part of the group. Bob
15 Dworkin was part of the group. Simon was part of
16 the group, and you see the three over here. And
17 each one of the group brought three opinions to
18 every topic we discussed.
19 (Laughter.)
20 DR. FREEMAN: I've decided to ignore most of
21 those. And so what you're going to hear today,
22 now, in the next five minutes, is going to be kind

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1 of brief, a distillate of all of that. But don't
2 be too surprised if Bob Dworkin says, "That is not
3 what I said."
4 (Laughter.)
5 DR. FREEMAN: And when he does that, just
6 ignore him.
7 Okay. So here we go. We were the central
8 and peripheral neuropathic pain group. We decided
9 to combine the two groups together and to come up
10 with an approach that was concordant with the
11 diseases that were within both set of charges that
12 we were given.
13 These are the disorders: central post-
14 stroke pain; spinal cord injury pain; pain
15 associated with MS and peripheral DPN; idiopathic
16 peripheral neuropathy; post-traumatic neuropathy,
17 including that induced by surgery; complex regional
18 pain syndrome; and PHN.
19 Now, in putting this together -- and we are
20 going to focus purely on Dimension 1 -- we
21 negotiated our way between and wanted to provide
22 some value added to what was put out by the IASP,

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1 the two articles by Rolf-Detlef Treede and Troels
2 Jensen, and also position papers that have been
3 taken by various diabetic peripheral neuropathy
4 groups. So what we hope, particularly in the
5 peripheral side of things, is that we would provide
6 some value added to that.
7 So these are the proposed core diagnostic
8 criteria. I mentioned one that would fall in the
9 basis of the diagnosis. And we showed as the first
10 criterion to focus on history. It's going to look
11 as if this was a no-brainer, but I would say a good
12 hour was spent discussing where history should be
13 in these criteria -- so a disease that affects the
14 somatosensory central or peripheral nervous system;
15 for example, spinal cord injury, stroke, MS,
16 diabetes, chemotherapy, trauma, surgery, and herpes
17 zoster shingles.
18 Now, the challenge was, at least for the
19 peripheral people, that in 50 percent of peripheral
20 neuropathies, generalized peripheral neuropathies
21 that look, to all intents and purposes, like HIV
22 and DPN and all of the other causes of a peripheral

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1 neuropathy, no cause is found.
2 This is a challenge. And the way we chose
3 to deal with this was that these would be the
4 building blocks upon which the classification was
5 built and would apply to a greater or lesser
6 extent, and most times to a greater extent to the
7 various disorders that were subsumed under these
8 specific core diagnostic criteria. So this is
9 Criterion 1.
10 Then we said that pain for at least three
11 months -- and there was some debate as to the
12 duration -- that confirms to a recognized
13 neuroanatomical distribution of a simple nervous
14 system lesion or one or more cranial nerves,
15 peripheral nerves, or nerve roots.
16 I appreciate, with respect to the nerve
17 roots, that there's going to be some overlap with
18 John Markman and his group looking at spinal and
19 low back pain. But certainly, radiculopathies are
20 midway between the peripheral nervous system and
21 the central nervous system. So we felt it had to
22 include that just in the interest of completeness,

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1 not to leave a void between the central and
2 peripheral nervous system and look at pain over
3 that. We'll come back to that in a second.
4 There also needed to be positive
5 signs -- for example, allodynia,
6 hyperalgesia -- and/or negative signs -- sensory
7 loss and/or weakness -- that conforms to the
8 distribution of either a central nervous system
9 lesion, one or more cranial nerves, peripheral
10 nerves, or nerve roots. So we've got a
11 combination. We've got a history. We've got
12 symptoms, and we've got signs.
13 Then -- and this is the challenge. And this
14 is the missing piece on all of the attempts to come
15 up with -- various organizations -- how many and
16 what positive signs and what positive symptoms
17 using what questionnaire are necessary to make the
18 diagnosis. And we proposed, our best guess, that
19 one of each was sufficient, but we do not know
20 that. And nobody knows that. And surprisingly
21 nobody knows that, and this is part of our research
22 agenda.

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1 Then we thought -- and here was another one
2 of the challenges that we faced -- what about the
3 general practitioner operating in an environment
4 where he doesn't have access to the special
5 investigations? So we added, when possible to
6 confirmation of a lesion by objective tests; for
7 example, neuroimaging for the central guys,
8 neurophysiology for the peripheral people or
9 perhaps for the central people, and pathology, and
10 in particular, skin biopsy.
11 Then finally, this specific condition could
12 not be better explained by anything else.
13 There were issues, which we barely touched
14 on, on how to deal -- when we specify a particular
15 territory. And I don't have time to go into the
16 topographical approach that we proposed to this,
17 how to deal with referred pain, very common, for
18 example, in entrapment neuropathies such as carpal
19 tunnel syndrome, extending beyond the innervation
20 territory; how to deal with extension outside the
21 innervation territory due to central sensitization.
22 These are the challenges with any such

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1 taxonomy. And also, we did not define specifically
2 the temporal relationship to the toxin, the insult,
3 the infection, or the injury.
4 Research agenda we thought would be divided
5 into stages. The first stage, we would make use of
6 a number of existing databases in which signs exist
7 and symptoms exist. And there are a number of
8 databases using pain detect, the NPSI, various
9 other symptom inventories.
10 Also, using quantitative sensory testing,
11 both bedside, easily performed at the bedside, and
12 more complex using sophisticated instruments, we
13 would use these to look at what combinations, what
14 patterns of signs and symptoms, were necessary to
15 specify a diagnosis. And we would use the -- let's
16 call it the Steve approach, stage 1, that he had
17 with CRPS to try and look for patterns that would
18 actually give an evidence-based numeric basis to
19 the one or other sign or symptom that we proposed
20 for criterion number 2 and 3.
21 Then -- and this is still under
22 discussion -- we proposed a more extensive study in

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1 which we would pick one or two of our disorders,
2 and we would prospectively, using prespecified
3 symptoms and signs, define what are the ideal
4 combinations. And in that situation, we would have
5 a prespecified comparator disease.
6 For example, for diabetic or any other
7 peripheral neuropathy in which there is foot pain,
8 we would have as a comparator plantar fasciitis.
9 And this is all topics for additional discussion.
10 I think that summarizes -- that I think is a
11 reasonable summary of what we discussed over the
12 past two days. I don't know if Rob and Eva want to
13 add anything.
14 We are open for questions.
15 (No response.)
16 DR. BRUEHL: Somebody must have a question.
17 DR. FREEMAN: Just to make us feel that this
18 was not all in vain.
19 (Laughter.)
20 DR. BRUEHL: We're in such awe.
21 DR. FREEMAN: Let's get out of here.
22 DR. BRUEHL: Before they pin you down on

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1 tough questions, right?
2 I do think that the research agenda part of
3 this -- when we came up with this -- well, let me
4 back up. For the CRPS, there were a multitude of
5 features to look at, the edema, color, temperature,
6 range of motion, all these things. And when we
7 came down -- I'm just being honest here with what
8 happened.
9 When we came down to looking at this,
10 really, there's that one area in our diagnostic
11 criteria where we've got a positive and a negative
12 sign or symptom, and that was it. We couldn't even
13 come up with exactly what those should be, some
14 things like allodynia, some numbness, sensory
15 testing that indicated numbness, that kind of
16 thing.
17 So what we were trying to do, though, is
18 look at the literature and what prior diagnostic
19 criteria had suggested as features to look at and
20 diagnosing it. And those were the positive and
21 negative things we were considering. But we also
22 wanted to go a little broader than that and

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1 consider looking at the neuropathic pain
2 questionnaires that have a lot of descriptors of
3 pain to see, for example, whether maybe burning
4 pain is something that is common enough in most
5 people that would have this diagnosis, that would
6 actually be useful in diagnosis. But we weren't
7 sure it was.
8 That's the kind of thing we're leaving open
9 to empirical testing later on and hopefully would
10 be able to find away to justify whether that needs
11 or doesn't need to be included in there.
12 Yes?
13 DR. WESSELMANN: This is Ursula Wesselmann
14 from the German Neuropathic Pain Network, which is
15 such a long testing paradigm, which as you said is
16 not possible really to do in mass settings. But
17 has anything filtered out to be more useful than
18 the other one to phenotype?
19 DR. FREEMAN: So let me answer you. I want
20 to just elaborate -- you get a taste of what our
21 group was like -- on something that Steve said.
22 And that is, I think in designing our clinical

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1 trials, we also want to be very careful -- in
2 designing our research studies, we want to be very
3 careful of the circularity that is a huge part of
4 all of these kind of research studies in which best
5 available clinician diagnosis is that burning pain
6 represents small fiber neuropathy. So the gold
7 standard is burning, and the conclusion is burning
8 is the core feature of peripheral neuropathy.
9 You can look at all of these studies and
10 bang your head against the wall. So I think in
11 designing this -- and we discussed this in some
12 detail. And why I said more to come is that we
13 want to try and do a study of that nature and avoid
14 the circularity, but it's not so simple.
15 So that's the one point. Then the other
16 point about the German network, the German network
17 doesn't really address this question. It brings in
18 patients that have specific disorders and they look
19 at the pattern. It doesn't go backwards, which is
20 the way we want to do. That's one thing.
21 The other is that I put together a very
22 short evoked pain, quantitative sensory testing

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1 assessment, which can be done at the bedside using
2 tools from Home Depot, and can be done in
3 15-20 minutes. And Pfizer actually has used this
4 to make clinical trials, and we've reported in Pain
5 last year.
6 So there is a potential tool available that
7 can be used in 20 minutes, which will use -- von
8 Frey has -- a series of evoked pain assessments,
9 including temporal summation, and can be done at
10 the bedside. So there is something available to do
11 something prospectively.
12 DR. BRUEHL: So we were trying to factor in
13 the bedside issue versus requiring a lot of fancy
14 testing, and we tried to fudge that by the wording
15 about "if possible" the confirmation by objective
16 test.
17 In the circularity issue, just to reiterate
18 because this will be across all groups -- so the
19 options we have are something like Roy just
20 proposed up here, which is looking at a database of
21 signs, symptoms, test results, and looking at
22 frequencies, correspondence between things. You

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1 can use factor analysis, cluster analysis, to try
2 to identify patterns in those things that hang
3 together; things that overlap and may be redundant.
4 So those kinds of questions.
5 We've got the sensitivity/specificity issue
6 in the -- honestly, these are like bootstrapped
7 research studies because there is a circular
8 argument in them. But in essence, what we can do
9 is we can take our criteria that we come up with
10 that we want to test, and then we've got a
11 comparison group that we have to diagnose somehow.
12 But let's say that we just have some
13 clinician agreed upon this is what the other
14 condition is. And then we use those criteria that
15 we used to define the first group to see if we can
16 discriminate between those two groups.
17 It sounds ridiculous, but it actually can
18 provide some useful information, especially when
19 you talk about what happens if I add an extra
20 requirement for this sign, or that sign, or change
21 this. You can look at relative changes. So that's
22 kind of what we have.

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1 The third option we've got, which is
2 problematic but it's a possibility and it provides
3 a bronze standard is clinician agreement. So if we
4 can get expert clinicians who can look at the same
5 package of data and say we both agree that this
6 person has X disorder, then that becomes another
7 source of information for validating the criteria,
8 validating it against clinician opinion, which also
9 may be not very good, but it's another approach.
10 So all of those approaches can be used for
11 any one of these conditions potentially. I just
12 wanted to say that one time. I won't say it again.
13 DR. FREEMAN: John, you look like you've got
14 a good question.
15 DR. FARRAR: Me?
16 DR. FREEMAN: Yes, you.
17 DR. FARRAR: John Farrar. I'm hesitant to
18 say this, but I'll say it anyway. What about using
19 prospective testing using drugs that we think have
20 an effect on the mechanism? You're clearly going
21 to be influenced by the fact that there are lots of
22 other reasons why certain people might not respond.

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1 But if you took two diverse groups -- if you took a
2 group, and you looked at those who had an
3 outstanding response versus those who had no
4 response, could you use that as a way of
5 bootstrapping, again, to come up with the major
6 issues?
7 DR. FREEMAN: This came up briefly, and I'm
8 going to defer to Eva to answer this question. It
9 came up briefly in our discussions. And it came up
10 specifically with spinal cord injury pain, where
11 the spinal cord injury pain was mechanical,
12 neuropathic, and mixed. And Eva mentioned that the
13 mechanical responds to non-steroidals and the
14 neuropathic presumably responds to neuropathic
15 drugs.
16 We didn't discuss this in detail. We let it
17 drop. But I did think about that, and I want to
18 hear what you think about John's suggestion.
19 DR. WIDERSTROM-NOGA: First, logistically,
20 it's difficult to do, of course. It will take a
21 long time for us to get an appropriate sample size.
22 One of the issues that we have in spinal

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1 cord injury is that people have
2 concomitant -- several types of pain with different
3 mechanistic underpinnings. Some of them are
4 probably overlapping and some of them are
5 different, so it makes it very difficult for us to
6 do it in spinal cord injury.
7 DR. FARRAR: Could I follow up?
8 DR. BRUEHL: Let me just let you know.
9 We're at 17 minutes already, so we're over this
10 first one. Some of these questions are kind of
11 going to be things that will apply going forward.
12 That's probably okay. But make sure it's urgent at
13 this point now. Urgent questions? You can bring
14 them up with the next group I'm sure.
15 (No response.)
16 DR. BRUEHL: All right. Let's move on to
17 the next one. And again, if there's something that
18 you didn't feel got resolved adequately in this
19 discussion, write it down, bring it up after the
20 meeting, and we can talk about it some more maybe.
21 So we've got Steve George and John Markman
22 who are going to be covering the spine pain.

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1 Presentation - John Markman
2 DR. MARKMAN: Good afternoon, everyone.
3 This is Steve George, and I'm John Markman. We're
4 from the low back pain group. We just want to give
5 you a window into our deliberations. We have a
6 diverse working group, so we began with a series of
7 exercises just to develop a core, sort of trust,
8 among the group. So we just began our
9 deliberations with this process.
10 (Laughter - slide shown.)
11 DR. MARKMAN: We found it very helpful. The
12 reason that was so important because we started
13 talking about back pain, and we had a chiropractor,
14 a psychologist, a physical therapist, a psychiatry
15 expert with a degree in philosophy, a neurosurgeon,
16 and a neurologist all talking about low back pain.
17 So we really need to find a little common ground to
18 start.
19 I'm going to let Steve talk about
20 Dimension 1, where we tried to address and
21 inoculate against what Roy just talked about with
22 the circularity issue.

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1 Presentation - Steven George
2 DR. GEORGE: Dimension 1, I think,
3 conceptually, one of the things that helped us
4 define Dimension 1 was sensitivity versus
5 specificity. And we took a very sensitive approach
6 to Dimension 1 and really took also a philosophy of
7 this being more purely a taxonomy than a diagnostic
8 criteria because the diagnosis of back pain is not
9 really a major issue right now. I think what may
10 be of more value is that this is, on a scale or on
11 the continuum, much closer to description of
12 syndromes.
13 So we actually for Dimension 1 -- and it may
14 have been the trust exercises. After that, I think
15 we made some good progress. We felt pretty
16 comfortable with having it be patient self-report
17 of chronic low back pain, used the NIH definition
18 of chronicity to define the temporal part, and then
19 the location is actually part of Dimension 1, where
20 it's in the region between T12 and the gluteal
21 fold. So that's our Dimension 1.
22 Really, we talked about including signs

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1 here, but we really -- there is essentially no sign
2 that we're aware of that can rule us out at this
3 time if someone reports these symptom
4 characteristics. So that was our take on
5 Dimension 1.
6 DR. MARKMAN: We were also I think trying to
7 address what happened with the NIH low back pain
8 working group --
9 DR. GEORGE: Yes.
10 DR. MARKMAN: -- where their attempt to
11 develop a research diagnostic criteria really, as
12 our fight with this, was a bit of a modified effort
13 where they felt they couldn't do that because they
14 didn't start like this. And instead ended up just
15 with a minimal data set. So we wanted to navigate
16 away from those shoals, and that's why we really
17 focused on sensitivity in Dimension 1.
18 So we had a lot of constructive dialogue
19 between the members of our group, and this was part
20 of an ongoing discussion.
21 (Laughter - slide shown.)
22 DR. MARKMAN: And here we have a lot of

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1 contemplation as well, which we found very helpful.
2 And then in Dimension 2, we tried to think about
3 how do we now pull up the lever on specificity.
4 We thought about the different kind of
5 systemic illnesses directly involving the
6 lumbosacral region that we would want to exclude or
7 we'd want to look for if we were [inaudible -
8 intermittent mike] -- file patients out, look at
9 the effects of previous therapies, the lumbosacral
10 spine, whether it's surgery or radiation therapy,
11 or other types of interventional approaches which
12 modify the anatomy. And then, we were also going
13 to look obviously at associated symptoms signs and
14 different diagnostic testing results.
15 So this is kind of what we decided we were
16 going to make our overview of Dimension 2. And why
17 don't we start with those systemic diseases.
18 Steve?
19 DR. GEORGE: These are just examples.
20 Frankly, these are what are most commonly used as
21 exclusion criteria in trials for this. But since
22 we had Dimension 1 be so broad, we thought this

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1 would give the option of people looking at some of
2 these subsets of people that typically are excluded
3 from the non-specific chronic back pain. And
4 certainly you can still have that option because
5 these can be all yes/no and present or absent, and
6 you can start, as John mentioned, dialing in the
7 specificity.
8 So we used the APS and the American College
9 of Physicians' clinical guidelines that were
10 published in 2007 as our foundation for looking at
11 which types of systemic illness we would want to be
12 aware of after identifying the general
13 characteristics of back pain. And they're all
14 listed there. I don't think there are any
15 surprises there.
16 DR. MARKMAN: This is where the discussion
17 got a little bit knottier as we started to think
18 not so much about these therapies, pharmacologic
19 therapies, non-pharmacologic therapies, including a
20 whole range of behavioral and multimodal
21 interventions, as well as, as I mentioned, surgery
22 and radiation therapy.

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1 Again, this would be how we might parse
2 different populations that we wanted to look at.
3 And these weren't so much I think looking at
4 necessarily responsiveness to these pharmacologic
5 interventions as really [inaudible - intermittent
6 mike].
7 Other, as you would expect, associated
8 symptoms with chronic low back pain present for
9 three months within the last six months, that was
10 between T12 on the gluteal fold, we would look at
11 these associated symptoms, the lateralization of
12 the legs or a bilateral presentation, whether it
13 was axial or leg predominant, other sites of pain,
14 weakness, perceived weakness, sensory disturbance
15 and evoked pain. Then there, we're really thinking
16 about syndromes such as neurogenic claudication or
17 patients who have pain, which is evoked by standing
18 and walking.
19 We discussed looking at different signs,
20 including the ones you would all expect would be
21 typically done on a neurologic exam or any standard
22 primary care exam of chronic low back pain.

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1 Impairments here, we broadly talked about things
2 like loss of range of motion.
3 What we really got stuck on, I think
4 struggled with a little bit, was really how to
5 incorporate -- and myself in particular -- the
6 global assessment of pain behavior within these
7 categories and how do we handle that, so much I
8 think that if we were going to use the bronze
9 standard, as Steve talked about, and look at
10 clinician agreement, I think so much of clinician
11 assessment of chronic low back pain syndrome is
12 informed by what the patient's face looks like when
13 they take off their socks or other pain behaviors
14 of the grimacing and the groaning and the slowed
15 movements.
16 The question is how do you bake that in to
17 these associated signs that the clinician is
18 observing.
19 So I don't know that we have an answer for
20 that yet. But I do think that if we were to show
21 videos to five clinicians and ask them to make the
22 diagnosis in the subtyping, we may have a challenge

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1 if we don't figure out how to do that.
2 Again, this is standard diagnostic testing,
3 whether it be differential diagnostic blockade with
4 local anesthetic injections, neurophysiology with
5 EMG or, as you would expect, all the MR and CT and
6 plain film imaging guidance, as well as ultrasound
7 of non-osteo structures.
8 DR. MARKMAN: Then comorbid conditions that
9 we thought for Dimension 3, and I'll let Steve take
10 it.
11 DR. GEORGE: Yes, and we can kind of speed
12 through these. And we realized that these may be
13 federal issues, so we just put some down that had
14 some linkage to chronic back pain, mental health
15 substance abuse, osteoarthritis, and obesity. And
16 then this idea of picking up on whether it was
17 isolated chronic low back pain or it involved pain
18 in different areas, we thought were ones that if
19 they're not covered federally, we could cover them
20 specific to back pain.
21 Consequences are along the same route. I
22 don't know if these are specific back pain or not,

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1 but we were just thinking of putting some of these
2 up here. And again, if these end up being federal
3 issues, that's fine. We certainly have our work
4 cut out for us in Dimension 2.
5 Then these are risk factors that are more or
6 less established in back pain. And again, I don't
7 know if any of these are specific to back pain.
8 There may be a few in there, but, again, these may
9 be federal issues. But we just kind of wanted to
10 get those. I think it helped us hash some things
11 out.
12 DR. MARKMAN: And then we're sort of talking
13 about the next steps for where we're headed. I
14 think we see our immediate needs as sharpening
15 Dimension 2 as best we can and using that
16 conversation over the next couple months to
17 finalize the data collection form, and then
18 probably working I think next toward a vignette
19 development to look at what these cases might
20 actually look like.
21 Then maybe go for some preliminary
22 validation along those lines. And then go from

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1 there and collect comprehensive data and undergo
2 data reduction, look for empirical derivation of
3 subgroups. And then work toward harmonizing this
4 with some of the other efforts out there like the
5 NIH low back pain, minimal data set, as well as
6 some of the other registries. So that's some of
7 the other work that we saw ahead for our group.
8 So we'll stop there and just take any
9 questions. Steve, do you have any comments to
10 start?
11 DR. BRUEHL: I would have actually a
12 question. You notice on the one that we
13 did -- this is Steve Bruehl -- for neuropathic
14 pain, Dimension 1 is the Chinese menu list required
15 for diagnosis. And I notice that you've got a
16 dimension 1 that is extremely brief, and it
17 basically diagnosis back pain.
18 My question is, are you going to further
19 subcategorize specific diagnostic labels for
20 radicular back pain, and then the associated signs
21 that were listed under Dimension 2 here become part
22 of that menu, Chinese menu, in Dimension 1? How

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1 are you planning to do that? Or is there just
2 going to be an overall back pain diagnosis?
3 DR. MARKMAN: Well, I think this is the
4 challenge. As you know, one of the reasons we
5 wanted to leave the back pain diagnosis as sort of
6 the anchor for all of these is because, on the
7 basis of prevalence, it's 95 or 90 percent of the
8 cases, and it's so often non-specific. So we
9 wanted to honor that fundamental observation that
10 everyone shares.
11 I think what we felt the risk was of moving
12 those things up to the first category, or exactly
13 what Roy was talking about, that if we a priori say
14 that having a disc herniation is important or
15 having radicular syndrome is important, we're going
16 to foreclose on the journey of empirically
17 validating this. We're just going to be basically
18 codifying the received wisdom.
19 I think that to the extent that that's what
20 we're doing, why are we doing it, really? We're
21 obviously not going to -- unless that's what we're
22 really just trying to do, is put the imprimatur of

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1 this group on what's already been done, I think
2 we're going to get stuck if we do that. I think we
3 have to start with the fact that [inaudible -
4 intermittent mike].
5 DR. MACFARLANE: Gary Macfarlane from the
6 University of Aberdeen. I'm just thinking of using
7 these in epidemiological studies, and I'm thinking
8 that in Dimension 1, someone could be positive for
9 that, even though they do not currently have low
10 back pain. Dimension 1, is it a part of chronic
11 low back pain, which is described as more than
12 three months from the past six. So people could
13 still be positive for that even though they're not
14 reporting.
15 DR. MARKMAN: In the actual interview.
16 DR. MACFARLANE: I'm just --
17 DR. MARKMAN: Absolutely. Obviously, we
18 have this problem, patients with lumbar stenosis
19 will be sitting in front of you and be pain-free,
20 and only when they get up to walk will they be
21 symptomatic. So again, it's an analogous situation
22 on the minute-to-minute basis, let alone on the

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1 month-to-month or the year-to-year.
2 DR. MACFARLANE: But I just wonder whether
3 in Dimension 1 you want to have some measure of
4 current low back pain because I can just see us in
5 larger research studies misclassifying people as
6 having chronic low back pain who actually may have
7 recovered. And it's just a challenge of having to
8 use these in different settings.
9 DR. MARKMAN: So maybe we can work on that,
10 and I'll bring that to our group about somehow
11 integrating the idea of present pain intensity.
12 Sam?
13 DR. S. DWORKIN: Hi. This is Sam Dworkin.
14 The research task force of the pain consortium that
15 I referred to took exactly the same tact that you
16 are taking, with some differences in Dimension 1
17 that I'll mention in a minute; that is to relegate
18 all of those putative diagnostic categories of
19 chronic pain to the research agenda because they,
20 too, could not come up with diagnostic -- reliable
21 and valid criteria for back pain.
22 But there were two exceptions that I

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1 wondered if you deliberately excluded or just
2 failed to discuss. One was the addition to the
3 definition of chronic pain, which was six months, I
4 believe. But that part's not so important. But it
5 also included to address the issue just raised, was
6 that it was present on at least three days of -- it
7 had -- I can't remember exactly, and I don't know
8 whether Dennis or Partap remembers exactly.
9 So it's pain over, say, three months, pain
10 present on at least three days in the last three
11 months or three days out of a week or something.
12 DR. TURK: They included that. They had 30
13 days of pain within six months, which would
14 basically be you have to have it --
15 DR. S. DWORKIN: But the task force included
16 it.
17 DR. TURK: No, theirs said so.
18 DR. S. DWORKIN: Oh, I didn't see that. I
19 didn't hear about it.
20 DR. KHALSA: This group, the working group,
21 essentially adopted precisely the definition that
22 the task force recommended.

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1 DR. S. DWORKIN: Oh. I'm sorry. I missed
2 that. Congratulations.
3 DR. KHALSA: So chronic is defined as
4 greater than three months within the last six
5 months. So it's the idea that within a six-month
6 time period, someone could have pain every other
7 week, that kind of thing.
8 DR. S. DWORKIN: Okay. Then the other thing
9 that I didn't hear you say was that the task force
10 further extended the definition to include an
11 assessment of the impact of pain, and again, with
12 good evidence for doing that, and wondered whether
13 you had considered that as part of the definition
14 or rejected it and had reason for rejecting it.
15 But that's in the NIH report. It's both on
16 the website of the NIH Pain Consortium and in
17 articles that have appeared in the Journal of Pain,
18 the clinical Journal of Pain, and other journals,
19 the report describing the products of this research
20 task force on standards for research in back pain.
21 DR. MARKMAN: So I just want to make sure I
22 understand. In Criteria 1, you would have a

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1 functional impact write-up in Dimension 1?
2 DR. S. DWORKIN: Yes.
3 DR. MARKMAN: Okay. John? And then we'll
4 stop, I guess.
5 DR. FARRAR: John Farrar. I think an issue
6 that might affect the way this is done, it seems to
7 me at the end of the day, a person who comes in and
8 says my back hurts, their back hurts. And so I'm
9 not at all sure that we need to validate this with
10 regards to whether or not they're malingering,
11 which I think is sort of the only other
12 alternative.
13 Your fourth bullet on your research agenda
14 was to come up with subgroups. And I would argue
15 that the biggest issue in this process is whether
16 the pain is predominantly neuropathic: local
17 inflammatory, a mix because you've got discs that's
18 pressing on nerve, et cetera. It obviously
19 overlaps with the neuropathic pain group. But I
20 would prompt or suggest that a major focus be on
21 looking at those issues. And there should be data
22 sets out there that would perhaps help you with

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1 that, that I'm happy to talk about more.
2 DR. MARKMAN: Just so I understand. If
3 you're going to try and create a nociceptive versus
4 neuropathic dichotomy, where would that fit into
5 the dimensional structure of this? Would that be a
6 sign, a symptom, or that would be a separate access
7 along Dimension 2, would be neuropathic versus
8 nociceptive?
9 DR. FARRAR: I would argue that back pain is
10 a category of syndromes and that you need to define
11 each syndrome separately within that. And you
12 would come up with criteria so if I wanted to look
13 for predominantly neuropathic back pain, I would
14 choose this set of symptoms, this set of signs,
15 this set of issues. And if I wanted to look at
16 predominantly muscle-related pain, I would choose
17 this set of symptoms, this set of signs with these
18 issues.
19 DR. KHALSA: So we did discuss that actually
20 at some length. I think the paradigm that the
21 working group adopted here was the idea that within
22 Dimension 2, you would have -- you're essentially

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1 building this matrix of all these different
2 aspects, including signs and symptoms.
3 Without prejudging it -- and this was the
4 challenge of we don't want to just sort of jump in
5 and say, well, everyone knows what a disc
6 herniation is. It consists of this and this and
7 this. But rather develop the whole matrix, and
8 then apply research to essentially be able to, can
9 we in fact validate that these constellations of
10 things result in what we call discogenic back pain
11 and that kind of thing.
12 DR. BRUEHL: We're kind of out of time here.
13 I would like to point out one thing, just usability
14 of this. If this were to get published and becomes
15 clinically usable, it would probably end up being
16 like DSM has used for psychiatric disorders, where
17 what you'd see on a report or something is the
18 diagnostic code for Axis I.
19 So just keep in mind that if all Axis I is,
20 is it says this person has chronic back pain, that
21 is going to be the diagnosis that patient will
22 carry on the clinical report, and there may not be

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1 room to put all the Axis II information.
2 I think that was a little bit, John, what
3 you're getting at. That was kind of where my
4 question was coming from. I agree with you
5 completely that not prejudging what the mechanisms
6 are makes a lot of sense. But at some point after
7 reviewing all the Axis II information with
8 research, would there be a plan to move towards
9 separate subcategories for these different types of
10 pain.
11 DR. FARRAR: And doing that with a table
12 makes absolute sense. But I completely agree with
13 you. It needs to be 179.1, 2, 3, 4, 5, 6, 7, which
14 defines different kinds of back pain.
15 DR. BRUEHL: Right. Okay. Can we move on?
16 Next, we have Fibromyalgia and Chronic
17 Myofascial and Widespread Pain. We've got
18 co-chairs Lesley Arnold, Robert Bennett, and Leslie
19 Crofford
20 Presentation - Leslie Crofford
21 DR. CROFFORD: As Lesley Arnold is pulling
22 that up, I'd like to thank everybody who was here

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1 and participating. I'm Lesley Crofford. We had a
2 very wonderful international group. We had Dan
3 Buskila from Israel, Dan Clauw from Michigan.
4 DR. BRUEHL: Excuse me. Everybody who's
5 speaking, speak into the microphone.
6 DR. CROFFORD: I'm lighting up. Can you
7 hear me? Okay.
8 So Dan Buskila from Israel; Dan Clauw from
9 Michigan; Jan Dommerholt, who was our myofascial
10 pain representative from Bethesda; Mary-Ann
11 Fitzcharles from Montreal; Gary Macfarlane from
12 Aberdeen, Scotland; Li Alemo Munters from Sweden;
13 Eduardo Paiva from Brazil; Piercarlo Sarzi-Puttini
14 from Italy; and Roland Staud from Florida. So I'd
15 like to thank everybody for participating in our
16 little group.
17 Presentation - Lesley Arnold
18 DR. ARNOLD: Thank you. Lesley Arnold here.
19 And, unfortunately, Rob could not be here today.
20 Ironically, he has a pain condition that he's
21 dealing with.
22 When we came to this meeting, we had a lot

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1 of barriers. Happily, we were able to overcome
2 many of them, surprisingly in the fibromyalgia
3 world. As many of you know, we have a history of
4 some established criteria, dating back to 1990, and
5 more recently some revisions to the criteria for
6 fibromyalgia. I think we came to a consensus that
7 we need to reevaluate how we approach the diagnosis
8 of fibromyalgia, and this is a great forum for us
9 to be able to do that work.
10 Our approach to Dimension 1, we followed the
11 plan set forth by this organization. What we came
12 to in our proposal was that Dimension 1 should
13 include only symptoms, and this is what we came to
14 consensus on. And this would include chronic,
15 widespread pain, which we all agree is the core
16 symptom of fibromyalgia.
17 However, with the way that the field has
18 evolved from 1990 to the 2010-2011 criteria,
19 something about the definition of chronic,
20 widespread pain got lost. There was a difference
21 in terms of how much of the body's affected versus
22 how many points or, if you will, counting up the

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1 regions, et cetera.
2 So we felt that there was need now to go
3 back to our existing databases to really evaluate
4 the best way to define chronic, widespread pain.
5 Is it localization three out of four quadrants or
6 above and below the waist plus bedside, or a count
7 of sites? And fortunately, we have some excellent
8 researchers and people who have rich databases, and
9 Gary is going to take the lead on this to help us
10 evaluate this question.
11 We all agreed that this symptom of chronic,
12 widespread pain being the core symptom of
13 fibromyalgia is absolutely required. But we also
14 recognize that patients have other associated
15 symptoms that we thought are very important to
16 consider.
17 Among the group, we all felt fatigue and
18 unrefreshing sleep were the two most important
19 symptoms, and these turned out to be very common in
20 patient reports and in the other criteria and
21 analyses that have been done. But we also
22 recognize -- and I'll come back to this in a

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1 second -- that there were other symptoms that we
2 needed to consider and perhaps include in a study.
3 So we wanted to come back in our reliability
4 validation study and include a question about the
5 following symptoms -- again, most days for the past
6 three months, fatigue, unrefreshing sleep -- and
7 also to rate the level of severity on a zero to 3
8 scale and also include these other symptoms.
9 We ultimately believe, but we don't know
10 yet, that it will end up being just fatigue and
11 unrefreshing sleep that will end up being part of
12 the core criteria in Dimension 1, but we are going
13 to leave that for the research to help us decide
14 that.
15 Now, other issues that we addressed in
16 Dimension 1 were the differential diagnosis
17 considerations, which I'll come to in the next
18 slide. We also have our plans going forward for
19 studies, again reviewing existing data sets to
20 assess the chronic, widespread pain definition and
21 other core symptoms.
22 We also wanted Gary to evaluate in his

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1 assessment of chronic, widespread pain whether
2 there was indeed sexual dimorphism in the comorbid
3 symptoms like fatigue and unrefreshing sleep
4 because that will inform our reliability and
5 validity study because the other groups are
6 grappling with how to do that study.
7 We had thought that using the 1990 criteria
8 to categorize patients with chronic pain as
9 fibromyalgia or non-fibromyalgia would be a good
10 first step. However, we recognize that the 1990
11 criteria do bias the diagnosis towards women who
12 are naturally more sensitive to the tender point
13 exam.
14 So we're hoping to learn more about sexual
15 dimorphism when we evaluate, again, those data sets
16 that look at chronic, widespread pain and the
17 relationship of that with some of the existing
18 symptoms. So that will hopefully inform our study
19 going forward.
20 As far as differential, I put this up. And
21 it was really hard to read. Everyone was getting a
22 big headache. But it just gives you an idea of the

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1 sense of what we consider in our usual evaluation
2 of patients. And of course this would be included
3 in our differential diagnosis, and there are others
4 that aren't on here that the group is going to
5 accumulate. But it gives you an idea of -- some
6 sense of what the disorder is, what are the
7 differentiating signs and symptoms, and any other
8 tests that are used to evaluate these other
9 conditions. And it gives you a flavor for what
10 we're thinking going forward.
11 Moving on to Dimension 2, we wanted to
12 include other common features, firstly, the common
13 pain characteristics. And a history of a lifetime
14 multiple other pain conditions was a very important
15 part of the characteristics of these patients to
16 help us identify them.
17 The pain tends to worsen with common
18 mechanical stimulations, such as blood pressure
19 cuff being hugged, tight clothing, et cetera., the
20 pain being difficult to localize precisely; moving
21 from place to place; a variable onset often
22 difficult to describe; commonly, though, a deep

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1 tissue ache but can have neuropathic pain
2 characteristics such as burning. Exertional pain
3 is a common feature or also worse with inactivity
4 or with stress, and the severity waxes and wanes.
5 So this is a flavor for some of the common
6 pain characteristics that we felt in our group were
7 important to note in Dimension 2. There may be
8 others. This is a beginning of our work in
9 defining that.
10 Dimension 2, we did include our signs. And
11 here's where we thought tenderness could go. We
12 wanted to move it out of Dimension 1 but include it
13 in Dimension 2 as a potential importance to some
14 clinicians and researchers who wanted to assess
15 tenderness. And it can be done by doing the 1990
16 exam.
17 We have something called the Clauw exam that
18 we're going to include. He had put his tenderness
19 examination in a recent JAMA article, so we put
20 that as another option, which is an abbreviated
21 version of an exam. Skin-fold tenderness is in
22 deference to Rob, who likes to use that in his

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1 exam. So there are other possible approaches to
2 assessing tenderness. Another sign that some
3 thought were common enough to include in
4 Dimension 2 were signs of dysautonomia.
5 Then there were non-pain features. And
6 again, this would include any of those non-pain
7 features that end up not being part of Dimension 1
8 we would put down here in Dimension 2. Other
9 things include depressed mood and anxious mood.
10 And notice that we use the term "mood" here. So
11 we're not talking about the major depressive
12 disorder, which we will include in Dimension 3 as a
13 comorbidity. So now we're just talking about
14 symptoms of a mood, disturbance. Balance problems,
15 again, something from Rob's work that we included.
16 This dimension, we also began to discuss
17 epidemiology and discuss the importance of family
18 history, age. And again, here we talk about
19 juvenile onset and other more common ages of onset
20 in adulthood. The sexual dimorphism question is
21 very important, demographics, prevalence.
22 We have a fair amount of data now on

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1 worldwide prevalence of fibromyalgia that will be
2 included. There's some less evidence of incidence,
3 but there are some data, and a considerable amount
4 on new onset. And then we wanted to address
5 course, including prognosis and changes with aging.
6 And some of these may be federal issues, but we
7 wanted to put down what we thought was unique to
8 fibromyalgia.

9 We touched on the comorbidity issue. This
10 is just a subset of what we talked about. Other
11 things that we would include in addition to these
12 pain disorders, that seemed to overlap a great deal
13 with fibromyalgia as well as a psychiatric
14 disorder, are things like sleep disorders,
15 Ehlers-Danlos syndrome, myofascial pain syndrome,
16 restless legs, other autoimmune disorders,
17 inflammatory arthritides, degenerative
18 musculoskeletal diseases, arthritis, obesity,
19 chronic, viral illnesses, et cetera.

20 So we're working together as a group to pool
21 together the common comorbidities in these
22 patients.

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1 So here we are to myofascial pain. We had
2 one sole representative in our group. He was
3 helpful in getting this started. Dimension 1 would
4 include both symptoms and signs, and both will be
5 required. So symptoms would be acute or chronic
6 regional musculoskeletal pain, and the signs would
7 be the taut band in the muscle and tender spots in
8 these taut bands that are reproducible. They
9 reproduce the musculoskeletal pain upon touch or
10 palpation.

11 Then as far as Dimension 2, there were other
12 characteristics, trigger points, which include
13 aspects of referred pain, a local twitch response,
14 a needling, an autonomic response to palpation or
15 stimulation, the fact that myofascial pain is often
16 precipitated by injury or repetitive or sustained
17 muscle loading. It can be associated with visceral
18 pain such as pelvic pain and can occur in one or
19 more regions. Not typically characterized as
20 diffuse, but there are cases of widespread
21 myofascial pain, so we wanted to acknowledge that.

22 Also, weakness is a characteristic and also

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1 restricted range of motion. But we recognize that
2 we probably do need additional input. And here's a
3 list of people that we think could be invited to
4 join us. And we believe now -- and we probably
5 want to check with our group overall whether we do
6 want to create a subgroup and a separate manuscript
7 for myofascial pain syndrome, being that it has its
8 unique characteristics.

9 DR. BRUEHL: Questions?

10 DR. ZELTZER: So when you talk about age, is
11 that through the data or is that through
12 retrospective getting past histories on adults with
13 fibromyalgia? So the question is, when does
14 fibromyalgia really start, and does juvenile
15 fibromyalgia in children and adolescents progress
16 to adult fibromyalgia or is it a very different
17 condition?

18 DR. CROFFORD: Our group feels that the
19 signs and symptoms are essentially the same in
20 juvenile fibromyalgia versus adult onset
21 fibromyalgia. We took the charge from the
22 committee that in Dimension 2 we should describe

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1 the epidemiology. And so what we listed up there
2 was the work that we intended to do to put in the
3 epidemiology section of Dimension 2.

4 DR. ZEMPSKY: I guess to follow up on
5 Lonnie's question -- Bill Zempsky -- are you going
6 to use existing data sets from the pediatric
7 fibromyalgia leaders? Because I think that's going
8 to be important.

9 DR. ARNOLD: Yes. This is Lesley Arnold. I
10 work closely with the group at the Cincinnati
11 Children's Hospital, where we have been doing a
12 longitudinal study of juvenile fibromyalgia. So,
13 yes, absolutely we're going to draw on that
14 information.

15 DR. CROFFORD: Well, to be clear, for the
16 first study, where we're trying to look at what's
17 the best way to describe chronic, widespread pain,
18 that study that will be in Gary MacFarlane's group
19 is adults. But once we get to the validation of
20 the criteria, we'll do additional studies looking
21 at adults and children.

22 DR. FARRAR: John Farrar. Two questions.

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1 One I think is quick, which is what's the gold
2 standard. And I assume it's expert opinion. The
3 second is, although these are clearly very
4 different syndromes, they're often mixed up. And I
5 think it would be a major service to putting them
6 either in the same paper or next to each other so
7 that the criteria that differentiate the two are
8 clearly expressed. And I wondered what you
9 thought.

10 DR. CROFFORD: So we agree, and we had a lot
11 of discussion in our group about what are the
12 distinguishing features. After sitting through
13 this session and listening to Jan and listening to
14 everybody else in the group, I think it might be
15 useful to separate them into two papers back to
16 back. And the issue, we'll leave that to the
17 organizers. I think we could do that either way.

18 DR. FARRAR: And differentiate between the
19 two.

20 DR. CROFFORD: And differentiate between the
21 two. I mean, the truth of the matter is we had
22 lots of discussion about what was the same and what

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1 was different. And I think we've philosophically
2 come to the agreement that when we think of
3 myofascial pain, we think of a peripheral pain
4 syndrome.

5 When we think of fibromyalgia, we think that
6 there's necessarily a central component to it. And
7 we tried to put in the myofascial pain that it was
8 not widespread, kind of clearly identifying that
9 regional or peripheral focus on how we think about
10 myofascial pain. But again, we only had one
11 person, and I think it's going to be very important
12 to have a bigger group think about myofascial pain
13 and help us.

14 DR. FARRAR: The group here is the
15 converted, and so I think you've got us convinced
16 or at least we've been convinced over time. But I
17 think that the majority of the world still thinks
18 of these as being nearly the same, and I agree
19 they're not. But my point is, a table which
20 indicates what's what, what the symptoms are that
21 differentiate, in either article or maybe both,
22 would really help.

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1 DR. CROFFORD: Thank you.

2 DR. BRUEHL: We've got time for a short
3 question.

4 DR. S. DWORKIN: With regard to taut bands
5 and trigger points, in our TMD group, we could not
6 define them. And we found the inter-rater
7 reliability so poor that we eliminated them from
8 contention. And that was a long time ago, and
9 hopefully things have changed. And the way around
10 it would be simply to provide very careful
11 operational definitions of taut bands and trigger
12 points to justify their inclusion. And the
13 research would determine whether your definitions
14 were reliable or not.

15 DR. CROFFORD: Jan, did you make note of
16 that?

17 DR. DOMMERHOLT: This is Jan Dommerholt. As
18 the one representative of the myofascial pain
19 person, I felt very lonely in the group of
20 fibromyalgia people, I must say.

21 (Laughter.)

22 DR. DOMMERHOLT: When the TMD criteria were

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1 done, there were very few, if any, reliable studies
2 on the reliability of trigger points and things.
3 That has changed dramatically since 1997. There
4 are several intra- and several good inter-rater
5 reliability now in the literature and more to come,
6 actually. So I think that problem is a problem of
7 the past. But I agree that it should be defined
8 what it is.

9 DR. BRUEHL: Our next group, we have
10 Temporomandibular Disorders and Other Facial Pain.
11 The chair of the working group is Werner Ceusters.
12 Presentation - Werner Ceusters

13 DR. CEUSTERS: The take on here is a little
14 bit different. Instead of summarizing in
15 10 minutes the last day, I was asked to summarize
16 my three-year collaboration with TMD groups,
17 specifically with respect to ontology, which is
18 kind of a new word I think for most people here in
19 the room.

20 It grew out of my participation in the Miami
21 international consensus workshop on convergence on
22 orofacial pain taxonomy, where one of the

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1 conclusions was that we should put more emphasis on
2 the terminology and ontology of pain as it is
3 currently defined. And that resulted in a funded
4 grant by NIH, through which I have been working
5 with them.

6 Now, the reason for my invitation was the
7 fact that it was observed that many classifications
8 and taxonomies, developed by very intelligent
9 people, have problems. This one for instance is
10 MeSH. It's an old system, but it's updated
11 regularly. This is from the last year still.

12 Wolfram syndrome is classified in something
13 that seems to be a very reasonable structure if you
14 know something about Wolfram syndrome. However, if
15 you would use it as a diagnosis, and you say, "I
16 have Wolfram syndrome," then it means also that I
17 have an optic atrophy and that I have an optic
18 nerve disease and so on. And that goes for all
19 those things. But I tend, then, to have also a
20 female urogenital disease. That's what MeSH
21 claims.

22 We used our analysis to analyze the

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1 definition of pain provided by the AISP [sic], and
2 there we discovered that actually in one
3 definition, they are defining five different
4 things. There's nothing specifically wrong there,
5 but if you do not look carefully, you are not aware
6 of that.

7 Another example is the international
8 headache classification, ICHD, International
9 Classification of Headache Disorders. So look at
10 the painful, trigeminal neuropathy, which is stated
11 to be a kind of trigeminal neuralgia. Look at the
12 same time at the definitions. They have neuralgia,
13 pain, and neuropathy, and now you see it doesn't
14 make any sense. It should be the other way around.

15 So this here is a problem where no adequate
16 tools have been used to see whether the definitions
17 finally fit the taxonomy or the other way around.
18 So I have been working now for 30 years in trying
19 to prevent these kind of things in various domains.
20 And it's only by coincidence that I became involved
21 in these pain domains.

22 So the trick here is ontology, which is a

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1 kind of philosophical discipline, which is a part
2 of metaphysics. Where metaphysics study how the
3 world works, ontology studies what type of entities
4 exist in the world. So you can have discussions
5 among ontologists, where the pain exist, and some
6 will say yes; others will say no. All ontologists,
7 nevertheless, agree metaphysically that patients
8 who suffer from pain -- and now we have to use
9 quotes -- do exist.

10 So the task is for others -- so what do you
11 take into your ontology and what do you not take
12 into your ontology, and what do you need to
13 describe in different ways. You can apply that in
14 different ways. So this is for statisticians
15 absolutely no problem. It says that what you
16 measure is not really what you are thinking you are
17 measuring because there are errors, systematic
18 errors and random errors.

19 Ontology can help to tell you something.
20 For instance, does that Vr, which is the real
21 value, does it really exist? Identities are
22 involved in bringing about that systematic error

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1 and that random error. And if the Vr really
2 exists, how does it relate to those errors? You
3 can figure those things out. If you have multiple
4 things that you are testing -- in pain patients,
5 you test multiple things -- ontology can help you
6 already in telling how such things that you measure
7 relate to each other without doing statistics.

8 There is a second sense of ontology, which
9 came up in the mid '90s that is kind of a system,
10 so kind of a super taxonomy. That's the way that I
11 would classify it. The idea is if you have
12 something nicely designed like this with formal
13 relations between your things, for instance, you
14 can use that to describe data unambiguously.

15 You can describe very clearly that that
16 little one there in the spreadsheet about some TMD
17 thing actually means that this patient with such
18 and such patient identifier is stated to have a
19 panoramic X-ray of the mouth, which is interpreted
20 to show such and such and such; all that in a
21 little one. In your databases, that is there
22 implicitly. It is not explicitly in there.

<p style="text-align: right;">Page 61</p> <p>1 You can connect different kinds of data 2 sets, and then you can see how they match up with 3 that very unique ontology there. If you do 4 that -- now, for instance, you can see that here if 5 you do a statistical analysis, you see that 6 characteristic 1 and characteristic 4 statistically 7 correlate, I as an ontologist wouldn't say, "Duh, 8 it was already there in your ontology." Right? 9 On the other hand, if you find by doing your 10 statistical analysis that they do not correlate, 11 then there is probably a problem in the ontology or 12 in the taxonomy. So you can make this work in both 13 ways. So there is a caveat. 14 So the computer science approach to ontology 15 does not take the philosophical principles into 16 account, and now you get some problems. Most of 17 the approaches use what is called the semiotic or 18 the semantic triangles, for when we use a certain 19 word like "dog" -- that's displaced there -- you 20 think you have the concept of a dog. And it 21 actually refers to things that walk on the street, 22 and that bark, and so on.</p>	<p style="text-align: right;">Page 63</p> <p>1 you are describing, are related. It was actually 2 true that slaves had a propensity to run away, but 3 it's not true that it was a disorder. You can 4 relate the terms to each other. 5 Now, this drapetomania, the term itself 6 tells that it's a mania, so a disorder. And 7 "drape" comes from the Greek, running away. So it 8 makes some sense to have that kind of term. But at 9 the same time, how sensitive are patient advocates 10 not about what terms you give to diseases? So 11 there are rules that should be applied to that as 12 well. So that's that aspect. 13 There is the ontology of general medical 14 science, which has described a couple of 15 fundamental notions in the diagnostic process and 16 how disorders and symptoms and everything works. 17 Doesn't that look very close to the kind of 18 dimensions that you want to have in your system? 19 The nice part here is that all those 20 relationships are formally defined so that humans 21 can understand it, machines can understand it and 22 can reason with it automatically. One of the</p>
<p style="text-align: right;">Page 62</p> <p>1 Now, that's very heavily used in medicine as 2 well. There was the term "drapetomania" in 3 psychiatry in '84. Probably, you don't know what 4 it meant, but it was a disease which caused the 5 slaves to suffer from an unexplainable propensity 6 to run away. 7 (Laughter.) 8 DR. CEUSTERS: I found that in the Buffalo 9 Medical Journal of '84. 10 Of course, you need to apply principles to 11 what you put in your taxonomy. Many do that 12 already. Here is a list of ontologies which are 13 free to use, which are curated, which are updated 14 regularly, and which describe organisms, anatomical 15 entities, organ functions, phenotypic qualities, 16 biological processes, molecular functions. All 17 that exists to use it. 18 If you do it that way, instead of just 19 relating your ideas there, you can relate in 20 different ways. So this was how beliefs are taught 21 to be related. The bottom-right corner, you can 22 use it to express how the actual reference, what</p>	<p style="text-align: right;">Page 64</p> <p>1 advantages here, for instance, is a clear 2 distinction between disorder and disease that some 3 already brought up and the one with diagnosis that 4 I brought up, diagnosis in the head of the 5 physician, and the rest is there. 6 It is, for instance, used in cirrhosis and 7 other examples. People are using these to 8 characterize diseases. So in this case, cirrhosis 9 is due to environmental exposure, while the 10 etiological process is a phenobarbital-induced 11 hepatic cell event [indiscernible]. The disorder 12 is a necrotic liver. The disposition, which is the 13 disease, is the cirrhosis. The pathological 14 processes involved are abnormal tissue repair with 15 cell proliferation, and so forth, and so forth. 16 Now, the elements themselves -- so the 17 values that you put in your axis there, they are 18 taken from the ontologies that I have just referred 19 to on that sheet. So what you need to do is to 20 bring those things together in your specific 21 domain. 22 There are some principles for the</p>

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1 ontology-based taxonomies. One principle is be
2 explicit with assertions about particulars or types
3 of individual patients or groups of patients. I
4 have had people -- I've heard people arguing about
5 the existence of a mixed gender. And what they
6 actually were talking about was populations of
7 cows. And some populations were composed of
8 60 percent of male cows, 40 percent bulls, and the
9 other rate.

10 So the way that they wanted to represent it
11 is not to have just male gender and female gender,
12 but also to have a mixed gender. The mistake there
13 of course is that you are trying to define
14 characteristics which is inherent to a single
15 entity to a population. You shouldn't do that.
16 I'm not going in to detail because I've run out
17 already I think in my 10 minutes.

18 But these different principles all are
19 violated in the international headache
20 classification. Look at this persistent idiopathic
21 facial pain, for instance. You can imagine that
22 you have three different types of pain. For

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1 instance, my pain, her pain, and his pain. So
2 there are three different instances we call it. My
3 pain might be such that all the time it has
4 presentation type 1, which is a combination of
5 certain symptoms, which goes into your Dimension 2.
6 Her pain might be of a different nature. So
7 time 1, it is presentation type 1. Time 2 is
8 presentation type 2 because a symptom disappears or
9 another came in and so on. And you can have
10 another configuration for his pain.

11 Now, why is that important? Well, if I read
12 those terms, and I look at the definition in ICHD
13 and they don't say whether that is about types or
14 about instances, if it is about types, then those
15 three particular pains -- those three different
16 pains -- they fall under the same heading.

17 So when the description is about
18 particulars, then only her pain, the middle one,
19 falls under there. Why is that relevant? I mean,
20 it's not just building a taxonomy that you do. You
21 want specific patients to be classified under one
22 of them, under those categories. Well, if the

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1 classification is built in such a way that you
2 can't do it, you have a problem.

3 The second one, and that's the last one I'm
4 going to show, what are you exactly going to
5 classify? ICHD is not sure about it. Disorders is
6 in the title, International Classification of
7 Headache Disorders. But then is it headaches you
8 read in the introduction? Many questions are not
9 needed in order to classify primary headaches,
10 et cetera, et cetera. Is it patients?

11 The second edition will hopefully further
12 promote unity in the way we classify, diagnose, and
13 treat headache patients throughout the world.
14 Patients are not disorders and are not headaches
15 and so on.

16 Conclusion. Realism-based ontology. That
17 has a lot to offer to build faithful
18 representation, but it's hard. You have to do a
19 little bit more work than what you normally would
20 do. But you can ask for help of skilled
21 ontologists. Pain classifications, and for all
22 other classifications made by domain experts, they

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1 would benefit. Now, domain experts are not
2 ontologists and the opposite way around, so we need
3 collaboration.

4 The problem might be there are old habits
5 under this mainstream thinking, and there is
6 guru-ism. But I honestly think that hampers the
7 advice of science, and sometimes we need to
8 rearrange things in the way that we are used to.
9 Thank you.

10 DR. BRUEHL: We do have a couple of minutes
11 left for questions. I would ask -- this hopefully
12 is a 1-minute answer or question. I have not
13 really been thinking about what we're doing is
14 coming up with diagnostic criteria. Implied in
15 that in my head was that we're trying to capture
16 some underlying disorder disease. But the truth
17 is, the way we plan on using it is to identify
18 patients who have the disease.

19 Is what you presented there, would it have a
20 practical -- how would that change, practically,
21 what we do when we're coming up, for example, with
22 Dimension 1 to list how to diagnose a given

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1 patient?

2 DR. CEUSTERS: Well, it will help you when

3 determining -- I heard a couple of good questions a

4 couple of times. It will help you in determining,

5 for instance, what goes in Axis I and what goes in

6 Dimension 2 and in Dimension 3. So there are

7 certain principles that we can apply for that, and

8 that is one thing.

9 DR. BRUEHL: Okay.

10 DR. SARZI-PUTTINI: Can I just make a

11 comment? I think these ontologists are really very

12 interesting. But the point is, when you talk about

13 pain, you're talking about subjective symptoms.

14 And we are also missing some of the

15 pathophysiological mechanisms.

16 So in a way, we cannot follow what you are

17 saying. We have to realize that we have to group

18 these symptoms because, otherwise, each patient

19 will be a different patient. So we would have to

20 do a classification of pain that is individualized

21 and is not instead put in together.

22 Ontology is okay when you have objective

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1 symptoms. When you have subjective symptoms, it

2 doesn't feel as much for --

3 DR. CEUSTERS: It applies in exactly the

4 same way because what is objective in that case is

5 what the patient says. So when you work with what

6 a patient says in contrast to what you see, you can

7 correlate them.

8 What ontology is about is about figuring out

9 what the entities are and how they relate to each

10 other. Objective or subjective, I mean, it's for

11 ontology all the same in the sense you can deal

12 with them in the same way. I'm not saying that

13 they are the same things, but you can deal with

14 them using the same principles, and in that way not

15 making mistakes or eliminating certain mistakes.

16 DR. BRUEHL: Thank you. Next, we have the

17 Visceral, Pelvis and Urogenital Pain group,

18 including IBS and IC. This is Nicholas Verne and

19 Ursula Wesselmann.

20 Presentation - Ursula Wesselmann

21 DR. WESSELMANN: While Nick is putting up

22 the slides, I just wanted to say what kind of group

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1 we were because we were a very diverse group with a

2 lot of different expertises. For abdominal and

3 pelvic pain, we had GI expertise, which is Nick

4 Verne from Galveston; and Qiqi Zhou from Galveston,

5 basic scientists; and Linda Li from Hopkins.

6 For gynecology, we had Mary Pat FitzGerald

7 from Chicago from the VA; Gloria Bachmann from

8 Rutgers; and Andrea Rapkin from UCLA. For urology,

9 it was Quentin Clemens from Michigan; Chris Payne

10 from Stanford; and Robert Moldwin from Long Island

11 Jewish Medical Center.

12 Because a lot of these abdominal and pelvic

13 pain syndromes start already in childhood, in

14 adolescence, but there is less known about it, we

15 had two experts in that area, Lynn Walker, from

16 Vanderbilt, who is a psychologist; and Lonnie

17 Zeltzer from UCLA, who is a pediatrician; and then

18 myself, Ursula Wesselmann. I'm a neurologist with

19 specialty training in pain management.

20 We started out trying to fit the different

21 pelvic and abdominal pain syndromes into the grid

22 that was provided to us or that is in the paper

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1 that is provided to everybody, that Roger was the

2 first author, and we had some difficulty with it.

3 We will show you an example using bladder pain

4 later on, and we went through the exercise as well

5 for gynecological pain and also for itchy eye pain.

6 But we came up with a more general term,

7 which I want to present here for discussion because

8 we discussed it a lot over the last two days.

9 Abdominal and pelvic pain present as pain or

10 discomfort -- so it's not necessarily always pain

11 localized to anatomical regions in the abdominal

12 and pelvic area -- for at least three months

13 duration. And three months was suggested at our

14 initial get-together yesterday, to use three months

15 for most of the pain syndromes we want to make a

16 taxonomy of.

17 But we also wonder if it can be longer or

18 less, especially -- Lonnie had pointed out in the

19 pediatric population, the diagnosis is often made

20 after a shorter time, whereas we who see adult

21 patients usually see the patients and make the

22 diagnosis after they had the symptoms for a long

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1 time just because of the logistics, until they get
2 an appointment.
3 Abdominal and pelvic pain is often
4 considered just as visceral pain, but there is
5 visceral somatic interaction. So we have actually
6 visceral-visceral interactions from one visceral
7 organ to the other, and we have visceral somatic
8 interactions. And what is often not thought about
9 it is there is also somatic visceral interactions.
10 So patients, for instance, who have burn
11 injuries to the cutaneous and muscular structures
12 also have visceral hypersensitivity. And in the
13 animal literature, there are experiments where you
14 inflame muscles in the lower back or in the upper
15 legs, and you can demonstrate visceral
16 hypersensitivity. So it can go both ways, and we
17 are often not so aware of it.
18 So we put this on top, somatic and visceral
19 mechanisms and somatic and visceral presentations
20 for these abdominal and pelvic pain syndromes. And
21 below that, you see a category with organ-specific
22 symptoms and without organ-specific symptoms.

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1 With organ-specific symptoms -- I will give
2 you an example later -- bladder pain or irritable
3 bowel syndrome. We went through that exercise but
4 did not present it here. Vulvodynia is another
5 example, where there are very specific symptoms, as
6 we see it also with other pain syndromes. For
7 example, with headache, you have migraine headache,
8 cluster headache, which has very specific symptoms,
9 and then others are just pain in the head,
10 basically.
11 So both of these presentations, with or
12 without organ-specific symptoms, will need a
13 diagnostic workup, but the specifics of the
14 diagnostic workup might be different. So these
15 patients typically have a gynecological,
16 gastroenterological, urological, urogenital,
17 somatic -- somatoform -- workup. But it will be
18 different because, obviously, if there are no
19 organ-specific symptoms, you will not do some of
20 the procedures that are targeted to a certain
21 organ.
22 So all these mechanisms and etiologies,

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1 however, have to be considered. And with somatic,
2 we meant that many of these patients have
3 myofascial pain features. They might have a
4 neuropathy where you would actually inject an
5 entrapped nerve, and the pain syndrome would go
6 away, and you might have cutaneous
7 hypersensitivity. And with somatoform, we tried to
8 indicate that some psychiatric disorders can
9 present in the differential diagnosis with
10 abdominal and pelvic pain.
11 With organ-specific symptoms, we have
12 examples, really, in every category, for GI, for
13 pelvic, gynecological, for urologic, and also for
14 the pelvic floor for the external genitalia. As an
15 example, here in this diagram, we have presented a
16 GI where the Rome criteria -- a very well
17 established criteria for IBS. And there's a
18 certain differential diagnosis that is included in
19 those criteria.
20 I don't want to go through the other
21 examples. I will just show you our example on
22 bladder pain. You probably have heard interstitial

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1 cystitis, painful bladder syndrome, and bladder
2 pain syndrome. So there are many different words
3 actually for it.
4 This is a table out of a review paper that
5 came out in Pain two years ago that Chris Payne,
6 who is in our working group, had published. And it
7 just shows -- briefly, for those of you who are not
8 so familiar with bladder pain -- how the taxonomy
9 moved from focusing on organ pathology in the
10 bladder -- those were Hunner's ulcers or
11 glomerulations -- to a chronic pain syndrome in the
12 bladder.
13 In the current definitions, bladder pain is
14 defined as an unpleasant sensation, pain, pressure
15 discomfort perceived to be related to the urinary
16 bladder, associated with lower urinary tract
17 symptoms, urinary urgency and frequency and other
18 misconceptions of the -- or misfeelings, really, of
19 the bladder in the absence of infection or other
20 identifiable causes. This definition is also
21 endorsed by the American Urological Association in
22 the IC guidelines that were published in 2011 and

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1 are currently being revised.
2 So it started out, actually historically, a
3 long, long time ago before the NIDDK criteria for
4 research were established about 20 years ago. It
5 started out with thinking that this was some
6 pathology that is in the bladder, and now it has
7 moved to understanding bladder pain as a chronic
8 pain syndrome.
9 So we tried -- rather than trying to find a
10 new name for it, we called it bladder pain for our
11 exercise here. For Dimension 1, for the core
12 diagnostic criteria, we decided to stick with the
13 American Urological Association criteria, which
14 require pain, pressure, and/or discomfort in the
15 bladder area for a period of at least three months,
16 excluding other diseases that could mimic bladder
17 pain: cancer, stones, hematuria, and neurogenic
18 bladder.
19 Importantly, in order to exclude those
20 diseases, a cystoscopy might be required and
21 further invasive urological workup, but it is not
22 required for the diagnosis of bladder pain.

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1 What are the common features? So we moved
2 on to Dimension 2, and we could extend this
3 list -- there is actually a lot of literature
4 spread out in many different journals about this.
5 So there's nocturia, dysuria, pain with ejaculation
6 in men, hesitance, decreased flow. I don't want to
7 read this all to you. It's just an example, also,
8 of the research that we could go into as a group to
9 verify some of this information.
10 Epidemiological aspects. Bladder pain and
11 many of the pelvic pains are difficult to study
12 because they are waxing and waning symptoms.
13 Bladder pain usually presents in young and
14 middle-aged females, and the female-to-male ratio
15 is 5 to 1. So if you find bladder pain in an
16 elderly patient with new onset, that is usually a
17 red flag.
18 Comorbidities, we have a whole list, and it
19 can be replaced in many cases by the lists that
20 were previously shown from the other working
21 groups. We grouped many of the pain syndromes
22 together as functional somatic symptoms, the

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1 psychological/psychiatric comorbidities as negative
2 affect, ultra-immune diagnosis, endometriosis. So
3 a pathology, actually, in the pelvic cavity is
4 often associated with bladder pain. Functional
5 bowel disorders. Autonomic dysfunction is
6 something that is currently being researched for
7 bladder pain and the history of abuse and trauma.
8 Dimension 4, again, we find many of those
9 consequences that are really quite typical for all
10 the pain syndromes that are studied here. What is
11 important for the pelvic and abdominal pain is
12 sexual dysfunction that is more prominent than for
13 many of the other pain syndromes.
14 Again, the mechanisms are similar to what
15 has been presented. Before, the focus is currently
16 on pain mechanisms, central and peripheral. The
17 reproductive history aspects play a role.
18 Autoimmune mechanisms have been demonstrated.
19 Search for bladder abnormalities have not been so
20 successful so far, and an important aspect of
21 research is actually to start in childhood. A lot
22 of the studies on bladder pain have only included

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1 patients as of the age of 18 or 19, depending in
2 which state you live.
3 Can I have the last slide? I briefly wanted
4 to say we were a multidisciplinary group with
5 physicians and researchers from different
6 specialties who all see abdominal and pelvic pain.
7 And we actually rarely get together, so this was a
8 great forum for us to discuss and exchange ideas.
9 It really requires a setting also in the
10 healthcare system, where we can work together for
11 this particular patient group because right now,
12 the taxonomies, were made and are focused on the
13 different abdominal pelvic organs. But as we
14 showed in the first slide, it is probably more
15 useful, for studying the etiology and for treating
16 those patients, to start out from a global level of
17 abdominal/pelvic pain, and then move down.
18 In Britain, they are already at this stage.
19 The government a few years ago implemented that
20 there should be pain pathways for these patients,
21 not only the pelvic pain patients but also other
22 pain groups. And this concept needs to be

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1 implemented also in the medical school training for
2 the medical students and residents. So I just
3 wanted you to be aware of this government effort in
4 the UK. Thank you.

5 DR. BRUEHL: Thanks. We don't have much
6 time for questions. Is there a burning question?
7 (No response.)

8 DR. BRUEHL: No? Okay. Let's do Cancer
9 pain with Judy Paice.

10 Presentation - Judith Paice

11 DR. PAICE: While we're pulling up those
12 slides, I'm Judy Paice from Chicago. We had a
13 robust committee with an interdisciplinary,
14 international perspective. We'll see that list in
15 just a moment.

16 My co-chair is Tom Smith, who is a physician
17 at Hopkins, does palliative care, and he was unable
18 to be with us today. Michael Bennett and Matt
19 Mulvey from the UK also couldn't be with us. They
20 began the hard work of this committee by conducting
21 a systematic review of the literature related to
22 cancer pain syndromes, and that review informed our

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1 work for these past two days, and it continues.

2 We have the advantage and disadvantage of
3 not having any preexisting classification systems,
4 really, for cancer pain. We developed four
5 conditions or we identified four conditions, both
6 through the systematic review and from the advice
7 of the committee.

8 So we started with bone pain, and we
9 particularly specified without radiculopathy so
10 there wouldn't be overlap with the low back pain
11 group. And we were trying to ensure throughout
12 this entire process that we were being so specific
13 that we could clearly discern is this a
14 cancer-related syndrome and how is it different
15 than some of the other syndromes that have been
16 defined in the past two days. So we tried very
17 hard to adapt to this system, the different
18 dimensions. We have the symptoms, pain in one or
19 more locations, it increases over time.

20 I should take a step back. There were
21 several ways in which we identified cancer pain
22 being very different -- any of these conditions

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1 that I'm going to be describing -- very, very
2 different than some of the others that have been
3 defined already. One is in the timing. There's no
4 way that we could state that three months needs to
5 be that magic time period before we would call it a
6 chronic pain syndrome. So that's one.

7 The second is that this is a dynamic
8 phenomenon with cancer pain and that as we're
9 looking at the actual syndrome or condition, there
10 are also changes going on in the tumor. The tumor
11 is maybe getting bigger or hopefully responding to
12 our treatment. And then the other variable is that
13 the treatments are being administered, and there's
14 usually more than one treatment, which makes it
15 somewhat complex to specifically define a time
16 course or an epidemiology.

17 We had a really fascinating conversation
18 before finishing today, where Pat Dougherty
19 mentioned that we should probably come up with a
20 morphine-equivalent daily dose for some of the
21 neurotoxicities of some of the agents. So most of
22 our patients don't get one neurotoxic drug; they're

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1 getting multiple agents. And so is there a way
2 that we could come up with an equianalgesic ratio,
3 if you will, that would be reflective of the
4 neurotoxicity ratio so that some of our patients
5 may get X amount of paclitaxel. They might get X
6 amount of another neurotoxic agent. How could
7 those be defined and combined to give us some sort
8 of indicator of the risk for patients with
9 chemo-induced neuropathy?

10 Then throughout all of these is the
11 contribution of the tumor microenvironment. And
12 Brian Schmidt was wonderful in reminding us
13 throughout about the underlying genetic profile of
14 the cancer, but also the microenvironment produced
15 by this tumor and how it's also contributing to
16 these pain syndromes.

17 So back to bone pain, we have pain in more
18 than one location. Clearly, the individuals have a
19 cancer diagnosis and then generally defined through
20 the diagnostic testing imaging. The pain is worse
21 with movement, with pressure. In other words, the
22 patient stands, and they have severe pain. And

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1 these patients oftentimes have no pain when they're
2 lying flat but severe pain when standing, or if the
3 pain at the bone metastasis is in the upper
4 extremity, for example, it's pain when lifting
5 something or picking up something.
6 You can see there's no minimal duration, and
7 then the functional consequences that might be
8 different -- we kept trying to ascertain the
9 difference between cancer and other syndromes -- is
10 that with the decreased ADLs, these patients are at
11 greater risk for the complications of cancer such
12 as deep vein thrombosis and others.
13 I'll move on. The second we defined, and we
14 began by calling this CIPN. It's what most of the
15 literature refers to as chemotherapy-induced
16 peripheral neuropathy, although we are now
17 beginning to use biologics, which are not
18 technically chemotherapy type drugs. So overall,
19 these are drug-induced peripheral neuropathies in
20 cancer, and yet since the nomenclature that most
21 know is CIPN, we're going to call it that.
22 It's pain, at least as described by

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1 patients. But not all will use the word "pain."
2 Many will use the word "discomfort" but it's always
3 in the face of something unpleasant. And I sort of
4 heard a little of that today as other groups were
5 describing their conditions; generally described as
6 tingling, numb, and burning. Again, the factors
7 that need to be in place are cancer diagnosis and
8 that it's definitely treatment related.
9 So we clearly have a drug being
10 administered, and then in a time course that's
11 somewhat anticipated, the individual will then
12 report these sensations. And we can see some of
13 the other signs like the balance and proprioception
14 changes, which we think might be somewhat unique to
15 chemo-induced neuropathy.
16 In fact, when Rob Edwards and I were
17 kibitzing afterwards, trying to make sure we were
18 all on the same page, that would be an interesting
19 research study and a relatively simple one for a
20 fellow or a grad student to compare the experiences
21 of the person with diabetic neuropathy with the
22 person with chemotherapy-induced neuropathy.

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1 Here are the other dimensions, the temporal
2 onset consistent with the administration of the
3 chemotherapeutic agent. And again, emphasizing
4 that proprioception change occurs, leading to falls
5 and other really serious consequences on the
6 quality of life for those patients. The
7 neurobiologic mechanisms we're beginning to
8 understand through work that Pat is conducting, Pat
9 Mantyh is conducting, and others.
10 Our third condition that we selected was
11 pancreatic cancer. And we chose this as an
12 exemplar of pain related to the tumor. And the
13 reason that we chose this is that it has global
14 implications. It has lousy survival rates
15 regardless of whether you're in a developed country
16 or the developing country.
17 So we wanted to reflect not just our
18 advanced medicine views where we have sophisticated
19 diagnostic techniques and sophisticated therapies,
20 but we wanted to reflect a syndrome that would be a
21 problem regardless of where you might live
22 throughout the world.

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1 So it's pain at the site, in the right-upper
2 quadrant in general. It may refer to the back. It
3 increases with time as tumor progression advances.
4 It may radiate. We don't know that for sure. We
5 have a lot of questions, as you can see in these
6 tables. It can be perceived as pain in the back as
7 well, but it's very different than the back pain
8 kinds of descriptors that you would see with
9 someone who has tumor-related vertebral body
10 metastases.
11 The common features are somewhat unique,
12 with cachexia obstruction, and then depression.
13 Yes, with all the syndromes we've discussed,
14 depression is a comorbid condition, and yet
15 depression seems to be a consequence. It occurs in
16 a very different way than what we see with
17 individuals who have chronic pain states. It can
18 occur acutely, and it's profound. Hiccups,
19 fatigue, and other syndromes can occur. And we
20 believe that we need to begin doing genotyping to
21 profile the microenvironment again.
22 The last one we tried to tackle is the

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1 post-cancer or post-surgical cancer pain syndromes.
2 And we were looking at post-thoracotomy or
3 post-mastectomy syndrome as a model. And again,
4 this is where it's challenging. Is it
5 post-mastectomy, post-lumpectomy, post-axillary
6 node dissection, post-sentinel node dissection? So
7 there were all these different variations that are
8 being done to our patients.
9 So the signs, again, cancer diagnosis, the
10 surgery, allodynia guarding, hyperalgesia,
11 hypoesthesia, and there's the plus/minuses because
12 we don't know. We need to better characterize
13 these conditions.
14 The symptoms, this is where we acquiesce to
15 the pain greater than three months, pain at the
16 site, paresthesia, sensations of swelling, changes
17 in activities of daily living because of the pain.
18 Many patients report that they cannot sleep on the
19 affected side, and that's true in Brian's head and
20 neck cancer patients and Chris' breast cancer
21 patients.
22 We were recommending, in terms of diagnostic

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1 techniques, quantitative sensory testing, again,
2 for the research setting. We're not ready to go
3 prime time for the clinical setting in making that
4 a strong recommendation. We were fascinated by
5 some of the common features that might put patients
6 at risk, like perioperative events. I've learned
7 that the word is not "complications" but "events"
8 from a legal perspective, whether the individual
9 gets infection.
10 The individuals who are more likely to have
11 drains or chest tubes after a procedure, are they
12 more likely to have more of a persistent pain
13 syndrome if they had preoperative pain, poor
14 postoperative pain control?
15 Neoadjuvant chemotherapy/radiation. This is
16 in the setting for those of you who are not
17 familiar with cancer, where individuals get chemo
18 and/or radiotherapy prior to their surgical
19 procedure to shrink the tumor to limit the
20 invasiveness of the surgical technique. Are they
21 more likely to have persistent pain when compared
22 to people who never saw chemo or radiotherapy

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1 before surgery?
2 One of the consequences we identified was
3 lymphedema, and, again, that's true across
4 different tumor types. And then risk
5 factors -- and I saw this in several of your
6 explanations today -- the lower socioeconomic
7 status, in part because patients have fewer
8 resources. But probably a huge indicator for the
9 cancer population is that these individuals are
10 diagnosed much later because of their illness.
11 So that's where our group came up. We were
12 under the wonderful leadership of Dr. Turk. Any
13 questions?
14 Am I getting us back on time, Steve?
15 DR. BRUEHL: Oh, you're great. You've
16 actually got 3 minutes and 15 seconds.
17 DR. PAICE: Thoughts, questions, concerns?
18 No? Ursula?
19 DR. WESSELMANN: [Inaudible - microphone
20 off.]
21 DR. PAICE: So the question is how do we
22 assess the pain burden of the many different

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1 good --
2 DR. WESSELMANN: [Inaudible - microphone
3 off.]
4 DR. PAICE: Good question. So patients
5 rarely have one syndrome or one condition alone.
6 How do we assess multiple conditions, the burden
7 associated with multiple conditions? I don't think
8 we got that far.
9 Group? Chris?
10 DR. WESSELMANN: Especially the temporal
11 something, it might get worse, but something else
12 might get better.
13 DR. PAICE: Right.
14 DR. WESSELMANN: [Inaudible - microphone
15 off.]
16 DR. PAICE: That's what we were speaking to
17 the dynamics of this. But, Chris, go ahead.
18 DR. MIASKOWSKI: Chris Miaskowski. Ursula,
19 I love your question. I think it's a really
20 critical one. And what we did talk about was the
21 fact that the data is now showing that 50 percent
22 of people who have a cancer pain problem also have

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1 a non-cancer related pain problem, so that whole
2 interplay as well. And I think with the
3 demographics of the society changing and the number
4 of people who are aging who are predicted to have a
5 cancer diagnosis in the next 20 years, it's going
6 to become a much more complex problem to sort out.
7 DR. PAICE: We came up with a huge list of
8 research questions and some wonderful opportunities
9 with preexisting data sets that Chris has, Pat
10 Dougherty has, and others.
11 DR. KHALSA: I just wanted to follow up on
12 that, this idea of how do you measure the -- this
13 comes back to the impact of the pain. And I just
14 wanted to advocate for something that the NIH task
15 force on low back pain -- which I think was very
16 clever and I think is generalizable because of what
17 they did.
18 So the task force was trying to assess the
19 difference between pain intensity, which you can
20 measure on a standard numerical rating scale or
21 VAS, whatever, versus how this really impacts
22 people, which takes into account really looking at

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1 pain function and pain behavior.
2 Because the task force in its minimal data
3 set adopted a lot of the domains that the NIH
4 PROMIS tool utilizes, a few of the members of the
5 task force kept looking at that and said, "Well,
6 gee. I wonder if we could sort of go beyond what
7 PROMIS itself developed and try to develop an
8 IMPACT metric using these PROMIS domains."
9 So the task force essentially came up and
10 proposed and had some preliminary data to support
11 the use of an IMPACT measure, which comes directly
12 from the PROMIS measures. And it's a very simple,
13 linear addition when you sum up some of these
14 scores, and showed that at least for low back pain,
15 it has equal validity, if not better, than some of
16 the other functional measures that are commonly
17 used in the back pain world.
18 So it's something that other groups might
19 want to consider if they're looking at these
20 domains that PROMIS addresses that gives you a very
21 straightforward way of measuring impact of the pain
22 itself.

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1 DR. MIASKOWSKI: Chris Miaskowski. I think
2 this whole notion of functional appraisal is
3 really, really important. In all the work we've
4 done in cancer pain and symptoms, it's amazed me
5 that this very simple scale that Karnofsky
6 developed back in '49 -- okay, he studied nitrogen
7 mustard, basically. And he made this scale that's
8 used in oncology, that goes from zero, which is
9 dead, to 100, which is fully functional in 10-unit
10 increments. And the patient reports the kind of
11 level of function they have.
12 It is highly correlative with every symptom
13 we've studied. It's sensitive to different pain
14 groups, mild, moderate and severe. And even in our
15 breast cancer work, where we've had highly
16 functional women in terms of our mild, moderate and
17 severe pain groups, small changes in function were
18 discriminated among those groups. So I agree with
19 you that we need to fine-tune this metric in our
20 pain taxonomy.
21 DR. BRUEHL: Thank you. And we're ready for
22 our last group, the Sickle Cell Pain group, Carlton

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1 Dampier and Tonya Palermo. Go for it.
2 Presentation - Carlton Dampier
3 DR. DAMPIER: Thank you. I'd like to
4 certainly thank the organizers for including this
5 particular disease pain. We felt that we've come
6 somewhat late to the party, so we're very grateful
7 for being included and think that much of this work
8 can very uniquely inform our community and assist
9 our patients.
10 Our working group was myself and Tonya
11 Palermo, and then a number of hematologists who
12 treat both or either adult or pediatric patients,
13 and then another pediatric psychologist, and Bill
14 Zempsky, a pediatric pain person. So while we were
15 not particularly international at this point, we
16 were certain multidisciplinary.
17 This is one of the diaries that one of my
18 patients completed over a several-year period, as
19 you can see, quite a while ago. And this has been
20 the understanding of what sickle cell pain is like,
21 and really up until the 1970s and 1980s, in part,
22 because many of the more severely affected

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1 individuals did not survive and live beyond
2 childhood.
3 Now we're recognizing that many of the
4 individuals, both in the adolescent age group and
5 certainly in the adult age group, look much more
6 like this. So again, someone, with except for some
7 missed diaries, really seems to have persistent
8 daily pain. And this is the group that we really
9 felt it was quite important clinically to bring to
10 the attention of both our clinical providers as
11 well as to the pain community because we really
12 have very little information about these
13 individuals.
14 Certainly, they're unique features. It's
15 certainly almost exclusively a disorder of minority
16 individuals, onset and early infancy. And while
17 frequent acute pain occurs in childhood, the
18 persistent pain that we're seeing is relatively
19 rare prior to the early teenage years, but then
20 becomes remarkably common in adults. So there is
21 we think much to learn and much to do.
22 Issues that we really had to struggle with

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1 in terms of this taxonomy exercise is it's really
2 very limited, both research and clinical data,
3 describing these pain conditions, and really very
4 limited reliability of any diagnostic testing with
5 a possible exception of certain complications that
6 we'll describe, and virtually no data on etiologies
7 or mechanisms.
8 We've proposed four different conditions,
9 perhaps largest group -- although, again, part of
10 the research agenda would be really to ascertain
11 some prevalence of these various conditions -- is a
12 persistent pain without any other specific painful
13 complication of the disorder, and then a group of
14 three additional conditions where there are
15 well-demonstrated pathologies related to sickle
16 cell disease, but not directly related to
17 vaso-occlusion, that have separate diagnostic
18 criteria and separate treatments and separate
19 natural histories.
20 We struggled much like I think the cancer
21 group did in terms of recognizing that the
22 temporality of the pain is a very important issue,

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1 that this is really an episodic pain disorder. And
2 we need to exclude those individuals who continue
3 to have episodic pain and not persistent pain, and
4 chose at least for our initial criteria a pattern
5 similar to what the headache folks have done, which
6 is a pain frequency on more than half of the days
7 in a month.
8 Again, we're happy, at least initially, with
9 a three-month period, although that's an area that,
10 again, we'd like to be informed, as I'll mention
11 later, by research and reanalysis of existing data
12 sets.
13 The overlap between this persistent pain
14 syndrome and the co-occurrence of acute pain is
15 something that is, again, relatively unique to this
16 disorder and whether that would need to be factored
17 into a diagnostic criteria or whether that would
18 simply be a common feature was, again, part of the
19 information that we interested in obtaining, and
20 again, whether the number and locations of the pain
21 might be a diagnostic criteria or perhaps a common
22 feature. Again, much like the cancer pain

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1 literature, there may be characteristics and
2 descriptors that are important. But we really
3 don't have sufficient data.
4 We then recognized that we have this, again,
5 group of other conditions generally with bone or
6 skin or visceral involvement, and in those we can
7 use the diagnostic criteria that are available in
8 the clinical literature as additional diagnostic
9 criteria.
10 So where the group is now is really kind of
11 working through what needs to be in common features
12 versus common comorbidities and functional or
13 psychosocial consequences. And there is some
14 information that we can work from with the
15 literature, although they're not often necessarily
16 specific to chronic pain scenarios. So again,
17 maybe an area where we need to develop a larger
18 research agenda.
19 I tried to focus our current research
20 agenda, for the purposes of this exercise, really
21 around symptom prevalence and temporal patterns.
22 We're particularly interested in the prevalence of

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1 these four conditions and recognizing that there
2 may very well be co-occurrence of several of these
3 conditions. And again, as a lifelong disorder,
4 better understanding the [inaudible - intermittent
5 mike] as they reflect either prevalence or perhaps
6 diagnostic criteria.
7 From a funding perspective, we do have a few
8 existing data sets that would be worthy of
9 reanalysis for some of these considerations. And
10 much of the time today was spent on developing a
11 draft data collection instrument that we could use
12 to address these specific considerations, with a
13 caveat that we weren't sure how much additional
14 data might be more global across these pain
15 disorders and might need to be included in our data
16 collection.
17 So that's where we stand and, again, would
18 be happy to answer questions.
19 Presentation – Tonya Palermo
20 DR. PALERMO: Just to add, one of the
21 discussion points for us -- and this is probably
22 true for the cancer group, too, is what's an

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1 appropriate comparator. And our discussion was
2 really around we can't really compare to someone
3 who doesn't have the disease [inaudible -
4 intermittent mike] -- we thought about was just
5 collecting this data on all sickle cell patients
6 and discriminating between those with and without a
7 [inaudible - intermittent mike] persistent pain.
8 I don't know how the cancer group is
9 handling that, but that was something we talked
10 about as well.
11 DR. DAMPIER: Yes?
12 DR. FARRAR: I'm going to sound like a
13 broken record. This is John Farrar. Do you have a
14 sense that you're going to be able to collect data
15 that might be useful in differentiating different
16 types of pain syndromes in this population? Is
17 that even a rational thing to think about? Are
18 there patients with persistent pain that affects
19 certain organ systems or for certain joints or
20 other things?
21 DR. DAMPIER: Part of that is limited by our
22 current understanding. But the expectation

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1 was -- and particularly over a broad age group and
2 potentially across -- there are a number of
3 clinical sites that we could have information on,
4 on a broad range of these, for conditions,
5 recognizing that some may commonly co-occur.
6 Particularly in the adult population, it might be a
7 little bit more difficult for us to have unique
8 features of one particular condition, but that
9 might very well be possible in the pediatric
10 population.
11 DR. FARRAR: Just to follow up, I guess the
12 question is how often do you see people who have
13 one or the other as opposed to multiple
14 combinations? And are there subgroups of this
15 population that are worth looking at to try and
16 understand something more about it?
17 DR. DAMPIER: Agreed, and certainly
18 anecdotally, the experience is that -- for example,
19 individuals with leg ulcers often may have that as
20 an isolated symptom. Certainly in pediatrics, we
21 may very well have some individuals who
22 specifically have avascular necrosis without some

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1 sort of generalized pain syndrome.
2 So again, given a broad enough net, I think
3 we can, to a degree. Now, there may be some age
4 and other confounds that might make it a little bit
5 difficult to broadly characterize across all age
6 groups, all diagnoses, but we can make a stab.
7 DR. PALERMO: Even that first category,
8 there has not been a well-defined -- or there's not
9 a well-accepted definition of persistent pain in
10 sickle cell disease -- category, in addition to
11 current classification.
12 DR. S. DWORKIN: Sam Dworkin. I was
13 wondering what accounts for the increased longevity
14 that you now observe, and are there any hypotheses
15 about how the increased longevity interacts with
16 pain since the pain pattern seems to be
17 observed --
18 DR. DAMPIER: No. It's an interesting
19 question and something that we're beginning to
20 struggle with as we look at fairly older data sets,
21 data sets from the '70s, and compare them to
22 current data. Clearly, the difference is related

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1 to our greatly improved ability to manage
2 infectious diseases in these patients. So that has
3 really been the profound difference.
4 Whether we're now indeed seeing a much more
5 chronically ill population, I think that some of us
6 with white hair certainly think that way. Whether
7 we'd be able to really demonstrate that is going to
8 be hard to say.
9 DR. S. DWORKIN: Chronically ill with regard
10 to sickle cell with and without pain or the pain
11 persists even though your interventions allow
12 greater longevity?
13 DR. DAMPIER: Repeat that question again.
14 I'm sorry.
15 DR. S. DWORKIN: The thing that's intriguing
16 to me is that the longevity that you've depicted
17 from the disease not progressing -- the
18 individuals, patients not progressing beyond
19 childhood into adult life doesn't seem to -- the
20 pain patterns in the younger and older patients
21 don't seem to be different. And so I was wondering
22 what it was that was accounting for the longevity

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1 and its non-interaction with prevalence of pain.
2 DR. DAMPIER: We don't really understand
3 etiologies and mechanisms, so I think that's hard
4 to speculate on. Since many of these individuals
5 probably -- we don't have data from the '70s and
6 '80s because these individuals just didn't live
7 long enough. It's interesting to speculate, but it
8 will be kind of hard to prove.
9 DR. BRUEHL: Thank you.
10 MS. DARBARI: Can I add an answer to one of
11 those things?
12 DR. BRUEHL: Briefly.
13 MS. DARBARI: Our collaborative study had
14 shown that if you had more pain crisis, the life
15 span was shorter. So I looked at the NIH database,
16 which is like more recent because now we are using
17 hydroxyurea transfusion and patients are living
18 longer. So in this era, is pain still related to
19 the shorter life span? So it was still positive
20 and that we published.
21 So there is something. Either these are the
22 patients who have more severe disease and die early

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1 or some other factor. So we also looked at some of
2 the other factors that are high risk for early
3 death, and pain was still very significant in that.
4 DR. BRUEHL: All right. Very good. Thank
5 you.
6 We are running out of time, so let's do
7 this. Let's take a 10-minute break for coffee,
8 bathroom, whatever. It's now 3:09. So around
9 3:20, if we can come back, we want to kind of have
10 an overall wrap-up of things and get everybody out
11 of here by 4:00.
12 (Whereupon, a recess was taken.)
13 Next Steps
14 DR. FILLINGIM: Okay. Let's go ahead and
15 get started here. So we've got a wrap-up session
16 here. I'd like to say, if you'll look at your
17 agenda, my name is not on the list during this
18 segment, and I was ambushed shortly before the
19 break.
20 (Laughter.)
21 UNIDENTIFIED SPEAKER: It was a typo.
22 DR. R. DWORKIN: It's a demonstration of

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1 Fillingimectomy [ph].
2 DR. FILLINGIM: Yes. And before we get
3 started, somebody asked me about disclosures at the
4 break. I'll say two things about that.
5 One is, we sent a form to everybody because
6 we want to be able to say, if we're ever asked,
7 that all potential conflicts and relationships of
8 AAPT participants and principals were disclosed to
9 us. So if you haven't sent that form back to
10 Cassie Corvo at the American Pain Society, please
11 do. And if you're not sure whether you sent it
12 back or not, email me or email Cassie, and I think
13 we can tell you.
14 The other question that came up is when
15 you're doing other disclosures, do you now need to
16 disclose this relationship? And I think that
17 depends on your institutional guidelines and what
18 they think a disclosure is. I don't think we have
19 stock options in ACTION now. So for many
20 definitions of disclosure, it would be no, but
21 you'll have to look at the fine print and your
22 institutional guidelines.

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1 Does that help? Okay.
2 So we've had a great couple of days as far
3 as I can tell. We've heard from each of the
4 working groups, excellent progress across the
5 board. I'll just mention one or two cross-cutting
6 issues that I know came up in the group I sat in on
7 and I've heard from other people, and then we'll
8 open the floor for discussion and questions and so
9 on and so forth. And many of these questions
10 revolve around the research that will be done and
11 what that's going to look like. And I just spoke
12 with Bob.
13 So one proposal that came out of their
14 working group was AAPT 1, which is what we're
15 working on now, will be published -- each working
16 group will publish their AAPT 1 classifications
17 using literature review and existing data that they
18 currently have access to and can reanalyze without
19 new data collection; that is you will create the
20 most evidence-based criteria that you can, and that
21 way, by this time next year, all of the AAPT
22 articles will have been published, we hope.

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1 So that's one thing I'll put on the table
2 because how we respond to that will sort of drive
3 some of the other things we might talk about with
4 research. So how does that sit with people?
5 Do any of the working groups feel
6 uncomfortable about publishing things that they
7 have confabulated without additional data?
8 DR. R. DWORKIN: I think the only
9 clarification is, as I think we saw right before
10 the break, some of the research that needs to be
11 done is not going to take six months or maybe even
12 a year to year and a half. It might take a couple
13 of years.
14 We thought, rather than waiting for this
15 AAPT effort, the initial AAPT effort to be complete
16 with all new data collection underpinning it, which
17 would be a three- or four-year process, let's do
18 AAPT 1 as the most evidence-based criteria we can
19 come up with, as Roger said, based on existing
20 literature and reanalyses of data that we have
21 access to, that's AAPT 1.
22 We could roll that out over the next 6 to

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1 12 months while at the same time Steve and the
2 other members of the research committee will be
3 getting the research going that will provide the
4 basis for AAPT 2, that we would expect would appear
5 in, I don't know, three years.
6 DR. FILLINGIM: Sam first, and then --
7 DR. S. DWORKIN: I think that is a fantastic
8 idea, and I would from our experience encourage
9 people not to be intimidated or reluctant to
10 undertake such publications because they had few
11 evidence-based criteria, but rather to distinguish
12 in their publication the evidence-based criteria
13 very clearly from the non-evidence-based because it
14 will be a stimulus to research.
15 In addition to your research, there are
16 other people out there -- some people in this room.
17 There are other people out there looking for good
18 ideas to do research on, and you'll be identifying
19 a multitude of issues that are researchable. So I
20 would encourage that. I think that's just a
21 fantastic idea.
22 DR. FILLINGIM: Chris?

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1 DR. MIASKOWSKI: Chris Miaskowski. I also
2 agree that it's a good idea, but I do have a
3 question or maybe a point for consideration or
4 clarification.
5 I was really intrigued with Steve's
6 presentation yesterday, and I really like the
7 methodology. I think the challenge for many of
8 us -- and I can speak for the cancer pain
9 group -- is that we don't have a gold standard.
10 And so my question for us to consider is, is there
11 an approach -- I'm not even sure it's a
12 method -- that we should consider using, or trying
13 to use, across these different pain conditions,
14 rather than cancer say we're going to try this, and
15 back pain says they're going to try this?
16 I ask the question, and I have no sense of
17 the answer. But I'm wondering if it's something we
18 should think a little bit about.
19 DR. BRUEHL: Yes. The short answer is yes,
20 we should think about that. There are
21 some -- there are certain conditions that it's
22 easier to find a comparison group to do the kind of

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1 study I talked about than it is for others. So I
2 think some of it is going to necessarily be
3 dependent on the specifics of the condition and
4 those comparators that are available.
5 For some conditions which may have a -- like
6 the sickle cell pain group, where it's very
7 difficult to find another condition that makes
8 sense as differential diagnosis that we're going to
9 try to distinguish between these two groups, we may
10 have to use other approaches. And we may have to
11 simply say for now we're not going to try to do the
12 sensitivity and specificity, but rather focus on
13 the internal validity and just getting the
14 structure of it in a way that it fits with what we
15 know about the existing literature.
16 An example that we brought up I think in one
17 of the groups was if you've got a -- let's say
18 we're trying to do a diabetic neuropathy and we're
19 putting in the criteria that you have to have
20 burning pain. And then we go and do research, and
21 we ask in a systematic way about burning pain, and
22 it turns out only 40 percent of the patients

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1 describe their pain as burning. We've got a
2 disconnect between what the data say and what we've
3 got in the criteria. That should require a change
4 of the criteria.
5 It's very simple. I mean, this is not like
6 high-level research, but that's the kind of thing
7 that if we systematically collect those data sheets
8 on signs and symptoms, we can go back and answer
9 questions like that. That alone is advance beyond
10 what we have now.
11 I think that's kind of what Sam's getting
12 at, is don't be afraid just because there's nothing
13 out there. Well, we can start with something. And
14 the something is we do our best to put together
15 some draft criteria -- and this is one thing I want
16 to throw out, too, kind of in response to the
17 previous question, which is there was a lot of
18 variability across groups. Some of us had one or
19 two things we're using to diagnose. Some had a
20 laundry list of 10 things.
21 The truth is, none of us really know whether
22 it should be 2 or 10 or what combination of those.

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1 The back pain group I think was brave enough to
2 come right out and say we don't know, so we're not
3 going to even bother to put them in there because
4 we haven't done the research yet. That is
5 theoretically legitimate.
6 Now, pragmatically, if we're trying to
7 suggest some draft criteria to say this is the best
8 we've got so far -- the back pain group I'll pick
9 on you a little bit -- how do you want to handle
10 that? Do you want to say we really don't know
11 enough to even label things as likely neuropathic
12 or nociceptive, so here's what we're going to
13 recommend and here's why? So you don't really
14 suggest criteria, but you say here's what the
15 problem is based on our literature review. That
16 might be acceptable.
17 Some of us clearly have done enough looking
18 at the literature that we know it's possible to
19 come up with some draft criteria that would at
20 least make sense to a clinician, that you might be
21 able to get some agreement on, even if the
22 specifics aren't finely detailed. In that

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1 circumstance, I'm going to say go ahead and do it.
2 Take your best shot at it. Suggest two of these
3 symptoms and one of these signs and just go with
4 it. And we'll test later on whether that is wrong,
5 or we will seek to do that later on.
6 The question is, should you make them very
7 stringent or relatively less stringent? Especially
8 in a situation where it's going to be difficult to
9 do the sensitivity and specificity research, you
10 might want to set the bar a little lower so that
11 you don't have to require as quite as many
12 symptoms, so it's a little easier to get that
13 diagnosis.
14 Anyway, I just wanted to throw all that out
15 there. So it's going to vary from condition to
16 condition. And talk with me about the specifics.
17 I will be available as a kind of consultant on this
18 stuff. I may or may not be able to give you better
19 ideas, but at least we can talk about it and try to
20 define how to handle this stuff.
21 DR. GEORGE: So the other implication of
22 this is that that means there are going to be two

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1 research streams for pretty much all the working
2 groups, one of analyses of existing data when such
3 data exists, and that can begin quickly; and then
4 the second stream of designing new studies to
5 collect data that would answer the questions that
6 we need answered and that aren't easily answered by
7 existing literature or data. And so those two
8 streams will happen in parallel. One will finish,
9 as Roger said, over the next 6 to 9 months. The
10 other could go on for three years.

11 DR. BRUEHL: John, did you have --

12 DR. MARKMAN: Just a quick question. Given
13 that for some of these conditions like low back
14 pain there's a wealth of clinical trial data and
15 that ACTTION has access to some of those data sets
16 through relationships with the sponsors, and/or
17 FDA, or both, would it be possible potentially to
18 use some of that existing data as part of the
19 validation effort? If we're reanalyzing data, but
20 for this new purpose, it might kind of what we're
21 doing more compelling I think.

22 DR. R. DWORKIN: Our working group talked

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1 about getting raw data from Pfizer clinical trials.
2 And as you know, there are a couple -- well, at
3 least one lumbosacral radiculopathy clinical trial
4 that Pfizer conducted of pregabalin, and then there
5 are two or three trials that Lilly did of Cymbalta
6 in axial low back pain. And I think it would be
7 great to try and get those data and analyze them.

8 DR. MARKMAN: And some of the opioids, too.
9 If we could pull that in, that would be great.

10 DR. ARNOLD: This is Lesley Arnold. Is
11 there some danger or something we have to be
12 careful about if we're putting out proposed
13 criteria that people will start to use them
14 [inaudible - intermittent mike] -- are now the
15 accepted endorsed criteria. I'm a little concerned
16 about that, especially since [inaudible] -- some
17 criteria out there that we're actually challenging
18 a little bit. And without data to support what
19 we're saying, I'm a little hesitant to put it out
20 there.

21 DR. BRUEHL: I have a little hesitation.
22 And I will say with the CRPS, what happened was we

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1 kind of ran these criteria up the flagpole just to
2 kind of see what they looked like and said here's a
3 proposal for some research criteria. And we made
4 very clear we weren't talking about using it for
5 clinical purposes yet.

6 We didn't really have the intent of trying
7 to change the way everybody did research, but what
8 actually happened was many research groups, because
9 they were desperate for a better way to diagnose
10 it, picked up on it and started using it.

11 Fortunately, when we replicated the validation
12 study, it came out supporting them as being
13 reasonably good.

14 I do think it is appropriate, in writing any
15 articles at this stage, for us to say that we
16 don't -- I mean, explicitly, it's like a cautionary
17 paragraph that will be in every single article, "We
18 do not recommend using this for routine clinical
19 use yet. Possible use for research is up to the
20 discretion of the researchers." The caveat is we
21 have not yet validated X. I think that's
22 appropriate to say that.

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1 DR. R. DWORKIN: Lesley, couldn't you also
2 say that there are existing from Aberdeen that you
3 would be able to analyze quickly?

4 DR. ARNOLD: Yes, we were going to do that,
5 but that was just to help us better define chronic,
6 widespread pain. But as far as putting forward the
7 idea of widespread pain plus two symptoms, it's not
8 yet -- that's never been proposed as a criteria for
9 fibromyalgia.

10 DR. R. DWORKIN: But do the Aberdeen data
11 have the symptom data also?

12 DR. FILLINGIM: Well, why don't we ask Gary?

13 DR. MACFARLANE: First of all, I would
14 support Lesley's reticence because in fibromyalgia,
15 we have a set of validated criteria. We have three
16 sets of proposed criteria in the literature. And I
17 worry a little about coming forward with a fourth
18 set of proposed criteria without any data to back
19 it up.

20 Having said that, in the fibromyalgia group,
21 we felt that it was possible to move quite quickly.
22 At Aberdeen, we're committed to doing some analysis

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1 of existing data that could help us finalize the
2 study that we thought we needed to do in order to
3 validate the criteria. Although a small amount of
4 resources -- I think we're only talking about a
5 small amount of resources, we felt that we could
6 move fairly fast.

7 DR. R. DWORKIN: So the fibromyalgia group
8 will do AAPT 1 and 2 at the same time, and then can
9 begin working on AAPT 3 while we're still
10 struggling with AAPT 2.

11 DR. BRUEHL: I think that it's important
12 that we finesse this because we have to -- in
13 anything we write about this, we have to make clear
14 what the point of it is, which is for most chronic
15 pain conditions, the diagnostic criteria have not
16 been systematically validated in any way or
17 subjected to any empirical tests. That is what
18 we're trying to do, is to address the multitude of
19 different diagnostic criteria and the absence of
20 data to support them.

21 If you've got a situation with an accepted
22 set of criteria like fibromyalgia and three

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1 different proposals already, I agree, putting a
2 fourth proposal of what's unvalidated out there is
3 probably not a great idea, but you might write
4 about what the problem is and say we've got these
5 three. These criteria don't match. They haven't
6 considered X, Y, Z. This part has been validated.
7 And then say this is why we're going to try to go
8 this different approach, and then you've got data
9 to support it. But I think we just need to be
10 really clear in explaining in the text why it is we
11 are even bothering to do this.

12 DR. ARNOLD: But I mean -- this is
13 Lesley -- would you object to our being a little
14 bit delayed in getting our paper out in the next
15 year --

16 DR. BRUEHL: I don't.

17 DR. ARNOLD: -- if we could collect data
18 within say --

19 DR. BRUEHL: Do it well, not fast.

20 DR. ARNOLD: So we could be one of the last
21 to be published?
22 (Laughter.)

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1 DR. FILLINGIM: Yes. And that's what I was
2 going to say, Lesley, is that the target would be
3 to do the best you can as long as you can get the
4 paper out in the next year-ish. If it's going to
5 be three years, then that's a different story.

6 Sam?

7 DR. S. DWORKIN: I'd just like to add
8 another level of emphasis and reiterate and support
9 what Steve said, and then add another dimension;
10 that is all those caveats clearly explicated, and a
11 description of the mission of this ACTION/AAPT
12 thing, which is to promise reiterations so that in
13 the next year, and the next year, you are promising
14 to -- or that's your model system -- to
15 undertake --

16 This is the initiation of a program of
17 research and validation of the criteria. This is
18 the first shot. It has all those caveats in it,
19 and we will do the next sets, so then years 2 and 3
20 will be the next steps of what this group does.
21 That will give your group a kind of leg-up on
22 acceptability and respectability that is missing

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1 from when there are a bunch of people that have put
2 together some diagnostic criteria for back pain or
3 cancer or anything else.

4 Also, I don't know how -- Steve, I can't
5 remember how you handled the sensitivity and
6 specificity. You must have had control people.

7 DR. BRUEHL: Our controls were people with
8 other kinds of neuropathic pain conditions --

9 DR. S. DWORKIN: Yes. So that's equally
10 easy data to collect amongst multisite willing
11 collaborators within the same condition to simply
12 ask people who don't have the pain under
13 consideration as a control group. And just make
14 sure you have some number larger than the number of
15 clinical subjects because you're doing mini or
16 quasi-epidemiologic studies. And it's clearly that
17 the first level of research that's needed are the
18 epidemiologic studies.

19 What we did, we did a full-scale, major
20 epidemiologic study eventually, and it wasn't very
21 expensive, at least not at that time. But what it
22 did was we could compare the data generated or our

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1 algorithm-generated diagnoses with the expert
2 diagnoses and found, hey, these things, don't
3 bother mentioning them. They never appear in our
4 data. Nobody -- and the epidemiologic subjects
5 don't have these kinds of things, like the burning
6 symptoms that you talk about only occur. That
7 eliminated for us occlusion, disc-joint noises.
8 That's absolutely irrelevant because they were
9 never associated with any pain.
10 DR. TURK: I'll just reinforce how you're
11 talking.
12 DR. MIASKOWSKI: Chris Miaskowski again.
13 Maybe this is a little naive as well, but I'm
14 sitting here thinking across the presentations and
15 thinking about a common yet perhaps disparate,
16 differential, diagnostic taxonomy.
17 So that leads me to, is there -- should we
18 be considering a common set of data elements? And
19 if we believe that is the case -- so I'm going to
20 use pain intensity because that's probably the
21 simplest one. If we're all going to ask pain
22 intensity, are we all going to ask it the same way?

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1 So that we have some reference point, if we're
2 going to do function, are we going to consider
3 maybe one common functional question? And I raise
4 that as something -- I'd like to know the answer to
5 that or maybe we derive that for 2.
6 DR. R. DWORKIN: So the answer is yes. So I
7 think we've all thought -- when we've thought about
8 the prospective research that we would be
9 supporting, whether it was a small network -- for
10 example, sickle cell pain -- of specialized sites,
11 or whether it's a network that's going to do both
12 spine pain and neuropathic pain and fibromyalgia
13 because those are prevalent conditions, that there
14 should be as much consistency in data collection as
15 possible. I don't know how anyone could disagree
16 with that.
17 DR. MIASKOWSKI: I'm saying we should do the
18 same pain question for cancer pain.
19 DR. R. DWORKIN: Yes.
20 DR. MIASKOWSKI: And who's going to guide us
21 on that? When are we going to get directions?
22 DR. R. DWORKIN: We have a research

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1 committee.
2 DR. MIASKOWSKI: Okay. That wasn't clear.
3 DR. BRUEHL: So there are also things like
4 allodynia that pop up again and again, so having a
5 standard procedure we'll recommend for testing
6 that, just operational definitions for things like
7 that.
8 DR. MIASKOWSKI: You see that for phase 2.
9 DR. BRUEHL: Yes. I'm talking about --
10 DR. R. DWORKIN: The prospective research.
11 DR. BRUEHL: Yes. The retrospective, we're
12 just going to have to use whatever was used.
13 DR. FILLINGIM: Ursula?
14 DR. WESSELMANN: The same question arises
15 for collecting data on the comorbidities because
16 the two large studies that are currently ongoing,
17 the OPPERA study and the MAPP study, collect those
18 data for specific pain syndromes, but the
19 questionnaires they are using are slightly
20 different. For example, for the pain syndrome that
21 I have been studying for many years, vulvodinia,
22 that has only been included more recently into some

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1 of the comorbidities.
2 So if we want to make this a large effort,
3 then it would be good to have a very wide tool to
4 collect it. But that would probably require a
5 separate effort to collect this tool and then maybe
6 to discuss what has worked better in the MAPP
7 study, what has worked better in the OPPERA study,
8 so that we don't have to start from scratch.
9 DR. R. DWORKIN: Questions like this are
10 obviously is going to be something the research
11 committee has to struggle with, how much time can
12 we devote to collecting comprehensive data on
13 comorbidities with keeping the study feasible in a
14 pain clinic setting. I know we all are familiar
15 with those research trade-offs.
16 DR. S. DWORKIN: I just have to encourage
17 you to look at the research task force on back
18 pain. It has a minimal data set, which will answer
19 for many of the pain conditions and doesn't have
20 stuff relevant to neuropathic pain. But for most
21 of the common pain conditions is a very good
22 research tool. And I wanted to throw out that it

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1 will be a part of all NIH studies funded for
2 research on back pain.
3 So if you add that to what your effort would
4 do, we'd have a much broader universe of people
5 using a common set of pain measures and then
6 modified uniquely for the conditions that the back
7 pain put forth did not include in its minimal data
8 set. And that applies to psychosocial,
9 psychological status, functional status. Those
10 questions will be virtually universal across all
11 the pain conditions, and there's evidence already
12 to show that impact, et cetera. It will be the
13 same sets of questions -- could be the same sets of
14 questions that are already used in research in
15 similar ways.
16 So you could have one epidemiologic study
17 that had an Axis 1 and an Axis 2 component, and the
18 Axis 2 component contained all these questions
19 common to the psychosocial domain, and the Axis 1
20 questions, batteries of questions, specific to each
21 pain site. And the epidemiologic analysis would
22 break those apart in one single, large-scale,

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1 epidemiologic study for the future. But a group
2 like this could compel. That would be a very
3 compelling and powerful study.
4 DR. TURK: Let me amplify that, if I will,
5 because by disclosure I was on that task force.
6 And one of the things that we wrestled with was how
7 to get this to be used in the real world versus
8 just the clinic. So we made every effort we could
9 to have the smallest number of questions that we
10 thought were appropriate.
11 Now, obviously, it was for back pain, so
12 there are some things that are unique. But at
13 least the research committee could begin there,
14 look at what we did, and then see what if anything
15 we want to modify. But just so you know, there was
16 a major effort to make sure that we kept this as
17 short and as simple because we wanted surgeons to
18 use it in their general practice and all types of
19 circumstances. So there are some precedence to
20 help us get started on that.
21 DR. S. DWORKIN: Also, that it's suitable
22 for clinical research in clinical settings and

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1 epidemiologic research, so that both domains of
2 research enterprise generate the same set of basic
3 questions.
4 DR. FILLINGIM: Other questions? Comments?
5 (No response.)
6 DR. TURK: Why don't we try to wind up with
7 sort of going-forward steps and how we're going to
8 help and keep the energy going over time?
9 DR. BRUEHL: I have the solution to this
10 problem
11 (Laughter.)
12 DR. S. DWORKIN: He's smarter than you. He
13 asked the question first.
14 (Laughter.)
15 DR. BRUEHL: Yes. I think most of you got
16 the idea that what we need concrete out of this is
17 a couple of things. One would be ideally a draft
18 set of criteria. Now, you may elect not to publish
19 that right away. That's okay. But a draft set of
20 criteria, your best shot, and then a form, which
21 parallels what I showed up on the screen for the
22 CRPS database that just has the basic information

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1 you would want to collect in a clinical setting on
2 each patient.
3 I agree that starting out with -- like this
4 back pain task force is a way to identify an ideal
5 way of asking certain questions. We can add to
6 that different conditions. There may be certain
7 things that aren't covered. Like the neuropathic
8 questions may not be adequate, so maybe we need to
9 operationally define testing allodynia,
10 hyperalgesia, and things like that.
11 But we'll try to come up, I think, with a
12 common set of ways of assessing all those key
13 characteristics. And then each group is going to
14 be tasked with -- each task has to put together
15 those into what they think should be on their
16 database form that they're going to use for their
17 area. And as much as possible, we want to have
18 similar wording -- or identical, ideally, wording
19 across groups for similar concepts.
20 So we need the draft criteria. We need a
21 data form. The research committee -- and I would I
22 guess be the point man on that for contacting me if

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1 you have questions. I'll try to help you with
2 that. If it's a question that is more complicated,
3 we'll probably have a discussion on the phone as a
4 committee about these things. And anything that is
5 going to affect multiple groups, we may respond, I
6 would assume, to all the groups to say this
7 question's been asked by this group. All of you
8 from now on do it this way, to try to keep some
9 consistency.

10 DR. R. DWORKIN: So Steve, you're referring
11 to the prospective research.

12 DR. BRUEHL: Yes.

13 DR. R. DWORKIN: Right. All I would add to
14 that is you should also be thinking of whether
15 there are literature reviews, systematic reviews of
16 the literature, that would help your working group
17 that can get started right away. And we can
18 provide modest honoraria for a fellow or a graduate
19 student or a junior faculty member if you need a
20 systematic literature review done. So that's one
21 thing that can get started right away that isn't
22 directly related to the prospective research.

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1 The other thing that of course we've
2 mentioned is studies of existing databases. So let
3 us know if we can help you either identify existing
4 databases, kind of negotiating with pharmaceutical
5 companies who have clinical trials, or whether,
6 again, modest financial support would allow you to
7 begin an analysis of existing data quickly.

8 So those are two types of help that would
9 occur before what Steve was talking about, which is
10 the prospective research. So just get in touch
11 with us about any of those needs.

12 DR. BRUEHL: I just want to mention, I'm not
13 going to be a control freak about the analyses.
14 You are welcome -- if you have some idea of how you
15 want to proceed with analyzing this stuff, if you
16 get access to databases, go for it. I'm willing to
17 help if I can and if you want me to. But by all
18 means go do it on your own if you feel capable of
19 doing that.

20 I mean, a lot of these things are going to
21 be self-evident. And a lot of the questions you
22 can ask and the answers you can get will be pretty

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1 obvious once you see the way the data are laid out
2 and you know what you're looking for.

3 DR. PAICE: This is Judy Paice. Steve just
4 raised an interesting point. For AAPT 1, are you
5 going to want to look at all of our draft criteria
6 so that you will standardize some of the
7 terminology?

8 DR. BRUEHL: That was something we hadn't
9 addressed yet. And I think we should probably talk
10 about that and maybe get back to you. I think it
11 would make some sense for all of you to send your
12 best version of your draft by -- and we'll have to
13 set a deadline. But give that to us so we can take
14 a look at it. I'm not sure if we're going to do an
15 editing process or not.

16 DR. R. DWORKIN: So this is an important
17 point. Someone who isn't here now, because he had
18 to leave early, relayed a message to us that he
19 thought one of the real strengths of this effort
20 will be the consistency in how the diagnostic
21 criteria and information is laid out across
22 conditions. And so I think that point is very well

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1 taken. And we want to do everything possible,
2 Judy, so that the cancer pain article and chapter
3 look kind of similar to the neuropathic pain
4 chapter and the back pain chapter.

5 So the kind of specific ways in which the
6 boxes are filled are going to be different, but I
7 think the structure, the approach, should be as
8 consistent as possible.

9 DR. PAICE: I'm even thinking -- the papers,
10 that's very helpful, too. I'm even thinking about
11 the actual criteria. Some of the words we're
12 using, we're using different words for paresthesias
13 or dysesthesias.

14 DR. BRUEHL: Yes. Think about the DSM
15 model. If you go look at the DSM, it's very
16 consistent from disorder to disorder in terms of
17 how they word things.

18 DR. R. DWORKIN: And it's got a glossary.

19 DR. BRUEHL: Yes. And I think we would want
20 to do the same thing, operational definitions very
21 clearly defined and similar wording. But we don't
22 have to worry about now. We can come back and edit

1 that to improve the consistency. The first step is
2 just to get kind of laid down what the concepts are
3 and what you think the criteria should be, and then
4 we'll I guess take a look at it and maybe give
5 feedback.

6 Adjournment

7 DR. FILLINGIM: Okay. And with that, we're
8 done. Thank you all very much.

9 (Applause.)

10 DR. TURK: We're beginning. We're not done.

11 (Laughter.)

12 (Whereupon, at 3:57 p.m., the meeting was
13 adjourned.)

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