

Is the World Ready for a New Definition of Chronic Pain That Lacks Broad Support—and Evidence of Benefit?

A disappointing new guideline from the UK may well complicate the management of chronic low back pain around the world—and confuse patients and providers alike.

The new guideline is the latest chronic pain guidance from NICE—the National Institute of Health Care and Excellence. This prominent evidence review group formulates policy for Britain’s National Health Service—and influences medical policies in other countries around the world. The guideline is still in draft form. NICE recently solicited public comments on it. The final guideline will be published early in 2021.

The review is disappointing because it endorses a controversial new definition of chronic low back pain developed by the International Association for the Study of Pain (IASP) and the World Health Organization (WHO).

The definition promotes the hypothesis that pain is often a disease in its own right—rather than secondary to some other disease, condition, or abnormality.

As NICE defined it, “Chronic primary pain represents chronic pain as a condition in itself and which can’t be accounted for by another diagnosis, or where it is not the symptom of an underlying condition.”

The criteria for diagnosing it, according to NICE, include chronic pain of no obvious origin accompanied by “significant” emotional distress and/or “significant” functional disability.

Many people with chronic back pain—which generally has no identifiable cause or pain mechanism and often leads to psychological distress and functional disability—are likely to fall into this diagnostic category. Millions may be misdiagnosed.

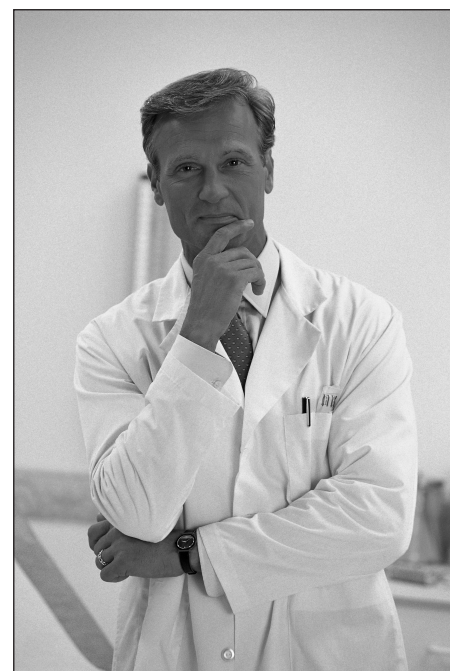
Is Pain a Disease in its Own Right?

That chronic pain can represent a disease in its own right is a viable hypothesis—one

that is particularly popular among pain specialists. But other professions, research groups, and policy-making organizations disagree about this notion. And there is not sufficient evidence at the moment to prove which point of view is correct.

The new definition is largely supported by the consensus of a subgroup of pain experts rather than compelling scientific evidence. It hasn’t been tested or validated in rigorous clinical trials or in high-quality observational studies in a broad variety of settings around the world.

Yet this definition is on the verge of being accepted by almost 200 countries in the World Health Organization as part of the new diagnostic coding system ICD-11—slated to take effect in 2022. It could have a profound influence on the management of



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Opioid Deaths Undercounted

This sounds incredible, but a new study suggests that public health authorities may have significantly *underestimated* the number of opioid overdose deaths in the United States over recent years.

This is reminder of the devastating effects of a drug overdose epidemic that began with the inappropriate and excessive treatment of back and other forms of musculoskeletal pain with powerful narcotics.

By way of background, it is often difficult to determine the cause of death among patients who succumb to an opioid or other drug overdose. Some die of respiratory failure, and others die from drug-related infections, and, according to the new study, many sudden cardiac deaths may stem from overdoses.

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Most Medical Marijuana Products Too Strong for Patients With Back Pain?

A new study concludes that 90% of medical marijuana products offered in dispensaries are too strong for the safe and effective management of chronic pain.

“We know that high-potency products should not have a place in the medical realm because of the high risk of developing cannabis-use disorders, which are related to exposure to high THC-content products,” said the study’s senior author, E. Alfonso Romero-Sandoval, MD, PhD, associate professor of anesthesiology at Wake Forest School of Medicine.

“Several earlier studies showed that levels of up to 5% tetrahydrocannabinol (THC) – the main psychoactive compound in marijuana that provides pain relief as well as intoxication – were sufficient to reduce chronic pain with minimal side effects,” according to Romero-Sandoval.

M.C. Cash and colleagues assessed THC levels in 8500 marijuana/cannabinoid products from dispensaries in nine states. They compared THC concentrations in medical marijuana and recreational marijuana dispensaries. They expected that recreational marijuana dispensaries would be offering marijuana products with high levels of THC, as these are highly valued among marijuana users. (See Cash et al., 2020.)

However, they hoped that medical marijuana dispensaries would be offering marijuana products with lower THC concentrations than those at dispensaries aimed at recreational marijuana use, as the available evidence suggests the former have a more favorable risk/benefit profile for people with chronic pain.

However, both types of dispensaries were offering products with similarly high levels of THC.

“The first major observation of our study was that the average concentration of THC in all states was two to three times the THC content known to be efficacious in the treatment of pain (i.e. >5–10%), according to Cash et al.

“The second major finding of our study was that a vast majority of products in all states, including medical-only programs, contained THC designed for recreational use (i.e. > 15% THC concentration). Patients who find this information in their online searches may subsequently deem high potency products suitable for medical purposes, placing themselves at higher risk of cannabis intoxication. Severe intoxication, hyperemesis, psychiatric symptoms, and severe cardiovascular events have been reported to be a major cause of cannabis-related visits to emergency departments in Colorado.”

Better regulation of the potency of medical marijuana products is critical.

“Better regulation of the potency of medical marijuana products is critical,” said Romero-Sandoval. “The [U.S. Food and Drug Administration] regulates the level of over-the-counter pain medications such as ibuprofen that have dose-specific side effects, so why don’t we have policies and regulations for cannabis, something that is far more dangerous?”

Editor’s note: Statements that different types of marijuana products are “efficacious” in the treatment of pain should be interpreted cautiously. Some reviews have concluded that marijuana is an effective treatment for chronic pain. But other more critical reviews suggest that the evidence to date is simply inconclusive.

Disclosures: None declared.

Reference:

Cash MC et al., Mapping cannabis potency in medical and recreational programs in the United States, *PLOS One*, 2020; 15(3): e0230167. doi:10.1371/journal.pone.0230167.

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Executive Editor

Sam W. Wiesel, MD
Professor and Chairman, Department of Orthopaedic Surgery, Georgetown University Medical Center, Washington, D.C.

Publisher

John M. Ewers

Editor

Mark L. Schoene
25 Storey Avenue, Suite 154, Newburyport, MA 01950

Associate Editor

Colin Nelson

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Haymo Wilhelm Thiel, DC, Anglo-European College of Chiropractic, Bournemouth, UK

C. David Tollison, PhD, Carolinas Center for Advanced Management of Pain



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Transition to Telemedicine Leaving Older Patients Behind

Because of the COVID-19 pandemic, medical systems around the world are in a wholesale transition from in-person healthcare consultations to telemedicine or telehealth interventions. It is true in spine care as in other fields.

The medical community was derelict in not planning adequately for this transition—although a world pandemic was eminently predictable. As a result, many medical systems, reimbursement systems, and individual medical providers are having to fly by the seat of their pants in dealing with this transition.

For example, no one had calculated what proportion of the general populations of low-, middle-, and high-income countries was even capable of connecting to a healthcare provider remotely. Or who might be left behind in this massive transition.

Older People to Be Left Behind?

In the United States, people 65 years and older are some of the major users of medical services. Older individuals account for about 25% of all medical visits. And these visits often address multiple complex medical problems and conditions. The U.S. Department of Health and Human Services is actively promoting telehealth consultations but has not assessed the ability of older individuals to access this form of medical interaction.

Geriatrician Kenneth Lam, MD, and colleagues from the University of California recently conducted a study of “telemedicine unreadiness” among a nationally representative sample of 4525 people 65 years or older—culled from the National Health and Aging Trends study. (See Lam et al., 2020.)

Multiple Types of “Telemedicine Unreadiness”

They defined telemedicine as the use of any form of communications technology to deliver healthcare at a distance.

They classified telemedicine unreadiness as any of the following: (1) difficulty hearing well enough to use a telephone even with a hearing aid; (2) problems speaking or making oneself understood; (3) possible or probable dementia; (4) difficulty seeing well enough to watch television or read a newspaper, even with glasses; (5) owning

no Internet-enabled devices or being unaware of how to use them; or (6) no use of email, texting, or Internet over the past month.

The study population consisted of 57% women and 42% men, with a mean age of 79.6 years. Sixty-nine percent of the sample were non-Hispanic White individuals; 21% non-Hispanic Black individuals; and 6% Hispanic individuals. An additional 4% self-identified as American Indian, Asian, Native Hawaiian, or Pacific Islander.

Over a Third of Elders Unable to Access Video Telemedicine Programs

Unfortunately, telemedicine unreadiness was extremely common. Projecting from this study, for the year 2018, 38% of older Americans are not ready for video visits—largely due to inexperience with relevant technology. Even if there were family or friends capable of setting up a video visit, 32% still met the definition of unreadiness. A shocking 72% of those 85 years and older were not ready for video consultations.

Unfortunately, telemedicine unreadiness was extremely common.

The study suggested that telephone visits would be more feasible for the group as a whole. But even in this area, a full 20% of older individuals were unready because of hearing problems, communication problems, or dementia.

Telemedicine unreadiness was most common among males, older individuals, unmarried people, Black and Hispanic subjects, rural residents, and those with less education, lower income, and poorer self-rated health.

These are thorny problems and ones not likely to be solved quickly. Yet millions of older people will require access to telehealth services until the pandemic comes to an end—or can be addressed more conveniently.

“Telemedicine is not inherently accessible, and mandating its use leaves many older adults without access to their medical



care,” said lead author Kenneth Lam, MD, a clinical fellow in geriatrics at the University of California, San Francisco. “We need further innovation in devices, services and policy to make sure older adults are not left behind during this migration.”

“To build an accessible telemedicine system, we need actionable plans and contingencies to overcome the high prevalence of inexperience with technology and disability in the older population,” Lam said. “This includes devices with better designed user interfaces to get connected, digital accommodations for hearing and visual impairments, services to train older adults in the use of devices and, for some clinicians, keeping their offices open during the pandemic.”

A *BackLetter* editor asked geriatrician Lam what specific changes he would like to see in order to improve this situation.

“As my study indicates, the older population is heterogenous and you need tiers of solutions to tackle different barriers. I tried to highlight these multiple issues (experience with technology, social isolation, sensory impairments, and dementia) in my analysis to show that solving one issue still leaves many older adults disconnected,” Lam explained.

He believes it is important to lobby medical societies, government agencies, and political leaders to address these issues. “Broadly speaking and for the long term, we need to highlight the following points to politicians: we have rules dictating that medical facilities must be physically accessible under the Americans with Disabilities Act; shouldn’t [similar rules] extend to the current situation now that medical facilities are virtual? Personally, I think Medicare should consider including telecommunication devices and internet access under Durable Medical Equipment,” said Lam.

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Chronic Primary Pain—Breakthrough or Boondoggle? If the Condition Exists, What Treatments Work?

It is wise to take the new definition of chronic primary pain—and the NICE guideline on its management—with a large grain of salt. (See feature article on page 109.)

The provisional definition from the International Association for the Study of Pain (IASP) and the World Health Organization could be a breakthrough in pain management—or a complete boondoggle. For off-shore readers who don't understand American slang, a boondoggle is “work or activity that is wasteful or pointless but gives the appearance of having value.” (See Google Oxford Languages Dictionary.) The ultimate verdict on this novel pain definition and the new guideline likely won't be apparent for several years. Its underlying rationale is not easily testable in scientific studies.

As mentioned in the feature article of this issue, NICE is the prominent review group that conducts evidence reviews and formulates policy for Britain's National Health Service—and influences medical policies around the world.

The review from NICE was fairly straightforward if less than conclusive—because of the meager evidence base on chronic primary pain. The NICE panel identified only a few therapies where there is some evidence of benefit for this putative condition.

Chronic Primary Pain Part of a Larger Classification System

By way of background, chronic primary pain is part of a new pain classification system developed by IASP for inclusion in the 2022 World Health Organization ICD-11 disease classification and coding system.

According to the WHO, the ICD (International Classification of Diseases) is the foundation for identifying health trends and statistics worldwide, and contains around 55,000 unique codes for injuries, diseases and causes of death. It provides a common language that allows health professionals to share health information across the globe.

New Classification System for Pain

The IASP panel proposed classifying chronic pain (pain of at least 3 months' duration) into seven main categories:

1. Chronic primary pain;

2. Chronic cancer-related pain;
3. Chronic postsurgical and posttraumatic pain;
4. Chronic neuropathic pain;
5. Chronic secondary headache and/or orofacial pain;
6. Chronic secondary visceral pain; and
7. Chronic secondary musculoskeletal pain.

Optional specifiers: a) Severity (intensity, distress, disability); b) Temporal course; c) With evidence of psychosocial factors. (See Treede et al., 2015.)

The NICE guideline addressed the management of pain classification #1. Unfortunately, NICE did not include a review of the evidence base on the actual definition of chronic primary pain, i.e. evidence that might support or refute this proposed definition. This definition is basically a hypothesis that is popular in the pain medicine community—but one that hasn't been tested adequately.

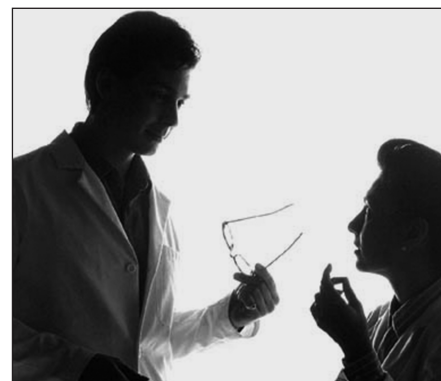
Here is the definition of chronic primary pain from the original IASP proposal by Rolf-Detlef Treede, MD et al. in 2015.

“Chronic primary pain is chronic pain in one or more anatomical regions that is characterized by significant emotional distress (anxiety, anger/frustration or depressed mood) or functional disability (interference in daily life activities and reduced participation in social roles). Chronic primary pain is multifactorial: biological, psychological and social factors contribute to the pain syndrome. The diagnosis is appropriate unless another diagnosis would better account for the presenting symptoms.” (See Treede et al., 2015.)

And here is an explanation from NICE: “Chronic primary pain represents chronic pain as a condition in itself and which can't be accounted for by another diagnosis, or where it is not the symptom of an underlying condition.” (See NICE, 2020.)

Definition Doesn't Mesh Well with Low Back Pain?

At first glance, the definition of chronic primary pain does not appear to mesh well with chronic low back pain. The vast majority of back pain cases are “nonspecific”, i.e., they do not have an obvious anatomic explanation or pain mechanism.



So according to the NICE guidance, nonspecific chronic back pain accompanied by any “significant” emotional distress and/or disability and would qualify as chronic primary pain.

So this definition could embrace a large proportion of people with chronic back pain—including many people on workers' compensation claims.

But why should the presence of significant emotional distress and/or disability turn chronic pain from a secondary complaint (secondary to another disease or condition) into a primary chronic pain complaint?

This doesn't make a whole lot of sense. Given the primitive diagnostic capabilities regarding low back pain there is no easy method of determining whether chronic primary pain would be an accurate classification or not. So adopting and employing this definition would require a significant leap of faith in the back care community. Needless to say, the potential for misclassification appears to be substantial.

It will be fascinating to see whether patients, healthcare providers, and payers buy into it to any great extent. In a world with rising medical costs, why implement an untested new classification system?

New Draft Guideline Came with a Splashy Press Release

The new draft NICE guideline came with a splashy press release emphasizing some of its main points.

It drew media attention by suggesting that people with chronic primary pain should avoid most commonly used pain medications for chronic primary pain.

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Chronic Primary Pain

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Here is an excerpt from *The Guardian*:
 “Painkillers such as paracetamol, ibuprofen, aspirin and opioids can do ‘more harm than good’ and should not be prescribed to treat chronic primary pain, health officials have said. The National Institute for Health and Care Excellence (NICE) said there was ‘little or no evidence’ the commonly used drugs for chronic primary pain made any difference to people’s quality of life, pain or psychological distress. But the draft guidance, published on Monday, said there was evidence they can cause harm, including

addiction,” according to *The Guardian* article. (See *The Guardian*, 2020.)

This is accurate. NICE recommended against the use of opioids, nonsteroidal anti-inflammatory drugs, acetaminophen/paracetamol, benzodiazepines, gabapentinoids, local anaesthetics, ketamine, corticosteroids and antipsychotics.

And NICE endorsed the use of only a handful of treatments: exercise, psychological therapies, antidepressants, acupuncture, and continuing normal exercise and physical activity for general health. But it couldn’t find evidence to support many common non-drug treatments.

Here are the recommended therapies—i.e., recommended for some patients

in some circumstances (See guideline summary for further detail.) This is not a group of therapies that will excite patients or healthcare providers.

Exercise: “Offer a supervised group exercise program (for example, cardiovascular, mind–body, strength, or a combination of approaches) to people aged 16 years and over to manage chronic primary pain. Take people’s specific needs, preferences and abilities into account.”

“Encourage people with chronic primary pain to carry on with their exercise for longer-term general health benefits.”

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Table I: Will Consumers Buy into the Limited Treatments for “Chronic Primary Pain?”

Comparison of the NICE Guideline and a US Back Pain Guideline

NICE Guideline on the Management of Chronic Primary Pain (See NICE, 2020)	American College of Physicians Guideline on Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain (See Qaseem et al., 2017)
<p>Definition of target condition: “Chronic primary pain represents chronic pain as a condition in itself and which can’t be accounted for by another diagnosis, or where it is not the symptom of an underlying condition.” (See NICE, 2020) Must be accompanied by significant emotional distress or significant functional disability. (See Treede et al., 2015)</p>	<p>Definition of target condition: All types of chronic back pain lasting more than three months.</p>
<p>Evidence base: RCTs on treatment of any relevant pain condition that employed a similar definition of chronic pain</p>	<p>Evidence base: RCTs on the treatment of chronic back pain as defined above</p>
<p>Recommended treatments:</p> <ol style="list-style-type: none"> 1. Supervised group exercise 2. Psychological therapies 3. Antidepressants 4. Acupuncture 5. Continuing normal activity/exercise for general health 	<p>Recommended treatments for Chronic Back Pain:</p> <p>First line treatments:</p> <ol style="list-style-type: none"> 1. Exercise 2. Multidisciplinary rehabilitation 3. Acupuncture 4. Mindfulness-based stress reduction 5. Tai chi 6. Yoga 7. Motor control exercise 8. Progressive relaxation 9. Electromyography biofeedback 10. Low-level laser therapy 11. Operant therapy 12. Cognitive behavioral therapy 13. Spinal manipulation <p>Second line treatments:</p> <ol style="list-style-type: none"> 1. NSAIDs (1st choice) 2. Tramadol or antidepressant duloxetine (2nd choices) 3. Opioids (uncommon treatment of last resort)
<p>General recommendations:</p> <ol style="list-style-type: none"> 1. Know the patient as an individual 2. Enable patients to participate in their care 3. Foster a collaborative supportive relationship 4. Inquire about the way pain affects their lifestyle 5. Query understanding/acceptance of pain condition 6. Acknowledge uncertain prognosis 7. Develop a care plan 8. Discuss the benefits/risks/uncertainties of therapies 9. Provide advice relevant to preferences/expectations 10. Avoid invalidating patient’s pain experience 	

The Poor Reporting of Scientific Evidence During the COVID-19 Pandemic

One of the major problems in the COVID-19 pandemic has been the inadequate and inconsistent reporting of scientific research. This is nothing new in the scientific and mass media. This has been a problem across medicine for decades—the reporting of back pain research being a perfect example.

However, the COVID-19 pandemic has certainly exacerbated these problems. The reporting and misreporting of scientific evidence have led to worldwide confusion on the best ways to prevent and manage COVID-19. And it has almost certainly led to increased suffering and mortality.

Addiction specialist Richard Saitz, MD, of Boston University and media researcher Gary Schwitzer of the University of Minnesota recently outlined some of the major

failures in reporting on scientific research during the COVID-19 pandemic:

- A focus on the results of single studies, without adequate scientific context—and without acknowledging that single studies generally do not provide definitive results;
- Overemphasis on results, particularly relevant effects, without recognition of important limitations; and
- Communications based on incomplete reports of studies—and studies that have not undergone adequate independent review.

“The COVID-19 pandemic has created perhaps the most challenging time for science communication in decades. Races are underway in parallel: to find answers to perplexing coronavirus questions, to

announce research findings to clinical and scientific colleagues, and to report those findings to a confused and concerned global audience. There are no winners in these races if harm—even though unintentional—is wrought by the dissemination of hurried, incomplete, and biased misinformation. Trust in science, medicine, public relations, and journalism may be in jeopardy in the intersection where these professions meet,” according to Saitz and Schwitzer. (See Saitz and Schwitzer, 2020.)

Disclosures: None declared.

Reference:

Saitz R and Schwitzer G, Communicating science in the time of a pandemic, *JAMA*, 2020; 324(5):443–4.

A More Flexible Approach to Obesity—as It Affects Back Pain and Other Health Issues

Obesity has a complicated relationship with low back pain. There is no proof that obesity is a direct cause of low back pain. It *might* be—though the evidence is difficult to interpret.

However, obesity can certainly complicate return to healthy physical activity and normal function among people with low back problems. In other words, it is likely to be a contributor to back pain-related disability in some people and some patients.

A new Canadian guideline recommends a flexible and patient-centered approach to the management of obesity and related health issues. It is relevant to spine care in both primary care and specialty settings.

Complex Progressive and Intermittent Disease

The new Canadian guideline suggests that obesity should be viewed as a complex disease. “Obesity is a prevalent, complex, progressive and relapsing chronic disease, characterized by abnormal or excessive body fat (adiposity), that impairs health,” according to the guideline. (See Wharton et al., 2020.)

Obesity has often been defined crudely across medicine, via assessment of body mass index (BMI). However, a single number—a BMI of 30, 32, or 35—does not have much significance in terms of understanding obesity-related problems. Some people with a BMI of 32 can be in excellent health and have no major functional limitations. Healthcare providers need to carefully listen to a patient’s story and carefully assess the potential contribution of obesity to health problems and day-to-day functioning.

BMI Not an Accurate Tool for Assessing the Impact of Obesity

The guideline noted that BMI “is not an accurate tool for identifying obesity-related complications.”

There is no “one size fits all” approach to the assessment and management of obesity.

“Working with people to understand their context and culture, integrating their root causes, which include biology, genetics, social determinants of health, trauma and mental health issues, are essential to developing personalized plans,” said David Lau,

MD, of the University of Calgary in a published statement accompanying the guideline. “These plans can become part of a long-term therapeutic relationship with follow-up of obesity-related chronic diseases.”

The guideline suggests approaching discussions of obesity with sensitivity. Healthcare providers should politely ask for permission from patients to even discuss weight and obesity issues.

Five Main Recommendations

Here are the five main recommendations from the guideline:

1. *Ask permission to discuss weight.* Healthcare practitioners must recognize obesity as a chronic disease with stigma and should not assume all patients with obesity are prepared to address it. This step helps to manage bias against people living with obesity.
2. *Assess their story.* Discuss the patient’s history to understand the root causes of obesity, combined with

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Is the World Ready?

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low back pain in high-, middle-, and low-income countries.

But given the lack of research, no one really knows what type of impact it will have in real-world settings. Scientific studies are only just beginning to study the clinical utility of this classification system in a few medical settings. (See Korwisi et al., 2020.)

Chris Maher, PhD, professor at the University of Sydney, is one of the world's most influential back pain researchers and evidence reviewers. A *BackLetter* editor asked him whether patients, healthcare providers, and policy makers should regard this new diagnostic category as unvalidated or unproven.

He was caustic in his response. “Unproven” is sitting on the fence; this step is completely daft,” said Maher. [Daft is Old English for “silly, stupid, or foolish”] “When you invent new health conditions it does come at a considerable cost: we know nothing about the diagnosis, clinical course, treatment, prevention, and people's experience of the new condition.”

And it is difficult to study the management of this new chronic pain condition, since previous randomized controlled trials and systematic reviews employed a much broader definition of chronic pain—generally defining it as persistent or intermittent pain of three or more months duration. So those studies cannot inform the management of chronic primary pain. They just don't apply, leaving a narrow evidence base.

“The NICE guideline has no evidence to work from and it forces people to either extrapolate from similar conditions or go back to the bad old days of consensus-based guidelines.” Maher asserted.

Rachelle Buchbinder, MBBS, PhD, is another distinguished back pain researcher. She is a professor at the University of Melbourne and is the Coordinating Editor of the Cochrane Collaboration Musculoskeletal Group. She was recently awarded the Medal of the Order of Australia for her contributions to medical education, epidemiology, and rheumatology.

Buchbinder is insistent that this or any other new definition of a disease or condition needs to be studied thoroughly *before* it is imposed on patients, healthcare providers, and the general public.

“I think before defining a new condition, one should think very carefully about the likely benefits as well as the potential for harm. So yes, this new term and proposed condition should be validated in different populations to see if it is helpful from both the clinician and the consumer perspective. This definition seems made for ‘pain specialists’,” she remarked. But pain specialists, of course, represent only a small minority of the universe of back care providers.

Neither Maher nor Buchbinder are convinced that the definition of chronic primary pain can actually differentiate primary from secondary back pain with any certainty.

“I do not know how you would decide that the average person with chronic low back pain fits the ICD-11 category chronic primary pain versus chronic secondary

musculoskeletal pain,” according to Maher. “For low back pain and many other musculoskeletal conditions we lack tests to implicate [specific] anatomical structures as the nociceptive source.” So classification would often be a guess.

Buchbinder says she is also skeptical about lumping so many different pain conditions under a single hypothetical label. “It would need to be shown that this is appropriate,” she explained. So the lack of extensive testing of this new pain definition is a major problem.

Buchbinder says these aren't her only worries regarding the new definition. “My major concerns are medicalizing pain and the risk of iatrogenic harm from the label,” she added. Both are realistic possibilities and leave a cloud hanging over this definition.

Buchbinder believes the concept of “positive health” is a better way of addressing chronic low back pain than the introduction of a hypothetical new pain condition. For those who want to read up about this increasingly influential concept, the authors of the widely cited *Lancet* Low Back Pain series addressed the concept of positive health in detail. (See Buchbinder et al., 2018.)

Traditionally, over the last few decades good health has been defined in terms of the absence of pain, symptoms, and disease. If one looks at good health that way, almost all humans are to some extent ill at any given time. And potentially in need of medical care.

However, in 2009 Dutch researcher Machteld Huber and colleagues proposed a new definition of good health as “the ability

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A More Flexible Approach

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physical examination, calculation of BMI, and other investigations.

3. *Advise on management.* Discuss treatment options, such as nutrition and exercise, psychological interventions, medications to achieve and maintain weight loss, and bariatric surgery.
4. *Agree on goals.* Collaborate on a personalized, sustainable long-term action plan with realistic expectations.
5. *Assist with barriers and drivers of weight gain.* Barriers include lack of access to healthcare providers with expertise in obesity, lack of coverage of obesity medications by drug plans in Canada, and long wait times for bariatric surgery.

Reduce Bias and Stigma

To help obese people grapple with their problems, healthcare providers need to look to themselves as well—in terms of their own beliefs and biases.

“People with obesity experience weight bias and stigma, which contribute to increased complications and mortality, independent of weight or BMI,” said Sean Wharton, MD, of McMaster University, the other lead author of the guideline. “The first step to obesity management is to recognize your own bias. If you see people living with obesity as lacking willpower, or as noncompliant, then you likely have weight bias. Obesity needs to be managed with a focus on giving unbiased care to patients, showing compassion and empathy and using evidence-based interventions with an emphasis on patient-centered outcomes.”

All these points apply to back care providers. They need to fully understand their patients' problems, their other health concerns, their functional limitations, and coping issues. And dialogue about these complicated issues needs to be on-going. Neither back pain nor obesity is an area of medicine where a single five-minute conversation and formulaic response will suffice. Life is not that simple.

Disclosures: None declared.

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Wharton S, et al., Obesity in adults: A clinical practice guideline, *CMAJ*, 2020; 192(31):E875–91. doi:10.1503/cmaj.191707.

Is the World Ready?

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to adapt and to self-manage, in the face of social, physical and emotional challenges.” The positive health concept has profound implications in thinking about and managing pain. (See Huber et al., 2016.)

The New Definition Could Be Implemented in Almost 200 Countries Around the World

If the new definition of chronic pain—i.e. chronic primary pain—is applied prematurely in the World Health Organization’s ICD-11 coding system, it could be applied to every branch of medicine, in primary care, secondary care, and tertiary care—in low-, middle-, and high-income countries. And most users of the classification system will not be aware that it hasn’t been validated or tested adequately. And, as mentioned above, it rests largely on the opinions of a subgroup of experts rather than strong scientific evidence. The world deserves better.

WHO Should Retreat from This Approach

There is still time for WHO to retreat from this initiative and encourage thorough testing of the new definition to see if it actually benefits patients with chronic pain—and to see what the risks and benefits are in multiple and varied real-world settings.

One hopes that any further development and research effort will be conducted by a panel that is independent of the group that developed the definition.

Maher said he has been concerned about the groups promoting the premature adoption of this new definition of chronic pain—and whether commercial organizations might be playing a role in advancing this initiative.

“I worry about what is driving all of this,” said Maher via email. “I knew IASP was lobbying for these changes to ICD-11 for chronic pain and had read their marketing around ‘Pain as a disease in its own right’.”

However, he pointed out that previous initiatives in the pain medicine field to reform the management of pain have a checkered track record. Some have proven to be tragic mistakes. “IASP also lobbied for ‘Pain as the fifth vital sign’ in its Declaration of Montreal; and that initiative turned out to be a complete disaster, fueling

tremendous harm [in the form of the opioid crisis],” Maher noted. (See IASP, 2010.)

Major drug companies have also begun to support the hypothesis that pain is a primary disease. “If you look at the websites of pharmaceutical companies, you will also see prominent mentions of “pain as a disease in its own right,” Maher added.

“For example, you will find this statement on the website of Grünenthal—a prominent developer of pain treatments, including opioids: ‘Given the prevalence and debilitating effects of pain, Grünenthal considers it to be a disease in its own right rather than just a symptom.’ As a global leader in pain management for nearly 50 years, we’re fully aware that patients are still hugely underserved in this area.” (See Grünenthal, 2020.)

US Healthcare Systems May Be Reluctant to Adopt the New Definition

Patient advocate Terry Corbin of Minneapolis is a former board member and current consultant for HealthPartners of Minnesota. He believes that US-based healthcare systems will be reluctant to adopt the new definition.

“My sense is that healthcare systems and payers in the United States have built a fence around untested initiatives from the pain medicine and pain intervention communities because of the lethal opioid crisis and the rapid growth of pain interventions in the absence of compelling evidence of benefit. And they appear reluctant to agree to new pain-treatment initiatives from these groups unless there is really striking evidence that they help patients, without adverse effects—and at a reasonable cost.”

“If healthcare systems and payers adopt this new approach, it would punch a hole in that fence. And I would imagine that US healthcare systems and payers are more likely to simply ignore this untested definition and revised coding.” He noted, however, that there is an elephant in the room. “Of course, if Medicare and Medicaid adopted the new definition and coding, it would be a game-changer.”

Drug Companies Looking to Expand Drug Therapies for Chronic Pain?

Although this initial guideline from NICE discourages the use of most medications for chronic primary pain, there is only a tiny body of evidence on their risks and benefits for this condition. As mentioned above, most

major studies in the past have used a much broader definition of chronic pain. And future studies, including those supported by the pharmaceutical industry, may come to different conclusions, and lead to significantly different treatment recommendations.

Regarding this “new” condition—and its management—the future is unwritten. This again highlights the hazards of creating new conditions or diseases without studying their impact in multiple real-world settings.

What About an Independent Task Force to Guide Further Research in This Area?

There is clearly a need for a major research effort in this area. And that research effort should be led by scientists who have equipoise about the benefits and risks of the new definition—and who do not have financial conflicts-of-interest with drug, device, and technology companies. Having a group independent of financial conflicts-of-interest to guide the research process would be a win for everyone.

This would reflect the movement across medicine to disentangle guideline panels and policy-making task forces from commercial interests. An influential 2009 report from the U.S. Institute of Medicine argued that industry influence in medical policy making may be jeopardizing the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public’s trust in medicine. (See Lo and Field, 2009; IOM, 2009.)

“Groups that develop guidelines should not accept direct industry funding for this work and generally should exclude individuals with conflicts of interest from the panels that draft guidelines,” according to the authors of that report. The same principles should apply to policy-making task forces today. A recent series of articles in the *BMJ* reiterated the importance of those principles. (See Moynihan et al., 2019.)

Potential Conflicts-of-Interest in the IASP Task Force That Developed the New Definition

Multiple members of the IASP Task Force that developed the new definition reported financial relationships with drug companies and other commercial entities. The list of potential conflicts-of-interest filled most of a printed page. (See Treede et al., 2015.) It included multiple opioid manufacturers, including Grünenthal and Mundipharma.

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The IASP itself accepts industry sponsorship of various society activities. It asserts that industry has no direct influence over the content of IASP policies and educational activities. However, a variety of research has suggested that commercial sponsorship and other financial relationships can have an insidious and/or unconscious effect on scientists and policy makers. Hence the need for independent guideline panels and policy task forces.

WHO Has Had to Grapple with Conflicts-of-Interest in the Past

WHO has had to grapple with issues relating to conflicts of interest in the development of its pain management policies in the recent past. And it has shown that it is capable of acting quickly to alter projects where conflicts-of-interest come into play. One hopes WHO will take quick action to delay the implementation of the new chronic pain definition until there is better evidence.

In 2019, WHO had to rescind its opioid treatment guidelines after a US Congressional investigation concluded that a major opioid manufacturer had had an undue influence on their development.

“The World Health Organization has rescinded its opioid-prescribing guidelines after a congressional report accused the agency of being corrupted by the powerful drug-maker Purdue Pharma,” according to a report at the website of US congresswoman Katherine Clark. She cited reporting from the *Boston Globe* to summarize this situation.

“The May report from US Representatives Katherine Clark, a Massachusetts Democrat, and Hal Rogers, a Kentucky Republican, said Purdue Pharma funded organizations, people, and research to influence the WHO. As a result, the organization’s opioid prescribing guidelines from 2011 and 2012 contained ‘dangerously misleading and, in some instances, outright false claims about the safety and efficacy of prescription opioids,’” Clark and Rogers said.

Fortunately, WHO responded quickly, as noted in the same article at Clark’s website. “WHO is discontinuing these guidelines in light of new scientific evidence that has emerged since the time of their publication.” (See Clark, 2019.)

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Transition to Telemedicine

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“In the meantime, the Federal Lifeline Program is one option for low income older adults, though that doesn’t get around issues of digital literacy. That training I see happening at a more local level, where health-care systems collate resources for training those inexperienced with technology on how to get connected. Good design can also improve accessibility but won’t happen over the short term and requires innovation,” he added.

He suggested that medical systems not forget the importance of the telephone. “The plain old telephone call is still useful (and there is evidence that [many] people have been relying on telephone calls rather than

mucking around with video visits), especially for simple visits.”

Reimbursement is a key issue. “Regarding reimbursement, the Center for Medicare and Medicaid Services and the Department of Health and Human Services have already led the way in changing several policies that previously stymied telemedicine adoption, and thankfully phone visits are reimbursed at rates similar to video visits through the 1135 Waivers (which authorized reimbursement for telehealth services during the pandemic). They should be encouraged to keep this provision in the future rather than just as a temporary measure during COVID. It certainly simplifies billing,” Lam explained.

“Finally, combinations of disabilities (e.g., dementia AND social isolation) make it very hard to use telemedicine no matter what.

Keeping clinics and especially home visiting services open is incredibly important to reach this population. This would mean lobbying that funds are allocated to keep clinics running and adapting to provide greater outreach (with adequate personal protective equipment),” Lam stressed.

Disclosures: None declared.

Reference:

- Lam K et al., Assessing telemedicine unreadiness among older adults in the United States during the COVID-19 pandemic [published online ahead of print August 3, 2020], *JAMA Internal Medicine*; doi:10.1001/jamainternmed.2020.2671.

Opioid Deaths Undercounted

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To investigate the relationship of cardiac deaths to opioid overdose, researchers from the University of California at San Francisco—along with the office of the Chief Medical Examiner of San Francisco—performed a multiyear study of out-of-hospital fatal cardiac arrests.

Robert M. Rodriguez, MD, and colleagues examined all out-of-hospital cardiac deaths of people aged 18 to 90 years who were attended to by emergency medical services from February 2011 to March 2014. (See Rodriguez et al., 2020.)

All the deceased underwent full autopsies, comprehensive blood toxicological analysis, and adjudication of the cause of death by an expert panel that included the medical examiner, a cardiac pathologist, a neurologist, and two cardiologists/cardiac electrophysiologists.

After careful analysis the study tallied 540 people who experienced sudden cardiac death and underwent an autopsy.

In addition, the researchers counted an additional 242 people with sudden cardiac death between March 2014 and December 2017, using slightly less stringent criteria (not all underwent autopsy).

Rodriguez and colleagues also studied the study subjects' medication lists and medical records over the year before death—to determine which deaths might have related to prescription opioids and other drugs and which might have stemmed from nonprescription opioids and accompanying medications.

15% to 22.3% Died of an Overdose

In the initial cohort from 2011 to 2014, the adjudication panel determined that 15% likely died from an opioid overdose—or an overdose of multiple drugs. In the extended cohort from 2014 to 2017, the panel concluded that 22.3% likely died in the wake of an opioid and/or other drug overdose.

Compared with non-opioid-related sudden cardiac deaths, those with opioid overdose-related deaths were more likely to be younger and more commonly White or Black than Asian or Latino.

Most of the people with overdose deaths had multiple intoxicants in their systems—75.9% in the initial cohort and 55.6% in the extended period. “The most

common drug classes were opioids (68.4% and 48.1% for the initial and extended periods, respectively), sedative-hypnotics (49.4% and 51.9%), and stimulants (48.1% and 51.9%),” according to Tseng et al.

Most opioid deaths involved sedative-hypnotic drugs, stimulants, or psychiatric medications.

Grim Conclusions

Here are the authors' grim conclusions: “In this 7-year comprehensive study of OHCA [out-of-hospital cardiac arrest] deaths in San Francisco County, we found that more than 1 in 6 actually resulted from occult overdose—a finding with broad implications for epidemiologic estimates of overdose-related mortality, particularly opioid-related mortality. Published national mortality estimates based on recognized overdoses may be a substantial underestimate of the true burden, because occult overdose deaths masquerading as sudden cardiac deaths are missed without postmortem toxicologic analysis. Most occult overdose OHCA deaths involved multiple drugs, including opioids, and approximately one half of intoxicants were prescribed. Our findings affirm the need for continued efforts to combat the opioid epidemic and consideration of naloxone in selected OHCA resuscitations,” according to Rodriguez et al.

Study Results Have Relevance Well Beyond Opioids

A *BackLetter* editor asked senior author Zian H. Tseng, MD if the results were a surprise to him. “Yes and no,” Tseng responded. “This is a sub-study of my NIH-funded parent comprehensive study on causes of sudden cardiac death, the POST SCD (Postmortem Systematic Investigation of Sudden Cardiac Death) Study” (<https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.117.033427>).

He pointed out that the study appears to have relevance well beyond drug overdoses. “Causes of sudden death throughout the country and world are presumed cardiac because autopsies are almost never done. POST SCD is the first study to define all presumed sudden cardiac deaths county-wide by autopsy,” Tseng explained.

“To our surprise, almost half of deaths ascribed to cardiac arrest by paramedics and presumed cardiac by medical examiners/coroners and physicians are actually

non-cardiac. The largest category of non-cardiac causes was occult overdoses only discovered by toxicology—paramedics had called these cardiac arrests and the medical examiners had discovered no evidence of drugs at the scene and had no suspicion of drug overdose.

Tseng was also asked how he would like to see public health authorities respond to this new study. With broader and more careful classification of sudden deaths? Greater funding for cause-of-death research? With a renewed effort to use both naloxone for resuscitation and medication-assisted treatment of drug addiction and dependency?

“Causes of death, particularly sudden death, are unknown and presumed without autopsy. All research into sudden cardiac deaths that are not confirmed by autopsy is potentially affected. This includes risk factors, treatments, resuscitation strategies, and genetics,” he responded.

“Should there be broader and more careful classification of sudden deaths? Yes, but this is impossible without autopsies in every case, which is impractical because medical examiners and coroners are too busy with criminal cases to investigate natural deaths. Thus, POST SCD remains the only study to provide comprehensive postmortem data on these sudden deaths,” he explained.

Should there be greater funding for cause-of-death research? “Absolutely. Without postmortem confirmation, all causes of death on death certificates are just educated guesses. Therefore, all aggregate mortality data reported by the Centers for Disease Control and Prevention, American Health Association [and other groups] on cancer mortality, heart disease mortality, etc. should be taken with a grain of salt.”

A Reminder of the Value of Naloxone and Drug-Assisted Addiction Treatment

Tseng would definitely like to see greater use of naloxone and effective treatment of drug addiction and dependency. “Exactly. Many of these lives may have been potentially saved. Naloxone is an inexpensive, low-risk intervention that could potentially save many lives if incorporated into resuscitation strategies by paramedics for presumed cardiac arrests [either in a targeted or universal fashion].”

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Chronic Primary Pain

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Psychological therapies: Consider acceptance and commitment therapy (ACT) or cognitive behavioral therapy (CBT).

Acupuncture: “Consider a course of acupuncture or dry needling, within a traditional Chinese or Western acupuncture system for people aged 16 years and over to manage chronic primary pain.” However, the panel specified that acupuncture should occur in a community setting and should involve no more than five hours of a health-care professional’s time.

Antidepressants: Consider an antidepressant, such as duloxetine, fluoxetine, paroxetine, citalopram, sertraline or amitriptyline to manage chronic primary pain, after a full discussion of the benefits and risks. Confusingly, this is an “off-label” use of these antidepressants in the UK.

What about other common treatments for low back pain? Here is a brief summary:

Common treatments where NICE found no conclusive evidence of benefit: spinal manipulation, mobilization, and massage; relaxation therapy, mindfulness, psychotherapy; social interventions; pain management programs; yoga, tai chi, hypnosis, biofeedback—and electrophysical therapies such as ultrasound, PENS, TENS, cranial direct current stimulation, and interferential therapies.

Several therapies showed enough hints of promise that the NICE panel did recommend a research agenda to determine if they are beneficial or not. These included manual therapies; relaxation therapy, mindfulness, psychotherapy; social interventions, and pain management programs.

Some Useful Common-Sense Recommendations

The NICE panel did make useful, common-sense recommendations that would apply to the enlightened treatment of anyone with bothersome chronic pain:

1. Know the patient as an individual;
2. Enable patients to participate in their care;
3. Foster a collaborative supportive relationship;
4. Inquire about the way pain affects lifestyle and day-to-day activities, including work and sleep, physical and psychological wellbeing, and social interactions and relationships;
5. Ask about the patient’s understanding and acceptance of the pain condition;
6. Acknowledge that the pain condition might not get better and might get worse;
7. Develop a care plan;
8. Discuss the benefits, risks, and uncertainties of all management approaches;

9. Provide advice that is relevant to the person’s preferences and expectations; and
10. When communicating test results and other information, avoid invalidating the person’s pain experience.

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Coming Soon:

- Could Back Pain Lead Paradoxically to Improved Health and Function?
- Is a New Guideline on the Treatment of Acute Pain Fundamentally Flawed?
- Key Question: How Should Researchers and Healthcare Providers Mentor Their Students and Trainees?
- Controversy Over Conflicts-of-Interest at Two Major Pain Societies

Opioid Deaths Undercounted

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And he would like to physicians and other healthcare providers be more vigilant for signs of addiction and drug dependency. “Physicians should carefully evaluate for drug-drug interactions, appropriateness of

prescriptions, and drug dependency,” according to Tseng.

Disclosures: None declared.

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THE **BACKPAGE**

Orthopedists Slow to Embrace Evidence-Based Medicine

Although the number of randomized controlled trials has surged in recent years, orthopedic surgeons have been slow to embrace evidence-based medicine, according to a commentary in *JAMA Surgery* by two orthopedic surgeons and an orthopedic researcher. “The use of EBS [evidence-based surgery] faces numerous hurdles in orthopedic surgery. Whenever high-quality evidence is available, challenges present in its dissemination and adoption by surgeons,” according to Ahmed K. Emara, MD, et al.

They suggest that compliance with EBS guidelines remains low in orthopedics for a number of reasons: socialized knowledge and consensus appear to affect the decision-making process more than high-quality evidence.

“In many instances, mentor-trainee guidance or practices of colleagues seem to take precedence over EBS guidelines. In addition, the evidence presented from outside the community is often disregarded in many ways. Furthermore, the application of EBS to patient specific circumstances necessitates its alignment with patient preferences, case details, surgeon expertise, and available resources,” they observed. (See *JAMA Surgery*, August 5, 2020. doi:10.1001/jamasurg.2020.1521.)

However, it is important to note that adoption of evidence-based medicine is not all that common in any area of back or spine care. For example, studies have yet to demonstrate broad implementation of evidence-based guidelines in any area of spinal medicine in the United States. And this may help explain why the United States has made scant progress in reducing the prevalence of

low back pain and back pain-related disability.

Placebo Diagnostics Falling Out of Favor?

According to a recent review in *BMJ*, placebo diagnostic procedures are on the wane—and do not provide valid or useful results.

Ted Kaptchuk, MD, and colleagues discussed placebo denervation of the facet joints. For example, placebo injections are sometimes used to determine whether patients qualify for denervation of those joints; if they respond to placebos, they

the evidence they cite to support this point dates from 2005.

Placebos in general still appear to be used widely across medicine with and without informed consent, in both open and closed-label formats. This is still a murky area of medicine. And opinions about the optimal use of placebos vary dramatically. (See *BMJ*, 2020; 370:m1668. doi:10.1136/bmj.m1668.)

Self-Isolation Not Risk-Free

One of the main weapons against the spread of COVID-19 has been

It is not much of a leap to suggest that social isolation, loss of work, and familial conflict might increase vulnerability to the coronavirus by altering responses in the immune system.

“It is generally accepted that sheltering at home, quarantine for ill patients, and job loss can trigger psychological distress, anxiety, and depression and that strong support networks may attenuate these effects,” according to Cohen.

“Our work suggests that chronic interpersonal and employment-related stressors are also potent risks for upper respiratory disease for those exposed to respiratory viruses and that social integration and social support may confer resilience,” he said.

So in other words, Cohen is suggesting that psychosocial factors affect the immune system and thereby increase vulnerability to certain diseases.

These are issues that go well beyond the current pandemic—and may even be relevant to the development and persistence of chronic back pain. Healthcare providers often advise patients with back pain to miss work, rest, and avoid unnecessary stresses on the back. The net result is often an unhealthy level of social isolation.

There is some persuasive evidence that social isolation can exacerbate problems related to low back pain. In a 2015 study, V. C. Oliveira and colleagues found that perceived social isolation predicted disability related to low back pain—for reasons that are not clear. (See *European Journal of Pain*, 2015; 19(4):538–45.)

These are not surprising findings. Humans are social animals. Taking them out of their supportive social networks can be risky and counterproductive. (See *Perspectives on Psychological Science*, July 8, 2020; doi:10.1177/1745691620942516.)

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are often denied the real treatment on the premise that their pain might be “psychogenic” or “greatly exaggerated.”

Unfortunately, placebos cannot adequately help discriminate between pain related to a specific anatomic source and pain of psychogenic or nonspecific origin. Placebo responses can occur in many situations.

These reviewers asserted that the use of placebos in diagnostic procedures has waned dramatically, although the evidence they cited is not particularly definitive.

A consensus exists in most professional organizations that use of placebo diagnostics is unethical without informed consent and generally “does not provide any useful information about the genesis or severity of pain,” they suggested. Although

self-isolation. However effective this might be, it is not a risk-free intervention—in infectious diseases or in the management of back problems.

A psychologist at Carnegie Mellon University recently suggested that the widespread use of social isolation may actually increase personal susceptibility to COVID-19 and other health conditions.

Research by Sheldon Cohen, PhD, has focused on the way social and psychological factors lead to the development of infection and illness. In a variety of studies, he has demonstrated that interpersonal stressors such as social isolation may increase susceptibility to cold and influenza viruses. (See *Perspectives on Psychological Science*, 2020, 1–14; doi:10.1177/1745691620942516.)