## THE BACKLETTER®

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### Usual Care for Back Pain All Too Often the Wrong Care—Despite 25 Years of Evidence-Based Guidelines

recent systematic review from Australia confirms a long-standing suspicion: that people with back pain all too often get the wrong kinds of advice and wrong kinds of care. This is undoubtedly a major contributor to the huge international back-pain disability crisis.

This systematic review touches on some of the major problems in the back pain field. It should be a wake-up call for spine care providers, researchers, healthcare systems, insurers, and policy makers. These splintered groups need to start working together to resolve these issues.

Steven J. Kamper, PhD, of the University of Sydney and colleagues conducted a systematic review to determine what constitutes usual care among first-contact physicians for patients with low back pain. They included 26 studies from seven countries that reported on 195,000 patients—18 from family practice and 8 from emergency department settings. (See study description on page 42.)

The results painted a stark picture of what is wrong with back care in the countries where these studies took place.

"Usual care for patients with LBP did not align well with recommendations in clinical practice guidelines. Around 1 in 4 patients that presented to family practice and 1 in 3 that presented to ED with back pain were referred for imaging...Rates of prescribing of opioids were up to 30% in family practice and up to 60% of patients received an opioid while in ED. Only around 20% of patients received information and advice that aligns with clinical practice guideline recommendations," according to Kamper et al.

For those who follow the evidence in this field closely, these results are not a tremendous surprise. However, they remain a major disappointment. And they don't augur well for the resolution of the backpain disability crisis any time soon.

"The results paint a bleak picture: only a minority of patients apparently receive simple positive messages to stay active and exercise, whilst inappropriate use of analgesia and imaging persists. The review adds to evidence that the care doctors give patients with low back pain is dominated by guideline-discordant interventions that are unnecessary, expensive, and 'low-value' (i.e., harm is more likely than benefit.)," according to an accompanying editorial in the journal Pain by Peter Croft and Nadine Foster of Keele University in the UK and Saurab Sharma of Kathmandu University in Nepal and Dunedin University in New Zealand.

Although these conclusions apply to only two types of back care providersfamily physicians and emergency specialists—they likely are relevant to a broad range of healthcare professions. No single back care profession has a glowing track record of success in this area—or broadly proven superiority over other professions.

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### **Rooting Out Toxic Billing**

edical billing practices should be an important measure in rating the quality of hospitals and healthcare clinics, according to a recent

"Financial toxicity—the difficulties a patient has related to the cost of medical care—is a medical complication," according to Johns Hopkins surgeon and researcher Marty Makary, MD. "Taking care of a patient means taking care of the whole person."

Given that US billing practices often border on being fraudulent, many prominent medical institutions would likely get failing grades—for overcharging patients, billing for phantom procedures, victimizing patients who lack health insurance, permitting "drive-by" or surprise billing, suing

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# Modest Reduction in Opioid Disorders, Including Addiction

he United States and other countries with elevated use of opioids should not get complacent about the *modest* reductions in opioid use disorders (OUDs)/addiction in medicine in recent years.

duration of 3 or more months], non-fatal (HR = 1.67,95% CI = 1.53-1.82) and fatal opioid overdose (HR = 2.24,95% CI = 1.91-2.61)."

Concomitant benzodiazepine use was also associated with an elevated rate of

"The United States will ... probably continue to have a serious opioid prescription use disorder problem until it returns to prescribing at the level of other developed countries, as it did for most of the 20th century."

A recent retrospective longitudinal study from Massachusetts looked at more than 2 million opioid-naive subjects 11 years and older who received an opioid prescription from 2011 to 2015. Their mean age was 49.1 years, 55.3% were female, and 47.3% had commercial insurance.

Laura G. Burke, MD, and colleagues wanted to see how many developed OUDs and both fatal and nonfatal overdoses over the five-year period. (See Burke et al., 1919.)

#### Modest Decline in Opioid Use Disorders But Not in Overdoses

The risk of OUD declined gradually over the course of the study. The one-year rate of OUD declined from 1.18% in 2011 to 0.94% in 2014. However, there was no decline in the rate of opioid overdose, fatal and otherwise.

Not surprisingly, longer opioid therapy—greater than three months—was associated with a higher risk of overdose. Here are the odds ratios: "Longer therapy duration was associated with higher risk of OUD [hazard ratio (HR) = 2.24, 95% confidence interval (CI) = 2.19–2.29 for

OUD along with nonfatal and fatal overdoses

However, an accompanying editorial by Keith Humphreys suggests this is cause for optimism but not complacency. (See Humphreys, 2020.)

He noted that the introduction of safer opioid prescribing practices, along with heightened concern about the opioid crisis, has resulted in a decline in opioid use—and a reduction in the development of opioid use disorders. However, the United States needs to intensify its efforts in this area and reduce opioid utilization even further.

"Contrary to what legions of opioid manufacturing representatives once claimed, prescription opioids carry significant risk of opioid use disorder even in environments where this risk is the focus of enormous clinical and policy attention. The United States will thus probably continue to have a serious opioid prescription use disorder problem until it returns to prescribing at the level of other developed countries, as it did for most of the 20th century," according to the editorial.

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# Patients Not Getting Access to Their Medical Records—Despite a Legal Right to Do So

Patients in the United States have a legal right to see their medical records. And it is important that they do so.

"For example, individuals with access to their health information are better able to monitor chronic conditions, adhere to treatment plans, find and fix errors in their health records, track progress in wellness or disease management programs, and directly contribute their information to research," noted a website at the US Department of Health and Human Services (HHS).

"With the increasing use of and continued advances in health information technology, individuals have ever expanding and innovative opportunities to access their health information electronically, more quickly and easily, in real time and on demand. Putting individuals 'in the driver's seat' with respect to their health also is a key component of health reform and the movement to a more patient-centered health care system," according to the HHS. (See HHS, 2020.)

In an era rife with medical errors it is important for back pain patients to access their records to see if the critical details of their cases are correct. Does the record accurately identify their diagnosis—if there is one—and any treatment recommendations? In an era where burnout among physicians is common, the medical record might indicate whether the healthcare provider has correctly recorded key elements of the case and any potentially confounding factors. Is the medical interaction on track in terms of enhancing patient outcomes? Were any imaging scans or lab tests interpreted appropriately?

And, of course, another reason that patients should have access to their medical records is to check whether the record mentions any expensive, fraudulent, and/or surprise services patients might have received.

### The Information Patients Have a Right to Access

According to HHS, here is a description of the information patients should be able to access: "Individuals have a right to a broad array of health information about themselves maintained by or for covered entities, including: medical records; billing and payment records; insurance information; clinical laboratory test results; medical images, such as X-rays; wellness and disease management

program files; and clinical case notes; among other information used to make decisions about individuals. In responding to a request for access, a covered entity is not, however, required to create new information, such as explanatory materials or analyses, that does not already exist in the designated record set," noted the authors of the HHS website.

### Only 10% of Patients Accessing Their Health Records

According to a study by Sunny C. Lin and colleagues in late 2019, an impressive 95% of hospitals have a system for giving patients access to their records. However, only about 10% of eligible patients have availed themselves of this information. And there was no indication that this proportion is rising quickly. (See Lin et al., 2019.)

A 2018 study observed that there are socioeconomic and other barriers to patients accessing their records through hospital portals. Patients with the lowest education levels, those insured by Medicaid, and those without a regular provider are less likely to report that they were offered access to an online portal or that they used one. In addition, members of racial and ethnic minority groups are less likely to report being offered access to a portal, according to Denise L. Anthony and colleagues. (See Anthony et al., 2018.)

### Jumping Through Bureaucratic Hoops

A group of consumer advocates recently penned a commentary pointing out that patients want to see their medical records but are frustrated by the bureaucratic and electronic hoops they must jump through to access them.

"Survey data have consistently shown that patients want and would, in fact, access their information, if they knew the capability existed and the process wasn't too difficult relative to the value received. Despite patient interest, the process remains rife with obstacles and frustration, as illustrated by the GetMyHealthData campaign, which spent a year documenting what happened when patients requested their health records in electronic formats, as is their right under the law. The campaign showed that consumers definitely want their health data, but they are thwarted at almost every turn by outdated



formats for information, inefficient delivery methods, cultural pushback, and exorbitant fees," according to Christine Bechtel and colleagues. (See Bechtel et al., 2020.)

They pointed out that the best way to encourage patient access to medical records is to have physicians recommend it.

"Providers must play the central role in educating and encouraging consumers to access their data because most people trust their doctor more than anyone else when it comes to matters of health. Studies have shown that 63 percent of patients who viewed their medical records were encouraged to do so by their providers. Only 38 percent of patients took the initiative on their own," according to these patient advocates.

Disclosures: None declared.

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# Medicare—the Largest Payer in the United States—Gives Acupuncture a Thumbs-up

n an eagerly anticipated National Coverage Determination (NCD), the Centers for Medicare & Medicaid Services (CMS) has approved coverage for acupuncture in the treatment of chronic back pain. (See CMS, 2020.)

This will be a huge boost for acupuncture as Medicare is the single largest payer in the United States, underwriting care for nearly 90 million individuals in retirement, disability, and pediatric programs.

Seniors and others with Medicare/Medicaid coverage will be able to access up to 12 acupuncture sessions each year. If there is improvement, Medicare will cover an additional eight sessions. If treatment does not result in improvement, it should be discontinued, according to the new policy.

The new decision applies to all types of acupuncture, including dry needling.

### A Relaxation of Evidence Standards?

This decision is not without controversy. In its decision on acupuncture, the CMS appears to have relaxed its usual evidence requirements—because of the opioid crisis and the current push to manage back pain with nonpharmacologic treatments.

There is actually a major gap in the evidence regarding the role of acupuncture among seniors—one that might have scuttled a National Coverage Determination in previous years. There are simply not a lot of data on acupuncture for seniors.

Alex Azar, Secretary of Health and Human Services in the Trump Administration, downplayed that fact in his public announcement of the recent decision.

"Expanding options for pain treatment is a key piece of the Trump Administrations' strategy for defeating our country's opioid crisis," said Azar. "President Trump has promised to protect and improve Medicare for our seniors and deciding to cover this new treatment option is another sign of that commitment. Medicare beneficiaries will now have a new option at their disposal to help them deal with chronic low back pain, which is a common and sometimes debilitating condition."

According to the CMS, the decision regarding coverage takes into account an assessment of benefits and harms and the opioid public health crisis. "While a small number of adults 65 years of age or older have been enrolled in published acupuncture studies, patients with chronic low back pain in these studies showed improvements in function and pain."

"The evidence reviewed for this decision supports clinical strategies that include non-pharmacologic therapies for chronic low back pain," he added. This statement appears to allude to the strategy recommended by the 2017 guideline on the management of low back pain (LBP) from the American College of Physicians. (See Qaseem et al., 2017.)

That guideline broke new ground by suggesting that nonpharmacologic therapies, including acupuncture, should be the initial treatment of choice for both acute and chronic back symptoms.

CMS also rationalized its decision based on acupuncture coverage by other major payers. CMS noted that, while there is variation in covered indications and frequency of services, a number of large private payers provide some coverage of acupuncture for certain indications.

"We are dedicated to increasing access to alternatives to prescription opioids and believe that covering acupuncture for chronic low back pain is in the best interest of Medicare patients," said CMS Principal Deputy Administrator of Operations and Policy Kimberly Brandt. "We are building on important lessons learned from the private sector in this critical aspect of patient care. Overreliance on opioids for people with chronic pain is one of the factors that led to the crisis, so it is vital that we offer a range of treatment options for our beneficiaries."

## What Are the Specific Indications for Acupuncture Among Seniors?

According to the CMS, the NCD will apply to individuals with:

- Back pain lasting 12 weeks or more;
- Nonspecific back pain: i.e. "has no identifiable systemic cause (i.e. not associated with metastatic, inflammatory, infectious, etc, disease)";
- Back pain not associated with surgery; or



 Back pain not associated with pregnancy.

It is worth noting that CMS is defining "nonspecific back pain" in an unusual way. Nonspecific back pain is normally defined as back pain that does not have a clear or identifiable cause. CMS instead defined it as "no identifiable *systemic* cause."

### How Can Acupuncturists Treat Patients Under the New Policy?

Licensed acupuncturists at the moment cannot even bill Medicare for acupuncture services. And it is not clear how the new acupuncture program will roll out.

CMS specified that the following personnel can offer acupuncture treatments, if they have adequate training and supervision, as defined in the following section of the NCD:

"Physician assistants, nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM); and
- Current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.

Auxiliary personnel furnishing acupuncture must do so under the appropriate level of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist required by our regulations at 42 CFR §§ 410.26 and 410.27."

### Licensed Acupuncturists in a Secondary Role?

So licensed acupuncturists who are not physicians, physician assistants, nurse practitioners, and clinical nurse specialists will be able to provide acupuncture services only under the supervision of individuals from those four professions.

The CMS decision is based largely on a review of systematic reviews published over the last five years. The CMS did not commission an external review of the literature for this decision. Nor did it stage a Medicare Evidence Development & Coverage Advisory meeting on this issue.

The interpretation of the evidence on acupuncture in international guidelines varies. Readers can find a positive view of that evidence in the guideline from the American College of Physicians by Qaseem et al., (See Qaseem et al., 2017)—and a more skeptical view in the 2016 NICE guidance from the UK. (See NICE, 2016.)

Readers can find a variety of comments on the acupuncture decision in the appendix of the CMS website. They are mostly "pro" with only a few "cons."

### **Support From Emergency Physicians**

For example, here is the comment from the American College of Emergency Physicians:

"On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a National Coverage Analysis (NCA) that the Centers for Medicare & Medicaid Services (CMS) is opening related to the use of acupuncture for chronic low back pain."

The ACEP fully supports the use of nonopioid alternatives for pain management. As emergency physicians, we see the devastating effects of the opioid crisis every day. In fact, according to the Centers for Disease Control and Prevention, there was a 30% increase in opioid overdoses presenting in the emergency department (ED) for treatment from July 2016 through September 2017. Emergency physicians are taking steps right now to address the opioid crisis by implementing innovative alternative treatments to opioids (ALTO) programs. The ALTO program uses evidence-based protocols like nitrous oxide, nerve blocks, trigger point injections, and other nonopioid pain management tools to treat a patient's pain in the ED. Successful ALTO programs in New Jersey and Colorado have dramatically and quickly reduced opioid prescriptions in the ED. In New Jersey, the ALTO program at St Joseph's Hospital saw opioid prescriptions drop by 82% over two years.

These results were replicated at 10 hospitals in Colorado, where hospital systems noted a 36% drop in opioid prescriptions in just the first six months of the program. The recently enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act authorizes grants to expand the ALTO program in EDs across the country.

With respect to the use of acupuncture to treat chronic LBP, the ACEP supports a technique called "dry needling." This technique is a form of acupuncture that is now being performed in many EDs to provide pain relief for patients. We believe insurers should reimburse for procedures such as these since they have been successfully used to control pain and avoid opioid use."

#### A Skeptical View of Acupuncture

Here is an example of a negative comment on the new policy, from Bernie Garrett, PhD, of the University of British Columbia Faculty of Medicine.

"We would advise against funding further acupuncture for LBP studies. There has been considerable work done on this already (i.e. Cochrane), and results are mediocre for clinical efficacy, and likely represent a placebo effect. Other new adjunctive therapeutics such as virtual reality exercise or distraction to improve function and reduce pain are more likely to be productive. The tide is steadily turning against acupuncture as a genuine useful therapeutic. If studies are commissioned, they should be undertaken by independent professionals such as physicians, physiotherapists, or nurses trained in the technique. Additionally, blinded using modern sham acupuncture techniques (see https://journals.plos.org/plosone/ article?id=10.1371/journal.pone.0140825) and nonstandard acupuncture points as a control in naive acupuncture LBP patients. Additionally, actual studies to test theories of Qi as the theoretical foundation of the therapy would be more useful than further clinical studies."

#### Calls for Further Research

And there are also calls for further research to identify the risks and benefits of acupuncture—and on how to roll out this policy without fraudulent practices. Here is a comment from Howard Levinson, DC, who is the Director of

Fraud Investigations at Anthem, one of the largest insurance carriers in the United States. Anthem had 40 million customers in 2018.

"As a chiropractor and director of fraud investigations for Anthem, we often conduct interventions with providers who are suspected of FWA (Fraud, Waste, and Abuse Training). Acupuncture is a timed service and can involve insertion of needles, re-insertion of a new set of needles and the use of electrical stimulation with the needles. We have done studies on acupuncturists. We find that some are either not well versed in how to code and bill for acupuncture, or are gaming the system for increased revenue.

"There are also acupuncturists who submit additional claims for services such as E/M and/ or physical therapy which we have found to be controversial. There is a diplomat professional organization (NCCAOM) that one would hope would include acupuncturists who are trained in delivering and billing the service appropriately and ethically. The research on complementary care for LBP such as acupuncture and chiropractic is often conflicting with some studies showing good evidence of improving outcomes and others not so much. Further research is required. Acupuncture is based on unseen energy forces promoting health and apparently decreasing pain. It's been around longer than western medicine so I think it's worth exploring for Medicare members."

So there may be some growing pains for the new Medicare policy, as acupuncture practitioners learn how to bill and code for acupuncture services.

Disclosures: None declared.

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## Study of Usual Care for 195,000 Patients With Low Back Pain

The feature article of this *BackLetter* edition focused on the larger issues posed by the recent systematic review on usual care for back pain from Steven Kamper, PhD, et al. Readers who would like to delve into the details of that review can find it in the references on page 43. (See Kamper et al., 2019.)

In brief, Kamper et al. set out to describe usual care provided by first-contact physicians to patients with low back pain. They confined their study to family practice physicians and emergency specialists.

The review looked at studies reporting on the assessment, treatment, and referral of patients with low back pain. It included studies based on retrospective and prospective chart reviews. RCTs were included if one arm offered usual care. The review excluded research published before 2000 to avoid describing back pain management practices that are of historical interest only.

The authors found 26 studies from seven countries—18 from family practice, and 8 from emergency department settings—that reported on 195,000 patients. "Study quality was assessed with reference to representativeness of samples, potential misclassification of patients, potential

misclassification of outcomes, inconsistent data and precision of the estimate, and the findings of high-quality studies were prioritized in the data synthesis."

Kamper et al. compared the usual care provided by these physicians to recommendations in widely utilized clinical guidelines such as the 2016 guideline from NICE in the UK. (See Nice, 2016.) Usual care generally did not meet the recommendations in clinical guidelines. Here are some of the results:

- Roughly a quarter of family practice patients and a third of emergency patients were referred for imaging.
- Although NSAIDs are widely recommended as the first-line drug treatment for low back pain, only 35% of family practice patients and 50% of emergency patients received NSAIDs.
- Opioids are not recommended as a first-line treatment for low back pain.
   Yet 30% of family practice patients, and 60% of emergency patients, received an opioid.
- "Only around 20% of patients received education, reassurance, and advice regarding exercise from their family

- practitioner. We found no high-quality data concerning the provision of advice regarding bed rest and return to work, and no high-quality data regarding treatment advice at all for ED settings."
- There were no high-quality studies on usual care in low- and middleincome countries.
- The review found no uniform system of reporting data on back pain management. Healthcare is lagging badly behind other industries in reporting accurate and contemporaneous data on its customers.
- This review has potential limitations. The study basically looked at 26 snapshots of usual care for 195,000 patients in seven countries. These practices may not be representative of the broader population of people under treatment for low back pain. The accuracy of the study results depends on the quality of the data reporting in each clinical setting. The studies were heterogenous. Few provided high-quality data. These were concentrated in a few high-income countries. So the results should be interpreted cautiously.

#### Usual Care

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The Lancet series on low back pain looked at a broad range of evidence and came to similar conclusions. "Despite multiple clinical guidelines providing similar recommendations for managing low back pain, a substantial gap between evidence and practice exists worldwide in high-income as well as low-income and middle-income countries. Problems include both overuse of low-value care and underuse of high-value care," according to Foster and colleagues in part 2 of that influential series. (See Foster et al., 2018.)

In other words, these are problems that likely extend across professions, across socioeconomic and cultural settings, and across borders.

### Why Hasn't Evidence-Based Back Care Been More Successful?

A *BackLetter* editor asked both Kamper and Croft whether they were surprised that

evidence-based guidelines haven't had more of an impact—25 years into the evidence-based guideline movement.

"In a word: no," said Kamper via email.
"The evidence-practice gap in back pain care is not a new [finding], neither is the idea that publishing guidelines doesn't change practice. I think we (the field: policy-makers, health administrators, clinicians and researchers) have been very slow to react."

### Many Unanswered Questions About Evidence-Based Approaches

Croft suggested that there are many unanswered questions about evidence-based approaches to low back pain. "We don't know how successful or unsuccessful various components of the EBM approach to low back pain have been," he commented via email.

And the role of guidelines remains up in the air. "We have to show they are being followed before we can reflect on whether they are successful or not," he added.

The review by Kamper et al. suggested they are having a minimal or limited impact, at least in the seven countries and 26 studies covered in the review.

Croft suspects that that some guideline recommendations may have had a positive impact over the years, even if this review didn't reflect that. "In the UK in the 1980s, when I was first a GP, our routine advice for acute back pain was 'lie on a hard surface and take a week off work," he reported.

He said that after Gordon Waddell and others engineered the first British evidence-based guidelines there appeared to be a change in attitudes and behavior regarding both bed rest and sick leave. "The message that you can keep moving with a bit of help from analgesia, and do not need to take time off work, got out there," Croft

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#### Usual Care

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observed. To what extent, however, has been difficult to measure.

And this uncertainty reflects a fundamental lack of information. "Clear strong information on what is being done for whom remains very sparse," according to the British researcher.

### **Implementation Failure?**

So a quarter century into the evidence-based guideline movement key messages are still not getting through to patients, providers, and their healthcare systems.

There are several potential reasons for this. One is optimism bias—i.e. an overly optimistic view among researchers. In the early stages of the evidence-based guideline movement there was an innocent belief among many researchers that high-quality persuasive evidence would lead naturally to major changes in clinical practice. And would do so without a sophisticated, multitiered implementation effort.

Richard A. Deyo, MD, alluded to this issue in a keynote address at the International Forum for Back and Neck Pain Research in Primary Care in Quebec City, Canada last summer. He discussed the *Lancet* Series on Low Back Pain, which offered a state-of-the-art view of the existing evidence. (See Hartvigsen et al., 2018; Foster et al., 2018; Buchbinder et al., 2018.)

"There was a time in my career, right after I finished my research and clinical training, when I would have said 'Mission Accomplished. We have done it folks. We have gotten the best evidence out, in a place where everybody is going to see it, where everybody can evaluate the evidence for themselves. They'll see how good it is. And in a year or two everybody will be on the same page," according to Deyo. "However, my whole career has been a lesson in why things never work out that way." (See Deyo, 2019, Schoene, 2019.)

And there is a growing awareness now that any major change in real-world practice will require an implementation effort at multiple levels. And a challenging one.

### Implementation Efforts Alone Won't Solve These Problems

However, Kamper explained via email that implementation efforts alone won't solve these problems. He pointed out that current back care systems in many countries are fragmented, with participants and stakeholders often working at cross-purposes.

"I think implementation research is really important but it won't solve a fundamental issue—if research 'belongs' exclusively to academics, systems solutions to policy-makers and administrators, and service delivery to clinicians," Kamper asserted.

He believes it is important to get these groups onside—and working together towards common goals.

"In my opinion the way forward is co-produced solutions in the conduct of clinical research and in addressing service delivery problems. The reality is that we have a poor record of working together, which is responsible for people having bad outcomes. The 'optimism' you mention might also be described as hubris – although perhaps that is going too far."

In Greek tragedy, of course, hubris is excessive pride leading to self-destruction.

### **Top-Down and Bottom-Up Strategies**

The review by Kamper et al. discussed potential strategies that might combat both the overuse and underuse of medical services.

They discussed the importance of topdown measures "whereby governments, payers, and system administrators enact changes" and bottom-up measures "where the public and clinicians alter practice to align with best available evidence."

"Numerous top-down initiatives may serve this purpose including removal of capacity within the system to provide inappropriate care, financial restrictions, education and support for clinicians, and revision of diagnostic criteria and thresholds. In addition, stakeholder (clinicians and patients) engagement, support for shared decision-making, and inclusion of (in)appropriate use recommendations in clinical practice guidelines may improve alignment of clinical services with best available evidence."

Where would Kamper recommend starting this effort?

"I think the strategy should be identification of the most pressing problem(s), which in my opinion needs to come via consensus of involved parties (probably with researchers as the least important voice!)." This should be followed, he added, by identification of obstacles to change and to optimal practices.

"These could be followed by co-produced strategies aimed at changing behavior which could then be evaluated for effectiveness. Whether strategies are top-down or bottom-up, the design process can be the same," according to Kamper.

(See following, related articles "Back Care Out of Sync with the Information Revolution" on page 44 and "What About Back Care in Low- and Middle-Income Countries?" on page 45.

Disclosures: None declared.

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## **Back Care Out-of-Sync With the Information Revolution**

The recent review on usual care by Steven Kamper, PhD, et al. brought another key issue to the fore: the lack of real-time data on the way back pain is being managed across healthcare systems, cultures, and countries around the world. (See Kamper et al., 2019, in reference section on page 43.)

It is difficult to track back care with current systems. If this is not remedied, it will likely cripple attempts to study back care around the world.

"From a policy perspective, the findings...highlight the need for health systems to invest in and maintain data collection infrastructure. Robust clinical audits are only possible if there is reliable and complete capture of clinical data, such audits being vital to identify problems and inefficiencies in patient care, and evaluate whether remedial strategies are effective," according to Kamper et al.

The back care system appears out of sync with many other industries in terms of efficient information retrieval.

"It is a strange situation to contemplate. In an information-dominated world where people's purchasing actions are instantly known, retrievable, linked to other data, and acted upon, the health care most people are receiving for the world's leading cause of long-term disability is not known because it is either not recorded or the data is not accessible or reported," according to Peter Croft et al. in their commentary in *Pain*.

### Healthcare Systems Stand Out for Their Inability to Provide Important Data

Kamper pointed out via email that health care is an industry that stands out in its inability to provide important data regarding real-world practices.

"Imagine another business that knows and can access so little information about its clients as healthcare!" he expounded.

"It's probably only a slight exaggeration to suggest that Google likely knows more about my health than the people looking after me when I get sick – and if that is an exaggeration it likely won't be in a couple of years' time," said Kamper.

"We have situations in Australia where information systems that collect different data from a single patient within the same hospital can't be integrated. For example, imaging data lives on one database, medications on another, clinical info from the EMR in another, etc. To me that is insane. This is even before we get into 'what' information lives in the data capture systems. This is the sort of thing that needs a coordinated, top-down solution, at a government level if we are serious about improving healthcare across populations."

### "How the Hell Can This Be Happening?"

Croft made similar points.

This situation has flown under the radar and needs to be discussed at every conference on back pain and spinal medicine—and brought to the attention of administrators and policy makers across the medical field.

An appropriate response to this lack of information should be "How the hell can this be happening," Croft quipped in a recent email. "Supermarkets have routine access to this type of information. How come healthcare delivery systems do not?" said Croft via email.

"In primary care there are of course many wider aspects to the topic of information gathering - e.g. confidentiality, the need to preserve the direct human interaction of a consultation without it becoming an exchange mediated by the computer key board - but, as more facets of e-health enter the arena with positive intent - e.g. self-referral, online counseling, and the like— we have reached the point where there should be a focused drive to gather and analyze relevant information that is not solely driven by the need to promote profit-making interventions," said Croft.

"As a patient, I would not personally mind if, when I contacted primary care at any time, I had to provide routinely on an iPad or phone some systematic information which I knew would be used in anonymized analyses, that all interactions with the health care system (from spoken advice to prescriptions) also entered that same system, plus specified areas of daily life (daily pain, exercise measurements like steps, treatments, work activity). There are all the Big Brother, confidentiality issues - but, as you say, these are happening in all the commercially relevant areas of our life like shopping, so why not a drive for information gathering in health and health care that is for altruistic as well as the inevitable profit-making motives."

"This absence of information about relevant areas of the primary care consultation should concern us as much as the size of the evidence-practice gap or how to close it. Having the right information will itself help change policy and training and behavior about guideline treatments, for example by easing the path to audit as a means to improve practice," according to Croft et al. in their editorial. And it would facilitate research on the appropriate management of low back pain.

### A Problem That Affects the Entire Spinal Medicine Field

The absence of comprehensive data on the way back care is being managed—and on back pain outcomes—applies to all areas of back care—and not just primary care. The spinal medicine field is one that has been rife with the premature introduction of interventions that are ineffective and/or risky. Yet it has traditionally taken years or decades before rigorous clinical trials assessed their risks and benefits.

Think of the succession of rogue treatments that might have been headed off—if information about their overuse and negative impact had been apparent early rather than late. Think of the hundreds of thousands of lives that might have been saved in the opioid overuse epidemic alone. (See references on page 43.)

## What About Back Care in Low- and Middle-Income Countries?

The review on usual care by Steven Kamper et al. offered an important observation about back care worldwide. (See Kamper et al., 2019 in the references on page 43.)

They found a nearly complete absence of evidence regarding back care in low- and middle-income countries. All the high-quality studies on the management of low back pain in their recent review came from high-income societies. And the degree to which the conclusions of that review apply to the management of back pain in low- and middle-income settings isn't clear.

"The authors of the review could find no high-quality studies using actual practice data from first-contact low back pain care in low- and middle-income countries (LMICs). This is of particular concern because LMIC populations are being exposed to technology and treatments for low back pain (such as opioids) that high-income countries have popularized and made profitable but that are often inappropriate and harmful. LMICs need appropriately strong systems to support delivery of high-value care, including guideline-concordant approaches to low back pain prevention and care that align with local practices and cultures of health and wellbeing," according to Peter Croft et al. in a related commentary in Pain.

### Growing Back Pain Research Movement in Low- and Middle-Income Countries

Although the review by Kamper et al. couldn't find much evidence on back care in LMICs, there is a growing research movement on all aspects of low back pain in these societies. There has been an impressive proliferation of bright, ambitious researchers from LMICs. And major back pain, spine, and pain societies are starting to pay much greater attention to back pain in less affluent nations.

At the 2019 Forum on Back and Neck Pain Research in Quebec City, Canada, researchers presented a series of reports on back pain in low-and middle-income countries. Geoff Outerbridge, MSc, DC of World Spine presented a broad overview of that international organization's experience with back care initiatives in low- and middle-income counties—particularly Botswana. (https://www.worldspinecare.org/).

Luciola Menezes Costa, PhD, of Universidade Cidade de São Paulo spoke about the challenges of the epidemic of back pain and related disability in Brazil—a middle-income country which is in danger of replicating some of the mistakes of high-income countries in addressing low back pain. And Sweekriti Sharma delivered an eloquent presentation on the intricacies of back pain in her native country of Nepal.

#### **Impressive Research**

*BackLetter* editors are also starting to routinely run across impressive articles and studies on back pain research in LMICs. For example, G.K. Bayera and colleagues recently performed a ground-breaking, population-based study on back care utilization in Ethiopia. (See Bayera et al., 2020.)

Many back pain researchers from LMICs fear their countries will end up repeating some of the worst mistakes of wealthy nations, particularly the deadly opioid crisis that has ravaged the United States, Canada, and some other societies. And there are well-founded fears that opioid manufacturers and marketers have their eyes on LMICs around the world.

As an example, Mexican and Mexican-American researchers published an important study on these issues in 2019, one that suggested that opioid manufacturers and their political supporters may be lining up Mexico for a glut of opioid utilization. (See Goodman-Meza et al., 2018.)

#### Lessons to be Learned From Low- and Middle-Income Countries

Researchers from high-income countries are increasingly interested in studying back pain and back care in low- and middleincome countries—and working with researchers from those societies.

Croft pointed that there is scope for a wide range of research in those countries. However, there is also the ever-present hazard that some well-funded researchers from high-income countries might impose their views and methods on local researchers.

"There is a wider issue that some of the young researchers from LMICs raised at the Quebec Forum," Croft explained. "That we need ideas and experience driven by those countries as well as bright young researchers doing Western-style research there."

#### **New Ideas From Different Cultures**

"For example, there is a clear role for well-conducted surveys of back pain in different countries across the globe—and studies of healthcare provision and delivery. However, there is also a need to understand the different experience of back pain in different countries—especially the specific cultural and social ways in which it might be understood and explained and dealt with," according to Croft.

"One of the points made by our third Lancet paper was that there are almost certainly lessons to be learned from other cultures about the role of back pain in life, and a need to avoid the assumption that guidelines and content of care policies originating from settings in high-income countries are going to be necessarily the right model for health care in LMICs."

"We (i.e., the international community of back pain researchers, clinicians and policymakers) need to find ways to prioritize, support, encourage, and resource people from these countries to deliver ideas and approaches relevant to their societies which are also likely to have important messages for the rest of the world."

As Croft, Sharma, and Foster noted in their commentary in *Pain*, "LMICs need appropriately strong systems to support delivery of high-value care, including guideline-concordant approaches to low back pain prevention and care that align with local practices and cultures."

Scott Haldeman, MD, PhD, DC, the founder of World Spine, has repeatedly made some of those same points. Any improvements in back pain management have to be firmly grounded in local experience, traditions, and culture—with the full participation of local researchers and healthcare providers. Haldeman has been insistent that there is simply no place for "helicopter research"—where well-funded western researchers jet in, perform an intervention or study, and then chopper back to their affluent homelands—leaving local researchers, planners, and governments in the lurch. (See Schoene, 2017.)

Disclosures: None declared.

### Rooting Out Toxic Billing

Continued from page 37

patients, and putting liens on their homes and other property after surgery and other expensive procedures.

"In the same way that medical complication rates are collected for improvement purposes and some are available to the public, metrics of billing quality could be used to create public accountability," according to Simon C. Mathews, MD, and Makary in a recent commentary in *JAMA*. (See Mathews and Makary, 2020.)

However, as yet there are no widely embraced metrics for evaluating billing practices, according to Makary.

"In recent years, patient care and outcomes have been significantly improved by applying quality science to medicine, benchmarking the performance of both health care providers and facilities, yet there are no standardized metrics for billing quality," says Makary, professor of surgery at the Johns Hopkins University School of Medicine and a prominent researcher on healthcare quality.

### Indications That US Patients Are Suffering Under the Current System

American patients are suffering under the current medical system. These researchers from Johns Hopkins University provided ample evidence of this in their commentary in *JAMA*:

- An analysis of a nationally representative sample of US consumers found that 25% had delinquent debt on their credit reports, with medical bills constituting 58% of all debt.
- A survey of 1513 patients with stage IV breast cancer found that 50% had been contacted by debt collectors regarding overdue bills.
- In a recent survey, 64% of patients said they had delayed or neglected medical care in the previous year

because of concerns over costly medical bills.

- About 30% of medical bills are paid for out-of-pocket, according to an accompanying statement from Johns Hopkins.
- An alarming 67% of Americans are "very worried" or "somewhat worried" about unexpected medical bills. By contrast, only 41% of US residents are concerned about paying rent or mortgage payments.

Given that US billing practices often border on being fraudulent, many prominent medical institutions would likely get failing grades on their billing performance—for overcharging patients, billing for phantom procedures, victimizing patients who lack health insurance, permitting "drive-by" or surprise billing, suing patients, and putting liens on their homes and other property after surgery and other expensive procedures.

Do these cost and billing concerns apply to the management of back pain and other spinal problems? The answer to that question is a definite "yes." The treatment of back and neck problems is one of the most expensive areas of US medicine and one of the most rapidly growing areas of medical expenditure. (See Dieleman et al., 2016.)

So billing practices are an important metric in this area.

#### Proposed Billing Quality Measures

In their *JAMA* commentary, Mathews and Makary proposed 6 major criteria that could be applied to every healthcare facility in the United States:

- 1. *Itemized bills*. Are patients routinely provided an itemized bill explained in plain English?
- 2. *Price transparency*. Are patients provided "real prices" for common medical services?
- 3. Service quality. Do patients have prompt access to a billing representative about their billing concerns? And does the healthcare facility offer a transparent review process?
- 4. Suing patients. For patients who have not entered into a written agreement specifying a price for a medical service, does the institution sue patients to garnish their wages, place a lien on their home, or involuntarily withdraw money from a patient's income tax return?
- 5. Surprise billing. Are out-of-network patients paying out-of-pocket expected to pay more than the standard reference pricing of US health insurance carriers?

Disclosures: None declared.

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#### **Modest Reduction**

Continued from page 38

This would require a major reduction in opioid prescription for chronic pain across medicine.

Disclosures: None declared.

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### MEETING CALENDAR

 47th Annual Meeting, International Society for the Study of the Lumbar Spine, Combined with SpineWeek, 2020

April 27-May 1, 2020 Melbourne, Australia

Contact: Katarina Olinder Eriksson, Administator, ISSLS

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 American College of Rheumatology/ Association of Rheumatology Health Professionals 2020 Annual Meeting

May 16-20, 2020 Washington DC

Contact: American College of Rheumatology

Association of Rheumatology Health Professionals

Rheumatology Research Foundation

2200 Lake Boulevard NE Atlanta, GA 30319 Tel: 404-633-3777 Fax: 404-633-1870 www.rheumatology.org

 International Association for the Study of Pain 2020 World Pain Congress

August 4-8, 2020

Amsterdam, The Netherlands

Contact: IASP

1510 H Street NW, Suite 600 Washington, DC 20005 Tel: 202-856-7400 Fax: 202-856-7401 Scoliosis Research Society 53rd Annual Meeting

September 9-12, 2020 Phoenix, Arizona

Contact: Scoliosis Research Society

555 East Wells Street, Suite 1100

Milwaukee, WI 53202 Tel: 414-289-9107 E-mail: meetings@srs.org

■ Eurospine 2020

October 7-9, 2020 Vienna, Austria

Contact: Eurospine, Spine Society of Europe

Attn: Judith Reichert

Schild Seefeldstrasse 16 8610 Uster-Zurich, Switzerland Tel: 41-44-994-1404 www.eurospinemeeting.org

NASS 2020: Annual Meeting of the North American Spine Society

October 7-10, 2020 San Diego, California

Contact: North American Spine Society

7075 Veterans Boulevard Burr Ridge, IL 60527 Tel: 630-230-3600 Fax: 630-230-3700 www.spine.org

Cervical Spine Research Society

December 10-12, 2020 Las Vegas, Nevada

Contact: Cervical Spine Research Society

9400 W. Higgins Road, Suite 500 Rosemont, IL 60018-4976 Tel: 847-698-1628 Fax: 847-268-9699 E-mail: csrs@aaos.org

### Coming Soon:

- Back Pain Now the Single Most Expensive Health Condition in United States
- Musculoskeletal Problems Weighing Heavily on the US Population
- What is the Future for the Label "Nonspecific Low Back Pain?"
- The Ins and Outs of Placebo Treatments

### THE BACK PAGE

### Advice for Patients About Medical Marijuana

The JAMA "Patient Page" recently offered advice to prospective patients on the risks and benefits of medical marijuana. Unfortunately, at this point in time, the documentation of risks is superior to that of benefits.

Kevin Hill, MD, offered a useful list of potential hazards related to the use of medical cannabis. These include impairment of memory, judgment, and motor skills, long-term psychiatric conditions, addiction, dizziness, nausea and vomiting, sedation, confusion and disorientation, and hallucinations.

Hill pointed out quite properly that the current level of evidence does not support medical cannabis as an established treatment for any condition.

"The scientific evidence suggests that medical cannabis is neither a first- nor second-line treatment for any medical condition. However, if a patient has tried many medications or procedures to treat a medical condition and none has worked, it is reasonable to try medical cannabis after a conversation between the patient and their clinician about its potential risks and benefits. Whenever possible, the medical cannabis certification and associated follow-up should be handled by the clinician treating the medical condition and not a clinician who only provides certificates for medical cannabis use," according to Hill.

However, this advice would seem to exaggerate the degree to which most physicians are familiar with the risks or benefits of medical marijuana. This is a difficult area to follow in the medical literature and has not traditionally been covered in medical school curricula.

So as medicine heads into massive marijuana use, there is an unfortunate element of the blind leading the blind. (*See JAMA* Patient Page, *JAMA*, 2020; 323:6.)

### Evidence Map on Medical Cannabis Treatments

So what do the available randomized controlled trials and systematic reviews say about the therapeutic uses of marijuana, cannabis, and cannabinoids? Nadia Montero-Oleas, MD, and colleagues from Ecuador and Spain recently set out to construct an evidence map regarding therapeutic uses of these treatments.

After an extensive literature search, they found 158 individual studies and 44 systematic reviews (SRs).

They found studies on multiple sclerosis, movement disorders (e.g. Tourette syndrome and Parkinson This evidence mapping effort clearly defines an urgent research agenda. "To support the use of cannabis in different clinical conditions additional efforts are needed, as the approval for the use of cannabis and cannabinoids, as any other drug, should rely on well-designed and statistically powered clinical trials." Those have not occurred yet. (See *BMC Complementary Medicine and Therapies*, 2020; 20:12. doi:10.1186/s12906-019-2803-2.)

### Pain and Suffering Among Marginalized People

A recent issue of the journal *Pain* offered a review on one of the most vitally important issues in

experienced violence and trauma, among others, are vulnerable to a higher prevalence of painful medical conditions, relative to nonmarginalized people, as well as to experiencing barriers to pain management services," they added.

Complicating this situation is a near-complete lack of research in many marginalized groups. Most studies of chronic pain have systematically ignored or excluded these groups.

And there is a total lack of guidelines for managing pain—and associated complicating features—in marginalized groups.

"Systematic guidelines addressing specific requirements for care have not been developed for populations experiencing pain and social marginalization. Best practices will be needed that specifically consider experiences of stigma, bias, and discrimination," according to Craig et al. (See *Pain*, 2020; 161(2):262–5.)

The opioid overuse and overdose epidemic provides eloquent support for the points in this review. A recent paper from the US Department of Health and Human Services documented that the opioid crisis had a disproportionate impact on the poor, the unemployed, and the marginally employed.

"Poverty, unemployment rates, and the employment-to-population ratio are highly correlated with the prevalence of prescription opioids and with substance use measures. On average, counties with worse economic prospects are more likely to have higher rates of opioid prescriptions, opioid-related hospitalizations, and drug overdose deaths," according to Robin Ghertner and Lincoln Groves. (See ASPE Research Brief, 2018; see https:// aspe.hhs.gov/system/files/ pdf/259261/ASPEEconomicOpportunityOpioidCrisis.pdf)

### The BackPage Online

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- Medical Burnout or Moral Injury?
- Life Expectancy Increasing Again in the United States After a Drop in Overdose Death Rates

disease), psychiatric conditions, Alzheimer's disease, epilepsy, acute and chronic pain, cancer, neuropathic pain, symptoms related to cancer (e.g. emesis and anorexia related with chemotherapy), rheumatic disorders, HIV-related symptoms, glaucoma, and chronic obstructive pulmonary disease.

According to Montero-Oleas the evidence on cannabis is broad but of poor quality. Due to methodological limitations, conclusions were weak in most of the assessed comparisons.

"We noticed that the evidence for medical cannabis effects on these conditions is heterogeneous regarding the conclusions and the quality of the collected studies. Most of the conclusions extracted from SRs were classified as 'probably beneficial' and 'unclear.' Furthermore, for some comparisons, conclusions claimed by SRs were inconsistent and even contradictory." the management of back and other forms of acute and chronic pain. When it comes to pain, people in marginalized social, economic, and educational groups suffer disproportionately—in terms of prevalence, prognosis, and medical management.

"Pain is often poorly recognized, inadequately assessed, and unsuccessfully managed among people in mainstream society but this is particularly the case for people who have been historically, economically, and socially marginalized, although access to pain management is considered a basic human right," according to Kenneth Craig and colleagues.

"People who are indigenous, recent immigrants or refugees, of color, less well educated, living with mental health or substance-use challenges, or have